

1     **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SE-**  
2                     **CURITY ACT; REFERENCES TO BIPA AND**  
3                     **SECRETARY; TABLE OF CONTENTS.**

4             (a) SHORT TITLE.—This Act may be cited as the “Medi-  
5     care Prescription Drug, Improvement, and Modernization Act  
6     of 2003”.

7             (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as  
8     otherwise specifically provided, whenever in division A of this  
9     Act an amendment is expressed in terms of an amendment to  
10    or repeal of a section or other provision, the reference shall be  
11    considered to be made to that section or other provision of the  
12    Social Security Act.

13            (c) BIPA; SECRETARY.—In this Act:

14                (1) BIPA.—The term “BIPA” means the Medicare,  
15     Medicaid, and SCHIP Benefits Improvement and Protec-  
16     tion Act of 2000, as enacted into law by section 1(a)(6) of  
17     Public Law 106–554.

18                (2) SECRETARY.—The term “Secretary” means the  
19     Secretary of Health and Human Services.

20            (d) TABLE OF CONTENTS.—The table of contents of this  
21    Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA and  
Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Medicare prescription drug benefit.

“PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

“Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

“Sec. 1860D–1. Eligibility, enrollment, and information.

“Sec. 1860D–2. Prescription drug benefits.

“Sec. 1860D–3. Access to a choice of qualified prescription drug coverage.

“Sec. 1860D–4. Beneficiary protections for qualified prescription drug cov-  
erage.

“Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

“Sec. 1860D–11. PDP regions; submission of bids; plan approval.

“Sec. 1860D–12. Requirements for and contracts with prescription drug  
plan (PDP) sponsors.

“Sec. 1860D–13. Premiums; late enrollment penalty.

“Sec. 1860D–14. Premium and cost-sharing subsidies for low-income indi-  
viduals.

“Sec. 1860D–15. Subsidies for part D eligible individuals for qualified prescription drug coverage.

“Sec. 1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

“Subpart 3—Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans

“Sec. 1860D–21. Application to Medicare Advantage program and related managed care programs.

“Sec. 1860D–22. Special rules for employer-sponsored programs.

“Sec. 1860D–23. State pharmaceutical assistance programs.

“Sec. 1860D–24. Coordination requirements for plans providing prescription drug coverage.

“Subpart 4—Medicare Prescription Drug Discount Card and Transitional Assistance Program

“Sec. 1860D–31. Medicare prescription drug discount card and transitional assistance program.

“Subpart 5—Definitions and Miscellaneous Provisions

“Sec. 1860D–41. Definitions; treatment of references to provisions in part C.

“Sec. 1860D–42. Miscellaneous provisions.

Sec. 102. Medicare Advantage conforming amendments.

Sec. 103. Medicaid amendments.

Sec. 104. Medigap amendments.

Sec. 105. Additional provisions relating to medicare prescription drug discount card and transitional assistance program.

Sec. 106. State Pharmaceutical Assistance Transition Commission.

Sec. 107. Studies and reports.

Sec. 108. Grants to physicians to implement electronic prescription drug programs.

Sec. 109. Expanding the work of medicare Quality Improvement Organizations to include parts C and D.

Sec. 110. Conflict of interest study.

Sec. 111. Study on employment-based retiree health coverage.

## TITLE II—MEDICARE ADVANTAGE

### Subtitle A—Implementation of Medicare Advantage Program

Sec. 201. Implementation of Medicare Advantage program.

### Subtitle B—Immediate Improvements

Sec. 211. Immediate improvements.

### Subtitle C—Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition

Sec. 221. Establishment of MA regional plans.

Sec. 222. Competition program beginning in 2006.

Sec. 223. Effective date.

### Subtitle D—Additional Reforms

- Sec. 231. Specialized MA plans for special needs individuals.
- Sec. 232. Avoiding duplicative State regulation.
- Sec. 233. Medicare MSAs.
- Sec. 234. Extension of reasonable cost contracts.
- Sec. 235. 2-year extension of municipal health service demonstration projects.
- Sec. 236. Payment by PACE providers for medicare and medicaid services furnished by noncontract providers.
- Sec. 237. Reimbursement for Federally qualified health centers providing services under MA plans.
- Sec. 238. Institute of Medicine evaluation and report on health care performance measures.

#### Subtitle E—Comparative Cost Adjustment (CCA) Program

- Sec. 241. Comparative Cost Adjustment (CCA) program.

### TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

- Sec. 301. Medicare secondary payor (MSP) provisions.
- Sec. 302. Payment for durable medical equipment; competitive acquisition of certain items and services.
- Sec. 303. Payment reform for covered outpatient drugs and biologicals.
- Sec. 304. Extension of application of payment reform for covered outpatient drugs and biologicals to other physician specialties.
- Sec. 305. Payment for inhalation drugs.
- Sec. 306. Demonstration project for use of recovery audit contractors.
- Sec. 307. Pilot program for national and State background checks on direct patient access employees of long-term care facilities or providers.

### TITLE IV—RURAL PROVISIONS

#### Subtitle A—Provisions Relating to Part A Only

- Sec. 401. Equalizing urban and rural standardized payment amounts under the medicare inpatient hospital prospective payment system.
- Sec. 402. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.
- Sec. 403. Adjustment to the medicare inpatient hospital prospective payment system wage index to revise the labor-related share of such index.
- Sec. 404. More frequent update in weights used in hospital market basket.
- Sec. 405. Improvements to critical access hospital program.
- Sec. 406. Medicare inpatient hospital payment adjustment for low-volume hospitals.
- Sec. 407. Treatment of missing cost reporting periods for sole community hospitals.
- Sec. 408. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.
- Sec. 409. Rural hospice demonstration project.
- Sec. 410. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.
- Sec. 410A. Rural community hospital demonstration program.

#### Subtitle B—Provisions Relating to Part B Only

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- Sec. 411. 2-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under the prospective payment system for hospital outpatient department services.
- Sec. 412. Establishment of floor on work geographic adjustment.
- Sec. 413. Medicare incentive payment program improvements for physician scarcity.
- Sec. 414. Payment for rural and urban ambulance services.
- Sec. 415. Providing appropriate coverage of rural air ambulance services.
- Sec. 416. Treatment of certain clinical diagnostic laboratory tests furnished to hospital outpatients in certain rural areas.
- Sec. 417. Extension of telemedicine demonstration project.
- Sec. 418. Report on demonstration project permitting skilled nursing facilities to be originating telehealth sites; authority to implement.

## Subtitle C—Provisions Relating to Parts A and B

- Sec. 421. 1-year increase for home health services furnished in a rural area.
- Sec. 422. Redistribution of unused resident positions.

## Subtitle D—Other Provisions

- Sec. 431. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
- Sec. 432. Office of Rural Health Policy improvements.
- Sec. 433. MedPAC study on rural hospital payment adjustments.
- Sec. 434. Frontier extended stay clinic demonstration project.

## TITLE V—PROVISIONS RELATING TO PART A

## Subtitle A—Inpatient Hospital Services

- Sec. 501. Revision of acute care hospital payment updates.
- Sec. 502. Revision of the indirect medical education (IME) adjustment percentage.
- Sec. 503. Recognition of new medical technologies under inpatient hospital prospective payment system.
- Sec. 504. Increase in Federal rate for hospitals in Puerto Rico.
- Sec. 505. Wage index adjustment reclassification reform.
- Sec. 506. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.
- Sec. 507. Clarifications to certain exceptions to medicare limits on physician referrals.
- Sec. 508. 1-Time appeals process for hospital wage index classification.

## Subtitle B—Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services.
- Sec. 512. Coverage of hospice consultation services.
- Sec. 513. Study on portable diagnostic ultrasound services for beneficiaries in skilled nursing facilities.

## TITLE VI—PROVISIONS RELATING TO PART B

## Subtitle A—Provisions Relating to Physicians' Services

- Sec. 601. Revision of updates for physicians' services.
- Sec. 602. Treatment of physicians' services furnished in Alaska.

- Sec. 603. Inclusion of podiatrists, dentists, and optometrists under private contracting authority.
- Sec. 604. GAO study on access to physicians' services.
- Sec. 605. Collaborative demonstration-based review of physician practice expense geographic adjustment data.
- Sec. 606. MedPAC report on payment for physicians' services.

#### Subtitle B—Preventive Services

- Sec. 611. Coverage of an initial preventive physical examination.
- Sec. 612. Coverage of cardiovascular screening blood tests.
- Sec. 613. Coverage of diabetes screening tests.
- Sec. 614. Improved payment for certain mammography services.

#### Subtitle C—Other Provisions

- Sec. 621. Hospital outpatient department (HOPD) payment reform.
- Sec. 622. Limitation of application of functional equivalence standard.
- Sec. 623. Payment for renal dialysis services.
- Sec. 624. 2-year moratorium on therapy caps; provisions relating to reports.
- Sec. 625. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 626. Payment for services furnished in ambulatory surgical centers.
- Sec. 627. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
- Sec. 628. Payment for clinical diagnostic laboratory tests.
- Sec. 629. Indexing part B deductible to inflation.
- Sec. 630. 5-year authorization of reimbursement for all medicare part B services furnished by certain Indian hospitals and clinics.

#### Subtitle D—Additional Demonstrations, Studies, and Other Provisions

- Sec. 641. Demonstration project for coverage of certain prescription drugs and biologicals.
- Sec. 642. Extension of coverage of Intravenous Immune Globulin (IVIG) for the treatment of primary immune deficiency diseases in the home.
- Sec. 643. MedPAC study of coverage of surgical first assisting services of certified registered nurse first assistants.
- Sec. 644. MedPAC study of payment for cardio-thoracic surgeons.
- Sec. 645. Studies relating to vision impairments.
- Sec. 646. Medicare health care quality demonstration programs.
- Sec. 647. MedPAC study on direct access to physical therapy services.
- Sec. 648. Demonstration project for consumer-directed chronic outpatient services.
- Sec. 649. Medicare care management performance demonstration.
- Sec. 650. GAO study and report on the propagation of concierge care.
- Sec. 651. Demonstration of coverage of chiropractic services under medicare.

### TITLE VII—PROVISIONS RELATING TO PARTS A AND B

#### Subtitle A—Home Health Services

- Sec. 701. Update in home health services.
- Sec. 702. Demonstration project to clarify the definition of homebound.
- Sec. 703. Demonstration project for medical adult day care services.

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- Sec. 704. Temporary suspension of OASIS requirement for collection of data on non-medicare and non-medicaid patients.
- Sec. 705. MedPAC study on medicare margins of home health agencies.
- Sec. 706. Coverage of religious nonmedical health care institution services furnished in the home.

## Subtitle B—Graduate Medical Education

- Sec. 711. Extension of update limitation on high cost programs.
- Sec. 712. Exception to initial residency period for geriatric residency or fellowship programs.
- Sec. 713. Treatment of volunteer supervision.

## Subtitle C—Chronic Care Improvement

- Sec. 721. Voluntary chronic care improvement under traditional fee-for-service.
- Sec. 722. Medicare Advantage quality improvement programs.
- Sec. 723. Chronically ill medicare beneficiary research, data, demonstration strategy.

## Subtitle D—Other Provisions

- Sec. 731. Improvements in national and local coverage determination process to respond to changes in technology.
- Sec. 732. Extension of treatment of certain physician pathology services under medicare.
- Sec. 733. Payment for pancreatic islet cell investigational transplants for medicare beneficiaries in clinical trials.
- Sec. 734. Restoration of medicare trust funds.
- Sec. 735. Modifications to Medicare Payment Advisory Commission (MedPAC).
- Sec. 736. Technical amendments.

## TITLE VIII—COST CONTAINMENT

## Subtitle A—Cost Containment

- Sec. 801. Inclusion in annual report of medicare trustees of information on status of medicare trust funds.
- Sec. 802. Presidential submission of legislation.
- Sec. 803. Procedures in the House of Representatives.
- Sec. 804. Procedures in the Senate.

## Subtitle B—Income-Related Reduction in Part B Premium Subsidy

- Sec. 811. Income-related reduction in part B premium subsidy.

## TITLE IX—ADMINISTRATIVE IMPROVEMENTS, REGULATORY REDUCTION, AND CONTRACTING REFORM

- Sec. 900. Administrative improvements within the Centers for Medicare & Medicaid Services (CMS).

## Subtitle A—Regulatory Reform

- Sec. 901. Construction; definition of supplier.
- Sec. 902. Issuance of regulations.
- Sec. 903. Compliance with changes in regulations and policies.
- Sec. 904. Reports and studies relating to regulatory reform.

## Subtitle B—Contracting Reform

- Sec. 911. Increased flexibility in medicare administration.
- Sec. 912. Requirements for information security for medicare administrative contractors.

## Subtitle C—Education and Outreach

- Sec. 921. Provider education and technical assistance.
- Sec. 922. Small provider technical assistance demonstration program.
- Sec. 923. Medicare Beneficiary Ombudsman.
- Sec. 924. Beneficiary outreach demonstration program.
- Sec. 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits.
- Sec. 926. Information on medicare-certified skilled nursing facilities in hospital discharge plans.

## Subtitle D—Appeals and Recovery

- Sec. 931. Transfer of responsibility for medicare appeals.
- Sec. 932. Process for expedited access to review.
- Sec. 933. Revisions to medicare appeals process.
- Sec. 934. Prepayment review.
- Sec. 935. Recovery of overpayments.
- Sec. 936. Provider enrollment process; right of appeal.
- Sec. 937. Process for correction of minor errors and omissions without pursuing appeals process.
- Sec. 938. Prior determination process for certain items and services; advance beneficiary notices.
- Sec. 939. Appeals by providers when there is no other party available.
- Sec. 940. Revisions to appeals timeframes and amounts.
- Sec. 940A. Mediation process for local coverage determinations.

## Subtitle E—Miscellaneous Provisions

- Sec. 941. Policy development regarding evaluation and management (E & M) documentation guidelines.
- Sec. 942. Improvement in oversight of technology and coverage.
- Sec. 943. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.
- Sec. 944. EMTALA improvements.
- Sec. 945. Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group.
- Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.
- Sec. 947. Application of OSHA bloodborne pathogens standard to certain hospitals.
- Sec. 948. BIPA-related technical amendments and corrections.
- Sec. 949. Conforming authority to waive a program exclusion.
- Sec. 950. Treatment of certain dental claims.
- Sec. 951. Furnishing hospitals with information to compute DSH formula.
- Sec. 952. Revisions to reassignment provisions.
- Sec. 953. Other provisions.

## TITLE X—MEDICAID AND MISCELLANEOUS PROVISIONS

## Subtitle A—Medicaid Provisions

- Sec. 1001. Medicaid disproportionate share hospital (DSH) payments.
- Sec. 1002. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.
- Sec. 1003. Extension of moratorium.

Subtitle B—Miscellaneous Provisions

- Sec. 1011. Federal reimbursement of emergency health services furnished to undocumented aliens.
- Sec. 1012. Commission on Systemic Interoperability.
- Sec. 1013. Research on outcomes of health care items and services.
- Sec. 1014. Health care that works for all Americans: Citizens Health Care Working Group.
- Sec. 1015. Funding start-up administrative costs for medicare reform.
- Sec. 1016. Health care infrastructure improvement program.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

- Sec. 1101. 30-month stay-of-effectiveness period.
- Sec. 1102. Forfeiture of 180-day exclusivity period.
- Sec. 1103. Bioavailability and bioequivalence.
- Sec. 1104. Conforming amendments.

Subtitle B—Federal Trade Commission Review

- Sec. 1111. Definitions.
- Sec. 1112. Notification of agreements.
- Sec. 1113. Filing deadlines.
- Sec. 1114. Disclosure exemption.
- Sec. 1115. Enforcement.
- Sec. 1116. Rulemaking.
- Sec. 1117. Savings clause.
- Sec. 1118. Effective date.

Subtitle C—Importation of Prescription Drugs

- Sec. 1121. Importation of prescription drugs.
- Sec. 1122. Study and report on importation of drugs.
- Sec. 1123. Study and report on trade in pharmaceuticals.

TITLE XII—TAX INCENTIVES FOR HEALTH AND RETIREMENT SECURITY

- Sec. 1201. Health savings accounts.
- Sec. 1202. Exclusion from gross income of certain Federal subsidies for prescription drug plans.
- Sec. 1203. Exception to information reporting requirements related to certain health arrangements.

1 **TITLE I—MEDICARE**  
 2 **PRESCRIPTION DRUG BENEFIT**

3 **SEC. 101. MEDICARE PRESCRIPTION DRUG BENEFIT.**

4 (a) IN GENERAL.—Title XVIII is amended—



1 (1) by redesignating part D as part E; and  
2 (2) by inserting after part C the following new part:  
3 “PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT  
4 PROGRAM  
5 “Subpart 1—Part D Eligible Individuals and Prescription  
6 Drug Benefits  
7 “ELIGIBILITY, ENROLLMENT, AND INFORMATION  
8 “SEC. 1860D–1. (a) PROVISION OF QUALIFIED PRESCRIP-  
9 TION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—  
10 “(1) IN GENERAL.—Subject to the succeeding provi-  
11 sions of this part, each part D eligible individual (as de-  
12 fined in paragraph (3)(A)) is entitled to obtain qualified  
13 prescription drug coverage (described in section 1860D–  
14 2(a)) as follows:  
15 “(A) FEE-FOR-SERVICE ENROLLEES MAY RECEIVE  
16 COVERAGE THROUGH A PRESCRIPTION DRUG PLAN.—A  
17 part D eligible individual who is not enrolled in an MA  
18 plan may obtain qualified prescription drug coverage  
19 through enrollment in a prescription drug plan (as de-  
20 fined in section 1860D–41(a)(14)).  
21 “(B) MEDICARE ADVANTAGE ENROLLEES.—  
22 “(i) ENROLLEES IN A PLAN PROVIDING QUALI-  
23 FIED PRESCRIPTION DRUG COVERAGE RECEIVE  
24 COVERAGE THROUGH THE PLAN.—A part D eligible  
25 individual who is enrolled in an MA–PD plan ob-  
26 tains such coverage through such plan.  
27 “(ii) LIMITATION ON ENROLLMENT OF MA  
28 PLAN ENROLLEES IN PRESCRIPTION DRUG  
29 PLANS.—Except as provided in clauses (iii) and  
30 (iv), a part D eligible individual who is enrolled in  
31 an MA plan may not enroll in a prescription drug  
32 plan under this part.  
33 “(iii) PRIVATE FEE-FOR-SERVICE ENROLLEES  
34 IN MA PLANS NOT PROVIDING QUALIFIED PRE-  
35 SCRIPTON DRUG COVERAGE PERMITTED TO EN-  
36 ROLL IN A PRESCRIPTION DRUG PLAN.—A part D  
37 eligible individual who is enrolled in an MA private

1 fee-for-service plan (as defined in section  
2 1859(b)(2)) that does not provide qualified pre-  
3 scription drug coverage may obtain qualified pre-  
4 scription drug coverage through enrollment in a  
5 prescription drug plan.

6 “(iv) ENROLLEES IN MSA PLANS PERMITTED  
7 TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A  
8 part D eligible individual who is enrolled in an  
9 MSA plan (as defined in section 1859(b)(3)) may  
10 obtain qualified prescription drug coverage through  
11 enrollment in a prescription drug plan.

12 “(2) COVERAGE FIRST EFFECTIVE JANUARY 1, 2006.—  
13 Coverage under prescription drug plans and MA-PD plans  
14 shall first be effective on January 1, 2006.

15 “(3) DEFINITIONS.—For purposes of this part:

16 “(A) PART D ELIGIBLE INDIVIDUAL.—The term  
17 ‘part D eligible individual’ means an individual who is  
18 entitled to benefits under part A or enrolled under part  
19 B.

20 “(B) MA PLAN.—The term ‘MA plan’ has the  
21 meaning given such term in section 1859(b)(1).

22 “(C) MA-PD PLAN.—The term ‘MA-PD plan’  
23 means an MA plan that provides qualified prescription  
24 drug coverage.

25 “(b) ENROLLMENT PROCESS FOR PRESCRIPTION DRUG  
26 PLANS.—

27 “(1) ESTABLISHMENT OF PROCESS.—

28 “(A) IN GENERAL.—The Secretary shall establish  
29 a process for the enrollment, disenrollment, termi-  
30 nation, and change of enrollment of part D eligible in-  
31 dividuals in prescription drug plans consistent with this  
32 subsection.

33 “(B) APPLICATION OF MA RULES.—In establishing  
34 such process, the Secretary shall use rules similar to  
35 (and coordinated with) the rules for enrollment,  
36 disenrollment, termination, and change of enrollment

1 with an MA–PD plan under the following provisions of  
2 section 1851:

3 “(i) RESIDENCE REQUIREMENTS.—Section  
4 1851(b)(1)(A), relating to residence requirements.

5 “(ii) EXERCISE OF CHOICE.—Section 1851(c)  
6 (other than paragraph (3)(A) of such section), re-  
7 lating to exercise of choice.

8 “(iii) COVERAGE ELECTION PERIODS.—Subject  
9 to paragraphs (2) and (3) of this subsection, sec-  
10 tion 1851(e) (other than subparagraphs (B) and  
11 (C) of paragraph (2) and the second sentence of  
12 paragraph (4) of such section), relating to coverage  
13 election periods, including initial periods, annual  
14 coordinated election periods, special election peri-  
15 ods, and election periods for exceptional cir-  
16 cumstances.

17 “(iv) COVERAGE PERIODS.—Section 1851(f),  
18 relating to effectiveness of elections and changes of  
19 elections.

20 “(v) GUARANTEED ISSUE AND RENEWAL.—  
21 Section 1851(g) (other than paragraph (2) of such  
22 section and clause (i) and the second sentence of  
23 clause (ii) of paragraph (3)(C) of such section), re-  
24 lating to guaranteed issue and renewal.

25 “(vi) MARKETING MATERIAL AND APPLICA-  
26 TION FORMS.—Section 1851(h), relating to ap-  
27 proval of marketing material and application forms.

28 In applying clauses (ii), (iv), and (v) of this subpara-  
29 graph, any reference to section 1851(e) shall be treated  
30 as a reference to such section as applied pursuant to  
31 clause (iii) of this subparagraph.

32 “(C) SPECIAL RULE.—The process established  
33 under subparagraph (A) shall include, in the case of a  
34 part D eligible individual who is a full-benefit dual eli-  
35 gible individual (as defined in section 1935(c)(6)) who  
36 has failed to enroll in a prescription drug plan or an  
37 MA–PD plan, for the enrollment in a prescription drug

1 plan that has a monthly beneficiary premium that does  
2 not exceed the premium assistance available under sec-  
3 tion 1860D–14(a)(1)(A)). If there is more than one  
4 such plan available, the Secretary shall enroll such an  
5 individual on a random basis among all such plans in  
6 the PDP region. Nothing in the previous sentence shall  
7 prevent such an individual from declining or changing  
8 such enrollment.

9 “(2) INITIAL ENROLLMENT PERIOD.—

10 “(A) PROGRAM INITIATION.—In the case of an in-  
11 dividual who is a part D eligible individual as of No-  
12 vember 15, 2005, there shall be an initial enrollment  
13 period that shall be the same as the annual, coordi-  
14 nated open election period described in section  
15 1851(e)(3)(B)(iii), as applied under paragraph  
16 (1)(B)(iii).

17 “(B) CONTINUING PERIODS.—In the case of an in-  
18 dividual who becomes a part D eligible individual after  
19 November 15, 2005, there shall be an initial enrollment  
20 period which is the period under section 1851(e)(1), as  
21 applied under paragraph (1)(B)(iii) of this section, as  
22 if ‘entitled to benefits under part A or enrolled under  
23 part B’ were substituted for ‘entitled to benefits under  
24 part A and enrolled under part B’, but in no case shall  
25 such period end before the period described in subpara-  
26 graph (A).

27 “(3) ADDITIONAL SPECIAL ENROLLMENT PERIODS.—  
28 The Secretary shall establish special enrollment periods, in-  
29 cluding the following:

30 “(A) INVOLUNTARY LOSS OF CREDITABLE PRE-  
31 SCRPTION DRUG COVERAGE.—

32 “(i) IN GENERAL.—In the case of a part D eli-  
33 gible individual who involuntarily loses creditable  
34 prescription drug coverage (as defined in section  
35 1860D–13(b)(4)).

36 “(ii) NOTICE.—In establishing special enroll-  
37 ment periods under clause (i), the Secretary shall

1 take into account when the part D eligible individ-  
2 uals are provided notice of the loss of creditable  
3 prescription drug coverage.

4 “(iii) FAILURE TO PAY PREMIUM.—For pur-  
5 poses of clause (i), a loss of coverage shall be treat-  
6 ed as voluntary if the coverage is terminated be-  
7 cause of failure to pay a required beneficiary pre-  
8 mium.

9 “(iv) REDUCTION IN COVERAGE.—For pur-  
10 poses of clause (i), a reduction in coverage so that  
11 the coverage no longer meets the requirements  
12 under section 1860D–13(b)(5) (relating to actu-  
13 arial equivalence) shall be treated as an involuntary  
14 loss of coverage.

15 “(B) ERRORS IN ENROLLMENT.—In the case de-  
16 scribed in section 1837(h) (relating to errors in enroll-  
17 ment), in the same manner as such section applies to  
18 part B.

19 “(C) EXCEPTIONAL CIRCUMSTANCES.—In the case  
20 of part D eligible individuals who meet such exceptional  
21 conditions (in addition to those conditions applied  
22 under paragraph (1)(B)(iii)) as the Secretary may pro-  
23 vide.

24 “(D) MEDICAID COVERAGE.—In the case of an in-  
25 dividual (as determined by the Secretary) who is a full-  
26 benefit dual eligible individual (as defined in section  
27 1935(c)(6)).

28 “(E) DISCONTINUANCE OF MA–PD ELECTION DUR-  
29 ING FIRST YEAR OF ELIGIBILITY.—In the case of a  
30 part D eligible individual who discontinues enrollment  
31 in an MA–PD plan under the second sentence of sec-  
32 tion 1851(e)(4) at the time of the election of coverage  
33 under such sentence under the original medicare fee-  
34 for-service program.

35 “(4) INFORMATION TO FACILITATE ENROLLMENT.—

36 “(A) IN GENERAL.—Notwithstanding any other  
37 provision of law but subject to subparagraph (B), the

1 Secretary may provide to each PDP sponsor and MA  
2 organization such identifying information about part D  
3 eligible individuals as the Secretary determines to be  
4 necessary to facilitate efficient marketing of prescrip-  
5 tion drug plans and MA–PD plans to such individuals  
6 and enrollment of such individuals in such plans.

7 “(B) LIMITATION.—

8 “(i) PROVISION OF INFORMATION.—The Sec-  
9 retary may provide the information under subpara-  
10 graph (A) only to the extent necessary to carry out  
11 such subparagraph.

12 “(ii) USE OF INFORMATION.—Such informa-  
13 tion provided by the Secretary to a PDP sponsor  
14 or an MA organization may be used by such spon-  
15 sor or organization only to facilitate marketing of,  
16 and enrollment of part D eligible individuals in,  
17 prescription drug plans and MA–PD plans.

18 “(5) REFERENCE TO ENROLLMENT PROCEDURES FOR  
19 MA–PD PLANS.—For rules applicable to enrollment,  
20 disenrollment, termination, and change of enrollment of  
21 part D eligible individuals in MA–PD plans, see section  
22 1851.

23 “(6) REFERENCE TO PENALTIES FOR LATE ENROLL-  
24 MENT.—Section 1860D–13(b) imposes a late enrollment  
25 penalty for part D eligible individuals who—

26 “(A) enroll in a prescription drug plan or an MA–  
27 PD plan after the initial enrollment period described in  
28 paragraph (2); and

29 “(B) fail to maintain continuous creditable pre-  
30 scription drug coverage during the period of non-enroll-  
31 ment.

32 “(c) PROVIDING INFORMATION TO BENEFICIARIES.—

33 “(1) ACTIVITIES.—The Secretary shall conduct activi-  
34 ties that are designed to broadly disseminate information to  
35 part D eligible individuals (and prospective part D eligible  
36 individuals) regarding the coverage provided under this  
37 part. Such activities shall ensure that such information is

1 first made available at least 30 days prior to the initial en-  
2 rollment period described in subsection (b)(2)(A).

3 “(2) REQUIREMENTS.—The activities described in  
4 paragraph (1) shall—

5 “(A) be similar to the activities performed by the  
6 Secretary under section 1851(d), including dissemina-  
7 tion (including through the toll-free telephone number  
8 1–800–MEDICARE) of comparative information for  
9 prescription drug plans and MA–PD plans; and

10 “(B) be coordinated with the activities performed  
11 by the Secretary under such section and under section  
12 1804.

13 “(3) COMPARATIVE INFORMATION.—

14 “(A) IN GENERAL.—Subject to subparagraph (B),  
15 the comparative information referred to in paragraph  
16 (2)(A) shall include a comparison of the following with  
17 respect to qualified prescription drug coverage:

18 “(i) BENEFITS.—The benefits provided under  
19 the plan.

20 “(ii) MONTHLY BENEFICIARY PREMIUM.—The  
21 monthly beneficiary premium under the plan.

22 “(iii) QUALITY AND PERFORMANCE.—The  
23 quality and performance under the plan.

24 “(iv) BENEFICIARY COST-SHARING.—The cost-  
25 sharing required of part D eligible individuals  
26 under the plan.

27 “(v) CONSUMER SATISFACTION SURVEYS.—  
28 The results of consumer satisfaction surveys re-  
29 garding the plan conducted pursuant to section  
30 1860D–4(d).

31 “(B) EXCEPTION FOR UNAVAILABILITY OF INFOR-  
32 MATION.—The Secretary is not required to provide  
33 comparative information under clauses (iii) and (v) of  
34 subparagraph (A) with respect to a plan—

35 “(i) for the first plan year in which it is of-  
36 fered; and

1                   “(ii) for the next plan year if it is impracti-  
2                   cable or the information is otherwise unavailable.

3                   “(4) INFORMATION ON LATE ENROLLMENT PEN-  
4                   ALTY.—The information disseminated under paragraph (1)  
5                   shall include information concerning the methodology for  
6                   determining the late enrollment penalty under section  
7                   1860D–13(b).

8                   “PRESCRIPTION DRUG BENEFITS

9                   “SEC. 1860D–2. (a) REQUIREMENTS.—

10                   “(1) IN GENERAL.—For purposes of this part and  
11                   part C, the term ‘qualified prescription drug coverage’  
12                   means either of the following:

13                   “(A) STANDARD PRESCRIPTION DRUG COVERAGE  
14                   WITH ACCESS TO NEGOTIATED PRICES.—Standard pre-  
15                   scription drug coverage (as defined in subsection (b))  
16                   and access to negotiated prices under subsection (d).

17                   “(B) ALTERNATIVE PRESCRIPTION DRUG COV-  
18                   ERAGE WITH AT LEAST ACTUARIALLY EQUIVALENT  
19                   BENEFITS AND ACCESS TO NEGOTIATED PRICES.—Cov-  
20                   erage of covered part D drugs which meets the alter-  
21                   native prescription drug coverage requirements of sub-  
22                   section (c) and access to negotiated prices under sub-  
23                   section (d), but only if the benefit design of such cov-  
24                   erage is approved by the Secretary, as provided under  
25                   subsection (c).

26                   “(2) PERMITTING SUPPLEMENTAL PRESCRIPTION  
27                   DRUG COVERAGE.—

28                   “(A) IN GENERAL.—Subject to subparagraph (B),  
29                   qualified prescription drug coverage may include sup-  
30                   plemental prescription drug coverage consisting of ei-  
31                   ther or both of the following:

32                   “(i) CERTAIN REDUCTIONS IN COST-SHAR-  
33                   ING.—

34                   “(I) IN GENERAL.—A reduction in the an-  
35                   nual deductible, a reduction in the coinsurance  
36                   percentage, or an increase in the initial cov-  
37                   erage limit with respect to covered part D



1 drugs, or any combination thereof, insofar as  
2 such a reduction or increase increases the actu-  
3 arial value of benefits above the actuarial value  
4 of basic prescription drug coverage.

5 “(II) CONSTRUCTION.—Nothing in this  
6 paragraph shall be construed as affecting the  
7 application of subsection (c)(3).

8 “(ii) OPTIONAL DRUGS.—Coverage of any  
9 product that would be a covered part D drug but  
10 for the application of subsection (e)(2)(A).

11 “(B) REQUIREMENT.—A PDP sponsor may not  
12 offer a prescription drug plan that provides supple-  
13 mental prescription drug coverage pursuant to subpara-  
14 graph (A) in an area unless the sponsor also offers a  
15 prescription drug plan in the area that only provides  
16 basic prescription drug coverage.

17 “(3) BASIC PRESCRIPTION DRUG COVERAGE.—For  
18 purposes of this part and part C, the term ‘basic prescrip-  
19 tion drug coverage’ means either of the following:

20 “(A) Coverage that meets the requirements of  
21 paragraph (1)(A).

22 “(B) Coverage that meets the requirements of  
23 paragraph (1)(B) but does not have any supplemental  
24 prescription drug coverage described in paragraph  
25 (2)(A).

26 “(4) APPLICATION OF SECONDARY PAYOR PROVI-  
27 SIONS.—The provisions of section 1852(a)(4) shall apply  
28 under this part in the same manner as they apply under  
29 part C.

30 “(5) CONSTRUCTION.—Nothing in this subsection  
31 shall be construed as changing the computation of incurred  
32 costs under subsection (b)(4).

33 “(b) STANDARD PRESCRIPTION DRUG COVERAGE.—For  
34 purposes of this part and part C, the term ‘standard prescrip-  
35 tion drug coverage’ means coverage of covered part D drugs  
36 that meets the following requirements:

37 “(1) DEDUCTIBLE.—

1           “(A) IN GENERAL.—The coverage has an annual  
2 deductible—

3           “(i) for 2006, that is equal to \$250; or

4           “(ii) for a subsequent year, that is equal to  
5 the amount specified under this paragraph for the  
6 previous year increased by the percentage specified  
7 in paragraph (6) for the year involved.

8           “(B) ROUNDING.—Any amount determined under  
9 subparagraph (A)(ii) that is not a multiple of \$5 shall  
10 be rounded to the nearest multiple of \$5.

11           “(2) BENEFIT STRUCTURE.—

12           “(A) 25 PERCENT COINSURANCE.—The coverage  
13 has coinsurance (for costs above the annual deductible  
14 specified in paragraph (1) and up to the initial cov-  
15 erage limit under paragraph (3)) that is—

16           “(i) equal to 25 percent; or

17           “(ii) actuarially equivalent (using processes  
18 and methods established under section 1860D-  
19 11(c)) to an average expected payment of 25 per-  
20 cent of such costs.

21           “(B) USE OF TIERS.—Nothing in this part shall  
22 be construed as preventing a PDP sponsor or an MA  
23 organization from applying tiered copayments under a  
24 plan, so long as such tiered copayments are consistent  
25 with subparagraph (A)(ii).

26           “(3) INITIAL COVERAGE LIMIT.—

27           “(A) IN GENERAL.—Except as provided in para-  
28 graph (4), the coverage has an initial coverage limit on  
29 the maximum costs that may be recognized for pay-  
30 ment purposes (including the annual deductible)—

31           “(i) for 2006, that is equal to \$2,250; or

32           “(ii) for a subsequent year, that is equal to  
33 the amount specified in this paragraph for the pre-  
34 vious year, increased by the annual percentage in-  
35 crease described in paragraph (6) for the year in-  
36 volved.

1                   “(B) ROUNDING.—Any amount determined under  
2                   subparagraph (A)(ii) that is not a multiple of \$10 shall  
3                   be rounded to the nearest multiple of \$10.

4                   “(4) PROTECTION AGAINST HIGH OUT-OF-POCKET EX-  
5                   PENDITURES.—

6                   “(A) IN GENERAL.—

7                   “(i) IN GENERAL.—The coverage provides ben-  
8                   efits, after the part D eligible individual has in-  
9                   curred costs (as described in subparagraph (C)) for  
10                   covered part D drugs in a year equal to the annual  
11                   out-of-pocket threshold specified in subparagraph  
12                   (B), with cost-sharing that is equal to the greater  
13                   of—

14                   “(I) a copayment of \$2 for a generic drug  
15                   or a preferred drug that is a multiple source  
16                   drug (as defined in section 1927(k)(7)(A)(i))  
17                   and \$5 for any other drug; or

18                   “(II) coinsurance that is equal to 5 per-  
19                   cent.

20                   “(ii) ADJUSTMENT OF AMOUNT.—For a year  
21                   after 2006, the dollar amounts specified in clause  
22                   (i)(I) shall be equal to the dollar amounts specified  
23                   in this subparagraph for the previous year, in-  
24                   creased by the annual percentage increase de-  
25                   scribed in paragraph (6) for the year involved. Any  
26                   amount established under this clause that is not a  
27                   multiple of a 5 cents shall be rounded to the near-  
28                   est multiple of 5 cents.

29                   “(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

30                   “(i) IN GENERAL.—For purposes of this part,  
31                   the ‘annual out-of-pocket threshold’ specified in  
32                   this subparagraph—

33                   “(I) for 2006, is equal to \$3,600; or

34                   “(II) for a subsequent year, is equal to the  
35                   amount specified in this subparagraph for the  
36                   previous year, increased by the annual percent-

1                   age increase described in paragraph (6) for the  
2                   year involved.

3                   “(ii) ROUNDING.—Any amount determined  
4                   under clause (i)(II) that is not a multiple of \$50  
5                   shall be rounded to the nearest multiple of \$50.

6                   “(C) APPLICATION.—In applying subparagraph  
7                   (A)—

8                   “(i) incurred costs shall only include costs in-  
9                   curred with respect to covered part D drugs for the  
10                  annual deductible described in paragraph (1), for  
11                  cost-sharing described in paragraph (2), and for  
12                  amounts for which benefits are not provided be-  
13                  cause of the application of the initial coverage limit  
14                  described in paragraph (3), but does not include  
15                  any costs incurred for covered part D drugs which  
16                  are not included (or treated as being included) in  
17                  the plan’s formulary; and

18                  “(ii) such costs shall be treated as incurred  
19                  only if they are paid by the part D eligible indi-  
20                  vidual (or by another person, such as a family  
21                  member, on behalf of the individual), under section  
22                  1860D–14, or under a State Pharmaceutical As-  
23                  sistance Program and the part D eligible individual  
24                  (or other person) is not reimbursed through insur-  
25                  ance or otherwise, a group health plan, or other  
26                  third-party payment arrangement (other than  
27                  under such section or such a Program) for such  
28                  costs.

29                  “(D) INFORMATION REGARDING THIRD-PARTY RE-  
30                  IMBURSEMENT.—

31                  “(i) PROCEDURES FOR EXCHANGING INFOR-  
32                  MATION.—In order to accurately apply the require-  
33                  ments of subparagraph (C)(ii), the Secretary is au-  
34                  thorized to establish procedures, in coordination  
35                  with the Secretary of the Treasury and the Sec-  
36                  retary of Labor—

1           “(I) for determining whether costs for  
2           part D eligible individuals are being reimbursed  
3           through insurance or otherwise, a group health  
4           plan, or other third-party payment arrange-  
5           ment; and

6           “(II) for alerting the PDP sponsors and  
7           MA organizations that offer the prescription  
8           drug plans and MA–PD plans in which such in-  
9           dividuals are enrolled about such reimburse-  
10          ment arrangements.

11          “(ii) AUTHORITY TO REQUEST INFORMATION  
12          FROM ENROLLEES.—A PDP sponsor or an MA or-  
13          ganization may periodically ask part D eligible indi-  
14          viduals enrolled in a prescription drug plan or an  
15          MA–PD plan offered by the sponsor or organiza-  
16          tion whether such individuals have or expect to re-  
17          ceive such third-party reimbursement. A material  
18          misrepresentation of the information described in  
19          the preceding sentence by an individual (as defined  
20          in standards set by the Secretary and determined  
21          through a process established by the Secretary)  
22          shall constitute grounds for termination of enroll-  
23          ment in any plan under section 1851(g)(3)(B) (and  
24          as applied under this part under section 1860D-  
25          1(b)(1)(B)(v)) for a period specified by the Sec-  
26          retary.

27          “(5) CONSTRUCTION.—Nothing in this part shall be  
28          construed as preventing a PDP sponsor or an MA organi-  
29          zation offering an MA–PD plan from reducing to 0 the  
30          cost-sharing otherwise applicable to preferred or generic  
31          drugs.

32          “(6) ANNUAL PERCENTAGE INCREASE.—The annual  
33          percentage increase specified in this paragraph for a year  
34          is equal to the annual percentage increase in average per  
35          capita aggregate expenditures for covered part D drugs in  
36          the United States for part D eligible individuals, as deter-  
37          mined by the Secretary for the 12-month period ending in

1 July of the previous year using such methods as the Sec-  
2 retary shall specify.

3 “(c) ALTERNATIVE PRESCRIPTION DRUG COVERAGE RE-  
4 QUIREMENTS.—A prescription drug plan or an MA–PD plan  
5 may provide a different prescription drug benefit design from  
6 standard prescription drug coverage so long as the Secretary  
7 determines (consistent with section 1860D–11(c)) that the fol-  
8 lowing requirements are met and the plan applies for, and re-  
9 ceives, the approval of the Secretary for such benefit design:

10 “(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT  
11 COVERAGE.—

12 “(A) ASSURING EQUIVALENT VALUE OF TOTAL  
13 COVERAGE.—The actuarial value of the total coverage  
14 is at least equal to the actuarial value of standard pre-  
15 scription drug coverage.

16 “(B) ASSURING EQUIVALENT UNSUBSIDIZED  
17 VALUE OF COVERAGE.—The unsubsidized value of the  
18 coverage is at least equal to the unsubsidized value of  
19 standard prescription drug coverage. For purposes of  
20 this subparagraph, the unsubsidized value of coverage  
21 is the amount by which the actuarial value of the cov-  
22 erage exceeds the actuarial value of the subsidy pay-  
23 ments under section 1860D–15 with respect to such  
24 coverage.

25 “(C) ASSURING STANDARD PAYMENT FOR COSTS  
26 AT INITIAL COVERAGE LIMIT.—The coverage is de-  
27 signed, based upon an actuarially representative pat-  
28 tern of utilization, to provide for the payment, with re-  
29 spect to costs incurred that are equal to the initial cov-  
30 erage limit under subsection (b)(3) for the year, of an  
31 amount equal to at least the product of—

32 “(i) the amount by which the initial coverage  
33 limit described in subsection (b)(3) for the year ex-  
34 ceeds the deductible described in subsection (b)(1)  
35 for the year; and

36 “(ii) 100 percent minus the coinsurance per-  
37 centage specified in subsection (b)(2)(A)(i).

1           “(2) MAXIMUM REQUIRED DEDUCTIBLE.—The deduct-  
2           ible under the coverage shall not exceed the deductible  
3           amount specified under subsection (b)(1) for the year.

4           “(3) SAME PROTECTION AGAINST HIGH OUT-OF-POCK-  
5           ET EXPENDITURES.—The coverage provides the coverage  
6           required under subsection (b)(4).

7           “(d) ACCESS TO NEGOTIATED PRICES.—

8           “(1) ACCESS.—

9           “(A) IN GENERAL.—Under qualified prescription  
10           drug coverage offered by a PDP sponsor offering a pre-  
11           scription drug plan or an MA organization offering an  
12           MA–PD plan, the sponsor or organization shall provide  
13           enrollees with access to negotiated prices used for pay-  
14           ment for covered part D drugs, regardless of the fact  
15           that no benefits may be payable under the coverage  
16           with respect to such drugs because of the application  
17           of a deductible or other cost-sharing or an initial cov-  
18           erage limit (described in subsection (b)(3)).

19           “(B) NEGOTIATED PRICES.—For purposes of this  
20           part, negotiated prices shall take into account nego-  
21           tiated price concessions, such as discounts, direct or in-  
22           direct subsidies, rebates, and direct or indirect remu-  
23           nerations, for covered part D drugs, and include any  
24           dispensing fees for such drugs.

25           “(C) MEDICAID-RELATED PROVISIONS.—The  
26           prices negotiated by a prescription drug plan, by an  
27           MA–PD plan with respect to covered part D drugs, or  
28           by a qualified retiree prescription drug plan (as defined  
29           in section 1860D–22(a)(2)) with respect to such drugs  
30           on behalf of part D eligible individuals, shall (notwith-  
31           standing any other provision of law) not be taken into  
32           account for the purposes of establishing the best price  
33           under section 1927(c)(1)(C).

34           “(2) DISCLOSURE.—A PDP sponsor offering a pre-  
35           scription drug plan or an MA organization offering an MA–  
36           PD plan shall disclose to the Secretary (in a manner speci-  
37           fied by the Secretary) the aggregate negotiated price con-

1        cessions described in paragraph (1)(B) made available to  
2        the sponsor or organization by a manufacturer which are  
3        passed through in the form of lower subsidies, lower  
4        monthly beneficiary prescription drug premiums, and lower  
5        prices through pharmacies and other dispensers. The provi-  
6        sions of section 1927(b)(3)(D) apply to information dis-  
7        closed to the Secretary under this paragraph.

8        “(3) AUDITS.—To protect against fraud and abuse  
9        and to ensure proper disclosures and accounting under this  
10       part and in accordance with section 1857(d)(2)(B) (as ap-  
11       plied under section 1860D–12(b)(3)(C)), the Secretary may  
12       conduct periodic audits, directly or through contracts, of  
13       the financial statements and records of PDP sponsors with  
14       respect to prescription drug plans and MA organizations  
15       with respect to MA–PD plans.

16       “(e) COVERED PART D DRUG DEFINED.—

17       “(1) IN GENERAL.—Except as provided in this sub-  
18       section, for purposes of this part, the term ‘covered part D  
19       drug’ means—

20       “(A) a drug that may be dispensed only upon a  
21       prescription and that is described in subparagraph  
22       (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2); or

23       “(B) a biological product described in clauses (i)  
24       through (iii) of subparagraph (B) of such section or in-  
25       sulin described in subparagraph (C) of such section and  
26       medical supplies associated with the injection of insulin  
27       (as defined in regulations of the Secretary),

28       and such term includes a vaccine licensed under section  
29       351 of the Public Health Service Act and any use of a cov-  
30       ered part D drug for a medically accepted indication (as  
31       defined in section 1927(k)(6)).

32       “(2) EXCLUSIONS.—

33       “(A) IN GENERAL.—Such term does not include  
34       drugs or classes of drugs, or their medical uses, which  
35       may be excluded from coverage or otherwise restricted  
36       under section 1927(d)(2), other than subparagraph (E)



1 of such section (relating to smoking cessation agents),  
2 or under section 1927(d)(3).

3 “(B) MEDICARE COVERED DRUGS.—A drug pre-  
4 scribed for a part D eligible individual that would oth-  
5 erwise be a covered part D drug under this part shall  
6 not be so considered if payment for such drug as so  
7 prescribed and dispensed or administered with respect  
8 to that individual is available (or would be available but  
9 for the application of a deductible) under part A or B  
10 for that individual.

11 “(3) APPLICATION OF GENERAL EXCLUSION PROVI-  
12 SIONS.—A prescription drug plan or an MA–PD plan may  
13 exclude from qualified prescription drug coverage any cov-  
14 ered part D drug—

15 “(A) for which payment would not be made if sec-  
16 tion 1862(a) applied to this part; or

17 “(B) which is not prescribed in accordance with  
18 the plan or this part.

19 Such exclusions are determinations subject to reconsider-  
20 ation and appeal pursuant to subsections (g) and (h), re-  
21 spectively, of section 1860D–4.

22 “ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG  
23 COVERAGE

24 “SEC. 1860D–3. (a) ASSURING ACCESS TO A CHOICE OF  
25 COVERAGE.—

26 “(1) CHOICE OF AT LEAST TWO PLANS IN EACH  
27 AREA.—The Secretary shall ensure that each part D eligi-  
28 ble individual has available, consistent with paragraph (2),  
29 a choice of enrollment in at least 2 qualifying plans (as de-  
30 fined in paragraph (3)) in the area in which the individual  
31 resides, at least one of which is a prescription drug plan.  
32 In any such case in which such plans are not available, the  
33 part D eligible individual shall be given the opportunity to  
34 enroll in a fallback prescription drug plan.

35 “(2) REQUIREMENT FOR DIFFERENT PLAN SPON-  
36 SORS.—The requirement in paragraph (1) is not satisfied

1 with respect to an area if only one entity offers all the  
2 qualifying plans in the area.

3 “(3) QUALIFYING PLAN DEFINED.—For purposes of  
4 this section, the term ‘qualifying plan’ means—

5 “(A) a prescription drug plan; or

6 “(B) an MA–PD plan described in section  
7 1851(a)(2)(A)(i) that provides—

8 “(i) basic prescription drug coverage; or

9 “(ii) qualified prescription drug coverage that  
10 provides supplemental prescription drug coverage  
11 so long as there is no MA monthly supplemental  
12 beneficiary premium applied under the plan, due to  
13 the application of a credit against such premium of  
14 a rebate under section 1854(b)(1)(C).

15 “(b) FLEXIBILITY IN RISK ASSUMED AND APPLICATION  
16 OF FALLBACK PLAN.—In order to ensure access pursuant to  
17 subsection (a) in an area—

18 “(1) the Secretary may approve limited risk plans  
19 under section 1860D–11(f) for the area; and

20 “(2) only if such access is still not provided in the  
21 area after applying paragraph (1), the Secretary shall pro-  
22 vide for the offering of a fallback prescription drug plan for  
23 that area under section 1860D–11(g).

24 “BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION  
25 DRUG COVERAGE

26 “SEC. 1860D–4. (a) DISSEMINATION OF INFORMATION.—

27 “(1) GENERAL INFORMATION.—

28 “(A) APPLICATION OF MA INFORMATION.—A PDP  
29 sponsor shall disclose, in a clear, accurate, and stand-  
30 arized form to each enrollee with a prescription drug  
31 plan offered by the sponsor under this part at the time  
32 of enrollment and at least annually thereafter, the in-  
33 formation described in section 1852(e)(1) relating to  
34 such plan, insofar as the Secretary determines appro-  
35 priate with respect to benefits provided under this part,  
36 and including the information described in subpara-  
37 graph (B).

1           “(B) DRUG SPECIFIC INFORMATION.—The infor-  
2 mation described in this subparagraph is information  
3 concerning the following:

4           “(i) Access to specific covered part D drugs,  
5 including access through pharmacy networks.

6           “(ii) How any formulary (including any tiered  
7 formulary structure) used by the sponsor functions,  
8 including a description of how a part D eligible in-  
9 dividual may obtain information on the formulary  
10 consistent with paragraph (3).

11           “(iii) Beneficiary cost-sharing requirements  
12 and how a part D eligible individual may obtain in-  
13 formation on such requirements, including tiered or  
14 other copayment level applicable to each drug (or  
15 class of drugs), consistent with paragraph (3).

16           “(iv) The medication therapy management  
17 program required under subsection (c).

18           “(2) DISCLOSURE UPON REQUEST OF GENERAL COV-  
19 ERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—  
20 Upon request of a part D eligible individual who is eligible  
21 to enroll in a prescription drug plan, the PDP sponsor of-  
22 fering such plan shall provide information similar (as deter-  
23 mined by the Secretary) to the information described in  
24 subparagraphs (A), (B), and (C) of section 1852(c)(2) to  
25 such individual.

26           “(3) PROVISION OF SPECIFIC INFORMATION.—

27           “(A) RESPONSE TO BENEFICIARY QUESTIONS.—  
28 Each PDP sponsor offering a prescription drug plan  
29 shall have a mechanism for providing specific informa-  
30 tion on a timely basis to enrollees upon request. Such  
31 mechanism shall include access to information through  
32 the use of a toll-free telephone number and, upon re-  
33 quest, the provision of such information in writing.

34           “(B) AVAILABILITY OF INFORMATION ON  
35 CHANGES IN FORMULARY THROUGH THE INTERNET.—  
36 A PDP sponsor offering a prescription drug plan shall  
37 make available on a timely basis through an Internet

1 website information on specific changes in the for-  
2 mulary under the plan (including changes to tiered or  
3 preferred status of covered part D drugs).

4 “(4) CLAIMS INFORMATION.—A PDP sponsor offering  
5 a prescription drug plan must furnish to each enrollee in  
6 a form easily understandable to such enrollees—

7 “(A) an explanation of benefits (in accordance  
8 with section 1806(a) or in a comparable manner); and

9 “(B) when prescription drug benefits are provided  
10 under this part, a notice of the benefits in relation to—

11 “(i) the initial coverage limit for the current  
12 year; and

13 “(ii) the annual out-of-pocket threshold for the  
14 current year.

15 Notices under subparagraph (B) need not be provided  
16 more often than as specified by the Secretary and no-  
17 tices under subparagraph (B)(ii) shall take into ac-  
18 count the application of section 1860D–2(b)(4)(C) to  
19 the extent practicable, as specified by the Secretary.

20 “(b) ACCESS TO COVERED PART D DRUGS.—

21 “(1) ASSURING PHARMACY ACCESS.—

22 “(A) PARTICIPATION OF ANY WILLING PHAR-  
23 MACY.—A prescription drug plan shall permit the par-  
24 ticipation of any pharmacy that meets the terms and  
25 conditions under the plan.

26 “(B) DISCOUNTS ALLOWED FOR NETWORK PHAR-  
27 MACIES.—For covered part D drugs dispensed through  
28 in-network pharmacies, a prescription drug plan may,  
29 notwithstanding subparagraph (A), reduce coinsurance  
30 or copayments for part D eligible individuals enrolled  
31 in the plan below the level otherwise required. In no  
32 case shall such a reduction result in an increase in pay-  
33 ments made by the Secretary under section 1860D–15  
34 to a plan.

35 “(C) CONVENIENT ACCESS FOR NETWORK PHAR-  
36 MACIES.—

1                   “(i) IN GENERAL.—The PDP sponsor of the  
2                   prescription drug plan shall secure the participation  
3                   in its network of a sufficient number of pharmacies  
4                   that dispense (other than by mail order) drugs di-  
5                   rectly to patients to ensure convenient access (con-  
6                   sistent with rules established by the Secretary).

7                   “(ii) APPLICATION OF TRICARE STANDARDS.—  
8                   The Secretary shall establish rules for convenient  
9                   access to in-network pharmacies under this sub-  
10                  paragraph that are no less favorable to enrollees  
11                  than the rules for convenient access to pharmacies  
12                  included in the statement of work of solicitation  
13                  (#MDA906-03-R-0002) of the Department of De-  
14                  fense under the TRICARE Retail Pharmacy  
15                  (TRRx) as of March 13, 2003.

16                  “(iii) ADEQUATE EMERGENCY ACCESS.—Such  
17                  rules shall include adequate emergency access for  
18                  enrollees.

19                  “(iv) CONVENIENT ACCESS IN LONG-TERM  
20                  CARE FACILITIES.—Such rules may include stand-  
21                  ards with respect to access for enrollees who are re-  
22                  siding in long-term care facilities and for phar-  
23                  macies operated by the Indian Health Service, In-  
24                  dian tribes and tribal organizations, and urban In-  
25                  dian organizations (as defined in section 4 of the  
26                  Indian Health Care Improvement Act).

27                  “(D) LEVEL PLAYING FIELD.—Such a sponsor  
28                  shall permit enrollees to receive benefits (which may in-  
29                  clude a 90-day supply of drugs or biologicals) through  
30                  a pharmacy (other than a mail order pharmacy), with  
31                  any differential in charge paid by such enrollees.

32                  “(E) NOT REQUIRED TO ACCEPT INSURANCE  
33                  RISK.—The terms and conditions under subparagraph  
34                  (A) may not require participating pharmacies to accept  
35                  insurance risk as a condition of participation.

36                  “(2) USE OF STANDARDIZED TECHNOLOGY.—

1           “(A) IN GENERAL.—The PDP sponsor of a pre-  
2           scription drug plan shall issue (and reissue, as appro-  
3           priate) such a card (or other technology) that may be  
4           used by an enrollee to assure access to negotiated  
5           prices under section 1860D–2(d).

6           “(B) STANDARDS.—

7           “(i) IN GENERAL.—The Secretary shall pro-  
8           vide for the development, adoption, or recognition  
9           of standards relating to a standardized format for  
10          the card or other technology required under sub-  
11          paragraph (A). Such standards shall be compatible  
12          with part C of title XI and may be based on stand-  
13          ards developed by an appropriate standard setting  
14          organization.

15          “(ii) CONSULTATION.—In developing the  
16          standards under clause (i), the Secretary shall con-  
17          sult with the National Council for Prescription  
18          Drug Programs and other standard setting organi-  
19          zations determined appropriate by the Secretary.

20          “(iii) IMPLEMENTATION.—The Secretary shall  
21          develop, adopt, or recognize the standards under  
22          clause (i) by such date as the Secretary determines  
23          shall be sufficient to ensure that PDP sponsors uti-  
24          lize such standards beginning January 1, 2006.

25          “(3) REQUIREMENTS ON DEVELOPMENT AND APPLICA-  
26          TION OF FORMULARIES.—If a PDP sponsor of a prescrip-  
27          tion drug plan uses a formulary (including the use of tiered  
28          cost-sharing), the following requirements must be met:

29                  “(A) DEVELOPMENT AND REVISION BY A PHAR-  
30                  MACY AND THERAPEUTIC (P&T) COMMITTEE.—

31                  “(i) IN GENERAL.—The formulary must be de-  
32                  veloped and reviewed by a pharmacy and thera-  
33                  peutic committee. A majority of the members of  
34                  such committee shall consist of individuals who are  
35                  practicing physicians or practicing pharmacists (or  
36                  both).

1                   “(ii) INCLUSION OF INDEPENDENT EX-  
2                   PERTS.—Such committee shall include at least one  
3                   practicing physician and at least one practicing  
4                   pharmacist, each of whom—

5                   “(I) is independent and free of conflict  
6                   with respect to the sponsor and plan; and

7                   “(II) has expertise in the care of elderly or  
8                   disabled persons.

9                   “(B) FORMULARY DEVELOPMENT.—In developing  
10                  and reviewing the formulary, the committee shall—

11                  “(i) base clinical decisions on the strength of  
12                  scientific evidence and standards of practice, in-  
13                  cluding assessing peer-reviewed medical literature,  
14                  such as randomized clinical trials,  
15                  pharmacoeconomic studies, outcomes research data,  
16                  and on such other information as the committee  
17                  determines to be appropriate; and

18                  “(ii) take into account whether including in  
19                  the formulary (or in a tier in such formulary) par-  
20                  ticular covered part D drugs has therapeutic ad-  
21                  vantages in terms of safety and efficacy.

22                  “(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC  
23                  CATEGORIES AND CLASSES.—

24                  “(i) IN GENERAL.—The formulary must in-  
25                  clude drugs within each therapeutic category and  
26                  class of covered part D drugs, although not nec-  
27                  essarily all drugs within such categories and class-  
28                  es.

29                  “(ii) MODEL GUIDELINES.—The Secretary  
30                  shall request the United States Pharmacopeia to  
31                  develop, in consultation with pharmaceutical benefit  
32                  managers and other interested parties, a list of cat-  
33                  egories and classes that may be used by prescrip-  
34                  tion drug plans under this paragraph and to revise  
35                  such classification from time to time to reflect  
36                  changes in therapeutic uses of covered part D

1 drugs and the additions of new covered part D  
2 drugs.

3 “(iii) LIMITATION ON CHANGES IN THERA-  
4 PEUTIC CLASSIFICATION.—The PDP sponsor of a  
5 prescription drug plan may not change the thera-  
6 peutic categories and classes in a formulary other  
7 than at the beginning of each plan year except as  
8 the Secretary may permit to take into account new  
9 therapeutic uses and newly approved covered part  
10 D drugs.

11 “(D) PROVIDER AND PATIENT EDUCATION.—The  
12 PDP sponsor shall establish policies and procedures to  
13 educate and inform health care providers and enrollees  
14 concerning the formulary.

15 “(E) NOTICE BEFORE REMOVING DRUG FROM  
16 FORMULARY OR CHANGING PREFERRED OR TIER STA-  
17 TUS OF DRUG.—Any removal of a covered part D drug  
18 from a formulary and any change in the preferred or  
19 tiered cost-sharing status of such a drug shall take ef-  
20 fect only after appropriate notice is made available  
21 (such as under subsection (a)(3)) to the Secretary, af-  
22 fected enrollees, physicians, pharmacies, and phar-  
23 macists.

24 “(F) PERIODIC EVALUATION OF PROTOCOLS.—In  
25 connection with the formulary, the sponsor of a pre-  
26 scription drug plan shall provide for the periodic eval-  
27 uation and analysis of treatment protocols and proce-  
28 dures.

29 The requirements of this paragraph may be met by a PDP  
30 sponsor directly or through arrangements with another en-  
31 tity.

32 “(c) COST AND UTILIZATION MANAGEMENT; QUALITY AS-  
33 SURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

34 “(1) IN GENERAL.—The PDP sponsor shall have in  
35 place, directly or through appropriate arrangements, with  
36 respect to covered part D drugs, the following:



1           “(A) A cost-effective drug utilization management  
2           program, including incentives to reduce costs when  
3           medically appropriate, such as through the use of mul-  
4           tiple source drugs (as defined in section  
5           1927(k)(7)(A)(i)).

6           “(B) Quality assurance measures and systems to  
7           reduce medication errors and adverse drug interactions  
8           and improve medication use.

9           “(C) A medication therapy management program  
10          described in paragraph (2).

11          “(D) A program to control fraud, abuse, and  
12          waste.

13          Nothing in this section shall be construed as impairing a  
14          PDP sponsor from utilizing cost management tools (includ-  
15          ing differential payments) under all methods of operation.

16          “(2) MEDICATION THERAPY MANAGEMENT PRO-  
17          GRAM.—

18                 “(A) DESCRIPTION.—

19                         “(i) IN GENERAL.—A medication therapy  
20                         management program described in this paragraph  
21                         is a program of drug therapy management that  
22                         may be furnished by a pharmacist and that is de-  
23                         signed to assure, with respect to targeted bene-  
24                         ficiaries described in clause (ii), that covered part  
25                         D drugs under the prescription drug plan are ap-  
26                         propriately used to optimize therapeutic outcomes  
27                         through improved medication use, and to reduce  
28                         the risk of adverse events, including adverse drug  
29                         interactions. Such a program may distinguish be-  
30                         tween services in ambulatory and institutional set-  
31                         tings.

32                         “(ii) TARGETED BENEFICIARIES DE-  
33                         SCRIBED.—Targeted beneficiaries described in this  
34                         clause are part D eligible individuals who—

35                                 “(I) have multiple chronic diseases (such  
36                                 as diabetes, asthma, hypertension,  
37                                 hyperlipidemia, and congestive heart failure);

1                   “(II) are taking multiple covered part D  
2                   drugs; and

3                   “(III) are identified as likely to incur an-  
4                   nual costs for covered part D drugs that exceed  
5                   a level specified by the Secretary.

6                   “(B) ELEMENTS.—Such program may include ele-  
7                   ments that promote—

8                   “(i) enhanced enrollee understanding to pro-  
9                   mote the appropriate use of medications by enroll-  
10                  ees and to reduce the risk of potential adverse  
11                  events associated with medications, through bene-  
12                  ficiary education, counseling, and other appropriate  
13                  means;

14                  “(ii) increased enrollee adherence with pre-  
15                  scription medication regimens through medication  
16                  refill reminders, special packaging, and other com-  
17                  pliance programs and other appropriate means; and

18                  “(iii) detection of adverse drug events and pat-  
19                  terns of overuse and underuse of prescription  
20                  drugs.

21                  “(C) DEVELOPMENT OF PROGRAM IN COOPERA-  
22                  TION WITH LICENSED PHARMACISTS.—Such program  
23                  shall be developed in cooperation with licensed and  
24                  practicing pharmacists and physicians.

25                  “(D) COORDINATION WITH CARE MANAGEMENT  
26                  PLANS.—The Secretary shall establish guidelines for  
27                  the coordination of any medication therapy manage-  
28                  ment program under this paragraph with respect to a  
29                  targeted beneficiary with any care management plan  
30                  established with respect to such beneficiary under a  
31                  chronic care improvement program under section 1807.

32                  “(E) CONSIDERATIONS IN PHARMACY FEES.—The  
33                  PDP sponsor of a prescription drug plan shall take  
34                  into account, in establishing fees for pharmacists and  
35                  others providing services under such plan, the resources  
36                  used, and time required to, implement the medication  
37                  therapy management program under this paragraph.

1           Each such sponsor shall disclose to the Secretary upon  
2           request the amount of any such management or dis-  
3           pensing fees. The provisions of section 1927(b)(3)(D)  
4           apply to information disclosed under this subpara-  
5           graph.

6           “(d) CONSUMER SATISFACTION SURVEYS.—In order to  
7           provide for comparative information under section 1860D–  
8           1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction  
9           surveys with respect to PDP sponsors and prescription drug  
10          plans in a manner similar to the manner such surveys are con-  
11          ducted for MA organizations and MA plans under part C.

12          “(e) ELECTRONIC PRESCRIPTION PROGRAM.—

13           “(1) APPLICATION OF STANDARDS.—As of such date  
14           as the Secretary may specify, but not later than 1 year  
15           after the date of promulgation of final standards under  
16           paragraph (4)(D), prescriptions and other information de-  
17           scribed in paragraph (2)(A) for covered part D drugs pre-  
18           scribed for part D eligible individuals that are transmitted  
19           electronically shall be transmitted only in accordance with  
20           such standards under an electronic prescription drug pro-  
21           gram that meets the requirements of paragraph (2).

22           “(2) PROGRAM REQUIREMENTS.—Consistent with uni-  
23           form standards established under paragraph (3)—

24           “(A) PROVISION OF INFORMATION TO PRE-  
25           SCRIBING HEALTH CARE PROFESSIONAL AND DIS-  
26           PENSING PHARMACIES AND PHARMACISTS.—An elec-  
27           tronic prescription drug program shall provide for the  
28           electronic transmittal to the prescribing health care  
29           professional and to the dispensing pharmacy and phar-  
30           macist of the prescription and information on eligibility  
31           and benefits (including the drugs included in the appli-  
32           cable formulary, any tiered formulary structure, and  
33           any requirements for prior authorization) and of the  
34           following information with respect to the prescribing  
35           and dispensing of a covered part D drug:

36           “(i) Information on the drug being prescribed  
37           or dispensed and other drugs listed on the medica-

1           tion history, including information on drug-drug  
2           interactions, warnings or cautions, and, when indi-  
3           cated, dosage adjustments.

4           “(ii) Information on the availability of lower  
5           cost, therapeutically appropriate alternatives (if  
6           any) for the drug prescribed.

7           “(B) APPLICATION TO MEDICAL HISTORY INFOR-  
8           MATION.—Effective on and after such date as the Sec-  
9           retary specifies and after the establishment of appro-  
10          priate standards to carry out this subparagraph, the  
11          program shall provide for the electronic transmittal in  
12          a manner similar to the manner under subparagraph  
13          (A) of information that relates to the medical history  
14          concerning the individual and related to a covered part  
15          D drug being prescribed or dispensed, upon request of  
16          the professional or pharmacist involved.

17          “(C) LIMITATIONS.—Information shall only be dis-  
18          closed under subparagraph (A) or (B) if the disclosure  
19          of such information is permitted under the Federal reg-  
20          ulations (concerning the privacy of individually identifi-  
21          able health information) promulgated under section  
22          264(c) of the Health Insurance Portability and Ac-  
23          countability Act of 1996.

24          “(D) TIMING.—To the extent feasible, the infor-  
25          mation exchanged under this paragraph shall be on an  
26          interactive, real-time basis.

27          “(3) STANDARDS.—

28          “(A) IN GENERAL.—The Secretary shall provide  
29          consistent with this subsection for the promulgation of  
30          uniform standards relating to the requirements for  
31          electronic prescription drug programs under paragraph  
32          (2).

33          “(B) OBJECTIVES.—Such standards shall be con-  
34          sistent with the objectives of improving—

35                  “(i) patient safety;

36                  “(ii) the quality of care provided to patients;

37                  and

1                   “(iii) efficiencies, including cost savings, in the  
2 delivery of care.

3                   “(C) DESIGN CRITERIA.—Such standards shall—

4                   “(i) be designed so that, to the extent prac-  
5 ticable, the standards do not impose an undue ad-  
6 ministrative burden on prescribing health care pro-  
7 fessionals and dispensing pharmacies and phar-  
8 macists;

9                   “(ii) be compatible with standards established  
10 under part C of title XI, standards established  
11 under subsection (b)(2)(B)(i), and with general  
12 health information technology standards; and

13                   “(iii) be designed so that they permit elec-  
14 tronic exchange of drug labeling and drug listing  
15 information maintained by the Food and Drug Ad-  
16 ministration and the National Library of Medicine.

17                   “(D) PERMITTING USE OF APPROPRIATE MES-  
18 SAGING.—Such standards shall allow for the messaging  
19 of information only if it relates to the appropriate pre-  
20 scribing of drugs, including quality assurance measures  
21 and systems referred to in subsection (c)(1)(B).

22                   “(E) PERMITTING PATIENT DESIGNATION OF DIS-  
23 PENSING PHARMACY.—

24                   “(i) IN GENERAL.—Consistent with clause (ii),  
25 such standards shall permit a part D eligible indi-  
26 vidual to designate a particular pharmacy to dis-  
27 pense a prescribed drug.

28                   “(ii) NO CHANGE IN BENEFITS.—Clause (i)  
29 shall not be construed as affecting—

30                   “(I) the access required to be provided to  
31 pharmacies by a prescription drug plan; or

32                   “(II) the application of any differences in  
33 benefits or payments under such a plan based  
34 on the pharmacy dispensing a covered part D  
35 drug.

36                   “(4) DEVELOPMENT, PROMULGATION, AND MODIFICA-  
37 TION OF STANDARDS.—

1           “(A) INITIAL STANDARDS.—Not later than Sep-  
2           tember 1, 2005, the Secretary shall develop, adopt, rec-  
3           ognize, or modify initial uniform standards relating to  
4           the requirements for electronic prescription drug pro-  
5           grams described in paragraph (2) taking into consider-  
6           ation the recommendations (if any) from the National  
7           Committee on Vital and Health Statistics (as estab-  
8           lished under section 306(k) of the Public Health Serv-  
9           ice Act (42 U.S.C. 242k(k))) under subparagraph (B).

10           “(B) ROLE OF NCVHS.—The National Committee  
11           on Vital and Health Statistics shall develop rec-  
12           ommendations for uniform standards relating to such  
13           requirements in consultation with the following:

14                   “(i) Standard setting organizations (as defined  
15                   in section 1171(8))

16                   “(ii) Practicing physicians.

17                   “(iii) Hospitals.

18                   “(iv) Pharmacies.

19                   “(v) Practicing pharmacists.

20                   “(vi) Pharmacy benefit managers.

21                   “(vii) State boards of pharmacy.

22                   “(viii) State boards of medicine.

23                   “(ix) Experts on electronic prescribing.

24                   “(x) Other appropriate Federal agencies.

25           “(C) PILOT PROJECT TO TEST INITIAL STAND-  
26           ARDS.—

27                   “(i) IN GENERAL.—During the 1-year period  
28                   that begins on January 1, 2006, the Secretary shall  
29                   conduct a pilot project to test the initial standards  
30                   developed under subparagraph (A) prior to the pro-  
31                   mulgation of the final uniform standards under  
32                   subparagraph (D) in order to provide for the effi-  
33                   cient implementation of the requirements described  
34                   in paragraph (2).

35                   “(ii) EXCEPTION.—Pilot testing of standards  
36                   is not required under clause (i) where there already  
37                   is adequate industry experience with such stand-

1           ards, as determined by the Secretary after con-  
2           sultation with effected standard setting organiza-  
3           tions and industry users.

4           “(iii) VOLUNTARY PARTICIPATION OF PHYSI-  
5           CIANS AND PHARMACIES.—In order to conduct the  
6           pilot project under clause (i), the Secretary shall  
7           enter into agreements with physicians, physician  
8           groups, pharmacies, hospitals, PDP sponsors, MA  
9           organizations, and other appropriate entities under  
10          which health care professionals electronically trans-  
11          mit prescriptions to dispensing pharmacies and  
12          pharmacists in accordance with such standards.

13          “(iv) EVALUATION AND REPORT.—

14           “(I) EVALUATION.—The Secretary shall  
15           conduct an evaluation of the pilot project con-  
16           ducted under clause (i).

17           “(II) REPORT TO CONGRESS.—Not later  
18           than April 1, 2007, the Secretary shall submit  
19           to Congress a report on the evaluation con-  
20           ducted under subclause (I).

21           “(D) FINAL STANDARDS.—Based upon the evalua-  
22           tion of the pilot project under subparagraph (C)(iv)(I)  
23           and not later than April 1, 2008, the Secretary shall  
24           promulgate uniform standards relating to the require-  
25           ments described in paragraph (2).

26           “(5) RELATION TO STATE LAWS.—The standards pro-  
27           mulgated under this subsection shall supersede any State  
28           law or regulation that—

29           “(A) is contrary to the standards or restricts the  
30           ability to carry out this part; and

31           “(B) pertains to the electronic transmission of  
32           medication history and of information on eligibility,  
33           benefits, and prescriptions with respect to covered part  
34           D drugs under this part.

35           “(6) ESTABLISHMENT OF SAFE HARBOR.—The Sec-  
36           retary, in consultation with the Attorney General, shall pro-  
37           mulgate regulations that provide for a safe harbor from

1 sanctions under paragraphs (1) and (2) of section  
2 1128B(b) and an exception to the prohibition under sub-  
3 section (a)(1) of section 1877 with respect to the provision  
4 of nonmonetary remuneration (in the form of hardware,  
5 software, or information technology and training services)  
6 necessary and used solely to receive and transmit electronic  
7 prescription information in accordance with the standards  
8 promulgated under this subsection—

9 “(A) in the case of a hospital, by the hospital to  
10 members of its medical staff;

11 “(B) in the case of a group practice (as defined  
12 in section 1877(h)(4)), by the practice to prescribing  
13 health care professionals who are members of such  
14 practice; and

15 “(C) in the case of a PDP sponsor or MA organi-  
16 zation, by the sponsor or organization to pharmacists  
17 and pharmacies participating in the network of such  
18 sponsor or organization, and to prescribing health care  
19 professionals.

20 “(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall  
21 provide meaningful procedures for hearing and resolving griev-  
22 ances between the sponsor (including any entity or individual  
23 through which the sponsor provides covered benefits) and en-  
24 rollees with prescription drug plans of the sponsor under this  
25 part in accordance with section 1852(f).

26 “(g) COVERAGE DETERMINATIONS AND RECONSIDER-  
27 ATIONS.—

28 “(1) APPLICATION OF COVERAGE DETERMINATION  
29 AND RECONSIDERATION PROVISIONS.—A PDP sponsor  
30 shall meet the requirements of paragraphs (1) through (3)  
31 of section 1852(g) with respect to covered benefits under  
32 the prescription drug plan it offers under this part in the  
33 same manner as such requirements apply to an MA organi-  
34 zation with respect to benefits it offers under an MA plan  
35 under part C.

36 “(2) REQUEST FOR A DETERMINATION FOR THE  
37 TREATMENT OF TIERED FORMULARY DRUG.—In the case of



1 a prescription drug plan offered by a PDP sponsor that  
2 provides for tiered cost-sharing for drugs included within a  
3 formulary and provides lower cost-sharing for preferred  
4 drugs included within the formulary, a part D eligible indi-  
5 vidual who is enrolled in the plan may request an exception  
6 to the tiered cost-sharing structure. Under such an excep-  
7 tion, a nonpreferred drug could be covered under the terms  
8 applicable for preferred drugs if the prescribing physician  
9 determines that the preferred drug for treatment of the  
10 same condition either would not be as effective for the indi-  
11 vidual or would have adverse effects for the individual or  
12 both. A PDP sponsor shall have an exceptions process  
13 under this paragraph consistent with guidelines established  
14 by the Secretary for making a determination with respect  
15 to such a request. Denial of such an exception shall be  
16 treated as a coverage denial for purposes of applying sub-  
17 section (h).

18 “(h) APPEALS.—

19 “(1) IN GENERAL.—Subject to paragraph (2), a PDP  
20 sponsor shall meet the requirements of paragraphs (4) and  
21 (5) of section 1852(g) with respect to benefits (including a  
22 determination related to the application of tiered cost-shar-  
23 ing described in subsection (g)(2)) in a manner similar (as  
24 determined by the Secretary) to the manner such require-  
25 ments apply to an MA organization with respect to benefits  
26 under the original medicare fee-for-service program option  
27 it offers under an MA plan under part C. In applying this  
28 paragraph only the part D eligible individual shall be enti-  
29 tled to bring such an appeal.

30 “(2) LIMITATION IN CASES ON NONFORMULARY DE-  
31 TERMINATIONS.—A part D eligible individual who is en-  
32 rolled in a prescription drug plan offered by a PDP sponsor  
33 may appeal under paragraph (1) a determination not to  
34 provide for coverage of a covered part D drug that is not  
35 on the formulary under the plan only if the prescribing  
36 physician determines that all covered part D drugs on any  
37 tier of the formulary for treatment of the same condition

1 would not be as effective for the individual as the nonfor-  
2 mulary drug, would have adverse effects for the individual,  
3 or both.

4 “(3) TREATMENT OF NONFORMULARY DETERMINA-  
5 TIONS.—If a PDP sponsor determines that a plan provides  
6 coverage for a covered part D drug that is not on the for-  
7 mulary of the plan, the drug shall be treated as being in-  
8 cluded on the formulary for purposes of section 1860D-  
9 2(b)(4)(C)(i).

10 “(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF EN-  
11 ROLLEE RECORDS.—The provisions of section 1852(h) shall  
12 apply to a PDP sponsor and prescription drug plan in the same  
13 manner as it applies to an MA organization and an MA plan.

14 “(j) TREATMENT OF ACCREDITATION.—Subparagraph (A)  
15 of section 1852(e)(4) (relating to treatment of accreditation)  
16 shall apply to a PDP sponsor under this part with respect to  
17 the following requirements, in the same manner as it applies  
18 to an MA organization with respect to the requirements in sub-  
19 paragraph (B) (other than clause (vii) thereof) of such section:

20 “(1) Subsection (b) of this section (relating to access  
21 to covered part D drugs).

22 “(2) Subsection (c) of this section (including quality  
23 assurance and medication therapy management).

24 “(3) Subsection (i) of this section (relating to con-  
25 fidentiality and accuracy of enrollee records).

26 “(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES  
27 FOR EQUIVALENT DRUGS.—

28 “(1) IN GENERAL.—A PDP sponsor offering a pre-  
29 scription drug plan shall provide that each pharmacy that  
30 dispenses a covered part D drug shall inform an enrollee  
31 of any differential between the price of the drug to the en-  
32 rollee and the price of the lowest priced generic covered  
33 part D drug under the plan that is therapeutically equiva-  
34 lent and bioequivalent and available at such pharmacy.

35 “(2) TIMING OF NOTICE.—

36 “(A) IN GENERAL.—Subject to subparagraph (B),  
37 the information under paragraph (1) shall be provided

1 at the time of purchase of the drug involved, or, in the  
2 case of dispensing by mail order, at the time of delivery  
3 of such drug.

4 “(B) WAIVER.—The Secretary may waive sub-  
5 paragraph (A) in such circumstances as the Secretary  
6 may specify.

7 “Subpart 2—Prescription Drug Plans; PDP Sponsors;  
8 Financing

9 “PDP REGIONS; SUBMISSION OF BIDS; PLAN APPROVAL

10 “SEC. 1860D–11. (a) ESTABLISHMENT OF PDP REGIONS;  
11 SERVICE AREAS.—

12 “(1) COVERAGE OF ENTIRE PDP REGION.—The service  
13 area for a prescription drug plan shall consist of an entire  
14 PDP region established under paragraph (2).

15 “(2) ESTABLISHMENT OF PDP REGIONS.—

16 “(A) IN GENERAL.—The Secretary shall establish,  
17 and may revise, PDP regions in a manner that is con-  
18 sistent with the requirements for the establishment and  
19 revision of MA regions under subparagraphs (B) and  
20 (C) of section 1858(a)(2).

21 “(B) RELATION TO MA REGIONS.—To the extent  
22 practicable, PDP regions shall be the same as MA re-  
23 gions under section 1858(a)(2). The Secretary may es-  
24 tablish PDP regions which are not the same as MA re-  
25 gions if the Secretary determines that the establish-  
26 ment of different regions under this part would improve  
27 access to benefits under this part.

28 “(C) AUTHORITY FOR TERRITORIES.—The Sec-  
29 retary shall establish, and may revise, PDP regions for  
30 areas in States that are not within the 50 States or the  
31 District of Columbia.

32 “(3) NATIONAL PLAN.—Nothing in this subsection  
33 shall be construed as preventing a prescription drug plan  
34 from being offered in more than one PDP region (including  
35 all PDP regions).

36 “(b) SUBMISSION OF BIDS, PREMIUMS, AND RELATED IN-  
37 FORMATION.—

1           “(1) IN GENERAL.—A PDP sponsor shall submit to  
2 the Secretary information described in paragraph (2) with  
3 respect to each prescription drug plan it offers. Such infor-  
4 mation shall be submitted at the same time and in a simi-  
5 lar manner to the manner in which information described  
6 in paragraph (6) of section 1854(a) is submitted by an MA  
7 organization under paragraph (1) of such section.

8           “(2) INFORMATION DESCRIBED.—The information de-  
9 scribed in this paragraph is information on the following:

10           “(A) COVERAGE PROVIDED.—The prescription  
11 drug coverage provided under the plan, including the  
12 deductible and other cost-sharing.

13           “(B) ACTUARIAL VALUE.—The actuarial value of  
14 the qualified prescription drug coverage in the region  
15 for a part D eligible individual with a national average  
16 risk profile for the factors described in section 1860D-  
17 15(c)(1)(A) (as specified by the Secretary).

18           “(C) BID.—Information on the bid, including an  
19 actuarial certification of—

20           “(i) the basis for the actuarial value described  
21 in subparagraph (B) assumed in such bid;

22           “(ii) the portion of such bid attributable to  
23 basic prescription drug coverage and, if applicable,  
24 the portion of such bid attributable to supplemental  
25 benefits;

26           “(iii) assumptions regarding the reinsurance  
27 subsidy payments provided under section 1860D-  
28 15(b) subtracted from the actuarial value to  
29 produce such bid; and

30           “(iv) administrative expenses assumed in the  
31 bid.

32           “(D) SERVICE AREA.—The service area for the  
33 plan.

34           “(E) LEVEL OF RISK ASSUMED.—

35           “(i) IN GENERAL.—Whether the PDP sponsor  
36 requires a modification of risk level under clause  
37 (ii) and, if so, the extent of such modification. Any

1 such modification shall apply with respect to all  
2 prescription drug plans offered by a PDP sponsor  
3 in a PDP region. This subparagraph shall not  
4 apply to an MA–PD plan.

5 “(ii) RISK LEVELS DESCRIBED.—A modifica-  
6 tion of risk level under this clause may consist of  
7 one or more of the following:

8 “(I) INCREASE IN FEDERAL PERCENTAGE  
9 ASSUMED IN INITIAL RISK CORRIDOR.—An  
10 equal percentage point increase in the percents  
11 applied under subparagraphs (B)(i), (B)(ii)(I),  
12 (C)(i), and (C)(ii)(I) of section 1860D–  
13 15(e)(2). In no case shall the application of  
14 previous sentence prevent the application of a  
15 higher percentage under section 1869D–  
16 15(e)(2)(B)(iii).

17 “(II) INCREASE IN FEDERAL PERCENTAGE  
18 ASSUMED IN SECOND RISK CORRIDOR.—An  
19 equal percentage point increase in the percents  
20 applied under subparagraphs (B)(ii)(II) and  
21 (C)(ii)(II) of section 1860D–15(e)(2).

22 “(III) DECREASE IN SIZE OF RISK COR-  
23 RIDORS.—A decrease in the threshold risk per-  
24 centages specified in section 1860D–  
25 15(e)(3)(C).

26 “(F) ADDITIONAL INFORMATION.—Such other in-  
27 formation as the Secretary may require to carry out  
28 this part.

29 “(3) PAPERWORK REDUCTION FOR OFFERING OF PRE-  
30 SCRIPTIION DRUG PLANS NATIONALLY OR IN MULTI-REGION  
31 AREAS.—The Secretary shall establish requirements for in-  
32 formation submission under this subsection in a manner  
33 that promotes the offering of such plans in more than one  
34 PDP region (including all regions) through the filing of  
35 consolidated information.

36 “(c) ACTUARIAL VALUATION.—

1           “(1) PROCESSES.—For purposes of this part, the Sec-  
2           retary shall establish processes and methods for deter-  
3           mining the actuarial valuation of prescription drug cov-  
4           erage, including—

5                   “(A) an actuarial valuation of standard prescrip-  
6                   tion drug coverage under section 1860D–2(b);

7                   “(B) actuarial valuations relating to alternative  
8                   prescription drug coverage under section 1860D–  
9                   2(c)(1);

10                   “(C) an actuarial valuation of the reinsurance sub-  
11                   sidy payments under section 1860D–15(b);

12                   “(D) the use of generally accepted actuarial prin-  
13                   ciples and methodologies; and

14                   “(E) applying the same methodology for deter-  
15                   minations of actuarial valuations under subparagraphs  
16                   (A) and (B).

17           “(2) ACCOUNTING FOR DRUG UTILIZATION.—Such  
18           processes and methods for determining actuarial valuation  
19           shall take into account the effect that providing alternative  
20           prescription drug coverage (rather than standard prescrip-  
21           tion drug coverage) has on drug utilization.

22           “(3) RESPONSIBILITIES.—

23                   “(A) PLAN RESPONSIBILITIES.—PDP sponsors  
24                   and MA organizations are responsible for the prepara-  
25                   tion and submission of actuarial valuations required  
26                   under this part for prescription drug plans and MA-  
27                   PD plans they offer.

28                   “(B) USE OF OUTSIDE ACTUARIES.—Under the  
29                   processes and methods established under paragraph  
30                   (1), PDP sponsors offering prescription drug plans and  
31                   MA organizations offering MA–PD plans may use actu-  
32                   arial opinions certified by independent, qualified actu-  
33                   aries to establish actuarial values.

34           “(d) REVIEW OF INFORMATION AND NEGOTIATION.—

35                   “(1) REVIEW OF INFORMATION.—The Secretary shall  
36                   review the information filed under subsection (b) for the  
37                   purpose of conducting negotiations under paragraph (2).

1           “(2) NEGOTIATION REGARDING TERMS AND CONDI-  
2           TIONS.—Subject to subsection (i), in exercising the author-  
3           ity under paragraph (1), the Secretary—

4           “(A) has the authority to negotiate the terms and  
5           conditions of the proposed bid submitted and other  
6           terms and conditions of a proposed plan; and

7           “(B) has authority similar to the authority of the  
8           Director of the Office of Personnel Management with  
9           respect to health benefits plans under chapter 89 of  
10          title 5, United States Code.

11          “(e) APPROVAL OF PROPOSED PLANS.—

12          “(1) IN GENERAL.—After review and negotiation  
13          under subsection (d), the Secretary shall approve or dis-  
14          approve the prescription drug plan.

15          “(2) REQUIREMENTS FOR APPROVAL.—The Secretary  
16          may approve a prescription drug plan only if the following  
17          requirements are met:

18          “(A) COMPLIANCE WITH REQUIREMENTS.—The  
19          plan and the PDP sponsor offering the plan comply  
20          with the requirements under this part, including the  
21          provision of qualified prescription drug coverage.

22          “(B) ACTUARIAL DETERMINATIONS.—The Sec-  
23          retary determines that the plan and PDP sponsor meet  
24          the requirements under this part relating to actuarial  
25          determinations, including such requirements under sec-  
26          tion 1860D–2(e).

27          “(C) APPLICATION OF FEHBP STANDARD.—

28          “(i) IN GENERAL.—The Secretary determines  
29          that the portion of the bid submitted under sub-  
30          section (b) that is attributable to basic prescription  
31          drug coverage is supported by the actuarial bases  
32          provided under such subsection and reasonably and  
33          equitably reflects the revenue requirements (as  
34          used for purposes of section 1302(8)(C) of the  
35          Public Health Service Act) for benefits provided  
36          under that plan, less the sum (determined on a  
37          monthly per capita basis) of the actuarial value of

1 the reinsurance payments under section 1860D–  
2 15(b).

3 “(ii) SUPPLEMENTAL COVERAGE.—The Sec-  
4 retary determines that the portion of the bid sub-  
5 mitted under subsection (b) that is attributable to  
6 supplemental prescription drug coverage pursuant  
7 to section 1860D–2(a)(2) is supported by the actu-  
8 arial bases provided under such subsection and rea-  
9 sonably and equitably reflects the revenue require-  
10 ments (as used for purposes of section 1302(8)(C)  
11 of the Public Health Service Act) for such coverage  
12 under the plan.

13 “(D) PLAN DESIGN.—

14 “(i) IN GENERAL.—The Secretary does not  
15 find that the design of the plan and its benefits (in-  
16 cluding any formulary and tiered formulary struc-  
17 ture) are likely to substantially discourage enroll-  
18 ment by certain part D eligible individuals under  
19 the plan.

20 “(ii) USE OF CATEGORIES AND CLASSES IN  
21 FORMULARIES.—The Secretary may not find that  
22 the design of categories and classes within a for-  
23 mulary violates clause (i) if such categories and  
24 classes are consistent with guidelines (if any) for  
25 such categories and classes established by the  
26 United States Pharmacopeia.

27 “(f) APPLICATION OF LIMITED RISK PLANS.—

28 “(1) CONDITIONS FOR APPROVAL OF LIMITED RISK  
29 PLANS.—The Secretary may only approve a limited risk  
30 plan (as defined in paragraph (4)(A)) for a PDP region if  
31 the access requirements under section 1860D–3(a) would  
32 not be met for the region but for the approval of such a  
33 plan (or a fallback prescription drug plan under subsection  
34 (g)).

35 “(2) RULES.—The following rules shall apply with re-  
36 spect to the approval of a limited risk plan in a PDP re-  
37 gion:



1           “(A) LIMITED EXERCISE OF AUTHORITY.—Only  
2           the minimum number of such plans may be approved  
3           in order to meet the access requirements under section  
4           1860D–3(a).

5           “(B) MAXIMIZING ASSUMPTION OF RISK.—The  
6           Secretary shall provide priority in approval for those  
7           plans bearing the highest level of risk (as computed by  
8           the Secretary), but the Secretary may take into ac-  
9           count the level of the bids submitted by such plans.

10           “(C) NO FULL UNDERWRITING FOR LIMITED RISK  
11           PLANS.—In no case may the Secretary approve a lim-  
12           ited risk plan under which the modification of risk level  
13           provides for no (or a de minimis) level of financial risk.

14           “(3) ACCEPTANCE OF ALL FULL RISK CONTRACTS.—  
15           There shall be no limit on the number of full risk plans  
16           that are approved under subsection (e).

17           “(4) RISK-PLANS DEFINED.—For purposes of this  
18           subsection:

19           “(A) LIMITED RISK PLAN.—The term ‘limited risk  
20           plan’ means a prescription drug plan that provides  
21           basic prescription drug coverage and for which the  
22           PDP sponsor includes a modification of risk level de-  
23           scribed in subparagraph (E) of subsection (b)(2) in its  
24           bid submitted for the plan under such subsection. Such  
25           term does not include a fallback prescription drug plan.

26           “(B) FULL RISK PLAN.—The term ‘full risk plan’  
27           means a prescription drug plan that is not a limited  
28           risk plan or a fallback prescription drug plan.

29           “(g) GUARANTEEING ACCESS TO COVERAGE.—

30           “(1) SOLICITATION OF BIDS.—

31           “(A) IN GENERAL.—Separate from the bidding  
32           process under subsection (b), the Secretary shall pro-  
33           vide for a process for the solicitation of bids from eligi-  
34           ble fallback entities (as defined in paragraph (2)) for  
35           the offering in all fallback service areas (as defined in  
36           paragraph (3)) in one or more PDP regions of a fall-  
37           back prescription drug plan (as defined in paragraph

1 (4)) during the contract period specified in paragraph  
2 (5)).

3 “(B) ACCEPTANCE OF BIDS.—

4 “(i) IN GENERAL.—Except as provided in this  
5 subparagraph, the provisions of subsection (e) shall  
6 apply with respect to the approval or disapproval of  
7 fallback prescription drug plans. The Secretary  
8 shall enter into contracts under this subsection  
9 with eligible fallback entities for the offering of fall-  
10 back prescription drug plans so approved in fall-  
11 back service areas.

12 “(ii) LIMITATION OF 1 PLAN FOR ALL FALL-  
13 BACK SERVICE AREAS IN A PDP REGION.—With re-  
14 spect to all fallback service areas in any PDP re-  
15 gion for a contract period, the Secretary shall ap-  
16 prove the offering of only 1 fallback prescription  
17 drug plan.

18 “(iii) COMPETITIVE PROCEDURES.—Competi-  
19 tive procedures (as defined in section 4(5) of the  
20 Office of Federal Procurement Policy Act (41  
21 U.S.C. 403(5))) shall be used to enter into a con-  
22 tract under this subsection. The provisions of sub-  
23 section (d) of section 1874A shall apply to a con-  
24 tract under this section in the same manner as  
25 they apply to a contract under such section.

26 “(iv) TIMING.—The Secretary shall approve a  
27 fallback prescription drug plan for a PDP region in  
28 a manner so that, if there are any fallback service  
29 areas in the region for a year, the fallback prescrip-  
30 tion drug plan is offered at the same time as pre-  
31 scription drug plans would otherwise be offered.

32 “(V) NO NATIONAL FALLBACK PLAN.—The  
33 Secretary shall not enter into a contract with a sin-  
34 gle fallback entity for the offering of fallback plans  
35 throughout the United States.

36 “(2) ELIGIBLE FALLBACK ENTITY.—For purposes of  
37 this section, the term ‘eligible fallback entity’ means, with

1 respect to all fallback service areas in a PDP region for a  
2 contract period, an entity that—

3 “(A) meets the requirements to be a PDP sponsor  
4 (or would meet such requirements but for the fact that  
5 the entity is not a risk-bearing entity); and

6 “(B) does not submit a bid under section 1860D–  
7 11(b) for any prescription drug plan for any PDP re-  
8 gion for the first year of such contract period.

9 For purposes of subparagraph (B), an entity shall be treat-  
10 ed as submitting a bid with respect to a prescription drug  
11 plan if the entity is acting as a subcontractor of a PDP  
12 sponsor that is offering such a plan. The previous sentence  
13 shall not apply to entities that are subcontractors of an MA  
14 organization except insofar as such organization is acting  
15 as a PDP sponsor with respect to a prescription drug plan.

16 “(3) FALLBACK SERVICE AREA.—For purposes of this  
17 subsection, the term ‘fallback service area’ means, for a  
18 PDP region with respect to a year, any area within such  
19 region for which the Secretary determines before the begin-  
20 ning of the year that the access requirements of the first  
21 sentence of section 1860D–3(a) will not be met for part D  
22 eligible individuals residing in the area for the year.

23 “(4) FALLBACK PRESCRIPTION DRUG PLAN.—For pur-  
24 poses of this part, the term ‘fallback prescription drug  
25 plan’ means a prescription drug plan that—

26 “(A) only offers the standard prescription drug  
27 coverage and access to negotiated prices described in  
28 section 1860D–2(a)(1)(A) and does not include any  
29 supplemental prescription drug coverage; and

30 “(B) meets such other requirements as the Sec-  
31 retary may specify.

32 “(5) PAYMENTS UNDER THE CONTRACT.—

33 “(A) IN GENERAL.—A contract entered into under  
34 this subsection shall provide for—

35 “(i) payment for the actual costs (taking into  
36 account negotiated price concessions described in  
37 section 1860D–2(d)(1)(B)) of covered part D drugs

1 provided to part D eligible individuals enrolled in a  
2 fallback prescription drug plan offered by the enti-  
3 ty; and

4 “(ii) payment of management fees that are  
5 tied to performance measures established by the  
6 Secretary for the management, administration, and  
7 delivery of the benefits under the contract.

8 “(B) PERFORMANCE MEASURES.—The perform-  
9 ance measures established by the Secretary pursuant to  
10 subparagraph (A)(ii) shall include at least measures for  
11 each of the following:

12 “(i) COSTS.—The entity contains costs to the  
13 Medicare Prescription Drug Account and to part D  
14 eligible individuals enrolled in a fallback prescrip-  
15 tion drug plan offered by the entity through mecha-  
16 nisms such as generic substitution and price dis-  
17 counts.

18 “(ii) QUALITY PROGRAMS.—The entity pro-  
19 vides such enrollees with quality programs that  
20 avoid adverse drug reactions and overutilization  
21 and reduce medical errors.

22 “(iii) CUSTOMER SERVICE.—The entity pro-  
23 vides timely and accurate delivery of services and  
24 pharmacy and beneficiary support services.

25 “(iv) BENEFIT ADMINISTRATION AND CLAIMS  
26 ADJUDICATION.—The entity provides efficient and  
27 effective benefit administration and claims adju-  
28 dication.

29 “(6) MONTHLY BENEFICIARY PREMIUM.—Except as  
30 provided in section 1860D–13(b) (relating to late enroll-  
31 ment penalty) and subject to section 1860D–14 (relating to  
32 low-income assistance), the monthly beneficiary premium to  
33 be charged under a fallback prescription drug plan offered  
34 in all fallback service areas in a PDP region shall be uni-  
35 form and shall be equal to 25.5 percent of an amount equal  
36 to the Secretary’s estimate of the average monthly per cap-  
37 ita actuarial cost, including administrative expenses, under

1 the fallback prescription drug plan of providing coverage in  
2 the region, as calculated by the Chief Actuary of the Cen-  
3 ters for Medicare & Medicaid Services. In calculating such  
4 administrative expenses, the Chief Actuary shall use a fac-  
5 tor that is based on similar expenses of prescription drug  
6 plans that are not fallback prescription drug plans.

7 “(7) GENERAL CONTRACT TERMS AND CONDITIONS.—

8 “(A) IN GENERAL.—Except as may be appropriate  
9 to carry out this section, the terms and conditions of  
10 contracts with eligible fallback entities offering fallback  
11 prescription drug plans under this subsection shall be  
12 the same as the terms and conditions of contracts  
13 under this part for prescription drug plans.

14 “(B) PERIOD OF CONTRACT.—

15 “(i) IN GENERAL.—Subject to clause (ii), a  
16 contract approved for a fallback prescription drug  
17 plan for fallback service areas for a PDP region  
18 under this section shall be for a period of 3 years  
19 (except as may be renewed after a subsequent bid-  
20 ding process).

21 “(ii) LIMITATION.—A fallback prescription  
22 drug plan may be offered under a contract in an  
23 area for a year only if that area is a fallback serv-  
24 ice area for that year.

25 “(C) ENTITY NOT PERMITTED TO MARKET OR  
26 BRAND FALLBACK PRESCRIPTION DRUG PLANS.—An el-  
27 igible fallback entity with a contract under this sub-  
28 section may not engage in any marketing or branding  
29 of a fallback prescription drug plan.

30 “(h) ANNUAL REPORT ON USE OF LIMITED RISK PLANS  
31 AND FALLBACK PLANS.—The Secretary shall submit to Con-  
32 gress an annual report that describes instances in which limited  
33 risk plans and fallback prescription drug plans were offered  
34 under subsections (f) and (g). The Secretary shall include in  
35 such report such recommendations as may be appropriate to  
36 limit the need for the provision of such plans and to maximize  
37 the assumption of financial risk under section subsection (f).

1 “(i) NONINTERFERENCE.—In order to promote competi-  
2 tion under this part and in carrying out this part, the  
3 Secretary—

4 “(1) may not interfere with the negotiations between  
5 drug manufacturers and pharmacies and PDP sponsors;  
6 and

7 “(2) may not require a particular formulary or insti-  
8 tute a price structure for the reimbursement of covered  
9 part D drugs.

10 “(j) COORDINATION OF BENEFITS.—A PDP sponsor offer-  
11 ing a prescription drug plan shall permit State Pharmaceutical  
12 Assistance Programs and Rx plans under sections 1860D–23  
13 and 1860D–24 to coordinate benefits with the plan and, in con-  
14 nection with such coordination with such a Program, not to im-  
15 pose fees that are unrelated to the cost of coordination.

16 “REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION  
17 DRUG PLAN (PDP) SPONSORS

18 “SEC. 1860D–12. (a) GENERAL REQUIREMENTS.—Each  
19 PDP sponsor of a prescription drug plan shall meet the fol-  
20 lowing requirements:

21 “(1) LICENSURE.—Subject to subsection (c), the spon-  
22 sor is organized and licensed under State law as a risk-  
23 bearing entity eligible to offer health insurance or health  
24 benefits coverage in each State in which it offers a pre-  
25 scription drug plan.

26 “(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUB-  
27 SIDIZED COVERAGE.—

28 “(A) IN GENERAL.—Subject to subparagraph (B),  
29 to the extent that the entity is at risk the entity as-  
30 sumes financial risk on a prospective basis for benefits  
31 that it offers under a prescription drug plan and that  
32 is not covered under section 1860D–15(b).

33 “(B) REINSURANCE PERMITTED.—The plan spon-  
34 sor may obtain insurance or make other arrangements  
35 for the cost of coverage provided to any enrollee to the  
36 extent that the sponsor is at risk for providing such  
37 coverage.

1           “(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the  
2 case of a PDP sponsor that is not described in paragraph  
3 (1) and for which a waiver has been approved under sub-  
4 section (c), such sponsor shall meet solvency standards es-  
5 tablished by the Secretary under subsection (d).

6           “(b) CONTRACT REQUIREMENTS.—

7           “(1) IN GENERAL.—The Secretary shall not permit  
8 the enrollment under section 1860D–1 in a prescription  
9 drug plan offered by a PDP sponsor under this part, and  
10 the sponsor shall not be eligible for payments under section  
11 1860D–14 or 1860D–15, unless the Secretary has entered  
12 into a contract under this subsection with the sponsor with  
13 respect to the offering of such plan. Such a contract with  
14 a sponsor may cover more than one prescription drug plan.  
15 Such contract shall provide that the sponsor agrees to com-  
16 ply with the applicable requirements and standards of this  
17 part and the terms and conditions of payment as provided  
18 for in this part.

19           “(2) LIMITATION ON ENTITIES OFFERING FALLBACK  
20 PRESCRIPTION DRUG PLANS.—The Secretary shall not  
21 enter into a contract with a PDP sponsor for the offering  
22 of a prescription drug plan (other than a fallback prescrip-  
23 tion drug plan) in a PDP region for a year if the sponsor—

24           “(A) submitted a bid under section 1860D–11(g)  
25 for such year (as the first year of a contract period  
26 under such section) to offer a fallback prescription  
27 drug plan in any PDP region;

28           “(B) offers a fallback prescription drug plan in  
29 any PDP region during the year; or

30           “(C) offered a fallback prescription drug plan in  
31 that PDP region during the previous year.

32 For purposes of this paragraph, an entity shall be treated  
33 as submitting a bid with respect to a prescription drug plan  
34 or offering a fallback prescription drug plan if the entity  
35 is acting as a subcontractor of a PDP sponsor that is offer-  
36 ing such a plan. The previous sentence shall not apply to  
37 entities that are subcontractors of an MA organization ex-

1           cept insofar as such organization is acting as a PDP spon-  
2           sor with respect to a prescription drug plan.

3           “(3) INCORPORATION OF CERTAIN MEDICARE ADVAN-  
4           TAGE CONTRACT REQUIREMENTS.—Except as otherwise  
5           provided, the following provisions of section 1857 shall  
6           apply to contracts under this section in the same manner  
7           as they apply to contracts under section 1857(a):

8           “(A) MINIMUM ENROLLMENT.—Paragraphs (1)  
9           and (3) of section 1857(b), except that—

10           “(i) the Secretary may increase the minimum  
11           number of enrollees required under such paragraph  
12           (1) as the Secretary determines appropriate; and

13           “(ii) the requirement of such paragraph (1)  
14           shall be waived during the first contract year with  
15           respect to an organization in a region.

16           “(B) CONTRACT PERIOD AND EFFECTIVENESS.—  
17           Section 1857(c), except that in applying paragraph  
18           (4)(B) of such section any reference to payment  
19           amounts under section 1853 shall be deemed payment  
20           amounts under section 1860D–15.

21           “(C) PROTECTIONS AGAINST FRAUD AND BENE-  
22           FICIARY PROTECTIONS.—Section 1857(d).

23           “(D) ADDITIONAL CONTRACT TERMS.—Section  
24           1857(e); except that section 1857(e)(2) shall apply as  
25           specified to PDP sponsors and payments under this  
26           part to an MA–PD plan shall be treated as expendi-  
27           tures made under part D.

28           “(E) INTERMEDIATE SANCTIONS.—Section  
29           1857(g) (other than paragraph (1)(F) of such section),  
30           except that in applying such section the reference in  
31           section 1857(g)(1)(B) to section 1854 is deemed a ref-  
32           erence to this part.

33           “(F) PROCEDURES FOR TERMINATION.—Section  
34           1857(h).

35           “(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND  
36           CHOICE.—

37           “(1) AUTHORIZING WAIVER.—



1           “(A) IN GENERAL.—In the case of an entity that  
2 seeks to offer a prescription drug plan in a State, the  
3 Secretary shall waive the requirement of subsection  
4 (a)(1) that the entity be licensed in that State if the  
5 Secretary determines, based on the application and  
6 other evidence presented to the Secretary, that any of  
7 the grounds for approval of the application described in  
8 paragraph (2) have been met.

9           “(B) APPLICATION OF REGIONAL PLAN WAIVER  
10 RULE.—In addition to the waiver available under sub-  
11 paragraph (A), the provisions of section 1858(d) shall  
12 apply to PDP sponsors under this part in a manner  
13 similar to the manner in which such provisions apply  
14 to MA organizations under part C, except that no ap-  
15 plication shall be required under paragraph (1)(B) of  
16 such section in the case of a State that does not pro-  
17 vide a licensing process for such a sponsor.

18           “(2) GROUNDS FOR APPROVAL.—

19           “(A) IN GENERAL.—The grounds for approval  
20 under this paragraph are—

21           “(i) subject to subparagraph (B), the grounds  
22 for approval described in subparagraphs (B), (C),  
23 and (D) of section 1855(a)(2); and

24           “(ii) the application by a State of any grounds  
25 other than those required under Federal law.

26           “(B) SPECIAL RULES.—In applying subparagraph  
27 (A)(i)—

28           “(i) the ground of approval described in sec-  
29 tion 1855(a)(2)(B) is deemed to have been met if  
30 the State does not have a licensing process in effect  
31 with respect to the PDP sponsor; and

32           “(ii) for plan years beginning before January  
33 1, 2008, if the State does have such a licensing  
34 process in effect, such ground for approval de-  
35 scribed in such section is deemed to have been met  
36 upon submission of an application described in  
37 such section.

1           “(3) APPLICATION OF WAIVER PROCEDURES.—With  
2           respect to an application for a waiver (or a waiver granted)  
3           under paragraph (1)(A) of this subsection, the provisions  
4           of subparagraphs (E), (F), and (G) of section 1855(a)(2)  
5           shall apply, except that clauses (i) and (ii) of such subpara-  
6           graph (E) shall not apply in the case of a State that does  
7           not have a licensing process described in paragraph  
8           (2)(B)(i) in effect.

9           “(4) REFERENCES TO CERTAIN PROVISIONS.—In ap-  
10          plying provisions of section 1855(a)(2) under paragraphs  
11          (2) and (3) of this subsection to prescription drug plans  
12          and PDP sponsors—

13                 “(A) any reference to a waiver application under  
14                 section 1855 shall be treated as a reference to a waiver  
15                 application under paragraph (1)(A) of this subsection;  
16                 and

17                 “(B) any reference to solvency standards shall be  
18                 treated as a reference to solvency standards established  
19                 under subsection (d) of this section.

20          “(d) SOLVENCY STANDARDS FOR NON-LICENSED ENTI-  
21          TIES.—

22                 “(1) ESTABLISHMENT AND PUBLICATION.—The Sec-  
23                 retary, in consultation with the National Association of In-  
24                 surance Commissioners, shall establish and publish, by not  
25                 later than January 1, 2005, financial solvency and capital  
26                 adequacy standards for entities described in paragraph (2).

27                 “(2) COMPLIANCE WITH STANDARDS.—A PDP spon-  
28                 sor that is not licensed by a State under subsection (a)(1)  
29                 and for which a waiver application has been approved  
30                 under subsection (c) shall meet solvency and capital ade-  
31                 quacy standards established under paragraph (1). The Sec-  
32                 retary shall establish certification procedures for such spon-  
33                 sors with respect to such solvency standards in the manner  
34                 described in section 1855(c)(2).

35          “(e) LICENSURE DOES NOT SUBSTITUTE FOR OR CON-  
36          STITUTE CERTIFICATION.—The fact that a PDP sponsor is li-  
37          censed in accordance with subsection (a)(1) or has a waiver ap-

1 plication approved under subsection (c) does not deem the  
2 sponsor to meet other requirements imposed under this part for  
3 a sponsor.

4 “(f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

5 “(1) IN GENERAL.—Subject to paragraph (2), the Sec-  
6 retary may periodically review the standards established  
7 under this section and, based on such review, may revise  
8 such standards if the Secretary determines such revision to  
9 be appropriate.

10 “(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF  
11 SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The  
12 Secretary may not implement, other than at the beginning  
13 of a calendar year, regulations under this section that im-  
14 pose new, significant regulatory requirements on a PDP  
15 sponsor or a prescription drug plan.

16 “(g) PROHIBITION OF STATE IMPOSITION OF PREMIUM  
17 TAXES; RELATION TO STATE LAWS.—The provisions of sec-  
18 tions 1854(g) and 1856(b)(3) shall apply with respect to PDP  
19 sponsors and prescription drug plans under this part in the  
20 same manner as such sections apply to MA organizations and  
21 MA plans under part C.

22 “PREMIUMS; LATE ENROLLMENT PENALTY

23 “SEC. 1860D–13. (a) MONTHLY BENEFICIARY PRE-  
24 MIUM.—

25 “(1) COMPUTATION.—

26 “(A) IN GENERAL.—The monthly beneficiary pre-  
27 mium for a prescription drug plan is the base bene-  
28 ficiary premium computed under paragraph (2) as ad-  
29 justed under this paragraph.

30 “(B) ADJUSTMENT TO REFLECT DIFFERENCE BE-  
31 TWEEN BID AND NATIONAL AVERAGE BID.—

32 “(i) ABOVE AVERAGE BID.—If for a month the  
33 amount of the standardized bid amount (as defined  
34 in paragraph (5)) exceeds the amount of the ad-  
35 justed national average monthly bid amount (as de-  
36 fined in clause (iii)), the base beneficiary premium

1 for the month shall be increased by the amount of  
2 such excess.

3 “(ii) BELOW AVERAGE BID.—If for a month  
4 the amount of the adjusted national average  
5 monthly bid amount for the month exceeds the  
6 standardized bid amount, the base beneficiary pre-  
7 mium for the month shall be decreased by the  
8 amount of such excess.

9 “(iii) ADJUSTED NATIONAL AVERAGE MONTH-  
10 LY BID AMOUNT DEFINED.—For purposes of this  
11 subparagraph, the term ‘adjusted national average  
12 monthly bid amount’ means the national average  
13 monthly bid amount computed under paragraph  
14 (4), as adjusted under section 1860D–15(c)(2).

15 “(C) INCREASE FOR SUPPLEMENTAL PRESCRIP-  
16 TION DRUG BENEFITS.—The base beneficiary premium  
17 shall be increased by the portion of the PDP approved  
18 bid that is attributable to supplemental prescription  
19 drug benefits.

20 “(D) INCREASE FOR LATE ENROLLMENT PEN-  
21 ALTY.—The base beneficiary premium shall be in-  
22 creased by the amount of any late enrollment penalty  
23 under subsection (b).

24 “(E) DECREASE FOR LOW-INCOME ASSISTANCE.—  
25 The monthly beneficiary premium is subject to decrease  
26 in the case of a subsidy eligible individual under section  
27 1860D–14.

28 “(F) UNIFORM PREMIUM.—Except as provided in  
29 subparagraphs (D) and (E), the monthly beneficiary  
30 premium for a prescription drug plan in a PDP region  
31 is the same for all part D eligible individuals enrolled  
32 in the plan.

33 “(2) BASE BENEFICIARY PREMIUM.—The base bene-  
34 ficiary premium under this paragraph for a prescription  
35 drug plan for a month is equal to the product—

36 “(A) the beneficiary premium percentage (as spec-  
37 ified in paragraph (3)); and

1                   “(B) the national average monthly bid amount  
2                   (computed under paragraph (4)) for the month.

3                   “(3) BENEFICIARY PREMIUM PERCENTAGE.—For pur-  
4                   poses of this subsection, the beneficiary premium percent-  
5                   age for any year is the percentage equal to a fraction—

6                   “(A) the numerator of which is 25.5 percent; and

7                   “(B) the denominator of which is 100 percent  
8                   minus a percentage equal to—

9                   “(i) the total reinsurance payments which the  
10                   Secretary estimates are payable under section  
11                   1860D–15(b) with respect to the coverage year; di-  
12                   vided by

13                   “(ii) the sum of—

14                   “(I) the amount estimated under clause (i)  
15                   for the year; and

16                   “(II) the total payments which the Sec-  
17                   retary estimates will be paid to prescription  
18                   drug plans and MA–PD plans that are attrib-  
19                   utable to the standardized bid amount during  
20                   the year, taking into account amounts paid by  
21                   the Secretary and enrollees.

22                   “(4) COMPUTATION OF NATIONAL AVERAGE MONTHLY  
23                   BID AMOUNT.—

24                   “(A) IN GENERAL.—For each year (beginning  
25                   with 2006) the Secretary shall compute a national av-  
26                   erage monthly bid amount equal to the average of the  
27                   standardized bid amounts (as defined in paragraph (5))  
28                   for each prescription drug plan and for each MA–PD  
29                   plan described in section 1851(a)(2)(A)(i). Such aver-  
30                   age does not take into account the bids submitted for  
31                   MSA plans, MA private fee-for-service plan, and spe-  
32                   cialized MA plans for special needs individuals, PACE  
33                   programs under section 1894 (pursuant to section  
34                   1860D–21(f)), and under reasonable cost reimburse-  
35                   ment contracts under section 1876(h) (pursuant to sec-  
36                   tion 1860D–21(e)).

37                   “(B) WEIGHTED AVERAGE.—

1                   “(i) IN GENERAL.—The monthly national av-  
2                   erage monthly bid amount computed under sub-  
3                   paragraph (A) for a year shall be a weighted aver-  
4                   age, with the weight for each plan being equal to  
5                   the average number of part D eligible individuals  
6                   enrolled in such plan in the reference month (as de-  
7                   fined in section 1858(f)(4)).

8                   “(ii) SPECIAL RULE FOR 2006.—For purposes  
9                   of applying this paragraph for 2006, the Secretary  
10                  shall establish procedures for determining the  
11                  weighted average under clause (i) for 2005.

12                  “(5) STANDARDIZED BID AMOUNT DEFINED.—For  
13                  purposes of this subsection, the term ‘standardized bid  
14                  amount’ means the following:

15                  “(A) PRESCRIPTION DRUG PLANS.—

16                  “(i) BASIC COVERAGE.—In the case of a pre-  
17                  scription drug plan that provides basic prescription  
18                  drug coverage, the PDP approved bid (as defined  
19                  in paragraph (6)).

20                  “(ii) SUPPLEMENTAL COVERAGE.—In the case  
21                  of a prescription drug plan that provides supple-  
22                  mental prescription drug coverage, the portion of  
23                  the PDP approved bid that is attributable to basic  
24                  prescription drug coverage.

25                  “(B) MA–PD PLANS.—In the case of an MA–PD  
26                  plan, the portion of the accepted bid amount that is at-  
27                  tributable to basic prescription drug coverage.

28                  “(6) PDP APPROVED BID DEFINED.—For purposes of  
29                  this part, the term ‘PDP approved bid’ means, with respect  
30                  to a prescription drug plan, the bid amount approved for  
31                  the plan under this part.

32                  “(b) LATE ENROLLMENT PENALTY.—

33                  “(1) IN GENERAL.—Subject to the succeeding provi-  
34                  sions of this subsection, in the case of a part D eligible in-  
35                  dividual described in paragraph (2) with respect to a con-  
36                  tinuous period of eligibility, there shall be an increase in

1 the monthly beneficiary premium established under sub-  
2 section (a) in an amount determined under paragraph (3).

3 “(2) INDIVIDUALS SUBJECT TO PENALTY.—A part D  
4 eligible individual described in this paragraph is, with re-  
5 spect to a continuous period of eligibility, an individual for  
6 whom there is a continuous period of 63 days or longer (all  
7 of which in such continuous period of eligibility) beginning  
8 on the day after the last date of the individual’s initial en-  
9 rollment period under section 1860D–1(b)(2) and ending  
10 on the date of enrollment under a prescription drug plan  
11 or MA–PD plan during all of which the individual was not  
12 covered under any creditable prescription drug coverage.

13 “(3) AMOUNT OF PENALTY.—

14 “(A) IN GENERAL.—The amount determined  
15 under this paragraph for a part D eligible individual  
16 for a continuous period of eligibility is the greater of—

17 “(i) an amount that the Secretary determines  
18 is actuarially sound for each uncovered month (as  
19 defined in subparagraph (B)) in the same contin-  
20 uous period of eligibility; or

21 “(ii) 1 percent of the base beneficiary pre-  
22 mium (computed under subsection (a)(2)) for each  
23 such uncovered month in such period.

24 “(B) UNCOVERED MONTH DEFINED.—For pur-  
25 poses of this subsection, the term ‘uncovered month’  
26 means, with respect to a part D eligible individual, any  
27 month beginning after the end of the initial enrollment  
28 period under section 1860D–1(b)(2) unless the indi-  
29 vidual can demonstrate that the individual had cred-  
30 itable prescription drug coverage (as defined in para-  
31 graph (4)) for any portion of such month.

32 “(4) CREDITABLE PRESCRIPTION DRUG COVERAGE DE-  
33 FINED.—For purposes of this part, the term ‘creditable  
34 prescription drug coverage’ means any of the following cov-  
35 erage, but only if the coverage meets the requirement of  
36 paragraph (5):

1           “(A) COVERAGE UNDER PRESCRIPTION DRUG  
2           PLAN OR MA–PD PLAN.—Coverage under a prescription  
3           drug plan or under an MA–PD plan.

4           “(B) MEDICAID.—Coverage under a medicaid plan  
5           under title XIX or under a waiver under section 1115.

6           “(C) GROUP HEALTH PLAN.—Coverage under a  
7           group health plan, including a health benefits plan  
8           under chapter 89 of title 5, United States Code (com-  
9           monly known as the Federal employees health benefits  
10          program), and a qualified retiree prescription drug plan  
11          (as defined in section 1860D–22(a)(2)).

12          “(D) STATE PHARMACEUTICAL ASSISTANCE PRO-  
13          GRAM.—Coverage under a State pharmaceutical assist-  
14          ance program described in section 1860D–23(b)(1).

15          “(E) VETERANS’ COVERAGE OF PRESCRIPTION  
16          DRUGS.—Coverage for veterans, and survivors and de-  
17          pendents of veterans, under chapter 17 of title 38,  
18          United States Code.

19          “(F) PRESCRIPTION DRUG COVERAGE UNDER  
20          MEDIGAP POLICIES.—Coverage under a medicare sup-  
21          plemental policy under section 1882 that provides bene-  
22          fits for prescription drugs (whether or not such cov-  
23          erage conforms to the standards for packages of bene-  
24          fits under section 1882(p)(1)).

25          “(G) MILITARY COVERAGE (INCLUDING  
26          TRICARE).—Coverage under chapter 55 of title 10,  
27          United States Code.

28          “(H) OTHER COVERAGE.—Such other coverage as  
29          the Secretary determines appropriate.

30          “(5) ACTUARIAL EQUIVALENCE REQUIREMENT.—Cov-  
31          erage meets the requirement of this paragraph only if the  
32          coverage is determined (in a manner specified by the Sec-  
33          retary) to provide coverage of the cost of prescription drugs  
34          the actuarial value of which (as defined by the Secretary)  
35          to the individual equals or exceeds the actuarial value of  
36          standard prescription drug coverage (as determined under  
37          section 1860D–11(c)).



1           “(6) PROCEDURES TO DOCUMENT CREDITABLE PRE-  
2       SCRIPTION DRUG COVERAGE.—

3           “(A) IN GENERAL.—The Secretary shall establish  
4       procedures (including the form, manner, and time) for  
5       the documentation of creditable prescription drug cov-  
6       erage, including procedures to assist in determining  
7       whether coverage meets the requirement of paragraph  
8       (5).

9           “(B) DISCLOSURE BY ENTITIES OFFERING CRED-  
10       ITABLE PRESCRIPTION DRUG COVERAGE.—

11           “(i) IN GENERAL.—Each entity that offers  
12       prescription drug coverage of the type described in  
13       subparagraphs (B) through (H) of paragraph (4)  
14       shall provide for disclosure, in a form, manner, and  
15       time consistent with standards established by the  
16       Secretary, to the Secretary and part D eligible indi-  
17       viduals of whether the coverage meets the require-  
18       ment of paragraph (5) or whether such coverage is  
19       changed so it no longer meets such requirement.

20           “(ii) DISCLOSURE OF NON-CREDITABLE COV-  
21       ERAGE.—In the case of such coverage that does not  
22       meet such requirement, the disclosure to part D eli-  
23       gible individuals under this subparagraph shall in-  
24       clude information regarding the fact that because  
25       such coverage does not meet such requirement  
26       there are limitations on the periods in a year in  
27       which the individuals may enroll under a prescrip-  
28       tion drug plan or an MA-PD plan and that any  
29       such enrollment is subject to a late enrollment pen-  
30       alty under this subsection.

31           “(C) WAIVER OF REQUIREMENT.—In the case of  
32       a part D eligible individual who was enrolled in pre-  
33       scription drug coverage of the type described in sub-  
34       paragraphs (B) through (H) of paragraph (4) which is  
35       not creditable prescription drug coverage because it  
36       does not meet the requirement of paragraph (5), the in-  
37       dividual may apply to the Secretary to have such cov-

1 erage treated as creditable prescription drug coverage  
2 if the individual establishes that the individual was not  
3 adequately informed that such coverage did not meet  
4 such requirement.

5 “(7) CONTINUOUS PERIOD OF ELIGIBILITY.—

6 “(A) IN GENERAL.—Subject to subparagraph (B),  
7 for purposes of this subsection, the term ‘continuous  
8 period of eligibility’ means, with respect to a part D eli-  
9 gible individual, the period that begins with the first  
10 day on which the individual is eligible to enroll in a  
11 prescription drug plan under this part and ends with  
12 the individual’s death.

13 “(B) SEPARATE PERIOD.—Any period during all  
14 of which a part D eligible individual is entitled to hos-  
15 pital insurance benefits under part A and—

16 “(i) which terminated in or before the month  
17 preceding the month in which the individual at-  
18 tained age 65; or

19 “(ii) for which the basis for eligibility for such  
20 entitlement changed between section 226(b) and  
21 section 226(a), between 226(b) and section 226A,  
22 or between section 226A and section 226(a),

23 shall be a separate continuous period of eligibility with  
24 respect to the individual (and each such period which  
25 terminates shall be deemed not to have existed for pur-  
26 poses of subsequently applying this paragraph).

27 “(c) COLLECTION OF MONTHLY BENEFICIARY PRE-  
28 MIUMS.—

29 “(1) IN GENERAL.—Subject to paragraphs (2) and  
30 (3), the provisions of section 1854(d) shall apply to PDP  
31 sponsors and premiums (and any late enrollment penalty)  
32 under this part in the same manner as they apply to MA  
33 organizations and beneficiary premiums under part C, ex-  
34 cept that any reference to a Trust Fund is deemed for this  
35 purpose a reference to the Medicare Prescription Drug Ac-  
36 count.

37 “(2) CREDITING OF LATE ENROLLMENT PENALTY.—

1           “(A) PORTION ATTRIBUTABLE TO INCREASED AC-  
2           TUARIAL COSTS.—With respect to late enrollment pen-  
3           alties imposed under subsection (b), the Secretary shall  
4           specify the portion of such a penalty that the Secretary  
5           estimates is attributable to increased actuarial costs as-  
6           sumed by the PDP sponsor or MA organization (and  
7           not taken into account through risk adjustment pro-  
8           vided under section 1860D–15(c)(1) or through rein-  
9           surance payments under section 1860D–15(b)) as a re-  
10          sult of such late enrollment.

11          “(B) COLLECTION THROUGH WITHHOLDING.—In  
12          the case of a late enrollment penalty that is collected  
13          from a part D eligible individual in the manner de-  
14          scribed in section 1854(d)(2)(A), the Secretary shall  
15          provide that only the portion of such penalty estimated  
16          under subparagraph (A) shall be paid to the PDP  
17          sponsor or MA organization offering the part D plan  
18          in which the individual is enrolled.

19          “(C) COLLECTION BY PLAN.—In the case of a late  
20          enrollment penalty that is collected from a part D eligi-  
21          ble individual in a manner other than the manner de-  
22          scribed in section 1854(d)(2)(A), the Secretary shall es-  
23          tablish procedures for reducing payments otherwise  
24          made to the PDP sponsor or MA organization by an  
25          amount equal to the amount of such penalty less the  
26          portion of such penalty estimated under subparagraph  
27          (A).

28          “(3) FALLBACK PLANS.—In applying this subsection  
29          in the case of a fallback prescription drug plan, paragraph  
30          (2) shall not apply and the monthly beneficiary premium  
31          shall be collected in the manner specified in section  
32          1854(d)(2)(A) (or such other manner as may be provided  
33          under section 1840 in the case of monthly premiums under  
34          section 1839).

1 “PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME  
2 INDIVIDUALS

3 “SEC. 1860D–14. (a) INCOME-RELATED SUBSIDIES FOR  
4 INDIVIDUALS WITH INCOME UP TO 150 PERCENT OF POV-  
5 ERTY LINE.—

6 “(1) INDIVIDUALS WITH INCOME BELOW 135 PERCENT  
7 OF POVERTY LINE.—In the case of a subsidy eligible indi-  
8 vidual (as defined in paragraph (3)) who is determined to  
9 have income that is below 135 percent of the poverty line  
10 applicable to a family of the size involved and who meets  
11 the resources requirement described in paragraph (3)(D) or  
12 who is covered under this paragraph under paragraph  
13 (3)(B)(i), the individual is entitled under this section to the  
14 following:

15 “(A) FULL PREMIUM SUBSIDY.—An income-re-  
16 lated premium subsidy equal to—

17 “(i) 100 percent of the amount described in  
18 subsection (b)(1), but not to exceed the premium  
19 amount specified in subsection (b)(2)(B); plus

20 “(ii) 80 percent of any late enrollment pen-  
21 alties imposed under section 1860D–13(b) for the  
22 first 60 months in which such penalties are im-  
23 posed for that individual, and 100 percent of any  
24 such penalties for any subsequent month.

25 “(B) ELIMINATION OF DEDUCTIBLE.—A reduction  
26 in the annual deductible applicable under section  
27 1860D–2(b)(1) to \$0.

28 “(C) CONTINUATION OF COVERAGE ABOVE THE  
29 INITIAL COVERAGE LIMIT.—The continuation of cov-  
30 erage from the initial coverage limit (under paragraph  
31 (3) of section 1860D–2(b)) for expenditures incurred  
32 through the total amount of expenditures at which ben-  
33 efits are available under paragraph (4) of such section,  
34 subject to the reduced cost-sharing described in sub-  
35 paragraph (D).

36 “(D) REDUCTION IN COST-SHARING BELOW OUT-  
37 OF-POCKET THRESHOLD.—

1                   “(i) INSTITUTIONALIZED INDIVIDUALS.—In  
2                   the case of an individual who is a full-benefit dual  
3                   eligible individual and who is an institutionalized  
4                   individual or couple (as defined in section  
5                   1902(q)(1)(B)), the elimination of any beneficiary  
6                   coinsurance described in section 1860D–2(b)(2)  
7                   (for all amounts through the total amount of ex-  
8                   penditures at which benefits are available under  
9                   section 1860D–2(b)(4)).

10                   “(ii) LOWEST INCOME DUAL ELIGIBLE INDI-  
11                   VIDUALS.—In the case of an individual not de-  
12                   scribed in clause (i) who is a full-benefit dual eligi-  
13                   ble individual and whose income does not exceed  
14                   100 percent of the poverty line applicable to a fam-  
15                   ily of the size involved, the substitution for the ben-  
16                   eficiary coinsurance described in section 1860D–  
17                   2(b)(2) (for all amounts through the total amount  
18                   of expenditures at which benefits are available  
19                   under section 1860D–2(b)(4)) of a copayment  
20                   amount that does not exceed \$1 for a generic drug  
21                   or a preferred drug that is a multiple source drug  
22                   (as defined in section 1927(k)(7)(A)(i)) and \$3 for  
23                   any other drug, or, if less, the copayment amount  
24                   applicable to an individual under clause (iii).

25                   “(iii) OTHER INDIVIDUALS.—In the case of an  
26                   individual not described in clause (i) or (ii), the  
27                   substitution for the beneficiary coinsurance de-  
28                   scribed in section 1860D–2(b)(2) (for all amounts  
29                   through the total amount of expenditures at which  
30                   benefits are available under section 1860D–  
31                   2(b)(4)) of a copayment amount that does not ex-  
32                   ceed the copayment amount specified under section  
33                   1860D–2(b)(4)(A)(i)(I) for the drug and year in-  
34                   volved.

35                   “(E) ELIMINATION OF COST-SHARING ABOVE AN-  
36                   NUAL OUT-OF-POCKET THRESHOLD.—The elimination

1 of any cost-sharing imposed under section 1860D–  
2 2(b)(4)(A).

3 “(2) OTHER INDIVIDUALS WITH INCOME BELOW 150  
4 PERCENT OF POVERTY LINE.—In the case of a subsidy eli-  
5 gible individual who is not described in paragraph (1), the  
6 individual is entitled under this section to the following:

7 “(A) SLIDING SCALE PREMIUM SUBSIDY.—An in-  
8 come-related premium subsidy determined on a linear  
9 sliding scale ranging from 100 percent of the amount  
10 described in paragraph (1)(A) for individuals with in-  
11 comes at or below 135 percent of such level to 0 per-  
12 cent of such amount for individuals with incomes at  
13 150 percent of such level.

14 “(B) REDUCTION OF DEDUCTIBLE.—A reduction  
15 in the annual deductible applicable under section  
16 1860D–2(b)(1) to \$50.

17 “(C) CONTINUATION OF COVERAGE ABOVE THE  
18 INITIAL COVERAGE LIMIT.—The continuation of cov-  
19 erage from the initial coverage limit (under paragraph  
20 (3) of section 1860D–2(b)) for expenditures incurred  
21 through the total amount of expenditures at which ben-  
22 efits are available under paragraph (4) of such section,  
23 subject to the reduced coinsurance described in sub-  
24 paragraph (D).

25 “(D) REDUCTION IN COST-SHARING BELOW OUT-  
26 OF-POCKET THRESHOLD.—The substitution for the  
27 beneficiary coinsurance described in section 1860D–  
28 2(b)(2) (for all amounts above the deductible under  
29 subparagraph (B) through the total amount of expendi-  
30 tures at which benefits are available under section  
31 1860D–2(b)(4)) of coinsurance of ‘15 percent’ instead  
32 of coinsurance of ‘25 percent’ in section 1860D–  
33 2(b)(2).

34 “(E) REDUCTION OF COST-SHARING ABOVE AN-  
35 NUAL OUT-OF-POCKET THRESHOLD.—Subject to sub-  
36 section (c), the substitution for the cost-sharing im-  
37 posed under section 1860D–2(b)(4)(A) of a copayment

1 or coinsurance not to exceed the copayment or coinsur-  
2 ance amount specified under section 1860D-  
3 2(b)(4)(A)(i)(I) for the drug and year involved.

4 “(3) DETERMINATION OF ELIGIBILITY.—

5 “(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—  
6 For purposes of this part, subject to subparagraph (F),  
7 the term ‘subsidy eligible individual’ means a part D el-  
8 igible individual who—

9 “(i) is enrolled in a prescription drug plan or  
10 MA–PD plan;

11 “(ii) has income below 150 percent of the pov-  
12 erty line applicable to a family of the size involved;  
13 and

14 “(iii) meets the resources requirement de-  
15 scribed in subparagraph (D) or (E).

16 “(B) DETERMINATIONS.—

17 “(i) IN GENERAL.—The determination of  
18 whether a part D eligible individual residing in a  
19 State is a subsidy eligible individual and whether  
20 the individual is described in paragraph (1) shall be  
21 determined under the State plan under title XIX  
22 for the State under section 1935(a) or by the Com-  
23 missioner of Social Security. There are authorized  
24 to be appropriated to the Social Security Adminis-  
25 tration such sums as may be necessary for the de-  
26 termination of eligibility under this subparagraph.

27 “(ii) EFFECTIVE PERIOD.—Determinations  
28 under this subparagraph shall be effective begin-  
29 ning with the month in which the individual applies  
30 for a determination that the individual is a subsidy  
31 eligible individual and shall remain in effect for a  
32 period specified by the Secretary, but not to exceed  
33 1 year.

34 “(iii) REDETERMINATIONS AND APPEALS  
35 THROUGH MEDICAID.—Redeterminations and ap-  
36 peals, with respect to eligibility determinations  
37 under clause (i) made under a State plan under

1 title XIX, shall be made in accordance with the fre-  
2 quency of, and manner in which, redeterminations  
3 and appeals of eligibility are made under such plan  
4 for purposes of medical assistance under such title.

5 “(iv) REDETERMINATIONS AND APPEALS  
6 THROUGH COMMISSIONER.—With respect to eligi-  
7 bility determinations under clause (i) made by the  
8 Commissioner of Social Security—

9 “(I) redeterminations shall be made at  
10 such time or times as may be provided by the  
11 Commissioner; and

12 “(II) the Commissioner shall establish pro-  
13 cedures for appeals of such determinations that  
14 are similar to the procedures described in the  
15 third sentence of section 1631(c)(1)(A).

16 “(v) TREATMENT OF MEDICAID BENE-  
17 FICIARIES.—Subject to subparagraph (F), the  
18 Secretary—

19 “(I) shall provide that part D eligible indi-  
20 viduals who are full-benefit dual eligible indi-  
21 viduals (as defined in section 1935(c)(6)) or  
22 who are recipients of supplemental security in-  
23 come benefits under title XVI shall be treated  
24 as subsidy eligible individuals described in  
25 paragraph (1); and

26 “(II) may provide that part D eligible in-  
27 dividuals not described in subclause (I) who are  
28 determined for purposes of the State plan  
29 under title XIX to be eligible for medical as-  
30 sistance under clause (i), (iii), or (iv) of section  
31 1902(a)(10)(E) are treated as being deter-  
32 mined to be subsidy eligible individuals de-  
33 scribed in paragraph (1).

34 Insofar as the Secretary determines that the eligi-  
35 bility requirements under the State plan for med-  
36 ical assistance referred to in subclause (II) are sub-  
37 stantially the same as the requirements for being



1 treated as a subsidy eligible individual described in  
2 paragraph (1), the Secretary shall provide for the  
3 treatment described in such subclause.

4 “(C) INCOME DETERMINATIONS.—For purposes of  
5 applying this section—

6 “(i) in the case of a part D eligible individual  
7 who is not treated as a subsidy eligible individual  
8 under subparagraph (B)(v), income shall be deter-  
9 mined in the manner described in section  
10 1905(p)(1)(B), without regard to the application of  
11 section 1902(r)(2); and

12 “(ii) the term ‘poverty line’ has the meaning  
13 given such term in section 673(2) of the Commu-  
14 nity Services Block Grant Act (42 U.S.C. 9902(2)),  
15 including any revision required by such section.

16 Nothing in clause (i) shall be construed to affect the  
17 application of section 1902(r)(2) for the determination  
18 of eligibility for medical assistance under title XIX.

19 “(D) RESOURCE STANDARD APPLIED TO FULL  
20 LOW-INCOME SUBSIDY TO BE BASED ON THREE TIMES  
21 SSI RESOURCE STANDARD.—The resources requirement  
22 of this subparagraph is that an individual’s resources  
23 (as determined under section 1613 for purposes of the  
24 supplemental security income program) do not  
25 exceed—

26 “(i) for 2006 three times the maximum  
27 amount of resources that an individual may have  
28 and obtain benefits under that program; and

29 “(ii) for a subsequent year the resource limita-  
30 tion established under this clause for the previous  
31 year increased by the annual percentage increase in  
32 the consumer price index (all items; U.S. city aver-  
33 age) as of September of such previous year.

34 Any resource limitation established under clause (ii)  
35 that is not a multiple of \$10 shall be rounded to the  
36 nearest multiple of \$10.

37 “(E) ALTERNATIVE RESOURCE STANDARD.—

1           “(i) IN GENERAL.—The resources requirement  
2 of this subparagraph is that an individual’s re-  
3 sources (as determined under section 1613 for pur-  
4 poses of the supplemental security income pro-  
5 gram) do not exceed—

6           “(I) for 2006, \$10,000 (or \$20,000 in the  
7 case of the combined value of the individual’s  
8 assets or resources and the assets or resources  
9 of the individual’s spouse); and

10          “(II) for a subsequent year the dollar  
11 amounts specified in this subclause (or sub-  
12 clause (I)) for the previous year increased by  
13 the annual percentage increase in the consumer  
14 price index (all items; U.S. city average) as of  
15 September of such previous year.

16 Any dollar amount established under subclause (II)  
17 that is not a multiple of \$10 shall be rounded to  
18 the nearest multiple of \$10.

19          “(ii) USE OF SIMPLIFIED APPLICATION FORM  
20 AND PROCESS.—The Secretary, jointly with the  
21 Commissioner of Social Security, shall—

22          “(I) develop a model, simplified applica-  
23 tion form and process consistent with clause  
24 (iii) for the determination and verification of a  
25 part D eligible individual’s assets or resources  
26 under this subparagraph; and

27          “(II) provide such form to States.

28          “(iii) DOCUMENTATION AND SAFEGUARDS.—  
29 Under such process—

30          “(I) the application form shall consist of  
31 an attestation under penalty of perjury regard-  
32 ing the level of assets or resources (or com-  
33 bined assets and resources in the case of a  
34 married part D eligible individual) and valu-  
35 ations of general classes of assets or resources;

36          “(II) such form shall be accompanied by  
37 copies of recent statements (if any) from finan-

1                   cial institutions in support of the application;  
2                   and

3                   “(III) matters attested to in the applica-  
4                   tion shall be subject to appropriate methods of  
5                   verification.

6                   “(iv) METHODOLOGY FLEXIBILITY.—The Sec-  
7                   retary may permit a State in making eligibility de-  
8                   terminations for premium and cost-sharing sub-  
9                   sidies under this section to use the same asset or  
10                  resource methodologies that are used with respect  
11                  to eligibility for medical assistance for medicare  
12                  cost-sharing described in section 1905(p) so long as  
13                  the Secretary determines that the use of such  
14                  methodologies will not result in any significant dif-  
15                  ferences in the number of individuals determined to  
16                  be subsidy eligible individuals.

17                  “(F) TREATMENT OF TERRITORIAL RESIDENTS.—  
18                  In the case of a part D eligible individual who is not  
19                  a resident of the 50 States or the District of Columbia,  
20                  the individual is not eligible to be a subsidy eligible in-  
21                  dividual under this section but may be eligible for fi-  
22                  nancial assistance with prescription drug expenses  
23                  under section 1935(e).

24                  “(4) INDEXING DOLLAR AMOUNTS.—

25                  “(A) COPAYMENT FOR LOWEST INCOME DUAL ELI-  
26                  GIBLE INDIVIDUALS.—The dollar amounts applied  
27                  under paragraph (1)(D)(ii)—

28                  “(i) for 2007 shall be the dollar amounts spec-  
29                  ified in such paragraph increased by the annual  
30                  percentage increase in the consumer price index (all  
31                  items; U.S. city average) as of September of such  
32                  previous year; or

33                  “(ii) for a subsequent year shall be the dollar  
34                  amounts specified in this clause (or clause (i)) for  
35                  the previous year increased by the annual percent-  
36                  age increase in the consumer price index (all items;

1 U.S. city average) as of September of such previous  
2 year.

3 Any amount established under clause (i) or (ii), that is  
4 based on an increase of \$1 or \$3, that is not a multiple  
5 of 5 cents or 10 cents, respectively, shall be rounded  
6 to the nearest multiple of 5 cents or 10 cents, respec-  
7 tively.

8 “(B) REDUCED DEDUCTIBLE.—The dollar amount  
9 applied under paragraph (2)(B)—

10 “(i) for 2007 shall be the dollar amount speci-  
11 fied in such paragraph increased by the annual per-  
12 centage increase described in section 1860D-  
13 2(b)(6) for 2007; or

14 “(ii) for a subsequent year shall be the dollar  
15 amount specified in this clause (or clause (i)) for  
16 the previous year increased by the annual percent-  
17 age increase described in section 1860D-2(b)(6)  
18 for the year involved.

19 Any amount established under clause (i) or (ii) that is  
20 not a multiple of \$1 shall be rounded to the nearest  
21 multiple of \$1.

22 “(b) PREMIUM SUBSIDY AMOUNT.—

23 “(1) IN GENERAL.—The premium subsidy amount de-  
24 scribed in this subsection for a subsidy eligible individual  
25 residing in a PDP region and enrolled in a prescription  
26 drug plan or MA-PD plan is the low-income benchmark  
27 premium amount (as defined in paragraph (2)) for the  
28 PDP region in which the individual resides or, if greater,  
29 the amount specified in paragraph (3).

30 “(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DE-  
31 FINED.—

32 “(A) IN GENERAL.—For purposes of this sub-  
33 section, the term ‘low-income benchmark premium  
34 amount’ means, with respect to a PDP region in  
35 which—

36 “(i) all prescription drug plans are offered by  
37 the same PDP sponsor, the weighted average of the

1 amounts described in subparagraph (B)(i) for such  
2 plans; or

3 “(ii) there are prescription drug plans offered  
4 by more than one PDP sponsor, the weighted aver-  
5 age of amounts described in subparagraph (B) for  
6 prescription drug plans and MA–PD plans de-  
7 scribed in section 1851(a)(2)(A)(i) offered in such  
8 region.

9 “(B) PREMIUM AMOUNTS DESCRIBED.—The pre-  
10 mium amounts described in this subparagraph are, in  
11 the case of—

12 “(i) a prescription drug plan that is a basic  
13 prescription drug plan, the monthly beneficiary pre-  
14 mium for such plan;

15 “(ii) a prescription drug plan that provides al-  
16 ternative prescription drug coverage the actuarial  
17 value of which is greater than that of standard pre-  
18 scription drug coverage, the portion of the monthly  
19 beneficiary premium that is attributable to basic  
20 prescription drug coverage; and

21 “(iii) an MA–PD plan, the portion of the MA  
22 monthly prescription drug beneficiary premium  
23 that is attributable to basic prescription drug bene-  
24 fits (described in section 1852(a)(6)(B)(ii)).

25 The premium amounts described in this subparagraph  
26 do not include any amounts attributable to late enroll-  
27 ment penalties under section 1860D–13(b).

28 “(3) ACCESS TO 0 PREMIUM PLAN.—In no case shall  
29 the premium subsidy amount under this subsection for a  
30 PDP region be less than the lowest monthly beneficiary  
31 premium for a prescription drug plan that offers basic pre-  
32 scription drug coverage in the region.

33 “(c) ADMINISTRATION OF SUBSIDY PROGRAM.—

34 “(1) IN GENERAL.—The Secretary shall provide a  
35 process whereby, in the case of a part D eligible individual  
36 who is determined to be a subsidy eligible individual and

1 who is enrolled in a prescription drug plan or is enrolled  
2 in an MA-PD plan—

3 “(A) the Secretary provides for a notification of  
4 the PDP sponsor or the MA organization offering the  
5 plan involved that the individual is eligible for a sub-  
6 sidy and the amount of the subsidy under subsection  
7 (a);

8 “(B) the sponsor or organization involved reduces  
9 the premiums or cost-sharing otherwise imposed by the  
10 amount of the applicable subsidy and submits to the  
11 Secretary information on the amount of such reduction;

12 “(C) the Secretary periodically and on a timely  
13 basis reimburses the sponsor or organization for the  
14 amount of such reductions; and

15 “(D) the Secretary ensures the confidentiality of  
16 individually identifiable information.

17 In applying subparagraph (C), the Secretary shall compute  
18 reductions based upon imposition under subsections  
19 (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts  
20 applied under such subsections.

21 “(2) USE OF CAPITATED FORM OF PAYMENT.—The re-  
22 imbursement under this section with respect to cost-sharing  
23 subsidies may be computed on a capitated basis, taking  
24 into account the actuarial value of the subsidies and with  
25 appropriate adjustments to reflect differences in the risks  
26 actually involved.

27 “(d) RELATION TO MEDICAID PROGRAM.—For special  
28 provisions under the medicaid program relating to medicare  
29 prescription drug benefits, see section 1935.

30 “SUBSIDIES FOR PART D ELIGIBLE INDIVIDUALS FOR  
31 QUALIFIED PRESCRIPTION DRUG COVERAGE

32 “SEC. 1860D-15. (a) SUBSIDY PAYMENT.—In order to re-  
33 duce premium levels applicable to qualified prescription drug  
34 coverage for part D eligible individuals consistent with an over-  
35 all subsidy level of 74.5 percent for basic prescription drug cov-  
36 erage, to reduce adverse selection among prescription drug  
37 plans and MA-PD plans, and to promote the participation of

1 PDP sponsors under this part and MA organizations under  
2 part C, the Secretary shall provide for payment to a PDP spon-  
3 sor that offers a prescription drug plan and an MA organiza-  
4 tion that offers an MA–PD plan of the following subsidies in  
5 accordance with this section:

6 “(1) DIRECT SUBSIDY.—A direct subsidy for each part  
7 D eligible individual enrolled in a prescription drug plan or  
8 MA–PD plan for a month equal to—

9 “(A) the amount of the plan’s standardized bid  
10 amount (as defined in section 1860D–13(a)(5)), ad-  
11 justed under subsection (c)(1), reduced by

12 “(B) the base beneficiary premium (as computed  
13 under paragraph (2) of section 1860D–13(a) and as  
14 adjusted under paragraph (1)(B) of such section).

15 “(2) SUBSIDY THROUGH REINSURANCE.—The reinsur-  
16 ance payment amount (as defined in subsection (b)).

17 This section constitutes budget authority in advance of appro-  
18 priations Acts and represents the obligation of the Secretary to  
19 provide for the payment of amounts provided under this sec-  
20 tion.

21 “(b) REINSURANCE PAYMENT AMOUNT.—

22 “(1) IN GENERAL.—The reinsurance payment amount  
23 under this subsection for a part D eligible individual en-  
24 rolled in a prescription drug plan or MA–PD plan for a  
25 coverage year is an amount equal to 80 percent of the al-  
26 lowable reinsurance costs (as specified in paragraph (2))  
27 attributable to that portion of gross covered prescription  
28 drug costs as specified in paragraph (3) incurred in the  
29 coverage year after such individual has incurred costs that  
30 exceed the annual out-of-pocket threshold specified in sec-  
31 tion 1860D–2(b)(4)(B).

32 “(2) ALLOWABLE REINSURANCE COSTS.—For pur-  
33 poses of this section, the term ‘allowable reinsurance costs’  
34 means, with respect to gross covered prescription drug  
35 costs under a prescription drug plan offered by a PDP  
36 sponsor or an MA–PD plan offered by an MA organization,  
37 the part of such costs that are actually paid (net of dis-

1 counts, chargebacks, and average percentage rebates) by  
2 the sponsor or organization or by (or on behalf of) an en-  
3 rollee under the plan, but in no case more than the part  
4 of such costs that would have been paid under the plan if  
5 the prescription drug coverage under the plan were basic  
6 prescription drug coverage, or, in the case of a plan pro-  
7 viding supplemental prescription drug coverage, if such cov-  
8 erage were standard prescription drug coverage.

9 “(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—  
10 For purposes of this section, the term ‘gross covered pre-  
11 scription drug costs’ means, with respect to a part D eligi-  
12 ble individual enrolled in a prescription drug plan or MA-  
13 PD plan during a coverage year, the costs incurred under  
14 the plan, not including administrative costs, but including  
15 costs directly related to the dispensing of covered part D  
16 drugs during the year and costs relating to the deductible.  
17 Such costs shall be determined whether they are paid by  
18 the individual or under the plan, regardless of whether the  
19 coverage under the plan exceeds basic prescription drug  
20 coverage.

21 “(4) COVERAGE YEAR DEFINED.—For purposes of this  
22 section, the term ‘coverage year’ means a calendar year in  
23 which covered part D drugs are dispensed if the claim for  
24 such drugs (and payment on such claim) is made not later  
25 than such period after the end of such year as the Sec-  
26 retary specifies.

27 “(c) ADJUSTMENTS RELATING TO BIDS.—

28 “(1) HEALTH STATUS RISK ADJUSTMENT.—

29 “(A) ESTABLISHMENT OF RISK ADJUSTORS.—The  
30 Secretary shall establish an appropriate methodology  
31 for adjusting the standardized bid amount under sub-  
32 section (a)(1)(A) to take into account variation in costs  
33 for basic prescription drug coverage among prescription  
34 drug plans and MA-PD plans based on the differences  
35 in actuarial risk of different enrollees being served. Any  
36 such risk adjustment shall be designed in a manner so  
37 as not to result in a change in the aggregate amounts



1 payable to such plans under subsection (a)(1) and  
2 through that portion of the monthly beneficiary pre-  
3 scription drug premiums described in subsection  
4 (a)(1)(B) and MA monthly prescription drug bene-  
5 ficiary premiums.

6 “(B) CONSIDERATIONS.—In establishing the meth-  
7 odology under subparagraph (A), the Secretary may  
8 take into account the similar methodologies used under  
9 section 1853(a)(3) to adjust payments to MA organiza-  
10 tions for benefits under the original medicare fee-for-  
11 service program option.

12 “(C) DATA COLLECTION.—In order to carry out  
13 this paragraph, the Secretary shall require—

14 “(i) PDP sponsors to submit data regarding  
15 drug claims that can be linked at the individual  
16 level to part A and part B data and such other in-  
17 formation as the Secretary determines necessary;  
18 and

19 “(ii) MA organizations that offer MA-PD  
20 plans to submit data regarding drug claims that  
21 can be linked at the individual level to other data  
22 that such organizations are required to submit to  
23 the Secretary and such other information as the  
24 Secretary determines necessary.

25 “(D) PUBLICATION.—At the time of publication of  
26 risk adjustment factors under section  
27 1853(b)(1)(B)(i)(II), the Secretary shall publish the  
28 risk adjusters established under this paragraph for the  
29 succeeding year.

30 “(2) GEOGRAPHIC ADJUSTMENT.—

31 “(A) IN GENERAL.—Subject to subparagraph (B),  
32 for purposes of section 1860D–13(a)(1)(B)(iii), the  
33 Secretary shall establish an appropriate methodology  
34 for adjusting the national average monthly bid amount  
35 (computed under section 1860D–13(a)(4)) to take into  
36 account differences in prices for covered part D drugs  
37 among PDP regions.

1           “(B) DE MINIMIS RULE.—If the Secretary deter-  
2           mines that the price variations described in subpara-  
3           graph (A) among PDP regions are de minimis, the Sec-  
4           retary shall not provide for adjustment under this para-  
5           graph.

6           “(C) BUDGET NEUTRAL ADJUSTMENT.—Any ad-  
7           justment under this paragraph shall be applied in a  
8           manner so as to not result in a change in the aggregate  
9           payments made under this part that would have been  
10          made if the Secretary had not applied such adjustment.

11          “(d) PAYMENT METHODS.—

12           “(1) IN GENERAL.—Payments under this section shall  
13          be based on such a method as the Secretary determines.  
14          The Secretary may establish a payment method by which  
15          interim payments of amounts under this section are made  
16          during a year based on the Secretary’s best estimate of  
17          amounts that will be payable after obtaining all of the in-  
18          formation.

19           “(2) REQUIREMENT FOR PROVISION OF INFORMA-  
20          TION.—

21           “(A) REQUIREMENT.—Payments under this sec-  
22          tion to a PDP sponsor or MA organization are condi-  
23          tioned upon the furnishing to the Secretary, in a form  
24          and manner specified by the Secretary, of such infor-  
25          mation as may be required to carry out this section.

26           “(B) RESTRICTION ON USE OF INFORMATION.—  
27          Information disclosed or obtained pursuant to subpara-  
28          graph (A) may be used by officers, employees, and con-  
29          tractors of the Department of Health and Human  
30          Services only for the purposes of, and to the extent  
31          necessary in, carrying out this section.

32           “(3) SOURCE OF PAYMENTS.—Payments under this  
33          section shall be made from the Medicare Prescription Drug  
34          Account.

35           “(4) APPLICATION OF ENROLLEE ADJUSTMENT.—The  
36          provisions of section 1853(a)(2) shall apply to payments to  
37          PDP sponsors under this section in the same manner as

1 they apply to payments to MA organizations under section  
2 1853(a).

3 “(e) PORTION OF TOTAL PAYMENTS TO A SPONSOR OR  
4 ORGANIZATION SUBJECT TO RISK (APPLICATION OF RISK  
5 CORRIDORS).—

6 “(1) COMPUTATION OF ADJUSTED ALLOWABLE RISK  
7 CORRIDOR COSTS.—

8 “(A) IN GENERAL.—For purposes of this sub-  
9 section, the term ‘adjusted allowable risk corridor costs’  
10 means, for a plan for a coverage year (as defined in  
11 subsection (b)(4))—

12 “(i) the allowable risk corridor costs (as de-  
13 fined in subparagraph (B)) for the plan for the  
14 year, reduced by

15 “(ii) the sum of (I) the total reinsurance pay-  
16 ments made under subsection (b) to the sponsor of  
17 the plan for the year, and (II) the total subsidy  
18 payments made under section 1860D–14 to the  
19 sponsor of the plan for the year.

20 “(B) ALLOWABLE RISK CORRIDOR COSTS.—For  
21 purposes of this subsection, the term ‘allowable risk  
22 corridor costs’ means, with respect to a prescription  
23 drug plan offered by a PDP sponsor or an MA–PD  
24 plan offered by an MA organization, the part of costs  
25 (not including administrative costs, but including costs  
26 directly related to the dispensing of covered part D  
27 drugs during the year) incurred by the sponsor or orga-  
28 nization under the plan that are actually paid (net of  
29 discounts, chargebacks, and average percentage re-  
30 bates) by the sponsor or organization under the plan,  
31 but in no case more than the part of such costs that  
32 would have been paid under the plan if the prescription  
33 drug coverage under the plan were basic prescription  
34 drug coverage, or, in the case of a plan providing sup-  
35 plemental prescription drug coverage, if such coverage  
36 were basic prescription drug coverage taking into ac-  
37 count the adjustment under section 1860D–11(c)(2).

1 In computing allowable costs under this paragraph, the  
2 Secretary shall compute such costs based upon imposi-  
3 tion under paragraphs (1)(D) and (2)(E) of section  
4 1860D-14(a) of the maximum amount of copayments  
5 permitted under such paragraphs.

6 “(2) ADJUSTMENT OF PAYMENT.—

7 “(A) NO ADJUSTMENT IF ADJUSTED ALLOWABLE  
8 RISK CORRIDOR COSTS WITHIN RISK CORRIDOR.—If the  
9 adjusted allowable risk corridor costs (as defined in  
10 paragraph (1)) for the plan for the year are at least  
11 equal to the first threshold lower limit of the risk cor-  
12 ridor (specified in paragraph (3)(A)(i)), but not greater  
13 than the first threshold upper limit of the risk corridor  
14 (specified in paragraph (3)(A)(iii)) for the plan for the  
15 year, then no payment adjustment shall be made under  
16 this subsection.

17 “(B) INCREASE IN PAYMENT IF ADJUSTED AL-  
18 LOWABLE RISK CORRIDOR COSTS ABOVE UPPER LIMIT  
19 OF RISK CORRIDOR.—

20 “(i) COSTS BETWEEN FIRST AND SECOND  
21 THRESHOLD UPPER LIMITS.—If the adjusted allow-  
22 able risk corridor costs for the plan for the year are  
23 greater than the first threshold upper limit, but not  
24 greater than the second threshold upper limit, of  
25 the risk corridor for the plan for the year, the Sec-  
26 retary shall increase the total of the payments  
27 made to the sponsor or organization offering the  
28 plan for the year under this section by an amount  
29 equal to 50 percent (or, for 2006 and 2007, 75  
30 percent or 90 percent if the conditions described in  
31 clause (iii) are met for the year) of the difference  
32 between such adjusted allowable risk corridor costs  
33 and the first threshold upper limit of the risk cor-  
34 ridor.

35 “(ii) COSTS ABOVE SECOND THRESHOLD  
36 UPPER LIMITS.—If the adjusted allowable risk cor-  
37 ridor costs for the plan for the year are greater

1 than the second threshold upper limit of the risk  
2 corridor for the plan for the year, the Secretary  
3 shall increase the total of the payments made to  
4 the sponsor or organization offering the plan for  
5 the year under this section by an amount equal to  
6 the sum of—

7 “(I) 50 percent (or, for 2006 and 2007,  
8 75 percent or 90 percent if the conditions de-  
9 scribed in clause (iii) are met for the year) of  
10 the difference between the second threshold  
11 upper limit and the first threshold upper limit;  
12 and

13 “(II) 80 percent of the difference between  
14 such adjusted allowable risk corridor costs and  
15 the second threshold upper limit of the risk  
16 corridor.

17 “(iii) CONDITIONS FOR APPLICATION OF HIGH-  
18 ER PERCENTAGE FOR 2006 AND 2007.—The condi-  
19 tions described in this clause are met for 2006 or  
20 2007 if the Secretary determines with respect to  
21 such year that—

22 “(I) at least 60 percent of prescription  
23 drug plans and MA-PD plans to which this  
24 subsection applies have adjusted allowable risk  
25 corridor costs for the plan for the year that are  
26 more than the first threshold upper limit of the  
27 risk corridor for the plan for the year; and

28 “(II) such plans represent at least 60 per-  
29 cent of part D eligible individuals enrolled in  
30 any prescription drug plan or MA-PD plan.

31 “(C) REDUCTION IN PAYMENT IF ADJUSTED AL-  
32 LOWABLE RISK CORRIDOR COSTS BELOW LOWER LIMIT  
33 OF RISK CORRIDOR.—

34 “(i) COSTS BETWEEN FIRST AND SECOND  
35 THRESHOLD LOWER LIMITS.—If the adjusted al-  
36 lowable risk corridor costs for the plan for the year  
37 are less than the first threshold lower limit, but not

1 less than the second threshold lower limit, of the  
2 risk corridor for the plan for the year, the Sec-  
3 retary shall reduce the total of the payments made  
4 to the sponsor or organization offering the plan for  
5 the year under this section by an amount (or other-  
6 wise recover from the sponsor or organization an  
7 amount) equal to 50 percent (or, for 2006 and  
8 2007, 75 percent) of the difference between the  
9 first threshold lower limit of the risk corridor and  
10 such adjusted allowable risk corridor costs.

11 “(ii) COSTS BELOW SECOND THRESHOLD  
12 LOWER LIMIT.—If the adjusted allowable risk cor-  
13 ridor costs for the plan for the year are less the  
14 second threshold lower limit of the risk corridor for  
15 the plan for the year, the Secretary shall reduce  
16 the total of the payments made to the sponsor or  
17 organization offering the plan for the year under  
18 this section by an amount (or otherwise recover  
19 from the sponsor or organization an amount) equal  
20 to the sum of—

21 “(I) 50 percent (or, for 2006 and 2007,  
22 75 percent) of the difference between the first  
23 threshold lower limit and the second threshold  
24 lower limit; and

25 “(II) 80 percent of the difference between  
26 the second threshold upper limit of the risk  
27 corridor and such adjusted allowable risk cor-  
28 ridor costs.

29 “(3) ESTABLISHMENT OF RISK CORRIDORS.—

30 “(A) IN GENERAL.—For each plan year the Sec-  
31 retary shall establish a risk corridor for each prescrip-  
32 tion drug plan and each MA–PD plan. The risk cor-  
33 ridor for a plan for a year shall be equal to a range  
34 as follows:

35 “(i) FIRST THRESHOLD LOWER LIMIT.—The  
36 first threshold lower limit of such corridor shall be  
37 equal to—

1                   “(I) the target amount described in sub-  
2                   paragraph (B) for the plan; minus

3                   “(II) an amount equal to the first thresh-  
4                   old risk percentage for the plan (as determined  
5                   under subparagraph (C)(i)) of such target  
6                   amount.

7                   “(ii) SECOND THRESHOLD LOWER LIMIT.—  
8                   The second threshold lower limit of such corridor  
9                   shall be equal to—

10                   “(I) the target amount described in sub-  
11                   paragraph (B) for the plan; minus

12                   “(II) an amount equal to the second  
13                   threshold risk percentage for the plan (as de-  
14                   termined under subparagraph (C)(ii)) of such  
15                   target amount.

16                   “(iii) FIRST THRESHOLD UPPER LIMIT.—The  
17                   first threshold upper limit of such corridor shall be  
18                   equal to the sum of—

19                   “(I) such target amount; and

20                   “(II) the amount described in clause  
21                   (i)(II).

22                   “(iv) SECOND THRESHOLD UPPER LIMIT.—  
23                   The second threshold upper limit of such corridor  
24                   shall be equal to the sum of—

25                   “(I) such target amount; and

26                   “(II) the amount described in clause  
27                   (ii)(II).

28                   “(B) TARGET AMOUNT DESCRIBED.—The target  
29                   amount described in this paragraph is, with respect to  
30                   a prescription drug plan or an MA-PD plan in a year,  
31                   the total amount of payments paid to the PDP sponsor  
32                   or MA-PD organization for the plan for the year, tak-  
33                   ing into account amounts paid by the Secretary and en-  
34                   rollees, based upon the standardized bid amount (as de-  
35                   fined in section 1860D-13(a)(5) and as risk adjusted  
36                   under subsection (c)(1)), reduced by the total amount

1 of administrative expenses for the year assumed in  
2 such standardized bid.

3 “(C) FIRST AND SECOND THRESHOLD RISK PER-  
4 CENTAGE DEFINED.—

5 “(i) FIRST THRESHOLD RISK PERCENTAGE.—  
6 Subject to clause (iii), for purposes of this section,  
7 the first threshold risk percentage is—

8 “(I) for 2006 and 2007, and 2.5 percent;

9 “(II) for 2008 through 2011, 5 percent;

10 and

11 “(III) for 2012 and subsequent years, a  
12 percentage established by the Secretary, but in  
13 no case less than 5 percent.

14 “(ii) SECOND THRESHOLD RISK PERCENT-  
15 AGE.—Subject to clause (iii), for purposes of this  
16 section, the second threshold risk percentage is—

17 “(I) for 2006 and 2007, 5 percent;

18 “(II) for 2008 through 2011, 10 percent;

19 and

20 “(III) for 2012 and subsequent years, a  
21 percentage established by the Secretary that is  
22 greater than the percent established for the  
23 year under clause (i)(III), but in no case less  
24 than 10 percent.

25 “(iii) REDUCTION OF RISK PERCENTAGE TO  
26 ENSURE 2 PLANS IN AN AREA.—Pursuant to sec-  
27 tion 1860D–11(b)(2)(E)(ii), a PDP sponsor may  
28 submit a bid that requests a decrease in the appli-  
29 cable first or second threshold risk percentages or  
30 an increase in the percents applied under para-  
31 graph (2).

32 “(4) PLANS AT RISK FOR ENTIRE AMOUNT OF SUP-  
33 PLEMENTAL PRESCRIPTION DRUG COVERAGE.—A PDP  
34 sponsor and MA organization that offers a plan that pro-  
35 vides supplemental prescription drug benefits shall be at  
36 full financial risk for the provision of such supplemental  
37 benefits.



1           “(5) NO EFFECT ON MONTHLY PREMIUM.—No adjust-  
2           ment in payments made by reason of this subsection shall  
3           affect the monthly beneficiary premium or the MA monthly  
4           prescription drug beneficiary premium.

5           “(f) DISCLOSURE OF INFORMATION.—

6           “(1) IN GENERAL.—Each contract under this part and  
7           under part C shall provide that—

8           “(A) the PDP sponsor offering a prescription drug  
9           plan or an MA organization offering an MA–PD plan  
10           shall provide the Secretary with such information as  
11           the Secretary determines is necessary to carry out this  
12           section; and

13           “(B) the Secretary shall have the right in accord-  
14           ance with section 1857(d)(2)(B) (as applied under sec-  
15           tion 1860D–12(b)(3)(C)) to inspect and audit any  
16           books and records of a PDP sponsor or MA organiza-  
17           tion that pertain to the information regarding costs  
18           provided to the Secretary under subparagraph (A).

19           “(2) RESTRICTION ON USE OF INFORMATION.—Infor-  
20           mation disclosed or obtained pursuant to the provisions of  
21           this section may be used by officers, employees, and con-  
22           tractors of the Department of Health and Human Services  
23           only for the purposes of, and to the extent necessary in,  
24           carrying out this section.

25           “(g) PAYMENT FOR FALLBACK PRESCRIPTION DRUG  
26           PLANS.—In lieu of the amounts otherwise payable under this  
27           section to a PDP sponsor offering a fallback prescription drug  
28           plan (as defined in section 1860D–3(c)(4)), the amount payable  
29           shall be the amounts determined under the contract for such  
30           plan pursuant to section 1860D–11(g)(5).

31           “MEDICARE PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL  
32           SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

33           “SEC. 1860D–16. (a) ESTABLISHMENT AND OPERATION  
34           OF ACCOUNT.—

35           “(1) ESTABLISHMENT.—There is created within the  
36           Federal Supplementary Medical Insurance Trust Fund es-  
37           tablished by section 1841 an account to be known as the

1 'Medicare Prescription Drug Account' (in this section re-  
2 ferred to as the 'Account').

3 "(2) FUNDING.—The Account shall consist of such  
4 gifts and bequests as may be made as provided in section  
5 201(i)(1), accrued interest on balances in the Account, and  
6 such amounts as may be deposited in, or appropriated to,  
7 such Account as provided in this part.

8 "(3) SEPARATE FROM REST OF TRUST FUND.—Funds  
9 provided under this part to the Account shall be kept sepa-  
10 rate from all other funds within the Federal Supplementary  
11 Medical Insurance Trust Fund, but shall be invested, and  
12 such investments redeemed, in the same manner as all  
13 other funds and investments within such Trust Fund.

14 "(b) PAYMENTS FROM ACCOUNT.—

15 "(1) IN GENERAL.—The Managing Trustee shall pay  
16 from time to time from the Account such amounts as the  
17 Secretary certifies are necessary to make payments to oper-  
18 ate the program under this part, including—

19 "(A) payments under section 1860D–14 (relating  
20 to low-income subsidy payments);

21 "(B) payments under section 1860D–15 (relating  
22 to subsidy payments and payments for fallback plans);

23 "(C) payments to sponsors of qualified retiree pre-  
24 scription drug plans under section 1860D–22(a); and

25 "(D) payments with respect to administrative ex-  
26 penses under this part in accordance with section  
27 201(g).

28 "(2) TRANSFERS TO MEDICAID ACCOUNT FOR IN-  
29 CREASED ADMINISTRATIVE COSTS.—The Managing Trustee  
30 shall transfer from time to time from the Account to the  
31 Grants to States for Medicaid account amounts the Sec-  
32 retary certifies are attributable to increases in payment re-  
33 sulting from the application of section 1935(b).

34 "(3) PAYMENTS OF PREMIUMS WITHHELD.—The Man-  
35 aging Trustee shall make payment to the PDP sponsor or  
36 MA organization involved of the premiums (and the portion  
37 of late enrollment penalties) that are collected in the man-

1 ner described in section 1854(d)(2)(A) and that are pay-  
2 able under a prescription drug plan or MA-PD plan offered  
3 by such sponsor or organization.

4 “(4) TREATMENT IN RELATION TO PART B PRE-  
5 MIUM.—Amounts payable from the Account shall not be  
6 taken into account in computing actuarial rates or pre-  
7 mium amounts under section 1839.

8 “(c) DEPOSITS INTO ACCOUNT.—

9 “(1) LOW-INCOME TRANSFER.—Amounts paid under  
10 section 1935(c) (and any amounts collected or offset under  
11 paragraph (1)(C) of such section) are deposited into the  
12 Account.

13 “(2) AMOUNTS WITHHELD.—Pursuant to sections  
14 1860D-13(c) and 1854(d) (as applied under this part),  
15 amounts that are withheld (and allocated) to the Account  
16 are deposited into the Account.

17 “(3) APPROPRIATIONS TO COVER GOVERNMENT CON-  
18 TRIBUTIONS.—There are authorized to be appropriated  
19 from time to time, out of any moneys in the Treasury not  
20 otherwise appropriated, to the Account, an amount equiva-  
21 lent to the amount of payments made from the Account  
22 under subsection (b) plus such amounts as the Managing  
23 Trustee certifies is necessary to maintain an appropriate  
24 contingency margin, reduced by the amounts deposited  
25 under paragraph (1) or subsection (a)(2).

26 “(4) INITIAL FUNDING AND RESERVE.—In order to  
27 assure prompt payment of benefits provided under this part  
28 and the administrative expenses thereunder during the  
29 early months of the program established by this part and  
30 to provide an initial contingency reserve, there are author-  
31 ized to be appropriated to the Account, out of any moneys  
32 in the Treasury not otherwise appropriated, such amount  
33 as the Secretary certifies are required, but not to exceed 10  
34 percent of the estimated total expenditures from such Ac-  
35 count in 2006.

36 “(5) TRANSFER OF ANY REMAINING BALANCE FROM  
37 TRANSITIONAL ASSISTANCE ACCOUNT.—Any balance in the

1 Transitional Assistance Account that is transferred under  
2 section 1860D–31(k)(5) shall be deposited into the Ac-  
3 count.

4 “Subpart 3—Application to Medicare Advantage Program and  
5 Treatment of Employer-Sponsored Programs and Other Pre-  
6 scription Drug Plans

7 “APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND  
8 RELATED MANAGED CARE PROGRAMS

9 “SEC. 1860D–21. (a) SPECIAL RULES RELATING TO OF-  
10 FERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

11 “(1) IN GENERAL.—An MA organization on and after  
12 January 1, 2006—

13 “(A) may not offer an MA plan described in sec-  
14 tion 1851(a)(2)(A) in an area unless either that plan  
15 (or another MA plan offered by the organization in  
16 that same service area) includes required prescription  
17 drug coverage (as defined in paragraph (2)); and

18 “(B) may not offer prescription drug coverage  
19 (other than that required under parts A and B) to an  
20 enrollee under an MSA plan or under another MA plan  
21 unless such drug coverage under such other plan pro-  
22 vides qualified prescription drug coverage and unless  
23 the requirements of this section with respect to such  
24 coverage are met.

25 “(2) QUALIFYING COVERAGE.—For purposes of para-  
26 graph (1)(A), the term ‘required coverage’ means with re-  
27 spect to an MA–PD plan—

28 “(A) basic prescription drug coverage; or

29 “(B) qualified prescription drug coverage that pro-  
30 vides supplemental prescription drug coverage, so long  
31 as there is no MA monthly supplemental beneficiary  
32 premium applied under the plan (due to the application  
33 of a credit against such premium of a rebate under sec-  
34 tion 1854(b)(1)(C)).

35 “(b) APPLICATION OF DEFAULT ENROLLMENT RULES.—

36 “(1) SEAMLESS CONTINUATION.—In applying section  
37 1851(c)(3)(A)(ii), an individual who is enrolled in a health

1 benefits plan shall not be considered to have been deemed  
2 to make an election into an MA-PD plan unless such  
3 health benefits plan provides any prescription drug cov-  
4 erage.

5 “(2) MA CONTINUATION.—In applying section  
6 1851(c)(3)(B), an individual who is enrolled in an MA plan  
7 shall not be considered to have been deemed to make an  
8 election into an MA-PD plan unless—

9 “(A) for purposes of the election as of January 1,  
10 2006, the MA plan provided as of December 31, 2005,  
11 any prescription drug coverage; or

12 “(B) for periods after January 1, 2006, such MA  
13 plan is an MA-PD plan.

14 “(3) DISCONTINUANCE OF MA-PD ELECTION DURING  
15 FIRST YEAR OF ELIGIBILITY.—In applying the second sen-  
16 tence of section 1851(e)(4) in the case of an individual who  
17 is electing to discontinue enrollment in an MA-PD plan,  
18 the individual shall be permitted to enroll in a prescription  
19 drug plan under part D at the time of the election of cov-  
20 erage under the original medicare fee-for-service program.

21 “(4) RULES REGARDING ENROLLEES IN MA PLANS  
22 NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COV-  
23 ERAGE.—In the case of an individual who is enrolled in an  
24 MA plan (other than an MSA plan) that does not provide  
25 qualified prescription drug coverage, if the organization of-  
26 fering such coverage discontinues the offering with respect  
27 to the individual of all MA plans that do not provide such  
28 coverage—

29 “(i) the individual is deemed to have elected  
30 the original medicare fee-for-service program op-  
31 tion, unless the individual affirmatively elects to en-  
32 roll in an MA-PD plan; and

33 “(ii) in the case of such a deemed election, the  
34 disenrollment shall be treated as an involuntary  
35 termination of the MA plan described in subpara-  
36 graph (B)(ii) of section 1882(s)(3) for purposes of  
37 applying such section.

1           The information disclosed under section 1852(c)(1) for in-  
2           dividuals who are enrolled in such an MA plan shall include  
3           information regarding such rules.

4           “(c) APPLICATION OF PART D RULES FOR PRESCRIPTION  
5           DRUG COVERAGE.—With respect to the offering of qualified  
6           prescription drug coverage by an MA organization under this  
7           part on and after January 1, 2006—

8                   “(1) IN GENERAL.—Except as otherwise provided, the  
9                   provisions of this part shall apply under part C with re-  
10                  spect to prescription drug coverage provided under MA–PD  
11                  plans in lieu of the other provisions of part C that would  
12                  apply to such coverage under such plans.

13                  “(2) WAIVER.—The Secretary shall waive the provi-  
14                  sions referred to in paragraph (1) to the extent the Sec-  
15                  retary determines that such provisions duplicate, or are in  
16                  conflict with, provisions otherwise applicable to the organi-  
17                  zation or plan under part C or as may be necessary in  
18                  order to improve coordination of this part with the benefits  
19                  under this part.

20                  “(3) TREATMENT OF MA OWNED AND OPERATED  
21                  PHARMACIES.—The Secretary may waive the requirement  
22                  of section 1860D–4(b)(1)(C) in the case of an MA–PD  
23                  plan that provides access (other than mail order) to quali-  
24                  fied prescription drug coverage through pharmacies owned  
25                  and operated by the MA organization, if the Secretary de-  
26                  termines that the organization’s pharmacy network is suffi-  
27                  cient to provide comparable access for enrollees under the  
28                  plan.

29                  “(d) SPECIAL RULES FOR PRIVATE FEE-FOR-SERVICE  
30                  PLANS THAT OFFER PRESCRIPTION DRUG COVERAGE.—With  
31                  respect to an MA plan described in section 1851(a)(2)(C) that  
32                  offers qualified prescription drug coverage, on and after Janu-  
33                  ary 1, 2006, the following rules apply:

34                   “(1) REQUIREMENTS REGARDING NEGOTIATED  
35                   PRICES.—Subsections (a)(1) and (d)(1) of section 1860D–  
36                   2 and section 1860D–4(b)(2)(A) shall not be construed to  
37                   require the plan to provide negotiated prices (described in

1 subsection (d)(1)(B) of such section), but shall apply to the  
2 extent the plan does so.

3 “(2) MODIFICATION OF PHARMACY ACCESS STANDARD  
4 AND DISCLOSURE REQUIREMENT.—If the plan provides  
5 coverage for drugs purchased from all pharmacies, without  
6 charging additional cost-sharing, and without regard to  
7 whether they are participating pharmacies in a network or  
8 have entered into contracts or agreements with pharmacies  
9 to provide drugs to enrollees covered by the plan, sub-  
10 sections (b)(1)(C) and (k) of section 1860D–4 shall not  
11 apply to the plan.

12 “(3) DRUG UTILIZATION MANAGEMENT PROGRAM AND  
13 MEDICATION THERAPY MANAGEMENT PROGRAM NOT RE-  
14 QUIRED.—The requirements of subparagraphs (A) and (C)  
15 of section 1860D–4(c)(1) shall not apply to the plan.

16 “(4) APPLICATION OF REINSURANCE.—The Secretary  
17 shall determine the amount of reinsurance payments under  
18 section 1860D–15(b) using a methodology that—

19 “(A) bases such amount on the Secretary’s esti-  
20 mate of the amount of such payments that would be  
21 payable if the plan were an MA–PD plan described in  
22 section 1851(a)(2)(A)(i) and the previous provisions of  
23 this subsection did not apply; and

24 “(B) takes into account the average reinsurance  
25 payments made under section 1860D–15(b) for popu-  
26 lations of similar risk under MA–PD plans described in  
27 such section.

28 “(5) EXEMPTION FROM RISK CORRIDOR PROVI-  
29 SIONS.—The provisions of section 1860D–15(e) shall not  
30 apply.

31 “(6) EXEMPTION FROM NEGOTIATIONS.—Subsections  
32 (d) and (e)(2)(C) of section 1860D–11 shall not apply and  
33 the provisions of section 1854(a)(5)(B) prohibiting the re-  
34 view, approval, or disapproval of amounts described in such  
35 section shall apply to the proposed bid and terms and con-  
36 ditions described in section 1860D–11(d).

1           “(7) TREATMENT OF INCURRED COSTS WITHOUT RE-  
2           GARD TO FORMULARY.—The exclusion of costs incurred for  
3           covered part D drugs which are not included (or treated as  
4           being included) in a plan’s formulary under section 1860D-  
5           2(b)(4)(B)(i) shall not apply insofar as the plan does not  
6           utilize a formulary.

7           “(e) APPLICATION TO REASONABLE COST REIMBURSE-  
8           MENT CONTRACTORS.—

9           “(1) IN GENERAL.—Subject to paragraphs (2) and (3)  
10           and rules established by the Secretary, in the case of an  
11           organization that is providing benefits under a reasonable  
12           cost reimbursement contract under section 1876(h) and  
13           that elects to provide qualified prescription drug coverage  
14           to a part D eligible individual who is enrolled under such  
15           a contract, the provisions of this part (and related provi-  
16           sions of part C) shall apply to the provision of such cov-  
17           erage to such enrollee in the same manner as such provi-  
18           sions apply to the provision of such coverage under an MA-  
19           PD local plan described in section 1851(a)(2)(A)(i) and  
20           coverage under such a contract that so provides qualified  
21           prescription drug coverage shall be deemed to be an MA-  
22           PD local plan.

23           “(2) LIMITATION ON ENROLLMENT.—In applying  
24           paragraph (1), the organization may not enroll part D eli-  
25           gible individuals who are not enrolled under the reasonable  
26           cost reimbursement contract involved.

27           “(3) BIDS NOT INCLUDED IN DETERMINING NATIONAL  
28           AVERAGE MONTHLY BID AMOUNT.—The bid of an organiza-  
29           tion offering prescription drug coverage under this sub-  
30           section shall not be taken into account in computing the  
31           national average monthly bid amount and low-income  
32           benchmark premium amount under this part.

33           “(f) APPLICATION TO PACE.—

34           “(1) IN GENERAL.—Subject to paragraphs (2) and (3)  
35           and rules established by the Secretary, in the case of a  
36           PACE program under section 1894 that elects to provide  
37           qualified prescription drug coverage to a part D eligible in-



1 individual who is enrolled under such program, the provisions  
2 of this part (and related provisions of part C) shall apply  
3 to the provision of such coverage to such enrollee in the  
4 same manner as such provisions apply to the provision of  
5 such coverage under an MA–PD local plan described in sec-  
6 tion 1851(a)(2)(A)(ii) and a PACE program that so pro-  
7 vides such coverage shall be deemed to be an MA–PD local  
8 plan.

9 “(2) LIMITATION ON ENROLLMENT.—In applying  
10 paragraph (1), the organization may not enroll part D eli-  
11 gible individuals who are not enrolled under the PACE pro-  
12 gram involved.

13 “(3) BIDS NOT INCLUDED IN DETERMINING STAND-  
14 ARDIZED BID AMOUNT.—The bid of an organization offer-  
15 ing prescription drug coverage under this subsection is not  
16 be taken into account in computing any average benchmark  
17 bid amount and low-income benchmark premium amount  
18 under this part.

19 “SPECIAL RULES FOR EMPLOYER-SPONSORED PROGRAMS

20 “SEC. 1860D–22. (a) SUBSIDY PAYMENT.—

21 “(1) IN GENERAL.—The Secretary shall provide in ac-  
22 cordance with this subsection for payment to the sponsor  
23 of a qualified retiree prescription drug plan (as defined in  
24 paragraph (2)) of a special subsidy payment equal to the  
25 amount specified in paragraph (3) for each qualified cov-  
26 ered retiree under the plan (as defined in paragraph (4)).  
27 This subsection constitutes budget authority in advance of  
28 appropriations Acts and represents the obligation of the  
29 Secretary to provide for the payment of amounts provided  
30 under this section.

31 “(2) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN  
32 DEFINED.—For purposes of this subsection, the term  
33 ‘qualified retiree prescription drug plan’ means employ-  
34 ment-based retiree health coverage (as defined in sub-  
35 section (c)(1)) if, with respect to a part D eligible indi-  
36 vidual who is a participant or beneficiary under such cov-  
37 erage, the following requirements are met:

1           “(A) ATTESTATION OF ACTUARIAL EQUIVALENCE  
2 TO STANDARD COVERAGE.—The sponsor of the plan  
3 provides the Secretary, annually or at such other time  
4 as the Secretary may require, with an attestation that  
5 the actuarial value of prescription drug coverage under  
6 the plan (as determined using the processes and meth-  
7 ods described in section 1860D–11(c)) is at least equal  
8 to the actuarial value of standard prescription drug  
9 coverage.

10           “(B) AUDITS.—The sponsor of the plan, or an ad-  
11 ministrator of the plan designated by the sponsor, shall  
12 maintain (and afford the Secretary access to) such  
13 records as the Secretary may require for purposes of  
14 audits and other oversight activities necessary to en-  
15 sure the adequacy of prescription drug coverage and  
16 the accuracy of payments made under this section. The  
17 provisions of section 1860D–2(d)(3) shall apply to such  
18 information under this section (including such actuarial  
19 value and attestation) in a manner similar to the man-  
20 ner in which they apply to financial records of PDP  
21 sponsors and MA organizations.

22           “(C) PROVISION OF DISCLOSURE REGARDING PRE-  
23 SCRIPTIION DRUG COVERAGE.—The sponsor of the plan  
24 shall provide for disclosure of information regarding  
25 prescription drug coverage in accordance with section  
26 1860D–13(b)(6)(B).

27           “(3) EMPLOYER AND UNION SPECIAL SUBSIDY  
28 AMOUNTS.—

29           “(A) IN GENERAL.—For purposes of this sub-  
30 section, the special subsidy payment amount under this  
31 paragraph for a qualifying covered retiree for a cov-  
32 erage year enrolled with the sponsor of a qualified re-  
33 tiree prescription drug plan is, for the portion of the  
34 retiree’s gross covered retiree plan-related prescription  
35 drug costs (as defined in subparagraph (C)(ii)) for such  
36 year that exceeds the cost threshold amount specified  
37 in subparagraph (B) and does not exceed the cost limit

1 under such subparagraph, an amount equal to 28 per-  
2 cent of the allowable retiree costs (as defined in sub-  
3 paragraph (C)(i)) attributable to such gross covered  
4 prescription drug costs.

5 “(B) COST THRESHOLD AND COST LIMIT APPLICA-  
6 BLE.—

7 “(i) IN GENERAL.—Subject to clause (ii)—

8 “(I) the cost threshold under this subpara-  
9 graph is equal to \$250 for plan years that end  
10 in 2006; and

11 “(II) the cost limit under this subpara-  
12 graph is equal to \$5,000 for plan years that  
13 end in 2006.

14 “(ii) INDEXING.—The cost threshold and cost  
15 limit amounts specified in subclauses (I) and (II)  
16 of clause (i) for a plan year that ends after 2006  
17 shall be adjusted in the same manner as the annual  
18 deductible and the annual out-of-pocket threshold,  
19 respectively, are annually adjusted under para-  
20 graphs (1) and (4)(B) of section 1860D–2(b).

21 “(C) DEFINITIONS.—For purposes of this para-  
22 graph:

23 “(i) ALLOWABLE RETIREE COSTS.—The term  
24 ‘allowable retiree costs’ means, with respect to  
25 gross covered prescription drug costs under a quali-  
26 fied retiree prescription drug plan by a plan spon-  
27 sor, the part of such costs that are actually paid  
28 (net of discounts, chargebacks, and average per-  
29 centage rebates) by the sponsor or by or on behalf  
30 of a qualifying covered retiree under the plan.

31 “(ii) GROSS COVERED RETIREE PLAN-RE-  
32 LATED PRESCRIPTION DRUG COSTS.—For purposes  
33 of this section, the term ‘gross covered retiree plan-  
34 related prescription drug costs’ means, with respect  
35 to a qualifying covered retiree enrolled in a quali-  
36 fied retiree prescription drug plan during a cov-  
37 erage year, the costs incurred under the plan, not

1 including administrative costs, but including costs  
2 directly related to the dispensing of covered part D  
3 drugs during the year. Such costs shall be deter-  
4 mined whether they are paid by the retiree or  
5 under the plan.

6 “(iii) COVERAGE YEAR.—The term ‘coverage year’  
7 has the meaning given such term in section 1860D–  
8 15(b)(4).

9 “(4) QUALIFYING COVERED RETIREE DEFINED.—For  
10 purposes of this subsection, the term ‘qualifying covered re-  
11 tiree’ means a part D eligible individual who is not enrolled  
12 in a prescription drug plan or an MA–PD plan but is cov-  
13 ered under a qualified retiree prescription drug plan.

14 “(5) PAYMENT METHODS, INCLUDING PROVISION OF  
15 NECESSARY INFORMATION.—The provisions of section  
16 1860D–15(d) (including paragraph (2), relating to require-  
17 ment for provision of information) shall apply to payments  
18 under this subsection in a manner similar to the manner  
19 in which they apply to payment under section 1860D–  
20 15(b).

21 “(6) CONSTRUCTION.—Nothing in this subsection  
22 shall be construed as—

23 “(A) precluding a part D eligible individual who is  
24 covered under employment-based retiree health cov-  
25 erage from enrolling in a prescription drug plan or in  
26 an MA–PD plan;

27 “(B) precluding such employment-based retiree  
28 health coverage or an employer or other person from  
29 paying all or any portion of any premium required for  
30 coverage under a prescription drug plan or MA–PD  
31 plan on behalf of such an individual;

32 “(C) preventing such employment-based retiree  
33 health coverage from providing coverage—

34 “(i) that is better than standard prescription  
35 drug coverage to retirees who are covered under a  
36 qualified retiree prescription drug plan; or

1                   “(ii) that is supplemental to the benefits pro-  
2                   vided under a prescription drug plan or an MA–PD  
3                   plan, including benefits to retirees who are not cov-  
4                   ered under a qualified retiree prescription drug  
5                   plan but who are enrolled in such a prescription  
6                   drug plan or MA–PD plan; or

7                   “(D) preventing employers to provide for flexibility  
8                   in benefit design and pharmacy access provisions, with-  
9                   out regard to the requirements for basic prescription  
10                  drug coverage, so long as the actuarial equivalence re-  
11                  quirement of paragraph (2)(A) is met.

12                  “(b) APPLICATION OF MA WAIVER AUTHORITY.—The  
13                  provisions of section 1857(i) shall apply with respect to pre-  
14                  scription drug plans in relation to employment-based retiree  
15                  health coverage in a manner similar to the manner in which  
16                  they apply to an MA plan in relation to employers, including  
17                  authorizing the establishment of separate premium amounts for  
18                  enrollees in a prescription drug plan by reason of such coverage  
19                  and limitations on enrollment to part D eligible individuals en-  
20                  rolled under such coverage.

21                  “(c) DEFINITIONS.—For purposes of this section:

22                  “(1) EMPLOYMENT-BASED RETIREE HEALTH COV-  
23                  ERAGE.—The term ‘employment-based retiree health cov-  
24                  erage’ means health insurance or other coverage of health  
25                  care costs (whether provided by voluntary insurance cov-  
26                  erage or pursuant to statutory or contractual obligation)  
27                  for part D eligible individuals (or for such individuals and  
28                  their spouses and dependents) under a group health plan  
29                  based on their status as retired participants in such plan.

30                  “(2) SPONSOR.—The term ‘sponsor’ means a plan  
31                  sponsor, as defined in section 3(16)(B) of the Employee  
32                  Retirement Income Security Act of 1974, in relation to a  
33                  group health plan, except that, in the case of a plan main-  
34                  tained jointly by one employer and an employee organiza-  
35                  tion and with respect to which the employer is the primary  
36                  source of financing, such term means such employer.

1           “(3) GROUP HEALTH PLAN.—The term ‘group health  
2 plan’ includes such a plan as defined in section 607(1) of  
3 the Employee Retirement Income Security Act of 1974 and  
4 also includes the following:

5           “(A) FEDERAL AND STATE GOVERNMENTAL  
6 PLANS.—Such a plan established or maintained for its  
7 employees by the Government of the United States, by  
8 the government of any State or political subdivision  
9 thereof, or by any agency or instrumentality of any of  
10 the foregoing, including a health benefits plan offered  
11 under chapter 89 of title 5, United States Code.

12           “(B) COLLECTIVELY BARGAINED PLANS.—Such a  
13 plan established or maintained under or pursuant to  
14 one or more collective bargaining agreements.

15           “(C) CHURCH PLANS.—Such a plan established  
16 and maintained for its employees (or their bene-  
17 ficiaries) by a church or by a convention or association  
18 of churches which is exempt from tax under section  
19 501 of the Internal Revenue Code of 1986.

20           “STATE PHARMACEUTICAL ASSISTANCE PROGRAMS

21           “SEC. 1860D–23. (a) REQUIREMENTS FOR BENEFIT CO-  
22 ORDINATION.—

23           “(1) IN GENERAL.—Before July 1, 2005, the Sec-  
24 retary shall establish consistent with this section require-  
25 ments for prescription drug plans to ensure the effective  
26 coordination between a part D plan (as defined in para-  
27 graph (5)) and a State Pharmaceutical Assistance Program  
28 (as defined in subsection (b)) with respect to—

29           “(A) payment of premiums and coverage; and

30           “(B) payment for supplemental prescription drug  
31 benefits,

32 for part D eligible individuals enrolled under both types of  
33 plans.

34           “(2) COORDINATION ELEMENTS.—The requirements  
35 under paragraph (1) shall include requirements relating to  
36 coordination of each of the following:

37           “(A) Enrollment file sharing.

1                   “(B) The processing of claims, including electronic  
2                   processing.

3                   “(C) Claims payment.

4                   “(D) Claims reconciliation reports.

5                   “(E) Application of the protection against high  
6                   out-of-pocket expenditures under section 1860D–  
7                   2(b)(4).

8                   “(F) Other administrative processes specified by  
9                   the Secretary.

10                  Such requirements shall be consistent with applicable law  
11                  to safeguard the privacy of any individually identifiable  
12                  beneficiary information.

13                  “(3) USE OF LUMP SUM PER CAPITA METHOD.—Such  
14                  requirements shall include a method for the application by  
15                  a part D plan of specified funding amounts from a State  
16                  Pharmaceutical Assistance Program for enrolled individuals  
17                  for supplemental prescription drug benefits.

18                  “(4) CONSULTATION.—In establishing requirements  
19                  under this subsection, the Secretary shall consult with  
20                  State Pharmaceutical Assistance Programs, MA organiza-  
21                  tions, States, pharmaceutical benefit managers, employers,  
22                  representatives of part D eligible individuals, the data proc-  
23                  essing experts, pharmacists, pharmaceutical manufacturers,  
24                  and other experts.

25                  “(5) PART D PLAN DEFINED.—For purposes of this  
26                  section and section 1860D–24, the term ‘part D plan’  
27                  means a prescription drug plan and an MA–PD plan.

28                  “(b) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—  
29                  For purposes of this part, the term ‘State Pharmaceutical As-  
30                  sistance Program’ means a State program—

31                         “(1) which provides financial assistance for the pur-  
32                         chase or provision of supplemental prescription drug cov-  
33                         erage or benefits on behalf of part D eligible individuals;

34                         “(2) which, in determining eligibility and the amount  
35                         of assistance to part D eligible individuals under the Pro-  
36                         gram, provides assistance to such individuals in all part D

1 plans and does not discriminate based upon the part D  
2 plan in which the individual is enrolled; and

3 “(3) which satisfies the requirements of subsections  
4 (a) and (c).

5 “(c) RELATION TO OTHER PROVISIONS.—

6 “(1) MEDICARE AS PRIMARY PAYOR.—The require-  
7 ments of this section shall not change or affect the primary  
8 payor status of a part D plan.

9 “(2) USE OF A SINGLE CARD.—A card that is issued  
10 under section 1860D–4(b)(2)(A) for use under a part D  
11 plan may also be used in connection with coverage of bene-  
12 fits provided under a State Pharmaceutical Assistance Pro-  
13 gram and, in such case, may contain an emblem or symbol  
14 indicating such connection.

15 “(3) OTHER PROVISIONS.—The provisions of section  
16 1860D–24(c) shall apply to the requirements under this  
17 section.

18 “(4) SPECIAL TREATMENT UNDER OUT-OF-POCKET  
19 RULE.—In applying section 1860D–2(b)(4)(C)(ii), expenses  
20 incurred under a State Pharmaceutical Assistance Program  
21 may be counted toward the annual out-of-pocket threshold.

22 “(5) CONSTRUCTION.—Nothing in this section shall be  
23 construed as requiring a State Pharmaceutical Assistance  
24 Program to coordinate or provide financial assistance with  
25 respect to any part D plan.

26 “(d) FACILITATION OF TRANSITION AND COORDINATION  
27 WITH STATE PHARMACEUTICAL ASSISTANCE PROGRAMS.—

28 “(1) TRANSITIONAL GRANT PROGRAM.—The Secretary  
29 shall provide payments to State Pharmaceutical Assistance  
30 Programs with an application approved under this sub-  
31 section.

32 “(2) USE OF FUNDS.—Payments under this section  
33 may be used by a Program for any of the following:

34 “(A) Educating part D eligible individuals enrolled  
35 in the Program about the prescription drug coverage  
36 available through part D plans under this part.



1           “(B) Providing technical assistance, phone sup-  
2           port, and counseling for such enrollees to facilitate se-  
3           lection and enrollment in such plans.

4           “(C) Other activities designed to promote the ef-  
5           fective coordination of enrollment, coverage, and pay-  
6           ment between such Program and such plans.

7           “(3) ALLOCATION OF FUNDS.—Of the amount appro-  
8           priated to carry out this subsection for a fiscal year, the  
9           Secretary shall allocate payments among Programs that  
10          have applications approved under paragraph (4) for such  
11          fiscal year in proportion to the number of enrollees enrolled  
12          in each such Program as of October 1, 2003.

13          “(4) APPLICATION.—No payments may be made under  
14          this subsection except pursuant to an application that is  
15          submitted and approved in a time, manner, and form speci-  
16          fied by the Secretary.

17          “(5) FUNDING.—Out of any funds in the Treasury not  
18          otherwise appropriated, there are appropriated for each of  
19          fiscal years 2005 and 2006, \$62,500,000 to carry out this  
20          subsection.

21          “COORDINATION REQUIREMENTS FOR PLANS PROVIDING  
22          PRESCRIPTION DRUG COVERAGE

23          “SEC. 1860D–24. (a) APPLICATION OF BENEFIT COORDI-  
24          NATION REQUIREMENTS TO ADDITIONAL PLANS.—

25          “(1) IN GENERAL.—The Secretary shall apply the co-  
26          ordination requirements established under section 1860D–  
27          23(a) to Rx plans described in subsection (b) in the same  
28          manner as such requirements apply to a State Pharma-  
29          ceutical Assistance Program.

30          “(2) APPLICATION TO TREATMENT OF CERTAIN OUT-  
31          OF-POCKET EXPENDITURES.—To the extent specified by  
32          the Secretary, the requirements referred to in paragraph  
33          (1) shall apply to procedures established under section  
34          1860D–2(b)(4)(D).

35          “(3) USER FEES.—

36          “(A) IN GENERAL.—The Secretary may impose  
37          user fees for the transmittal of information necessary

1 for benefit coordination under section 1860D–  
2 2(b)(4)(D) in a manner similar to the manner in which  
3 user fees are imposed under section 1842(h)(3)(B), ex-  
4 cept that the Secretary may retain a portion of such  
5 fees to defray the Secretary’s costs in carrying out pro-  
6 cedures under section 1860D–2(b)(4)(D).

7 “(B) APPLICATION.—A user fee may not be im-  
8 posed under subparagraph (A) with respect to a State  
9 Pharmaceutical Assistance Program.

10 “(b) RX PLAN.—An Rx plan described in this subsection  
11 is any of the following:

12 “(1) MEDICAID PROGRAMS.—A State plan under title  
13 XIX, including such a plan operating under a waiver under  
14 section 1115, if it meets the requirements of section  
15 1860D–23(b)(2).

16 “(2) GROUP HEALTH PLANS.—An employer group  
17 health plan.

18 “(3) FEHBP.—The Federal employees health benefits  
19 plan under chapter 89 of title 5, United States Code.

20 “(4) MILITARY COVERAGE (INCLUDING TRICARE).—  
21 Coverage under chapter 55 of title 10, United States Code.

22 “(5) OTHER PRESCRIPTION DRUG COVERAGE.—Such  
23 other health benefit plans or programs that provide cov-  
24 erage or financial assistance for the purchase or provision  
25 of prescription drug coverage on behalf of part D eligible  
26 individuals as the Secretary may specify.

27 “(c) RELATION TO OTHER PROVISIONS.—

28 “(1) USE OF COST MANAGEMENT TOOLS.—The re-  
29 quirements of this section shall not impair or prevent a  
30 PDP sponsor or MA organization from applying cost man-  
31 agement tools (including differential payments) under all  
32 methods of operation.

33 “(2) NO AFFECT ON TREATMENT OF CERTAIN OUT-  
34 OF-POCKET EXPENDITURES.—The requirements of this sec-  
35 tion shall not affect the application of the procedures estab-  
36 lished under section 1860D–2(b)(4)(D).

1 “Subpart 4—Medicare Prescription Drug Discount Card and  
2 Transitional Assistance Program

3 “MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND  
4 TRANSITIONAL ASSISTANCE PROGRAM

5 “SEC. 1860D–31. (a) ESTABLISHMENT OF PROGRAM.—

6 “(1) IN GENERAL.—The Secretary shall establish a  
7 program under this section—

8 “(A) to endorse prescription drug discount card  
9 programs that meet the requirements of this section in  
10 order to provide access to prescription drug discounts  
11 through prescription drug card sponsors for discount  
12 card eligible individuals throughout the United States;  
13 and

14 “(B) to provide for transitional assistance for  
15 transitional assistance eligible individuals enrolled in  
16 such endorsed programs.

17 “(2) PERIOD OF OPERATION.—

18 “(A) IMPLEMENTATION DEADLINE.—The Sec-  
19 retary shall implement the program under this section  
20 so that discount cards and transitional assistance are  
21 first available by not later than 6 months after the date  
22 of the enactment of this section.

23 “(B) EXPEDITING IMPLEMENTATION.—The Sec-  
24 retary shall promulgate regulations to carry out the  
25 program under this section which may be effective and  
26 final immediately on an interim basis as of the date of  
27 publication of the interim final regulation. If the Sec-  
28 retary provides for an interim final regulation, the Sec-  
29 retary shall provide for a period of public comments on  
30 such regulation after the date of publication. The Sec-  
31 retary may change or revise such regulation after com-  
32 pletion of the period of public comment.

33 “(C) TERMINATION AND TRANSITION.—

34 “(i) IN GENERAL.—Subject to clause (ii)—

35 “(I) the program under this section shall  
36 not apply to covered discount card drugs dis-  
37 pensed after December 31, 2005; and

1                   “(II) transitional assistance shall be avail-  
2                   able after such date to the extent the assistance  
3                   relates to drugs dispensed on or before such  
4                   date.

5                   “(ii) TRANSITION.—In the case of an indi-  
6                   vidual who is enrolled in an endorsed discount card  
7                   program as of December 31, 2005, during the indi-  
8                   vidual’s transition period (if any) under clause (iii),  
9                   in accordance with transition rules specified by the  
10                  Secretary—

11                  “(I) such endorsed program may continue  
12                  to apply to covered discount card drugs dis-  
13                  pensed to the individual under the program  
14                  during such transition period;

15                  “(II) no annual enrollment fee shall be ap-  
16                  plicable during the transition period;

17                  “(III) during such period the individual  
18                  may not change the endorsed program plan in  
19                  which the individual is enrolled; and

20                  “(IV) the balance of any transitional as-  
21                  sistance remaining on January 1, 2006, shall  
22                  remain available for drugs dispensed during the  
23                  individual’s transition period.

24                  “(iii) TRANSITION PERIOD.—The transition  
25                  period under this clause for an individual is the pe-  
26                  riod beginning on January 1, 2006, and ending in  
27                  the case of an individual who—

28                  “(I) is enrolled in a prescription drug plan  
29                  or an MA–PD plan before the last date of the  
30                  initial enrollment period under section 1860D–  
31                  1(b)(2)(A), on the effective date of the individ-  
32                  ual’s coverage under such part; or

33                  “(II) is not so enrolled, on the last day of  
34                  such initial period.

35                  “(3) VOLUNTARY NATURE OF PROGRAM.—Nothing in  
36                  this section shall be construed as requiring a discount card

1 eligible individual to enroll in an endorsed discount card  
2 program under this section.

3 “(4) GLOSSARY AND DEFINITIONS OF TERMS.—For  
4 purposes of this section:

5 “(A) COVERED DISCOUNT CARD DRUG.—The term  
6 ‘covered discount card drug’ has the meaning given the  
7 term ‘covered part D drug’ in section 1860D–2(e).

8 “(B) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—  
9 The term ‘discount card eligible individual’ is defined  
10 in subsection (b)(1)(A).

11 “(C) ENDORSED DISCOUNT CARD PROGRAM; EN-  
12 DORSED PROGRAM.—The terms ‘endorsed discount card  
13 program’ and ‘endorsed program’ mean a prescription  
14 drug discount card program that is endorsed (and for  
15 which the sponsor has a contract with the Secretary)  
16 under this section.

17 “(D) NEGOTIATED PRICE.—Negotiated prices are  
18 described in subsection (e)(1)(A)(ii).

19 “(E) PRESCRIPTION DRUG CARD SPONSOR; SPON-  
20 SOR.—The terms ‘prescription drug card sponsor’ and  
21 ‘sponsor’ are defined in subsection (h)(1)(A).

22 “(F) STATE.—The term ‘State’ has the meaning  
23 given such term for purposes of title XIX.

24 “(G) TRANSITIONAL ASSISTANCE ELIGIBLE INDI-  
25 VIDUAL.—The term ‘transitional assistance eligible in-  
26 dividual’ is defined in subsection (b)(2).

27 “(b) ELIGIBILITY FOR DISCOUNT CARD AND FOR TRANSI-  
28 TIONAL ASSISTANCE.—For purposes of this section:

29 “(1) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—

30 “(A) IN GENERAL.—The term ‘discount card eligi-  
31 ble individual’ means an individual who—

32 “(i) is entitled to benefits, or enrolled, under  
33 part A or enrolled under part B; and

34 “(ii) subject to paragraph (4), is not an indi-  
35 vidual described in subparagraph (B).

36 “(B) INDIVIDUAL DESCRIBED.—An individual de-  
37 scribed in this subparagraph is an individual described

1 in subparagraph (A)(i) who is enrolled under title XIX  
2 (or under a waiver under section 1115 of the require-  
3 ments of such title) and is entitled to any medical as-  
4 sistance for outpatient prescribed drugs described in  
5 section 1905(a)(12).

6 “(2) TRANSITIONAL ASSISTANCE ELIGIBLE INDI-  
7 VIDUAL.—

8 “(A) IN GENERAL.—Subject to subparagraph (B),  
9 the term ‘transitional assistance eligible individual’  
10 means a discount card eligible individual who resides in  
11 one of the 50 States or the District of Columbia and  
12 whose income (as determined under subsection  
13 (f)(1)(B)) is not more than 135 percent of the poverty  
14 line (as defined in section 673(2) of the Community  
15 Services Block Grant Act, 42 U.S.C. 9902(2), including  
16 any revision required by such section) applicable to the  
17 family size involved (as determined under subsection  
18 (f)(1)(B)).

19 “(B) EXCLUSION OF INDIVIDUALS WITH CERTAIN  
20 PRESCRIPTION DRUG COVERAGE.—Such term does not  
21 include an individual who has coverage of, or assistance  
22 for, covered discount card drugs under any of the fol-  
23 lowing:

24 “(i) A group health plan or health insurance  
25 coverage (as such terms are defined in section 2791  
26 of the Public Health Service Act), other than cov-  
27 erage under a plan under part C and other than  
28 coverage consisting only of excepted benefits (as de-  
29 fined in such section).

30 “(ii) Chapter 55 of title 10, United States  
31 Code (relating to medical and dental care for mem-  
32 bers of the uniformed services).

33 “(iii) A plan under chapter 89 of title 5,  
34 United States Code (relating to the Federal em-  
35 ployees’ health benefits program).

36 “(3) SPECIAL TRANSITIONAL ASSISTANCE ELIGIBLE  
37 INDIVIDUAL.—The term ‘special transitional assistance eli-

1       gible individual' means a transitional assistance eligible in-  
2       dividual whose income (as determined under subsection  
3       (f)(1)(B)) is not more than 100 percent of the poverty line  
4       (as defined in section 673(2) of the Community Services  
5       Block Grant Act, 42 U.S.C. 9902(2), including any revision  
6       required by such section) applicable to the family size in-  
7       volved (as determined under subsection (f)(1)(B)).

8       “(4) TREATMENT OF MEDICAID MEDICALLY NEEDY.—  
9       For purposes of this section, the Secretary shall provide for  
10      appropriate rules for the treatment of medically needy indi-  
11      viduals described in section 1902(a)(10)(C) as discount  
12      card eligible individuals and as transitional assistance eligi-  
13      ble individuals.

14      “(c) ENROLLMENT AND ENROLLMENT FEES.—

15      “(1) ENROLLMENT PROCESS.—The Secretary shall es-  
16      tablish a process through which a discount card eligible in-  
17      dividual is enrolled and disenrolled in an endorsed discount  
18      card program under this section consistent with the fol-  
19      lowing:

20      “(A) CONTINUOUS OPEN ENROLLMENT.—Subject  
21      to the succeeding provisions of this paragraph and sub-  
22      section (h)(9), a discount card eligible individual who  
23      is not enrolled in an endorsed discount card program  
24      and is residing in a State may enroll in any such en-  
25      dorsed program—

26          “(i) that serves residents of the State; and

27          “(ii) at any time beginning on the initial en-  
28          rollment date, specified by the Secretary, and be-  
29          fore January 1, 2006.

30      “(B) USE OF STANDARD ENROLLMENT FORM.—  
31      An enrollment in an endorsed program shall only be ef-  
32      fected through completion of a standard enrollment  
33      form specified by the Secretary. Each sponsor of an en-  
34      dorsed program shall transmit to the Secretary (in a  
35      form and manner specified by the Secretary) informa-  
36      tion on individuals who complete such enrollment forms  
37      and, to the extent provided under subsection (f), infor-

1           mation regarding certification as a transitional assist-  
2           ance eligible individual.

3           “(C) ENROLLMENT ONLY IN ONE PROGRAM.—

4           “(i) IN GENERAL.—Subject to clauses (ii) and  
5           (iii), a discount card eligible individual may be en-  
6           rolled in only one endorsed discount card program  
7           under this section.

8           “(ii) CHANGE IN ENDORSED PROGRAM PER-  
9           MITTED FOR 2005.—The Secretary shall establish a  
10          process, similar to (and coordinated with) the proc-  
11          ess for annual, coordinated elections under section  
12          1851(e)(3) during 2004, under which an individual  
13          enrolled in an endorsed discount card program may  
14          change the endorsed program in which the indi-  
15          vidual is enrolled for 2005.

16          “(iii) ADDITIONAL EXCEPTIONS.—The Sec-  
17          retary shall permit an individual to change the en-  
18          dorsed discount card program in which the indi-  
19          vidual is enrolled in the case of an individual who  
20          changes residence to be outside the service area of  
21          such program and in such other exceptional cases  
22          as the Secretary may provide (taking into account  
23          the circumstances for special election periods under  
24          section 1851(e)(4)). Under the previous sentence,  
25          the Secretary may consider a change in residential  
26          setting (such as placement in a nursing facility) or  
27          enrollment in or disenrollment from a plan under  
28          part C through which the individual was enrolled in  
29          an endorsed program to be an exceptional cir-  
30          cumstance.

31          “(D) DISENROLLMENT.—

32          “(i) VOLUNTARY.—An individual may volun-  
33          tarily disenroll from an endorsed discount card pro-  
34          gram at any time. In the case of such a voluntary  
35          disenrollment, the individual may not enroll in an-  
36          other endorsed program, except under such excep-  
37          tional circumstances as the Secretary may recog-



1           nize under subparagraph (C)(iii) or during the an-  
2           nual coordinated enrollment period provided under  
3           subparagraph (C)(ii).

4           “(ii) INVOLUNTARY.—An individual who is en-  
5           rolled in an endorsed discount card program and  
6           not a transitional assistance eligible individual may  
7           be disenrolled by the sponsor of the program if the  
8           individual fails to pay any annual enrollment fee  
9           required under the program.

10          “(E) APPLICATION TO CERTAIN ENROLLEES.—In  
11          the case of a discount card eligible individual who is en-  
12          rolled in a plan described in section 1851(a)(2)(A) or  
13          under a reasonable cost reimbursement contract under  
14          section 1876(h) that is offered by an organization that  
15          also is a prescription discount card sponsor that offers  
16          an endorsed discount card program under which the in-  
17          dividual may be enrolled and that has made an election  
18          to apply the special rules under subsection (h)(9)(B)  
19          for such an endorsed program, the individual may only  
20          enroll in such an endorsed discount card program of-  
21          fered by that sponsor.

22          “(2) ENROLLMENT FEES.—

23          “(A) IN GENERAL.—Subject to the succeeding pro-  
24          visions of this paragraph, a prescription drug card  
25          sponsor may charge an annual enrollment fee for each  
26          discount card eligible individual enrolled in an endorsed  
27          discount card program offered by such sponsor. The  
28          annual enrollment fee for either 2004 or 2005 shall not  
29          be prorated for portions of a year. There shall be no  
30          annual enrollment fee for a year after 2005.

31          “(B) AMOUNT.—No annual enrollment fee  
32          charged under subparagraph (A) may exceed \$30.

33          “(C) UNIFORM ENROLLMENT FEE.—A prescrip-  
34          tion drug card sponsor shall ensure that the annual en-  
35          rollment fee (if any) for an endorsed discount card pro-  
36          gram is the same for all discount card eligible individ-  
37          uals enrolled in the program and residing in the State.

1           “(D) COLLECTION.—The annual enrollment fee (if  
2 any) charged for enrollment in an endorsed program  
3 shall be collected by the sponsor of the program.

4           “(E) PAYMENT OF FEE FOR TRANSITIONAL AS-  
5 SISTANCE ELIGIBLE INDIVIDUALS.—Under subsection  
6 (g)(1)(A), the annual enrollment fee (if any) otherwise  
7 charged under this paragraph with respect to a transi-  
8 tional assistance eligible individual shall be paid by the  
9 Secretary on behalf of such individual.

10          “(F) OPTIONAL PAYMENT OF FEE BY STATE.—

11           “(i) IN GENERAL.—The Secretary shall estab-  
12 lish an arrangement under which a State may pro-  
13 vide for payment of some or all of the enrollment  
14 fee for some or all enrollees who are not transi-  
15 tional assistance eligible individuals in the State, as  
16 specified by the State under the arrangement. Inso-  
17 far as such a payment arrangement is made with  
18 respect to an enrollee, the amount of the enroll-  
19 ment fee shall be paid directly by the State to the  
20 sponsor.

21           “(ii) NO FEDERAL MATCHING AVAILABLE  
22 UNDER MEDICAID OR SCHIP.—Expenditures made  
23 by a State for enrollment fees described in clause  
24 (i) shall not be treated as State expenditures for  
25 purposes of Federal matching payments under title  
26 XIX or XXI.

27          “(G) RULES IN CASE OF CHANGES IN PROGRAM  
28 ENROLLMENT DURING A YEAR.—The Secretary shall  
29 provide special rules in the case of payment of an an-  
30 nual enrollment fee for a discount card eligible indi-  
31 vidual who changes the endorsed program in which the  
32 individual is enrolled during a year.

33          “(3) ISSUANCE OF DISCOUNT CARD.—Each prescrip-  
34 tion drug card sponsor of an endorsed discount card pro-  
35 gram shall issue, in a standard format specified by the Sec-  
36 retary, to each discount card eligible individual enrolled in  
37 such program a card that establishes proof of enrollment

1 and that can be used in a coordinated manner to identify  
2 the sponsor, program, and individual for purposes of the  
3 program under this section.

4 “(4) PERIOD OF ACCESS.—In the case of a discount  
5 card eligible individual who enrolls in an endorsed program,  
6 access to negotiated prices and transitional assistance, if  
7 any, under such endorsed program shall take effect on such  
8 date as the Secretary shall specify.

9 “(d) PROVISION OF INFORMATION ON ENROLLMENT AND  
10 PROGRAM FEATURES.—

11 “(1) SECRETARIAL RESPONSIBILITIES.—

12 “(A) IN GENERAL.—The Secretary shall provide  
13 for activities under this subsection to broadly dissemi-  
14 nate information to discount card eligible individuals  
15 (and prospective eligible individuals) regarding—

16 “(i) enrollment in endorsed discount card pro-  
17 grams; and

18 “(ii) the features of the program under this  
19 section, including the availability of transitional as-  
20 sistance.

21 “(B) PROMOTION OF INFORMED CHOICE.—In  
22 order to promote informed choice among endorsed pre-  
23 scription drug discount card programs, the Secretary  
24 shall provide for the dissemination of information  
25 which—

26 “(i) compares the annual enrollment fee and  
27 other features of such programs, which may include  
28 comparative prices for covered discount card drugs;  
29 and

30 “(ii) includes educational materials on the var-  
31 iability of discounts on prices of covered discount  
32 card drugs under an endorsed program.

33 The dissemination of information under clause (i) shall,  
34 to the extent practicable, be coordinated with the dis-  
35 semination of educational information on other medi-  
36 care options.

1           “(C) SPECIAL RULE FOR INITIAL ENROLLMENT  
2           DATE UNDER THE PROGRAM.—To the extent prac-  
3           ticable, the Secretary shall ensure, through the activi-  
4           ties described in subparagraphs (A) and (B), that dis-  
5           count card eligible individuals are provided with such  
6           information at least 30 days prior to the initial enroll-  
7           ment date specified under subsection (c)(1)(A)(ii).

8           “(D) USE OF MEDICARE TOLL-FREE NUMBER.—  
9           The Secretary shall provide through the toll-free tele-  
10          phone number 1-800-MEDICARE for the receipt and  
11          response to inquiries and complaints concerning the  
12          program under this section and endorsed programs.

13          “(2) PRESCRIPTION DRUG CARD SPONSOR RESPON-  
14          SIBILITIES.—

15                 “(A) IN GENERAL.—Each prescription drug card  
16                 sponsor that offers an endorsed discount card program  
17                 shall make available to discount card eligible individ-  
18                 uals (through the Internet and otherwise) information  
19                 that the Secretary identifies as being necessary to pro-  
20                 mote informed choice among endorsed discount card  
21                 programs by such individuals, including information on  
22                 enrollment fees and negotiated prices for covered dis-  
23                 count card drugs charged to such individuals.

24                 “(B) RESPONSE TO ENROLLEE QUESTIONS.—  
25                 Each sponsor offering an endorsed discount card pro-  
26                 gram shall have a mechanism (including a toll-free tele-  
27                 phone number) for providing upon request specific in-  
28                 formation (such as negotiated prices and the amount of  
29                 transitional assistance remaining available through the  
30                 program) to discount card eligible individuals enrolled  
31                 in the program. The sponsor shall inform transitional  
32                 assistance eligible individuals enrolled in the program  
33                 of the availability of such toll-free telephone number to  
34                 provide information on the amount of available transi-  
35                 tional assistance.

36                 “(C) INFORMATION ON BALANCE OF TRANSI-  
37                 TIONAL ASSISTANCE AVAILABLE AT POINT-OF-SALE.—

1 Each sponsor offering an endorsed discount card pro-  
2 gram shall have a mechanism so that information on  
3 the amount of transitional assistance remaining under  
4 subsection (g)(1)(B) is available (electronically or by  
5 telephone) at the point-of-sale of covered discount card  
6 drugs.

7 “(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL  
8 PRICES FOR EQUIVALENT DRUGS.—

9 “(A) IN GENERAL.—A prescription drug card  
10 sponsor offering an endorsed discount card program  
11 shall provide that each pharmacy that dispenses a cov-  
12 ered discount card drug shall inform a discount card el-  
13 igible individual enrolled in the program of any dif-  
14 ferential between the price of the drug to the enrollee  
15 and the price of the lowest priced generic covered dis-  
16 count card drug under the program that is therapeuti-  
17 cally equivalent and bioequivalent and available at such  
18 pharmacy.

19 “(B) TIMING OF NOTICE.—

20 “(i) IN GENERAL.—Subject to clause (ii), the  
21 information under subparagraph (A) shall be pro-  
22 vided at the time of purchase of the drug involved,  
23 or, in the case of dispensing by mail order, at the  
24 time of delivery of such drug.

25 “(ii) WAIVER.—The Secretary may waive  
26 clause (i) in such circumstances as the Secretary  
27 may specify.

28 “(e) DISCOUNT CARD FEATURES.—

29 “(1) SAVINGS TO ENROLLEES THROUGH NEGOTIATED  
30 PRICES.—

31 “(A) ACCESS TO NEGOTIATED PRICES.—

32 “(i) IN GENERAL.—Each prescription drug  
33 card sponsor that offers an endorsed discount card  
34 program shall provide each discount card eligible  
35 individual enrolled in the program with access to  
36 negotiated prices.

1                   “(ii) NEGOTIATED PRICES.—For purposes of  
2                   this section, negotiated prices shall take into ac-  
3                   count negotiated price concessions, such as dis-  
4                   counts, direct or indirect subsidies, rebates, and di-  
5                   rect or indirect remunerations, for covered discount  
6                   card drugs, and include any dispensing fees for  
7                   such drugs.

8                   “(B) ENSURING PHARMACY ACCESS.—Each pre-  
9                   scription drug card sponsor offering an endorsed dis-  
10                  count card program shall secure the participation in its  
11                  network of a sufficient number of pharmacies that dis-  
12                  pense (other than solely by mail order) drugs directly  
13                  to enrollees to ensure convenient access to covered dis-  
14                  count card drugs at negotiated prices (consistent with  
15                  rules established by the Secretary). The Secretary shall  
16                  establish convenient access rules under this clause that  
17                  are no less favorable to enrollees than the standards for  
18                  convenient access to pharmacies included in the state-  
19                  ment of work of solicitation (#MDA906-03-R-0002)  
20                  of the Department of Defense under the TRICARE  
21                  Retail Pharmacy (TRRx) as of March 13, 2003.

22                  “(C) PROHIBITION ON CHARGES FOR REQUIRED  
23                  SERVICES.—

24                  “(i) IN GENERAL.—Subject to clause (ii), a  
25                  prescription drug card sponsor (and any pharmacy  
26                  contracting with such sponsor for the provision of  
27                  covered discount card drugs to individuals enrolled  
28                  in such sponsor’s endorsed discount card program)  
29                  may not charge an enrollee any amount for any  
30                  items and services required to be provided by the  
31                  sponsor under this section.

32                  “(ii) CONSTRUCTION.—Nothing in clause (i)  
33                  shall be construed to prevent—

34                  “(I) the sponsor from charging the annual  
35                  enrollment fee (except in the case of a transi-  
36                  tional assistance eligible individual); and

1                   “(II) the pharmacy dispensing the covered  
2                   discount card drug, from imposing a charge  
3                   (consistent with the negotiated price) for the  
4                   covered discount card drug dispensed, reduced  
5                   by the amount of any transitional assistance  
6                   made available.

7                   “(D) INAPPLICABILITY OF MEDICAID BEST PRICE  
8                   RULES.—The prices negotiated from drug manufactur-  
9                   ers for covered discount card drugs under an endorsed  
10                  discount card program under this section shall (not-  
11                  withstanding any other provision of law) not be taken  
12                  into account for the purposes of establishing the best  
13                  price under section 1927(c)(1)(C).

14                  “(2) REDUCTION OF MEDICATION ERRORS AND AD-  
15                  VERSE DRUG INTERACTIONS.—Each endorsed discount card  
16                  program shall implement a system to reduce the likelihood  
17                  of medication errors and adverse drug interactions and to  
18                  improve medication use.

19                  “(f) ELIGIBILITY PROCEDURES FOR ENDORSED PRO-  
20                  GRAMS AND TRANSITIONAL ASSISTANCE.—

21                   “(1) DETERMINATIONS.—

22                   “(A) PROCEDURES.—The determination of wheth-  
23                   er an individual is a discount card eligible individual or  
24                   a transitional assistance eligible individual or a special  
25                   transitional assistance eligible individual (as defined in  
26                   subsection (b)) shall be determined under procedures  
27                   specified by the Secretary consistent with this sub-  
28                   section.

29                   “(B) INCOME AND FAMILY SIZE DETERMINA-  
30                   TIONS.—For purposes of this section, the Secretary  
31                   shall define the terms ‘income’ and ‘family size’ and  
32                   shall specify the methods and period for which they are  
33                   determined. If under such methods income or family  
34                   size is determined based on the income or family size  
35                   for prior periods of time, the Secretary shall permit  
36                   (whether through a process of reconsideration or other-  
37                   wise) an individual whose income or family size has

1 changed to elect to have eligibility for transitional as-  
2 sistance determined based on income or family size for  
3 a more recent period.

4 “(2) USE OF SELF-CERTIFICATION FOR TRANSITIONAL  
5 ASSISTANCE.—

6 “(A) IN GENERAL.—Under the procedures speci-  
7 fied under paragraph (1)(A) an individual who wishes  
8 to be treated as a transitional assistance eligible indi-  
9 vidual or a special transitional assistance eligible indi-  
10 vidual under this section (or another qualified person  
11 on such individual’s behalf) shall certify on the enroll-  
12 ment form under subsection (c)(1)(B) (or similar form  
13 specified by the Secretary), through a simplified means  
14 specified by the Secretary and under penalty of perjury  
15 or similar sanction for false statements, as to the  
16 amount of the individual’s income, family size, and in-  
17 dividual’s prescription drug coverage (if any) insofar as  
18 they relate to eligibility to be a transitional assistance  
19 eligible individual or a special transitional assistance el-  
20 igible individual. Such certification shall be deemed as  
21 consent to verification of respective eligibility under  
22 paragraph (3). A certification under this paragraph  
23 may be provided before, on, or after the time of enroll-  
24 ment under an endorsed program.

25 “(B) TREATMENT OF SELF-CERTIFICATION.—The  
26 Secretary shall treat a certification under subparagraph  
27 (A) that is verified under paragraph (3) as a deter-  
28 mination that the individual involved is a transitional  
29 assistance eligible individual or special transitional as-  
30 sistance eligible individual (as the case may be) for the  
31 entire period of the enrollment of the individual in any  
32 endorsed program.

33 “(3) VERIFICATION.—

34 “(A) IN GENERAL.—The Secretary shall establish  
35 methods (which may include the use of sampling and  
36 the use of information described in subparagraph (B))  
37 to verify eligibility for individuals who seek to enroll in



1 an endorsed program and for individuals who provide  
2 a certification under paragraph (2).

3 “(B) INFORMATION DESCRIBED.—The information  
4 described in this subparagraph is as follows:

5 “(i) MEDICAID-RELATED INFORMATION.—In-  
6 formation on eligibility under title XIX and pro-  
7 vided to the Secretary under arrangements between  
8 the Secretary and States in order to verify the eli-  
9 gibility of individuals who seek to enroll in an en-  
10 dorsed program and of individuals who provide cer-  
11 tification under paragraph (2).

12 “(ii) SOCIAL SECURITY INFORMATION.—Fi-  
13 nancial information made available to the Secretary  
14 under arrangements between the Secretary and the  
15 Commissioner of Social Security in order to verify  
16 the eligibility of individuals who provide such cer-  
17 tification.

18 “(iii) INFORMATION FROM SECRETARY OF THE  
19 TREASURY.—Financial information made available  
20 to the Secretary under section 6103(l)(19) of the  
21 Internal Revenue Code of 1986 in order to verify  
22 the eligibility of individuals who provide such cer-  
23 tification.

24 “(C) VERIFICATION IN CASES OF MEDICAID EN-  
25 ROLLEES.—

26 “(i) IN GENERAL.—Nothing in this section  
27 shall be construed as preventing the Secretary from  
28 finding that a discount card eligible individual  
29 meets the income requirements under subsection  
30 (b)(2)(A) if the individual is within a category of  
31 discount card eligible individuals who are enrolled  
32 under title XIX (such as qualified medicare bene-  
33 ficiaries (QMBs), specified low-income medicare  
34 beneficiaries (SLMBs), and certain qualified indi-  
35 viduals (QI-1s)).

36 “(ii) AVAILABILITY OF INFORMATION FOR  
37 VERIFICATION PURPOSES.—As a condition of provi-

1           sion of Federal financial participation to a State  
2           that is one of the 50 States or the District of Co-  
3           lumbia under title XIX, for purposes of carrying  
4           out this section, the State shall provide the infor-  
5           mation it submits to the Secretary relating to such  
6           title in a manner specified by the Secretary that  
7           permits the Secretary to identify individuals who  
8           are described in subsection (b)(1)(B) or are transi-  
9           tional assistance eligible individuals or special tran-  
10          sitional assistance eligible individuals.

11          “(4) RECONSIDERATION.—

12           “(A) IN GENERAL.—The Secretary shall establish  
13           a process under which a discount card eligible indi-  
14           vidual, who is determined through the certification and  
15           verification methods under paragraphs (2) and (3) not  
16           to be a transitional assistance eligible individual or a  
17           special transitional assistance eligible individual, may  
18           request a reconsideration of the determination.

19           “(B) CONTRACT AUTHORITY.—The Secretary may  
20           enter into a contract to perform the reconsiderations  
21           requested under subparagraph (A).

22           “(C) COMMUNICATION OF RESULTS.—Under the  
23           process under subparagraph (A) the results of such re-  
24           consideration shall be communicated to the individual  
25           and the prescription drug card sponsor involved.

26          “(g) TRANSITIONAL ASSISTANCE.—

27           “(1) PROVISION OF TRANSITIONAL ASSISTANCE.—An  
28           individual who is a transitional assistance eligible individual  
29           (as determined under this section) and who is enrolled with  
30           an endorsed program is entitled—

31           “(A) to have payment made of any annual enroll-  
32           ment fee charged under subsection (c)(2) for enroll-  
33           ment under the program; and

34           “(B) to have payment made, up to the amount  
35           specified in paragraph (2), under such endorsed pro-  
36           gram of 90 percent (or 95 percent in the case of a spe-  
37           cial transitional assistance eligible individual) of the

1 costs incurred for covered discount card drugs obtained  
2 through the program taking into account the nego-  
3 tiated price (if any) for the drug under the program.

4 “(2) LIMITATION ON DOLLAR AMOUNT.—

5 “(A) IN GENERAL.—Subject to subparagraph (B),  
6 the amount specified in this paragraph for a transi-  
7 tional assistance eligible individual—

8 “(i) for costs incurred during 2004, is \$600;

9 or

10 “(ii) for costs incurred during 2005, is—

11 “(I) \$600, plus

12 “(II) except as provided in subparagraph  
13 (E), the amount by which the amount available  
14 under this paragraph for 2004 for that indi-  
15 vidual exceeds the amount of payment made  
16 under paragraph (1)(B) for that individual for  
17 costs incurred during 2004.

18 “(B) PRORATION.—

19 “(i) IN GENERAL.—In the case of an indi-  
20 vidual not described in clause (ii) with respect to  
21 a year, the Secretary may prorate the amount spec-  
22 ified in subparagraph (A) for the balance of the  
23 year involved in a manner specified by the Sec-  
24 retary.

25 “(ii) INDIVIDUAL DESCRIBED.—An individual  
26 described in this clause is a transitional assistance  
27 eligible individual who—

28 “(I) with respect to 2004, enrolls in an en-  
29 dorsed program, and provides a certification  
30 under subsection (f)(2), before the initial imple-  
31 mentation date of the program under this sec-  
32 tion; and

33 “(II) with respect to 2005, is enrolled in  
34 an endorsed program, and has provided such a  
35 certification, before February 1, 2005.

36 “(C) ACCOUNTING FOR AVAILABLE BALANCES IN  
37 CASES OF CHANGES IN PROGRAM ENROLLMENT.—In

1 the case of a transitional assistance eligible individual  
2 who changes the endorsed discount card program in  
3 which the individual is enrolled under this section, the  
4 Secretary shall provide a process under which the Sec-  
5 retary provides to the sponsor of the endorsed program  
6 in which the individual enrolls information concerning  
7 the balance of amounts available on behalf of the indi-  
8 vidual under this paragraph.

9 “(D) LIMITATION ON USE OF FUNDS.—Pursuant  
10 to subsection (a)(2)(C), no assistance shall be provided  
11 under paragraph (1)(B) with respect to covered dis-  
12 count card drugs dispensed after December 31, 2005.

13 “(E) NO ROLLOVER PERMITTED IN CASE OF VOL-  
14 UNTARY DISENROLLMENT.—Except in such exceptional  
15 cases as the Secretary may provide, in the case of a  
16 transitional assistance eligible individual who volun-  
17 tarily disenrolls from an endorsed plan, the provisions  
18 of subclause (II) of subparagraph (A)(ii) shall not  
19 apply.

20 “(3) PAYMENT.—The Secretary shall provide a meth-  
21 od for the reimbursement of prescription drug card spon-  
22 sors for assistance provided under this subsection.

23 “(4) COVERAGE OF COINSURANCE.—

24 “(A) WAIVER PERMITTED BY PHARMACY.—Noth-  
25 ing in this section shall be construed as precluding a  
26 pharmacy from reducing or waiving the application of  
27 coinsurance imposed under paragraph (1)(B) in accord-  
28 ance with section 1128B(b)(3)(G).

29 “(B) OPTIONAL PAYMENT OF COINSURANCE BY  
30 STATE.—

31 “(i) IN GENERAL.—The Secretary shall estab-  
32 lish an arrangement under which a State may pro-  
33 vide for payment of some or all of the coinsurance  
34 under paragraph (1)(B) for some or all enrollees in  
35 the State, as specified by the State under the ar-  
36 rangement. Insofar as such a payment arrange-  
37 ment is made with respect to an enrollee, the

1 amount of the coinsurance shall be paid directly by  
2 the State to the pharmacy involved.

3 “(ii) NO FEDERAL MATCHING AVAILABLE  
4 UNDER MEDICAID OR SCHIP.—Expenditures made  
5 by a State for coinsurance described in clause (i)  
6 shall not be treated as State expenditures for pur-  
7 poses of Federal matching payments under title  
8 XIX or XXI.

9 “(iii) NOT TREATED AS MEDICARE COST-SHAR-  
10 ING.—Coinsurance described in paragraph (1)(B)  
11 shall not be treated as coinsurance under this title  
12 for purposes of section 1905(p)(3)(B).

13 “(C) TREATMENT OF COINSURANCE.—The  
14 amount of any coinsurance imposed under paragraph  
15 (1)(B), whether paid or waived under this paragraph,  
16 shall not be taken into account in applying the limita-  
17 tion in dollar amount under paragraph (2).

18 “(5) ENSURING ACCESS TO TRANSITIONAL ASSIST-  
19 ANCE FOR QUALIFIED RESIDENTS OF LONG-TERM CARE FA-  
20 CILITIES AND AMERICAN INDIANS.—

21 “(A) RESIDENTS OF LONG-TERM CARE FACILI-  
22 TIES.—The Secretary shall establish procedures and  
23 may waive requirements of this section as necessary to  
24 negotiate arrangements with sponsors to provide ar-  
25 rangements with pharmacies that support long-term  
26 care facilities in order to ensure access to transitional  
27 assistance for transitional assistance eligible individuals  
28 who reside in long-term care facilities.

29 “(B) AMERICAN INDIANS.—The Secretary shall es-  
30 tablish procedures and may waive requirements of this  
31 section to ensure that, for purposes of providing transi-  
32 tional assistance, pharmacies operated by the Indian  
33 Health Service, Indian tribes and tribal organizations,  
34 and urban Indian organizations (as defined in section  
35 4 of the Indian Health Care Improvement Act) have  
36 the opportunity to participate in the pharmacy net-  
37 works of at least two endorsed programs in each of the

1           50 States and the District of Columbia where such a  
2           pharmacy operates.

3           “(6) NO IMPACT ON BENEFITS UNDER OTHER PRO-  
4           GRAMS.—The availability of negotiated prices or transi-  
5           tional assistance under this section shall not be treated as  
6           benefits or otherwise taken into account in determining an  
7           individual’s eligibility for, or the amount of benefits under,  
8           any other Federal program.

9           “(7) DISREGARD FOR PURPOSES OF PART C.—Nonuni-  
10          formity of benefits resulting from the implementation of  
11          this section (including the provision or nonprovision of  
12          transitional assistance and the payment or waiver of any  
13          enrollment fee under this section) shall not be taken into  
14          account in applying section 1854(f).

15          “(h) QUALIFICATION OF PRESCRIPTION DRUG CARD  
16          SPONSORS AND ENDORSEMENT OF DISCOUNT CARD PRO-  
17          GRAMS; BENEFICIARY PROTECTIONS.—

18          “(1) PRESCRIPTION DRUG CARD SPONSOR AND QUALI-  
19          FICATIONS.—

20          “(A) PRESCRIPTION DRUG CARD SPONSOR AND  
21          SPONSOR DEFINED.—For purposes of this section, the  
22          terms ‘prescription drug card sponsor’ and ‘sponsor’  
23          mean any nongovernmental entity that the Secretary  
24          determines to be appropriate to offer an endorsed dis-  
25          count card program under this section, which may  
26          include—

27                  “(i) a pharmaceutical benefit management  
28                  company;

29                  “(ii) a wholesale or retail pharmacy delivery  
30                  system;

31                  “(iii) an insurer (including an insurer that of-  
32                  fers medicare supplemental policies under section  
33                  1882);

34                  “(iv) an organization offering a plan under  
35                  part C; or

36                  “(v) any combination of the entities described  
37                  in clauses (i) through (iv).

1           “(B) ADMINISTRATIVE QUALIFICATIONS.—Each  
2 endorsed discount card program shall be operated di-  
3 rectly, or through arrangements with an affiliated orga-  
4 nization (or organizations), by one or more entities that  
5 have demonstrated experience and expertise in oper-  
6 ating such a program or a similar program and that  
7 meets such business stability and integrity require-  
8 ments as the Secretary may specify.

9           “(C) ACCOUNTING FOR TRANSITIONAL ASSIST-  
10 ANCE.—The sponsor of an endorsed discount card pro-  
11 gram shall have arrangements satisfactory to the Sec-  
12 retary to account for the assistance provided under  
13 subsection (g) on behalf of transitional assistance eligi-  
14 ble individuals.

15           “(2) APPLICATIONS FOR PROGRAM ENDORSEMENT.—

16           “(A) SUBMISSION.—Each prescription drug card  
17 sponsor that seeks endorsement of a prescription drug  
18 discount card program under this section shall submit  
19 to the Secretary, at such time and in such manner as  
20 the Secretary may specify, an application containing  
21 such information as the Secretary may require.

22           “(B) APPROVAL; COMPLIANCE WITH APPLICABLE  
23 REQUIREMENTS.—The Secretary shall review the appli-  
24 cation submitted under subparagraph (A) and shall de-  
25 termine whether to endorse the prescription drug dis-  
26 count card program. The Secretary may not endorse  
27 such a program unless—

28           “(i) the program and prescription drug card  
29 sponsor offering the program comply with the ap-  
30 plicable requirements under this section; and

31           “(ii) the sponsor has entered into a contract  
32 with the Secretary to carry out such requirements.

33           “(C) TERMINATION OF ENDORSEMENT AND CON-  
34 TRACTS.—An endorsement of an endorsed program and  
35 a contract under subparagraph (B) shall be for the du-  
36 ration of the program under this section (including any  
37 transition applicable under subsection (a)(2)(C)(ii)), ex-

1           cept that the Secretary may, with notice and for cause  
2           (as defined by the Secretary), terminate such endorse-  
3           ment and contract.

4           “(D) ENSURING CHOICE OF PROGRAMS.—

5           “(i) IN GENERAL.—The Secretary shall ensure  
6           that there is available to each discount card eligible  
7           individual a choice of at least 2 endorsed programs  
8           (each offered by a different sponsor).

9           “(ii) LIMITATION ON NUMBER.—The Sec-  
10          retary may limit (but not below 2) the number of  
11          sponsors in a State that are awarded contracts  
12          under this paragraph.

13          “(3) SERVICE AREA ENCOMPASSING ENTIRE  
14          STATES.—Except as provided in paragraph (9), if a pre-  
15          scription drug card sponsor that offers an endorsed pro-  
16          gram enrolls in the program individuals residing in any  
17          part of a State, the sponsor must permit any discount card  
18          eligible individual residing in any portion of the State to  
19          enroll in the program.

20          “(4) SAVINGS TO MEDICARE BENEFICIARIES.—Each  
21          prescription drug card sponsor that offers an endorsed dis-  
22          count card program shall pass on to discount card eligible  
23          individuals enrolled in the program negotiated prices on  
24          covered discount card drugs, including discounts negotiated  
25          with pharmacies and manufacturers, to the extent disclosed  
26          under subsection (i)(1).

27          “(5) GRIEVANCE MECHANISM.—Each prescription  
28          drug card sponsor shall provide meaningful procedures for  
29          hearing and resolving grievances between the sponsor (in-  
30          cluding any entity or individual through which the sponsor  
31          carries out the endorsed discount card program) and enroll-  
32          ees in endorsed discount card programs of the sponsor  
33          under this section in a manner similar to that required  
34          under section 1852(f).

35          “(6) CONFIDENTIALITY OF ENROLLEE RECORDS.—

36          “(A) IN GENERAL.—For purposes of the program  
37          under this section, the operations of an endorsed pro-



1           gram are covered functions and a prescription drug  
2           card sponsor is a covered entity for purposes of apply-  
3           ing part C of title XI and all regulatory provisions pro-  
4           mulgated thereunder, including regulations (relating to  
5           privacy) adopted pursuant to the authority of the Sec-  
6           retary under section 264(c) of the Health Insurance  
7           Portability and Accountability Act of 1996 (42 U.S.C.  
8           1320d–2 note).

9           “(B) WAIVER AUTHORITY.—In order to promote  
10          participation of sponsors in the program under this sec-  
11          tion, the Secretary may waive such relevant portions of  
12          regulations relating to privacy referred to in subpara-  
13          graph (A), for such appropriate, limited period of time,  
14          as the Secretary specifies.

15          “(7) LIMITATION ON PROVISION AND MARKETING OF  
16          PRODUCTS AND SERVICES.—The sponsor of an endorsed  
17          discount card program—

18               “(A) may provide under the program—

19                   “(i) a product or service only if the product or  
20                   service is directly related to a covered discount card  
21                   drug; or

22                   “(ii) a discount price for nonprescription  
23                   drugs; and

24               “(B) may, to the extent otherwise permitted under  
25          paragraph (6) (relating to application of HIPAA re-  
26          quirements), market a product or service under the  
27          program only if the product or service is directly re-  
28          lated to—

29                   “(i) a covered discount card drug; or

30                   “(ii) a drug described in subparagraph (A)(ii)  
31                   and the marketing consists of information on the  
32                   discounted price made available for the drug in-  
33                   volved.

34          “(8) ADDITIONAL PROTECTIONS.—Each endorsed dis-  
35          count card program shall meet such additional require-  
36          ments as the Secretary identifies to protect and promote  
37          the interest of discount card eligible individuals, including

1 requirements that ensure that discount card eligible indi-  
2 viduals enrolled in endorsed discount card programs are  
3 not charged more than the lower of the price based on ne-  
4 gotiated prices or the usual and customary price.

5 “(9) SPECIAL RULES FOR CERTAIN ORGANIZATIONS.—

6 “(A) IN GENERAL.—In the case of an organization  
7 that is offering a plan under part C or enrollment  
8 under a reasonable cost reimbursement contract under  
9 section 1876(h) that is seeking to be a prescription  
10 drug card sponsor under this section, the organization  
11 may elect to apply the special rules under subpara-  
12 graph (B) with respect to enrollees in any plan de-  
13 scribed in section 1851(a)(2)(A) that it offers or under  
14 such contract and an endorsed discount card program  
15 it offers, but only if it limits enrollment under such  
16 program to individuals enrolled in such plan or under  
17 such contract.

18 “(B) SPECIAL RULES.—The special rules under  
19 this subparagraph are as follows:

20 “(i) LIMITATION ON ENROLLMENT.—The  
21 sponsor limits enrollment under this section under  
22 the endorsed discount card program to discount  
23 card eligible individuals who are enrolled in the  
24 part C plan involved or under the reasonable cost  
25 reimbursement contract involved and is not re-  
26 quired nor permitted to enroll other individuals  
27 under such program.

28 “(ii) PHARMACY ACCESS.—Pharmacy access  
29 requirements under subsection (e)(1)(B) are  
30 deemed to be met if the access is made available  
31 through a pharmacy network (and not only through  
32 mail order) and the network used by the sponsor  
33 is approved by the Secretary.

34 “(iii) SPONSOR REQUIREMENTS.—The Sec-  
35 retary may waive the application of such require-  
36 ments for a sponsor as the Secretary determines to  
37 be duplicative or to conflict with a requirement of

1           the organization under part C or section 1876 (as  
2           the case may be) or to be necessary in order to im-  
3           prove coordination of this section with the benefits  
4           under such part or section.

5           “(i) DISCLOSURE AND OVERSIGHT.—

6           “(1) DISCLOSURE.—Each prescription drug card spon-  
7           sor offering an endorsed discount card program shall dis-  
8           close to the Secretary (in a manner specified by the Sec-  
9           retary) information relating to program performance, use  
10          of prescription drugs by discount card eligible individuals  
11          enrolled in the program, the extent to which negotiated  
12          price concessions described in subsection (e)(1)(A)(ii) made  
13          available to the entity by a manufacturer are passed  
14          through to enrollees through pharmacies or otherwise, and  
15          such other information as the Secretary may specify. The  
16          provisions of section 1927(b)(3)(D) shall apply to drug  
17          pricing data reported under the previous sentence (other  
18          than data in aggregate form).

19          “(2) OVERSIGHT; AUDIT AND INSPECTION AUTHOR-  
20          ITY.—The Secretary shall provide appropriate oversight to  
21          ensure compliance of endorsed discount card programs and  
22          their sponsors with the requirements of this section. The  
23          Secretary shall have the right to audit and inspect any  
24          books and records of a prescription discount card sponsor  
25          (and of any affiliated organization referred to in subsection  
26          (h)(1)(B)) that pertain to the endorsed discount card pro-  
27          gram under this section, including amounts payable to the  
28          sponsor under this section.

29          “(3) SANCTIONS FOR ABUSIVE PRACTICES.—The Sec-  
30          retary may implement intermediate sanctions or may re-  
31          voke the endorsement of a program offered by a sponsor  
32          under this section if the Secretary determines that the  
33          sponsor or the program no longer meets the applicable re-  
34          quirements of this section or that the sponsor has engaged  
35          in false or misleading marketing practices. The Secretary  
36          may impose a civil money penalty in an amount not to ex-  
37          ceed \$10,000 for conduct that a party knows or should

1 know is a violation of this section. The provisions of section  
2 1128A (other than subsections (a) and (b) and the second  
3 sentence of subsection (f)) shall apply to a civil money pen-  
4 alty under the previous sentence in the same manner as  
5 such provisions apply to a penalty or proceeding under sec-  
6 tion 1128A(a).

7 “(j) TREATMENT OF TERRITORIES.—

8 “(1) IN GENERAL.—The Secretary may waive any pro-  
9 vision of this section (including subsection (h)(2)(D)) in the  
10 case of a resident of a State (other than the 50 States and  
11 the District of Columbia) insofar as the Secretary deter-  
12 mines it is necessary to secure access to negotiated prices  
13 for discount card eligible individuals (or, at the option of  
14 the Secretary, individuals described in subsection  
15 (b)(1)(A)(i)).

16 “(2) TRANSITIONAL ASSISTANCE.—

17 “(A) IN GENERAL.—In the case of a State, other  
18 than the 50 States and the District of Columbia, if the  
19 State establishes a plan described in subparagraph (B)  
20 (for providing transitional assistance with respect to  
21 the provision of prescription drugs to some or all indi-  
22 viduals residing in the State who are described in sub-  
23 paragraph (B)(i)), the Secretary shall pay to the State  
24 for the entire period of the operation of this section an  
25 amount equal to the amount allotted to the State under  
26 subparagraph (C).

27 “(B) PLAN.—The plan described in this subpara-  
28 graph is a plan that—

29 “(i) provides transitional assistance with re-  
30 spect to the provision of covered discount card  
31 drugs to some or all individuals who are entitled to  
32 benefits under part A or enrolled under part B,  
33 who reside in the State, and who have income  
34 below 135 percent of the poverty line; and

35 “(ii) assures that amounts received by the  
36 State under this paragraph are used only for such  
37 assistance.

1           “(C) ALLOTMENT LIMIT.—The amount described  
2 in this subparagraph for a State is equal to  
3 \$35,000,000 multiplied by the ratio (as estimated by  
4 the Secretary) of—

5           “(i) the number of individuals who are entitled  
6 to benefits under part A or enrolled under part B  
7 and who reside in the State (as determined by the  
8 Secretary as of July 1, 2003), to

9           “(ii) the sum of such numbers for all States  
10 to which this paragraph applies.

11           “(D) CONTINUED AVAILABILITY OF FUNDS.—  
12 Amounts made available to a State under this para-  
13 graph which are not used under this paragraph shall be  
14 added to the amount available to that State for pur-  
15 poses of carrying out section 1935(e).

16           “(k) FUNDING.—

17           “(1) ESTABLISHMENT OF TRANSITIONAL ASSISTANCE  
18 ACCOUNT.—

19           “(A) IN GENERAL.—There is created within the  
20 Federal Supplementary Medical Insurance Trust Fund  
21 established by section 1841 an account to be known as  
22 the ‘Transitional Assistance Account’ (in this sub-  
23 section referred to as the ‘Account’).

24           “(B) FUNDS.—The Account shall consist of such  
25 gifts and bequests as may be made as provided in sec-  
26 tion 201(i)(1), accrued interest on balances in the Ac-  
27 count, and such amounts as may be deposited in, or  
28 appropriated to, the Account as provided in this sub-  
29 section.

30           “(C) SEPARATE FROM REST OF TRUST FUND.—  
31 Funds provided under this subsection to the Account  
32 shall be kept separate from all other funds within the  
33 Federal Supplementary Medical Insurance Trust Fund,  
34 but shall be invested, and such investments redeemed,  
35 in the same manner as all other funds and investments  
36 within such Trust Fund.

37           “(2) PAYMENTS FROM ACCOUNT.—

1           “(A) IN GENERAL.—The Managing Trustee shall  
2           pay from time to time from the Account such amounts  
3           as the Secretary certifies are necessary to make pay-  
4           ments for transitional assistance provided under sub-  
5           sections (g) and (j)(2).

6           “(B) TREATMENT IN RELATION TO PART B PRE-  
7           MIUM.—Amounts payable from the Account shall not  
8           be taken into account in computing actuarial rates or  
9           premium amounts under section 1839.

10          “(3) APPROPRIATIONS TO COVER BENEFITS.—There  
11          are appropriated to the Account in a fiscal year, out of any  
12          moneys in the Treasury not otherwise appropriated, an  
13          amount equal to the payments made from the Account in  
14          the year.

15          “(4) FOR ADMINISTRATIVE EXPENSES.—There are au-  
16          thorized to be appropriated to the Secretary such sums as  
17          may be necessary to carry out the Secretary’s responsibil-  
18          ities under this section.

19          “(5) TRANSFER OF ANY REMAINING BALANCE TO  
20          MEDICARE PRESCRIPTION DRUG ACCOUNT.—Any balance  
21          remaining in the Account after the Secretary determines  
22          that funds in the Account are no longer necessary to carry  
23          out the program under this section shall be transferred and  
24          deposited into the Medicare Prescription Drug Account  
25          under section 1860D–16.

26          “(6) CONSTRUCTION.—Nothing in this section shall be  
27          construed as authorizing the Secretary to provide for pay-  
28          ment (other than payment of an enrollment fee on behalf  
29          of a transitional assistance eligible individual under sub-  
30          section (g)(1)(A)) to a sponsor for administrative expenses  
31          incurred by the sponsor in carrying out this section (includ-  
32          ing in administering the transitional assistance provisions  
33          of subsections (f) and (g)).

1 “Subpart 5—Definitions and Miscellaneous Provisions

2 “DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS

3 IN PART C

4 “SEC. 1860D–41. (a) DEFINITIONS.—For purposes of this  
5 part:

6 “(1) BASIC PRESCRIPTION DRUG COVERAGE.—The  
7 term ‘basic prescription drug coverage’ is defined in section  
8 1860D–2(a)(3).

9 “(2) COVERED PART D DRUG.—The term ‘covered  
10 part D drug’ is defined in section 1860D–2(e).

11 “(3) CREDITABLE PRESCRIPTION DRUG COVERAGE.—  
12 The term ‘creditable prescription drug coverage’ has the  
13 meaning given such term in section 1860D–13(b)(4).

14 “(4) PART D ELIGIBLE INDIVIDUAL.—The term ‘part  
15 D eligible individual’ has the meaning given such term in  
16 section 1860D–1(a)(4)(A).

17 “(5) FALLBACK PRESCRIPTION DRUG PLAN.—The  
18 term ‘fallback prescription drug plan’ has the meaning  
19 given such term in section 1860D–11(g)(4).

20 “(6) INITIAL COVERAGE LIMIT.—The term ‘initial cov-  
21 erage limit’ means such limit as established under section  
22 1860D–2(b)(3), or, in the case of coverage that is not  
23 standard prescription drug coverage, the comparable limit  
24 (if any) established under the coverage.

25 “(7) INSURANCE RISK.—The term ‘insurance risk’  
26 means, with respect to a participating pharmacy, risk of  
27 the type commonly assumed only by insurers licensed by a  
28 State and does not include payment variations designed to  
29 reflect performance-based measures of activities within the  
30 control of the pharmacy, such as formulary compliance and  
31 generic drug substitution.

32 “(8) MA PLAN.—The term ‘MA plan’ has the meaning  
33 given such term in section 1860D–1(a)(4)(B).

34 “(9) MA–PD PLAN.—The term ‘MA–PD plan’ has the  
35 meaning given such term in section 1860D–1(a)(4)(C).

1           “(10) MEDICARE PRESCRIPTION DRUG ACCOUNT.—  
2           The term ‘Medicare Prescription Drug Account’ means the  
3           Account created under section 1860D–16(a).

4           “(11) PDP APPROVED BID.—The term ‘PDP ap-  
5           proved bid’ has the meaning given such term in section  
6           1860D–13(a)(6).

7           “(12) PDP REGION.—The term ‘PDP region’ means  
8           such a region as provided under section 1860D–11(a)(2).

9           “(13) PDP SPONSOR.—The term ‘PDP sponsor’  
10           means a nongovernmental entity that is certified under this  
11           part as meeting the requirements and standards of this  
12           part for such a sponsor.

13           “(14) PRESCRIPTION DRUG PLAN.—The term ‘pre-  
14           scription drug plan’ means prescription drug coverage that  
15           is offered—

16           “(A) under a policy, contract, or plan that has  
17           been approved under section 1860D–11(e); and

18           “(B) by a PDP sponsor pursuant to, and in ac-  
19           cordance with, a contract between the Secretary and  
20           the sponsor under section 1860D–12(b).

21           “(15) QUALIFIED PRESCRIPTION DRUG COVERAGE.—  
22           The term ‘qualified prescription drug coverage’ is defined  
23           in section 1860D–2(a)(1).

24           “(16) STANDARD PRESCRIPTION DRUG COVERAGE.—  
25           The term ‘standard prescription drug coverage’ is defined  
26           in section 1860D–2(b).

27           “(17) STATE PHARMACEUTICAL ASSISTANCE PRO-  
28           GRAM.—The term ‘State Pharmaceutical Assistance Pro-  
29           gram’ has the meaning given such term in section 1860D–  
30           23(b).

31           “(18) SUBSIDY ELIGIBLE INDIVIDUAL.—The term  
32           ‘subsidy eligible individual’ has the meaning given such  
33           term in section 1860D–14(a)(3)(A).

34           “(b) APPLICATION OF PART C PROVISIONS UNDER THIS  
35           PART.—For purposes of applying provisions of part C under  
36           this part with respect to a prescription drug plan and a PDP



1 sponsor, unless otherwise provided in this part such provisions  
2 shall be applied as if—

3 “(1) any reference to an MA plan included a reference  
4 to a prescription drug plan;

5 “(2) any reference to an MA organization or a pro-  
6 vider-sponsored organization included a reference to a PDP  
7 sponsor;

8 “(3) any reference to a contract under section 1857  
9 included a reference to a contract under section 1860D-  
10 12(b);

11 “(4) any reference to part C included a reference to  
12 this part; and

13 “(5) any reference to an election period under section  
14 1851 were a reference to an enrollment period under sec-  
15 tion 1860D-1.

16 “MISCELLANEOUS PROVISIONS

17 “SEC. 1860D-42. (a) ACCESS TO COVERAGE IN TERRI-  
18 TORIES.—The Secretary may waive such requirements of this  
19 part, including section 1860D-3(a)(1), insofar as the Secretary  
20 determines it is necessary to secure access to qualified prescrip-  
21 tion drug coverage for part D eligible individuals residing in a  
22 State (other than the 50 States and the District of Columbia).

23 “(b) APPLICATION OF DEMONSTRATION AUTHORITY.—  
24 The provisions of section 402 of the Social Security Amend-  
25 ments of 1967 (Public Law 90-248) shall apply with respect  
26 to this part and part C in the same manner it applies with re-  
27 spect to parts A and B, except that any reference with respect  
28 to a Trust Fund in relation to an experiment or demonstration  
29 project relating to prescription drug coverage under this part  
30 shall be deemed a reference to the Medicare Prescription Drug  
31 Account within the Federal Supplementary Medical Insurance  
32 Trust Fund.”.

33 (b) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later  
34 than 6 months after the date of the enactment of this Act, the  
35 Secretary shall submit to the appropriate committees of Con-  
36 gress a legislative proposal providing for such technical and

1 conforming amendments in the law as are required by the pro-  
2 visions of this title and title II.

3 (c) STUDY ON TRANSITIONING PART B PRESCRIPTION  
4 DRUG COVERAGE.—Not later than January 1, 2005, the Sec-  
5 retary shall submit a report to Congress that makes rec-  
6 ommendations regarding methods for providing benefits under  
7 subpart 1 of part D of title XVIII of the Social Security Act  
8 for outpatient prescription drugs for which benefits are pro-  
9 vided under part B of such title.

10 (d) REPORT ON PROGRESS IN IMPLEMENTATION OF PRE-  
11SCRIPTION DRUG BENEFIT.—Not later than March 1, 2005,  
12 the Secretary shall submit a report to Congress on the progress  
13 that has been made in implementing the prescription drug ben-  
14 efit under this title. The Secretary shall include in the report  
15 specific steps that have been taken, and that need to be taken,  
16 to ensure a timely start of the program on January 1, 2006.  
17 The report shall include recommendations regarding an appro-  
18 priate transition from the program under section 1860D–31 of  
19 the Social Security Act to prescription drug benefits under sub-  
20 part 1 of part D of title XVIII of such Act.

21 (e) ADDITIONAL CONFORMING CHANGES.—

22 (1) CONFORMING REFERENCES TO PREVIOUS PART  
23 D.—Any reference in law (in effect before the date of the  
24 enactment of this Act) to part D of title XVIII of the So-  
25 cial Security Act is deemed a reference to part E of such  
26 title (as in effect after such date).

27 (2) CONFORMING AMENDMENT PERMITTING WAIVER  
28 OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C.  
29 1320a–7b(b)(3)) is amended—

30 (A) by striking “and” at the end of subparagraph  
31 (E);

32 (B) by striking the period at the end of subpara-  
33 graph (F) and inserting “; and”; and

34 (C) by adding at the end the following new sub-  
35 paragraph:

36 “(G) the waiver or reduction by pharmacies (including  
37 pharmacies of the Indian Health Service, Indian tribes,

1 tribal organizations, and urban Indian organizations) of  
2 any cost-sharing imposed under part D of title XVIII, if  
3 the conditions described in clauses (i) through (iii) of sec-  
4 tion 1128A(i)(6)(A) are met with respect to the waiver or  
5 reduction (except that, in the case of such a waiver or re-  
6 duction on behalf of a subsidy eligible individual (as defined  
7 in section 1860D-14(a)(3)), section 1128A(i)(6)(A) shall  
8 be applied without regard to clauses (ii) and (iii) of that  
9 section).”.

10 (3) MEDICARE PRESCRIPTION DRUG ACCOUNT.—

11 (A) Section 201(g) (42 U.S.C. 401(g)) is  
12 amended—

13 (i) in paragraph (1)(B)(i)(V), by inserting  
14 “(and, of such portion, the portion of such costs  
15 which should have been borne by the Medicare Pre-  
16 scription Drug Account in such Trust Fund)” after  
17 “Trust Fund”; and

18 (ii) in paragraph (1)(B)(ii)(III), by inserting  
19 “(and, of such portion, the portion of such costs  
20 which should have been borne by the Medicare Pre-  
21 scription Drug Account in such Trust Fund)” after  
22 “Trust Fund”.

23 (B) Section 201(i)(1) (42 U.S.C. 401(i)(1)) is  
24 amended by inserting “(and for the Medicare Prescrip-  
25 tion Drug Account and the Transitional Assistance Ac-  
26 count in such Trust Fund)” after “Federal Supple-  
27 mentary Medical Insurance Trust Fund”.

28 (C) Section 1841 (42 U.S.C. 1395t) is amended—

29 (i) in the last sentence of subsection (a)—

30 (I) by striking “and” before “such  
31 amounts”; and

32 (II) by inserting before the period the fol-  
33 lowing: “, and such amounts as may be depos-  
34 ited in, or appropriated to, the Medicare Pre-  
35 scription Drug Account established by section  
36 1860D-16”;

1 (ii) in subsection (g), by adding at the end the  
2 following: “The payments provided for under part  
3 D, other than under section 1860D–31(k)(2), shall  
4 be made from the Medicare Prescription Drug Ac-  
5 count in the Trust Fund.”;

6 (iii) in subsection (h), by inserting “or pursu-  
7 ant to section 1860D–13(c)(1) or 1854(d)(2)(A)  
8 (in which case payments shall be made in appro-  
9 priate part from the Medicare Prescription Drug  
10 Account in the Trust Fund)” after “1840(d)”; and

11 (iv) in subsection (i), by inserting after “and  
12 section 1842(g)” the following: “and pursuant to  
13 sections 1860D–13(c)(1) and 1854(d)(2)(A) (in  
14 which case payments shall be made in appropriate  
15 part from the Medicare Prescription Drug Account  
16 in the Trust Fund)”.

17 (D) Section 1853(f) (42 U.S.C. 1395w–23(f)) is  
18 amended—

19 (i) in the heading by striking “TRUST FUND”  
20 and inserting “TRUST FUNDS”; and

21 (ii) by inserting after the first sentence the fol-  
22 lowing: “Payments to MA organizations for statu-  
23 tory drug benefits provided under this title are  
24 made from the Medicare Prescription Drug Ac-  
25 count in the Federal Supplementary Medical Insur-  
26 ance Trust Fund.”.

27 (4) APPLICATION OF CONFIDENTIALITY FOR DRUG  
28 PRICING DATA.—Section 1927(b)(3)(D) (42 U.S.C. 1396r–  
29 8(b)(3)(D)) is amended by adding after and below clause  
30 (iii) the following:

31 “The previous sentence shall also apply to information  
32 disclosed under section 1860D–2(d)(2) or 1860D–  
33 4(c)(2)(E).”.

34 (5) CLARIFICATION OF TREATMENT OF PART A EN-  
35 ROLLEES.—Section 1818(a) (42 U.S.C. 1395i–2(a)) is  
36 amended by adding at the end the following: “Except as  
37 otherwise provided, any reference to an individual entitled

1 to benefits under this part includes an individual entitled  
2 to benefits under this part pursuant to an enrollment under  
3 this section or section 1818A.”.

4 (6) DISCLOSURE.—Section 6103(l)(7)(D)(ii) of the In-  
5 ternal Revenue Code of 1986 is amended by inserting “or  
6 subsidies provided under section 1860D–14 of such Act”  
7 after “Social Security Act”.

8 (7) EXTENSION OF STUDY AUTHORITY.—Section  
9 1875(b) (42 U.S.C. 1395ll(b)) is amended by striking “the  
10 insurance programs under parts A and B” and inserting  
11 “this title”.

12 (8) CONFORMING AMENDMENTS RELATING TO FACILI-  
13 TATION OF ELECTRONIC PRESCRIBING.—

14 (A) Section 1128B(b)(3)(C) (42 U.S.C. 1320a-  
15 7b(b)(3)(C)) is amended by inserting “or in regulations  
16 under section 1860D–3(e)(6)” after “1987”.

17 (B) Section 1877(b) (42 U.S.C. 1395nn(b)) is  
18 amended by adding at the end the following new para-  
19 graph:

20 “(5) ELECTRONIC PRESCRIBING.—An exception estab-  
21 lished by regulation under section 1860D–3(e)(6).”.

22 (9) OTHER CHANGES.—Section 1927(g)(1)(B)(i) (42  
23 U.S.C. 1396r–8(g)(1)(B)(i)) is amended—

24 (A) by adding “and” at the end of subclause (II);  
25 and

26 (B) by striking subclause (IV).

27 **SEC. 102. MEDICARE ADVANTAGE CONFORMING AMEND-**  
28 **MENTS.**

29 (a) CONFORMING AMENDMENTS TO ENROLLMENT PROC-  
30 ESS.—

31 (1) EXTENDING OPEN ENROLLMENT PERIODS.—Sec-  
32 tion 1851(e) (42 U.S.C. 1395w–21(e)) is amended—

33 (A) in paragraph (2), by striking “2004” and  
34 “2005” and inserting “2005” and “2006” each place  
35 it appears; and

36 (B) in paragraph (4), by striking “2005” and in-  
37 serting “2006” each place it appears.

1 (2) ESTABLISHMENT OF SPECIAL ANNUAL, COORDI-  
2 NATED ELECTION PERIOD FOR 6 MONTHS BEGINNING NO-  
3 VEMBER 15, 2005.—Section 1851(e)(3)(B) (42 U.S.C.  
4 1395w-21(e)(3)(B)) is amended to read as follows:

5 “(B) ANNUAL, COORDINATED ELECTION PE-  
6 RIOD.—For purposes of this section, the term ‘annual,  
7 coordinated election period’ means—

8 “(i) with respect to a year before 2002, the  
9 month of November before such year;

10 “(ii) with respect to 2002, 2003, 2004, and  
11 2005, the period beginning on November 15 and  
12 ending on December 31 of the year before such  
13 year;

14 “(iii) with respect to 2006, the period begin-  
15 ning on November 15, 2005, and ending on May  
16 15, 2006; and

17 “(iv) with respect to 2007 and succeeding  
18 years, the period beginning on November 15 and  
19 ending on December 31 of the year before such  
20 year.”.

21 (3) SPECIAL INFORMATION CAMPAIGN.—Section  
22 1851(e)(3) (42 U.S.C. 1395w-21(e)(3)) is amended—

23 (A) in subparagraph (C), by inserting “and during  
24 the period described in subparagraph (B)(iii)” after  
25 “(beginning with 1999)”; and

26 (B) in subparagraph (D)—

27 (i) in the heading by striking “CAMPAIGN IN  
28 1998” and inserting “CAMPAIGNS”; and

29 (ii) by adding at the end the following: “Dur-  
30 ing the period described in subparagraph (B)(iii),  
31 the Secretary shall provide for an educational and  
32 publicity campaign to inform MA eligible individ-  
33 uals about the availability of MA plans (including  
34 MA-PD plans) offered in different areas and the  
35 election process provided under this section.”.

36 (4) COORDINATING INITIAL ENROLLMENT PERIODS.—  
37 Section 1851(e)(1) (42 U.S.C. 1395w-21(e)(1)) is amend-

1 ed by adding at the end the following new sentence: “If any  
2 portion of an individual’s initial enrollment period under  
3 part B occurs after the end of the annual, coordinated elec-  
4 tion period described in paragraph (3)(B)(iii), the initial  
5 enrollment period under this part shall further extend  
6 through the end of the individual’s initial enrollment period  
7 under part B.”.

8 (5) COORDINATION OF EFFECTIVENESS OF ELECTIONS  
9 DURING ANNUAL COORDINATED ELECTION PERIOD FOR  
10 2006.—Section 1851(f)(3) (42 U.S.C. 1395w–21(f)(3)) is  
11 amended by inserting “, other than the period described in  
12 clause (iii) of such subsection” after “subsection  
13 (e)(3)(B)”.

14 (6) LIMITATION ON ONE-CHANGE RULE TO SAME TYPE  
15 OF PLAN.—Section 1851(e)(2) (42 U.S.C. 1395w–21(e)(2))  
16 is amended—

17 (A) in subparagraph (B)(i), by inserting “, sub-  
18 paragraph (C)(iii),” after “clause (ii)”;

19 (B) in subparagraph (C)(i), by striking “clause  
20 (ii)” and inserting “clauses (ii) and (iii)”;

21 (C) by adding at the end of subparagraph (C) the  
22 following new clause:

23 “(iii) LIMITATION ON EXERCISE OF RIGHT  
24 WITH RESPECT TO PRESCRIPTION DRUG COV-  
25 ERAGE.—Effective for plan years beginning on or  
26 after January 1, 2006, in applying clause (i) (and  
27 clause (i) of subparagraph (B)) in the case of an  
28 individual who—

29 “(I) is enrolled in an MA plan that does  
30 provide qualified prescription drug coverage,  
31 the individual may exercise the right under  
32 such clause only with respect to coverage under  
33 the original fee-for-service plan or coverage  
34 under another MA plan that does not provide  
35 such coverage and may not exercise such right  
36 to obtain coverage under an MA–PD plan or

1 under a prescription drug plan under part D;  
2 or

3 “(II) is enrolled in an MA–PD plan, the  
4 individual may exercise the right under such  
5 clause only with respect to coverage under an-  
6 other MA–PD plan (and not an MA plan that  
7 does not provide qualified prescription drug  
8 coverage) or under the original fee-for-service  
9 plan and coverage under a prescription drug  
10 plan under part D.”.

11 (b) PROMOTION OF E-PRESCRIBING BY MA PLANS.—Sec-  
12 tion 1852(j) (42 U.S.C. 1395w–22(j)) is amended by adding at  
13 the end the following new paragraph:

14 “(7) PROMOTION OF E-PRESCRIBING BY MA  
15 PLANS.—

16 “(A) IN GENERAL.—An MA–PD plan may provide  
17 for a separate payment or otherwise provide for a dif-  
18 ferential payment for a participating physician that  
19 prescribes covered part D drugs in accordance with an  
20 electronic prescription drug program that meets stand-  
21 ards established under section 1860D–4(e).

22 “(B) CONSIDERATIONS.—Such payment may take  
23 into consideration the costs of the physician in imple-  
24 menting such a program and may also be increased for  
25 those participating physicians who significantly  
26 increase—

27 “(i) formulary compliance;

28 “(ii) lower cost, therapeutically equivalent al-  
29 ternatives;

30 “(iii) reductions in adverse drug interactions;  
31 and

32 “(iv) efficiencies in filing prescriptions through  
33 reduced administrative costs.

34 “(C) STRUCTURE.—Additional or increased pay-  
35 ments under this subsection may be structured in the  
36 same manner as medication therapy management fees  
37 are structured under section 1860D–4(c)(2)(E).”.



1 (c) OTHER CONFORMING AMENDMENTS.—

2 (1) Section 1851(a)(1) (42 U.S.C. 1395w-21(a)(1)) is  
3 amended—

4 (A) by inserting “(other than qualified prescrip-  
5 tion drug benefits)” after “benefits”;

6 (B) by striking the period at the end of subpara-  
7 graph (B) and inserting a comma; and

8 (C) by adding after and below subparagraph (B)  
9 the following:

10 “and may elect qualified prescription drug coverage in ac-  
11 cordance with section 1860D-1.”.

12 (2) EFFECTIVE DATE.—The amendments made by  
13 this subsection shall apply on and after January 1, 2006.

14 **SEC. 103. MEDICAID AMENDMENTS.**

15 (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME  
16 SUBSIDIES.—

17 (1) REQUIREMENT.—Section 1902(a) (42 U.S.C.  
18 1396a(a)) is amended—

19 (A) by striking “and” at the end of paragraph  
20 (64);

21 (B) by striking the period at the end of paragraph  
22 (65) and inserting “; and”; and

23 (C) by inserting after paragraph (65) the following  
24 new paragraph:

25 “(66) provide for making eligibility determinations  
26 under section 1935(a).”.

27 (2) NEW SECTION.—Title XIX is further amended—

28 (A) by redesignating section 1935 as section 1936;  
29 and

30 (B) by inserting after section 1934 the following  
31 new section:

32 “SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION  
33 DRUG BENEFIT

34 “SEC. 1935. (a) REQUIREMENTS RELATING TO MEDICARE  
35 PRESCRIPTION DRUG LOW-INCOME SUBSIDIES AND MEDICARE  
36 TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE.—As a con-  
37 dition of its State plan under this title under section

1 1902(a)(66) and receipt of any Federal financial assistance  
2 under section 1903(a), a State shall do the following:

3 “(1) INFORMATION FOR TRANSITIONAL PRESCRIPTION  
4 DRUG ASSISTANCE VERIFICATION.—The State shall provide  
5 the Secretary with information to carry out section 1860D–  
6 31(f)(3)(B)(i).

7 “(2) ELIGIBILITY DETERMINATIONS FOR LOW-INCOME  
8 SUBSIDIES.—The State shall—

9 “(A) make determinations of eligibility for pre-  
10 mium and cost-sharing subsidies under and in accord-  
11 ance with section 1860D–14;

12 “(B) inform the Secretary of such determinations  
13 in cases in which such eligibility is established; and

14 “(C) otherwise provide the Secretary with such in-  
15 formation as may be required to carry out part D,  
16 other than subpart 4, of title XVIII (including section  
17 1860D–14).

18 “(3) SCREENING FOR ELIGIBILITY, AND ENROLLMENT  
19 OF, BENEFICIARIES FOR MEDICARE COST-SHARING.—As  
20 part of making an eligibility determination required under  
21 paragraph (2) for an individual, the State shall make a de-  
22 termination of the individual’s eligibility for medical assist-  
23 ance for any medicare cost-sharing described in section  
24 1905(p)(3) and, if the individual is eligible for any such  
25 medicare cost-sharing, offer enrollment to the individual  
26 under the State plan (or under a waiver of such plan).

27 “(b) REGULAR FEDERAL SUBSIDY OF ADMINISTRATIVE  
28 COSTS.—The amounts expended by a State in carrying out  
29 subsection (a) are expenditures reimbursable under the appro-  
30 priate paragraph of section 1903(a).

31 (b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RE-  
32 SPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES  
33 FOR DUALY ELIGIBLE INDIVIDUALS.—Section 1935, as in-  
34 serted by subsection (a)(2), is amended by adding at the end  
35 the following new subsection:

36 “(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION  
37 DRUG COSTS FOR DUALY ELIGIBLE INDIVIDUALS.—

1           “(1) PHASED-DOWN STATE CONTRIBUTION.—

2           “(A) IN GENERAL.—Each of the 50 States and  
3 the District of Columbia for each month beginning with  
4 January 2006 shall provide for payment under this  
5 subsection to the Secretary of the product of—

6           “(i) the amount computed under paragraph  
7 (2)(A) for the State and month;

8           “(ii) the total number of full-benefit dual eligi-  
9 ble individuals (as defined in paragraph (6)) for  
10 such State and month; and

11           “(iii) the factor for the month specified in  
12 paragraph (5).

13           “(B) FORM AND MANNER OF PAYMENT.—Payment  
14 under subparagraph (A) shall be made in a manner  
15 specified by the Secretary that is similar to the manner  
16 in which State payments are made under an agreement  
17 entered into under section 1843, except that all such  
18 payments shall be deposited into the Medicare Prescrip-  
19 tion Drug Account in the Federal Supplementary Med-  
20 ical Insurance Trust Fund.

21           “(C) COMPLIANCE.—If a State fails to pay to the  
22 Secretary an amount required under subparagraph (A),  
23 interest shall accrue on such amount at the rate pro-  
24 vided under section 1903(d)(5). The amount so owed  
25 and applicable interest shall be immediately offset  
26 against amounts otherwise payable to the State under  
27 section 1903(a), in accordance with the Federal Claims  
28 Collection Act of 1996 and applicable regulations.

29           “(D) DATA MATCH.—The Secretary shall perform  
30 such periodic data matches as may be necessary to  
31 identify and compute the number of full-benefit dual el-  
32 ible individuals for purposes of computing the amount  
33 under subparagraph (A).

34           “(2) AMOUNT.—

35           “(A) IN GENERAL.—The amount computed under  
36 this paragraph for a State described in paragraph (1)  
37 and for a month in a year is equal to—

1 “(i)  $\frac{1}{12}$  of the product of—

2 “(I) the base year state medicaid per cap-  
3 ita expenditures for covered part D drugs for  
4 full-benefit dual eligible individuals (as com-  
5 puted under paragraph (3)); and

6 “(II) a proportion equal to 100 percent  
7 minus the Federal medical assistance percent-  
8 age (as defined in section 1905(b)) applicable  
9 to the State for the fiscal year in which the  
10 month occurs; and

11 “(ii) increased for each year (beginning with  
12 2004 up to and including the year involved) by the  
13 applicable growth factor specified in paragraph (4)  
14 for that year.

15 “(B) NOTICE.—The Secretary shall notify each  
16 State described in paragraph (1) not later than October  
17 15 before the beginning of each year (beginning with  
18 2006) of the amount computed under subparagraph  
19 (A) for the State for that year.

20 “(3) BASE YEAR STATE MEDICAID PER CAPITA EX-  
21 PENDITURES FOR COVERED PART D DRUGS FOR FULL-  
22 BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

23 “(A) IN GENERAL.—For purposes of paragraph  
24 (2)(A), the ‘base year State medicaid per capita ex-  
25 penditures for covered part D drugs for full-benefit  
26 dual eligible individuals’ for a State is equal to the  
27 weighted average (as weighted under subparagraph  
28 (C)) of—

29 “(i) the gross per capita medicaid expenditures  
30 for prescription drugs for 2003, determined under  
31 subparagraph (B); and

32 “(ii) the estimated actuarial value of prescrip-  
33 tion drug benefits provided under a capitated man-  
34 aged care plan per full-benefit dual eligible indi-  
35 vidual for 2003, as determined using such data as  
36 the Secretary determines appropriate.

1                   “(B) GROSS PER CAPITA MEDICAID EXPENDI-  
2                   TURES FOR PRESCRIPTION DRUGS.—

3                   “(i) IN GENERAL.—The gross per capita med-  
4                   icaid expenditures for prescription drugs for 2003  
5                   under this subparagraph is equal to the expendi-  
6                   tures, including dispensing fees, for the State  
7                   under this title during 2003 for covered outpatient  
8                   drugs, determined per full-benefit-dual-eligible-indi-  
9                   vidual for such individuals not receiving medical as-  
10                  sistance for such drugs through a medicaid man-  
11                  aged care plan.

12                  “(ii) DETERMINATION.—In determining the  
13                  amount under clause (i), the Secretary shall—

14                  “(I) use data from the Medicaid Statistical  
15                  Information System (MSIS) and other available  
16                  data;

17                  “(II) exclude expenditures attributable to  
18                  covered outpatient prescription drugs that are  
19                  not covered part D drugs (as defined in section  
20                  1860D–2(e)); and

21                  “(III) reduce such expenditures by the  
22                  product of such portion and the adjustment  
23                  factor (described in clause (iii)).

24                  “(iii) ADJUSTMENT FACTOR.—The adjustment  
25                  factor described in this clause for a State is equal  
26                  to the ratio for the State for 2003 of—

27                  “(I) aggregate payments under agree-  
28                  ments under section 1927; to

29                  “(II) the gross expenditures under this  
30                  title for covered outpatient drugs referred to in  
31                  clause (i).

32                  Such factor shall be determined based on informa-  
33                  tion reported by the State in the medicaid financial  
34                  management reports (form CMS–64) for the 4  
35                  quarters of calendar year 2003 and such other data  
36                  as the Secretary may require.

1           “(C) WEIGHTED AVERAGE.—The weighted aver-  
2           age under subparagraph (A) shall be determined taking  
3           into account—

4                   “(i) with respect to subparagraph (A)(i), the  
5                   average number of full-benefit dual eligible individ-  
6                   uals in 2003 who are not described in clause (ii);  
7                   and

8                   “(ii) with respect to subparagraph (A)(ii), the  
9                   average number of full-benefit dual eligible individ-  
10                  uals in such year who received in 2003 medical as-  
11                  sistance for covered outpatient drugs through a  
12                  medicaid managed care plan.

13           “(4) APPLICABLE GROWTH FACTOR.—The applicable  
14           growth factor under this paragraph for—

15                   “(A) each of 2004, 2005, and 2006, is the average  
16                   annual percent change (to that year from the previous  
17                   year) of the per capita amount of prescription drug ex-  
18                   penditures (as determined based on the most recent  
19                   National Health Expenditure projections for the years  
20                   involved); and

21                   “(B) a succeeding year, is the annual percentage  
22                   increase specified in section 1860D–2(b)(6) for the  
23                   year.

24           “(5) FACTOR.—The factor under this paragraph for a  
25           month—

26                   “(A) in 2006 is 90 percent;

27                   “(B) in 2007 is 88- $\frac{1}{3}$  percent;

28                   “(C) in 2008 is 86- $\frac{2}{3}$  percent;

29                   “(D) in 2009 is 85 percent;

30                   “(E) in 2010 is 83- $\frac{1}{3}$  percent;

31                   “(F) in 2011 is 81- $\frac{2}{3}$  percent;

32                   “(G) in 2012 is 80 percent;

33                   “(H) in 2013 is 78- $\frac{1}{3}$  percent;

34                   “(I) in 2014 is 76- $\frac{2}{3}$  percent; or

35                   “(J) after December 2014, is 75 percent.

36           “(6) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL DE-  
37           FINED.—

1           “(A) IN GENERAL.—For purposes of this section,  
2           the term ‘full-benefit dual eligible individual’ means for  
3           a State for a month an individual who—

4                   “(i) has coverage for the month for covered  
5                   part D drugs under a prescription drug plan under  
6                   part D of title XVIII, or under an MA–PD plan  
7                   under part C of such title; and

8                   “(ii) is determined eligible by the State for  
9                   medical assistance for full benefits under this title  
10                  for such month under section 1902(a)(10)(A) or  
11                  1902(a)(10)(C), by reason of section 1902(f), or  
12                  under any other category of eligibility for medical  
13                  assistance for full benefits under this title, as de-  
14                  termined by the Secretary.

15           “(B) TREATMENT OF MEDICALLY NEEDY AND  
16           OTHER INDIVIDUALS REQUIRED TO SPEND DOWN.—In  
17           applying subparagraph (A) in the case of an individual  
18           determined to be eligible by the State for medical as-  
19           sistance under section 1902(a)(10)(C) or by reason of  
20           section 1902(f), the individual shall be treated as meet-  
21           ing the requirement of subparagraph (A)(ii) for any  
22           month if such medical assistance is provided for in any  
23           part of the month.”.

24           (c) MEDICAID COORDINATION WITH MEDICARE PRE-  
25           SCRIPTION DRUG BENEFITS.—Section 1935, as so inserted and  
26           amended, is further amended by adding at the end the fol-  
27           lowing new subsection:

28                   “(d) COORDINATION OF PRESCRIPTION DRUG BENE-  
29                   FITS.—

30                   “(1) MEDICARE AS PRIMARY PAYOR.—In the case of  
31                   a part D eligible individual (as defined in section 1860D–  
32                   1(a)(3)(A)) who is described in subsection (c)(6)(A)(ii),  
33                   notwithstanding any other provision of this title, medical  
34                   assistance is not available under this title for such drugs  
35                   (or for any cost-sharing respecting such drugs), and the  
36                   rules under this title relating to the provision of medical as-  
37                   sistance for such drugs shall not apply. The provision of

1 benefits with respect to such drugs shall not be considered  
2 as the provision of care or services under the plan under  
3 this title. No payment may be made under section 1903(a)  
4 for prescribed drugs for which medical assistance is not  
5 available pursuant to this paragraph.

6 “(2) COVERAGE OF CERTAIN EXCLUDABLE DRUGS.—  
7 In the case of medical assistance under this title with re-  
8 spect to a covered outpatient drug (other than a covered  
9 part D drug) furnished to an individual who is enrolled in  
10 a prescription drug plan under part D of title XVIII or an  
11 MA–PD plan under part C of such title, the State may  
12 elect to provide such medical assistance in the manner oth-  
13 erwise provided in the case of individuals who are not full-  
14 benefit dual eligible individuals or through an arrangement  
15 with such plan.”.

16 (d) TREATMENT OF TERRITORIES.—

17 (1) IN GENERAL.—Section 1935, as so inserted and  
18 amended, is further amended—

19 (A) in subsection (a) in the matter preceding para-  
20 graph (1), by inserting “subject to subsection (e)” after  
21 “section 1903(a)”;

22 (B) in subsection (c)(1), by inserting “subject to  
23 subsection (e)” after “1903(a)(1)”; and

24 (C) by adding at the end the following new sub-  
25 section:

26 “(e) TREATMENT OF TERRITORIES.—

27 “(1) IN GENERAL.—In the case of a State, other than  
28 the 50 States and the District of Columbia—

29 “(A) the previous provisions of this section shall  
30 not apply to residents of such State; and

31 “(B) if the State establishes and submits to the  
32 Secretary a plan described in paragraph (2) (for pro-  
33 viding medical assistance with respect to the provision  
34 of prescription drugs to part D eligible individuals), the  
35 amount otherwise determined under section 1108(f) (as  
36 increased under section 1108(g)) for the State shall be



1 increased by the amount for the fiscal period specified  
2 in paragraph (3).

3 “(2) PLAN.—The Secretary shall determine that a  
4 plan is described in this paragraph if the plan—

5 “(A) provides medical assistance with respect to  
6 the provision of covered part D drugs (as defined in  
7 section 1860D–2(e)) to low-income part D eligible indi-  
8 viduals;

9 “(B) provides assurances that additional amounts  
10 received by the State that are attributable to the oper-  
11 ation of this subsection shall be used only for such as-  
12 sistance and related administrative expenses and that  
13 no more than 10 percent of the amount specified in  
14 paragraph (3)(A) for the State for any fiscal period  
15 shall be used for such administrative expenses; and

16 “(C) meets such other criteria as the Secretary  
17 may establish.

18 “(3) INCREASED AMOUNT.—

19 “(A) IN GENERAL.—The amount specified in this  
20 paragraph for a State for a year is equal to the product  
21 of—

22 “(i) the aggregate amount specified in sub-  
23 paragraph (B); and

24 “(ii) the ratio (as estimated by the Secretary)  
25 of—

26 “(I) the number of individuals who are en-  
27 titled to benefits under part A or enrolled  
28 under part B and who reside in the State (as  
29 determined by the Secretary based on the most  
30 recent available data before the beginning of  
31 the year); to

32 “(II) the sum of such numbers for all  
33 States that submit a plan described in para-  
34 graph (2).

35 “(B) AGGREGATE AMOUNT.—The aggregate  
36 amount specified in this subparagraph for—

1 “(i) the last 3 quarters of fiscal year 2006, is  
2 equal to \$28,125,000;

3 “(ii) fiscal year 2007, is equal to \$37,500,000;  
4 or

5 “(iii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the  
6 previous year increased by annual percentage increase specified in section 1860D–2(b)(6) for the  
7 year involved.  
8

9  
10 “(4) REPORT.—The Secretary shall submit to Congress a report on the application of this subsection and  
11 may include in the report such recommendations as the Secretary deems appropriate.”  
12

13  
14 (2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting “and section  
15 1935(e)(1)(B)” after “Subject to subsection (g)”.  
16

17 (e) AMENDMENT TO BEST PRICE.—

18 (1) IN GENERAL.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—  
19

20 (A) by striking “and” at the end of subclause  
21 (III);

22 (B) by striking the period at the end of subclause  
23 (IV) and inserting a semicolon; and

24 (C) by adding at the end the following new sub-  
25 clauses:

26 “(V) the prices negotiated from drug man-  
27 ufacturers for covered discount card drugs  
28 under an endorsed discount card program  
29 under section 1860D–31; and

30 “(VI) any prices charged which are nego-  
31 tiated by a prescription drug plan under part  
32 D of title XVIII, by an MA–PD plan under  
33 part C of such title with respect to covered part  
34 D drugs or by a qualified retiree prescription  
35 drug plan (as defined in section 1860D–  
36 22(a)(2)) with respect to such drugs on behalf

1 of individuals entitled to benefits under part A  
2 or enrolled under part B of such title.”.

3 (2) IN GENERAL.—Section 1927(c)(1)(C)(i)(VI) of the  
4 Social Security Act, as added by paragraph (1), shall apply  
5 to prices charged for drugs dispensed on or after January  
6 1, 2006.

7 (f) EXTENSION OF MEDICARE COST-SHARING FOR PART  
8 B PREMIUM FOR QUALIFYING INDIVIDUALS THROUGH SEP-  
9 TEMBER 2004.—

10 (1) IN GENERAL.—Section 1902(a)(10)(E)(iv) (42  
11 U.S.C. 1396a(a)(10)(E)(iv)), as amended by section 401(a)  
12 of Public Law 108–89, is amended by striking “ending  
13 with March 2004” and inserting “ending with September  
14 2004”.

15 (2) TOTAL AMOUNT AVAILABLE FOR ALLOCATION.—  
16 Section 1933(g) (42 U.S.C. 1396u–3(g)), as added by sec-  
17 tion 401(c) of Public Law 108–89, is amended—

18 (A) in the matter preceding paragraph (1), by  
19 striking “March 31, 2004” and inserting “September  
20 30, 2004”; and

21 (B) in paragraph (2), by striking “\$100,000,000”  
22 and inserting “\$300,000,000”.

23 (3) EFFECTIVE DATE.—The amendments made by  
24 this subsection shall apply to calendar quarters beginning  
25 on or after April 1, 2004.

26 (g) OUTREACH BY THE COMMISSIONER OF SOCIAL SECU-  
27 RITY.—Section 1144 (42 U.S.C. 1320b–14) is amended—

28 (1) in the section heading, by inserting “AND SUB-  
29 SIDIES FOR LOW-INCOME INDIVIDUALS UNDER TITLE  
30 XVIII” after “COST-SHARING”;

31 (2) in subsection (a)—

32 (A) in paragraph (1)—

33 (i) in subparagraph (A), by inserting “for the  
34 transitional assistance under section 1860D–31(f),  
35 or for premium and cost-sharing subsidies under  
36 section 1860D–14” before the semicolon; and

1 (ii) in subparagraph (B), by inserting “, pro-  
2 gram, and subsidies” after “medical assistance”;  
3 and

4 (B) in paragraph (2)—

5 (i) in the matter preceding subparagraph (A),  
6 by inserting “, the transitional assistance under  
7 section 1860D–31(f), or premium and cost-sharing  
8 subsidies under section 1860D–14” after “assist-  
9 ance”; and

10 (ii) in subparagraph (A), by striking “such eli-  
11 gibility” and inserting “eligibility for medicare cost-  
12 sharing under the medicaid program”; and

13 (3) in subsection (b)—

14 (A) in paragraph (1)(A), by inserting “, for transi-  
15 tional assistance under section 1860D–31(f), or for  
16 premium and cost-sharing subsidies for low-income in-  
17 dividuals under section 1860D–14” after “1933”; and

18 (B) in paragraph (2), by inserting “, program,  
19 and subsidies” after “medical assistance”.

20 **SEC. 104. MEDIGAP AMENDMENTS.**

21 (a) RULES RELATING TO MEDIGAP POLICIES THAT PRO-  
22 VIDE PRESCRIPTION DRUG COVERAGE.—

23 (1) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is  
24 amended by adding at the end the following new sub-  
25 section:

26 “(v) RULES RELATING TO MEDIGAP POLICIES THAT PRO-  
27 VIDE PRESCRIPTION DRUG COVERAGE.—

28 “(1) PROHIBITION ON SALE, ISSUANCE, AND RENEWAL  
29 OF NEW POLICIES THAT PROVIDE PRESCRIPTION DRUG  
30 COVERAGE.—

31 “(A) IN GENERAL.—Notwithstanding any other  
32 provision of law, on or after January 1, 2006, a  
33 medigap Rx policy (as defined in paragraph (6)(A))  
34 may not be sold, issued, or renewed under this  
35 section—

36 “(i) to an individual who is a part D enrollee  
37 (as defined in paragraph (6)(B)); or

1                   “(ii) except as provided in subparagraph (B),  
2                   to an individual who is not a part D enrollee.

3                   “(B) CONTINUATION PERMITTED FOR NON-PART  
4                   D ENROLLEES.—Subparagraph (A)(ii) shall not apply  
5                   to the renewal of a medigap Rx policy that was issued  
6                   before January 1, 2006.

7                   “(C) CONSTRUCTION.—Nothing in this subsection  
8                   shall be construed as preventing the offering on and  
9                   after January 1, 2006, of ‘H’, ‘I’, and ‘J’ policies de-  
10                  scribed in paragraph (2)(D)(i) if the benefit packages  
11                  are modified in accordance with paragraph (2)(C).

12                  “(2) ELIMINATION OF DUPLICATIVE COVERAGE UPON  
13                  PART D ENROLLMENT.—

14                  “(A) IN GENERAL.—In the case of an individual  
15                  who is covered under a medigap Rx policy and enrolls  
16                  under a part D plan—

17                         “(i) before the end of the initial part D enroll-  
18                         ment period, the individual may—

19                                 “(I) enroll in a medicare supplemental pol-  
20                                 icy without prescription drug coverage under  
21                                 paragraph (3); or

22                                 “(II) continue the policy in effect subject  
23                                 to the modification described in subparagraph  
24                                 (C)(i); or

25                                 “(ii) after the end of such period, the indi-  
26                                 vidual may continue the policy in effect subject to  
27                                 such modification.

28                  “(B) NOTICE REQUIRED TO BE PROVIDED TO  
29                  CURRENT POLICYHOLDERS WITH MEDIGAP RX POL-  
30                  ICY.—No medicare supplemental policy of an issuer  
31                  shall be deemed to meet the standards in subsection (c)  
32                  unless the issuer provides written notice (in accordance  
33                  with standards of the Secretary established in consulta-  
34                  tion with the National Association of Insurance Com-  
35                  missioners) during the 60-day period immediately pre-  
36                  ceding the initial part D enrollment period, to each in-  
37                  dividual who is a policyholder or certificate holder of a

1 medigap Rx policy (at the most recent available address  
2 of that individual) of the following:

3 “(i) If the individual enrolls in a plan under  
4 part D during the initial enrollment period under  
5 section 1860D–1(b)(2)(A), the individual has the  
6 option of—

7 “(I) continuing enrollment in the individ-  
8 ual’s current plan, but the plan’s coverage of  
9 prescription drugs will be modified under sub-  
10 paragraph (C)(i); or

11 “(II) enrolling in another medicare supple-  
12 mental policy pursuant to paragraph (3).

13 “(ii) If the individual does not enroll in a plan  
14 under part D during such period, the individual  
15 may continue enrollment in the individual’s current  
16 plan without change, but—

17 “(I) the individual will not be guaranteed  
18 the option of enrollment in another medicare  
19 supplemental policy pursuant to paragraph (3);  
20 and

21 “(II) if the current plan does not provide  
22 creditable prescription drug coverage (as de-  
23 fined in section 1860D–13(b)(4)), notice of  
24 such fact and that there are limitations on the  
25 periods in a year in which the individual may  
26 enroll under a part D plan and any such enroll-  
27 ment is subject to a late enrollment penalty.

28 “(iii) Such other information as the Secretary  
29 may specify (in consultation with the National As-  
30 sociation of Insurance Commissioners), including  
31 the potential impact of such election on premiums  
32 for medicare supplemental policies.

33 “(C) MODIFICATION.—

34 “(i) IN GENERAL.—The policy modification  
35 described in this subparagraph is the elimination of  
36 prescription coverage for expenses of prescription  
37 drugs incurred after the effective date of the indi-

1           vidual's coverage under a part D plan and the ap-  
2           propriate adjustment of premiums to reflect such  
3           elimination of coverage.

4           “(ii) CONTINUATION OF RENEWABILITY AND  
5           APPLICATION OF MODIFICATION.—No medicare  
6           supplemental policy of an issuer shall be deemed to  
7           meet the standards in subsection (c) unless the  
8           issuer—

9           “(I) continues renewability of medigap Rx  
10          policies that it has issued, subject to subclause  
11          (II); and

12          “(II) applies the policy modification de-  
13          scribed in clause (i) in the cases described in  
14          clauses (i)(II) and (ii) of subparagraph (A).

15          “(D) REFERENCES TO RX POLICIES.—

16          “(i) H, I, AND J POLICIES.—Any reference to  
17          a benefit package classified as ‘H’, ‘I’, or ‘J’ (in-  
18          cluding the benefit package classified as ‘J’ with a  
19          high deductible feature, as described in subsection  
20          (p)(11)) under the standards established under  
21          subsection (p)(2) shall be construed as including a  
22          reference to such a package as modified under sub-  
23          paragraph (C) and such packages as modified shall  
24          not be counted as a separate benefit package under  
25          such subsection.

26          “(ii) APPLICATION IN WAIVERED STATES.—  
27          Except for the modification provided under sub-  
28          paragraph (C), the waivers previously in effect  
29          under subsection (p)(2) shall continue in effect.

30          “(3) AVAILABILITY OF SUBSTITUTE POLICIES WITH  
31          GUARANTEED ISSUE.—

32          “(A) IN GENERAL.—The issuer of a medicare sup-  
33          plemental policy—

34          “(i) may not deny or condition the issuance or  
35          effectiveness of a medicare supplemental policy that  
36          has a benefit package classified as ‘A’, ‘B’, ‘C’, or  
37          ‘F’ (including the benefit package classified as ‘F’

1 with a high deductible feature, as described in sub-  
2 section (p)(11)), under the standards established  
3 under subsection (p)(2), or a benefit package de-  
4 scribed in subparagraph (A) or (B) of subsection  
5 (w)(2) and that is offered and is available for  
6 issuance to new enrollees by such issuer;

7 “(ii) may not discriminate in the pricing of  
8 such policy, because of health status, claims experi-  
9 ence, receipt of health care, or medical condition;  
10 and

11 “(iii) may not impose an exclusion of benefits  
12 based on a pre-existing condition under such policy,  
13 in the case of an individual described in subparagraph  
14 (B) who seeks to enroll under the policy not later than  
15 63 days after the effective date of the individual’s cov-  
16 erage under a part D plan.

17 “(B) INDIVIDUAL COVERED.—An individual de-  
18 scribed in this subparagraph with respect to the issuer  
19 of a medicare supplemental policy is an individual  
20 who—

21 “(i) enrolls in a part D plan during the initial  
22 part D enrollment period;

23 “(ii) at the time of such enrollment was en-  
24 rolled in a medigap Rx policy issued by such issuer;  
25 and

26 “(iii) terminates enrollment in such policy and  
27 submits evidence of such termination along with  
28 the application for the policy under subparagraph  
29 (A).

30 “(C) SPECIAL RULE FOR WAIVERED STATES.—For  
31 purposes of applying this paragraph in the case of a  
32 State that provides for offering of benefit packages  
33 other than under the classification referred to in sub-  
34 paragraph (A)(i), the references to benefit packages in  
35 such subparagraph are deemed references to com-  
36 parable benefit packages offered in such State.

37 “(4) ENFORCEMENT.—



1           “(A) PENALTIES FOR DUPLICATION.—The pen-  
2           alties described in subsection (d)(3)(A)(ii) shall apply  
3           with respect to a violation of paragraph (1)(A).

4           “(B) GUARANTEED ISSUE.—The provisions of  
5           paragraph (4) of subsection (s) shall apply with respect  
6           to the requirements of paragraph (3) in the same man-  
7           ner as they apply to the requirements of such sub-  
8           section.

9           “(5) CONSTRUCTION.—Any provision in this section or  
10          in a medicare supplemental policy relating to guaranteed  
11          renewability of coverage shall be deemed to have been met  
12          with respect to a part D enrollee through the continuation  
13          of the policy subject to modification under paragraph  
14          (2)(C) or the offering of a substitute policy under para-  
15          graph (3). The previous sentence shall not be construed to  
16          affect the guaranteed renewability of such a modified or  
17          substitute policy.

18          “(6) DEFINITIONS.—For purposes of this subsection:

19                 “(A) MEDIGAP RX POLICY.—The term ‘medigap  
20                 Rx policy’ means a medicare supplemental policy—

21                         “(i) which has a benefit package classified as  
22                         ‘H’, ‘I’, or ‘J’ (including the benefit package classi-  
23                         fied as ‘J’ with a high deductible feature, as de-  
24                         scribed in subsection (p)(11)) under the standards  
25                         established under subsection (p)(2), without regard  
26                         to this subsection; and

27                         “(ii) to which such standards do not apply (or  
28                         to which such standards have been waived under  
29                         subsection (p)(6)) but which provides benefits for  
30                         prescription drugs.

31          Such term does not include a policy with a benefit  
32          package as classified under clause (i) which has been  
33          modified under paragraph (2)(C)(i).

34                 “(B) PART D ENROLLEE.—The term ‘part D en-  
35                 rollee’ means an individual who is enrolled in a part D  
36                 plan.

1           “(C) PART D PLAN.—The term ‘part D plan’  
2           means a prescription drug plan or an MA–PD plan (as  
3           defined for purposes of part D).

4           “(D) INITIAL PART D ENROLLMENT PERIOD.—The  
5           term ‘initial part D enrollment period’ means the initial  
6           enrollment period described in section 1860D–  
7           1(b)(2)(A).”.

8           (2) CONFORMING CURRENT GUARANTEED ISSUE PROVI-  
9           SIONS.—

10           (A) EXTENDING GUARANTEED ISSUE POLICY FOR  
11           INDIVIDUALS ENROLLED IN MEDIGAP RX POLICIES  
12           WHO TRY MEDICARE ADVANTAGE.—Subsection  
13           (s)(3)(C)(ii) of such section is amended—

14           (i) by striking “(ii) Only” and inserting  
15           “(ii)(I) Subject to subclause (II), only”; and

16           (ii) by adding at the end the following new  
17           subclause:

18           “(II) If the medicare supplemental policy referred to in  
19           subparagraph (B)(v) was a medigap Rx policy (as defined in  
20           subsection (v)(6)(A)), a medicare supplemental policy described  
21           in this subparagraph is such policy in which the individual was  
22           most recently enrolled as modified under subsection (v)(2)(C)(i)  
23           or, at the election of the individual, a policy referred to in sub-  
24           section (v)(3)(A)(i).”.

25           (B) CONFORMING AMENDMENT.—Section  
26           1882(s)(3)(C)(iii) is amended by inserting “and subject  
27           to subsection (v)(1)” after “subparagraph (B)(vi)”.

28           (b) DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP  
29           POLICIES.—

30           (1) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is  
31           further amended by adding at the end the following new  
32           subsection:

33           “(w) DEVELOPMENT OF NEW STANDARDS FOR MEDICARE  
34           SUPPLEMENTAL POLICIES.—

35           “(1) IN GENERAL.—The Secretary shall request the  
36           National Association of Insurance Commissioners to review  
37           and revise the standards for benefit packages under sub-

1 section (p)(1), taking into account the changes in benefits  
2 resulting from enactment of the Medicare Prescription  
3 Drug, Improvement, and Modernization Act of 2003 and to  
4 otherwise update standards to reflect other changes in law  
5 included in such Act. Such revision shall incorporate the in-  
6 clusion of the 2 benefit packages described in paragraph  
7 (2). Such revisions shall be made consistent with the rules  
8 applicable under subsection (p)(1)(E) with the reference to  
9 the ‘1991 NAIC Model Regulation’ deemed a reference to  
10 the NAIC Model Regulation as published in the Federal  
11 Register on December 4, 1998, and as subsequently up-  
12 dated by the National Association of Insurance Commis-  
13 sioners to reflect previous changes in law (and subsection  
14 (v)) and the reference to ‘date of enactment of this sub-  
15 section’ deemed a reference to the date of enactment of the  
16 Medicare Prescription Drug, Improvement, and Moderniza-  
17 tion Act of 2003. To the extent practicable, such revision  
18 shall provide for the implementation of revised standards  
19 for benefit packages as of January 1, 2006.

20 “(2) NEW BENEFIT PACKAGES.—The benefit packages  
21 described in this paragraph are the following (notwith-  
22 standing any other provision of this section relating to a  
23 core benefit package):

24 “(A) FIRST NEW BENEFIT PACKAGE.—A benefit  
25 package consisting of the following:

26 “(i) Subject to clause (ii), coverage of 50 per-  
27 cent of the cost-sharing otherwise applicable under  
28 parts A and B, except there shall be no coverage  
29 of the part B deductible and coverage of 100 per-  
30 cent of any cost-sharing otherwise applicable for  
31 preventive benefits.

32 “(ii) Coverage for all hospital inpatient coin-  
33 surance and 365 extra lifetime days of coverage of  
34 inpatient hospital services (as in the current core  
35 benefit package).

36 “(iii) A limitation on annual out-of-pocket ex-  
37 penditures under parts A and B to \$4,000 in 2006

1 (or, in a subsequent year, to such limitation for the  
2 previous year increased by an appropriate inflation  
3 adjustment specified by the Secretary).

4 “(B) SECOND NEW BENEFIT PACKAGE.—A benefit  
5 package consisting of the benefit package described in  
6 subparagraph (A), except as follows:

7 “(i) Substitute ‘75 percent’ for ‘50 percent’ in  
8 clause (i) of such subparagraph.

9 “(ii) Substitute ‘\$2,000’ for ‘\$4,000’ in clause  
10 (iii) of such subparagraph.”

11 (2) CONFORMING AMENDMENTS.—Section 1882 (42  
12 U.S.C. 1395ss) is amended—

13 (A) in subsection (g)(1), by inserting “a prescrip-  
14 tion drug plan under part D or” after “but does not  
15 include”; and

16 (B) in subsection (o)(1), by striking “subsection  
17 (p)” and inserting “subsections (p), (v), and (w)”.

18 (c) RULE OF CONSTRUCTION.—

19 (1) IN GENERAL.—Nothing in this Act shall be con-  
20 strued to require an issuer of a medicare supplemental pol-  
21 icy under section 1882 of the Social Security Act (42  
22 U.S.C. 1395rr) to participate as a PDP sponsor under part  
23 D of title XVIII of such Act, as added by section 101, as  
24 a condition for issuing such policy.

25 (2) PROHIBITION ON STATE REQUIREMENT.—A State  
26 may not require an issuer of a medicare supplemental pol-  
27 icy under section 1882 of the Social Security Act (42  
28 U.S.C. 1395rr) to participate as a PDP sponsor under  
29 such part D as a condition for issuing such policy.

30 **SEC. 105. ADDITIONAL PROVISIONS RELATING TO MEDI-**  
31 **CARE PRESCRIPTION DRUG DISCOUNT CARD**  
32 **AND TRANSITIONAL ASSISTANCE PROGRAM.**

33 (a) EXCLUSION OF COSTS FROM DETERMINATION OF  
34 PART B MONTHLY PREMIUM.—Section 1839(g) (42 U.S.C.  
35 1395r(g)) is amended—

36 (1) by striking “attributable to the application of sec-  
37 tion” and inserting “attributable to—

1 “(1) the application of section”;  
2 (2) by striking the period and inserting “; and”; and  
3 (3) by adding at the end the following new paragraph:

4 “(2) the medicare prescription drug discount card and  
5 transitional assistance program under section 1860D–31.”.

6 (b) APPLICATION OF CONFIDENTIALITY FOR DRUG PRIC-  
7 ING DATA.—The last sentence of section 1927(b)(3)(D) (42  
8 U.S.C. 1396r–8(b)(3)(D)), as added by section 101(e)(4), is  
9 amended by inserting “and drug pricing data reported under  
10 the first sentence of section 1860D–31(i)(1)” after “section  
11 1860D–4(c)(2)(E)”.

12 (c) RULES FOR IMPLEMENTATION.—The following rules  
13 shall apply to the medicare prescription drug discount card and  
14 transitional assistance program under section 1860D–31 of the  
15 Social Security Act, as added by section 101(a):

16 (1) In promulgating regulations pursuant to sub-  
17 section (a)(2)(B) of such section 1860D–31—

18 (A) section 1871(a)(3) of the Social Security Act  
19 (42 U.S.C. 1395hh(a)(3)), as added by section  
20 902(a)(1), shall not apply;

21 (B) chapter 35 of title 44, United States Code,  
22 shall not apply; and

23 (C) sections 553(d) and 801(a)(3)(A) of title 5,  
24 United States Code, shall not apply.

25 (2) Section 1857(c)(5) of the Social Security Act (42  
26 U.S.C. 1395w–27(c)(5)) shall apply with respect to section  
27 1860D–31 of such Act, as added by section 101(a), in the  
28 same manner as it applies to part C of title XVIII of such  
29 Act.

30 (3) The administration of such program shall be made  
31 without regard to chapter 35 of title 44, United States  
32 Code.

33 (4)(A) There shall be no judicial review of a deter-  
34 mination not to endorse, or enter into a contract, with a  
35 prescription drug card sponsor under section 1860D–31 of  
36 the Social Security Act.

1 (B) In the case of any order issued to enjoin any pro-  
2 vision of section 1860D–31 of the Social Security Act (or  
3 of any provision of this section), such order shall not affect  
4 any other provision of such section (or of this section) and  
5 all such provisions shall be treated as severable.

6 (d) CONFORMING AMENDMENTS TO FEDERAL SMI TRUST  
7 FUND FOR TRANSITIONAL ASSISTANCE ACCOUNT.—Section  
8 1841 (42 U.S.C. 1395t), as amended by section 101(e)(3)(C),  
9 is amended—

10 (1) in the last sentence of subsection (a), by inserting  
11 after “section 1860D–16” the following: “or the Transi-  
12 tional Assistance Account established by section 1860D–  
13 31(k)(1)”; and

14 (2) in subsection (g), by adding at the end the fol-  
15 lowing: “The payments provided for under section 1860D–  
16 31(k)(2) shall be made from the Transitional Assistance  
17 Account in the Trust Fund.”.

18 (e) DISCLOSURE OF RETURN INFORMATION FOR PUR-  
19 POSSES OF PROVIDING TRANSITIONAL ASSISTANCE UNDER  
20 MEDICARE DISCOUNT CARD PROGRAM.—

21 (1) IN GENERAL.—Subsection (l) of section 6103 of  
22 the Internal Revenue Code of 1986 (relating to disclosure  
23 of returns and return information for purposes other than  
24 tax administration) is amended by adding at the end the  
25 following new paragraph:

26 “(19) DISCLOSURE OF RETURN INFORMATION FOR  
27 PURPOSES OF PROVIDING TRANSITIONAL ASSISTANCE  
28 UNDER MEDICARE DISCOUNT CARD PROGRAM.—

29 “(A) IN GENERAL.—The Secretary, upon written  
30 request from the Secretary of Health and Human Serv-  
31 ices pursuant to carrying out section 1860D–31 of the  
32 Social Security Act, shall disclose to officers, employ-  
33 ees, and contractors of the Department of Health and  
34 Human Services with respect to a taxpayer for the ap-  
35 plicable year—

36 “(i)(I) whether the adjusted gross income, as  
37 modified in accordance with specifications of the

1 Secretary of Health and Human Services for pur-  
2 poses of carrying out such section, of such taxpayer  
3 and, if applicable, such taxpayer's spouse, for the  
4 applicable year, exceeds the amounts specified by  
5 the Secretary of Health and Human Services in  
6 order to apply the 100 and 135 percent of the pov-  
7 erty lines under such section, (II) whether the re-  
8 turn was a joint return, and (III) the applicable  
9 year, or

10 “(ii) if applicable, the fact that there is no re-  
11 turn filed for such taxpayer for the applicable year.

12 “(B) DEFINITION OF APPLICABLE YEAR.—For the  
13 purposes of this subsection, the term ‘applicable year’  
14 means the most recent taxable year for which informa-  
15 tion is available in the Internal Revenue Service’s tax-  
16 payer data information systems, or, if there is no re-  
17 turn filed for such taxpayer for such year, the prior  
18 taxable year.

19 “(C) RESTRICTION ON USE OF DISCLOSED INFOR-  
20 MATION.—Return information disclosed under this  
21 paragraph may be used only for the purposes of deter-  
22 mining eligibility for and administering transitional as-  
23 sistance under section 1860D–31 of the Social Security  
24 Act.”

25 (2) CONFIDENTIALITY.—Paragraph (3) of section  
26 6103(a) of such Code is amended by striking “or (16)” and  
27 inserting “(16), or (19)”.

28 (3) PROCEDURES AND RECORDKEEPING RELATED TO  
29 DISCLOSURES.—Subsection (p)(4) of section 6103 of such  
30 Code is amended by striking “(l)(16) or (17)” each place  
31 it appears and inserting “(l)(16), (17), or (19)”.

32 (4) UNAUTHORIZED DISCLOSURE OR INSPECTION.—  
33 Paragraph (2) of section 7213(a) of such Code is amended  
34 by striking “or (16)” and inserting “(16), or (19)”.

35 **SEC. 106. STATE PHARMACEUTICAL ASSISTANCE TRAN-**  
36 **SITION COMMISSION.**

37 (a) ESTABLISHMENT.—

1           (1) IN GENERAL.—There is established, as of the first  
2 day of the third month beginning after the date of the en-  
3 actment of this Act, a State Pharmaceutical Assistance  
4 Transition Commission (in this section referred to as the  
5 “Commission”) to develop a proposal for addressing the  
6 unique transitional issues facing State pharmaceutical as-  
7 sistance programs, and program participants, due to the  
8 implementation of the voluntary prescription drug benefit  
9 program under part D of title XVIII of the Social Security  
10 Act, as added by section 101.

11           (2) DEFINITIONS.—For purposes of this section:

12           (A) STATE PHARMACEUTICAL ASSISTANCE PRO-  
13 GRAM DEFINED.—The term “State pharmaceutical as-  
14 sistance program” means a program (other than the  
15 medicaid program) operated by a State (or under con-  
16 tract with a State) that provides as of the date of the  
17 enactment of this Act financial assistance to medicare  
18 beneficiaries for the purchase of prescription drugs.

19           (B) PROGRAM PARTICIPANT.—The term “program  
20 participant” means a low-income medicare beneficiary  
21 who is a participant in a State pharmaceutical assist-  
22 ance program.

23           (b) COMPOSITION.—The Commission shall include the fol-  
24 lowing:

25           (1) A representative of each Governor of each State  
26 that the Secretary identifies as operating on a statewide  
27 basis a State pharmaceutical assistance program that pro-  
28 vides for eligibility and benefits that are comparable or  
29 more generous than the low-income assistance eligibility  
30 and benefits offered under section 1860D–14 of the Social  
31 Security Act.

32           (2) Representatives from other States that the Sec-  
33 retary identifies have in operation other State pharma-  
34 ceutical assistance programs, as appointed by the Sec-  
35 retary.

36           (3) Representatives of organizations that have an in-  
37 herent interest in program participants or the program



1           itself, as appointed by the Secretary but not to exceed the  
2           number of representatives under paragraphs (1) and (2).

3           (4) Representatives of Medicare Advantage organiza-  
4           tions, pharmaceutical benefit managers, and other private  
5           health insurance plans, as appointed by the Secretary.

6           (5) The Secretary (or the Secretary's designee) and  
7           such other members as the Secretary may specify.

8           The Secretary shall designate a member to serve as Chair of  
9           the Commission and the Commission shall meet at the call of  
10          the Chair.

11          (c) DEVELOPMENT OF PROPOSAL.—The Commission shall  
12          develop the proposal described in subsection (a) in a manner  
13          consistent with the following principles:

14               (1) Protection of the interests of program participants  
15               in a manner that is the least disruptive to such participants  
16               and that includes a single point of contact for enrollment  
17               and processing of benefits.

18               (2) Protection of the financial and flexibility interests  
19               of States so that States are not financially worse off as a  
20               result of the enactment of this title.

21               (3) Principles of medicare modernization under this  
22               Act.

23          (d) REPORT.—By not later than January 1, 2005, the  
24          Commission shall submit to the President and Congress a re-  
25          port that contains a detailed proposal (including specific legis-  
26          lative or administrative recommendations, if any) and such  
27          other recommendations as the Commission deems appropriate.

28          (e) SUPPORT.—The Secretary shall provide the Commis-  
29          sion with the administrative support services necessary for the  
30          Commission to carry out its responsibilities under this section.

31          (f) TERMINATION.—The Commission shall terminate 30  
32          days after the date of submission of the report under sub-  
33          section (d).

34          **SEC. 107. STUDIES AND REPORTS.**

35               (a) STUDY REGARDING REGIONAL VARIATIONS IN PRE-  
36               SCRIPTION DRUG SPENDING.—

1 (1) IN GENERAL.—The Secretary shall conduct a  
2 study that examines variations in per capita spending for  
3 covered part D drugs under part D of title XVIII of the  
4 Social Security Act among PDP regions and, with respect  
5 to such spending, the amount of such variation that is at-  
6 tributable to—

7 (A) price variations (described in section 1860D–  
8 15(c)(2) of such Act); and

9 (B) differences in per capita utilization that is not  
10 taken into account in the health status risk adjustment  
11 provided under section 1860D–15(c)(1) of such Act.

12 (2) REPORT AND RECOMMENDATIONS.—Not later than  
13 January 1, 2009, the Secretary shall submit to Congress  
14 a report on the study conducted under paragraph (1). Such  
15 report shall include—

16 (A) information regarding the extent of geographic  
17 variation described in paragraph (1)(B);

18 (B) an analysis of the impact on direct subsidies  
19 under section 1860D–15(a)(1) of the Social Security  
20 Act in different PDP regions if such subsidies were ad-  
21 justed to take into account the variation described in  
22 subparagraph (A); and

23 (C) recommendations regarding the appropriate-  
24 ness of applying an additional geographic adjustment  
25 factor under section 1860D–15(c)(2) that reflects some  
26 or all of the variation described in subparagraph (A).

27 (b) REVIEW AND REPORT ON CURRENT STANDARDS OF  
28 PRACTICE FOR PHARMACY SERVICES PROVIDED TO PATIENTS  
29 IN NURSING FACILITIES.—

30 (1) REVIEW.—

31 (A) IN GENERAL.—Not later than 12 months after  
32 the date of the enactment of this Act, the Secretary  
33 shall conduct a thorough review of the current stand-  
34 ards of practice for pharmacy services provided to pa-  
35 tients in nursing facilities.

1 (B) SPECIFIC MATTERS REVIEWED.—In con-  
2 ducting the review under subparagraph (A), the Sec-  
3 retary shall—

4 (i) assess the current standards of practice,  
5 clinical services, and other service requirements  
6 generally used for pharmacy services in long-term  
7 care settings; and

8 (ii) evaluate the impact of those standards  
9 with respect to patient safety, reduction of medica-  
10 tion errors and quality of care.

11 (2) REPORT.—

12 (A) IN GENERAL.—Not later than the date that is  
13 18 months after the date of the enactment of this Act,  
14 the Secretary shall submit a report to Congress on the  
15 study conducted under paragraph (1)(A).

16 (B) CONTENTS.—The report submitted under sub-  
17 paragraph (A) shall contain—

18 (i) a description of the plans of the Secretary  
19 to implement the provisions of this Act in a manner  
20 consistent with applicable State and Federal laws  
21 designed to protect the safety and quality of care  
22 of nursing facility patients; and

23 (ii) recommendations regarding necessary ac-  
24 tions and appropriate reimbursement to ensure the  
25 provision of prescription drugs to medicare bene-  
26 ficiaries residing in nursing facilities in a manner  
27 consistent with existing patient safety and quality  
28 of care standards under applicable State and Fed-  
29 eral laws.

30 (c) IOM STUDY ON DRUG SAFETY AND QUALITY.—

31 (1) IN GENERAL.—The Secretary shall enter into a  
32 contract with the Institutes of Medicine of the National  
33 Academies of Science (such Institutes referred to in this  
34 subsection as the “IOM”) to carry out a comprehensive  
35 study (in this subsection referred to as the “study”) of  
36 drug safety and quality issues in order to provide a blue-  
37 print for system-wide change.

1 (2) OBJECTIVES.—

2 (A) The study shall develop a full understanding  
3 of drug safety and quality issues through an evidence-  
4 based review of literature, case studies, and analysis.  
5 This review will consider the nature and causes of  
6 medication errors, their impact on patients, the dif-  
7 ferences in causation, impact, and prevention across  
8 multiple dimensions of health care delivery-including  
9 patient populations, care settings, clinicians, and insti-  
10 tutional cultures.

11 (B) The study shall attempt to develop credible es-  
12 timates of the incidence, severity, costs of medication  
13 errors that can be useful in prioritizing resources for  
14 national quality improvement efforts and influencing  
15 national health care policy.

16 (C) The study shall evaluate alternative ap-  
17 proaches to reducing medication errors in terms of  
18 their efficacy, cost-effectiveness, appropriateness in dif-  
19 ferent settings and circumstances, feasibility, institu-  
20 tional barriers to implementation, associated risks, and  
21 the quality of evidence supporting the approach.

22 (D) The study shall provide guidance to con-  
23 sumers, providers, payers, and other key stakeholders  
24 on high-priority strategies to achieve both short-term  
25 and long-term drug safety goals, to elucidate the goals  
26 and expected results of such initiatives and support the  
27 business case for them, and to identify critical success  
28 factors and key levers for achieving success.

29 (E) The study shall assess the opportunities and  
30 key impediments to broad nationwide implementation  
31 of medication error reductions, and to provide guidance  
32 to policy-makers and government agencies (including  
33 the Food and Drug Administration, the Centers for  
34 Medicare & Medicaid Services, and the National Insti-  
35 tutes of Health) in promoting a national agenda for  
36 medication error reduction.

1 (F) The study shall develop an applied research  
2 agenda to evaluate the health and cost impacts of alter-  
3 native interventions, and to assess collaborative public  
4 and private strategies for implementing the research  
5 agenda through AHRQ and other government agencies.

6 (3) CONDUCT OF STUDY.—

7 (A) EXPERT COMMITTEE.—In conducting the  
8 study, the IOM shall convene a committee of leading  
9 experts and key stakeholders in pharmaceutical man-  
10 agement and drug safety, including clinicians, health  
11 services researchers, pharmacists, system administra-  
12 tors, payer representatives, and others.

13 (B) COMPLETION.—The study shall be completed  
14 within an 18-month period.

15 (4) REPORT.—A report on the study shall be sub-  
16 mitted to Congress upon the completion of the study.

17 (5) AUTHORIZATION OF APPROPRIATIONS.—There are  
18 authorized to be appropriated to carry out this section such  
19 sums as may be necessary.

20 (d) STUDY OF MULTI-YEAR CONTRACTS.—

21 (1) IN GENERAL.—The Secretary shall provide for a  
22 study on the feasibility and advisability of providing for  
23 contracting with PDP sponsors and MA organizations  
24 under parts C and D of title XVIII on a multi-year basis.

25 (2) REPORT.—Not later than January 1, 2007, the  
26 Secretary shall submit to Congress a report on the study  
27 under paragraph (1). The report shall include such rec-  
28 ommendations as the Secretary deems appropriate.

29 (e) GAO STUDY REGARDING IMPACT OF ASSETS TEST  
30 FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

31 (1) STUDY.—The Comptroller General of the United  
32 States shall conduct a study to determine the extent to  
33 which drug utilization and access to covered part D drugs  
34 under part D of title XVIII of the Social Security Act by  
35 subsidy eligible individuals differs from such utilization and  
36 access for individuals who would qualify as such subsidy el-

1           igible individuals but for the application of section 1860D–  
2           14(a)(3)(A)(iii) of such Act.

3           (2) REPORT.—Not later than September 30, 2007, the  
4           Comptroller General shall submit a report to Congress on  
5           the study conducted under paragraph (1) that includes  
6           such recommendations for legislation as the Comptroller  
7           General determines are appropriate.

8           (f) STUDY ON MAKING PRESCRIPTION PHARMACEUTICAL  
9           INFORMATION ACCESSIBLE FOR BLIND AND VISUALLY-IM-  
10          PAIRED INDIVIDUALS.—

11          (1) STUDY.—

12           (A) IN GENERAL.—The Secretary shall undertake  
13           a study of how to make prescription pharmaceutical in-  
14           formation, including drug labels and usage instructions,  
15           accessible to blind and visually-impaired individuals.

16           (B) STUDY TO INCLUDE EXISTING AND EMERGING  
17           TECHNOLOGIES.—The study under subparagraph (A)  
18           shall include a review of existing and emerging tech-  
19           nologies, including assistive technology, that makes es-  
20           sential information on the content and prescribed use  
21           of pharmaceutical medicines available in a usable for-  
22           mat for blind and visually-impaired individuals.

23          (2) REPORT.—

24           (A) IN GENERAL.—Not later than 18 months after  
25           the date of the enactment of this Act, the Secretary  
26           shall submit a report to Congress on the study required  
27           under paragraph (1).

28           (B) CONTENTS OF REPORT.—The report required  
29           under paragraph (1) shall include recommendations for  
30           the implementation of usable formats for making pre-  
31           scription pharmaceutical information available to blind  
32           and visually-impaired individuals and an estimate of  
33           the costs associated with the implementation of each  
34           format.

1     **SEC. 108. GRANTS TO PHYSICIANS TO IMPLEMENT ELEC-**  
2                    **TRONIC PRESCRIPTION DRUG PROGRAMS.**

3           (a) IN GENERAL.—The Secretary is authorized to make  
4 grants to physicians for the purpose of assisting such physi-  
5 cians to implement electronic prescription drug programs that  
6 comply with the standards promulgated or modified under sec-  
7 tion 1860D–4(e) of the Social Security Act, as inserted by sec-  
8 tion 101(a).

9           (b) AWARDING OF GRANTS.—

10           (1) APPLICATION.—No grant may be made under this  
11 section except pursuant to a grant application that is sub-  
12 mitted and approved in a time, manner, and form specified  
13 by the Secretary.

14           (2) CONSIDERATIONS AND PREFERENCES.—In award-  
15 ing grants under this section, the Secretary shall—

16           (A) give special consideration to physicians who  
17 serve a disproportionate number of medicare patients;  
18 and

19           (B) give preference to physicians who serve a rural  
20 or underserved area.

21           (3) LIMITATION ON GRANTS.—Only 1 grant may be  
22 awarded under this section with respect to any physician or  
23 group practice of physicians.

24           (c) TERMS AND CONDITIONS.—

25           (1) IN GENERAL.—Grants under this section shall be  
26 made under such terms and conditions as the Secretary  
27 specifies consistent with this section.

28           (2) USE OF GRANT FUNDS.—Funds provided under  
29 grants under this section may be used for any of the fol-  
30 lowing:

31           (A) For purchasing, leasing, and installing com-  
32 puter software and hardware, including handheld com-  
33 puter technologies.

34           (B) Making upgrades and other improvements to  
35 existing computer software and hardware to enable e-  
36 prescribing.

1 (C) Providing education and training to eligible  
2 physician staff on the use of technology to implement  
3 the electronic transmission of prescription and patient  
4 information.

5 (3) PROVISION OF INFORMATION.—As a condition for  
6 the awarding of a grant under this section, an applicant  
7 shall provide to the Secretary such information as the Sec-  
8 retary may require in order to—

9 (A) evaluate the project for which the grant is  
10 made; and

11 (B) ensure that funding provided under the grant  
12 is expended only for the purposes for which it is made.

13 (4) AUDIT.—The Secretary shall conduct appropriate  
14 audits of grants under this section.

15 (5) MATCHING REQUIREMENT.—The applicant for a  
16 grant under this section shall agree, with respect to the  
17 costs to be incurred by the applicant in implementing an  
18 electronic prescription drug program, to make available (di-  
19 rectly or through donations from public or private entities)  
20 non-Federal contributions toward such costs in an amount  
21 that is not less than 50 percent of such costs. Non-Federal  
22 contributions under the previous sentence may be in cash  
23 or in kind, fairly evaluated, including plant, equipment, or  
24 services. Amounts provided by the Federal Government, or  
25 services assisted or subsidized to any significant extent by  
26 the Federal Government, may not be included in deter-  
27 mining the amount of such contributions.

28 (d) AUTHORIZATION OF APPROPRIATIONS.—There are au-  
29 thorized to be appropriated to carry out this section  
30 \$50,000,000 for fiscal year 2007 and such sums as may be  
31 necessary for each of fiscal years 2008 and 2009.

32 **SEC. 109. EXPANDING THE WORK OF MEDICARE QUAL-**  
33 **ITY IMPROVEMENT ORGANIZATIONS TO IN-**  
34 **CLUDE PARTS C AND D.**

35 (a) APPLICATION TO MEDICARE MANAGED CARE AND  
36 PRESCRIPTION DRUG COVERAGE.—Section 1154(a)(1) (42  
37 U.S.C. 1320c-3(a)(1)) is amended by inserting “, to Medicare



1 Advantage organizations pursuant to contracts under part C,  
2 and to prescription drug sponsors pursuant to contracts under  
3 part D” after “under section 1876”.

4 (b) PRESCRIPTION DRUG THERAPY QUALITY IMPROVE-  
5 MENT.—Section 1154(a) (42 U.S.C. 1320c–3(a)) is amended  
6 by adding at the end the following new paragraph:

7 “(17) The organization shall execute its responsibil-  
8 ities under subparagraphs (A) and (B) of paragraph (1) by  
9 offering to providers, practitioners, Medicare Advantage or-  
10 ganizations offering Medicare Advantage plans under part  
11 C, and prescription drug sponsors offering prescription  
12 drug plans under part D quality improvement assistance  
13 pertaining to prescription drug therapy. For purposes of  
14 this part and title XVIII, the functions described in this  
15 paragraph shall be treated as a review function.”.

16 (c) EFFECTIVE DATE.—The amendments made by this  
17 section shall apply on and after January 1, 2004.

18 (d) IOM STUDY OF QIOS.—

19 (1) IN GENERAL.—The Secretary shall request the In-  
20 stitute of Medicine of the National Academy of Sciences to  
21 conduct an evaluation of the program under part B of title  
22 XI of the Social Security Act. The study shall include a re-  
23 view of the following:

24 (A) An overview of the program under such part.

25 (B) The duties of organizations with contracts  
26 with the Secretary under such part.

27 (C) The extent to which quality improvement orga-  
28 nizations improve the quality of care for medicare bene-  
29 ficiaries.

30 (D) The extent to which other entities could per-  
31 form such quality improvement functions as well as, or  
32 better than, quality improvement organizations.

33 (E) The effectiveness of reviews and other actions  
34 conducted by such organizations in carrying out those  
35 duties.

36 (F) The source and amount of funding for such  
37 organizations.

1 (G) The conduct of oversight of such organiza-  
2 tions.

3 (2) REPORT TO CONGRESS.—Not later than June 1,  
4 2006, the Secretary shall submit to Congress a report on  
5 the results of the study described in paragraph (1), includ-  
6 ing any recommendations for legislation.

7 (3) INCREASED COMPETITION.—If the Secretary finds  
8 based on the study conducted under paragraph (1) that  
9 other entities could improve quality in the medicare pro-  
10 gram as well as, or better than, the current quality im-  
11 provement organizations, then the Secretary shall provide  
12 for such increased competition through the addition of new  
13 types of entities which may perform quality improvement  
14 functions.

15 **SEC. 110. CONFLICT OF INTEREST STUDY.**

16 (a) STUDY.—The Federal Trade Commission shall conduct  
17 a study of differences in payment amounts for pharmacy serv-  
18 ices provided to enrollees in group health plans that utilize  
19 pharmacy benefit managers. Such study shall include the fol-  
20 lowing:

21 (1) An assessment of the differences in costs incurred  
22 by such enrollees and plans for prescription drugs dis-  
23 pensed by mail-order pharmacies owned by pharmaceutical  
24 benefit managers compared to mail-order pharmacies not  
25 owned by pharmaceutical benefit managers, and community  
26 pharmacies.

27 (2) Whether such plans are acting in a manner that  
28 maximizes competition and results in lower prescription  
29 drug prices for enrollees.

30 (b) REPORT.—Not later than 18 months after the date of  
31 the enactment of this Act, the Commission shall submit to Con-  
32 gress a report on the study conducted under subsection (a).  
33 Such report shall include recommendations regarding any need  
34 for legislation to ensure the fiscal integrity of the voluntary  
35 prescription drug benefit program under part D of title XVIII,  
36 as added by section 101, that may be appropriated as the re-  
37 sult of such study.

1 (c) EXEMPTION FROM PAPERWORK REDUCTION ACT.—  
2 Chapter 35 of title 44, United States Code, shall not apply to  
3 the collection of information under subsection (a).

4 **SEC. 111. STUDY ON EMPLOYMENT-BASED RETIREE**  
5 **HEALTH COVERAGE.**

6 (a) STUDY.—The Comptroller General of the United  
7 States shall conduct an initial and final study under this sub-  
8 section to examine trends in employment-based retiree health  
9 coverage (as defined in 1860D–22(e)(1) of the Social Security  
10 Act, as added by section 101), including coverage under the  
11 Federal Employees Health Benefits Program (FEHBP), and  
12 the options and incentives available under this Act which may  
13 have an effect on the voluntary provision of such coverage.

14 (b) CONTENT OF INITIAL STUDY.—The initial study under  
15 this section shall consider the following:

16 (1) Trends in employment-based retiree health cov-  
17 erage prior to the date of the enactment of this Act.

18 (2) The opinions of sponsors of employment-based re-  
19 tiree health coverage concerning which of the options avail-  
20 able under this Act they are most likely to utilize for the  
21 provision of health coverage to their medicare-eligible retir-  
22 ees, including an assessment of the administrative burdens  
23 associated with the available options.

24 (3) The likelihood of sponsors of employment-based re-  
25 tiree health coverage to maintain or adjust their levels of  
26 retiree health benefits beyond coordination with medicare,  
27 including for prescription drug coverage, provided to medi-  
28 care-eligible retirees after the date of the enactment of this  
29 Act.

30 (4) The factors that sponsors of employment-based re-  
31 tiree health coverage expect to consider in making decisions  
32 about any changes they may make in the health coverage  
33 provided to medicare-eligible retirees.

34 (5) Whether the prescription drug plan options avail-  
35 able, or the health plan options available under the Medi-  
36 care Advantage program, are likely to cause employers and  
37 other entities that did not provide health coverage to retir-

1           ees prior to the date of the enactment of this Act to provide  
2           supplemental coverage or contributions toward premium ex-  
3           penses for medicare-eligible retirees who may enroll in such  
4           options in the future.

5           (c) CONTENTS OF FINAL STUDY.—The final study under  
6 this section shall consider the following:

7           (1) Changes in the trends in employment-based retiree  
8           health coverage since the completion of the initial study by  
9           the Comptroller General.

10          (2) Factors contributing to any changes in coverage  
11          levels.

12          (3) The number and characteristics of sponsors of em-  
13          ployment-based retiree health coverage who receive the spe-  
14          cial subsidy payments under section 1860D–22 of the So-  
15          cial Security Act, as added by section 101, for the provision  
16          of prescription drug coverage to their medicare-eligible re-  
17          tirees that is the same or greater actuarial value as the  
18          prescription drug coverage available to other medicare  
19          beneficiaries without employment-based retiree health cov-  
20          erage.

21          (4) The extent to which sponsors of employment-based  
22          retiree health coverage provide supplemental health cov-  
23          erage or contribute to the premiums for medicare-eligible  
24          retirees who enroll in a prescription drug plan or an MA-  
25          PD plan.

26          (5) Other coverage options, including tax-preferred re-  
27          irement or health savings accounts, consumer-directed  
28          health plans, or other vehicles that sponsors of employ-  
29          ment-based retiree health coverage believe would assist re-  
30          tirees with their future health care needs and their willing-  
31          ness to sponsor such alternative plan designs.

32          (6) The extent to which employers or other entities  
33          that did not provide employment-based retiree health cov-  
34          erage prior to the date of the enactment of this Act pro-  
35          vided some form of coverage or financial assistance for re-  
36          tiree health care needs after the date of the enactment of  
37          this Act.

1           (7) Recommendations by employers, benefits experts,  
2           academics, and others on ways that the voluntary provision  
3           of employment-based retiree health coverage may be im-  
4           proved and expanded.

5           (d) REPORTS.—The Comptroller General shall submit a  
6           report to Congress on—

7           (1) the initial study under subsection (b) not later  
8           than 1 year after the date of the enactment of this Act;  
9           and

10          (2) the final study under subsection (c) not later than  
11          January 1, 2007.

12          (e) CONSULTATION.—The Comptroller General shall con-  
13          sult with sponsors of employment-based retiree health coverage,  
14          benefits experts, human resources professionals, employee bene-  
15          fits consultants, and academics with experience in health bene-  
16          fits and survey research in the development and design of the  
17          initial and final studies under this section.

18           **TITLE II—MEDICARE ADVANTAGE**  
19           **Subtitle A—Implementation of**  
20           **Medicare Advantage Program**

21           **SEC. 201. IMPLEMENTATION OF MEDICARE ADVANTAGE**  
22           **PROGRAM.**

23          (a) IN GENERAL.—There is hereby established the Medi-  
24          care Advantage program. The Medicare Advantage program  
25          shall consist of the program under part C of title XVIII of the  
26          Social Security Act (as amended by this Act).

27          (b) REFERENCES.—Subject to subsection (c), any ref-  
28          erence to the program under part C of title XVIII of the Social  
29          Security Act shall be deemed a reference to the Medicare Ad-  
30          vantage program and, with respect to such part, any reference  
31          to “Medicare+Choice” is deemed a reference to “Medicare Ad-  
32          vantage” and “MA”.

33          (c) TRANSITION.—In order to provide for an orderly tran-  
34          sition and avoid beneficiary and provider confusion, the Sec-  
35          retary shall provide for an appropriate transition in the use of  
36          the terms “Medicare+Choice” and “Medicare Advantage” (or  
37          “MA”) in reference to the program under part C of title XVIII

1 of the Social Security Act. Such transition shall be fully com-  
2 pleted for all materials for plan years beginning not later than  
3 January 1, 2006. Before the completion of such transition, any  
4 reference to “Medicare Advantage” or “MA” shall be deemed  
5 to include a reference to “Medicare+Choice”.

## 6 **Subtitle B—Immediate Improvements**

### 7 **SEC. 211. IMMEDIATE IMPROVEMENTS.**

8 (a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

9 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.  
10 1395w-23(c)(1)) is amended by adding at the end the fol-  
11 lowing:

12 “(D) 100 PERCENT OF FEE-FOR-SERVICE  
13 COSTS.—

14 “(i) IN GENERAL.—For each year specified in  
15 clause (ii), the adjusted average per capita cost for  
16 the year involved, determined under section  
17 1876(a)(4) and adjusted as appropriate for the  
18 purpose of risk adjustment, for the MA payment  
19 area for individuals who are not enrolled in an MA  
20 plan under this part for the year, but adjusted to  
21 exclude costs attributable to payments under sec-  
22 tion 1886(h).

23 “(ii) PERIODIC REBASING.—The provisions of  
24 clause (i) shall apply for 2004 and for subsequent  
25 years as the Secretary shall specify (but not less  
26 than once every 3 years).

27 “(iii) INCLUSION OF COSTS OF VA AND DOD  
28 MILITARY FACILITY SERVICES TO MEDICARE-ELIGI-  
29 BLE BENEFICIARIES.—In determining the adjusted  
30 average per capita cost under clause (i) for a year,  
31 such cost shall be adjusted to include the Sec-  
32 retary’s estimate, on a per capita basis, of the  
33 amount of additional payments that would have  
34 been made in the area involved under this title if  
35 individuals entitled to benefits under this title had  
36 not received services from facilities of the Depart-

1                   ment of Defense or the Department of Veterans  
2                   Affairs.”.

3                   (2) CONFORMING AMENDMENT.—Such section is fur-  
4                   ther amended, in the matter before subparagraph (A), by  
5                   striking “or (C)” and inserting “(C), or (D)”.

6                   (b) CHANGE IN BUDGET NEUTRALITY FOR BLEND.—Sec-  
7                   tion 1853(c) (42 U.S.C. 1395w-23(c)) is amended—

8                   (1) in paragraph (1)(A), by inserting “(for a year  
9                   other than 2004)” after “multiplied”; and

10                   (2) in paragraph (5), by inserting “(other than 2004)”  
11                   after “for each year”.

12                   (c) INCREASING MINIMUM PERCENTAGE INCREASE TO  
13                   NATIONAL GROWTH RATE.—

14                   (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.  
15                   1395w-23(c)(1)) is amended—

16                   (A) in subparagraph (A), by striking “The sum”  
17                   and inserting “For a year before 2005, the sum”;

18                   (B) in subparagraph (B)(iv), by striking “and  
19                   each succeeding year” and inserting “, 2003, and  
20                   2004”;

21                   (C) in subparagraph (C)(iv), by striking “and each  
22                   succeeding year” and inserting “and 2003”; and

23                   (D) by adding at the end of subparagraph (C) the  
24                   following new clause:

25                   “ (v) For 2004 and each succeeding year, the  
26                   greater of—

27                   “ (I) 102 percent of the annual MA capita-  
28                   tion rate under this paragraph for the area for  
29                   the previous year; or

30                   “ (II) the annual MA capitation rate under  
31                   this paragraph for the area for the previous  
32                   year increased by the national per capita MA  
33                   growth percentage, described in paragraph (6)  
34                   for that succeeding year, but not taking into  
35                   account any adjustment under paragraph  
36                   (6)(C) for a year before 2004.”.

1           (2)           CONFORMING           AMENDMENT.—Section  
2           1853(c)(6)(C) (42 U.S.C. 1395w-23(c)(6)(C)) is amended  
3           by inserting before the period at the end the following: “,  
4           except that for purposes of paragraph (1)(C)(v)(II), no  
5           such adjustment shall be made for a year before 2004”.

6           (d) INCLUSION OF COSTS OF DOD AND VA MILITARY FA-  
7           CILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN  
8           CALCULATION OF PAYMENT RATES.—Section 1853(c)(3) (42  
9           U.S.C. 1395w-23(c)(3)) is amended—

10           (1) in subparagraph (A), by striking “subparagraph  
11           (B)” and inserting “subparagraphs (B) and (E)”; and

12           (2) by adding at the end the following new subpara-  
13           graph:

14           “(E) INCLUSION OF COSTS OF DOD AND VA MILI-  
15           TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE  
16           BENEFICIARIES.—In determining the area-specific MA  
17           capitation rate under subparagraph (A) for a year (be-  
18           ginning with 2004), the annual per capita rate of pay-  
19           ment for 1997 determined under section 1876(a)(1)(C)  
20           shall be adjusted to include in the rate the Secretary’s  
21           estimate, on a per capita basis, of the amount of addi-  
22           tional payments that would have been made in the area  
23           involved under this title if individuals entitled to bene-  
24           fits under this title had not received services from fa-  
25           cilities of the Department of Defense or the Depart-  
26           ment of Veterans Affairs.”.

27           (e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT  
28           HOSPITAL STAYS TO REHABILITATION HOSPITALS AND LONG-  
29           TERM CARE HOSPITALS.—

30           (1) IN GENERAL.—Section 1853(g) (42 U.S.C.  
31           1395w-23(g)) is amended—

32           (A) in the matter preceding paragraph (1), by in-  
33           serting “, a rehabilitation hospital described in section  
34           1886(d)(1)(B)(ii) or a distinct part rehabilitation unit  
35           described in the matter following clause (v) of section  
36           1886(d)(1)(B), or a long-term care hospital (described



1 in section 1886(d)(1)(B)(iv))” after “1886(d)(1)(B))”;  
2 and

3 (B) in paragraph (2)(B), by inserting “or other  
4 payment provision under this title for inpatient services  
5 for the type of facility, hospital, or unit involved, de-  
6 scribed in the matter preceding paragraph (1), as the  
7 case may be,” after “1886(d)”.

8 (2) EFFECTIVE DATE.—The amendments made by  
9 paragraph (1) shall apply to contract years beginning on or  
10 after January 1, 2004.

11 (f) MEDPAC STUDY OF AAPCC.—

12 (1) STUDY.—The Medicare Payment Advisory Com-  
13 mission shall conduct a study that assesses the method  
14 used for determining the adjusted average per capita cost  
15 (AAPCC) under section 1876(a)(4) of the Social Security  
16 Act (42 U.S.C. 1395mm(a)(4)) as applied under section  
17 1853(c)(1)(A) of such Act (as amended by subsection (a)).  
18 Such study shall include an examination of—

19 (A) the bases for variation in such costs between  
20 different areas, including differences in input prices,  
21 utilization, and practice patterns;

22 (B) the appropriate geographic area for payment  
23 of MA local plans under the Medicare Advantage pro-  
24 gram under part C of title XVIII of such Act; and

25 (C) the accuracy of risk adjustment methods in re-  
26 flecting differences in costs of providing care to dif-  
27 ferent groups of beneficiaries served under such pro-  
28 gram.

29 (2) REPORT.—Not later than 18 months after the  
30 date of the enactment of this Act, the Commission shall  
31 submit to Congress a report on the study conducted under  
32 paragraph (1).

33 (g) REPORT ON IMPACT OF INCREASED FINANCIAL AS-  
34 SISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than  
35 July 1, 2006, the Secretary shall submit to Congress a report  
36 that describes the impact of additional financing provided  
37 under this Act and other Acts (including the Medicare, Med-

1    icaid, and SCHIP Balanced Budget Refinement Act of 1999  
2    and BIPA) on the availability of Medicare Advantage plans in  
3    different areas and its impact on lowering premiums and in-  
4    creasing benefits under such plans.

5           (h) MEDPAC STUDY AND REPORT ON CLARIFICATION OF  
6    AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE  
7    BENEFICIARY COST-SHARING.—

8           (1) STUDY.—The Medicare Payment Advisory Com-  
9    mission, in consultation with beneficiaries, consumer  
10   groups, employers, and organizations offering plans under  
11   part C of title XVIII of the Social Security Act, shall con-  
12   duct a study to determine the extent to which the cost-  
13   sharing structures under such plans affect access to cov-  
14   ered services or select enrollees based on the health status  
15   of eligible individuals described in section 1851(a)(3) of the  
16   Social Security Act (42 U.S.C. 1395w–21(a)(3)).

17           (2) REPORT.—Not later than December 31, 2004, the  
18   Commission shall submit a report to Congress on the study  
19   conducted under paragraph (1) together with recommenda-  
20   tions for such legislation and administrative actions as the  
21   Commission considers appropriate.

22           (i) IMPLEMENTATION OF PROVISIONS.—

23           (1) ANNOUNCEMENT OF REVISED MEDICARE ADVAN-  
24   TAGE PAYMENT RATES.—Within 6 weeks after the date of  
25   the enactment of this Act, the Secretary shall determine,  
26   and shall announce (in a manner intended to provide notice  
27   to interested parties) MA capitation rates under section  
28   1853 of the Social Security Act (42 U.S.C. 1395w–23) for  
29   2004, revised in accordance with the provisions of this sec-  
30   tion.

31           (2) TRANSITION TO REVISED PAYMENT RATES.—The  
32   provisions of section 604 of BIPA (114 Stat. 2763A–555)  
33   (other than subsection (a)) shall apply to the provisions of  
34   subsections (a) through (d) of this section for 2004 in the  
35   same manner as the provisions of such section 604 applied  
36   to the provisions of BIPA for 2001.

37           (3) SPECIAL RULE FOR PAYMENT RATES IN 2004.—

1 (A) JANUARY AND FEBRUARY.—Notwithstanding  
2 the amendments made by subsections (a) through (d),  
3 for purposes of making payments under section 1853  
4 of the Social Security Act (42 U.S.C. 1395w-23) for  
5 January and February 2004, the annual capitation  
6 rate for a payment area shall be calculated and the ex-  
7 cess amount under section 1854(f)(1)(B) of such Act  
8 (42 U.S.C. 1395w-24(f)(1)(B)) shall be determined as  
9 if such amendments had not been enacted.

10 (B) MARCH THROUGH DECEMBER.—Notwith-  
11 standing the amendments made by subsections (a)  
12 through (d), for purposes of making payments under  
13 section 1853 of the Social Security Act (42 U.S.C.  
14 1395w-23) for March through December 2004, the an-  
15 nual capitation rate for a payment area shall be cal-  
16 culated and the excess amount under section  
17 1854(f)(1)(B) of such Act (42 U.S.C. 1395w-  
18 24(f)(1)(B)) shall be determined, in such manner as  
19 the Secretary estimates will ensure that the total of  
20 such payments with respect to 2004 is the same as the  
21 amounts that would have been if subparagraph (A) had  
22 not been enacted.

23 (C) CONSTRUCTION.—Subparagraphs (A) and (B)  
24 shall not be taken into account in computing such capi-  
25 tation rate for 2005 and subsequent years.

26 (4) PLANS REQUIRED TO PROVIDE NOTICE OF  
27 CHANGES IN PLAN BENEFITS.—In the case of an organiza-  
28 tion offering a plan under part C of title XVIII of the So-  
29 cial Security Act that revises its submission of the informa-  
30 tion described in section 1854(a)(1) of such Act (42 U.S.C.  
31 1395w-23(a)(1)) for a plan pursuant to the application of  
32 paragraph (2), if such revision results in changes in bene-  
33 ficiary premiums, beneficiary cost-sharing, or benefits  
34 under the plan, then by not later than 3 weeks after the  
35 date the Secretary approves such submission, the organiza-  
36 tion offering the plan shall provide each beneficiary enrolled  
37 in the plan with written notice of such changes.

1 (5) LIMITATION ON REVIEW.—There shall be no ad-  
2 ministrative or judicial review under section 1869 or sec-  
3 tion 1878 of the Social Security Act (42 U.S.C. 1395ff and  
4 1395oo), or otherwise of any determination made by the  
5 Secretary under this subsection or the application of the  
6 payment rates determined pursuant to this subsection.

7 (j) ADDITIONAL AMENDMENTS.—Section 1852(d)(4) (42  
8 U.S.C. 1395w–22(d)(4)) is amended—

9 (1) in subparagraph (B), by inserting “(other than  
10 deemed contracts or agreements under subsection (j)(6))”  
11 after “the plan has contracts or agreements”; and

12 (2) in the last sentence, by inserting before the period  
13 at the end the following: “, except that, if a plan entirely  
14 meets such requirement with respect to a category of health  
15 care professional or provider on the basis of subparagraph  
16 (B), it may provide for a higher beneficiary copayment in  
17 the case of health care professionals and providers of that  
18 category who do not have contracts or agreements (other  
19 than deemed contracts or agreements under subsection  
20 (j)(6)) to provide covered services under the terms of the  
21 plan”.

## 22 **Subtitle C—Offering of Medicare Ad-** 23 **vantage (MA) Regional Plans; Medi-** 24 **care Advantage Competition**

### 25 **SEC. 221. ESTABLISHMENT OF MA REGIONAL PLANS.**

26 (a) OFFERING OF MA REGIONAL PLANS.—

27 (1) IN GENERAL.—Section 1851(a)(2)(A) is  
28 amended—

29 (A) by striking “COORDINATED CARE PLANS.—Co-  
30 ordinated” and inserting the following: “COORDINATED  
31 CARE PLANS (INCLUDING REGIONAL PLANS).—

32 “(i) IN GENERAL.—Coordinated”;

33 (B) by inserting “regional or local” before “pre-  
34 ferred provider organization plans”; and

35 (C) by inserting “ (including MA regional plans)”  
36 after “preferred provider organization plans”.

1 (2) MORATORIUM ON NEW LOCAL PREFERRED PRO-  
2 VIDER ORGANIZATION PLANS.—The Secretary shall not  
3 permit the offering of a local preferred provider organiza-  
4 tion plan under part C of title XVIII of the Social Security  
5 Act during 2006 or 2007 in a service area unless such plan  
6 was offered under such part (including under a demonstra-  
7 tion project under such part) in such area as of December  
8 31, 2005.

9 (b) DEFINITION OF MA REGIONAL PLAN; MA LOCAL  
10 PLAN.—

11 (1) IN GENERAL.—Section 1859(b) (42 U.S.C.  
12 1395w–29(b)) is amended by adding at the end the fol-  
13 lowing new paragraphs:

14 “(4) MA REGIONAL PLAN.—The term ‘MA regional  
15 plan’ means an MA plan described in section  
16 1851(a)(2)(A)(i)—

17 “(A) that has a network of providers that have  
18 agreed to a contractually specified reimbursement for  
19 covered benefits with the organization offering the plan;

20 “(B) that provides for reimbursement for all cov-  
21 ered benefits regardless of whether such benefits are  
22 provided within such network of providers; and

23 “(C) the service area of which is one or more en-  
24 tire MA regions.

25 “(5) MA LOCAL PLAN.—The term ‘MA local plan’  
26 means an MA plan that is not an MA regional plan.”.

27 (2) CONSTRUCTION.—Nothing in part C of title XVIII  
28 of the Social Security Act shall be construed as preventing  
29 an MSA plan or MA private fee-for-service plan from hav-  
30 ing a service area that covers one or more MA regions or  
31 the entire nation.

32 (c) RULES FOR MA REGIONAL PLANS.—Part C of title  
33 XVIII (42 U.S.C. 1395w–21 et seq.) is amended by inserting  
34 after section 1857 the following new section:

35 “SPECIAL RULES FOR MA REGIONAL PLANS

36 “SEC. 1858. (a) REGIONAL SERVICE AREA; ESTABLISH-  
37 MENT OF MA REGIONS.—

1           “(1) COVERAGE OF ENTIRE MA REGION.—The service  
2 area for an MA regional plan shall consist of an entire MA  
3 region established under paragraph (2) and the provisions  
4 of section 1854(h) shall not apply to such a plan.

5           “(2) ESTABLISHMENT OF MA REGIONS.—

6           “(A) MA REGION.—For purposes of this title, the  
7 term ‘MA region’ means such a region within the 50  
8 States and the District of Columbia as established by  
9 the Secretary under this paragraph.

10          “(B) ESTABLISHMENT.—

11          “(i) INITIAL ESTABLISHMENT.—Not later than  
12 January 1, 2005, the Secretary shall first establish  
13 and publish MA regions.

14          “(ii) PERIODIC REVIEW AND REVISION OF  
15 SERVICE AREAS.—The Secretary may periodically  
16 review MA regions under this paragraph and, based  
17 on such review, may revise such regions if the Sec-  
18 retary determines such revision to be appropriate.

19          “(C) REQUIREMENTS FOR MA REGIONS.—The Sec-  
20 retary shall establish, and may revise, MA regions  
21 under this paragraph in a manner consistent with the  
22 following:

23          “(i) NUMBER OF REGIONS.—There shall be no  
24 fewer than 10 regions, and no more than 50 re-  
25 gions.

26          “(ii) MAXIMIZING AVAILABILITY OF PLANS.—  
27 The regions shall maximize the availability of MA  
28 regional plans to all MA eligible individuals without  
29 regard to health status, especially those residing in  
30 rural areas.

31          “(D) MARKET SURVEY AND ANALYSIS.—Before  
32 establishing MA regions, the Secretary shall conduct a  
33 market survey and analysis, including an examination  
34 of current insurance markets, to determine how the re-  
35 gions should be established.

36          “(3) NATIONAL PLAN.—Nothing in this subsection  
37 shall be construed as preventing an MA regional plan from

1 being offered in more than one MA region (including all re-  
2 gions).

3 “(b) APPLICATION OF SINGLE DEDUCTIBLE AND CATA-  
4 STROPHIC LIMIT ON OUT-OF-POCKET EXPENSES.—An MA re-  
5 gional plan shall include the following:

6 “(1) SINGLE DEDUCTIBLE.—Any deductible for bene-  
7 fits under the original medicare fee-for-service program op-  
8 tion shall be a single deductible (instead of a separate inpa-  
9 tient hospital deductible and a part B deductible) and may  
10 be applied differentially for in-network services and may be  
11 waived for preventive or other items and services.

12 “(2) CATASTROPHIC LIMIT.—

13 “(A) IN-NETWORK.—A catastrophic limit on out-  
14 of-pocket expenditures for in-network benefits under  
15 the original medicare fee-for-service program option.

16 “(B) TOTAL.—A catastrophic limit on out-of-pock-  
17 et expenditures for all benefits under the original medi-  
18 care fee-for-service program option.

19 “(c) PORTION OF TOTAL PAYMENTS TO AN ORGANIZA-  
20 TION SUBJECT TO RISK FOR 2006 AND 2007.—

21 “(1) APPLICATION OF RISK CORRIDORS.—

22 “(A) IN GENERAL.—This subsection shall only  
23 apply to MA regional plans offered during 2006 or  
24 2007.

25 “(B) NOTIFICATION OF ALLOWABLE COSTS UNDER  
26 THE PLAN.—In the case of an MA organization that of-  
27 fers an MA regional plan in an MA region in 2006 or  
28 2007, the organization shall notify the Secretary, be-  
29 fore such date in the succeeding year as the Secretary  
30 specifies, of—

31 “(i) its total amount of costs that the organi-  
32 zation incurred in providing benefits covered under  
33 the original medicare fee-for-service program option  
34 for all enrollees under the plan in the region in the  
35 year and the portion of such costs that is attrib-  
36 utable to administrative expenses described in sub-  
37 paragraph (C); and

1           “(ii) its total amount of costs that the organi-  
2           zation incurred in providing rebatable integrated  
3           benefits (as defined in subparagraph (D)) and with  
4           respect to such benefits the portion of such costs  
5           that is attributable to administrative expenses de-  
6           scribed in subparagraph (C) and not described in  
7           clause (i) of this subparagraph.

8           “(C) ALLOWABLE COSTS DEFINED.—For purposes  
9           of this subsection, the term ‘allowable costs’ means,  
10          with respect to an MA regional plan for a year, the  
11          total amount of costs described in subparagraph (B)  
12          for the plan and year, reduced by the portion of such  
13          costs attributable to administrative expenses incurred  
14          in providing the benefits described in such subpara-  
15          graph.

16          “(D) REBATABLE INTEGRATED BENEFITS.—For  
17          purposes of this subsection, the term ‘rebatable inte-  
18          grated benefits’ means such non-drug supplemental  
19          benefits under subclause (I) of section  
20          1854(b)(1)(C)(ii) pursuant to a rebate under such sec-  
21          tion that the Secretary determines are integrated with  
22          the benefits described in subparagraph (B)(i).

23          “(2) ADJUSTMENT OF PAYMENT.—

24          “(A) NO ADJUSTMENT IF ALLOWABLE COSTS  
25          WITHIN 3 PERCENT OF TARGET AMOUNT.—If the allow-  
26          able costs for the plan for the year are at least 97 per-  
27          cent, but do not exceed 103 percent, of the target  
28          amount for the plan and year, there shall be no pay-  
29          ment adjustment under this subsection for the plan and  
30          year.

31          “(B) INCREASE IN PAYMENT IF ALLOWABLE  
32          COSTS ABOVE 103 PERCENT OF TARGET AMOUNT.—

33          “(i) COSTS BETWEEN 103 AND 108 PERCENT  
34          OF TARGET AMOUNT.—If the allowable costs for  
35          the plan for the year are greater than 103 percent,  
36          but not greater than 108 percent, of the target  
37          amount for the plan and year, the Secretary shall



1 increase the total of the monthly payments made to  
2 the organization offering the plan for the year  
3 under section 1853(a) by an amount equal to 50  
4 percent of the difference between such allowable  
5 costs and 103 percent of such target amount.

6 “(ii) COSTS ABOVE 108 PERCENT OF TARGET  
7 AMOUNT.—If the allowable costs for the plan for  
8 the year are greater than 108 percent of the target  
9 amount for the plan and year, the Secretary shall  
10 increase the total of the monthly payments made to  
11 the organization offering the plan for the year  
12 under section 1853(a) by an amount equal to the  
13 sum of—

14 “(I) 2.5 percent of such target amount;

15 and

16 “(II) 80 percent of the difference between  
17 such allowable costs and 108 percent of such  
18 target amount.

19 “(C) REDUCTION IN PAYMENT IF ALLOWABLE  
20 COSTS BELOW 97 PERCENT OF TARGET AMOUNT.—

21 “(i) COSTS BETWEEN 92 AND 97 PERCENT OF  
22 TARGET AMOUNT.—If the allowable costs for the  
23 plan for the year are less than 97 percent, but  
24 greater than or equal to 92 percent, of the target  
25 amount for the plan and year, the Secretary shall  
26 reduce the total of the monthly payments made to  
27 the organization offering the plan for the year  
28 under section 1853(a) by an amount (or otherwise  
29 recover from the plan an amount) equal to 50 per-  
30 cent of the difference between 97 percent of the  
31 target amount and such allowable costs.

32 “(ii) COSTS BELOW 92 PERCENT OF TARGET  
33 AMOUNT.—If the allowable costs for the plan for  
34 the year are less than 92 percent of the target  
35 amount for the plan and year, the Secretary shall  
36 reduce the total of the monthly payments made to  
37 the organization offering the plan for the year

1 under section 1853(a) by an amount (or otherwise  
2 recover from the plan an amount) equal to the sum  
3 of—

4 “(I) 2.5 percent of such target amount;

5 and

6 “(II) 80 percent of the difference between  
7 92 percent of such target amount and such al-  
8 lowable costs.

9 “(D) TARGET AMOUNT DESCRIBED.—For pur-  
10 poses of this paragraph, the term ‘target amount’  
11 means, with respect to an MA regional plan offered by  
12 an organization in a year, an amount equal to—

13 “(i) the sum of—

14 “(I) the total monthly payments made to  
15 the organization for enrollees in the plan for  
16 the year that are attributable to benefits under  
17 the original medicare fee-for-service program  
18 option (as defined in section 1852(a)(1)(B));

19 “(II) the total of the MA monthly basic  
20 beneficiary premium collectable for such enroll-  
21 ees for the year; and

22 “(III) the total amount of the rebates  
23 under section 1854(b)(1)(C)(ii) that are attrib-  
24 utable to rebatable integrated benefits; reduced  
25 by

26 “(ii) the amount of administrative expenses  
27 assumed in the bid insofar as the bid is attrib-  
28 utable to benefits described in clause (i)(I) or  
29 (i)(III).

30 “(3) DISCLOSURE OF INFORMATION.—

31 “(A) IN GENERAL.—Each contract under this part  
32 shall provide—

33 “(i) that an MA organization offering an MA  
34 regional plan shall provide the Secretary with such  
35 information as the Secretary determines is nec-  
36 essary to carry out this subsection; and

1                   “(ii) that, pursuant to section 1857(d)(2)(B),  
2                   the Secretary has the right to inspect and audit  
3                   any books and records of the organization that per-  
4                   tain to the information regarding costs provided to  
5                   the Secretary under paragraph (1)(B).

6                   “(B) RESTRICTION ON USE OF INFORMATION.—  
7                   Information disclosed or obtained pursuant to the pro-  
8                   visions of this subsection may be used by officers, em-  
9                   ployees, and contractors of the Department of Health  
10                  and Human Services only for the purposes of, and to  
11                  the extent necessary in, carrying out this subsection.

12                  “(d) ORGANIZATIONAL AND FINANCIAL REQUIRE-  
13                  MENTS.—

14                  “(1) IN GENERAL.—In the case of an MA organization  
15                  that is offering an MA regional plan in an MA region  
16                  and—

17                         “(A) meets the requirements of section 1855(a)(1)  
18                         with respect to at least one such State in such region;  
19                         and

20                         “(B) with respect to each other State in such re-  
21                         gion in which it does not meet requirements, it dem-  
22                         onstrates to the satisfaction of the Secretary that it has  
23                         filed the necessary application to meet such require-  
24                         ments,

25                  the Secretary may waive such requirement with respect to  
26                  each State described in subparagraph (B) for such period  
27                  of time as the Secretary determines appropriate for the  
28                  timely processing of such an application by the State (and,  
29                  if such application is denied, through the end of such plan  
30                  year as the Secretary determines appropriate to provide for  
31                  a transition).

32                  “(2) SELECTION OF APPROPRIATE STATE.—In apply-  
33                  ing paragraph (1) in the case of an MA organization that  
34                  meets the requirements of section 1855(a)(1) with respect  
35                  to more than one State in a region, the organization shall  
36                  select, in a manner specified by the Secretary among such

1 States, one State the rules of which shall apply in the case  
2 of the States described in paragraph (1)(B).

3 “(e) STABILIZATION FUND.—

4 “(1) ESTABLISHMENT.—The Secretary shall establish  
5 under this subsection an MA Regional Plan Stabilization  
6 Fund (in this subsection referred to as the ‘Fund’) which  
7 shall be available for 2 purposes:

8 “(A) PLAN ENTRY.—To provide incentives to have  
9 MA regional plans offered in each MA region under  
10 paragraph (3).

11 “(B) PLAN RETENTION.—To provide incentives to  
12 retain MA regional plans in certain MA regions with  
13 below-national-average MA market penetration under  
14 paragraph (4).

15 “(2) FUNDING.—

16 “(A) INITIAL FUNDING.—

17 “(i) IN GENERAL.—There shall be available to  
18 the Fund, for expenditures from the Fund during  
19 the period beginning on January 1, 2007, and end-  
20 ing on December 31, 2013, a total of  
21 \$10,000,000,000.

22 “(ii) PAYMENT FROM TRUST FUNDS.—Such  
23 amount shall be available to the Fund, as expendi-  
24 tures are made from the Fund, from the Federal  
25 Hospital Insurance Trust Fund and the Federal  
26 Supplementary Medical Insurance Trust Fund in  
27 the proportion specified in section 1853(f).

28 “(B) ADDITIONAL FUNDING FROM SAVINGS.—

29 “(i) IN GENERAL.—There shall also be made  
30 available to the Fund, 50 percent of savings de-  
31 scribed in clause (ii).

32 “(ii) SAVINGS.—The savings described in this  
33 clause are 25 percent of the average per capita sav-  
34 ings described in section 1854(b)(4)(C) for which  
35 monthly rebates are provided under section  
36 1854(b)(1)(C) in the fiscal year involved that are  
37 attributable to MA regional plans.

1           “(iii) AVAILABILITY.—Funds made available  
2           under this subparagraph shall be transferred into a  
3           special account in the Treasury from the Federal  
4           Hospital Insurance Trust Fund and the Federal  
5           Supplementary Medical Insurance Trust Fund in  
6           the proportion specified in section 1853(f) on a  
7           monthly basis.

8           “(C) OBLIGATIONS.—Amounts in the Fund shall  
9           be available in advance of appropriations to MA re-  
10          gional plans in qualifying MA regions only in accord-  
11          ance with paragraph (5).

12          “(D) ORDERING.—Expenditures from the Fund  
13          shall first be made from amounts made available under  
14          subparagraph (A).

15          “(3) PLAN ENTRY FUNDING.—

16          “(A) IN GENERAL.—Funding is available under  
17          this paragraph for a year only as follows:

18               “(i) NATIONAL PLAN.—For a national bonus  
19               payment described in subparagraph (B) for the of-  
20               fering by a single MA organization of an MA re-  
21               gional plan in each MA region in the year, but only  
22               if there was not such a plan offered in each such  
23               region in the previous year. Funding under this  
24               clause is only available with respect to any indi-  
25               vidual MA organization for a single year, but may  
26               be made available to more than one such organiza-  
27               tion in the same year.

28               “(ii) REGIONAL PLANS.—Subject to clause  
29               (iii), for an increased amount under subparagraph  
30               (C) for an MA regional plan offered in an MA re-  
31               gion which did not have any MA regional plan of-  
32               fered in the prior year.

33               “(iii) LIMITATION ON REGIONAL PLAN FUND-  
34               ING IN CASE OF NATIONAL PLAN.—In no case shall  
35               there be any payment adjustment under subpara-  
36               graph (C) for a year for which a national payment  
37               adjustment is made under subparagraph (B).

1                   “(B) NATIONAL BONUS PAYMENT.—The national  
2 bonus payment under this subparagraph shall—

3                   “(i) be available to an MA organization only if  
4 the organization offers MA regional plans in every  
5 MA region;

6                   “(ii) be available with respect to all MA re-  
7 gional plans of the organization regardless of  
8 whether any other MA regional plan is offered in  
9 any region; and

10                   “(iii) subject to amounts available under para-  
11 graph (5) for a year, be equal to 3 percent of the  
12 benchmark amount otherwise applicable for each  
13 MA regional plan offered by the organization.

14                   “(C) REGIONAL PAYMENT ADJUSTMENT.—

15                   “(i) IN GENERAL.—The increased amount  
16 under this subparagraph for an MA regional plan  
17 in an MA region for a year shall be an amount, de-  
18 termined by the Secretary, based on the bid sub-  
19 mitted for such plan (or plans) and shall be avail-  
20 able to all MA regional plans offered in such region  
21 and year. Such amount may be based on the mean,  
22 mode, or median, or other measure of such bids  
23 and may vary from region to region. The Secretary  
24 may not limit the number of plans or bids in a re-  
25 gion.

26                   “(ii) MULTI-YEAR FUNDING.—

27                   “(I) IN GENERAL.—Subject to amounts  
28 available under paragraph (5), funding under  
29 this subparagraph shall be available for a pe-  
30 riod determined by the Secretary.

31                   “(II) REPORT.—If the Secretary deter-  
32 mines that funding will be provided for a sec-  
33 ond consecutive year with respect to an MA re-  
34 gion, the Secretary shall submit to the Con-  
35 gress a report that describes the underlying  
36 market dynamics in the region and that in-  
37 cludes recommendations concerning changes in

1                   the payment methodology otherwise provided  
2                   for MA regional plans under this part.

3                   “(iii) APPLICATION TO ALL PLANS IN A RE-  
4                   GION.—Funding under this subparagraph with re-  
5                   spect to an MA region shall be made available with  
6                   respect to all MA regional plans offered in the re-  
7                   gion.

8                   “(iv) LIMITATION ON AVAILABILITY OF PLAN  
9                   RETENTION FUNDING IN NEXT YEAR.—If an in-  
10                  creased amount is made available under this sub-  
11                  paragraph with respect to an MA region for a pe-  
12                  riod determined by the Secretary under clause  
13                  (ii)(I), in no case shall funding be available under  
14                  paragraph (4) with respect to MA regional plans  
15                  offered in the region in the year following such pe-  
16                  riod.

17                  “(D) APPLICATION.—Any additional payment  
18                  under this paragraph provided for an MA regional plan  
19                  for a year shall be treated as if it were an addition to  
20                  the benchmark amount otherwise applicable to such  
21                  plan and year, but shall not be taken into account in  
22                  the computation of any benchmark amount for any  
23                  subsequent year.

24                  “(4) PLAN RETENTION FUNDING.—

25                  “(A) IN GENERAL.—Funding is available under  
26                  this paragraph for a year with respect to MA regional  
27                  plans offered in an MA region for the increased amount  
28                  specified in subparagraph (B) but only if the region  
29                  meets the requirements of subparagraphs (C) and (E).

30                  “(B) PAYMENT INCREASE.—The increased amount  
31                  under this subparagraph for an MA regional plan in an  
32                  MA region for a year shall be an amount, determined  
33                  by the Secretary, that does not exceed the greater of—

34                          “(i) 3 percent of the benchmark amount appli-  
35                          cable in the region; or

1           “(ii) such amount as (when added to the  
2 benchmark amount applicable to the region) will re-  
3 sult in the ratio of—

4           “(I) such additional amount plus the  
5 benchmark amount computed under section  
6 1854(b)(4)(B)(i) for the region and year, to the  
7 adjusted average per capita cost for the region  
8 and year, as estimated by the Secretary under  
9 section 1876(a)(4) and adjusted as appropriate  
10 for the purpose of risk adjustment; being equal  
11 to

12           “(II) the weighted average of such bench-  
13 mark amounts for all the regions and such  
14 year, to the average per capita cost for the  
15 United States and such year, as estimated by  
16 the Secretary under section 1876(a)(4) and ad-  
17 justed as appropriate for the purpose of risk  
18 adjustment.

19           “(C) REGIONAL REQUIREMENTS.—The require-  
20 ments of this subparagraph for an MA region for a  
21 year are as follows:

22           “(i) NOTIFICATION OF PLAN EXIT.—The Sec-  
23 retary has received notice (in such form and man-  
24 ner as the Secretary specifies) before a year that  
25 one or more MA regional plans that were offered  
26 in the region in the previous year will not be of-  
27 fered in the succeeding year.

28           “(ii) REGIONAL PLANS AVAILABLE FROM  
29 FEWER THAN 2 MA ORGANIZATIONS IN THE RE-  
30 GION.—The Secretary determines that if the plans  
31 referred to in clause (i) are not offered in the year,  
32 fewer than 2 MA organizations will be offering MA  
33 regional plans in the region in the year involved.

34           “(iii) PERCENTAGE ENROLLMENT IN MA RE-  
35 GIONAL PLANS BELOW NATIONAL AVERAGE.—For  
36 the previous year, the Secretary determines that  
37 the average percentage of MA eligible individuals



1           residing in the region who are enrolled in MA re-  
2           gional plans is less than the average percentage of  
3           such individuals in the United States enrolled in  
4           such plans.

5           “(D) APPLICATION.—Any additional payment  
6           under this paragraph provided for an MA regional plan  
7           for a year shall be treated as if it were an addition to  
8           the benchmark amount otherwise applicable to such  
9           plan and year, but shall not be taken into account in  
10          the computation of any benchmark amount for any  
11          subsequent year.

12          “(E) 2-CONSECUTIVE-YEAR LIMITATION.—

13           “(i) IN GENERAL.—In no case shall any fund-  
14           ing be available under this paragraph in an MA re-  
15           gion in a period of consecutive years that exceeds  
16           2 years.

17           “(ii) REPORT.—If the Secretary determines  
18           that funding will be provided under this paragraph  
19           for a second consecutive year with respect to an  
20           MA region, the Secretary shall submit to the Con-  
21           gress a report that describes the underlying market  
22           dynamics in the region and that includes rec-  
23           ommendations concerning changes in the payment  
24           methodology otherwise provided for MA regional  
25           plans under this part.

26          “(5) FUNDING LIMITATION.—

27           “(A) IN GENERAL.—The total amount expended  
28           from the Fund as a result of the application of this  
29           subsection through the end of a calendar year may not  
30           exceed the amount available to the Fund as of the first  
31           day of such year. For purposes of this subsection,  
32           amounts that are expended under this title insofar as  
33           such amounts would not have been expended but for  
34           the application of this subsection shall be counted as  
35           amounts expended as a result of such application.

36           “(B) APPLICATION OF LIMITATION.—The Sec-  
37           retary may obligate funds from the Fund for a year

1           only if the Secretary determines (and the Chief Actuary  
2           of the Centers for Medicare & Medicaid Services and  
3           the appropriate budget officer certify) that there are  
4           available in the Fund at the beginning of the year suf-  
5           ficient amounts to cover all such obligations incurred  
6           during the year consistent with subparagraph (A). The  
7           Secretary shall take such steps, in connection with  
8           computing additional payment amounts under para-  
9           graphs (3) and (4) and including limitations on enroll-  
10          ment in MA regional plans receiving such payments, as  
11          will ensure that sufficient funds are available to make  
12          such payments for the entire year. Funds shall only be  
13          made available from the Fund pursuant to an appor-  
14          tionment made in accordance with applicable proce-  
15          dures.

16          “(6) SECRETARY REPORTS.—Not later than April 1 of  
17          each year (beginning in 2008), the Secretary shall submit  
18          a report to Congress and the Comptroller General of the  
19          United States that includes—

20                 “(A) a detailed description of—

21                         “(i) the total amount expended as a result of  
22                         the application of this subsection in the previous  
23                         year compared to the total amount that would have  
24                         been expended under this title in the year if this  
25                         subsection had not been enacted;

26                         “(ii) the projections of the total amount that  
27                         will be expended as a result of the application of  
28                         this subsection in the year in which the report is  
29                         submitted compared to the total amount that would  
30                         have been expended under this title in the year if  
31                         this subsection had not been enacted;

32                         “(iii) amounts remaining within the funding  
33                         limitation specified in paragraph (5); and

34                         “(iv) the steps that the Secretary will take  
35                         under paragraph (5)(B) to ensure that the applica-  
36                         tion of this subsection will not cause expenditures  
37                         to exceed the amount available in the Fund; and

1           “(B) a certification from the Chief Actuary of the  
2           Centers for Medicare & Medicaid Services that the de-  
3           scription provided under subparagraph (A) is reason-  
4           able, accurate, and based on generally accepted actu-  
5           arial principles and methodologies.

6           “(7) BIENNIAL GAO REPORTS.—Not later than Janu-  
7           ary 1 of 2009, 2011, 2013, and 2015, the Comptroller  
8           General of the United States shall submit to the Secretary  
9           and Congress a report on the application of additional pay-  
10          ments under this subsection. Each report shall include—

11           “(A) an evaluation of—

12           “(i) the quality of care provided to individuals  
13           enrolled in MA regional plans for which additional  
14           payments were made under this subsection;

15           “(ii) the satisfaction of such individuals with  
16           benefits under such a plan;

17           “(iii) the costs to the medicare program for  
18           payments made to such plans; and

19           “(iv) any improvements in the delivery of  
20           health care services under such a plan;

21           “(B) a comparative analysis of the performance of  
22           MA regional plans receiving payments under this sub-  
23           section with MA regional plans not receiving such pay-  
24           ments; and

25           “(C) recommendations for such legislation or ad-  
26           ministrative action as the Comptroller General deter-  
27           mines to be appropriate.

28           “(f) COMPUTATION OF APPLICABLE MA REGION-SPECIFIC  
29          NON-DRUG MONTHLY BENCHMARK AMOUNTS.—

30           “(1) COMPUTATION FOR REGIONS.—For purposes of  
31           section 1853(j)(2) and this section, subject to subsection  
32           (e), the term ‘MA region-specific non-drug monthly bench-  
33           mark amount’ means, with respect to an MA region for a  
34           month in a year, the sum of the 2 components described  
35           in paragraph (2) for the region and year. The Secretary  
36           shall compute such benchmark amount for each MA region  
37           before the beginning of each annual, coordinated election

1 period under section 1851(e)(3)(B) for each year (begin-  
2 ning with 2006).

3 “(2) 2 COMPONENTS.—For purposes of paragraph (1),  
4 the 2 components described in this paragraph for an MA  
5 region and a year are the following:

6 “(A) STATUTORY COMPONENT.—The product of  
7 the following:

8 “(i) STATUTORY REGION-SPECIFIC NON-DRUG  
9 AMOUNT.—The statutory region-specific non-drug  
10 amount (as defined in paragraph (3)) for the re-  
11 gion and year.

12 “(ii) STATUTORY NATIONAL MARKET  
13 SHARE.—The statutory national market share per-  
14 centage, determined under paragraph (4) for the  
15 year.

16 “(B) PLAN-BID COMPONENT.—The product of the  
17 following:

18 “(i) WEIGHTED AVERAGE OF MA PLAN BIDS  
19 IN REGION.—The weighted average of the plan bids  
20 for the region and year (as determined under para-  
21 graph (5)(A)).

22 “(ii) NON-STATUTORY MARKET SHARE.—1  
23 minus the statutory national market share percent-  
24 age, determined under paragraph (4) for the year.

25 “(3) STATUTORY REGION-SPECIFIC NON-DRUG  
26 AMOUNT.—For purposes of paragraph (2)(A)(i), the term  
27 ‘statutory region-specific non-drug amount’ means, for an  
28 MA region and year, an amount equal the sum (for each  
29 MA local area within the region) of the product of—

30 “(A) MA area-specific non-drug monthly bench-  
31 mark amount under section 1853(j)(1)(A) for that area  
32 and year; and

33 “(B) the number of MA eligible individuals resid-  
34 ing in the local area, divided by the total number of  
35 MA eligible individuals residing in the region.

36 “(4) COMPUTATION OF STATUTORY MARKET SHARE  
37 PERCENTAGE.—

1           “(A) IN GENERAL.—The Secretary shall determine  
2 for each year a statutory national market share per-  
3 centage that is equal to the proportion of MA eligible  
4 individuals nationally who were not enrolled in an MA  
5 plan during the reference month.

6           “(B) REFERENCE MONTH DEFINED.—For pur-  
7 poses of this part, the term ‘reference month’ means,  
8 with respect to a year, the most recent month during  
9 the previous year for which the Secretary determines  
10 that data are available to compute the percentage spec-  
11 ified in subparagraph (A) and other relevant percent-  
12 ages under this part.

13           “(5) DETERMINATION OF WEIGHTED AVERAGE MA  
14 BIDS FOR A REGION.—

15           “(A) IN GENERAL.—For purposes of paragraph  
16 (2)(B)(i), the weighted average of plan bids for an MA  
17 region and a year is the sum, for MA regional plans  
18 described in subparagraph (D) in the region and year,  
19 of the products (for each such plan) of the following:

20           “(i) MONTHLY MA STATUTORY NON-DRUG BID  
21 AMOUNT.—The unadjusted MA statutory non-drug  
22 monthly bid amount for the plan.

23           “(ii) PLAN’S SHARE OF MA ENROLLMENT IN  
24 REGION.—The factor described in subparagraph  
25 (B) for the plan.

26           “(B) PLAN’S SHARE OF MA ENROLLMENT IN RE-  
27 GION.—

28           “(i) IN GENERAL.—Subject to the succeeding  
29 provisions of this subparagraph, the factor de-  
30 scribed in this subparagraph for a plan is equal to  
31 the number of individuals described in subpara-  
32 graph (C) for such plan, divided by the total num-  
33 ber of such individuals for all MA regional plans  
34 described in subparagraph (D) for that region and  
35 year.

36           “(ii) SINGLE PLAN RULE.—In the case of an  
37 MA region in which only a single MA regional plan

1 is being offered, the factor described in this sub-  
2 paragraph shall be equal to 1.

3 “(iii) EQUAL DIVISION AMONG MULTIPLE  
4 PLANS IN YEAR IN WHICH PLANS ARE FIRST AVAIL-  
5 ABLE.—In the case of an MA region in the first  
6 year in which any MA regional plan is offered, if  
7 more than one MA regional plan is offered in such  
8 year, the factor described in this subparagraph for  
9 a plan shall (as specified by the Secretary) be equal  
10 to—

11 “(I) 1 divided by the number of such plans  
12 offered in such year; or

13 “(II) a factor for such plan that is based  
14 upon the organization’s estimate of projected  
15 enrollment, as reviewed and adjusted by the  
16 Secretary to ensure reasonableness and as is  
17 certified by the Chief Actuary of the Centers  
18 for Medicare & Medicaid Services.

19 “(C) COUNTING OF INDIVIDUALS.—For purposes  
20 of subparagraph (B)(i), the Secretary shall count for  
21 each MA regional plan described in subparagraph (D)  
22 for an MA region and year, the number of individuals  
23 who reside in the region and who were enrolled under  
24 such plan under this part during the reference month.

25 “(D) PLANS COVERED.—For an MA region and  
26 year, an MA regional plan described in this subpara-  
27 graph is an MA regional plan that is offered in the re-  
28 gion and year and was offered in the region in the ref-  
29 erence month.

30 “(g) ELECTION OF UNIFORM COVERAGE DETERMINA-  
31 TION.—Instead of applying section 1852(a)(2)(C) with respect  
32 to an MA regional plan, the organization offering the plan may  
33 elect to have a local coverage determination for the entire MA  
34 region be the local coverage determination applied for any part  
35 of such region (as selected by the organization).

36 “(h) ASSURING NETWORK ADEQUACY.—

1           “(1) IN GENERAL.—For purposes of enabling MA or-  
2           ganizations that offer MA regional plans to meet applicable  
3           provider access requirements under section 1852 with re-  
4           spect to such plans, the Secretary may provide for payment  
5           under this section to an essential hospital that provides in-  
6           patient hospital services to enrollees in such a plan where  
7           the MA organization offering the plan certifies to the Sec-  
8           retary that the organization was unable to reach an agree-  
9           ment between the hospital and the organization regarding  
10          provision of such services under the plan. Such payment  
11          shall be available only if—

12                 “(A) the organization provides assurances satisfac-  
13                 tory to the Secretary that the organization will make  
14                 payment to the hospital for inpatient hospital services  
15                 of an amount that is not less than the amount that  
16                 would be payable to the hospital under section 1886  
17                 with respect to such services; and

18                 “(B) with respect to specific inpatient hospital  
19                 services provided to an enrollee, the hospital dem-  
20                 onstrates to the satisfaction of the Secretary that the  
21                 hospital’s costs of such services exceed the payment  
22                 amount described in subparagraph (A).

23          “(2) PAYMENT AMOUNTS.—The payment amount  
24          under this subsection for inpatient hospital services pro-  
25          vided by a subsection (d) hospital to an enrollee in an MA  
26          regional plan shall be, subject to the limitation of funds  
27          under paragraph (3), the amount (if any) by which—

28                 “(A) the amount of payment that would have been  
29                 paid for such services under this title if the enrollees  
30                 were covered under the original medicare fee-for-service  
31                 program option and the hospital were a critical access  
32                 hospital; exceeds

33                 “(B) the amount of payment made for such serv-  
34                 ices under paragraph (1)(A).

35          “(3) AVAILABLE AMOUNTS.—There shall be available  
36          for payments under this subsection—

37                 “(A) in 2006, \$25,000,000; and

1           “(B) in each succeeding year the amount specified  
2           in this paragraph for the preceding year increased by  
3           the market basket percentage increase (as defined in  
4           section 1886(b)(3)(B)(iii)) for the fiscal year ending in  
5           such succeeding year.

6           Payments under this subsection shall be made from the  
7           Federal Hospital Insurance Trust Fund.

8           “(4) ESSENTIAL HOSPITAL.—In this subsection, the  
9           term ‘essential hospital’ means, with respect to an MA re-  
10          gional plan offered by an MA organization, a subsection (d)  
11          hospital (as defined in section 1886(d)) that the Secretary  
12          determines, based upon an application filed by the organi-  
13          zation with the Secretary, is necessary to meet the require-  
14          ments referred to in paragraph (1) for such plan.”.

15          (d) CONFORMING AMENDMENTS.—

16                 (1) RELATING TO MA REGIONS.—Section 1853(d) (42  
17          U.S.C. 1395w-23(d)) is amended—

18                         (A) by amending the heading to read as follows:  
19                         “MA PAYMENT AREA; MA LOCAL AREA; MA REGION  
20                         DEFINED”;

21                         (B) by redesignating paragraphs (2) and (3) as  
22                         paragraphs (3) and (4), respectively;

23                         (C) by amending paragraph (1) to read as follows:

24                                 “(1) MA PAYMENT AREA.—In this part, except as pro-  
25                                 vided in this subsection, the term ‘MA payment area’  
26                                 means—

27   “(A) with respect to an MA local plan, an MA  
28   local area (as defined in paragraph (2)); and

29   “(B) with respect to an MA regional plan, an MA  
30   region (as established under section 1858(a)(2)).”;

31                                 (D) by inserting after paragraph (1) the following  
32                                 new paragraph:

33   “(2) MA LOCAL AREA.—The term ‘MA local area’  
34   means a county or equivalent area specified by the Sec-  
35   retary.”; and

36                                 (E) in paragraph (4), as so redesignated—



1 (i) in subparagraph (A), by inserting “for MA  
2 local plans” after “paragraph (1)”;

3 (ii) in subparagraph (A)(iii), by striking  
4 “paragraph (1)” and inserting “paragraph (1)(A)”;  
5 and

6 (iii) in subparagraph (B)—

7 (I) by inserting “with respect to MA local  
8 plans” after “established under this section”;

9 (II) by inserting “for such plans” after  
10 “payments under this section”; and

11 (III) by inserting “for such plans” after  
12 “made under this section”.

13 (2) MA LOCAL AREA DEFINED.—Section 1859(c) (42  
14 U.S.C. 1395w-29(c)) is amended by adding at the end the  
15 following:

16 “(5) MA LOCAL AREA.—The term ‘MA local area’ is  
17 defined in section 1853(d)(2).”.

18 (3) APPLICATION OF SPECIAL BENEFIT RULES TO  
19 PPOS AND REGIONAL PLANS.—Section 1852(a) (42 U.S.C.  
20 1395w-22(a)) is amended—

21 (A) in paragraph (1), by inserting “and except as  
22 provided in paragraph (6) for MA regional plans” after  
23 “MSA plans”; and

24 (B) by adding at the end the following new para-  
25 graph:

26 “(6) SPECIAL BENEFIT RULES FOR REGIONAL  
27 PLANS.—In the case of an MA plan that is an MA regional  
28 plan, benefits under the plan shall include the benefits de-  
29 scribed in paragraphs (1) and (2) of section 1858(b).”.

30 (4) APPLICATION OF CAPITATION RATES TO LOCAL  
31 AREAS.—Section 1853(c)(1) (42 U.S.C. 1395w-23(c)(1)) is  
32 amended by inserting “that is an MA local area” after “for  
33 a Medicare+Choice payment area”.

34 (5) NETWORK ADEQUACY HOSPITAL PAYMENTS.—Sec-  
35 tion 1851(i)(2) (42 U.S.C. 1395w-21(i)(2)) is amended by  
36 inserting “1858(h),” after “1857(f)(2),”.

1     **SEC. 222. COMPETITION PROGRAM BEGINNING IN 2006.**

2             (a) SUBMISSION OF BIDDING AND REBATE INFORMATION  
3 BEGINNING IN 2006.—

4             (1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w–  
5 24) is amended—

6             (A) by amending paragraph (1) of subsection (a)  
7 to read as follows:

8             “(1) IN GENERAL.—

9             “(A) INITIAL SUBMISSION.—Not later than the  
10 second Monday in September of 2002, 2003, and 2004  
11 (or the first Monday in June of each subsequent year),  
12 each MA organization shall submit to the Secretary, in  
13 a form and manner specified by the Secretary and for  
14 each MA plan for the service area (or segment of such  
15 an area if permitted under subsection (h)) in which it  
16 intends to be offered in the following year the fol-  
17 lowing:

18             “(i) The information described in paragraph  
19 (2), (3), (4), or (6)(A) for the type of plan and  
20 year involved.

21             “(ii) The plan type for each plan.

22             “(iii) The enrollment capacity (if any) in rela-  
23 tion to the plan and area.

24             “(B) BENEFICIARY REBATE INFORMATION.—In  
25 the case of a plan required to provide a monthly rebate  
26 under subsection (b)(1)(C) for a year, the MA organi-  
27 zation offering the plan shall submit to the Secretary,  
28 in such form and manner and at such time as the Sec-  
29 retary specifies, information on—

30             “(i) the manner in which such rebate will be  
31 provided under clause (ii) of such subsection; and

32             “(ii) the MA monthly prescription drug bene-  
33 ficiary premium (if any) and the MA monthly sup-  
34 plemental beneficiary premium (if any).

35             “(C) PAPERWORK REDUCTION FOR OFFERING OF  
36 MA REGIONAL PLANS NATIONALLY OR IN MULTI-RE-  
37 GION AREAS.—The Secretary shall establish require-

1           ments for information submission under this subsection  
2           in a manner that promotes the offering of MA regional  
3           plans in more than one region (including all regions)  
4           through the filing of consolidated information.”; and

5           (B) by adding at the end of subsection (a) the fol-  
6           lowing:

7           “(6) SUBMISSION OF BID AMOUNTS BY MA ORGANIZA-  
8           TIONS BEGINNING IN 2006.—

9           “(A) INFORMATION TO BE SUBMITTED.—For an  
10          MA plan (other than an MSA plan) for a plan year be-  
11          ginning on or after January 1, 2006, the information  
12          described in this subparagraph is as follows:

13          “(i) The monthly aggregate bid amount for  
14          the provision of all items and services under the  
15          plan, which amount shall be based on average rev-  
16          enue requirements (as used for purposes of section  
17          1302(8) of the Public Health Service Act) in the  
18          payment area for an enrollee with a national aver-  
19          age risk profile for the factors described in section  
20          1853(a)(1)(C) (as specified by the Secretary).

21          “(ii) The proportions of such bid amount that  
22          are attributable to—

23                  “(I) the provision of benefits under the  
24                  original medicare fee-for-service program option  
25                  (as defined in section 1852(a)(1)(B));

26                  “(II) the provision of basic prescription  
27                  drug coverage; and

28                  “(III) the provision of supplemental health  
29                  care benefits.

30          “(iii) The actuarial basis for determining the  
31          amount under clause (i) and the proportions de-  
32          scribed in clause (ii) and such additional informa-  
33          tion as the Secretary may require to verify such ac-  
34          tuarial bases and the projected number of enrollees  
35          in each MA local area.

36          “(iv) A description of deductibles, coinsurance,  
37          and copayments applicable under the plan and the

1           actuarial value of such deductibles, coinsurance,  
2           and copayments, described in subsection (e)(4)(A).

3           “(v) With respect to qualified prescription  
4           drug coverage, the information required under sec-  
5           tion 1860D–4, as incorporated under section  
6           1860D–11(b)(2), with respect to such coverage.

7           In the case of a specialized MA plan for special needs  
8           individuals, the information described in this subpara-  
9           graph is such information as the Secretary shall speci-  
10          fy.

11          “(B) ACCEPTANCE AND NEGOTIATION OF BID  
12          AMOUNTS.—

13           “(i) AUTHORITY.—Subject to clauses (iii) and  
14           (iv), the Secretary has the authority to negotiate  
15           regarding monthly bid amounts submitted under  
16           subparagraph (A) (and the proportions described in  
17           subparagraph (A)(ii)), including supplemental ben-  
18           efits provided under subsection (b)(1)(C)(ii)(I) and  
19           in exercising such authority the Secretary shall  
20           have authority similar to the authority of the Di-  
21           rector of the Office of Personnel Management with  
22           respect to health benefits plans under chapter 89  
23           of title 5, United States Code.

24           “(ii) APPLICATION OF FEHBP STANDARD.—  
25           Subject to clause (iv), the Secretary may only ac-  
26           cept such a bid amount or proportion if the Sec-  
27           retary determines that such amount and propor-  
28           tions are supported by the actuarial bases provided  
29           under subparagraph (A) and reasonably and equi-  
30           tably reflects the revenue requirements (as used for  
31           purposes of section 1302(8) of the Public Health  
32           Service Act) of benefits provided under that plan.

33           “(iii) NONINTERFERENCE.—In order to pro-  
34           mote competition under this part and part D and  
35           in carrying out such parts, the Secretary may not  
36           require any MA organization to contract with a  
37           particular hospital, physician, or other entity or in-

1           dividual to furnish items and services under this  
2           title or require a particular price structure for pay-  
3           ment under such a contract to the extent consistent  
4           with the Secretary's authority under this part.

5           “(iv) EXCEPTION.—In the case of a plan de-  
6           scribed in section 1851(a)(2)(C), the provisions of  
7           clauses (i) and (ii) shall not apply and the provi-  
8           sions of paragraph (5)(B), prohibiting the review,  
9           approval, or disapproval of amounts described in  
10          such paragraph, shall apply to the negotiation and  
11          rejection of the monthly bid amounts and the pro-  
12          portions referred to in subparagraph (A).”.

13          (2) DEFINITION OF BENEFITS UNDER THE ORIGINAL  
14          MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—Section  
15          1852(a)(1) (42 U.S.C. 1395w-22(a)(1)) is amended—

16                 (A) by striking “IN GENERAL.—Except” and in-  
17                 serting “REQUIREMENT.—

18                         “(A) IN GENERAL.—Except”; and

19                 (B) by striking “title XI” and all that follows and  
20                 inserting the following: “title XI, benefits under the  
21                 original medicare fee-for-service program option (and,  
22                 for plan years before 2006, additional benefits required  
23                 under section 1854(f)(1)(A)).

24                 “(B) BENEFITS UNDER THE ORIGINAL MEDICARE  
25                 FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—

26                         “(i) IN GENERAL.—For purposes of this part,  
27                         the term ‘benefits under the original medicare fee-  
28                         for-service program option’ means those items and  
29                         services (other than hospice care) for which bene-  
30                         fits are available under parts A and B to individ-  
31                         uals entitled to benefits under part A and enrolled  
32                         under part B, with cost-sharing for those services  
33                         as required under parts A and B or an actuarially  
34                         equivalent level of cost-sharing as determined in  
35                         this part.

36                         “(ii) SPECIAL RULE FOR REGIONAL PLANS.—  
37                         In the case of an MA regional plan in determining

1 an actuarially equivalent level of cost-sharing with  
2 respect to benefits under the original medicare fee-  
3 for-service program option, there shall only be  
4 taken into account, with respect to the application  
5 of section 1858(b)(2), such expenses only with re-  
6 spect to subparagraph (A) of such section.”.

7 (3) CONFORMING AMENDMENT RELATING TO SUPPLE-  
8 MENTAL HEALTH BENEFITS.—Section 1852(a)(3) (42  
9 U.S.C. 1395w–22(a)(3)) is amended by adding at the end  
10 the following: “Such benefits may include reductions in  
11 cost-sharing below the actuarial value specified in section  
12 1854(e)(4)(B).”.

13 (b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN  
14 PLANS.—

15 (1) BENEFICIARY REBATES.—Section 1854(b)(1) (42  
16 U.S.C. 1395w–24(b)(1)) is amended—

17 (A) in subparagraph (A), by striking “The month-  
18 ly amount” and inserting “Subject to the rebate under  
19 subparagraph (C), the monthly amount (if any)”; and

20 (B) by adding at the end the following new sub-  
21 paragraph:

22 “(C) BENEFICIARY REBATE RULE.—

23 “(i) REQUIREMENT.—The MA plan shall pro-  
24 vide to the enrollee a monthly rebate equal to 75  
25 percent of the average per capita savings (if any)  
26 described in paragraph (3)(C) or (4)(C), as appli-  
27 cable to the plan and year involved.

28 “(ii) FORM OF REBATE.—A rebate required  
29 under this subparagraph shall be provided through  
30 the application of the amount of the rebate toward  
31 one or more of the following:

32 “(I) PROVISION OF SUPPLEMENTAL  
33 HEALTH CARE BENEFITS AND PAYMENT FOR  
34 PREMIUM FOR SUPPLEMENTAL BENEFITS.—  
35 The provision of supplemental health care ben-  
36 efits described in section 1852(a)(3) in a man-  
37 ner specified under the plan, which may include

1 the reduction of cost-sharing otherwise applica-  
2 ble as well as additional health care benefits  
3 which are not benefits under the original medi-  
4 care fee-for-service program option, or crediting  
5 toward an MA monthly supplemental bene-  
6 ficiary premium (if any).

7 “(II) PAYMENT FOR PREMIUM FOR PRE-  
8 SCRIPTIION DRUG COVERAGE.—Crediting to-  
9 ward the MA monthly prescription drug bene-  
10 ficiary premium.

11 “(III) PAYMENT TOWARD PART B PRE-  
12 MIUM.—Crediting toward the premium imposed  
13 under part B (determined without regard to  
14 the application of subsections (b), (h), and (i)  
15 of section 1839).

16 “(iii) DISCLOSURE RELATING TO REBATES.—  
17 The plan shall disclose to the Secretary information  
18 on the form and amount of the rebate provided  
19 under this subparagraph or the actuarial value in  
20 the case of supplemental health care benefits.

21 “(iv) APPLICATION OF PART B PREMIUM RE-  
22 DUCTIION.—Insofar as an MA organization elects to  
23 provide a rebate under this subparagraph under a  
24 plan as a credit toward the part B premium under  
25 clause (ii)(III), the Secretary shall apply such cred-  
26 it to reduce the premium under section 1839 of  
27 each enrollee in such plan as provided in section  
28 1840(i).”.

29 (2) REVISION OF PREMIUM TERMINOLOGY.—Section  
30 1854(b)(2) (42 U.S.C. 1395w-24(b)(2)) is amended—

31 (A) in the heading, by inserting “AND BID” after  
32 “PREMIUM”;

33 (B) by redesignating subparagraph (C) as sub-  
34 paragraph (D);

35 (C) by striking subparagraphs (A) and (B) and in-  
36 serting the following:

1           “(A) MA MONTHLY BASIC BENEFICIARY PRE-  
2 MIUM.—The term ‘MA monthly basic beneficiary pre-  
3 mium’ means, with respect to an MA plan—

4           “(i) described in section 1853(a)(1)(B)(i) (re-  
5 lating to plans providing rebates), zero; or

6           “(ii) described in section 1853(a)(1)(B)(ii),  
7 the amount (if any) by which the unadjusted MA  
8 statutory non-drug monthly bid amount (as defined  
9 in subparagraph (E)) exceeds the applicable  
10 unadjusted MA area-specific non-drug monthly  
11 benchmark amount (as defined in section 1853(j)).

12           “(B) MA MONTHLY PRESCRIPTION DRUG BENE-  
13 FICIARY PREMIUM.—The term ‘MA monthly prescrip-  
14 tion drug beneficiary premium’ means, with respect to  
15 an MA plan, the base beneficiary premium (as deter-  
16 mined under section 1860D–13(a)(2) and as adjusted  
17 under section 1860D–13(a)(1)(B)), less the amount of  
18 rebate credited toward such amount under section  
19 1854(b)(1)(C)(ii)(II).

20           “(C) MA MONTHLY SUPPLEMENTAL BENEFICIARY  
21 PREMIUM.—The term ‘MA monthly supplemental bene-  
22 ficiary premium’ means, with respect to an MA plan,  
23 the portion of the aggregate monthly bid amount sub-  
24 mitted under clause (i) of subsection (a)(6)(A) for the  
25 year that is attributable under clause (ii)(III) of such  
26 subsection to the provision of supplemental health care  
27 benefits, less the amount of rebate credited toward  
28 such portion under section 1854(b)(1)(C)(ii)(I).”;

29           (D) by adding at the end the following:

30           “(E) UNADJUSTED MA STATUTORY NON-DRUG  
31 MONTHLY BID AMOUNT.—The term ‘unadjusted MA  
32 statutory non-drug monthly bid amount’ means the  
33 portion of the bid amount submitted under clause (i)  
34 of subsection (a)(6)(A) for the year that is attributable  
35 under clause (ii)(I) of such subsection to the provision  
36 of benefits under the original medicare fee-for-service  
37 program option (as defined in section 1852(a)(1)(B)).”.



1           (3) COMPUTATION OF SAVINGS.—Section 1854(b) (42  
2 U.S.C. 1395w-24(b)) is further amended by adding at the  
3 end the following new paragraphs:

4           “(3) COMPUTATION OF AVERAGE PER CAPITA MONTH-  
5 LY SAVINGS FOR LOCAL PLANS.—For purposes of para-  
6 graph (1)(C)(i), the average per capita monthly savings re-  
7 ferred to in such paragraph for an MA local plan and year  
8 is computed as follows:

9           “(A) DETERMINATION OF STATEWIDE AVERAGE  
10 RISK ADJUSTMENT FOR LOCAL PLANS.—

11           “(i) IN GENERAL.—Subject to clause (iii), the  
12 Secretary shall determine, at the same time rates  
13 are promulgated under section 1853(b)(1) (begin-  
14 ning with 2006) for each State, the average of the  
15 risk adjustment factors to be applied under section  
16 1853(a)(1)(C) to payment for enrollees in that  
17 State for MA local plans.

18           “(ii) TREATMENT OF STATES FOR FIRST YEAR  
19 IN WHICH LOCAL PLAN OFFERED.—In the case of  
20 a State in which no MA local plan was offered in  
21 the previous year, the Secretary shall estimate such  
22 average. In making such estimate, the Secretary  
23 may use average risk adjustment factors applied to  
24 comparable States or applied on a national basis.

25           “(iii) AUTHORITY TO DETERMINE RISK AD-  
26 JUSTMENT FOR AREAS OTHER THAN STATES.—The  
27 Secretary may provide for the determination and  
28 application of risk adjustment factors under this  
29 subparagraph on the basis of areas other than  
30 States or on a plan-specific basis.

31           “(B) DETERMINATION OF RISK ADJUSTED BENCH-  
32 MARK AND RISK-ADJUSTED BID FOR LOCAL PLANS.—  
33 For each MA plan offered in a local area in a State,  
34 the Secretary shall—

35           “(i) adjust the applicable MA area-specific  
36 non-drug monthly benchmark amount (as defined  
37 in section 1853(j)(1)) for the area by the average

1 risk adjustment factor computed under subpara-  
2 graph (A); and

3 “(ii) adjust the unadjusted MA statutory non-  
4 drug monthly bid amount by such applicable aver-  
5 age risk adjustment factor.

6 “(C) DETERMINATION OF AVERAGE PER CAPITA  
7 MONTHLY SAVINGS.—The average per capita monthly  
8 savings described in this subparagraph for an MA local  
9 plan is equal to the amount (if any) by which—

10 “(i) the risk-adjusted benchmark amount com-  
11 puted under subparagraph (B)(i); exceeds

12 “(ii) the risk-adjusted bid computed under  
13 subparagraph (B)(ii).

14 “(4) COMPUTATION OF AVERAGE PER CAPITA MONTH-  
15 LY SAVINGS FOR REGIONAL PLANS.—For purposes of para-  
16 graph (1)(C)(i), the average per capita monthly savings re-  
17 ferred to in such paragraph for an MA regional plan and  
18 year is computed as follows:

19 “(A) DETERMINATION OF REGIONWIDE AVERAGE  
20 RISK ADJUSTMENT FOR REGIONAL PLANS.—

21 “(i) IN GENERAL.—The Secretary shall deter-  
22 mine, at the same time rates are promulgated  
23 under section 1853(b)(1) (beginning with 2006) for  
24 each MA region the average of the risk adjustment  
25 factors to be applied under section 1853(a)(1)(C)  
26 to payment for enrollees in that region for MA re-  
27 gional plans.

28 “(ii) TREATMENT OF REGIONS FOR FIRST  
29 YEAR IN WHICH REGIONAL PLAN OFFERED.—In  
30 the case of an MA region in which no MA regional  
31 plan was offered in the previous year, the Secretary  
32 shall estimate such average. In making such esti-  
33 mate, the Secretary may use average risk adjust-  
34 ment factors applied to comparable regions or ap-  
35 plied on a national basis.

36 “(iii) AUTHORITY TO DETERMINE RISK AD-  
37 JUSTMENT FOR AREAS OTHER THAN REGIONS.—

1           The Secretary may provide for the determination  
2           and application of risk adjustment factors under  
3           this subparagraph on the basis of areas other than  
4           MA regions or on a plan-specific basis.

5           “(B) DETERMINATION OF RISK-ADJUSTED BENCH-  
6           MARK AND RISK-ADJUSTED BID FOR REGIONAL  
7           PLANS.—For each MA regional plan offered in a re-  
8           gion, the Secretary shall—

9                   “(i) adjust the applicable MA area-specific  
10                  non-drug monthly benchmark amount (as defined  
11                  in section 1853(j)(2)) for the region by the average  
12                  risk adjustment factor computed under subpara-  
13                  graph (A); and

14                   “(ii) adjust the unadjusted MA statutory non-  
15                  drug monthly bid amount by such applicable aver-  
16                  age risk adjustment factor.

17           “(C) DETERMINATION OF AVERAGE PER CAPITA  
18           MONTHLY SAVINGS.—The average per capita monthly  
19           savings described in this subparagraph for an MA re-  
20           gional plan is equal to the amount (if any) by which—

21                   “(i) the risk-adjusted benchmark amount com-  
22                  puted under subparagraph (B)(i); exceeds

23                   “(ii) the risk-adjusted bid computed under  
24                  subparagraph (B)(ii).”.

25           (c) COLLECTION OF PREMIUMS.—Section 1854(d) (42  
26           U.S.C. 1395w-24(d)) is amended—

27                   (1) by striking “PREMIUMS.—Each” and inserting  
28                  “PREMIUMS.—

29                   “(1) IN GENERAL.—Each”; and

30                   (2) by adding at the end the following new para-  
31                  graphs:

32                   “(2) BENEFICIARY’S OPTION OF PAYMENT THROUGH  
33                  WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE  
34                  OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In ac-  
35                  cordance with regulations, an MA organization shall permit  
36                  each enrollee, at the enrollee’s option, to make payment of

1 premiums (if any) under this part to the organization  
2 through—

3 “(A) withholding from benefit payments in the  
4 manner provided under section 1840 with respect to  
5 monthly premiums under section 1839;

6 “(B) an electronic funds transfer mechanism (such  
7 as automatic charges of an account at a financial insti-  
8 tution or a credit or debit card account); or

9 “(C) such other means as the Secretary may speci-  
10 fy, including payment by an employer or under employ-  
11 ment-based retiree health coverage (as defined in sec-  
12 tion 1860D–22(c)(1)) on behalf of an employee or  
13 former employee (or dependent).

14 All premium payments that are withheld under subpara-  
15 graph (A) shall be credited to the appropriate Trust Fund  
16 (or Account thereof), as specified by the Secretary, under  
17 this title and shall be paid to the MA organization involved.  
18 No charge may be imposed under an MA plan with respect  
19 to the election of the payment option described in subpara-  
20 graph (A). The Secretary shall consult with the Commis-  
21 sioner of Social Security and the Secretary of the Treasury  
22 regarding methods for allocating premiums withheld under  
23 subparagraph (A) among the appropriate Trust Funds and  
24 Account.

25 “(3) INFORMATION NECESSARY FOR COLLECTION.—In  
26 order to carry out paragraph (2)(A) with respect to an en-  
27 rollee who has elected such paragraph to apply, the Sec-  
28 retary shall transmit to the Commissioner of Social  
29 Security—

30 “(A) by the beginning of each year, the name, so-  
31 cial security account number, consolidated monthly  
32 beneficiary premium described in paragraph (4) owed  
33 by such enrollee for each month during the year, and  
34 other information determined appropriate by the Sec-  
35 retary, in consultation with the Commissioner of Social  
36 Security; and

1                   “(B) periodically throughout the year, information  
2                   to update the information previously transmitted under  
3                   this paragraph for the year.

4                   “(4) CONSOLIDATED MONTHLY BENEFICIARY PRE-  
5                   MIUM.—In the case of an enrollee in an MA plan, the Sec-  
6                   retary shall provide a mechanism for the consolidation of—

7                   “(A) the MA monthly basic beneficiary premium  
8                   (if any);

9                   “(B) the MA monthly supplemental beneficiary  
10                  premium (if any); and

11                  “(C) the MA monthly prescription drug bene-  
12                  ficiary premium (if any).”.

13                  (d) COMPUTATION OF MA AREA-SPECIFIC NON-DRUG  
14                  BENCHMARK.—Section 1853 (42 U.S.C. 1395w-23) is amend-  
15                  ed by adding at the end the following new subsection:

16                  “(j) COMPUTATION OF BENCHMARK AMOUNTS.—For pur-  
17                  poses of this part, the term ‘MA area-specific non-drug month-  
18                  ly benchmark amount’ means for a month in a year—

19                  “(1) with respect to—

20                  “(A) a service area that is entirely within an MA  
21                  local area, an amount equal to  $\frac{1}{12}$  of the annual MA  
22                  capitation rate under section 1853(c)(1) for the area  
23                  for the year, adjusted as appropriate for the purpose of  
24                  risk adjustment; or

25                  “(B) a service area that includes more than one  
26                  MA local area, an amount equal to the average of the  
27                  amounts described in subparagraph (A) for each such  
28                  local MA area, weighted by the projected number of en-  
29                  rollees in the plan residing in the respective local MA  
30                  areas (as used by the plan for purposes of the bid and  
31                  disclosed to the Secretary under section  
32                  1854(a)(6)(A)(iii)), adjusted as appropriate for the  
33                  purpose of risk adjustment; or

34                  “(2) with respect to an MA region for a month in a  
35                  year, the MA region-specific non-drug monthly benchmark  
36                  amount, as defined in section 1858(f) for the region for the  
37                  year.”.

1 (e) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

2 (1) IN GENERAL.—Section 1853(a)(1) (42 U.S.C.  
3 1395w-23(a)(1)) (42 U.S.C. 1395w-23) is amended—

4 (A) by redesignating subparagraph (B) as sub-  
5 paragraph (H); and

6 (B) in subparagraph (A), by striking “in an  
7 amount” and all that follows and inserting the fol-  
8 lowing: “in an amount determined as follows:

9 “(i) PAYMENT BEFORE 2006.—For years be-  
10 fore 2006, the payment amount shall be equal to  
11  $\frac{1}{12}$  of the annual MA capitation rate (as calculated  
12 under subsection (c)(1)) with respect to that indi-  
13 vidual for that area, adjusted under subparagraph  
14 (C) and reduced by the amount of any reduction  
15 elected under section 1854(f)(1)(E).

16 “(ii) PAYMENT FOR ORIGINAL FEE-FOR-SERV-  
17 ICE BENEFITS BEGINNING WITH 2006.—For years  
18 beginning with 2006, the amount specified in sub-  
19 paragraph (B).

20 “(B) PAYMENT AMOUNT FOR ORIGINAL FEE-FOR-  
21 SERVICE BENEFITS BEGINNING WITH 2006.—

22 “(i) PAYMENT OF BID FOR PLANS WITH BIDS  
23 BELOW BENCHMARK.—In the case of a plan for  
24 which there are average per capita monthly savings  
25 described in section 1854(b)(3)(C) or  
26 1854(b)(4)(C), as the case may be, the amount  
27 specified in this subparagraph is equal to the  
28 unadjusted MA statutory non-drug monthly bid  
29 amount, adjusted under subparagraph (C) and (if  
30 applicable) under subparagraphs (F) and (G), plus  
31 the amount (if any) of any rebate under subpara-  
32 graph (E).

33 “(ii) PAYMENT OF BENCHMARK FOR PLANS  
34 WITH BIDS AT OR ABOVE BENCHMARK.—In the  
35 case of a plan for which there are no average per  
36 capita monthly savings described in section  
37 1854(b)(3)(C) or 1854(b)(4)(C), as the case may

1 be, the amount specified in this subparagraph is  
2 equal to the MA area-specific non-drug monthly  
3 benchmark amount, adjusted under subparagraph  
4 (C) and (if applicable) under subparagraphs (F)  
5 and (G).

6 “(iii) PAYMENT OF BENCHMARK FOR MSA  
7 PLANS.—Notwithstanding clauses (i) and (ii), in  
8 the case of an MSA plan, the amount specified in  
9 this subparagraph is equal to the MA area-specific  
10 non-drug monthly benchmark amount, adjusted  
11 under subparagraph (C).

12 “(C) DEMOGRAPHIC ADJUSTMENT, INCLUDING AD-  
13 JUSTMENT FOR HEALTH STATUS.—The Secretary shall  
14 adjust the payment amount under subparagraph (A)(i)  
15 and the amount specified under subparagraph (B)(i),  
16 (B)(ii), and (B)(iii) for such risk factors as age, dis-  
17 ability status, gender, institutional status, and such  
18 other factors as the Secretary determines to be appro-  
19 priate, including adjustment for health status under  
20 paragraph (3), so as to ensure actuarial equivalence.  
21 The Secretary may add to, modify, or substitute for  
22 such adjustment factors if such changes will improve  
23 the determination of actuarial equivalence.

24 “(D) SEPARATE PAYMENT FOR FEDERAL DRUG  
25 SUBSIDIES.—In the case of an enrollee in an MA-PD  
26 plan, the MA organization offering such plan also  
27 receives—

28 “(i) subsidies under section 1860D–15 (other  
29 than under subsection (g)); and

30 “(ii) reimbursement for premium and cost-  
31 sharing reductions for low-income individuals under  
32 section 1860D–14(c)(1)(C).

33 “(E) PAYMENT OF REBATE FOR PLANS WITH BIDS  
34 BELOW BENCHMARK.—In the case of a plan for which  
35 there are average per capita monthly savings described  
36 in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case  
37 may be, the amount specified in this subparagraph is

1 the amount of the monthly rebate computed under sec-  
2 tion 1854(b)(1)(C)(i) for that plan and year (as re-  
3 duced by the amount of any credit provided under sec-  
4 tion 1854(b)(1)(C)(iv)).

5 “(F) ADJUSTMENT FOR INTRA-AREA VARI-  
6 ATIONS.—

7 “(i) INTRA-REGIONAL VARIATIONS.—In the  
8 case of payment with respect to an MA regional  
9 plan for an MA region, the Secretary shall also ad-  
10 just the amounts specified under subparagraphs  
11 (B)(i) and (B)(ii) in a manner to take into account  
12 variations in MA local payment rates under this  
13 part among the different MA local areas included  
14 in such region.

15 “(ii) INTRA-SERVICE AREA VARIATIONS.—In  
16 the case of payment with respect to an MA local  
17 plan for a service area that covers more than one  
18 MA local area, the Secretary shall also adjust the  
19 amounts specified under subparagraphs (B)(i) and  
20 (B)(ii) in a manner to take into account variations  
21 in MA local payment rates under this part among  
22 the different MA local areas included in such serv-  
23 ice area.

24 “(G) ADJUSTMENT RELATING TO RISK ADJUST-  
25 MENT.—The Secretary shall adjust payments with re-  
26 spect to MA plans as necessary to ensure that—

27 “(i) the sum of—

28 “(I) the monthly payment made under  
29 subparagraph (A)(ii); and

30 “(II) the MA monthly basic beneficiary  
31 premium under section 1854(b)(2)(A); equals

32 “(ii) the unadjusted MA statutory non-drug  
33 monthly bid amount, adjusted in the manner de-  
34 scribed in subparagraph (C) and, for an MA re-  
35 gional plan, subparagraph (F).”.



1 (f) CONFORMING CHANGES TO ANNUAL ANNOUNCEMENT  
2 PROCESS.—Section 1853(b) (42 U.S.C. 1395w-23(b)(1)) is  
3 amended—

4 (1) by amending paragraph (1) to read as follows:

5 “(1) ANNUAL ANNOUNCEMENTS.—

6 “(A) FOR 2005.—The Secretary shall determine,  
7 and shall announce (in a manner intended to provide  
8 notice to interested parties), not later than the second  
9 Monday in May of 2004, with respect to each MA pay-  
10 ment area, the following:

11 “(i) MA CAPITATION RATES.—The annual MA  
12 capitation rate for each MA payment area for  
13 2005.

14 “(ii) ADJUSTMENT FACTORS.—The risk and  
15 other factors to be used in adjusting such rates  
16 under subsection (a)(1)(C) for payments for  
17 months in 2005.

18 “(B) FOR 2006 AND SUBSEQUENT YEARS.—For a  
19 year after 2005—

20 “(i) INITIAL ANNOUNCEMENT.—The Secretary  
21 shall determine, and shall announce (in a manner  
22 intended to provide notice to interested parties),  
23 not later than the first Monday in April before the  
24 calendar year concerned, with respect to each MA  
25 payment area, the following:

26 “(I) MA CAPITATION RATES; MA LOCAL  
27 AREA BENCHMARK.—The annual MA capita-  
28 tion rate for each MA payment area for the  
29 year.

30 “(II) ADJUSTMENT FACTORS.—The risk  
31 and other factors to be used in adjusting such  
32 rates under subsection (a)(1)(C) for payments  
33 for months in such year.

34 “(ii) REGIONAL BENCHMARK ANNOUNCE-  
35 MENT.—The Secretary shall determine, and shall  
36 announce (in a manner intended to provide notice  
37 to interested parties), on a timely basis before the

1 calendar year concerned, with respect to each MA  
2 region and each MA regional plan for which a bid  
3 was submitted under section 1854, the MA region-  
4 specific non-drug monthly benchmark amount for  
5 that region for the year involved.”; and

6 (2) in paragraph (3), by striking “in the announce-  
7 ment” and all that follows and inserting “in such an-  
8 nouncement.”.

9 (g) OTHER AMENDMENTS RELATING TO PREMIUMS AND  
10 BID AMOUNTS.—

11 (1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w-  
12 24) is amended—

13 (A) by amending the section heading to read as  
14 follows:

15 “PREMIUMS AND BID AMOUNTS”;

16 (B) in the heading of subsection (a), by inserting  
17 “, BID AMOUNTS,” after “PREMIUMS”;

18 (C) in subsection (a)(2)—

19 (i) by inserting “BEFORE 2006” after “FOR CO-  
20 ORDINATED CARE PLANS”; and

21 (ii) by inserting “for a year before 2006” after  
22 “section 1851(a)(2)(A)”;

23 (D) in subsection (a)(3), by striking “described”  
24 and inserting “for any year”;

25 (E) in subsection (a)(4)—

26 (i) by inserting “BEFORE 2006” after “FOR  
27 PRIVATE FEE-FOR-SERVICE PLANS”; and

28 (ii) by inserting “for a year before 2006” after  
29 “section 1852(a)(1)(A)”;

30 (F) in subsection (a)(5)(A), by inserting “para-  
31 graphs (2) and (4) of” after “filed under”;

32 (G) in subsection (a)(5)(B), by inserting after  
33 “paragraph (3) or” the following: “, in the case of an  
34 MA private fee-for-service plan,”; and

35 (H) in subsection (b)(1)(A) by striking “and” and  
36 inserting a comma and by inserting before the period  
37 at the end the following: “, and, if the plan provides

1 qualified prescription drug coverage, the MA monthly  
2 prescription drug beneficiary premium”.

3 (2) UNIFORMITY.—Section 1854(c) (42 U.S.C.  
4 1395w-24(c)) is amended to read as follows:

5 “(c) UNIFORM PREMIUM AND BID AMOUNTS.—Except as  
6 permitted under section 1857(i), the MA monthly bid amount  
7 submitted under subsection (a)(6), the amounts of the MA  
8 monthly basic, prescription drug, and supplemental beneficiary  
9 premiums, and the MA monthly MSA premium charged under  
10 subsection (b) of an MA organization under this part may not  
11 vary among individuals enrolled in the plan.”.

12 (3) PREMIUMS.—Section 1854(d)(1) (42 U.S.C.  
13 1395w-24(d)(1)), as amended by subsection (c)(1), is  
14 amended by inserting “, prescription drug,” after “basic”.

15 (4) LIMITATION ON ENROLLEE LIABILITY.—Section  
16 1854(e) (42 U.S.C. 1395w-24(e)) is amended—

17 (A) in paragraph (1), by striking “.—In” and in-  
18 serting “BEFORE 2006.—For periods before 2006, in”;

19 (B) in paragraph (2), by striking “.—If” and in-  
20 sert “BEFORE 2006.—For periods before 2006, if”;

21 (C) in paragraph (3), by striking “or (2)” and in-  
22 serting “, (2), or (4)”; and

23 (D) in paragraph (4)—

24 (i) by inserting “AND FOR BASIC BENEFITS  
25 BEGINNING IN 2006” after “PLANS”;

26 (ii) in the matter before subparagraph (A), by  
27 inserting “and for periods beginning with 2006,  
28 with respect to an MA plan described in section  
29 1851(a)(2)(A)” after “MSA plan”;

30 (iii) in subparagraph (A), by striking “re-  
31 quired benefits described in section 1852(a)(1)”  
32 and inserting “benefits under the original medicare  
33 fee-for-service program option”; and

34 (iv) in subparagraph (B), by inserting “with  
35 respect to such benefits” after “would be applica-  
36 ble”.

1 (5) MODIFICATION OF ACR PROCESS.—Section 1854(f)  
2 (42 U.S.C. 1395w–24(f)) is amended—

3 (A) in the heading, by inserting “BEFORE 2006”  
4 after “ADDITIONAL BENEFITS”; and

5 (B) in paragraph (1)(A), by striking “Each” and  
6 inserting “For years before 2006, each”.

7 (h) PLAN INCENTIVES.—Section 1852(j)(4) (42 U.S.C.  
8 1395w–22(j)(4)) is amended—

9 (1) by inserting “the organization provides assurances  
10 satisfactory to the Secretary that” after “unless”;

11 (2) in clause (ii)—

12 (A) by striking “the organization—” and all that  
13 follows through “(I) provides” and inserting “the orga-  
14 nization provides”;

15 (B) by striking “, and” and inserting a period;  
16 and

17 (C) by striking subclause (II); and

18 (3) by striking clause (iii).

19 (i) CONTINUATION OF TREATMENT OF ENROLLEES WITH  
20 END-STAGE RENAL DISEASE.—Section 1853(a)(1)(H), as re-  
21 designated under subsection (d)(1)(A), is amended—

22 (1) by amending the second sentence to read as fol-  
23 lows: “Such rates of payment shall be actuarially equivalent  
24 to rates that would have been paid with respect to other  
25 enrollees in the MA payment area (or such other area as  
26 specified by the Secretary) under the provisions of this sec-  
27 tion as in effect before the date of the enactment of the  
28 Medicare Prescription Drug, Improvement, and Moderniza-  
29 tion Act of 2003.”; and

30 (2) by adding at the end the following new sentence:  
31 “The Secretary may apply the competitive bidding method-  
32 ology provided for in this section, with appropriate adjust-  
33 ments to account for the risk adjustment methodology ap-  
34 plied to end stage renal disease payments.”.

35 (j) FACILITATION OF EMPLOYER SPONSORSHIP OF MA  
36 PLANS.—Section 1857(i) (42 U.S.C. 1395w–27(i)) is  
37 amended—

1 (1) by designating the matter following the heading as  
2 a paragraph (1) with the heading “CONTRACTS WITH MA  
3 ORGANIZATIONS.—” and appropriate indentation; and

4 (2) by adding at the end the following new paragraph:

5 “(2) EMPLOYER SPONSORED MA PLANS.—To facilitate  
6 the offering of MA plans by employers, labor organizations,  
7 or the trustees of a fund established by one or more em-  
8 ployers or labor organizations (or combination thereof) to  
9 furnish benefits to the entity’s employees, former employees  
10 (or combination thereof) or members or former members  
11 (or combination thereof) of the labor organizations, the  
12 Secretary may waive or modify requirements that hinder  
13 the design of, the offering of, or the enrollment in such MA  
14 plans. Notwithstanding section 1851(g), an MA plan de-  
15 scribed in the previous sentence may restrict the enrollment  
16 of individuals under this part to individuals who are bene-  
17 ficiaries and participants in such plan.”

18 (k) EXPANSION OF MEDICARE BENEFICIARY EDUCATION  
19 AND INFORMATION CAMPAIGN.—Section 1857(e)(2) (42 U.S.C.  
20 1395w–27(e)(2)) is amended—

21 (1) in subparagraph (A) by inserting “and a PDP  
22 sponsor under part D” after “organization”;

23 (2) in subparagraph (B)—

24 (A) by inserting “and each PDP sponsor with a  
25 contract under part D” after “contract under this  
26 part”;

27 (B) by inserting “or sponsor’s” after “organiza-  
28 tion’s”; and

29 (C) by inserting “, section 1860D–1(c),” after “in-  
30 formation”;

31 (3) in subparagraph (C)—

32 (A) by inserting “and ending with fiscal year  
33 2005” after “beginning with fiscal year 2001”;

34 (B) by inserting “and for each fiscal year begin-  
35 ning with fiscal year 2006 an amount equal to  
36 \$200,000,000,” after “\$100,000,000,”; and

1 (C) by inserting “and section 1860D–  
2 12(b)(3)(D)” after “under this paragraph”;

3 (4) in subparagraph (D)—

4 (A) in clause (i) by inserting “and section 1860D–  
5 1(c)” after “section 1851”;

6 (B) in clause (ii)(III), by striking “and” at the  
7 end of subclause (III);

8 (C) in clause (ii)(IV), by striking “each succeeding  
9 fiscal year.” and inserting “each succeeding fiscal year  
10 before fiscal year 2006; and”;

11 (D) in clause (ii), by adding at the end the fol-  
12 lowing new subclause:

13 “(V) the applicable portion (as defined in sub-  
14 paragraph (F)) of \$200,000,000 in fiscal year  
15 2006 and each succeeding fiscal year.”; and

16 (5) by adding at the end the following new subpara-  
17 graph:

18 “(F) APPLICABLE PORTION DEFINED.—In this  
19 paragraph, the term ‘applicable portion’ means, for a  
20 fiscal year—

21 “(i) with respect to MA organizations, the Sec-  
22 retary’s estimate of the total proportion of expendi-  
23 tures under this title that are attributable to ex-  
24 penditures made under this part (including pay-  
25 ments under part D that are made to such organi-  
26 zations); or

27 “(ii) with respect to PDP sponsors, the Sec-  
28 retary’s estimate of the total proportion of expendi-  
29 tures under this title that are attributable to ex-  
30 penditures made to such sponsors under part D.”.

31 (I) CONFORMING AMENDMENTS.—

32 (1) PROTECTION AGAINST BENEFICIARY SELECTION.—  
33 Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is  
34 amended by adding at the end the following: “The Sec-  
35 retary shall not approve a plan of an organization if the  
36 Secretary determines that the design of the plan and its

1 benefits are likely to substantially discourage enrollment by  
2 certain MA eligible individuals with the organization.”.

3 (2) RELATING TO REBATES.—

4 (A) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is  
5 amended by striking “80 percent of any reduction  
6 elected under section 1854(f)(1)(E)” and inserting  
7 “any credit provided under section  
8 1854(b)(1)(C)(ii)(III)”.

9 (B) The first sentence of section 1840(i) (42  
10 U.S.C. 1395s(i)) is amended by inserting “and to re-  
11 flect any credit provided under section  
12 1854(b)(1)(C)(iv)” after “section 1854(f)(1)(E)”.

13 (C) Section 1844(c) (42 U.S.C. 1395w(e)) is  
14 amended by inserting “or any credits provided under  
15 section 1854(b)(1)(C)(iv)” after “section  
16 1854(f)(1)(E)”.

17 (3) OTHER CONFORMING AND TECHNICAL AMEND-  
18 MENTS.—

19 (A) Section 1851(b)(1) (42 U.S.C. 1395w-  
20 21(b)(1)) is amended—

21 (i) in subparagraph (B), by striking “a plan”  
22 and inserting “an MA local plan”;

23 (ii) in subparagraph (B), by striking “basic  
24 benefits described in section 1852(a)(1)(A)” and  
25 inserting “benefits under the original medicare fee-  
26 for-service program option”; and

27 (iii) in subparagraph (C), by striking “in a  
28 Medicare+Choice plan” and inserting “in an MA  
29 local plan”.

30 (B) Section 1851(d) (42 U.S.C. 1395w-21(d)) is  
31 amended—

32 (i) in paragraph (3), by adding at the end the  
33 following new subparagraph:

34 “(F) CATASTROPHIC COVERAGE AND SINGLE DE-  
35 DUCTIBLE.—In the case of an MA regional plan, a de-  
36 scription of the catastrophic coverage and single de-  
37 ductible applicable under the plan.”;

1 (ii) in paragraph (4)(A)(ii), by inserting “, in-  
2 cluding information on the single deductible (if ap-  
3 plicable) under section 1858(b)(1)” after “cost  
4 sharing”;

5 (iii) in paragraph (4)(B)(i), by striking  
6 “Medicare+Choice monthly basic” and all that fol-  
7 lows and inserting “monthly amount of the pre-  
8 mium charged to an individual.”; and

9 (iv) by amending subparagraph (E) of sub-  
10 section (d)(4) to read as follows:

11 “(E) SUPPLEMENTAL BENEFITS.—Supplemental  
12 health care benefits, including any reductions in cost-  
13 sharing under section 1852(a)(3) and the terms and  
14 conditions (including premiums) for such benefits.”.

15 (C) Section 1857(d)(1) (42 U.S.C. 1395w-  
16 27(d)(1)) is amended by striking “, costs, and com-  
17 putation of the adjusted community rate” and inserting  
18 “and costs, including allowable costs under section  
19 1858(c)”.

20 (D) Section 1851(a)(3)(B)(ii) (42 U.S.C. 1395w-  
21 21(a)(3)(B)(ii)) is amended by striking “section  
22 1851(e)(4)(A)” and inserting “subsection (e)(4)(A)”.

23 (E) Section 1851(f)(1) (42 U.S.C. 1395w-  
24 21(f)(1)) is amended by striking “subsection (e)(1)(A)”  
25 and inserting “subsection (e)(1)”.

26 **SEC. 223. EFFECTIVE DATE.**

27 (a) EFFECTIVE DATE.—The amendments made by this  
28 subtitle shall apply with respect to plan years beginning on or  
29 after January 1, 2006.

30 (b) ISSUANCE OF REGULATIONS.—The Secretary shall re-  
31 vise the regulations previously promulgated to carry out part  
32 C of title XVIII of the Social Security Act to carry out the pro-  
33 visions of this Act.



## Subtitle D—Additional Reforms

### SEC. 231. SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)), as amended by section 221(a), is amended by adding at the end the following new clause:

“(ii) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—Specialized MA plans for special needs individuals (as defined in section 1859(b)(6)) may be any type of coordinated care plan.”.

(b) SPECIALIZED MA PLAN FOR SPECIAL NEEDS INDIVIDUALS DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)), as amended by section 221(b), is amended by adding at the end the following new paragraph:

“(6) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—

“(A) IN GENERAL.—The term ‘specialized MA plan for special needs individuals’ means an MA plan that exclusively serves special needs individuals (as defined in subparagraph (B)).

“(B) SPECIAL NEEDS INDIVIDUAL.—The term ‘special needs individual’ means an MA eligible individual who—

“(i) is institutionalized (as defined by the Secretary);

“(ii) is entitled to medical assistance under a State plan under title XIX; or

“(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.

The Secretary may waive application of section 1851(a)(3)(B) in the case of an individual described in clause (i), (ii), or (iii) of this subparagraph and may

1           apply rules similar to the rules of section 1894(c)(4)  
2           for continued eligibility of special needs individuals.”.

3           (c) RESTRICTION ON ENROLLMENT PERMITTED.—Section  
4 1859 (42 U.S.C. 1395w–29) is amended by adding at the end  
5 the following new subsection:

6           “(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED  
7 MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In the case of  
8 a specialized MA plan for special needs individuals (as defined  
9 in subsection (b)(6)), notwithstanding any other provision of  
10 this part and in accordance with regulations of the Secretary  
11 and for periods before January 1, 2009, the plan may restrict  
12 the enrollment of individuals under the plan to individuals who  
13 are within one or more classes of special needs individuals.”.

14           (d) AUTHORITY TO DESIGNATE OTHER PLANS AS SPE-  
15 CIALIZED MA PLANS.—In promulgating regulations to carry  
16 out section 1851(a)(2)(A)(ii) of the Social Security Act (as  
17 added by subsection (a)) and section 1859(b)(6) of such Act  
18 (as added by subsection (b)), the Secretary may provide (not-  
19 withstanding section 1859(b)(6)(A) of such Act) for the offer-  
20 ing of specialized MA plans for special needs individuals by MA  
21 plans that disproportionately serve special needs individuals.

22           (e) REPORT TO CONGRESS.—Not later than December 31,  
23 2007, the Secretary shall submit to Congress a report that as-  
24 sesses the impact of specialized MA plans for special needs in-  
25 dividuals on the cost and quality of services provided to enroll-  
26 ees. Such report shall include an assessment of the costs and  
27 savings to the medicare program as a result of amendments  
28 made by subsections (a), (b), and (c).

29           (f) EFFECTIVE DATES.—

30           (1) IN GENERAL.—The amendments made by sub-  
31 sections (a), (b), and (c) shall take effect upon the date of  
32 the enactment of this Act.

33           (2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR  
34 SPECIAL NEEDS INDIVIDUALS; TRANSITION.—No later than  
35 1 year after the date of the enactment of this Act, the Sec-  
36 retary shall issue final regulations to establish requirements  
37 for special needs individuals under section

1 1859(b)(6)(B)(iii) of the Social Security Act, as added by  
2 subsection (b).

3 **SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.**

4 (a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–  
5 26(b)(3)) is amended to read as follows:

6 “(3) RELATION TO STATE LAWS.—The standards es-  
7 tablished under this part shall supersede any State law or  
8 regulation (other than State licensing laws or State laws  
9 relating to plan solvency) with respect to MA plans which  
10 are offered by MA organizations under this part.”.

11 (b) CONFORMING AMENDMENT.—Section 1854(g) (42  
12 U.S.C. 1395w–24(g)) is amended by inserting “or premiums  
13 paid to such organizations under this part” after “section  
14 1853”.

15 (c) EFFECTIVE DATE.—The amendments made by this  
16 subsection shall take effect on the date of the enactment of this  
17 Act.

18 **SEC. 233. MEDICARE MSAS.**

19 (a) EXEMPTION FROM REPORTING REQUIREMENT.—

20 (1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C.  
21 1395w–22(e)(1)) is amended by inserting “(other than  
22 MSA plans)” after “plans”.

23 (2) CONFORMING AMENDMENTS.—Section 1852 (42  
24 U.S.C. 1395w–22) is amended—

25 (A) in subsection (c)(1)(I), by inserting before the  
26 period at the end the following: “, if required under  
27 such section”; and

28 (B) in subsection (e)(2)(A), by striking “, a non-  
29 network MSA plan,”; and

30 (C) in subsection (e)(2)(B), by striking “, NON-  
31 NETWORK MSA PLANS,” and “, a non-network MSA  
32 plan,”.

33 (3) EFFECTIVE DATE.—The amendments made by  
34 this subsection shall apply on and after the date of the en-  
35 actment of this Act but shall not apply to contract years  
36 beginning on or after January 1, 2006.

1 (b) MAKING PROGRAM PERMANENT AND ELIMINATING  
2 CAP.—Section 1851(b)(4) (42 U.S.C. 1395w-21(b)(4)) is  
3 amended—

4 (1) in the heading, by striking “ON A DEMONSTRATION  
5 BASIS”;

6 (2) by striking the first sentence of subparagraph (A);  
7 and

8 (3) by striking the second sentence of subparagraph  
9 (C).

10 (c) APPLYING LIMITATIONS ON BALANCE BILLING.—Sec-  
11 tion 1852(k)(1) (42 U.S.C. 1395w-22(k)(1)) is amended by in-  
12 sserting “or with an organization offering an MSA plan” after  
13 “section 1851(a)(2)(A)”.

14 (d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A)  
15 (42 U.S.C. 1395w-21(e)(5)(A)) is amended—

16 (1) by adding “or” at the end of clause (i);

17 (2) by striking “, or” at the end of clause (ii) and in-  
18 sserting a semicolon; and

19 (3) by striking clause (iii).

20 **SEC. 234. EXTENSION OF REASONABLE COST CON-**  
21 **TRACTS.**

22 Subparagraph (C) of section 1876(h)(5) (42 U.S.C.  
23 1395mm(h)(5)) is amended to read as follows:

24 “(C)(i) Subject to clause (ii), a reasonable cost reimburse-  
25 ment contract under this subsection may be extended or re-  
26 newed indefinitely.

27 “(ii) For any period beginning on or after January 1,  
28 2008, a reasonable cost reimbursement contract under this sub-  
29 section may not be extended or renewed for a service area inso-  
30 far as such area during the entire previous year was within the  
31 service area of—

32 “(I) 2 or more MA regional plans described in clause  
33 (iii); or

34 “(II) 2 or more MA local plans described in clause  
35 (iii).

36 “(iii) A plan described in this clause for a year for a serv-  
37 ice area is a plan described in section 1851(a)(2)(A)(i) if the

1 service area for the year meets the following minimum enroll-  
2 ment requirements:

3 “(I) With respect to any portion of the area involved  
4 that is within a Metropolitan Statistical Area with a popu-  
5 lation of more than 250,000 and counties contiguous to  
6 such Metropolitan Statistical Area, 5,000 individuals.

7 “(II) With respect to any other portion of such area,  
8 1,500 individuals.”.

9 **SEC. 235. 2-YEAR EXTENSION OF MUNICIPAL HEALTH**  
10 **SERVICE DEMONSTRATION PROJECTS.**

11 The last sentence of section 9215(a) of the Consolidated  
12 Omnibus Budget Reconciliation Act of 1985 (42 U.S.C.  
13 1395b-1 note), as amended by section 6135 of the Omnibus  
14 Budget Reconciliation Act of 1989, section 13557 of the Omni-  
15 bus Budget Reconciliation Act of 1993, section 4017 of BBA,  
16 section 534 of BBRA (113 Stat. 1501A-390), and section 633  
17 of BIPA, is amended by striking “December 31, 2004” and in-  
18 sserting “December 31, 2006”.

19 **SEC. 236. PAYMENT BY PACE PROVIDERS FOR MEDI-**  
20 **CARE AND MEDICAID SERVICES FURNISHED**  
21 **BY NONCONTRACT PROVIDERS.**

22 (a) MEDICARE SERVICES.—

23 (1) MEDICARE SERVICES FURNISHED BY PROVIDERS  
24 OF SERVICES.—Section 1866(a)(1)(O) (42 U.S.C.  
25 1395cc(a)(1)(O)) is amended—

26 (A) by striking “part C or” and inserting “part C,  
27 with a PACE provider under section 1894 or 1934,  
28 or”;

29 (B) by striking “(i)”;

30 (C) by striking “and (ii)”;

31 (D) by inserting “(or, in the case of a PACE pro-  
32 vider, contract or other agreement)” after “have a con-  
33 tract”; and

34 (E) by striking “members of the organization”  
35 and inserting “members of the organization or PACE  
36 program eligible individuals enrolled with the PACE  
37 provider,”.

1           (2) MEDICARE SERVICES FURNISHED BY PHYSICIANS  
2           AND OTHER ENTITIES.—Section 1894(b) (42 U.S.C.  
3           1395eee(b)) is amended by adding at the end the following  
4           new paragraphs:

5           “(3) TREATMENT OF MEDICARE SERVICES FURNISHED  
6           BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

7           “(A) APPLICATION OF MEDICARE ADVANTAGE RE-  
8           QUIREMENT WITH RESPECT TO MEDICARE SERVICES  
9           FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER  
10          ENTITIES.—Section 1852(k)(1) (relating to limitations  
11          on balance billing against MA organizations for non-  
12          contract physicians and other entities with respect to  
13          services covered under this title) shall apply to PACE  
14          providers, PACE program eligible individuals enrolled  
15          with such PACE providers, and physicians and other  
16          entities that do not have a contract or other agreement  
17          establishing payment amounts for services furnished to  
18          such an individual in the same manner as such section  
19          applies to MA organizations, individuals enrolled with  
20          such organizations, and physicians and other entities  
21          referred to in such section.

22          “(B) REFERENCE TO RELATED PROVISION FOR  
23          NONCONTRACT PROVIDERS OF SERVICES.—For the pro-  
24          vision relating to limitations on balance billing against  
25          PACE providers for services covered under this title  
26          furnished by noncontract providers of services, see sec-  
27          tion 1866(a)(1)(O).

28          “(4) REFERENCE TO RELATED PROVISION FOR SERV-  
29          ICES COVERED UNDER TITLE XIX BUT NOT UNDER THIS  
30          TITLE.—For provisions relating to limitations on payments  
31          to providers participating under the State plan under title  
32          XIX that do not have a contract or other agreement with  
33          a PACE provider establishing payment amounts for serv-  
34          ices covered under such plan (but not under this title) when  
35          such services are furnished to enrollees of that PACE pro-  
36          vider, see section 1902(a)(66).”.

37          (b) MEDICAID SERVICES.—

1           (1) REQUIREMENT UNDER STATE PLAN.—Section  
2           1902(a) (42 U.S.C. 1396a(a)), as amended by section  
3           103(a), is amended—

4           (A) in paragraph (65), by striking “and” at the  
5           end;

6           (B) in paragraph (66), by striking the period at  
7           the end and inserting “; and”; and

8           (C) by inserting after paragraph (66) the following  
9           new paragraph:

10          “(67) provide, with respect to services covered under  
11          the State plan (but not under title XVIII) that are fur-  
12          nished to a PACE program eligible individual enrolled with  
13          a PACE provider by a provider participating under the  
14          State plan that does not have a contract or other agree-  
15          ment with the PACE provider that establishes payment  
16          amounts for such services, that such participating provider  
17          may not require the PACE provider to pay the partici-  
18          pating provider an amount greater than the amount that  
19          would otherwise be payable for the service to the partici-  
20          pating provider under the State plan for the State where  
21          the PACE provider is located (in accordance with regula-  
22          tions issued by the Secretary).”.

23          (2) APPLICATION UNDER MEDICAID.—Section 1934(b)  
24          (42 U.S.C. 1396u–4(b)) is amended by adding at the end  
25          the following new paragraphs:

26          “(3) TREATMENT OF MEDICARE SERVICES FURNISHED  
27          BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

28                 “(A) APPLICATION OF MEDICAID ADVANTAGE RE-  
29                 QUIREMENT WITH RESPECT TO MEDICARE SERVICES  
30                 FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER  
31                 ENTITIES.—Section 1852(k)(1) (relating to limitations  
32                 on balance billing against MA organizations for non-  
33                 contract physicians and other entities with respect to  
34                 services covered under title XVIII) shall apply to  
35                 PACE providers, PACE program eligible individuals  
36                 enrolled with such PACE providers, and physicians and  
37                 other entities that do not have a contract or other

1 agreement establishing payment amounts for services  
2 furnished to such an individual in the same manner as  
3 such section applies to MA organizations, individuals  
4 enrolled with such organizations, and physicians and  
5 other entities referred to in such section.

6 “(B) REFERENCE TO RELATED PROVISION FOR  
7 NONCONTRACT PROVIDERS OF SERVICES.—For the pro-  
8 vision relating to limitations on balance billing against  
9 PACE providers for services covered under title XVIII  
10 furnished by noncontract providers of services, see sec-  
11 tion 1866(a)(1)(O).

12 “(4) REFERENCE TO RELATED PROVISION FOR SERV-  
13 ICES COVERED UNDER THIS TITLE BUT NOT UNDER TITLE  
14 XVIII.—For provisions relating to limitations on payments  
15 to providers participating under the State plan under this  
16 title that do not have a contract or other agreement with  
17 a PACE provider establishing payment amounts for serv-  
18 ices covered under such plan (but not under title XVIII)  
19 when such services are furnished to enrollees of that PACE  
20 provider, see section 1902(a)(67).”.

21 (c) EFFECTIVE DATE.—The amendments made by this  
22 section shall apply to services furnished on or after January 1,  
23 2004.

24 **SEC. 237. REIMBURSEMENT FOR FEDERALLY QUALI-**  
25 **FIED HEALTH CENTERS PROVIDING SERV-**  
26 **ICES UNDER MA PLANS.**

27 (a) REIMBURSEMENT.—Section 1833(a)(3) (42 U.S.C.  
28 1395l(a)(3)) is amended to read as follows:

29 “(3) in the case of services described in section  
30 1832(a)(2)(D)—

31 “(A) except as provided in subparagraph (B), the  
32 costs which are reasonable and related to the cost of  
33 furnishing such services or which are based on such  
34 other tests of reasonableness as the Secretary may pre-  
35 scribe in regulations, including those authorized under  
36 section 1861(v)(1)(A), less the amount a provider may  
37 charge as described in clause (ii) of section



1 1866(a)(2)(A), but in no case may the payment for  
2 such services (other than for items and services de-  
3 scribed in section 1861(s)(10)(A)) exceed 80 percent of  
4 such costs; or

5 “(B) with respect to the services described in  
6 clause (ii) of section 1832(a)(2)(D) that are furnished  
7 to an individual enrolled with a MA plan under part C  
8 pursuant to a written agreement described in section  
9 1853(a)(4), the amount (if any) by which—

10 “(i) the amount of payment that would have  
11 otherwise been provided under subparagraph (A)  
12 (calculated as if ‘100 percent’ were substituted for  
13 ‘80 percent’ in such subparagraph) for such serv-  
14 ices if the individual had not been so enrolled; ex-  
15 ceeds

16 “(ii) the amount of the payments received  
17 under such written agreement for such services  
18 (not including any financial incentives provided for  
19 in such agreement such as risk pool payments, bo-  
20 nuses, or withholds),

21 less the amount the Federally qualified health center  
22 may charge as described in section 1857(e)(3)(B);”.

23 (b) CONTINUATION OF MONTHLY PAYMENTS.—

24 (1) IN GENERAL.—Section 1853(a) (42 U.S.C.  
25 1395w-23(a)) is amended by adding at the end the fol-  
26 lowing new paragraph:

27 “(4) PAYMENT RULE FOR FEDERALLY QUALIFIED  
28 HEALTH CENTER SERVICES.—If an individual who is en-  
29 rolled with an MA plan under this part receives a service  
30 from a Federally qualified health center that has a written  
31 agreement with the MA organization that offers such plan  
32 for providing such a service (including any agreement re-  
33 quired under section 1857(e)(3))—

34 “(A) the Secretary shall pay the amount deter-  
35 mined under section 1833(a)(3)(B) directly to the Fed-  
36 erally qualified health center not less frequently than  
37 quarterly; and

1           “(B) the Secretary shall not reduce the amount of  
2           the monthly payments under this subsection as a result  
3           of the application of subparagraph (A).”.

4           (2) CONFORMING AMENDMENTS.—

5           (A) Section 1851(i) (42 U.S.C. 1395w-21(i)) is  
6           amended—

7                   (i) in paragraph (1), by inserting  
8                   “1853(a)(4),” after “Subject to sections  
9                   1852(a)(5),”; and

10                   (ii) in paragraph (2), by inserting  
11                   “1853(a)(4),” after “Subject to sections”.

12           (B) Section 1853(c)(5) is amended by striking  
13           “subsections (a)(3)(C)(iii) and (i)” and inserting “sub-  
14           sections (a)(3)(C)(iii), (a)(4), and (i)”.

15           (c) ADDITIONAL CONTRACT REQUIREMENTS.—Section  
16           1857(e) (42 U.S.C. 1395w-27(e)) is amended by adding at the  
17           end the following new paragraph:

18                   “(3) AGREEMENTS WITH FEDERALLY QUALIFIED  
19           HEALTH CENTERS.—

20                   “(A) PAYMENT LEVELS AND AMOUNTS.—A con-  
21                   tract under this section with an MA organization shall  
22                   require the organization to provide, in any written  
23                   agreement described in section 1853(a)(4) between the  
24                   organization and a Federally qualified health center,  
25                   for a level and amount of payment to the Federally  
26                   qualified health center for services provided by such  
27                   health center that is not less than the level and amount  
28                   of payment that the plan would make for such services  
29                   if the services had been furnished by a entity providing  
30                   similar services that was not a Federally qualified  
31                   health center.

32                   “(B) COST-SHARING.—Under the written agree-  
33                   ment referred to in subparagraph (A), a Federally  
34                   qualified health center must accept the payment  
35                   amount referred to in such subparagraph plus the Fed-  
36                   eral payment provided for in section 1833(a)(3)(B) as  
37                   payment in full for services covered by the agreement,

1           except that such a health center may collect any  
2           amount of cost-sharing permitted under the contract  
3           under this section, so long as the amounts of any de-  
4           ductible, coinsurance, or copayment comply with the re-  
5           quirements under section 1854(e).”.

6           (d) SAFE HARBOR.—Section 1128B(b)(3) (42 U.S.C.  
7 1320a–7b(b)(3)), as amended by section 101(f)(2), is  
8 amended—

9           (1) in subparagraph (F), by striking “and” after the  
10          semicolon at the end;

11          (2) in subparagraph (G), by striking the period at the  
12          end and inserting “; and”; and

13          (3) by adding at the end the following new subpara-  
14          graph:

15                 “(H) any remuneration between a Federally quali-  
16          fied health center (or an entity controlled by such a  
17          health center) and an MA organization pursuant to a  
18          written agreement described in section 1853(a)(4).”.

19          (e) EFFECTIVE DATE.—The amendments made by this  
20          section shall apply to services provided on or after January 1,  
21          2006, and contract years beginning on or after such date.

22         **SEC. 238. INSTITUTE OF MEDICINE EVALUATION AND**  
23                 **REPORT ON HEALTH CARE PERFORMANCE**  
24                 **MEASURES.**

25          (a) EVALUATION.—

26           (1) IN GENERAL.—Not later than the date that is 2  
27          months after the date of the enactment of this Act, the  
28          Secretary shall enter into an arrangement under which the  
29          Institute of Medicine of the National Academy of Sciences  
30          (in this section referred to as the “Institute”) shall conduct  
31          an evaluation of leading health care performance measures  
32          in the public and private sectors and options to implement  
33          policies that align performance with payment under the  
34          medicare program under title XVIII of the Social Security  
35          Act (42 U.S.C. 1395 et seq.).

36           (2) SPECIFIC MATTERS EVALUATED.—In conducting  
37          the evaluation under paragraph (1), the Institute shall—

1 (A) catalogue, review, and evaluate the validity of  
2 leading health care performance measures;

3 (B) catalogue and evaluate the success and utility  
4 of alternative performance incentive programs in public  
5 or private sector settings; and

6 (C) identify and prioritize options to implement  
7 policies that align performance with payment under the  
8 medicare program that indicate—

9 (i) the performance measurement set to be  
10 used and how that measurement set will be up-  
11 dated;

12 (ii) the payment policy that will reward per-  
13 formance; and

14 (iii) the key implementation issues (such as  
15 data and information technology requirements) that  
16 must be addressed.

17 (3) SCOPE OF HEALTH CARE PERFORMANCE MEAS-  
18 URES.—The health care performance measures described in  
19 paragraph (2)(A) shall encompass a variety of perspectives,  
20 including physicians, hospitals, other health care providers,  
21 health plans, purchasers, and patients.

22 (4) CONSULTATION WITH MEDPAC.—In evaluating the  
23 matters described in paragraph (2)(C), the Institute shall  
24 consult with the Medicare Payment Advisory Commission  
25 established under section 1805 of the Social Security Act  
26 (42 U.S.C. 1395b–6).

27 (b) REPORT.—Not later than the date that is 18 months  
28 after the date of enactment of this Act, the Institute shall sub-  
29 mit to the Secretary and appropriate committees of jurisdiction  
30 of the Senate and House of Representatives a report on the  
31 evaluation conducted under subsection (a)(1) describing the  
32 findings of such evaluation and recommendations for an overall  
33 strategy and approach for aligning payment with performance,  
34 including options for updating performance measures, in the  
35 original medicare fee-for-service program under parts A and B  
36 of title XVIII of the Social Security Act, the Medicare Advan-

1 tage program under part C of such title, and any other pro-  
2 grams under such title XVIII.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—There are au-  
4 thorized to be appropriated such sums as may be necessary for  
5 purposes of conducting the evaluation and preparing the report  
6 required by this section.

## 7 **Subtitle E—Comparative Cost** 8 **Adjustment (CCA) Program**

### 9 **SEC. 241. COMPARATIVE COST ADJUSTMENT (CCA) PRO-** 10 **GRAM.**

11 (a) IN GENERAL.—Part C of title XVIII is amended by  
12 adding at the end the following new section:

13 “COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM

14 “SEC. 1860C–1. (a) ESTABLISHMENT OF PROGRAM.—

15 “(1) IN GENERAL.—The Secretary shall establish a  
16 program under this section (in this section referred to as  
17 the ‘CCA program’) for the application of comparative cost  
18 adjustment in CCA areas selected under this section.

19 “(2) DURATION.—The CCA program shall begin Jan-  
20 uary 1, 2010, and shall extend over a period of 6 years,  
21 and end on December 31, 2015.

22 “(3) REPORT.—Upon the completion of the CCA pro-  
23 gram, the Secretary shall submit a report to Congress.  
24 Such report shall include the following, with respect to both  
25 this part and the original medicare fee-for-service program:

26 “(A) An evaluation of the financial impact of the  
27 CCA program.

28 “(B) An evaluation of changes in access to physi-  
29 cians and other health care providers.

30 “(C) Beneficiary satisfaction.

31 “(D) Recommendations regarding any extension or  
32 expansion of the CCA program.

33 “(b) REQUIREMENTS FOR SELECTION OF CCA AREAS.—

34 “(1) CCA AREA DEFINED.—

35 “(A) IN GENERAL.—For purposes of this section,  
36 the term ‘CCA area’ means an MSA that meets the re-

1           quirements of paragraph (2) and is selected by the Sec-  
2           retary under subsection (c).

3           “(B) MSA DEFINED.—For purposes of this sec-  
4           tion, the term ‘MSA’ means a Metropolitan Statistical  
5           Area (or such similar area as the Secretary recognizes).

6           “(2) REQUIREMENTS FOR CCA AREAS.—The require-  
7           ments of this paragraph for an MSA to be a CCA area are  
8           as follows:

9           “(A) MA ENROLLMENT REQUIREMENT.—For the  
10          reference month (as defined under section  
11          1858(f)(4)(B)) with respect to 2010, at least 25 per-  
12          cent of the total number of MA eligible individuals who  
13          reside in the MSA were enrolled in an MA local plan  
14          described in section 1851(a)(2)(A)(i).

15          “(B) 2 PLAN REQUIREMENT.—There will be of-  
16          fered in the MSA during the annual, coordinated elec-  
17          tion period under section 1851(e)(3)(B) before the be-  
18          ginning of 2010 at least 2 MA local plans described in  
19          section 1851(a)(2)(A)(i) (in addition to the fee-for-serv-  
20          ice program under parts A and B), each offered by a  
21          different MA organization and each of which met the  
22          minimum enrollment requirements of paragraph (1) of  
23          section 1857(b) (as applied without regard to para-  
24          graph (3) thereof) as of the reference month.

25          “(c) SELECTION OF CCA AREAS.—

26          “(1) GENERAL SELECTION CRITERIA.—The Secretary  
27          shall select CCA areas from among those MSAs qualifying  
28          under subsection (b) in a manner that—

29                  “(A) seeks to maximize the opportunity to test the  
30                  application of comparative cost adjustment under this  
31                  title;

32                  “(B) does not seek to maximize the number of MA  
33                  eligible individuals who reside in such areas; and

34                  “(C) provides for geographic diversity consistent  
35                  with the criteria specified in paragraph (2).

36          “(2) SELECTION CRITERIA.—With respect to the selec-  
37          tion of MSAs that qualify to be CCA areas under sub-

1 section (b), the following rules apply, to the maximum extent feasible:  
2

3 “(A) MAXIMUM NUMBER.—The number of such  
4 MSAs selected may not exceed the lesser of (i) 6, or  
5 (ii) 25 percent of the number of MSAs that meet the  
6 requirement of subsection (b)(2)(A).

7 “(B) ONE OF 4 LARGEST AREAS BY POPU-  
8 LATION.—At least one such qualifying MSA shall be se-  
9 lected from among the 4 such qualifying MSAs with  
10 the largest total population of MA eligible individuals.

11 “(C) ONE OF 4 AREAS WITH LOWEST POPULATION  
12 DENSITY.—At least one such qualifying MSA shall be  
13 selected from among the 4 such qualifying MSAs with  
14 the lowest population density (as measured by residents  
15 per square mile or similar measure of density).

16 “(D) MULTISTATE AREA.—At least one such  
17 qualifying MSA shall be selected that includes a multi-  
18 State area. Such an MSA may be an MSA described  
19 in subparagraph (B) or (C).

20 “(E) LIMITATION WITHIN SAME GEOGRAPHIC RE-  
21 GION.—No more than 2 such MSAs shall be selected  
22 that are, in whole or in part, within the same geo-  
23 graphic region (as specified by the Secretary) of the  
24 United States.

25 “(F) PRIORITY TO AREAS NOT WITHIN CERTAIN  
26 DEMONSTRATION PROJECTS.—Priority shall be pro-  
27 vided for those qualifying MSAs that do not have a  
28 demonstration project in effect as of the date of the en-  
29 actment of this section for medicare preferred provider  
30 organization plans under this part.

31 “(d) APPLICATION OF COMPARATIVE COST ADJUST-  
32 MENT.—

33 “(1) IN GENERAL.—In the case of a CCA area for a  
34 year—

35 “(A) for purposes of applying this part with re-  
36 spect to payment for MA local plans, any reference to  
37 an MA area-specific non-drug monthly benchmark

1 amount shall be treated as a reference to such bench-  
2 mark computed as if the CCA area-specific non-drug  
3 monthly benchmark amount (as defined in subsection  
4 (e)(1)) were substituted for the amount described in  
5 section 1853(j)(1)(A) for the CCA area and year in-  
6 volved, as phased in under paragraph (3); and

7 “(B) with respect to months in the year for indi-  
8 viduals residing in the CCA area who are not enrolled  
9 in an MA plan, the amount of the monthly premium  
10 under section 1839 is subject to adjustment under sub-  
11 section (f).

12 “(2) EXCLUSION OF MA LOCAL AREAS WITH FEWER  
13 THAN 2 ORGANIZATIONS OFFERING MA PLANS.—

14 “(A) IN GENERAL.—In no case shall an MA local  
15 area that is within an MSA be included as part of a  
16 CCA area unless for 2010 (and, except as provided in  
17 subparagraph (B), for a subsequent year) there is of-  
18 fered in each part of such MA local area at least 2 MA  
19 local plans described in section 1851(a)(2)(A)(i) each  
20 of which is offered by a different MA organization.

21 “(B) CONTINUATION.—If an MA local area meets  
22 the requirement of subparagraph (A) and is included in  
23 a CCA area for 2010, such local area shall continue to  
24 be included in such CCA area for a subsequent year  
25 notwithstanding that it no longer meets such require-  
26 ment so long as there is at least one MA local plan de-  
27 scribed in section 1851(a)(2)(A)(i) that is offered in  
28 such local area.

29 “(3) PHASE-IN OF CCA BENCHMARK.—

30 “(A) IN GENERAL.—In applying this section for a  
31 year before 2013, paragraph (1)(A) shall be applied as  
32 if the phase-in fraction under subparagraph (B) of the  
33 CCA non-drug monthly benchmark amount for the year  
34 were substituted for such fraction of the MA area-spe-  
35 cific non-drug monthly benchmark amount.

36 “(B) PHASE-IN FRACTION.—The phase-in fraction  
37 under this subparagraph is—



1 “(i) for 2010  $\frac{1}{4}$ ; and

2 “(ii) for a subsequent year is the phase-in  
3 fraction under this subparagraph for the previous  
4 year increased by  $\frac{1}{4}$ , but in no case more than 1.

5 “(e) COMPUTATION OF CCA BENCHMARK AMOUNT.—

6 “(1) CCA NON-DRUG MONTHLY BENCHMARK  
7 AMOUNT.—For purposes of this section, the term ‘CCA  
8 non-drug monthly benchmark amount’ means, with respect  
9 to a CCA area for a month in a year, the sum of the 2  
10 components described in paragraph (2) for the area and  
11 year. The Secretary shall compute such benchmark amount  
12 for each such CCA area before the beginning of each an-  
13 nual, coordinated election period under section  
14 1851(e)(3)(B) for each year (beginning with 2010) in  
15 which the CCA area is so selected.

16 “(2) 2 COMPONENTS.—For purposes of paragraph (1),  
17 the 2 components described in this paragraph for a CCA  
18 area and a year are the following:

19 “(A) MA LOCAL COMPONENT.—The product of the  
20 following:

21 “(i) WEIGHTED AVERAGE OF MEDICARE AD-  
22 VANTAGE PLAN BIDS IN AREA.—The weighted aver-  
23 age of the plan bids for the area and year (as de-  
24 termined under paragraph (3)(A)).

25 “(ii) NON-FFS MARKET SHARE.—1 minus the  
26 fee-for-service market share percentage, determined  
27 under paragraph (4) for the area and year.

28 “(B) FEE-FOR-SERVICE COMPONENT.—The prod-  
29 uct of the following:

30 “(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-  
31 DRUG AMOUNT.—The fee-for-service area-specific  
32 non-drug amount (as defined in paragraph (5)) for  
33 the area and year.

34 “(ii) FEE-FOR-SERVICE MARKET SHARE.—The  
35 fee-for-service market share percentage, determined  
36 under paragraph (4) for the area and year.

1           “(3) DETERMINATION OF WEIGHTED AVERAGE MA  
2 BIDS FOR A CCA AREA.—

3           “(A) IN GENERAL.—For purposes of paragraph  
4 (2)(A)(i), the weighted average of plan bids for a CCA  
5 area and a year is, subject to subparagraph (D), the  
6 sum of the following products for MA local plans de-  
7 scribed in subparagraph (C) in the area and year:

8           “(i) MONTHLY MEDICARE ADVANTAGE STATU-  
9 TORY NON-DRUG BID AMOUNT.—The accepted  
10 unadjusted MA statutory non-drug monthly bid  
11 amount.

12           “(ii) PLAN’S SHARE OF MEDICARE ADVANTAGE  
13 ENROLLMENT IN AREA.—The number of individ-  
14 uals described in subparagraph (B), divided by the  
15 total number of such individuals for all MA plans  
16 described in subparagraph (C) for that area and  
17 year.

18           “(B) COUNTING OF INDIVIDUALS.—The Secretary  
19 shall count, for each MA local plan described in sub-  
20 paragraph (C) for an area and year, the number of in-  
21 dividuals who reside in the area and who were enrolled  
22 under such plan under this part during the reference  
23 month for that year.

24           “(C) EXCLUSION OF PLANS NOT OFFERED IN PRE-  
25 VIOUS YEAR.—For an area and year, the MA local  
26 plans described in this subparagraph are MA local  
27 plans described in section 1851(a)(2)(A)(i) that are of-  
28 fered in the area and year and were offered in the CCA  
29 area in the reference month.

30           “(D) COMPUTATION OF WEIGHTED AVERAGE OF  
31 PLAN BIDS.—In calculating the weighted average of  
32 plan bids for a CCA area under subparagraph (A)—

33           “(i) in the case of an MA local plan that has  
34 a service area only part of which is within such  
35 CCA area, the MA organization offering such plan  
36 shall submit a separate bid for such plan for the  
37 portion within such CCA area; and

1                   “(ii) the Secretary shall adjust such separate  
2                   bid (or, in the case of an MA local plan that has  
3                   a service area entirely within such CCA area, the  
4                   plan bid) as may be necessary to take into account  
5                   differences between the service area of such plan  
6                   within the CCA area and the entire CCA area and  
7                   the distribution of plan enrollees of all MA local  
8                   plans offered within the CCA area.

9                   “(4) COMPUTATION OF FEE-FOR-SERVICE MARKET  
10                  SHARE PERCENTAGE.—The Secretary shall determine, for a  
11                  year and a CCA area, the proportion (in this subsection re-  
12                  ferred to as the ‘fee-for-service market share percentage’)  
13                  equal to—

14                  “(A) the total number of MA eligible individuals  
15                  residing in such area who during the reference month  
16                  for the year were not enrolled in any MA plan; divided  
17                  by

18                  “(B) the sum of such number and the total num-  
19                  ber of MA eligible individuals residing in such area who  
20                  during such reference month were enrolled in an MA  
21                  local plan described in section 1851(a)(2)(A)(i),  
22                  or, if greater, such proportion determined for individuals  
23                  nationally.

24                  “(5) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG  
25                  AMOUNT.—

26                  “(A) IN GENERAL.—For purposes of paragraph  
27                  (2)(B)(i) and subsection (f)(2)(A), subject to subpara-  
28                  graph (C), the term ‘fee-for-service area-specific non-  
29                  drug amount’ means, for a CCA area and a year, the  
30                  adjusted average per capita cost for such area and year  
31                  involved, determined under section 1876(a)(4) and ad-  
32                  justed as appropriate for the purpose of risk adjust-  
33                  ment for benefits under the original medicare fee-for-  
34                  service program option for individuals entitled to bene-  
35                  fits under part A and enrolled under part B who are  
36                  not enrolled in an MA plan for the year, but adjusted

1 to exclude costs attributable to payments under section  
2 1886(h).

3 “(B) USE OF FULL RISK ADJUSTMENT TO STAND-  
4 ARDIZE FEE-FOR-SERVICE COSTS TO TYPICAL BENE-  
5 FICIARY.—In determining the adjusted average per  
6 capita cost for an area and year under subparagraph  
7 (A), such costs shall be adjusted to fully take into ac-  
8 count the demographic and health status risk factors  
9 established under section 1853(a)(1)(A)(iv) so that  
10 such per capita costs reflect the average costs for a  
11 typical beneficiary residing in the CCA area.

12 “(C) INCLUSION OF COSTS OF VA AND DOD MILI-  
13 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE  
14 BENEFICIARIES.—In determining the adjusted average  
15 per capita cost under subparagraph (A) for a year,  
16 such cost shall be adjusted to include the Secretary’s  
17 estimate, on a per capita basis, of the amount of addi-  
18 tional payments that would have been made in the area  
19 involved under this title if individuals entitled to bene-  
20 fits under this title had not received services from fa-  
21 cilities of the Department of Veterans Affairs or the  
22 Department of Defense.

23 “(f) PREMIUM ADJUSTMENT.—

24 “(1) APPLICATION.—

25 “(A) IN GENERAL.—Except as provided in sub-  
26 paragraph (B), in the case of an individual who is en-  
27 rolled under part B, who resides in a CCA area, and  
28 who is not enrolled in an MA plan under this part, the  
29 monthly premium otherwise applied under part B (de-  
30 termined without regard to subsections (b), (f), and (i)  
31 of section 1839 or any adjustment under this sub-  
32 section) shall be adjusted in accordance with paragraph  
33 (2), but only in the case of premiums for months dur-  
34 ing the period in which the CCA program under this  
35 section for such area is in effect.

36 “(B) NO PREMIUM ADJUSTMENT FOR SUBSIDY EL-  
37 IGIBLE BENEFICIARIES.—No premium adjustment shall

1 be made under this subsection for a premium for a  
2 month if the individual is determined to be a subsidy  
3 eligible individual (as defined in section 1860D-  
4 14(a)(3)(A)) for the month.

5 “(2) AMOUNT OF ADJUSTMENT.—

6 “(A) IN GENERAL.—Under this paragraph, subject  
7 to the exemption under paragraph (1)(B) and the limi-  
8 tation under subparagraph (B), if the fee-for-service  
9 area-specific non-drug amount (as defined in section  
10 (e)(5)) for a CCA area in which an individual resides  
11 for a month—

12 “(i) does not exceed the CCA non-drug month-  
13 ly benchmark amount (as determined under sub-  
14 section (e)(1)) for such area and month, the  
15 amount of the premium for the individual for the  
16 month shall be reduced, by an amount equal to 75  
17 percent of the amount by which such CCA bench-  
18 mark exceeds such fee-for-service area-specific non-  
19 drug amount; or

20 “(ii) exceeds such CCA non-drug benchmark,  
21 the amount of the premium for the individual for  
22 the month shall be adjusted to ensure, that—

23 “(I) the sum of the amount of the ad-  
24 justed premium and the CCA non-drug bench-  
25 mark for the area; is equal to

26 “(II) the sum of the unadjusted premium  
27 plus the amount of such fee-for-service area-  
28 specific non-drug amount for the area.

29 “(B) LIMITATION.—In no case shall the actual  
30 amount of an adjustment under subparagraph (A) for  
31 an area and month in a year result in an adjustment  
32 that exceeds the maximum adjustment permitted under  
33 subparagraph (C) for the area and year, or, if less, the  
34 maximum annual adjustment permitted under subpara-  
35 graph (D) for the area and year.

36 “(C) PHASE-IN OF ADJUSTMENT.—The amount of  
37 an adjustment under subparagraph (A) for a CCA area

1 and year may not exceed the product of the phase-in  
2 fraction for the year under subsection (d)(3)(B) multi-  
3 plied by the amount of the adjustment otherwise com-  
4 puted under subparagraph (A) for the area and year,  
5 determined without regard to this subparagraph and  
6 subparagraph (D).

7 “(D) 5-PERCENT LIMITATION ON ADJUSTMENT.—

8 The amount of the adjustment under this subsection  
9 for months in a year shall not exceed 5 percent of the  
10 amount of the monthly premium amount determined  
11 for months in the year under section 1839 without re-  
12 gard to subsections (b), (f), and (i) of such section and  
13 this subsection.”.

14 (b) CONFORMING AMENDMENTS.—

15 (1) MA LOCAL PLANS.—

16 (A) Section 1853(j)(1)(A) (42 U.S.C. 1395w-  
17 23(j)(1)(A)), as added by section 222(d), is amended  
18 by inserting “subject to section 1860C–1(d)(2)(A),”  
19 after “within an MA local area,”.

20 (B) Section 1853(b)(1)(B), as amended by section  
21 222(f)(1), is amended by adding at the end the fol-  
22 lowing new clause:

23 “(iii) BENCHMARK ANNOUNCEMENT FOR CCA  
24 LOCAL AREAS.—The Secretary shall determine, and  
25 shall announce (in a manner intended to provide  
26 notice to interested parties), on a timely basis be-  
27 fore the calendar year concerned, with respect to  
28 each CCA area (as defined in section 1860C–  
29 1(b)(1)(A)), the CCA non-drug monthly benchmark  
30 amount under section 1860C–1(e)(1) for that area  
31 for the year involved.”.

32 (2) PREMIUM ADJUSTMENT.—

33 (A) Section 1839 (42 U.S.C. 1395r) is amended  
34 by adding at the end the following new subsection:

35 “(h) POTENTIAL APPLICATION OF COMPARATIVE COST  
36 ADJUSTMENT IN CCA AREAS.—

1           “(1) IN GENERAL.—Certain individuals who are resid-  
2           ing in a CCA area under section 1860C–1 who are not en-  
3           rolled in an MA plan under part C may be subject to a pre-  
4           mium adjustment under subsection (f) of such section for  
5           months in which the CCA program under such section is  
6           in effect in such area.

7           “(2) NO EFFECT ON LATE ENROLLMENT PENALTY OR  
8           INCOME-RELATED ADJUSTMENT IN SUBSIDIES.—Nothing in  
9           this subsection or section 1860C–1(f) shall be construed as  
10          affecting the amount of any premium adjustment under  
11          subsection (b) or (i). Subsection (f) shall be applied without  
12          regard to any premium adjustment referred to in para-  
13          graph (1).

14          “(3) IMPLEMENTATION.—In order to carry out a pre-  
15          mium adjustment under this subsection and section  
16          1860C–1(f) (insofar as it is effected through the manner  
17          of collection of premiums under section 1840(a)), the Sec-  
18          retary shall transmit to the Commissioner of Social  
19          Security—

20                 “(A) at the beginning of each year, the name, so-  
21                 cial security account number, and the amount of the  
22                 premium adjustment (if any) for each individual en-  
23                 rolled under this part for each month during the year;  
24                 and

25                 “(B) periodically throughout the year, information  
26                 to update the information previously transmitted under  
27                 this paragraph for the year.”.

28                 (B) Section 1844(c) (42 U.S.C. 1395w(c)) is  
29                 amended by inserting “and without regard to any pre-  
30                 mium adjustment effected under sections 1839(h) and  
31                 1860C–1(f)” before the period at the end.

32          (c) NO CHANGE IN MEDICARE’S DEFINED BENEFIT  
33          PACKAGE.—Nothing in this part (or the amendments made by  
34          this part) shall be construed as changing the entitlement to de-  
35          fined benefits under parts A and B of title XVIII of the Social  
36          Security Act.

1           **TITLE III—COMBATTING WASTE,**  
2           **FRAUD, AND ABUSE**

3           **SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVI-**  
4           **SIONS.**

5           (a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S  
6 AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CER-  
7 TAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—Section  
8 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

9           (1) in subparagraph (A)(ii), by striking “promptly (as  
10 determined in accordance with regulations)”; and

11           (2) in subparagraph (B)—

12           (A) by redesignating clauses (i) through (v) as  
13 clauses (ii) through (vi), respectively; and

14           (B) by inserting before clause (ii), as so redesign-  
15 ated, the following new clause:

16           “(i) AUTHORITY TO MAKE CONDITIONAL PAY-  
17 MENT.—The Secretary may make payment under  
18 this title with respect to an item or service if a pri-  
19 mary plan described in subparagraph (A)(ii) has  
20 not made or cannot reasonably be expected to make  
21 payment with respect to such item or service  
22 promptly (as determined in accordance with regula-  
23 tions). Any such payment by the Secretary shall be  
24 conditioned on reimbursement to the appropriate  
25 Trust Fund in accordance with the succeeding pro-  
26 visions of this subsection.”.

27           (b) CLARIFYING AMENDMENTS TO CONDITIONAL PAY-  
28 MENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.  
29 1395y(b)(2)), as amended by subsection (a), is amended—

30           (1) in subparagraph (A), in the matter following  
31 clause (ii), by inserting the following sentence at the end:  
32 “An entity that engages in a business, trade, or profession  
33 shall be deemed to have a self-insured plan if it carries its  
34 own risk (whether by a failure to obtain insurance, or oth-  
35 erwise) in whole or in part.”;



1           (2) in subparagraph (B)(ii), as redesignated by sub-  
2 section (a)(2)(A)—

3           (A) by striking the first sentence and inserting the  
4 following: “A primary plan, and an entity that receives  
5 payment from a primary plan, shall reimburse the ap-  
6 propriate Trust Fund for any payment made by the  
7 Secretary under this title with respect to an item or  
8 service if it is demonstrated that such primary plan has  
9 or had a responsibility to make payment with respect  
10 to such item or service. A primary plan’s responsibility  
11 for such payment may be demonstrated by a judgment,  
12 a payment conditioned upon the recipient’s com-  
13 promise, waiver, or release (whether or not there is a  
14 determination or admission of liability) of payment for  
15 items or services included in a claim against the pri-  
16 mary plan or the primary plan’s insured, or by other  
17 means.”; and

18           (B) in the final sentence, by striking “on the date  
19 such notice or other information is received” and in-  
20 serting “on the date notice of, or information related  
21 to, a primary plan’s responsibility for such payment or  
22 other information is received”; and

23           (3) in subparagraph (B)(iii), as redesignated by sub-  
24 section (a)(2)(A), by striking the first sentence and insert-  
25 ing the following: “In order to recover payment made under  
26 this title for an item or service, the United States may  
27 bring an action against any or all entities that are or were  
28 required or responsible (directly, as an insurer or self-in-  
29 surer, as a third-party administrator, as an employer that  
30 sponsors or contributes to a group health plan, or large  
31 group health plan, or otherwise) to make payment with re-  
32 spect to the same item or service (or any portion thereof)  
33 under a primary plan. The United States may, in accord-  
34 ance with paragraph (3)(A) collect double damages against  
35 any such entity. In addition, the United States may recover  
36 under this clause from any entity that has received pay-

1 ment from a primary plan or from the proceeds of a pri-  
2 mary plan's payment to any entity.”.

3 (c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C.  
4 1395y(b)) is amended—

5 (1) in paragraph (1)(A), by moving the indentation of  
6 clauses (ii) through (v) 2 ems to the left; and

7 (2) in paragraph (3)(A), by striking “such” before  
8 “paragraphs”.

9 (d) EFFECTIVE DATES.—The amendments made by this  
10 section shall be effective—

11 (1) in the case of subsection (a), as if included in the  
12 enactment of title III of the Medicare and Medicaid Budget  
13 Reconciliation Amendments of 1984 (Public Law 98–369);  
14 and

15 (2) in the case of subsections (b) and (c), as if in-  
16 cluded in the enactment of section 953 of the Omnibus  
17 Reconciliation Act of 1980 (Public Law 96–499; 94 Stat.  
18 2647).

19 **SEC. 302. PAYMENT FOR DURABLE MEDICAL EQUIP-**  
20 **MENT; COMPETITIVE ACQUISITION OF CER-**  
21 **TAIN ITEMS AND SERVICES.**

22 (a) QUALITY ENHANCEMENT AND FRAUD REDUCTION.—

23 (1) ESTABLISHMENT OF QUALITY STANDARDS AND  
24 ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL  
25 EQUIPMENT SUPPLIERS.—Section 1834(a) (42 U.S.C.  
26 1395m(a)) is amended—

27 (A) by transferring paragraph (17), as added by  
28 section 4551(c)(1) of the Balanced Budget Act of 1997  
29 (111 Stat. 458), to the end of such section and redesign-  
30 ating such paragraph as paragraph (19); and

31 (B) by adding at the end the following new para-  
32 graph:

33 “(20) IDENTIFICATION OF QUALITY STANDARDS.—

34 “(A) IN GENERAL.—Subject to subparagraph (C),  
35 the Secretary shall establish and implement quality  
36 standards for suppliers of items and services described  
37 in subparagraph (D) to be applied by recognized inde-

1           pendent accreditation organizations (as designated  
2           under subparagraph (B)) and with which such sup-  
3           pliers shall be required to comply in order to—

4                   “(i) furnish any such item or service for which  
5                   payment is made under this part; and

6                   “(ii) receive or retain a provider or supplier  
7                   number used to submit claims for reimbursement  
8                   for any such item or service for which payment  
9                   may be made under this title.

10           “(B) DESIGNATION OF INDEPENDENT ACCREDITA-  
11           TION ORGANIZATIONS.—Not later than the date that is  
12           1 year after the date on which the Secretary imple-  
13           ments the quality standards under subparagraph (A),  
14           notwithstanding section 1865(b), the Secretary shall  
15           designate and approve one or more independent accred-  
16           itation organizations for purposes of such subpara-  
17           graph.

18           “(C) QUALITY STANDARDS.—The quality stand-  
19           ards described in subparagraph (A) may not be less  
20           stringent than the quality standards that would other-  
21           wise apply if this paragraph did not apply and shall in-  
22           clude consumer services standards.

23           “(D) ITEMS AND SERVICES DESCRIBED.—The  
24           items and services described in this subparagraph are  
25           the following items and services, as the Secretary deter-  
26           mines appropriate:

27                   “(i) Covered items (as defined in paragraph  
28                   (13)) for which payment may otherwise be made  
29                   under this subsection.

30                   “(ii) Prosthetic devices and orthotics and pros-  
31                   thetics described in section 1834(h)(4).

32                   “(iii) Items and services described in section  
33                   1842(s)(2).

34           “(E) IMPLEMENTATION.—The Secretary may es-  
35           tablish by program instruction or otherwise the quality  
36           standards under this paragraph, after consultation with  
37           representatives of relevant parties. Such standards

1           shall be applied prospectively and shall be published on  
2           the Internet website of the Centers for Medicare &  
3           Medicaid Services.”.

4           (2) ESTABLISHMENT OF CLINICAL CONDITIONS OF  
5           COVERAGE STANDARDS FOR ITEMS OF DURABLE MEDICAL  
6           EQUIPMENT.—Section 1834(a)(1) (42 U.S.C. 1395m(a)(1))  
7           is amended by adding at the end the following new sub-  
8           paragraph:

9                   “(E) CLINICAL CONDITIONS FOR COVERAGE.—

10                   “(i) IN GENERAL.—The Secretary shall estab-  
11                   lish standards for clinical conditions for payment  
12                   for covered items under this subsection.

13                   “(ii) REQUIREMENTS.—The standards estab-  
14                   lished under clause (i) shall include the specifica-  
15                   tion of types or classes of covered items that re-  
16                   quire, as a condition of payment under this sub-  
17                   section, a face-to-face examination of the individual  
18                   by a physician (as defined in section 1861(r)(1)),  
19                   a physician assistant, nurse practitioner, or a clin-  
20                   ical nurse specialist (as those terms are defined in  
21                   section 1861(aa)(5)) and a prescription for the  
22                   item.

23                   “(iii) PRIORITY OF ESTABLISHMENT OF  
24                   STANDARDS.—In establishing the standards under  
25                   this subparagraph, the Secretary shall first estab-  
26                   lish standards for those covered items for which the  
27                   Secretary determines there has been a proliferation  
28                   of use, consistent findings of charges for covered  
29                   items that are not delivered, or consistent findings  
30                   of falsification of documentation to provide for pay-  
31                   ment of such covered items under this part.

32                   “(iv) STANDARDS FOR POWER WHEEL-  
33                   CHAIRS.—Effective on the date of the enactment of  
34                   this subparagraph, in the case of a covered item  
35                   consisting of a motorized or power wheelchair for  
36                   an individual, payment may not be made for such  
37                   covered item unless a physician (as defined in sec-

1           tion 1861(r)(1)), a physician assistant, nurse prac-  
2           titioner, or a clinical nurse specialist (as those  
3           terms are defined in section 1861(aa)(5)) has con-  
4           ducted a face-to-face examination of the individual  
5           and written a prescription for the item.

6           “(v) LIMITATION ON PAYMENT FOR COVERED  
7           ITEMS.—Payment may not be made for a covered  
8           item under this subsection unless the item meets  
9           any standards established under this subparagraph  
10          for clinical condition of coverage.”.

11          (b) COMPETITIVE ACQUISITION.—

12           (1) IN GENERAL.—Section 1847 (42 U.S.C. 1395w-3)

13          is amended to read as follows:

14          “COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

15           “SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE AC-  
16          QUISITION PROGRAMS.—

17           “(1) IMPLEMENTATION OF PROGRAMS.—

18           “(A) IN GENERAL.—The Secretary shall establish  
19           and implement programs under which competitive ac-  
20           quisition areas are established throughout the United  
21           States for contract award purposes for the furnishing  
22           under this part of competitively priced items and serv-  
23           ices (described in paragraph (2)) for which payment is  
24           made under this part. Such areas may differ for dif-  
25           ferent items and services.

26           “(B) PHASED-IN IMPLEMENTATION.—The  
27          programs—

28           “(i) shall be phased in among competitive ac-  
29           quisition areas in a manner so that the competition  
30           under the programs occurs in—

31           “(I) 10 of the largest metropolitan statis-  
32           tical areas in 2007;

33           “(II) 80 of the largest metropolitan statis-  
34           tical areas in 2009; and

35           “(III) additional areas after 2009; and

36           “(ii) may be phased in first among the highest  
37          cost and highest volume items and services or those

1 items and services that the Secretary determines  
2 have the largest savings potential.

3 “(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such  
4 provisions of the Federal Acquisition Regulation as are  
5 necessary for the efficient implementation of this section, other than provisions relating to confidentiality of  
6 information and such other provisions as the Secretary  
7 determines appropriate.  
8

9  
10 “(2) ITEMS AND SERVICES DESCRIBED.—The items  
11 and services referred to in paragraph (1) are the following:

12 “(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section  
13 1834(a)(13)) for which payment would otherwise be  
14 made under section 1834(a), including items used in  
15 infusion and drugs (other than inhalation drugs) and  
16 supplies used in conjunction with durable medical  
17 equipment, but excluding class III devices under the  
18 Federal Food, Drug, and Cosmetic Act.  
19

20 “(B) OTHER EQUIPMENT AND SUPPLIES.—Items  
21 and services described in section 1842(s)(2)(D), other  
22 than parenteral nutrients, equipment, and supplies.

23 “(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would  
24 otherwise be made under section 1834(h) which require  
25 minimal self-adjustment for appropriate use and do not  
26 require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.  
27

28  
29 “(3) EXCEPTION AUTHORITY.—In carrying out the  
30 programs under this section, the Secretary may exempt—

31 “(A) rural areas and areas with low population  
32 density within urban areas that are not competitive,  
33 unless there is a significant national market through  
34 mail order for a particular item or service; and

35 “(B) items and services for which the application  
36 of competitive acquisition is not likely to result in significant savings.  
37

1           “(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF  
2 DURABLE MEDICAL EQUIPMENT AND OXYGEN.—In the case  
3 of a covered item for which payment is made on a rental  
4 basis under section 1834(a) and in the case of payment for  
5 oxygen under section 1834(a)(5), the Secretary shall estab-  
6 lish a process by which rental agreements for the covered  
7 items and supply arrangements with oxygen suppliers en-  
8 tered into before the application of the competitive acquisi-  
9 tion program under this section for the item may be contin-  
10 ued notwithstanding this section. In the case of any such  
11 continuation, the supplier involved shall provide for appro-  
12 priate servicing and replacement, as required under section  
13 1834(a).

14           “(5) PHYSICIAN AUTHORIZATION.—

15           “(A) IN GENERAL.—With respect to items or serv-  
16 ices included within a particular HCPCS code, the Sec-  
17 retary may establish a process for certain items and  
18 services under which a physician may prescribe a par-  
19 ticular brand or mode of delivery of an item or service  
20 within such code if the physician determines that use  
21 of the particular item or service would avoid an adverse  
22 medical outcome on the individual, as determined by  
23 the Secretary.

24           “(B) NO EFFECT ON PAYMENT AMOUNT.—A pre-  
25 scription under subparagraph (A) shall not affect the  
26 amount of payment otherwise applicable for the item or  
27 service under the code involved.

28           “(6) APPLICATION.—For each competitive acquisition  
29 area in which the program is implemented under this sub-  
30 section with respect to items and services, the payment  
31 basis determined under the competition conducted under  
32 subsection (b) shall be substituted for the payment basis  
33 otherwise applied under section 1834(a), section 1834(h),  
34 or section 1842(s), as appropriate.

35           “(b) PROGRAM REQUIREMENTS.—

36           “(1) IN GENERAL.—The Secretary shall conduct a  
37 competition among entities supplying items and services de-

1 scribed in subsection (a)(2) for each competitive acquisition  
2 area in which the program is implemented under subsection  
3 (a) with respect to such items and services.

4 “(2) CONDITIONS FOR AWARDING CONTRACT.—

5 “(A) IN GENERAL.—The Secretary may not award  
6 a contract to any entity under the competition con-  
7 ducted in an competitive acquisition area pursuant to  
8 paragraph (1) to furnish such items or services unless  
9 the Secretary finds all of the following:

10 “(i) The entity meets applicable quality stand-  
11 ards specified by the Secretary under section  
12 1834(a)(20).

13 “(ii) The entity meets applicable financial  
14 standards specified by the Secretary, taking into  
15 account the needs of small providers.

16 “(iii) The total amounts to be paid to contrac-  
17 tors in a competitive acquisition area are expected  
18 to be less than the total amounts that would other-  
19 wise be paid.

20 “(iv) Access of individuals to a choice of mul-  
21 tiple suppliers in the area is maintained.

22 “(B) TIMELY IMPLEMENTATION OF PROGRAM.—  
23 Any delay in the implementation of quality standards  
24 under section 1834(a)(20) or delay in the receipt of ad-  
25 vice from the program oversight committee established  
26 under subsection (c) shall not delay the implementation  
27 of the competitive acquisition program under this sec-  
28 tion.

29 “(3) CONTENTS OF CONTRACT.—

30 “(A) IN GENERAL.—A contract entered into with  
31 an entity under the competition conducted pursuant to  
32 paragraph (1) is subject to terms and conditions that  
33 the Secretary may specify.

34 “(B) TERM OF CONTRACTS.—The Secretary shall  
35 recompetete contracts under this section not less often  
36 than once every 3 years.

37 “(4) LIMIT ON NUMBER OF CONTRACTORS.—



1           “(A) IN GENERAL.—The Secretary may limit the  
2           number of contractors in a competitive acquisition area  
3           to the number needed to meet projected demand for  
4           items and services covered under the contracts. In  
5           awarding contracts, the Secretary shall take into ac-  
6           count the ability of bidding entities to furnish items or  
7           services in sufficient quantities to meet the anticipated  
8           needs of individuals for such items or services in the  
9           geographic area covered under the contract on a timely  
10          basis.

11          “(B) MULTIPLE WINNERS.—The Secretary shall  
12          award contracts to multiple entities submitting bids in  
13          each area for an item or service.

14          “(5) PAYMENT.—

15          “(A) IN GENERAL.—Payment under this part for  
16          competitively priced items and services described in  
17          subsection (a)(2) shall be based on bids submitted and  
18          accepted under this section for such items and services.  
19          Based on such bids the Secretary shall determine a sin-  
20          gle payment amount for each item or service in each  
21          competitive acquisition area.

22          “(B) REDUCED BENEFICIARY COST-SHARING.—

23          “(i) APPLICATION OF COINSURANCE.—Pay-  
24          ment under this section for items and services shall  
25          be in an amount equal to 80 percent of the pay-  
26          ment basis described in subparagraph (A).

27          “(ii) APPLICATION OF DEDUCTIBLE.—Before  
28          applying clause (i), the individual shall be required  
29          to meet the deductible described in section 1833(b).

30          “(C) PAYMENT ON ASSIGNMENT-RELATED  
31          BASIS.—Payment for any item or service furnished by  
32          the entity may only be made under this section on an  
33          assignment-related basis.

34          “(D) CONSTRUCTION.—Nothing in this section  
35          shall be construed as precluding the use of an advanced  
36          beneficiary notice with respect to a competitively priced  
37          item and service.

1           “(6) PARTICIPATING CONTRACTORS.—

2           “(A) IN GENERAL.—Except as provided in sub-  
3 section (a)(4), payment shall not be made for items  
4 and services described in subsection (a)(2) furnished by  
5 a contractor and for which competition is conducted  
6 under this section unless—

7           “(i) the contractor has submitted a bid for  
8 such items and services under this section; and

9           “(ii) the Secretary has awarded a contract to  
10 the contractor for such items and services under  
11 this section.

12           “(B) BID DEFINED.—In this section, the term  
13 ‘bid’ means an offer to furnish an item or service for  
14 a particular price and time period that includes, where  
15 appropriate, any services that are attendant to the fur-  
16 nishing of the item or service.

17           “(C) RULES FOR MERGERS AND ACQUISITIONS.—  
18 In applying subparagraph (A) to a contractor, the con-  
19 tractor shall include a successor entity in the case of  
20 a merger or acquisition, if the successor entity assumes  
21 such contract along with any liabilities that may have  
22 occurred thereunder.

23           “(D) PROTECTION OF SMALL SUPPLIERS.—In de-  
24 veloping procedures relating to bids and the awarding  
25 of contracts under this section, the Secretary shall take  
26 appropriate steps to ensure that small suppliers of  
27 items and services have an opportunity to be considered  
28 for participation in the program under this section.

29           “(7) CONSIDERATION IN DETERMINING CATEGORIES  
30 FOR BIDS.—The Secretary may consider the clinical effi-  
31 ciency and value of specific items within codes, including  
32 whether some items have a greater therapeutic advantage  
33 to individuals.

34           “(8) AUTHORITY TO CONTRACT FOR EDUCATION, MON-  
35 ITORING, OUTREACH, AND COMPLAINT SERVICES.—The  
36 Secretary may enter into contracts with appropriate enti-  
37 ties to address complaints from individuals who receive

1 items and services from an entity with a contract under  
2 this section and to conduct appropriate education of and  
3 outreach to such individuals and monitoring quality of serv-  
4 ices with respect to the program.

5 “(9) AUTHORITY TO CONTRACT FOR IMPLEMENTA-  
6 TION.—The Secretary may contract with appropriate enti-  
7 ties to implement the competitive bidding program under  
8 this section.

9 “(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—  
10 There shall be no administrative or judicial review under  
11 section 1869, section 1878, or otherwise, of—

12 “(A) the establishment of payment amounts under  
13 paragraph (5);

14 “(B) the awarding of contracts under this section;

15 “(C) the designation of competitive acquisition  
16 areas under subsection (a)(1)(A);

17 “(D) the phased-in implementation under sub-  
18 section (a)(1)(B);

19 “(E) the selection of items and services for com-  
20 petitive acquisition under subsection (a)(2); or

21 “(F) the bidding structure and number of contrac-  
22 tors selected under this section.

23 “(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

24 “(1) ESTABLISHMENT.—The Secretary shall establish  
25 a Program Advisory and Oversight Committee (hereinafter  
26 in this section referred to as the ‘Committee’).

27 “(2) MEMBERSHIP; TERMS.—The Committee shall  
28 consist of such members as the Secretary may appoint who  
29 shall serve for such term as the Secretary may specify.

30 “(3) DUTIES.—

31 “(A) ADVICE.—The Committee shall provide ad-  
32 vice to the Secretary with respect to the following func-  
33 tions:

34 “(i) The implementation of the program under  
35 this section.

36 “(ii) The establishment of financial standards  
37 for purposes of subsection (b)(2)(A)(ii).

1                   “(iii) The establishment of requirements for  
2                   collection of data for the efficient management of  
3                   the program.

4                   “(iv) The development of proposals for effi-  
5                   cient interaction among manufacturers, providers  
6                   of services, suppliers (as defined in section  
7                   1861(d)), and individuals.

8                   “(v) The establishment of quality standards  
9                   under section 1834(a)(20).

10                  “(B) ADDITIONAL DUTIES.—The Committee shall  
11                  perform such additional functions to assist the Sec-  
12                  retary in carrying out this section as the Secretary may  
13                  specify.

14                  “(4) INAPPLICABILITY OF FACA.—The provisions of  
15                  the Federal Advisory Committee Act (5 U.S.C. App.) shall  
16                  not apply.

17                  “(5) TERMINATION.—The Committee shall terminate  
18                  on December 31, 2009.

19                  “(d) REPORT.—Not later than July 1, 2009, the Secretary  
20                  shall submit to Congress a report on the programs under this  
21                  section. The report shall include information on savings, reduc-  
22                  tions in cost-sharing, access to and quality of items and serv-  
23                  ices, and satisfaction of individuals.

24                  “(e) DEMONSTRATION PROJECT FOR CLINICAL LABORA-  
25                  TORY SERVICES.—

26                  “(1) IN GENERAL.—The Secretary shall conduct a  
27                  demonstration project on the application of competitive ac-  
28                  quisition under this section to clinical diagnostic laboratory  
29                  tests—

30                         “(A) for which payment would otherwise be made  
31                         under section 1833(h) (other than for pap smear lab-  
32                         oratory tests under paragraph (7) of such section) or  
33                         section 1834(d)(1) (relating to colorectal cancer screen-  
34                         ing tests); and

35                         “(B) which are furnished by entities that did not  
36                         have a face-to-face encounter with the individual.

37                  “(2) TERMS AND CONDITIONS.—

1           “(A) IN GENERAL.—Except as provided in sub-  
2 paragraph (B), such project shall be under the same  
3 conditions as are applicable to items and services de-  
4 scribed in subsection (a)(2), excluding subsection  
5 (b)(5)(B) and other conditions as the Secretary deter-  
6 mines to be appropriate.

7           “(B) APPLICATION OF CLIA QUALITY STAND-  
8 ARDS.—The quality standards established by the Sec-  
9 retary under section 353 of the Public Health Service  
10 Act for clinical diagnostic laboratory tests shall apply  
11 to such tests under the demonstration project under  
12 this section in lieu of quality standards described in  
13 subsection (b)(2)(A)(i).

14           “(3) REPORT.—The Secretary shall submit to  
15 Congress—

16           “(A) an initial report on the project not later than  
17 December 31, 2005; and

18           “(B) such progress and final reports on the  
19 project after such date as the Secretary determines ap-  
20 propriate.”.

21           (2) CONFORMING AMENDMENTS.—Section 1833(a)(1)  
22 (42 U.S.C. 1395l(a)(1)) is amended—

23           (A) by striking “and (U)” and inserting “(U)”;

24           (B) by inserting before the semicolon at the end  
25 the following: “, and (V) notwithstanding subpara-  
26 graphs (I) (relating to durable medical equipment), (M)  
27 (relating to prosthetic devices and orthotics and pros-  
28 thetics), and (Q) (relating to 1842(s) items), with re-  
29 spect to competitively priced items and services (de-  
30 scribed in section 1847(a)(2)) that are furnished in a  
31 competitive area, the amounts paid shall be the  
32 amounts described in section 1847(b)(5)”;

33           (C) in clause (D)—

34           (i) by striking “or (ii)” and inserting “(ii)”;

35           and

36           (ii) by adding at the end the following: “or  
37 (iii) on the basis of a rate established under a dem-

1           onstration project under section 1847(e), the  
2           amount paid shall be equal to 100 percent of such  
3           rate.”.

4           (3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUI-  
5           SITION ON SUPPLIERS.—

6           (A) STUDY.—The Comptroller General of the  
7           United States shall conduct a study on the impact of  
8           competitive acquisition of durable medical equipment  
9           under section 1847 of the Social Security Act, as  
10          amended by paragraph (1), on suppliers and manufac-  
11          turers of such equipment and on patients. Such study  
12          shall specifically examine the impact of such competi-  
13          tive acquisition on access to, and quality of, such equip-  
14          ment and service related to such equipment.

15          (B) REPORT.—Not later than January 1, 2009,  
16          the Comptroller General shall submit to Congress a re-  
17          port on the study conducted under subparagraph (A)  
18          and shall include in the report such recommendations  
19          as the Comptroller General determines appropriate.

20          (c) TRANSITIONAL FREEZE.—

21           (1) DME.—

22           (A) IN GENERAL.—Section 1834(a)(14) (42  
23           U.S.C. 1395m(a)(14)) is amended—

24           (i) in subparagraph (E), by striking “and” at  
25           the end;

26           (ii) in subparagraph (F)—

27           (I) by striking “a subsequent year” and  
28           inserting “2003”; and

29           (II) by striking “the previous year.” and  
30           inserting “2002;” and

31           (iii) by adding at the end the following new  
32           subparagraphs:

33           “(G) for 2004 through 2006—

34           “(i) subject to clause (ii), in the case of class  
35           III medical devices described in section  
36           513(a)(1)(C) of the Federal Food, Drug, and Cos-  
37           metic Act (21 U.S.C. 360(c)(1)(C)), the percentage

1 increase described in subparagraph (B) for the year  
2 involved; and

3 “(ii) in the case of covered items not described  
4 in clause (i), 0 percentage points;

5 “(H) for 2007—

6 “(i) subject to clause (ii), in the case of class  
7 III medical devices described in section  
8 513(a)(1)(C) of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 360(c)(1)(C)), the percentage  
10 change determined by the Secretary to be appro-  
11 priate taking into account recommendations con-  
12 tained in the report of the Comptroller General of  
13 the United States under section 302(c)(1)(B) of  
14 the Medicare Prescription Drug, Improvement, and  
15 Modernization Act of 2003; and

16 “(ii) in the case of covered items not described  
17 in clause (i), 0 percentage points; and

18 “(I) for 2008—

19 “(i) subject to clause (ii), in the case of class  
20 III medical devices described in section  
21 513(a)(1)(C) of the Federal Food, Drug, and Cos-  
22 metic Act (21 U.S.C. 360(c)(1)(C)), the percentage  
23 increase described in subparagraph (B) (as applied  
24 to the payment amount for 2007 determined after  
25 the application of the percentage change under sub-  
26 paragraph (H)(i)); and

27 “(ii) in the case of covered items not described  
28 in clause (i), 0 percentage points; and

29 “(J) for a subsequent year, the percentage in-  
30 crease in the consumer price index for all urban con-  
31 sumers (U.S. urban average) for the 12-month period  
32 ending with June of the previous year.”.

33 (B) GAO REPORT ON CLASS III MEDICAL DE-  
34 VICES.—Not later than March 1, 2006, the Comptroller  
35 General of the United States shall submit to Congress,  
36 and transmit to the Secretary, a report containing rec-  
37 ommendations on the appropriate update percentage

1 under section 1834(a)(14) of the Social Security Act  
2 (42 U.S.C. 1395m(a)(14)) for class III medical devices  
3 described in section 513(a)(1)(C) of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) fur-  
5 nished to medicare beneficiaries during 2007 and 2008.

6 (2) PAYMENT RULE FOR SPECIFIED ITEMS.—Section  
7 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection  
8 (a), is further amended by adding at the end the following  
9 new paragraph:

10 “(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS  
11 AND SUPPLIES.—

12 “(A) IN GENERAL.—Notwithstanding the pre-  
13 ceding provisions of this subsection, for specified items  
14 and supplies (described in subparagraph (B)) furnished  
15 during 2005, the payment amount otherwise deter-  
16 mined under this subsection for such specified items  
17 and supplies shall be reduced by the percentage dif-  
18 ference between—

19 “(i) the amount of payment otherwise deter-  
20 mined for the specified item or supply under this  
21 subsection for 2002, and

22 “(ii) the amount of payment for the specified  
23 item or supply under chapter 89 of title 5, United  
24 States Code, as identified in the column entitled  
25 ‘Median FEHP Price’ in the table entitled ‘SUM-  
26 MARY OF MEDICARE PRICES COMPARED  
27 TO VA, MEDICAID, RETAIL, AND FEHP  
28 PRICES FOR 16 ITEMS’ included in the Testi-  
29 mony of the Inspector General before the Senate  
30 Committee on Appropriations, June 12, 2002, or  
31 any subsequent report by the Inspector General.

32 “(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—  
33 For purposes of subparagraph (A), a specified item or  
34 supply means oxygen and oxygen equipment, standard  
35 wheelchairs (including standard power wheelchairs),  
36 nebulizers, diabetic supplies consisting of lancets and  
37 testing strips, hospital beds, and air mattresses, but



1           only if the HCPCS code for the item or supply is iden-  
2           tified in a table referred to in subparagraph (A)(ii).

3           “(C) APPLICATION OF UPDATE TO SPECIAL PAY-  
4           MENT AMOUNT.—The covered item update under para-  
5           graph (14) for specified items and supplies for 2006  
6           and each subsequent year shall be applied to the pay-  
7           ment amount under subparagraph (A) unless payment  
8           is made for such items and supplies under section  
9           1847.”.

10          (3) PROSTHETIC DEVICES AND ORTHOTICS AND PROS-  
11          THETICS.—Section 1834(h)(4)(A) (42 U.S.C.  
12          1395m(h)(4)(A)) is amended—

13                (A) in clause (vii), by striking “and” at the end;

14                (B) in clause (viii), by striking “a subsequent  
15                year” and inserting “2003”; and

16                (C) by adding at the end the following new  
17                clauses:

18                       “(ix) for 2004, 2005, and 2006, 0 percent;  
19                       and

20                       “(x) for a subsequent year, the percentage in-  
21                       crease in the consumer price index for all urban  
22                       consumers (United States city average) for the 12-  
23                       month period ending with June of the previous  
24                       year;”.

25          (d) CONFORMING AMENDMENTS.—

26          (1) DURABLE MEDICAL EQUIPMENT; LIMITATION OF  
27          INHERENT REASONABLENESS AUTHORITY.—Section  
28          1834(a) (42 U.S.C. 1395m(a)) is amended—

29                (A) in paragraph (1)(B), by striking “The pay-  
30                ment basis” and inserting “Subject to subparagraph  
31                (F)(i), the payment basis”;

32                (B) in paragraph (1)(C), by striking “This sub-  
33                section” and inserting “Subject to subparagraph  
34                (F)(ii), this subsection”;

35                (C) by adding at the end of paragraph (1) the fol-  
36                lowing new subparagraph:

1           “(F) APPLICATION OF COMPETITIVE ACQUISITION;  
2           LIMITATION OF INHERENT REASONABLENESS AUTHOR-  
3           ITY.—In the case of covered items furnished on or after  
4           January 1, 2009, that are included in a competitive ac-  
5           quisition program in a competitive acquisition area  
6           under section 1847(a)—

7                   “(i) the payment basis under this subsection  
8                   for such items and services furnished in such area  
9                   shall be the payment basis determined under such  
10                  competitive acquisition program; and

11                  “(ii) the Secretary may use information on the  
12                  payment determined under such competitive acqui-  
13                  sition programs to adjust the payment amount oth-  
14                  erwise recognized under subparagraph (B)(ii) for  
15                  an area that is not a competitive acquisition area  
16                  under section 1847 and in the case of such adjust-  
17                  ment, paragraph (10)(B) shall not be applied.”;  
18                  and

19                  (D) in paragraph (10)(B), by inserting “in an  
20                  area and with respect to covered items and services for  
21                  which the Secretary does not make a payment amount  
22                  adjustment under paragraph (1)(F)” after “under this  
23                  subsection”.

24                  (2) OFF-THE-SHELF ORTHOTICS; LIMITATION OF IN-  
25                  HERENT REASONABLENESS AUTHORITY.—Section 1834(h)  
26                  (42 U.S.C. 1395m(h)) is amended—

27                   (A) in paragraph (1)(B), by striking “and (E)”  
28                   and inserting “, (E), and (H)(i)”;

29                   (B) in paragraph (1)(D), by striking “This sub-  
30                   section” and inserting “Subject to subparagraph  
31                   (H)(ii), this subsection”; and

32                   (C) by adding at the end of paragraph (1) the fol-  
33                   lowing new subparagraph:

34                           “(H) APPLICATION OF COMPETITIVE ACQUISITION  
35                           TO ORTHOTICS; LIMITATION OF INHERENT REASON-  
36                           ABLENESS AUTHORITY.—In the case of orthotics de-  
37                           scribed in paragraph (2)(C) of section 1847(a) fur-

1           nished on or after January 1, 2009, that are included  
2           in a competitive acquisition program in a competitive  
3           acquisition area under such section—

4                   “(i) the payment basis under this subsection  
5                   for such orthotics furnished in such area shall be  
6                   the payment basis determined under such competi-  
7                   tive acquisition program; and

8                   “(ii) the Secretary may use information on the  
9                   payment determined under such competitive acqui-  
10                  sition programs to adjust the payment amount oth-  
11                  erwise recognized under subparagraph (B)(ii) for  
12                  an area that is not a competitive acquisition area  
13                  under section 1847, and in the case of such adjust-  
14                  ment, paragraphs (8) and (9) of section 1842(b)  
15                  shall not be applied.”.

16           (3) OTHER ITEMS AND SERVICES; LIMITATION OF IN-  
17           HERENT REASONABLENESS AUTHORITY.—Section 1842(s)  
18           (42 U.S.C. 1395u(s)) is amended—

19                   (A) in the first sentence of paragraph (1), by  
20                   striking “The Secretary” and inserting “Subject to  
21                   paragraph (3), the Secretary”; and

22                   (B) by adding at the end the following new para-  
23                   graph:

24                   “(3) In the case of items and services described in para-  
25                   graph (2)(D) that are included in a competitive acquisition pro-  
26                   gram in a competitive acquisition area under section 1847(a)—

27                           “(A) the payment basis under this subsection for such  
28                           items and services furnished in such area shall be the pay-  
29                           ment basis determined under such competitive acquisition  
30                           program; and

31                           “(B) the Secretary may use information on the pay-  
32                           ment determined under such competitive acquisition pro-  
33                           grams to adjust the payment amount otherwise applicable  
34                           under paragraph (1) for an area that is not a competitive  
35                           acquisition area under section 1847, and in the case of  
36                           such adjustment, paragraphs (8) and (9) of section  
37                           1842(b) shall not be applied.”.

1 (e) REPORT ON ACTIVITIES OF SUPPLIERS.—The Inspec-  
2 tor General of the Department of Health and Human Services  
3 shall conduct a study to determine the extent to which (if any)  
4 suppliers of covered items of durable medical equipment that  
5 are subject to the competitive acquisition program under sec-  
6 tion 1847 of the Social Security Act, as amended by subsection  
7 (a), are soliciting physicians to prescribe certain brands or  
8 modes of delivery of covered items based on profitability. Not  
9 later than July 1, 2009, the Inspector General shall submit to  
10 Congress a report on such study.

11 **SEC. 303. PAYMENT REFORM FOR COVERED OUT-**  
12 **PATIENT DRUGS AND BIOLOGICALS.**

13 (a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

14 (1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE  
15 VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w-  
16 4(c)(2)) is amended—

17 (A) in subparagraph (B)—

18 (i) in clause (ii)(II), by striking “The adjust-  
19 ments” and inserting “Subject to clause (iv), the  
20 adjustments”; and

21 (ii) by adding at the end of subparagraph (B),  
22 the following new clause:

23 “(iv) EXEMPTION FROM BUDGET NEU-  
24 TRALITY.—The additional expenditures attributable  
25 to—

26 “(I) subparagraph (H) shall not be taken  
27 into account in applying clause (ii)(II) for  
28 2004;

29 “(II) subparagraph (I) insofar as it relates  
30 to a physician fee schedule for 2005 or 2006  
31 shall not be taken into account in applying  
32 clause (ii)(II) for drug administration services  
33 under the fee schedule for such year for a spe-  
34 cialty described in subparagraph (I)(ii)(II); and

35 “(III) subparagraph (J) insofar as it re-  
36 lates to a physician fee schedule for 2005 or  
37 2006 shall not be taken into account in apply-

1                   ing clause (ii)(II) for drug administration serv-  
2                   ices under the fee schedule for such year.”; and  
3                   (B) by adding at the end the following new sub-  
4                   paragraphs:

5                   “(H) ADJUSTMENTS IN PRACTICE EXPENSE REL-  
6                   ATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRA-  
7                   TION SERVICES BEGINNING IN 2004.—

8                   “(i) USE OF SURVEY DATA.—In establishing  
9                   the physician fee schedule under subsection (b)  
10                  with respect to payments for services furnished on  
11                  or after January 1, 2004, the Secretary shall, in  
12                  determining practice expense relative value units  
13                  under this subsection, utilize a survey submitted to  
14                  the Secretary as of January 1, 2003, by a physi-  
15                  cian specialty organization pursuant to section 212  
16                  of the Medicare, Medicaid, and SCHIP Balanced  
17                  Budget Refinement Act of 1999 if the survey—

18                  “(I) covers practice expenses for oncology  
19                  drug administration services; and

20                  “(II) meets criteria established by the Sec-  
21                  retary for acceptance of such surveys.

22                  “(ii) PRICING OF CLINICAL ONCOLOGY NURSES  
23                  IN PRACTICE EXPENSE METHODOLOGY.—If the  
24                  survey described in clause (i) includes data on  
25                  wages, salaries, and compensation of clinical oncol-  
26                  ogy nurses, the Secretary shall utilize such data in  
27                  the methodology for determining practice expense  
28                  relative value units under subsection (c).

29                  “(iii) WORK RELATIVE VALUE UNITS FOR CER-  
30                  TAIN DRUG ADMINISTRATION SERVICES.—In estab-  
31                  lishing the relative value units under this para-  
32                  graph for drug administration services described in  
33                  clause (iv) furnished on or after January 1, 2004,  
34                  the Secretary shall establish work relative value  
35                  units equal to the work relative value units for a  
36                  level 1 office medical visit for an established pa-  
37                  tient.

1                   “(iv) DRUG ADMINISTRATION SERVICES DE-  
2                   SCRIBED.—The drug administration services de-  
3                   scribed in this clause are physicians’ services—

4                   “(I) which are classified as of October 1,  
5                   2003, within any of the following groups of  
6                   procedures: therapeutic or diagnostic infusions  
7                   (excluding chemotherapy); chemotherapy ad-  
8                   ministration services; and therapeutic, prophylactic,  
9                   or diagnostic injections;

10                  “(II) for which there are no work relative  
11                  value units assigned under this subsection as of  
12                  such date; and

13                  “(III) for which national relative value  
14                  units have been assigned under this subsection  
15                  as of such date.

16                  “(I) ADJUSTMENTS IN PRACTICE EXPENSE REL-  
17                  ATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRA-  
18                  TION SERVICES BEGINNING WITH 2005.—

19                  “(i) IN GENERAL.—In establishing the physi-  
20                  cian fee schedule under subsection (b) with respect  
21                  to payments for services furnished on or after Jan-  
22                  uary 1, 2005 or 2006, the Secretary shall adjust  
23                  the practice expense relative value units for such  
24                  year consistent with clause (ii).

25                  “(ii) USE OF SUPPLEMENTAL SURVEY DATA.—

26                  “(I) IN GENERAL.—Subject to subclause  
27                  (II), if a specialty submits to the Secretary by  
28                  not later than March 1, 2004, for 2005, or  
29                  March 1, 2005, for 2006, data that includes  
30                  expenses for the administration of drugs and  
31                  biologicals for which the payment amount is de-  
32                  termined pursuant to section 1842(o), the Sec-  
33                  retary shall use such supplemental survey data  
34                  in carrying out this subparagraph for the years  
35                  involved insofar as they are collected and pro-  
36                  vided by entities and organizations consistent  
37                  with the criteria established by the Secretary

1                   pursuant to section 212(a) of the Medicare,  
2                   Medicaid, and SCHIP Balanced Budget Re-  
3                   finement Act of 1999.

4                   “(II) LIMITATION ON SPECIALTY.—Sub-  
5                   clause (I) shall apply to a specialty only insofar  
6                   as not less than 40 percent of payments for the  
7                   specialty under this title in 2002 are attrib-  
8                   utable to the administration of drugs and  
9                   biologicals, as determined by the Secretary.

10                   “(III) APPLICATION.—This clause shall  
11                   not apply with respect to a survey to which  
12                   subparagraph (H)(i) applies.

13                   “(J) PROVISIONS FOR APPROPRIATE REPORTING  
14                   AND BILLING FOR PHYSICIANS’ SERVICES ASSOCIATED  
15                   WITH THE ADMINISTRATION OF COVERED OUTPATIENT  
16                   DRUGS AND BIOLOGICALS.—

17                   “(i) EVALUATION OF CODES.—The Secretary  
18                   shall promptly evaluate existing drug administra-  
19                   tion codes for physicians’ services to ensure accu-  
20                   rate reporting and billing for such services, taking  
21                   into account levels of complexity of the administra-  
22                   tion and resource consumption.

23                   “(ii) USE OF EXISTING PROCESSES.—In car-  
24                   rying out clause (i), the Secretary shall use existing  
25                   processes for the consideration of coding changes  
26                   and, to the extent coding changes are made, shall  
27                   use such processes in establishing relative values  
28                   for such services.

29                   “(iii) IMPLEMENTATION.—In carrying out  
30                   clause (i), the Secretary shall consult with rep-  
31                   resentatives of physician specialties affected by the  
32                   implementation of section 1847A or section 1847B,  
33                   and shall take such steps within the Secretary’s au-  
34                   thority to expedite such considerations under clause  
35                   (ii).

36                   “(iv) SUBSEQUENT, BUDGET NEUTRAL AD-  
37                   JUSTMENTS PERMITTED.—Nothing in subpara-

1 graph (H) or (I) or this subparagraph shall be con-  
2 strued as preventing the Secretary from providing  
3 for adjustments in practice expense relative value  
4 units under (and consistent with) subparagraph  
5 (B) for years after 2004, 2005, or 2006, respec-  
6 tively.”.

7 (2) TREATMENT OF OTHER SERVICES CURRENTLY IN  
8 THE NONPHYSICIAN WORK POOL.—The Secretary shall  
9 make adjustments to the nonphysician work pool method-  
10 ology (as such term is used in the final rule promulgated  
11 by the Secretary in the Federal Register on December 31,  
12 2002 (67 Fed. Reg. 251)), for the determination of prac-  
13 tice expense relative value units under the physician fee  
14 schedule under section 1848(c)(2)(C)(ii) of the Social Secu-  
15 rity Act (42 U.S.C. 1395w-4(c)(2)(C)(ii)), so that the  
16 practice expense relative value units for services determined  
17 under such methodology are not affected relative to the  
18 practice expense relative value units of services not deter-  
19 mined under such methodology, as a result of the amend-  
20 ments made by paragraph (1).

21 (3) PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS  
22 FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECH-  
23 NIQUE.—

24 (A) REVIEW OF POLICY.—The Secretary shall re-  
25 view the policy, as in effect on October 1, 2003, with  
26 respect to payment under section 1848 of the Social  
27 Security Act (42 U.S.C. 1395w-4) for the administra-  
28 tion of more than 1 drug or biological to an individual  
29 on a single day through the push technique.

30 (B) MODIFICATION OF POLICY.—After conducting  
31 the review under subparagraph (A), the Secretary shall  
32 modify such payment policy as the Secretary deter-  
33 mines to be appropriate.

34 (C) EXEMPTION FROM BUDGET NEUTRALITY  
35 UNDER PHYSICIAN FEE SCHEDULE.—If the Secretary  
36 modifies such payment policy pursuant to subpara-  
37 graph (B), any increased expenditures under title



1 XVIII of the Social Security Act resulting from such  
2 modification shall be treated as additional expenditures  
3 attributable to subparagraph (H) of section 1848(c)(2)  
4 of the Social Security Act (42 U.S.C. 1395w-4(c)(2)),  
5 as added by paragraph (1)(B), for purposes of applying  
6 the exemption to budget neutrality under subparagraph  
7 (B)(iv) of such section, as added by paragraph (1)(A).

8 (4) TRANSITIONAL ADJUSTMENT.—

9 (A) IN GENERAL.—In order to provide for a tran-  
10 sition during 2004 and 2005 to the payment system es-  
11 tablished under the amendments made by this section,  
12 in the case of physicians' services consisting of drug  
13 administration services described in subparagraph  
14 (H)(iv) of section 1848(c)(2) of the Social Security Act  
15 (42 U.S.C. 1395w-4(c)(2)), as added by paragraph  
16 (1)(B), furnished on or after January 1, 2004, and be-  
17 fore January 1, 2006, in addition to the amount deter-  
18 mined under the fee schedule under section 1848(b) of  
19 such Act (42 U.S.C. 1395w-4(b)) there also shall be  
20 paid to the physician from the Federal Supplementary  
21 Medical Insurance Trust Fund an amount equal to the  
22 applicable percentage specified in subparagraph (B) of  
23 such fee schedule amount for the services so deter-  
24 mined.

25 (B) APPLICABLE PERCENTAGE.—The applicable  
26 percentage specified in this subparagraph for services  
27 furnished—

28 (i) during 2004, is 32 percent; and

29 (ii) during 2005, is 3 percent.

30 (5) MEDPAC REVIEW AND REPORTS; SECRETARIAL RE-  
31 SPONSE.—

32 (A) REVIEW.—The Medicare Payment Advisory  
33 Commission shall review the payment changes made  
34 under this section insofar as they affect payment under  
35 part B of title XVIII of the Social Security Act—

36 (i) for items and services furnished by  
37 oncologists; and

1 (ii) for drug administration services furnished  
2 by other specialists.

3 (B) OTHER MATTERS STUDIED.—In conducting  
4 the review under subparagraph (A), the Commission  
5 shall also review such changes as they affect—

6 (i) the quality of care furnished to individuals  
7 enrolled under part B and the satisfaction of such  
8 individuals with that care;

9 (ii) the adequacy of reimbursement as applied  
10 in, and the availability in, different geographic  
11 areas and to different physician practice sizes; and

12 (iii) the impact on physician practices.

13 (C) REPORTS.—The Commission shall submit to  
14 the Secretary and Congress—

15 (i) not later than January 1, 2006, a report  
16 on the review conducted under subparagraph  
17 (A)(i); and

18 (ii) not later than January 1, 2007, a report  
19 on the review conducted under subparagraph  
20 (A)(ii).

21 Each such report may include such recommendations  
22 regarding further adjustments in such payments as the  
23 Commission deems appropriate.

24 (D) SECRETARIAL RESPONSE.—As part of the  
25 rulemaking with respect to payment for physicians  
26 services under section 1848 of the Social Security Act  
27 (42 U.S.C. 1395w-4) for 2007, the Secretary may  
28 make appropriate adjustments to payment for items  
29 and services described in subparagraph (A)(i), taking  
30 into account the report submitted under such subpara-  
31 graph (C)(i).

32 (b) APPLICATION OF MARKET-BASED PAYMENT SYS-  
33 TEMS.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

34 (1) in paragraph (1), by striking “equal to 95 percent  
35 of the average wholesale price.” and inserting “equal to the  
36 following:

1           “(A) In the case of any of the following drugs or  
2 biologicals, 95 percent of the average wholesale price:

3           “(i) A drug or biological furnished before January  
4 1, 2004.

5           “(ii) Blood clotting factors furnished during 2004.

6           “(iii) A drug or biological furnished during 2004  
7 that was not available for payment under this part as  
8 of April 1, 2003.

9           “(iv) A vaccine described in subparagraph (A) or  
10 (B) of section 1861(s)(10) furnished on or after Janu-  
11 ary 1, 2004.

12           “(v) A drug or biological furnished during 2004 in  
13 connection with the furnishing of renal dialysis services  
14 if separately billed by renal dialysis facilities.

15           “(B) In the case of a drug or biological furnished dur-  
16 ing 2004 that is not described in—

17           “(i) clause (ii), (iii), (iv), or (v) of subparagraph  
18 (A),

19           “(ii) subparagraph (D)(i), or

20           “(iii) subparagraph (F),

21 the amount determined under paragraph (4).

22           “(C) In the case of a drug or biological that is not de-  
23 scribed in subparagraph (A)(iv), (D)(i), or (F) furnished on  
24 or after January 1, 2005, the amount provided under sec-  
25 tion 1847, section 1847A, section 1847B, or section  
26 1881(b)(13), as the case may be for the drug or biological.

27           “(D)(i) Except as provided in clause (ii), in the case  
28 of infusion drugs furnished through an item of durable  
29 medical equipment covered under section 1861(n) on or  
30 after January 1, 2004, 95 percent of the average wholesale  
31 price for such drug in effect on October 1, 2003.

32           “(ii) In the case of such infusion drugs furnished in  
33 a competitive acquisition area under section 1847 on or  
34 after January 1, 2007, the amount provided under section  
35 1847.

36           “(E) In the case of a drug or biological, consisting of  
37 intravenous immune globulin, furnished—

1           “(i) in 2004, the amount of payment provided  
2           under paragraph (4); and

3           “(ii) in 2005 and subsequent years, the amount of  
4           payment provided under section 1847A.

5           “(F) In the case of blood and blood products (other  
6           than blood clotting factors), the amount of payment shall  
7           be determined in the same manner as such amount of pay-  
8           ment was determined on October 1, 2003.

9           “(G) The provisions of subparagraphs (A) through (F)  
10          of this paragraph shall not apply to an inhalation drug or  
11          biological furnished through durable medical equipment  
12          covered under section 1861(n).”; and

13          (2) by adding at the end the following new paragraph:

14          “(4)(A) Subject to the succeeding provisions of this para-  
15          graph, the amount of payment for a drug or biological under  
16          this paragraph furnished in 2004 is equal to 85 percent of the  
17          average wholesale price (determined as of April 1, 2003) for  
18          the drug or biological.

19          “(B) The Secretary shall substitute for the percentage  
20          under subparagraph (A) for a drug or biological the percentage  
21          that would apply to the drug or biological under the column en-  
22          titled ‘Average of GAO and OIG data (percent)’ in the table  
23          entitled ‘Table 3.—Medicare Part B Drugs in the Most Recent  
24          GAO and OIG Studies’ published on August 20, 2003, in the  
25          Federal Register (68 Fed. Reg. 50445).

26          “(C)(i) The Secretary may substitute for the percentage  
27          under subparagraph (A) a percentage that is based on data  
28          and information submitted by the manufacturer of the drug or  
29          biological by October 15, 2003.

30          “(ii) The Secretary may substitute for the percentage  
31          under subparagraph (A) with respect to drugs and biologicals  
32          furnished during 2004 on or after April 1, 2004, a percentage  
33          that is based on data and information submitted by the manu-  
34          facturer of the drug or biological after October 15, 2003, and  
35          before January 1, 2004.

36          “(D) In no case may the percentage substituted under  
37          subparagraph (B) or (C) be less than 80 percent.”.

1 (c) APPLICATION OF AVERAGE SALES PRICE METHODS  
2 BEGINNING IN 2005.—

3 (1) IN GENERAL.—Title XVIII is amended by insert-  
4 ing after section 1847 (42 U.S.C. 1395w-3), as amended  
5 by section 302(b), the following new section:

6 “USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

7 “SEC. 1847A. (a) APPLICATION.—

8 “(1) IN GENERAL.—Except as provided in paragraph  
9 (2), this section shall apply to payment for drugs and  
10 biologicals that are described in section 1842(o)(1)(C) and  
11 that are furnished on or after January 1, 2005.

12 “(2) ELECTION.—This section shall not apply in the  
13 case of a physician who elects under subsection  
14 (a)(1)(A)(ii) of section 1847B for that section to apply in-  
15 stead of this section for the payment for drugs and  
16 biologicals.

17 “(b) PAYMENT AMOUNT.—

18 “(1) IN GENERAL.—Subject to subsections (d)(3)(C)  
19 and (e), the amount of payment determined under this sec-  
20 tion for the billing and payment code for a drug or biologi-  
21 cal (based on a minimum dosage unit) is, subject to appli-  
22 cable deductible and coinsurance—

23 “(A) in the case of a multiple source drug (as de-  
24 fined in subsection (c)(6)(C)), 106 percent of the  
25 amount determined under paragraph (3); or

26 “(B) in the case of a single source drug or biologi-  
27 cal (as defined in subsection (c)(6)(D)), 106 percent of  
28 the amount determined under paragraph (4).

29 “(2) SPECIFICATION OF UNIT.—

30 “(A) SPECIFICATION BY MANUFACTURER.—The  
31 manufacturer of a drug or biological shall specify the  
32 unit associated with each National Drug Code (includ-  
33 ing package size) as part of the submission of data  
34 under section 1927(b)(3)(A)(iii).

35 “(B) UNIT DEFINED.—In this section, the term  
36 ‘unit’ means, with respect to each National Drug Code  
37 (including package size) associated with a drug or bio-

1           logical, the lowest identifiable quantity (such as a cap-  
2           sule or tablet, milligram of molecules, or grams) of the  
3           drug or biological that is dispensed, exclusive of any  
4           diluent without reference to volume measures per-  
5           taining to liquids. For years after 2004, the Secretary  
6           may establish the unit for a manufacturer to report  
7           and methods for counting units as the Secretary deter-  
8           mines appropriate to implement this section.

9           “(3) MULTIPLE SOURCE DRUG.—For all drug prod-  
10          ucts included within the same multiple source drug billing  
11          and payment code, the amount specified in this paragraph  
12          is the volume-weighted average of the average sales prices  
13          reported under section 1927(b)(3)(A)(iii) determined by—

14                 “(A) computing the sum of the products (for each  
15                 National Drug Code assigned to such drug products)  
16                 of—

17                         “(i) the manufacturer’s average sales price (as  
18                         defined in subsection (c)); and

19                         “(ii) the total number of units specified under  
20                         paragraph (2) sold; and

21                 “(B) dividing the sum determined under subpara-  
22                 graph (A) by the sum of the total number of units  
23                 under subparagraph (A)(ii) for all National Drug  
24                 Codes assigned to such drug products.

25          “(4) SINGLE SOURCE DRUG OR BIOLOGICAL.—The  
26          amount specified in this paragraph for a single source drug  
27          or biological is the lesser of the following:

28                 “(A) AVERAGE SALES PRICE.—The average sales  
29                 price as determined using the methodology applied  
30                 under paragraph (3) for all National Drug Codes as-  
31                 signed to such drug or biological product.

32                 “(B) WHOLESAL ACQUISITION COST (WAC).—The  
33                 wholesale acquisition cost (as defined in subsection  
34                 (c)(6)(B)) using the methodology applied under para-  
35                 graph (3) for all National Drug Codes assigned to such  
36                 drug or biological product.

1           “(5) BASIS FOR PAYMENT AMOUNT.—The payment  
2 amount shall be determined under this subsection based on  
3 information reported under subsection (f) and without re-  
4 gard to any special packaging, labeling, or identifiers on  
5 the dosage form or product or package.

6           “(c) MANUFACTURER’S AVERAGE SALES PRICE.—

7           “(1) IN GENERAL.—For purposes of this section, sub-  
8 ject to paragraphs (2) and (3), the manufacturer’s ‘average  
9 sales price’ means, of a drug or biological for a National  
10 Drug Code for a calendar quarter for a manufacturer for  
11 a unit—

12           “(A) the manufacturer’s sales to all purchasers  
13 (excluding sales exempted in paragraph (2)) in the  
14 United States for such drug or biological in the cal-  
15 endar quarter; divided by

16           “(B) the total number of such units of such drug  
17 or biological sold by the manufacturer in such quarter.

18           “(2) CERTAIN SALES EXEMPTED FROM COMPUTA-  
19 TION.—In calculating the manufacturer’s average sales  
20 price under this subsection, the following sales shall be ex-  
21 cluded:

22           “(A) SALES EXEMPT FROM BEST PRICE.—Sales  
23 exempt from the inclusion in the determination of ‘best  
24 price’ under section 1927(c)(1)(C)(i).

25           “(B) SALES AT NOMINAL CHARGE.—Such other  
26 sales as the Secretary identifies as sales to an entity  
27 that are merely nominal in amount (as applied for pur-  
28 poses of section 1927(c)(1)(C)(ii)(III), except as the  
29 Secretary may otherwise provide).

30           “(3) SALE PRICE NET OF DISCOUNTS.—In calculating  
31 the manufacturer’s average sales price under this sub-  
32 section, such price shall include volume discounts, prompt  
33 pay discounts, cash discounts, free goods that are contin-  
34 gent on any purchase requirement, chargebacks, and re-  
35 bates (other than rebates under section 1927). For years  
36 after 2004, the Secretary may include in such price other  
37 price concessions, which may be based on recommendations

1 of the Inspector General, that would result in a reduction  
2 of the cost to the purchaser.

3 “(4) PAYMENT METHODOLOGY IN CASES WHERE AV-  
4 ERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS  
5 UNAVAILABLE.—In the case of a drug or biological during  
6 an initial period (not to exceed a full calendar quarter) in  
7 which data on the prices for sales for the drug or biological  
8 is not sufficiently available from the manufacturer to com-  
9 pute an average sales price for the drug or biological, the  
10 Secretary may determine the amount payable under this  
11 section for the drug or biological based on—

12 “(A) the wholesale acquisition cost; or

13 “(B) the methodologies in effect under this part  
14 on November 1, 2003, to determine payment amounts  
15 for drugs or biologicals.

16 “(5) FREQUENCY OF DETERMINATIONS.—

17 “(A) IN GENERAL ON A QUARTERLY BASIS.—The  
18 manufacturer’s average sales price, for a drug or bio-  
19 logical of a manufacturer, shall be calculated by such  
20 manufacturer under this subsection on a quarterly  
21 basis. In making such calculation insofar as there is a  
22 lag in the reporting of the information on rebates and  
23 chargebacks under paragraph (3) so that adequate data  
24 are not available on a timely basis, the manufacturer  
25 shall apply a methodology based on a 12-month rolling  
26 average for the manufacturer to estimate costs attrib-  
27 utable to rebates and chargebacks. For years after  
28 2004, the Secretary may establish a uniform method-  
29 ology under this subparagraph to estimate and apply  
30 such costs.

31 “(B) UPDATES IN PAYMENT AMOUNTS.—The pay-  
32 ment amounts under subsection (b) shall be updated by  
33 the Secretary on a quarterly basis and shall be applied  
34 based upon the manufacturer’s average sales price cal-  
35 culated for the most recent calendar quarter for which  
36 data is available.



1                   “(C) USE OF CONTRACTORS; IMPLEMENTATION.—  
2           The Secretary may contract with appropriate entities to  
3           calculate the payment amount under subsection (b).  
4           Notwithstanding any other provision of law, the Sec-  
5           retary may implement, by program instruction or oth-  
6           erwise, any of the provisions of this section.

7                   “(6) DEFINITIONS AND OTHER RULES.—In this sec-  
8           tion:

9                   “(A) MANUFACTURER.—The term ‘manufacturer’  
10           means, with respect to a drug or biological, the manu-  
11           facturer (as defined in section 1927(k)(5)).

12                   “(B) WHOLESALE ACQUISITION COST.—The term  
13           ‘wholesale acquisition cost’ means, with respect to a  
14           drug or biological, the manufacturer’s list price for the  
15           drug or biological to wholesalers or direct purchasers in  
16           the United States, not including prompt pay or other  
17           discounts, rebates or reductions in price, for the most  
18           recent month for which the information is available, as  
19           reported in wholesale price guides or other publications  
20           of drug or biological pricing data.

21                   “(C) MULTIPLE SOURCE DRUG.—

22                   “(i) IN GENERAL.—The term ‘multiple source  
23           drug’ means, for a calendar quarter, a drug for  
24           which there are 2 or more drug products which—

25                   “(I) are rated as therapeutically equivalent  
26                   (under the Food and Drug Administration’s  
27                   most recent publication of ‘Approved Drug  
28                   Products with Therapeutic Equivalence Evalua-  
29                   tions’),

30                   “(II) except as provided in subparagraph  
31                   (E), are pharmaceutically equivalent and bio-  
32                   equivalent, as determined under subparagraph  
33                   (F) and as determined by the Food and Drug  
34                   Administration, and

35                   “(III) are sold or marketed in the United  
36                   States during the quarter.

1                   “(ii) EXCEPTION.—With respect to single  
2 source drugs or biologicals that are within the same  
3 billing and payment code as of October 1, 2003,  
4 the Secretary shall treat such single source drugs  
5 or biologicals as if the single source drugs or  
6 biologicals were multiple source drugs.

7                   “(D) SINGLE SOURCE DRUG OR BIOLOGICAL.—  
8 The term ‘single source drug or biological’ means—

9                   “(i) a biological; or

10                   “(ii) a drug which is not a multiple source  
11 drug and which is produced or distributed under a  
12 new drug application approved by the Food and  
13 Drug Administration, including a drug product  
14 marketed by any cross-licensed producers or dis-  
15 tributors operating under the new drug application.

16                   “(E) EXCEPTION FROM PHARMACEUTICAL  
17 EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—  
18 Subparagraph (C)(ii) shall not apply if the Food and  
19 Drug Administration changes by regulation the require-  
20 ment that, for purposes of the publication described in  
21 subparagraph (C)(i), in order for drug products to be  
22 rated as therapeutically equivalent, they must be phar-  
23 maceutically equivalent and bioequivalent, as defined in  
24 subparagraph (F).

25                   “(F) DETERMINATION OF PHARMACEUTICAL  
26 EQUIVALENCE AND BIOEQUIVALENCE.—For purposes  
27 of this paragraph—

28                   “(i) drug products are pharmaceutically equiv-  
29 alent if the products contain identical amounts of  
30 the same active drug ingredient in the same dosage  
31 form and meet compendial or other applicable  
32 standards of strength, quality, purity, and identity;  
33 and

34                   “(ii) drugs are bioequivalent if they do not  
35 present a known or potential bioequivalence prob-  
36 lem, or, if they do present such a problem, they are

1 shown to meet an appropriate standard of bio-  
2 equivalence.

3 “(G) INCLUSION OF VACCINES.—In applying pro-  
4 visions of section 1927 under this section, ‘other than  
5 a vaccine’ is deemed deleted from section  
6 1927(k)(2)(B).

7 “(d) MONITORING OF MARKET PRICES.—

8 “(1) IN GENERAL.—The Inspector General of the De-  
9 partment of Health and Human Services shall conduct  
10 studies, which may include surveys, to determine the widely  
11 available market prices of drugs and biologicals to which  
12 this section applies, as the Inspector General, in consulta-  
13 tion with the Secretary, determines to be appropriate.

14 “(2) COMPARISON OF PRICES.—Based upon such stud-  
15 ies and other data for drugs and biologicals, the Inspector  
16 General shall compare the average sales price under this  
17 section for drugs and biologicals with—

18 “(A) the widely available market price for such  
19 drugs and biologicals (if any); and

20 “(B) the average manufacturer price (as deter-  
21 mined under section 1927(k)(1)) for such drugs and  
22 biologicals.

23 “(3) LIMITATION ON AVERAGE SALES PRICE.—

24 “(A) IN GENERAL.—The Secretary may disregard  
25 the average sales price for a drug or biological that ex-  
26 ceeds the widely available market price or the average  
27 manufacturer price for such drug or biological by the  
28 applicable threshold percentage (as defined in subpara-  
29 graph (B)).

30 “(B) APPLICABLE THRESHOLD PERCENTAGE DE-  
31 FINED.—In this paragraph, the term ‘applicable  
32 threshold percentage’ means—

33 “(i) in 2005, in the case of an average sales  
34 price for a drug or biological that exceeds widely  
35 available market price or the average manufacturer  
36 price, 5 percent; and

1                   “(ii) in 2006 and subsequent years, the per-  
2                   centage applied under this subparagraph subject to  
3                   such adjustment as the Secretary may specify for  
4                   the widely available market price or the average  
5                   manufacturer price, or both.

6                   “(C) AUTHORITY TO ADJUST AVERAGE SALES  
7                   PRICE.—If the Inspector General finds that the average  
8                   sales price for a drug or biological exceeds such widely  
9                   available market price or average manufacturer price  
10                  for such drug or biological by the applicable threshold  
11                  percentage, the Inspector General shall inform the Sec-  
12                  retary (at such times as the Secretary may specify to  
13                  carry out this subparagraph) and the Secretary shall,  
14                  effective as of the next quarter, substitute for the  
15                  amount of payment otherwise determined under this  
16                  section for such drug or biological the lesser of—

17                   “(i) the widely available market price for the  
18                   drug or biological (if any); or

19                   “(ii) 103 percent of the average manufacturer  
20                   price (as determined under section 1927(k)(1)) for  
21                   the drug or biological.

22                  “(4) CIVIL MONEY PENALTY.—

23                   “(A) IN GENERAL.—If the Secretary determines  
24                   that a manufacturer has made a misrepresentation in  
25                   the reporting of the manufacturer’s average sales price  
26                   for a drug or biological, the Secretary may apply a civil  
27                   money penalty in an amount of up to \$10,000 for each  
28                   such price misrepresentation and for each day in which  
29                   such price misrepresentation was applied.

30                   “(B) PROCEDURES.—The provisions of section  
31                   1128A (other than subsections (a) and (b)) shall apply  
32                   to civil money penalties under subparagraph (B) in the  
33                   same manner as they apply to a penalty or proceeding  
34                   under section 1128A(a).

35                  “(5) WIDELY AVAILABLE MARKET PRICE.—

36                   “(A) IN GENERAL.—In this subsection, the term  
37                   ‘widely available market price’ means the price that a

1 prudent physician or supplier would pay for the drug  
2 or biological. In determining such price, the Inspector  
3 General shall take into account the discounts, rebates,  
4 and other price concessions routinely made available to  
5 such prudent physicians or suppliers for such drugs or  
6 biologicals.

7 “(B) CONSIDERATIONS.—In determining the price  
8 under subparagraph (A), the Inspector General shall  
9 consider information from one or more of the following  
10 sources:

11 “(i) Manufacturers.

12 “(ii) Wholesalers.

13 “(iii) Distributors.

14 “(iv) Physician supply houses.

15 “(v) Specialty pharmacies.

16 “(vi) Group purchasing arrangements.

17 “(vii) Surveys of physicians.

18 “(viii) Surveys of suppliers.

19 “(ix) Information on such market prices from  
20 insurers.

21 “(x) Information on such market prices from  
22 private health plans.

23 “(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RE-  
24 SPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a  
25 public health emergency under section 319 of the Public Health  
26 Service Act in which there is a documented inability to access  
27 drugs and biologicals, and a concomitant increase in the price,  
28 of a drug or biological which is not reflected in the manufactur-  
29 er’s average sales price for one or more quarters, the Secretary  
30 may use the wholesale acquisition cost (or other reasonable  
31 measure of drug or biological price) instead of the manufactur-  
32 er’s average sales price for such quarters and for subsequent  
33 quarters until the price and availability of the drug or biologi-  
34 cal has stabilized and is substantially reflected in the applicable  
35 manufacturer’s average sales price.

36 “(f) QUARTERLY REPORT ON AVERAGE SALES PRICE.—  
37 For requirements for reporting the manufacturer’s average

1 sales price (and, if required to make payment, the manufactur-  
2 er's wholesale acquisition cost) for the drug or biological under  
3 this section, see section 1927(b)(3).

4 “(g) JUDICIAL REVIEW.—There shall be no administrative  
5 or judicial review under section 1869, section 1878, or other-  
6 wise, of—

7 “(1) determinations of payment amounts under this  
8 section, including the assignment of National Drug Codes  
9 to billing and payment codes;

10 “(2) the identification of units (and package size)  
11 under subsection (b)(2);

12 “(3) the method to allocate rebates, chargebacks, and  
13 other price concessions to a quarter if specified by the Sec-  
14 retary;

15 “(4) the manufacturer's average sales price when it is  
16 used for the determination of a payment amount under this  
17 section; and

18 “(5) the disclosure of the average manufacturer price  
19 by reason of an adjustment under subsection (d)(3)(C) or  
20 (e).”.

21 (2) REPORT ON SALES TO PHARMACY BENEFIT MAN-  
22 AGERS.—

23 (A) STUDY.—The Secretary shall conduct a study  
24 on sales of drugs and biologicals to large volume pur-  
25 chasers, such as pharmacy benefit managers and health  
26 maintenance organizations, for purposes of determining  
27 whether the price at which such drugs and biologicals  
28 are sold to such purchasers does not represent the price  
29 such drugs and biologicals are made available for pur-  
30 chase to prudent physicians.

31 (B) REPORT.—Not later than January 1, 2006,  
32 the Secretary shall submit to Congress a report on the  
33 study conducted under paragraph (1), and shall include  
34 recommendations on whether such sales to large volume  
35 purchasers should be excluded from the computation of  
36 a manufacturer's average sales price under section

1 1847A of the Social Security Act, as added by para-  
2 graph (1).

3 (3) INSPECTOR GENERAL REPORT ON ADEQUACY OF  
4 REIMBURSEMENT RATE UNDER AVERAGE SALES PRICE  
5 METHODOLOGY.—

6 (A) STUDY.—The Inspector General of the De-  
7 partment of Health and Human Services shall conduct  
8 a study on the ability of physician practices in the spe-  
9 cialties of hematology, hematology/oncology, and med-  
10 ical oncology of different sizes, especially particularly  
11 large practices, to obtain drugs and biologicals for the  
12 treatment of cancer patients at 106 percent of the av-  
13 erage sales price for the drugs and biologicals. In con-  
14 ducting the study, the Inspector General shall conduct  
15 an audit of a representative sample of such practices  
16 to determine the adequacy of reimbursement under sec-  
17 tion 1847A of the Social Security Act, as added by  
18 paragraph (1).

19 (B) REPORT.—Not later October 1, 2005, the In-  
20 spector General shall submit to Congress a report on  
21 the study conducted under subparagraph (A), and shall  
22 include recommendations on the adequacy of reim-  
23 bursement for such drugs and biologicals under such  
24 section 1847A.

25 (d) PAYMENT BASED ON COMPETITION.—

26 (1) IN GENERAL.—Title XVIII is amended by insert-  
27 ing after section 1847A, as added by subsection (c), the fol-  
28 lowing new section:

29 “COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND  
30 BIOLOGICALS

31 “SEC. 1847B. (a) IMPLEMENTATION OF COMPETITIVE AC-  
32 QUISSION.—

33 “(1) IMPLEMENTATION OF PROGRAM.—

34 “(A) IN GENERAL.—The Secretary shall establish  
35 and implement a competitive acquisition program under  
36 which—

1           “(i) competitive acquisition areas are estab-  
2           lished for contract award purposes for acquisition  
3           of and payment for categories of competitively bid-  
4           dable drugs and biologicals (as defined in para-  
5           graph (2)) under this part;

6           “(ii) each physician is given the opportunity  
7           annually to elect to obtain drugs and biologicals  
8           under the program, rather than under section  
9           1847A; and

10          “(iii) each physician who elects to obtain drugs  
11          and biologicals under the program makes an an-  
12          nual selection under paragraph (5) of the con-  
13          tractor through which drugs and biologicals within  
14          a category of drugs and biologicals will be acquired  
15          and delivered to the physician under this part.

16          This section shall not apply in the case of a physician  
17          who elects section 1847A to apply.

18          “(B) IMPLEMENTATION.—For purposes of imple-  
19          menting the program, the Secretary shall establish cat-  
20          egories of competitively biddable drugs and biologicals.  
21          The Secretary shall phase in the program with respect  
22          to those categories beginning in 2006 in such manner  
23          as the Secretary determines to be appropriate.

24          “(C) WAIVER OF CERTAIN PROVISIONS.—In order  
25          to promote competition, in carrying out the program  
26          the Secretary may waive such provisions of the Federal  
27          Acquisition Regulation as are necessary for the efficient  
28          implementation of this section, other than provisions  
29          relating to confidentiality of information and such other  
30          provisions as the Secretary determines appropriate.

31          “(D) EXCLUSION AUTHORITY.—The Secretary  
32          may exclude competitively biddable drugs and  
33          biologicals (including a class of such drugs and  
34          biologicals) from the competitive bidding system under  
35          this section if the application of competitive bidding to  
36          such drugs or biologicals—



1                   “(i) is not likely to result in significant sav-  
2                   ings; or

3                   “(ii) is likely to have an adverse impact on ac-  
4                   cess to such drugs or biologicals.

5                   “(2) COMPETITIVELY BIDDABLE DRUGS AND  
6                   BIOLOGICALS AND PROGRAM DEFINED.—For purposes of  
7                   this section—

8                   “(A) COMPETITIVELY BIDDABLE DRUGS AND  
9                   BIOLOGICALS DEFINED.—The term ‘competitively bid-  
10                   dable drugs and biologicals’ means a drug or biological  
11                   described in section 1842(o)(1)(C) and furnished on or  
12                   after January 1, 2006.

13                   “(B) PROGRAM.—The term ‘program’ means the  
14                   competitive acquisition program under this section.

15                   “(C) COMPETITIVE ACQUISITION AREA; AREA.—  
16                   The terms ‘competitive acquisition area’ and ‘area’  
17                   mean an appropriate geographic region established by  
18                   the Secretary under the program.

19                   “(D) CONTRACTOR.—The term ‘contractor’ means  
20                   an entity that has entered into a contract with the Sec-  
21                   retary under this section.

22                   “(3) APPLICATION OF PROGRAM PAYMENT METHOD-  
23                   OLOGY.—

24                   “(A) IN GENERAL.—With respect to competitively  
25                   biddable drugs and biologicals which are supplied under  
26                   the program in an area and which are prescribed by a  
27                   physician who has elected this section to apply—

28                   “(i) the claim for such drugs and biologicals  
29                   shall be submitted by the contractor that supplied  
30                   the drugs and biologicals;

31                   “(ii) collection of amounts of any deductible  
32                   and coinsurance applicable with respect to such  
33                   drugs and biologicals shall be the responsibility of  
34                   such contractor and shall not be collected unless  
35                   the drug or biological is administered to the indi-  
36                   vidual involved; and

1                   “(iii) the payment under this section (and re-  
2                   lated amounts of any applicable deductible and co-  
3                   insurance) for such drugs and biologicals—

4                   “(I) shall be made only to such contractor;

5                   and

6                   “(II) shall be conditioned upon the admin-  
7                   istration of such drugs and biologicals.

8                   “(B) PROCESS FOR ADJUSTMENTS.—The Sec-  
9                   retary shall provide a process for adjustments to pay-  
10                  ments in the case in which payment is made for drugs  
11                  and biologicals which were billed at the time of dis-  
12                  pensing but which were not actually administered.

13                  “(C) INFORMATION FOR PURPOSES OF COST-SHAR-  
14                  ING.—The Secretary shall provide a process by which  
15                  physicians submit information to contractors for pur-  
16                  poses of the collection of any applicable deductible or  
17                  coinsurance amounts under subparagraph (A)(ii).

18                  “(4) CONTRACT REQUIRED.—Payment may not be  
19                  made under this part for competitively biddable drugs and  
20                  biologicals prescribed by a physician who has elected this  
21                  section to apply within a category and a competitive acqui-  
22                  sition area with respect to which the program applies  
23                  unless—

24                  “(A) the drugs or biologicals are supplied by a  
25                  contractor with a contract under this section for such  
26                  category of drugs and biologicals and area; and

27                  “(B) the physician has elected such contractor  
28                  under paragraph (5) for such category and area.

29                  “(5) CONTRACTOR SELECTION PROCESS.—

30                  “(A) ANNUAL SELECTION.—

31                  “(i) IN GENERAL.—The Secretary shall pro-  
32                  vide a process for the selection of a contractor, on  
33                  an annual basis and in such exigent circumstances  
34                  as the Secretary may provide and with respect to  
35                  each category of competitively biddable drugs and  
36                  biologicals for an area by selecting physicians.

1                   “(ii) TIMING OF SELECTION.—The selection of  
2                   a contractor under clause (i) shall be made at the  
3                   time of the election described in section 1847A(a)  
4                   for this section to apply and shall be coordinated  
5                   with agreements entered into under section  
6                   1842(h).

7                   “(B) INFORMATION ON CONTRACTORS.—The Sec-  
8                   retary shall make available to physicians on an ongoing  
9                   basis, through a directory posted on the Internet  
10                  website of the Centers for Medicare & Medicaid Serv-  
11                  ices or otherwise and upon request, a list of the con-  
12                  tractors under this section in the different competitive  
13                  acquisition areas.

14                  “(C) SELECTING PHYSICIAN DEFINED.—For pur-  
15                  poses of this section, the term ‘selecting physician’  
16                  means, with respect to a contractor and category and  
17                  competitive acquisition area, a physician who has elect-  
18                  ed this section to apply and has selected to apply under  
19                  this section such contractor for such category and area.

20                  “(b) PROGRAM REQUIREMENTS.—

21                  “(1) CONTRACT FOR COMPETITIVELY BIDDABLE  
22                  DRUGS AND BIOLOGICALS.—The Secretary shall conduct a  
23                  competition among entities for the acquisition of competi-  
24                  tively biddable drugs and biologicals. Notwithstanding any  
25                  other provision of this title, in the case of a multiple source  
26                  drug, the Secretary shall conduct such competition among  
27                  entities for the acquisition of at least one competitively bid-  
28                  dable drug and biological within each billing and payment  
29                  code within each category for each competitive acquisition  
30                  area.

31                  “(2) CONDITIONS FOR AWARDED CONTRACT.—

32                  “(A) IN GENERAL.—The Secretary may not award  
33                  a contract to any entity under the competition con-  
34                  ducted in a competitive acquisition area pursuant to  
35                  paragraph (1) with respect to the acquisition of com-  
36                  petitively biddable drugs and biologicals within a cat-  
37                  egory unless the Secretary finds that the entity meets

1 all of the following with respect to the contract period  
2 involved:

3 “(i) CAPACITY TO SUPPLY COMPETITIVELY  
4 BIDDABLE DRUG OR BIOLOGICAL WITHIN CAT-  
5 EGORY.—

6 “(I) IN GENERAL.—The entity has suffi-  
7 cient arrangements to acquire and to deliver  
8 competitively biddable drugs and biologicals  
9 within such category in the area specified in  
10 the contract.

11 “(II) SHIPMENT METHODOLOGY.—The en-  
12 tity has arrangements in effect for the ship-  
13 ment at least 5 days each week of competitively  
14 biddable drugs and biologicals under the con-  
15 tract and for the timely delivery (including for  
16 emergency situations) of such drugs and  
17 biologicals in the area under the contract.

18 “(ii) QUALITY, SERVICE, FINANCIAL PERFORM-  
19 ANCE AND SOLVENCY STANDARDS.—The entity  
20 meets quality, service, financial performance, and  
21 solvency standards specified by the Secretary,  
22 including—

23 “(I) the establishment of procedures for  
24 the prompt response and resolution of com-  
25 plaints of physicians and individuals and of in-  
26 quiries regarding the shipment of competitively  
27 biddable drugs and biologicals; and

28 “(II) a grievance and appeals process for  
29 the resolution of disputes.

30 “(B) ADDITIONAL CONSIDERATIONS.—The Sec-  
31 retary may refuse to award a contract under this sec-  
32 tion, and may terminate such a contract, with an entity  
33 based upon—

34 “(i) the suspension or revocation, by the Fed-  
35 eral Government or a State government, of the en-  
36 tity’s license for the distribution of drugs or  
37 biologicals (including controlled substances); or

1                   “(ii) the exclusion of the entity under section  
2                   1128 from participation under this title.

3                   “(C) APPLICATION OF MEDICARE PROVIDER OM-  
4                   BUDSMAN.—For provision providing for a program-  
5                   wide Medicare Provider Ombudsman to review com-  
6                   plaints, see section 1868(b), as added by section 923  
7                   of the Medicare Prescription Drug, Improvement, and  
8                   Modernization Act of 2003.

9                   “(3) AWARDED MULTIPLE CONTRACTS FOR A CAT-  
10                   EGORY AND AREA.—The Secretary may limit (but not  
11                   below 2) the number of qualified entities that are awarded  
12                   such contracts for any category and area. The Secretary  
13                   shall select among qualified entities based on the following:

14                   “(A) The bid prices for competitively biddable  
15                   drugs and biologicals within the category and area.

16                   “(B) Bid price for distribution of such drugs and  
17                   biologicals.

18                   “(C) Ability to ensure product integrity.

19                   “(D) Customer service.

20                   “(E) Past experience in the distribution of drugs  
21                   and biologicals, including controlled substances.

22                   “(F) Such other factors as the Secretary may  
23                   specify.

24                   “(4) TERMS OF CONTRACTS.—

25                   “(A) IN GENERAL.—A contract entered into with  
26                   an entity under the competition conducted pursuant to  
27                   paragraph (1) is subject to terms and conditions that  
28                   the Secretary may specify consistent with this section.

29                   “(B) PERIOD OF CONTRACTS.—A contract under  
30                   this section shall be for a term of 3 years, but may be  
31                   terminated by the Secretary or the entity with appro-  
32                   priate, advance notice.

33                   “(C) INTEGRITY OF DRUG AND BIOLOGICAL DIS-  
34                   TRIBUTION SYSTEM.—A contractor (as defined in sub-  
35                   section (a)(2)(D)) shall—

36                   “(i) acquire all drug and biological products it  
37                   distributes directly from the manufacturer or from

1 a distributor that has acquired the products di-  
2 rectly from the manufacturer; and

3 “(ii) comply with any product integrity safe-  
4 guards as may be determined to be appropriate by  
5 the Secretary.

6 Nothing in this subparagraph shall be construed to re-  
7 lieve or exempt any contractor from the provisions of  
8 the Federal Food, Drug, and Cosmetic Act that relate  
9 to the wholesale distribution of prescription drugs or  
10 biologicals.

11 “(D) COMPLIANCE WITH CODE OF CONDUCT AND  
12 FRAUD AND ABUSE RULES.—Under the contract—

13 “(i) the contractor shall comply with a code of  
14 conduct, specified or recognized by the Secretary,  
15 that includes standards relating to conflicts of in-  
16 terest; and

17 “(ii) the contractor shall comply with all appli-  
18 cable provisions relating to prevention of fraud and  
19 abuse, including compliance with applicable guide-  
20 lines of the Department of Justice and the Inspec-  
21 tor General of the Department of Health and  
22 Human Services.

23 “(E) DIRECT DELIVERY OF DRUGS AND  
24 BIOLOGICALS TO PHYSICIANS.—Under the contract the  
25 contractor shall only supply competitively biddable  
26 drugs and biologicals directly to the selecting physi-  
27 cians and not directly to individuals, except under cir-  
28 cumstances and settings where an individual currently  
29 receives a drug or biological in the individual’s home or  
30 other non-physician office setting as the Secretary may  
31 provide. The contractor shall not deliver drugs and  
32 biologicals to a selecting physician except upon receipt  
33 of a prescription for such drugs and biologicals, and  
34 such necessary data as may be required by the Sec-  
35 retary to carry out this section. This section does not—

36 “(i) require a physician to submit a prescrip-  
37 tion for each individual treatment; or

1                   “(ii) change a physician’s flexibility in terms  
2                   of writing a prescription for drugs or biologicals for  
3                   a single treatment or a course of treatment.

4                   “(5) PERMITTING ACCESS TO DRUGS AND  
5                   BIOLOGICALS.—The Secretary shall establish rules under  
6                   this section under which drugs and biologicals which are  
7                   acquired through a contractor under this section may be  
8                   used to resupply inventories of such drugs and biologicals  
9                   which are administered consistent with safe drug practices  
10                  and with adequate safeguards against fraud and abuse.  
11                  The previous sentence shall apply if the physicians can  
12                  demonstrate to the Secretary all of the following:

13                  “(A) The drugs or biologicals are required imme-  
14                  diately.

15                  “(B) The physician could not have reasonably an-  
16                  ticipated the immediate requirement for the drugs or  
17                  biologicals.

18                  “(C) The contractor could not deliver to the physi-  
19                  cian the drugs or biologicals in a timely manner.

20                  “(D) The drugs or biologicals were administered  
21                  in an emergency situation.

22                  “(6) CONSTRUCTION.—Nothing in this section shall be  
23                  construed as waiving applicable State requirements relating  
24                  to licensing of pharmacies.

25                  “(c) BIDDING PROCESS.—

26                  “(1) IN GENERAL.—In awarding a contract for a cat-  
27                  egory of drugs and biologicals in an area under the pro-  
28                  gram, the Secretary shall consider with respect to each en-  
29                  tity seeking to be awarded a contract the bid price and the  
30                  other factors referred to in subsection (b)(3).

31                  “(2) BID DEFINED.—In this section, the term ‘bid’  
32                  means an offer to furnish a competitively biddable drug or  
33                  biological for a particular price and time period.

34                  “(3) BIDDING ON A NATIONAL OR REGIONAL BASIS.—  
35                  Nothing in this section shall be construed as precluding a  
36                  bidder from bidding for contracts in all areas of the United

1 States or as requiring a bidder to submit a bid for all areas  
2 of the United States.

3 “(4) UNIFORMITY OF BIDS WITHIN AREA.—The  
4 amount of the bid submitted under a contract offer for any  
5 competitively biddable drug or biological for an area shall  
6 be the same for that drug or biological for all portions of  
7 that area.

8 “(5) CONFIDENTIALITY OF BIDS.—The provisions of  
9 subparagraph (D) of section 1927(b)(3) shall apply to peri-  
10 ods during which a bid is submitted with respect to a com-  
11 petitively biddable drug or biological under this section in  
12 the same manner as it applies to information disclosed  
13 under such section, except that any reference—

14 “(A) in that subparagraph to a ‘manufacturer or  
15 wholesaler’ is deemed a reference to a ‘bidder’ under  
16 this section;

17 “(B) in that section to ‘prices charged for drugs’  
18 is deemed a reference to a ‘bid’ submitted under this  
19 section; and

20 “(C) in clause (i) of that section to ‘this section’,  
21 is deemed a reference to ‘part B of title XVIII’.

22 “(6) INCLUSION OF COSTS.—The bid price submitted  
23 in a contract offer for a competitively biddable drug or bio-  
24 logical shall—

25 “(A) include all costs related to the delivery of the  
26 drug or biological to the selecting physician (or other  
27 point of delivery); and

28 “(B) include the costs of dispensing (including  
29 shipping) of such drug or biological and management  
30 fees, but shall not include any costs related to the ad-  
31 ministration of the drug or biological, or wastage, spill-  
32 age, or spoilage.

33 “(7) PRICE ADJUSTMENTS DURING CONTRACT PERIOD;  
34 DISCLOSURE OF COSTS.—Each contract awarded shall pro-  
35 vide for—

36 “(A) disclosure to the Secretary the contractor’s  
37 reasonable, net acquisition costs for periods specified by



1 the Secretary, not more often than quarterly, of the  
2 contract; and

3 “(B) appropriate price adjustments over the pe-  
4 riod of the contract to reflect significant increases or  
5 decreases in a contractor’s reasonable, net acquisition  
6 costs, as so disclosed.

7 “(d) COMPUTATION OF PAYMENT AMOUNTS.—

8 “(1) IN GENERAL.—Payment under this section for  
9 competitively biddable drugs or biologicals shall be based on  
10 bids submitted and accepted under this section for such  
11 drugs or biologicals in an area. Based on such bids the Sec-  
12 retary shall determine a single payment amount for each  
13 competitively biddable drug or biological in the area.

14 “(2) SPECIAL RULES.—The Secretary shall establish  
15 rules regarding the use under this section of the alternative  
16 payment amount provided under section 1847A to the use  
17 of a price for specific competitively biddable drugs and  
18 biologicals in the following cases:

19 “(A) NEW DRUGS AND BIOLOGICALS.—A competi-  
20 tively biddable drug or biological for which a payment  
21 and billing code has not been established.

22 “(B) OTHER CASES.—Such other exceptional cases  
23 as the Secretary may specify in regulations.

24 “(e) COST-SHARING.—

25 “(1) APPLICATION OF COINSURANCE.—Payment under  
26 this section for competitively biddable drugs and biologicals  
27 shall be in an amount equal to 80 percent of the payment  
28 basis described in subsection (d)(1).

29 “(2) DEDUCTIBLE.—Before applying paragraph (1),  
30 the individual shall be required to meet the deductible de-  
31 scribed in section 1833(b).

32 “(3) COLLECTION.—Such coinsurance and deductible  
33 shall be collected by the contractor that supplies the drug  
34 or biological involved. Subject to subsection (a)(3)(B), such  
35 coinsurance and deductible may be collected in a manner  
36 similar to the manner in which the coinsurance and deduct-

1           ible are collected for durable medical equipment under this  
2           part.

3           “(f) SPECIAL PAYMENT RULES.—

4                 “(1) USE IN EXCLUSION CASES.—If the Secretary ex-  
5                 cludes a drug or biological (or class of drugs or biologicals)  
6                 under subsection (a)(1)(D), the Secretary may provide for  
7                 payment to be made under this part for such drugs and  
8                 biologicals (or class) using the payment methodology under  
9                 section 1847A.

10                “(2) APPLICATION OF REQUIREMENT FOR ASSIGN-  
11                MENT.—For provision requiring assignment of claims for  
12                competitively biddable drugs and biologicals, see section  
13                1842(o)(3).

14                “(3) PROTECTION FOR BENEFICIARY IN CASE OF MED-  
15                ICAL NECESSITY DENIAL.—For protection of individuals  
16                against liability in the case of medical necessity determina-  
17                tions, see section 1842(b)(3)(B)(ii)(III).

18                “(g) JUDICIAL REVIEW.—There shall be no administrative  
19                or judicial review under section 1869, section 1878, or other-  
20                wise, of—

21                    “(1) the establishment of payment amounts under  
22                    subsection (d)(1);

23                    “(2) the awarding of contracts under this section;

24                    “(3) the establishment of competitive acquisition areas  
25                    under subsection (a)(2)(C);

26                    “(4) the phased-in implementation under subsection  
27                    (a)(1)(B);

28                    “(5) the selection of categories of competitively bid-  
29                    dable drugs and biologicals for competitive acquisition  
30                    under such subsection or the selection of a drug in the case  
31                    of multiple source drugs; or

32                    “(6) the bidding structure and number of contractors  
33                    selected under this section.”.

34                (2) REPORT.—Not later than July 1, 2008, the Sec-  
35                retary shall submit to Congress a report on the program  
36                conducted under section 1847B of the Social Security Act,  
37                as added by paragraph (1). Such report shall include infor-

1 information on savings, reductions in cost-sharing, access to  
2 competitively biddable drugs and biologicals, the range of  
3 choices of contractors available to physicians, the satisfac-  
4 tion of physicians and of individuals enrolled under this  
5 part, and information comparing prices for drugs and  
6 biologicals under such section and section 1847A of such  
7 Act, as added by subsection (c).

8 (e) ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINIS-  
9 TRATION OF DRUGS AND BIOLOGICALS.—

10 (1) ITEMS AND SERVICES RELATING TO FURNISHING  
11 OF BLOOD CLOTTING FACTORS.—Section 1842(o) (42  
12 U.S.C. 1395u(o)), as amended by subsection (b)(2), is  
13 amended by adding at the end the following new para-  
14 graph:

15 “(5)(A) Subject to subparagraph (B), in the case of clot-  
16 ting factors furnished on or after January 1, 2005, the Sec-  
17 retary shall, after reviewing the January 2003 report to Con-  
18 gress by the Comptroller General of the United States entitled  
19 ‘Payment for Blood Clotting Factor Exceeds Providers Acquisi-  
20 tion Cost’, provide for a separate payment, to the entity which  
21 furnishes to the patient blood clotting factors, for items and  
22 services related to the furnishing of such factors in an amount  
23 that the Secretary determines to be appropriate. Such payment  
24 amount may take into account any or all of the following:

25 “(i) The mixing (if appropriate) and delivery of factors  
26 to an individual, including special inventory management  
27 and storage requirements.

28 “(ii) Ancillary supplies and patient training necessary  
29 for the self-administration of such factors.

30 “(B) In determining the separate payment amount under  
31 subparagraph (A) for blood clotting factors furnished in 2005,  
32 the Secretary shall ensure that the total amount of payments  
33 under this part (as estimated by the Secretary) for such factors  
34 under paragraph (1)(C) and such separate payments for such  
35 factors does not exceed the total amount of payments that  
36 would have been made for such factors under this part (as esti-  
37 mated by the Secretary) if the amendments made by section

1 303 of the Medicare Prescription Drug, Improvement, and  
2 Modernization Act of 2003 had not been enacted.

3 “(C) The separate payment amount under this subpara-  
4 graph for blood clotting factors furnished in 2006 or a subse-  
5 quent year shall be equal to the separate payment amount de-  
6 termined under this paragraph for the previous year increased  
7 by the percentage increase in the consumer price index for  
8 medical care for the 12-month period ending with June of the  
9 previous year.”.

10 (2) PHARMACY SUPPLYING FEE FOR CERTAIN DRUGS  
11 AND BIOLOGICALS.—Section 1842(o) (42 U.S.C. 1395u(o)),  
12 as previously amended, is amended by adding at the end  
13 the following new paragraph:

14 “(6) In the case of an immunosuppressive drug described  
15 in subparagraph (J) of section 1861(s)(2) and an oral drug de-  
16 scribed in subparagraph (Q) or (T) of such section, the Sec-  
17 retary shall pay to the pharmacy a supplying fee for such a  
18 drug determined appropriate by the Secretary (less the applica-  
19 ble deductible and coinsurance amounts).”.

20 (f) LINKAGE OF REVISED DRUG PAYMENTS AND IN-  
21 CREASES FOR DRUG ADMINISTRATION.—The Secretary shall  
22 not implement the revisions in payment amounts for drugs and  
23 biologicals administered by physicians as a result of the amend-  
24 ments made by subsection (b) with respect to 2004 unless the  
25 Secretary concurrently makes adjustments to the practice ex-  
26 pense payment adjustment under the amendments made by  
27 subsection (a).

28 (g) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL RE-  
29 VIEW.—

30 (1) DRUGS.—Section 1842(o) (42 U.S.C. 1395u(o)),  
31 as previously amended, is amended by adding at the end  
32 the following new paragraph:

33 “(7) There shall be no administrative or judicial review  
34 under section 1869, section 1878, or otherwise, of determina-  
35 tions of payment amounts, methods, or adjustments under  
36 paragraphs (4) through (6).”.

1           (2)     PHYSICIAN     FEE     SCHEDULE.—Section  
2     1848(i)(1)(B) (42 U.S.C. 1395w-4(i)(1)(B)) is amended by  
3     striking “subsection (c)(2)(F)” and inserting “subsections  
4     (c)(2)(F), (c)(2)(H), and (c)(2)(I)”.

5           (3) MULTIPLE CHEMOTHERAPY AGENTS, OTHER SERV-  
6     ICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL,  
7     AND TRANSITIONAL ADJUSTMENT.—There shall be no ad-  
8     ministrative or judicial review under section 1869, section  
9     1878, or otherwise, of determinations of payment amounts,  
10    methods, or adjustments under paragraphs (2) through (4)  
11    of subsection (a).

12          (h) CONTINUATION OF PAYMENT METHODOLOGY FOR  
13    RADIOPHARMACEUTICALS.—Nothing in the amendments made  
14    by this section shall be construed as changing the payment  
15    methodology under part B of title XVIII of the Social Security  
16    Act for radiopharmaceuticals, including the use by carriers of  
17    invoice pricing methodology.

18          (i) CONFORMING AMENDMENTS.—

19           (1) APPLICATION OF ASP AND COMPETITIVE BID-  
20    DING.—Section 1842(o)(2) (42 U.S.C. 1395u(o)(2)) is  
21    amended by adding at the end the following: “This para-  
22    graph shall not apply in the case of payment under para-  
23    graph (1)(C).”.

24           (2) NO CHANGE IN COVERAGE BASIS.—Section  
25    1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by  
26    inserting “(or would have been so included but for the ap-  
27    plication of section 1847B)” after “included in the physi-  
28    cians’ bills”.

29           (3) PAYMENT.—(A) Section 1833(a)(1)(S) (42 U.S.C.  
30    1395l(a)(1)(S)) is amended by inserting “(or, if applicable,  
31    under section 1847, 1847A, or 1847B)” after “1842(o)”.

32           (B) Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is  
33    amended—

34           (i) by striking “and” at the end of subparagraph  
35    (H);

36           (ii) by striking the semicolon at the end of sub-  
37    paragraph (I) and inserting “, and”; and

1 (iii) by adding at the end the following new sub-  
2 paragraph:

3 “(J) in the case of a drug or biological specified in  
4 section 1847A(c)(6)(C) for which payment is made under  
5 part B that is furnished in a competitive area under section  
6 1847B, that is not furnished by an entity under a contract  
7 under such section;”.

8 (4) CONSOLIDATED REPORTING OF PRICING INFORMA-  
9 TION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

10 (A) in subsection (a)(1), by inserting “or under  
11 part B of title XVIII” after “section 1903(a)”;

12 (B) in subsection (b)(3)(A)—

13 (i) in clause (i), by striking “and” at the end  
14 and inserting a semicolon;

15 (ii) in clause (ii), by striking the period and  
16 inserting “; and”; and

17 (iii) by adding at the end the following:

18 “(iii) for calendar quarters beginning on or  
19 after January 1, 2004, in conjunction with report-  
20 ing required under clause (i) and by National Drug  
21 Code (including package size)—

22 “(I) the manufacturer’s average sales  
23 price (as defined in section 1847A(c)) and the  
24 total number of units specified under section  
25 1847A(b)(2)(A);

26 “(II) if required to make payment under  
27 section 1847A, the manufacturer’s wholesale  
28 acquisition cost, as defined in subsection (c)(6)  
29 of such section; and

30 “(III) information on those sales that were  
31 made at a nominal price or otherwise described  
32 in section 1847A(c)(2)(B);

33 for a drug or biological described in subparagraph  
34 (C), (D), (E), or (G) of section 1842(o)(1) or sec-  
35 tion 1881(b)(13)(A)(ii).

1 Information reported under this subparagraph is sub-  
2 ject to audit by the Inspector General of the Depart-  
3 ment of Health and Human Services.”;

4 (C) in subsection (b)(3)(B)—

5 (i) in the heading, by inserting “AND MANU-  
6 FACTURER’S AVERAGE SALES PRICE” after  
7 “PRICE”; and

8 (ii) by inserting “and manufacturer’s average  
9 sales prices (including wholesale acquisition cost) if  
10 required to make payment” after “manufacturer  
11 prices”; and

12 (D) in subsection (b)(3)(D)—

13 (i) in the matter preceding clause (i), by in-  
14 serting “(other than the wholesale acquisition cost  
15 for purposes of carrying out section 1847A)” after  
16 “subsection (a)(6)(A)(ii)”; and

17 (ii) in clause (i), by inserting “, to carry out  
18 section 1847A (including the determination and im-  
19 plementation of the payment amount), or to carry  
20 out section 1847B” after “this section”.

21 (5) IMPLEMENTATION.—The provisions of chapter 8 of  
22 title 5, United States Code, shall not apply with respect to  
23 regulations implementing the amendments made by sub-  
24 sections (a), (b), and (e)(3), to regulations implementing  
25 section 304, and to regulations implementing the amend-  
26 ment made by section 305(a), insofar as such regulations  
27 apply in 2004.

28 (6) REPEAL OF STUDY.—Section 4556 of the Bal-  
29 anced Budget Act of 1997 (42 U.S.C. 1395u note) is  
30 amended by striking subsection (c).

31 (j) APPLICATION TO CERTAIN PHYSICIAN SPECIALTIES.—  
32 Insofar as the amendments made by this section apply to pay-  
33 ments for drugs or biologicals and drug administration services  
34 furnished by physicians, such amendments shall only apply to  
35 physicians in the specialties of hematology, hematology/oncol-  
36 ogy, and medical oncology under title XVIII of the Social Secu-  
37 rity Act.

1     **SEC. 304. EXTENSION OF APPLICATION OF PAYMENT RE-**  
2                   **FORM FOR COVERED OUTPATIENT DRUGS**  
3                   **AND BIOLOGICALS TO OTHER PHYSICIAN**  
4                   **SPECIALTIES.**

5             Notwithstanding section 303(j), the amendments made by  
6     section 303 shall also apply to payments for drugs or  
7     biologicals and drug administration services furnished by physi-  
8     cians in specialties other than the specialties of hematology, he-  
9     matology/oncology, and medical oncology.

10    **SEC. 305. PAYMENT FOR INHALATION DRUGS.**

11            (a) IN GENERAL.—Section 1842(o)(1)(G) (42 U.S.C.  
12     1395u(o)(1)(G)), as added by section 303(b), is amended to  
13     read as follows:

14               “(G) In the case of inhalation drugs or biologicals fur-  
15               nished through durable medical equipment covered under  
16               section 1861(n) that are furnished—

17                   “(i) in 2004, the amount provided under para-  
18                   graph (4) for the drug or biological; and

19                   “(ii) in 2005 and subsequent years, the amount  
20                   provided under section 1847A for the drug or biologi-  
21                   cal.”.

22            (b) GAO STUDY OF MEDICARE PAYMENT FOR INHALA-  
23     TION THERAPY.—

24               (1) STUDY.—The Comptroller General of the United  
25     States shall conduct a study to examine the adequacy of  
26     current reimbursements for inhalation therapy under the  
27     medicare program.

28               (2) REPORT.—Not later than 1 year after the date of  
29     the enactment of this Act, the Comptroller General shall  
30     submit to Congress a report on the study conducted under  
31     paragraph (1).

32    **SEC. 306. DEMONSTRATION PROJECT FOR USE OF RE-**  
33                   **COVERY AUDIT CONTRACTORS.**

34            (a) IN GENERAL.—The Secretary shall conduct a dem-  
35     onstration project under this section (in this section referred to  
36     as the “project”) to demonstrate the use of recovery audit con-  
37     tractors under the Medicare Integrity Program in identifying  
38     underpayments and overpayments and recouping overpayments



1 under the medicare program for services for which payment is  
2 made under part A or B of title XVIII of the Social Security  
3 Act. Under the project—

4 (1) payment may be made to such a contractor on a  
5 contingent basis;

6 (2) such percentage as the Secretary may specify of  
7 the amount recovered shall be retained by the Secretary  
8 and shall be available to the program management account  
9 of the Centers for Medicare & Medicaid Services; and

10 (3) the Secretary shall examine the efficacy of such  
11 use with respect to duplicative payments, accuracy of cod-  
12 ing, and other payment policies in which inaccurate pay-  
13 ments arise.

14 (b) SCOPE AND DURATION.—

15 (1) SCOPE.—The project shall cover at least 2 States  
16 that are among the States with—

17 (A) the highest per capita utilization rates of  
18 medicare services, and

19 (B) at least 3 contractors.

20 (2) DURATION.—The project shall last for not longer  
21 than 3 years.

22 (c) WAIVER.—The Secretary shall waive such provisions of  
23 title XVIII of the Social Security Act as may be necessary to  
24 provide for payment for services under the project in accord-  
25 ance with subsection (a).

26 (d) QUALIFICATIONS OF CONTRACTORS.—

27 (1) IN GENERAL.—The Secretary shall enter into a re-  
28 covery audit contract under this section with an entity only  
29 if the entity has staff that has the appropriate clinical  
30 knowledge of and experience with the payment rules and  
31 regulations under the medicare program or the entity has  
32 or will contract with another entity that has such knowl-  
33 edgeable and experienced staff.

34 (2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The  
35 Secretary may not enter into a recovery audit contract  
36 under this section with an entity to the extent that the en-  
37 tity is a fiscal intermediary under section 1816 of the So-

1           cial Security Act (42 U.S.C. 1395h), a carrier under sec-  
2           tion 1842 of such Act (42 U.S.C. 1395u), or a Medicare  
3           Administrative Contractor under section 1874A of such  
4           Act.

5           (3) PREFERENCE FOR ENTITIES WITH DEM-  
6           ONSTRATED PROFICIENCY.—In awarding contracts to re-  
7           covery audit contractors under this section, the Secretary  
8           shall give preference to those risk entities that the Sec-  
9           retary determines have demonstrated more than 3 years di-  
10          rect management experience and a proficiency for cost con-  
11          trol or recovery audits with private insurers, health care  
12          providers, health plans, or under the medicaid program  
13          under title XIX of the Social Security Act.

14          (e) CONSTRUCTION RELATING TO CONDUCT OF INVES-  
15          TIGATION OF FRAUD.—A recovery of an overpayment to a pro-  
16          vider by a recovery audit contractor shall not be construed to  
17          prohibit the Secretary or the Attorney General from inves-  
18          tigating and prosecuting, if appropriate, allegations of fraud or  
19          abuse arising from such overpayment.

20          (f) REPORT.—The Secretary shall submit to Congress a  
21          report on the project not later than 6 months after the date  
22          of its completion. Such reports shall include information on the  
23          impact of the project on savings to the medicare program and  
24          recommendations on the cost-effectiveness of extending or ex-  
25          panding the project.information’ means information about a  
26          conviction for a relevant crime or a finding of patient or resi-  
27          dent abuse.

28          **SEC. 307. PILOT PROGRAM FOR NATIONAL AND STATE**  
29                            **BACKGROUND CHECKS ON DIRECT PATIENT**  
30                            **ACCESS EMPLOYEES OF LONG-TERM CARE**  
31                            **FACILITIES OR PROVIDERS.**

32          (a) AUTHORITY TO CONDUCT PROGRAM.—The Secretary,  
33          in consultation with the Attorney General, shall establish a  
34          pilot program to identify efficient, effective, and economical  
35          procedures for long term care facilities or providers to conduct  
36          background checks on prospective direct patient access employ-  
37          ees.

1 (b) REQUIREMENTS.—

2 (1) IN GENERAL.—Under the pilot program, a long-  
3 term care facility or provider in a participating State, prior  
4 to employing a direct patient access employee that is first  
5 hired on or after the commencement date of the pilot pro-  
6 gram in the State, shall conduct a background check on the  
7 employee in accordance with such procedures as the partici-  
8 pating State shall establish.

9 (2) PROCEDURES.—

10 (A) IN GENERAL.—The procedures established by  
11 a participating State under paragraph (1) should be  
12 designed to—

13 (i) give a prospective direct access patient em-  
14 ployee notice that the long-term care facility or pro-  
15 vider is required to perform background checks  
16 with respect to new employees;

17 (ii) require, as a condition of employment, that  
18 the employee—

19 (I) provide a written statement disclosing  
20 any disqualifying information;

21 (II) provide a statement signed by the em-  
22 ployee authorizing the facility to request na-  
23 tional and State criminal history background  
24 checks;

25 (III) provide the facility with a rolled set  
26 of the employee's fingerprints; and

27 (IV) provide any other identification infor-  
28 mation the participating State may require;

29 (iii) require the facility or provider to check  
30 any available registries that would be likely to con-  
31 tain disqualifying information about a prospective  
32 employee of a long-term care facility or provider;  
33 and

34 (iv) permit the facility or provider to obtain  
35 State and national criminal history background  
36 checks on the prospective employee through a 10-  
37 fingerprint check that utilizes State criminal

1 records and the Integrated Automated Fingerprint  
2 Identification System of the Federal Bureau of In-  
3 vestigation.

4 (B) ELIMINATION OF UNNECESSARY CHECKS.—  
5 The procedures established by a participating State  
6 under paragraph (1) shall permit a long-term care fa-  
7 cility or provider to terminate the background check at  
8 any stage at which the facility or provider obtains dis-  
9 qualifying information regarding a prospective direct  
10 patient access employee.

11 (3) PROHIBITION ON HIRING OF ABUSIVE WORKERS.—

12 (A) IN GENERAL.—A long-term care facility or  
13 provider may not knowingly employ any direct patient  
14 access employee who has any disqualifying information.

15 (B) PROVISIONAL EMPLOYMENT.—

16 (i) IN GENERAL.—Under the pilot program, a  
17 participating State may permit a long-term care fa-  
18 cility or provider to provide for a provisional period  
19 of employment for a direct patient access employee  
20 pending completion of a background check, subject  
21 to such supervision during the employee's provi-  
22 sional period of employment as the participating  
23 State determines appropriate.

24 (ii) SPECIAL CONSIDERATION FOR CERTAIN  
25 FACILITIES AND PROVIDERS.—In determining what  
26 constitutes appropriate supervision of a provisional  
27 employee, a participating State shall take into ac-  
28 count cost or other burdens that would be imposed  
29 on small rural long-term care facilities or providers,  
30 as well as the nature of care delivered by such fa-  
31 cilities or providers that are home health agencies  
32 or providers of hospice care.

33 (4) USE OF INFORMATION; IMMUNITY FROM LIABIL-  
34 ITY.—

35 (A) USE OF INFORMATION.—A participating State  
36 shall ensure that a long-term care facility or provider  
37 that obtains information about a direct patient access

1 employee pursuant to a background check uses such in-  
2 formation only for the purpose of determining the suit-  
3 ability of the employee for employment.

4 (B) IMMUNITY FROM LIABILITY.—A participating  
5 State shall ensure that a long-term care facility or pro-  
6 vider that, in denying employment for an individual se-  
7 lected for hire as a direct patient access employee (in-  
8 cluding during any period of provisional employment),  
9 reasonably relies upon information obtained through a  
10 background check of the individual, shall not be liable  
11 in any action brought by the individual based on the  
12 employment determination resulting from the informa-  
13 tion.

14 (5) AGREEMENTS WITH EMPLOYMENT AGENCIES.—A  
15 participating State may establish procedures for facilitating  
16 the conduct of background checks on prospective direct pa-  
17 tient access employees that are hired by a long-term care  
18 facility or provider through an employment agency (includ-  
19 ing a temporary employment agency).

20 (6) PENALTIES.—A participating State may impose  
21 such penalties as the State determines appropriate to en-  
22 force the requirements of the pilot program conducted in  
23 that State.

24 (c) PARTICIPATING STATES.—

25 (1) IN GENERAL.—The Secretary shall enter into  
26 agreements with not more than 10 States to conduct the  
27 pilot program under this section in such States.

28 (2) REQUIREMENTS FOR STATES.—An agreement en-  
29 tered into under paragraph (1) shall require that a partici-  
30 pating State—

31 (A) be responsible for monitoring compliance with  
32 the requirements of the pilot program;

33 (B) have procedures by which a provisional em-  
34 ployee or an employee may appeal or dispute the accu-  
35 racy of the information obtained in a background check  
36 performed under the pilot program; and

37 (C) agree to—

1 (i) review the results of any State or national  
2 criminal history background checks conducted re-  
3 garding a prospective direct patient access em-  
4 ployee to determine whether the employee has any  
5 conviction for a relevant crime;

6 (ii) immediately report to the entity that re-  
7 quested the criminal history background checks the  
8 results of such review; and

9 (iii) in the case of an employee with a convic-  
10 tion for a relevant crime that is subject to report-  
11 ing under section 1128E of the Social Security Act  
12 (42 U.S.C. 1320a-7e), report the existence of such  
13 conviction to the database established under that  
14 section.

15 (3) APPLICATION AND SELECTION CRITERIA.—

16 (A) APPLICATION.—A State seeking to participate  
17 in the pilot program established under this section,  
18 shall submit an application to the Secretary containing  
19 such information and at such time as the Secretary  
20 may specify.

21 (B) SELECTION CRITERIA.—

22 (i) IN GENERAL.—In selecting States to par-  
23 ticipate in the pilot program, the Secretary shall  
24 establish criteria to ensure—

25 (I) geographic diversity;

26 (II) the inclusion of a variety of long-term  
27 care facilities or providers;

28 (III) the evaluation of a variety of pay-  
29 ment mechanisms for covering the costs of con-  
30 ducting the background checks required under  
31 the pilot program; and

32 (IV) the evaluation of a variety of pen-  
33 alties (monetary and otherwise) used by partici-  
34 pating States to enforce the requirements of  
35 the pilot program in such States.

36 (ii) ADDITIONAL CRITERIA.—The Secretary  
37 shall, to the greatest extent practicable, select

1 States to participate in the pilot program in ac-  
2 cordance with the following:

3 (I) At least one participating State should  
4 permit long-term care facilities or providers to  
5 provide for a provisional period of employment  
6 pending completion of a background check and  
7 at least one such State should not permit such  
8 a period of employment.

9 (II) At least one participating State  
10 should establish procedures under which em-  
11 ployment agencies (including temporary em-  
12 ployment agencies) may contact the State di-  
13 rectly to conduct background checks on pro-  
14 spective direct patient access employees.

15 (III) At least one participating State  
16 should include patient abuse prevention train-  
17 ing (including behavior training and interven-  
18 tions) for managers and employees of long-term  
19 care facilities and providers as part of the pilot  
20 program conducted in that State.

21 (iii) INCLUSION OF STATES WITH EXISTING  
22 PROGRAMS.—Nothing in this section shall be con-  
23 strued as prohibiting any State which, as of the  
24 date of the enactment of this Act, has procedures  
25 for conducting background checks on behalf of any  
26 entity described in subsection (g)(5) from being se-  
27 lected to participate in the pilot program conducted  
28 under this section.

29 (d) PAYMENTS.—Of the amounts made available under  
30 subsection (f) to conduct the pilot program under this section,  
31 the Secretary shall—

32 (1) make payments to participating States for the  
33 costs of conducting the pilot program in such States; and

34 (2) reserve up to 4 percent of such amounts to con-  
35 duct the evaluation required under subsection (e).

36 (e) EVALUATION.—The Secretary, in consultation with the  
37 Attorney General, shall conduct by grant, contract, or inter-

1 agency agreement an evaluation of the pilot program conducted  
2 under this section. Such evaluation shall—

3 (1) review the various procedures implemented by par-  
4 ticipating States for long-term care facilities or providers to  
5 conduct background checks of direct patient access employ-  
6 ees and identify the most efficient, effective, and economi-  
7 cal procedures for conducting such background checks;

8 (2) assess the costs of conducting such background  
9 checks (including start-up and administrative costs);

10 (3) consider the benefits and problems associated with  
11 requiring employees or facilities or providers to pay the  
12 costs of conducting such background checks;

13 (4) consider whether the costs of conducting such  
14 background checks should be allocated between the medi-  
15 care and medicaid programs and if so, identify an equitable  
16 methodology for doing so;

17 (5) determine the extent to which conducting such  
18 background checks leads to any unintended consequences,  
19 including a reduction in the available workforce for such fa-  
20 cilities or providers;

21 (6) review forms used by participating States in order  
22 to develop, in consultation with the Attorney General, a  
23 model form for such background checks;

24 (7) determine the effectiveness of background checks  
25 conducted by employment agencies; and

26 (8) recommend appropriate procedures and payment  
27 mechanisms for implementing a national criminal back-  
28 ground check program for such facilities and providers.

29 (f) FUNDING.—Out of any funds in the Treasury not oth-  
30 erwise appropriated, there are appropriated to the Secretary to  
31 carry out the pilot program under this section for the period  
32 of fiscal years 2004 through 2007, \$25,000,000.

33 (g) DEFINITIONS.—In this section:

34 (1) CONVICTION FOR A RELEVANT CRIME.—The term  
35 “conviction for a relevant crime” means any Federal or  
36 State criminal conviction for—



1 (A) any offense described in section 1128(a) of the  
2 Social Security Act (42 U.S.C. 1320a-7); and

3 (B) such other types of offenses as a participating  
4 State may specify for purposes of conducting the pilot  
5 program in such State.

6 (2) DISQUALIFYING INFORMATION.—The term “dis-  
7 qualifying information” means a conviction for a relevant  
8 crime or a finding of patient or resident abuse.

9 (3) FINDING OF PATIENT OR RESIDENT ABUSE.—The  
10 term “finding of patient or resident abuse” means any sub-  
11 stantiated finding by a State agency under section  
12 1819(g)(1)(C) or 1919(g)(1)(C) of the Social Security Act  
13 (42 U.S.C. 1395i-3(g)(1)(C), 1396r(g)(1)(C)) or a Federal  
14 agency that a direct patient access employee has  
15 committed—

16 (A) an act of patient or resident abuse or neglect  
17 or a misappropriation of patient or resident property;  
18 or

19 (B) such other types of acts as a participating  
20 State may specify for purposes of conducting the pilot  
21 program in such State.

22 (4) DIRECT PATIENT ACCESS EMPLOYEE.—The term  
23 “direct patient access employee” means any individual  
24 (other than a volunteer) that has access to a patient or  
25 resident of a long-term care facility or provider through  
26 employment or through a contract with such facility or pro-  
27 vider, as determined by a participating State for purposes  
28 of conducting the pilot program in such State.

29 (5) LONG-TERM CARE FACILITY OR PROVIDER.—

30 (A) IN GENERAL.—The term “long-term care fa-  
31 cility or provider” means the following facilities or pro-  
32 viders which receive payment for services under title  
33 XVIII or XIX of the Social Security Act:

34 (i) A skilled nursing facility (as defined in sec-  
35 tion 1819(a) of the Social Security Act) (42 U.S.C.  
36 1395i-3(a)).

1 (ii) A nursing facility (as defined in section  
2 1919(a) in such Act) (42 U.S.C. 1396r(a)).

3 (iii) A home health agency.

4 (iv) A provider of hospice care (as defined in  
5 section 1861(dd)(1) of such Act) (42 U.S.C.  
6 1395x(dd)(1)).

7 (v) A long-term care hospital (as described in  
8 section 1886(d)(1)(B)(iv) of such Act) (42 U.S.C.  
9 1395ww(d)(1)(B)(iv)).

10 (vi) A provider of personal care services.

11 (vii) A residential care provider that arranges  
12 for, or directly provides, long-term care services.

13 (viii) An intermediate care facility for the  
14 mentally retarded (as defined in section 1905(d) of  
15 such Act) 42 U.S.C. 1396d(d)).

16 (B) ADDITIONAL FACILITIES OR PROVIDERS.—  
17 During the first year in which a pilot program under  
18 this section is conducted in a participating State, the  
19 State may expand the list of facilities or providers  
20 under subparagraph (A) (on a phased-in basis or other-  
21 wise) to include such other facilities or providers of  
22 long-term care services under such titles as the partici-  
23 pating State determines appropriate.

24 (C) EXCEPTIONS.—Such term does not include—

25 (i) any facility or entity that provides, or is a  
26 provider of, services described in subparagraph (A)  
27 that are exclusively provided to an individual pur-  
28 suant to a self-directed arrangement that meets  
29 such requirements as the participating State may  
30 establish in accordance with guidance from the Sec-  
31 retary; or

32 (ii) any such arrangement that is obtained by  
33 a patient or resident functioning as an employer.

34 (6) PARTICIPATING STATE.—The term “participating  
35 State” means a State with an agreement under subsection  
36 (c)(1).

1                   **TITLE IV—RURAL PROVISIONS**  
2                   **Subtitle A—Provisions Relating to**  
3                   **Part A Only**

4                   **SEC. 401. EQUALIZING URBAN AND RURAL STANDARD-**  
5                   **IZED PAYMENT AMOUNTS UNDER THE MEDI-**  
6                   **CARE INPATIENT HOSPITAL PROSPECTIVE**  
7                   **PAYMENT SYSTEM.**

8                   (a) IN GENERAL.—Section 1886(d)(3)(A)(iv) (42 U.S.C.  
9                   1395ww(d)(3)(A)(iv)) is amended—

10                   (1) by striking “(iv) For discharges” and inserting  
11                   “(iv)(I) Subject to subclause (II), for discharges”; and

12                   (2) by adding at the end the following new subclause:

13                   “(II) For discharges occurring in a fiscal year (begin-  
14                   ning with fiscal year 2004), the Secretary shall compute a  
15                   standardized amount for hospitals located in any area with-  
16                   in the United States and within each region equal to the  
17                   standardized amount computed for the previous fiscal year  
18                   under this subparagraph for hospitals located in a large  
19                   urban area (or, beginning with fiscal year 2005, for all hos-  
20                   pitals in the previous fiscal year) increased by the applica-  
21                   ble percentage increase under subsection (b)(3)(B)(i) for  
22                   the fiscal year involved.”.

23                   (b) CONFORMING AMENDMENTS.—

24                   (1) COMPUTING DRG-SPECIFIC RATES.—Section  
25                   1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

26                   (A) in the heading, by striking “IN DIFFERENT  
27                   AREAS”;

28                   (B) in the matter preceding clause (i), by striking  
29                   “, each of”;

30                   (C) in clause (i)—

31                   (i) in the matter preceding subclause (I), by  
32                   inserting “for fiscal years before fiscal year 2004,”  
33                   before “for hospitals”; and

34                   (ii) in subclause (II), by striking “and” after  
35                   the semicolon at the end;

36                   (D) in clause (ii)—

1 (i) in the matter preceding subclause (I), by  
2 inserting “for fiscal years before fiscal year 2004,”  
3 before “for hospitals”; and

4 (ii) in subclause (II), by striking the period at  
5 the end and inserting “; and”; and

6 (E) by adding at the end the following new clause:

7 “(iii) for a fiscal year beginning after fiscal year  
8 2003, for hospitals located in all areas, to the product  
9 of—

10 “(I) the applicable standardized amount (com-  
11 puted under subparagraph (A)), reduced under  
12 subparagraph (B), and adjusted or reduced under  
13 subparagraph (C) for the fiscal year; and

14 “(II) the weighting factor (determined under  
15 paragraph (4)(B)) for that diagnosis-related  
16 group.”.

17 (2) TECHNICAL CONFORMING SUNSET.—Section  
18 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

19 (A) in the matter preceding subparagraph (A), by  
20 inserting “, for fiscal years before fiscal year 1997,”  
21 before “a regional adjusted DRG prospective payment  
22 rate”; and

23 (B) in subparagraph (D), in the matter preceding  
24 clause (i), by inserting “, for fiscal years before fiscal  
25 year 1997,” before “a regional DRG prospective pay-  
26 ment rate for each region,”.

27 (3) ADDITIONAL TECHNICAL AMENDMENT.—Section  
28 1886(d)(3)(A)(iii) (42 U.S.C. 1395ww(d)(3)(A)(iii)) is  
29 amended by striking “in an other urban area” and insert-  
30 ing “in an urban area”.

31 (c) EQUALIZING URBAN AND RURAL STANDARDIZED PAY-  
32 MENT AMOUNTS UNDER THE MEDICARE INPATIENT HOSPITAL  
33 PROSPECTIVE PAYMENT SYSTEM FOR HOSPITALS IN PUERTO  
34 RICO.—

35 (1) IN GENERAL.—Section 1886(d)(9)(A) (42 U.S.C.  
36 1395ww(d)(9)(A)), as amended by section 504, is  
37 amended—

1 (A) in clause (i), by striking “and” after the  
2 comma at the end; and

3 (B) by striking clause (ii) and inserting the fol-  
4 lowing new clause:

5 “(ii) the applicable Federal percentage (specified in  
6 subparagraph (E)) of—

7 “(I) for discharges beginning in a fiscal year be-  
8 ginning on or after October 1, 1997, and before Octo-  
9 ber 1, 2003, the discharge-weighted average of—

10 “(aa) the national adjusted DRG prospective  
11 payment rate (determined under paragraph (3)(D))  
12 for hospitals located in a large urban area,

13 “(bb) such rate for hospitals located in other  
14 urban areas, and

15 “(cc) such rate for hospitals located in a rural  
16 area,

17 for such discharges, adjusted in the manner provided in  
18 paragraph (3)(E) for different area wage levels; and

19 “(II) for discharges in a fiscal year beginning on  
20 or after October 1, 2003, the national DRG prospective  
21 payment rate determined under paragraph (3)(D)(iii)  
22 for hospitals located in any area for such discharges,  
23 adjusted in the manner provided in paragraph (3)(E)  
24 for different area wage levels.

25 As used in this section, the term ‘subsection (d) Puerto Rico  
26 hospital’ means a hospital that is located in Puerto Rico and  
27 that would be a subsection (d) hospital (as defined in para-  
28 graph (1)(B)) if it were located in one of the 50 States.”.

29 (2) APPLICATION OF PUERTO RICO STANDARDIZED  
30 AMOUNT BASED ON LARGE URBAN AREAS.—Section  
31 1886(d)(9)(C) (42 U.S.C. 1395ww(d)(9)(C)) is amended—

32 (A) in clause (i)—

33 (i) by striking “(i) The Secretary” and insert-  
34 ing “(i)(I) For discharges in a fiscal year after fis-  
35 cal year 1988 and before fiscal year 2004, the Sec-  
36 retary”; and

1 (ii) by adding at the end the following new  
2 subclause:

3 “(II) For discharges occurring in a fiscal year (begin-  
4 ning with fiscal year 2004), the Secretary shall compute an  
5 average standardized amount for hospitals located in any  
6 area of Puerto Rico that is equal to the average standard-  
7 ized amount computed under subclause (I) for fiscal year  
8 2003 for hospitals in a large urban area (or, beginning  
9 with fiscal year 2005, for all hospitals in the previous fiscal  
10 year) increased by the applicable percentage increase under  
11 subsection (b)(3)(B) for the fiscal year involved.”;

12 (B) in clause (ii), by inserting “(or for fiscal year  
13 2004 and thereafter, the average standardized  
14 amount)” after “each of the average standardized  
15 amounts”; and

16 (C) in clause (iii)(I), by striking “for hospitals lo-  
17 cated in an urban or rural area, respectively”.

18 (d) IMPLEMENTATION.—

19 (1) IN GENERAL.—The amendments made by sub-  
20 sections (a), (b), and (c)(1) of this section shall have no ef-  
21 fect on the authority of the Secretary, under subsection  
22 (b)(2) of section 402 of Public Law 108–89, to delay imple-  
23 mentation of the extension of provisions equalizing urban  
24 and rural standardized inpatient hospital payments under  
25 subsection (a) of such section 402.

26 (2) APPLICATION OF PUERTO RICO STANDARDIZED  
27 AMOUNT BASED ON LARGE URBAN AREAS.—The authority  
28 of the Secretary referred to in paragraph (1) shall apply  
29 with respect to the amendments made by subsection (c)(2)  
30 of this section in the same manner as that authority applies  
31 with respect to the extension of provisions equalizing urban  
32 and rural standardized inpatient hospital payments under  
33 subsection (a) of such section 402, except that any ref-  
34 erence in subsection (b)(2)(A) of such section 402 is  
35 deemed to be a reference to April 1, 2004.

1     **SEC. 402. ENHANCED DISPROPORTIONATE SHARE HOS-**  
2                   **PITAL (DSH) TREATMENT FOR RURAL HOS-**  
3                   **PITALS AND URBAN HOSPITALS WITH**  
4                   **FEWER THAN 100 BEDS.**

5           (a) DOUBLING THE CAP.—Section 1886(d)(5)(F) (42  
6 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the  
7 following new clause:

8           “(xiv)(I) In the case of discharges occurring on or after  
9 April 1, 2004, subject to subclause (II), there shall be sub-  
10 stituted for the disproportionate share adjustment percentage  
11 otherwise determined under clause (iv) (other than subclause  
12 (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the dis-  
13 proportionate share adjustment percentage determined under  
14 clause (vii) (relating to large, urban hospitals).

15           “(II) Under subclause (I), the disproportionate share ad-  
16 justment percentage shall not exceed 12 percent for a hospital  
17 that is not classified as a rural referral center under subpara-  
18 graph (C).”.

19           (b) CONFORMING AMENDMENTS.—Section 1886(d) (42  
20 U.S.C. 1395ww(d)) is amended—

21           (1) in paragraph (5)(F)—

22           (A) in each of subclauses (II), (III), (IV), (V), and  
23 (VI) of clause (iv), by inserting “subject to clause (xiv)  
24 and” before “for discharges occurring”;

25           (B) in clause (viii), by striking “The formula” and  
26 inserting “Subject to clause (xiv), the formula”; and

27           (C) in each of clauses (x), (xi), (xii), and (xiii), by  
28 striking “For purposes” and inserting “Subject to  
29 clause (xiv), for purposes”; and

30           (2) in paragraph (2)(C)(iv)—

31           (A) by striking “or” before “the enactment of sec-  
32 tion 303”; and

33           (B) by inserting before the period at the end the  
34 following: “, or the enactment of section 402(a)(1) of  
35 the Medicare Prescription Drug, Improvement, and  
36 Modernization Act of 2003”.

1     **SEC. 403. ADJUSTMENT TO THE MEDICARE INPATIENT**  
2                   **HOSPITAL PROSPECTIVE PAYMENT SYSTEM**  
3                   **WAGE INDEX TO REVISE THE LABOR-RE-**  
4                   **LATED SHARE OF SUCH INDEX.**

5           (a) ADJUSTMENT.—

6               (1) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C.  
7     1395ww(d)(3)(E)) is amended—

8                   (A) by striking “WAGE LEVELS.—The Secretary”  
9     and inserting “WAGE LEVELS.—

10                   “(i) IN GENERAL.—Except as provided in clause  
11     (ii), the Secretary”; and

12                   (B) by adding at the end the following new clause:

13                   “(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED  
14     BEGINNING IN FISCAL YEAR 2005.—For discharges oc-  
15     curring on or after October 1, 2004, the Secretary shall  
16     substitute ‘62 percent’ for the proportion described in  
17     the first sentence of clause (i), unless the application  
18     of this clause would result in lower payments to a hos-  
19     pital than would otherwise be made.”.

20               (2) WAIVING BUDGET NEUTRALITY.—Section  
21     1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended  
22     by subsection (a), is amended by adding at the end of  
23     clause (i) the following new sentence: “The Secretary shall  
24     apply the previous sentence for any period as if the amend-  
25     ments made by section 403(a)(1) of the Medicare Prescrip-  
26     tion Drug, Improvement, and Modernization Act of 2003  
27     had not been enacted.”.

28           (b) APPLICATION TO PUERTO RICO HOSPITALS.—Section  
29     1886(d)(9)(C)(iv) (42 U.S.C. 1395ww(d)(9)(C)(iv)) is  
30     amended—

31               (1) by inserting “(I)” after “(iv)”;

32               (2) by striking “paragraph (3)(E)” and inserting  
33     “paragraph (3)(E)(i)”; and

34               (3) by adding at the end the following new subclause:

35                   “(II) For discharges occurring on or after October 1,  
36     2004, the Secretary shall substitute ‘62 percent’ for the  
37     proportion described in the first sentence of clause (i), un-



1 less the application of this subclause would result in lower  
2 payments to a hospital than would otherwise be made.”.

3 **SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED**  
4 **IN HOSPITAL MARKET BASKET.**

5 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After re-  
6 vising the weights used in the hospital market basket under  
7 section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C.  
8 1395ww(b)(3)(B)(iii)) to reflect the most current data avail-  
9 able, the Secretary shall establish a frequency for revising such  
10 weights, including the labor share, in such market basket to re-  
11 flect the most current data available more frequently than once  
12 every 5 years.

13 (b) INCORPORATION OF EXPLANATION IN RULEMAKING.—  
14 The Secretary shall include in the publication of the final rule  
15 for payment for inpatient hospital services under section  
16 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) for  
17 fiscal year 2006, an explanation of the reasons for, and options  
18 considered, in determining frequency established under sub-  
19 section (a).

20 **SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOS-**  
21 **PITAL PROGRAM.**

22 (a) INCREASE IN PAYMENT AMOUNTS.—

23 (1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and  
24 1883(a)(3) (42 U.S.C. 1395f(l), 1395m(g)(1), and  
25 1395tt(a)(3)) are each amended by inserting “equal to 101  
26 percent of” before “the reasonable costs”.

27 (2) EFFECTIVE DATE.—The amendments made by  
28 paragraph (1) shall apply to payments for services fur-  
29 nished during cost reporting periods beginning on or after  
30 January 1, 2004.

31 (b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY  
32 ROOM ON-CALL PROVIDERS.—

33 (1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C.  
34 1395m(g)(5)) is amended—

35 (A) in the heading—

36 (i) by inserting “CERTAIN” before “EMER-  
37 GENCY”; and

1 (ii) by striking “PHYSICIANS” and inserting  
2 “PROVIDERS”;

3 (B) by striking “emergency room physicians who  
4 are on-call (as defined by the Secretary)” and inserting  
5 “physicians, physician assistants, nurse practitioners,  
6 and clinical nurse specialists who are on-call (as de-  
7 fined by the Secretary) to provide emergency services”;  
8 and

9 (C) by striking “physicians’ services” and insert-  
10 ing “services covered under this title”.

11 (2) EFFECTIVE DATE.—The amendments made by  
12 paragraph (1) shall apply with respect to costs incurred for  
13 services furnished on or after January 1, 2005.

14 (c) AUTHORIZATION OF PERIODIC INTERIM PAYMENT  
15 (PIP).—

16 (1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C.  
17 1395g(e)(2)) is amended—

18 (A) in the matter before subparagraph (A), by in-  
19 serting “, in the cases described in subparagraphs (A)  
20 through (D)” after “1986”;

21 (B) by striking “and” at the end of subparagraph  
22 (C);

23 (C) by adding “and” at the end of subparagraph  
24 (D); and

25 (D) by inserting after subparagraph (D) the fol-  
26 lowing new subparagraph:

27 “(E) inpatient critical access hospital services;”.

28 (2) DEVELOPMENT OF ALTERNATIVE TIMING METH-  
29 ODS OF PERIODIC INTERIM PAYMENTS.—With respect to  
30 periodic interim payments to critical access hospitals for in-  
31 patient critical access hospital services under section  
32 1815(e)(2)(E) of the Social Security Act, as added by para-  
33 graph (1), the Secretary shall develop alternative methods  
34 for the timing of such payments.

35 (3) AUTHORIZATION OF PIP.—The amendments made  
36 by paragraph (1) shall apply to payments made on or after  
37 July 1, 2004.

1 (d) CONDITION FOR APPLICATION OF SPECIAL PROFES-  
2 SIONAL SERVICE PAYMENT ADJUSTMENT.—

3 (1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C.  
4 1395m(g)(2)) is amended by adding after and below sub-  
5 paragraph (B) the following:

6 “The Secretary may not require, as a condition for apply-  
7 ing subparagraph (B) with respect to a critical access hos-  
8 pital, that each physician or other practitioner providing  
9 professional services in the hospital must assign billing  
10 rights with respect to such services, except that such sub-  
11 paragraph shall not apply to those physicians and practi-  
12 tioners who have not assigned such billing rights.”.

13 (2) EFFECTIVE DATE.—

14 (A) IN GENERAL.—Except as provided in subpara-  
15 graph (B), the amendment made by paragraph (1)  
16 shall apply to cost reporting periods beginning on or  
17 after July 1, 2004.

18 (B) RULE OF APPLICATION.—In the case of a crit-  
19 ical access hospital that made an election under section  
20 1834(g)(2) of the Social Security Act (42 U.S.C.  
21 1395m(g)(2)) before November 1, 2003, the amend-  
22 ment made by paragraph (1) shall apply to cost report-  
23 ing periods beginning on or after July 1, 2001.

24 (e) REVISION OF BED LIMITATION FOR HOSPITALS.—

25 (1) IN GENERAL.—Section 1820(c)(2)(B)(iii) (42  
26 U.S.C. 1395i-4(c)(2)(B)(iii)) is amended by striking “15  
27 (or, in the case of a facility under an agreement described  
28 in subsection (f), 25)” and inserting “25”.

29 (2) CONFORMING AMENDMENT.—Section 1820(f) (42  
30 U.S.C. 1395i-4(f)) is amended by striking “and the num-  
31 ber of beds used at any time for acute care inpatient serv-  
32 ices does not exceed 15 beds”.

33 (3) EFFECTIVE DATE.—The amendments made by  
34 this subsection shall apply to designations made before, on,  
35 or after January 1, 2004, but any election made pursuant  
36 to regulations promulgated to carry out such amendments  
37 shall only apply prospectively.

1 (f) PROVISIONS RELATING TO FLEX GRANTS.—

2 (1) ADDITIONAL 4-YEAR PERIOD OF FUNDING.—Sec-  
3 tion 1820(j) (42 U.S.C. 1395i-4(j)) is amended by insert-  
4 ing before the period at the end the following: “, and for  
5 making grants to all States under paragraphs (1) and (2)  
6 of subsection (g), \$35,000,000 in each of fiscal years 2005  
7 through 2008”.

8 (2) ADDITIONAL REQUIREMENTS AND ADMINISTRA-  
9 TION.—Section 1820(g) (42 U.S.C. 1395i-4(g)) is amend-  
10 ed by adding at the end the following new paragraphs:

11 “(4) ADDITIONAL REQUIREMENTS WITH RESPECT TO  
12 FLEX GRANTS.—With respect to grants awarded under  
13 paragraph (1) or (2) from funds appropriated for fiscal  
14 year 2005 and subsequent fiscal years—

15 “(A) CONSULTATION WITH THE STATE HOSPITAL  
16 ASSOCIATION AND RURAL HOSPITALS ON THE MOST AP-  
17 PROPRIATE WAYS TO USE GRANTS.—A State shall con-  
18 sult with the hospital association of such State and  
19 rural hospitals located in such State on the most ap-  
20 propriate ways to use the funds under such grant.

21 “(B) LIMITATION ON USE OF GRANT FUNDS FOR  
22 ADMINISTRATIVE EXPENSES.—A State may not expend  
23 more than the lesser of—

24 “(i) 15 percent of the amount of the grant for  
25 administrative expenses; or

26 “(ii) the State’s federally negotiated indirect  
27 rate for administering the grant.

28 “(5) USE OF FUNDS FOR FEDERAL ADMINISTRATIVE  
29 EXPENSES.—Of the total amount appropriated for grants  
30 under paragraphs (1) and (2) for a fiscal year (beginning  
31 with fiscal year 2005), up to 5 percent of such amount  
32 shall be available to the Health Resources and Services Ad-  
33 ministration for purposes of administering such grants.”.

34 (g) AUTHORITY TO ESTABLISH PSYCHIATRIC AND REHA-  
35 BILITATION DISTINCT PART UNITS.—

1           (1) IN GENERAL.—Section 1820(c)(2) (42 U.S.C.  
2           1395i-4(c)(2)) is amended by adding at the end the fol-  
3           lowing:

4                   “(E) AUTHORITY TO ESTABLISH PSYCHIATRIC  
5           AND REHABILITATION DISTINCT PART UNITS.—

6                           “(i) IN GENERAL.—Subject to the succeeding  
7                           provisions of this subparagraph, a critical access  
8                           hospital may establish—

9                                   “(I) a psychiatric unit of the hospital that  
10                                   is a distinct part of the hospital; and

11                                   “(II) a rehabilitation unit of the hospital  
12                                   that is a distinct part of the hospital,  
13                           if the distinct part meets the requirements (includ-  
14                           ing conditions of participation) that would other-  
15                           wise apply to the distinct part if the distinct part  
16                           were established by a subsection (d) hospital in ac-  
17                           cordance with the matter following clause (v) of  
18                           section 1886(d)(1)(B), including any regulations  
19                           adopted by the Secretary under such section.

20                                   “(ii) LIMITATION ON NUMBER OF BEDS.—The  
21                                   total number of beds that may be established under  
22                                   clause (i) for a distinct part unit may not exceed  
23                                   10.

24                                   “(iii) EXCLUSION OF BEDS FROM BED  
25                                   COUNT.—In determining the number of beds of a  
26                                   critical access hospital for purposes of applying the  
27                                   bed limitations referred to in subparagraph (B)(iii)  
28                                   and subsection (f), the Secretary shall not take into  
29                                   account any bed established under clause (i).

30                                   “(iv) EFFECT OF FAILURE TO MEET REQUIRE-  
31                                   MENTS.—If a psychiatric or rehabilitation unit es-  
32                                   tablished under clause (i) does not meet the re-  
33                                   quirements described in such clause with respect to  
34                                   a cost reporting period, no payment may be made  
35                                   under this title to the hospital for services fur-  
36                                   nished in such unit during such period. Payment to  
37                                   the hospital for services furnished in the unit may

1 resume only after the hospital has demonstrated to  
2 the Secretary that the unit meets such require-  
3 ments.”.

4 (2) PAYMENT ON A PROSPECTIVE PAYMENT BASIS.—  
5 Section 1814(l) (42 U.S.C. 1395f(l)) is amended—

6 (A) by striking “(l) The amount” and inserting  
7 “(l)(1) Except as provided in paragraph (2), the  
8 amount”; and

9 (B) by adding at the end the following new para-  
10 graph:

11 “(2) In the case of a distinct part psychiatric or rehabilita-  
12 tion unit of a critical access hospital described in section  
13 1820(c)(2)(E), the amount of payment for inpatient critical ac-  
14 cess hospital services of such unit shall be equal to the amount  
15 of the payment that would otherwise be made if such services  
16 were inpatient hospital services of a distinct part psychiatric or  
17 rehabilitation unit, respectively, described in the matter fol-  
18 lowing clause (v) of section 1886(d)(1)(B).”.

19 (3) EFFECTIVE DATE.—The amendments made by  
20 this subsection shall apply to cost reporting periods begin-  
21 ning on or after October 1, 2004.

22 (h) WAIVER AUTHORITY.—

23 (1) IN GENERAL.—Section 1820(c)(2)(B)(i)(II) (42  
24 U.S.C. 1395i-4(c)(2)(B)(i)(II)) is amended by inserting  
25 “before January 1, 2006,” after “is certified”.

26 (2) GRANDFATHERING WAIVER AUTHORITY FOR CER-  
27 TAIN FACILITIES.—Section 1820(h) (42 U.S.C. 1395i-  
28 4(h)) is amended—

29 (A) in the heading preceding paragraph (1), by  
30 striking “OF CERTAIN FACILITIES” and inserting  
31 “PROVISIONS”; and

32 (B) by adding at the end the following new para-  
33 graph:

34 “(3) STATE AUTHORITY TO WAIVE 35-MILE RULE.—In  
35 the case of a facility that was designated as a critical ac-  
36 cess hospital before January 1, 2006, and was certified by  
37 the State as being a necessary provider of health care serv-

1           ices to residents in the area under subsection  
2           (c)(2)(B)(i)(II), as in effect before such date, the authority  
3           under such subsection with respect to any redesignation of  
4           such facility shall continue to apply notwithstanding the  
5           amendment made by section 405(h)(1) of the Medicare  
6           Prescription Drug, Improvement, and Modernization Act of  
7           2003.”.

8           **SEC. 406. MEDICARE INPATIENT HOSPITAL PAYMENT**  
9           **ADJUSTMENT FOR LOW-VOLUME HOSPITALS.**

10           (a) IN GENERAL.—Section 1886(d) (42 U.S.C.  
11           1395ww(d)) is amended by adding at the end the following new  
12           paragraph:

13                   “(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOS-  
14           PITALS.—

15                           “(A) IN GENERAL.—In addition to any payments  
16                           calculated under this section for a subsection (d) hos-  
17                           pital, for discharges occurring during a fiscal year (be-  
18                           ginning with fiscal year 2005), the Secretary shall pro-  
19                           vide for an additional payment amount to each low-vol-  
20                           ume hospital (as defined in subparagraph (C)(i)) for  
21                           discharges occurring during that fiscal year that is  
22                           equal to the applicable percentage increase (determined  
23                           under subparagraph (B) for the hospital involved) in  
24                           the amount paid to such hospital under this section for  
25                           such discharges (determined without regard to this  
26                           paragraph).

27                           “(B) APPLICABLE PERCENTAGE INCREASE.—The  
28                           Secretary shall determine an applicable percentage in-  
29                           crease for purposes of subparagraph (A) as follows:

30                                   “(i) The Secretary shall determine the empir-  
31                                   ical relationship for subsection (d) hospitals be-  
32                                   tween the standardized cost-per-case for such hos-  
33                                   pitals and the total number of discharges of such  
34                                   hospitals and the amount of the additional incre-  
35                                   mental costs (if any) that are associated with such  
36                                   number of discharges.

1           “(ii) The applicable percentage increase shall  
2           be determined based upon such relationship in a  
3           manner that reflects, based upon the number of  
4           such discharges for a subsection (d) hospital, such  
5           additional incremental costs.

6           “(iii) In no case shall the applicable percent-  
7           age increase exceed 25 percent.

8           “(C) DEFINITIONS.—

9           “(i) LOW-VOLUME HOSPITAL.—For purposes  
10          of this paragraph, the term ‘low-volume hospital’  
11          means, for a fiscal year, a subsection (d) hospital  
12          (as defined in paragraph (1)(B)) that the Secretary  
13          determines is located more than 25 road miles from  
14          another subsection (d) hospital and has less than  
15          800 discharges during the fiscal year.

16          “(ii) DISCHARGE.—For purposes of subpara-  
17          graph (B) and clause (i), the term ‘discharge’  
18          means an inpatient acute care discharge of an indi-  
19          vidual regardless of whether the individual is enti-  
20          tled to benefits under part A.”.

21          (b) JUDICIAL REVIEW.—Section 1886(d)(7)(A) (42 U.S.C.  
22          1395ww(d)(7)(A)) is amended by inserting after “to subsection  
23          (e)(1)” the following: “or the determination of the applicable  
24          percentage increase under paragraph (12)(A)(ii)”.

25          **SEC. 407. TREATMENT OF MISSING COST REPORTING**  
26          **PERIODS FOR SOLE COMMUNITY HOS-**  
27          **PITALS.**

28          (a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C.  
29          1395ww(b)(3)(I)) is amended by adding at the end the fol-  
30          lowing new clause:

31          “(iii) In no case shall a hospital be denied treatment as  
32          a sole community hospital or payment (on the basis of a target  
33          rate as such as a hospital) because data are unavailable for any  
34          cost reporting period due to changes in ownership, changes in  
35          fiscal intermediaries, or other extraordinary circumstances, so  
36          long as data for at least one applicable base cost reporting pe-  
37          riod is available.”.



1 (b) EFFECTIVE DATE.—The amendment made by sub-  
2 section (a) shall apply to cost reporting periods beginning on  
3 or after January 1, 2004.

4 **SEC. 408. RECOGNITION OF ATTENDING NURSE PRACTI-**  
5 **TIONERS AS ATTENDING PHYSICIANS TO**  
6 **SERVE HOSPICE PATIENTS.**

7 (a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C.  
8 1395x(dd)(3)(B)) is amended by inserting “or nurse practi-  
9 tioner (as defined in subsection (aa)(5))” after “the physician  
10 (as defined in subsection (r)(1))”.

11 (b) CLARIFICATION OF HOSPICE ROLE OF NURSE PRACTI-  
12 TIONERS.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C.  
13 1395f(a)(7)(A)(i)(I)) is amended by inserting “(which for pur-  
14 poses of this subparagraph does not include a nurse practi-  
15 tioner)” after “attending physician (as defined in section  
16 1861(dd)(3)(B))”.

17 **SEC. 409. RURAL HOSPICE DEMONSTRATION PROJECT.**

18 (a) IN GENERAL.—The Secretary shall conduct a dem-  
19 onstration project for the delivery of hospice care to medicare  
20 beneficiaries in rural areas. Under the project medicare bene-  
21 ficiaries who are unable to receive hospice care in the facility  
22 for lack of an appropriate caregiver are provided such care in  
23 a facility of 20 or fewer beds which offers, within its walls, the  
24 full range of services provided by hospice programs under sec-  
25 tion 1861(dd) of the Social Security Act (42 U.S.C.  
26 1395x(dd)).

27 (b) SCOPE OF PROJECT.—The Secretary shall conduct the  
28 project under this section with respect to no more than 3 hos-  
29 pice programs over a period of not longer than 5 years each.

30 (c) COMPLIANCE WITH CONDITIONS.—Under the dem-  
31 onstration project—

32 (1) the hospice program shall comply with otherwise  
33 applicable requirements, except that it shall not be required  
34 to offer services outside of the home or to meet the require-  
35 ments of section 1861(dd)(2)(A)(iii) of the Social Security  
36 Act; and

1 (2) payments for hospice care shall be made at the  
2 rates otherwise applicable to such care under title XVIII of  
3 such Act.

4 The Secretary may require the program to comply with such  
5 additional quality assurance standards for its provision of serv-  
6 ices in its facility as the Secretary deems appropriate.

7 (d) REPORT.—Upon completion of the project, the Sec-  
8 retary shall submit a report to Congress on the project and  
9 shall include in the report recommendations regarding exten-  
10 sion of such project to hospice programs serving rural areas.

11 **SEC. 410. EXCLUSION OF CERTAIN RURAL HEALTH CLIN-**  
12 **IC AND FEDERALLY QUALIFIED HEALTH**  
13 **CENTER SERVICES FROM THE PROSPECTIVE**  
14 **PAYMENT SYSTEM FOR SKILLED NURSING**  
15 **FACILITIES.**

16 (a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C.  
17 1395yy(e)(2)(A)) is amended—

18 (1) in clause (i)(II), by striking “clauses (ii) and (iii)”  
19 and inserting “clauses (ii), (iii), and (iv)”;

20 (2) by adding at the end the following new clause:

21 “(iv) EXCLUSION OF CERTAIN RURAL HEALTH  
22 CLINIC AND FEDERALLY QUALIFIED HEALTH CEN-  
23 TER SERVICES.—Services described in this clause  
24 are—

25 “(I) rural health clinic services (as defined  
26 in paragraph (1) of section 1861(aa)); and

27 “(II) Federally qualified health center  
28 services (as defined in paragraph (3) of such  
29 section);

30 that would be described in clause (ii) if such serv-  
31 ices were not furnished by an individual affiliated  
32 with a rural health clinic or a Federally qualified  
33 health center.”.

34 (b) EFFECTIVE DATE.—The amendments made by sub-  
35 section (a) shall apply to services furnished on or after January  
36 1, 2005.

1     **SEC. 410A. RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.**  
2

3           (a) ESTABLISHMENT OF RURAL COMMUNITY HOSPITAL  
4 (RCH) DEMONSTRATION PROGRAM.—

5           (1) IN GENERAL.—The Secretary shall establish a  
6 demonstration program to test the feasibility and advis-  
7 ability of the establishment of rural community hospitals  
8 (as defined in subsection (f)(1)) to furnish covered inpa-  
9 tient hospital services (as defined in subsection (f)(2)) to  
10 medicare beneficiaries.

11           (2) DEMONSTRATION AREAS.—The program shall be  
12 conducted in rural areas selected by the Secretary in States  
13 with low population densities, as determined by the Sec-  
14 retary.

15           (3) APPLICATION.—Each rural community hospital  
16 that is located in a demonstration area selected under para-  
17 graph (2) that desires to participate in the demonstration  
18 program under this section shall submit an application to  
19 the Secretary at such time, in such manner, and containing  
20 such information as the Secretary may require.

21           (4) SELECTION OF HOSPITALS.—The Secretary shall  
22 select from among rural community hospitals submitting  
23 applications under paragraph (3) not more than 15 of such  
24 hospitals to participate in the demonstration program  
25 under this section.

26           (5) DURATION.—The Secretary shall conduct the dem-  
27 onstration program under this section for a 5-year period.

28           (6) IMPLEMENTATION.—The Secretary shall imple-  
29 ment the demonstration program not later than January 1,  
30 2005, but may not implement the program before October  
31 1, 2004.

32           (b) PAYMENT.—

33           (1) IN GENERAL.—The amount of payment under the  
34 demonstration program for covered inpatient hospital serv-  
35 ices furnished in a rural community hospital, other than  
36 such services furnished in a psychiatric or rehabilitation  
37 unit of the hospital which is a distinct part, is—

1 (A) for discharges occurring in the first cost re-  
2 porting period beginning on or after the implementa-  
3 tion of the demonstration program, the reasonable  
4 costs of providing such services; and

5 (B) for discharges occurring in a subsequent cost  
6 reporting period under the demonstration program, the  
7 lesser of—

8 (i) the reasonable costs of providing such serv-  
9 ices in the cost reporting period involved; or

10 (ii) the target amount (as defined in para-  
11 graph (2), applicable to the cost reporting period  
12 involved.

13 (2) TARGET AMOUNT.—For purposes of paragraph  
14 (1)(B)(ii), the term “target amount” means, with respect  
15 to a rural community hospital for a particular 12-month  
16 cost reporting period—

17 (A) in the case of the second such reporting period  
18 for which this subsection is in effect, the reasonable  
19 costs of providing such covered inpatient hospital serv-  
20 ices as determined under paragraph (1)(A), and

21 (B) in the case of a later reporting period, the tar-  
22 get amount for the preceding 12-month cost reporting  
23 period,

24 increased by the applicable percentage increase (under  
25 clause (i) of section 1886(b)(3)(B) of the Social Security  
26 Act (42 U.S.C. 1395ww(b)(3)(B))) in the market basket  
27 percentage increase (as defined in clause (iii) of such sec-  
28 tion) for that particular cost reporting period.

29 (c) FUNDING.—

30 (1) IN GENERAL.—The Secretary shall provide for the  
31 transfer from the Federal Hospital Insurance Trust Fund  
32 under section 1817 of the Social Security Act (42 U.S.C.  
33 1395i) of such funds as are necessary for the costs of car-  
34 rying out the demonstration program under this section.

35 (2) BUDGET NEUTRALITY.—In conducting the dem-  
36 onstration program under this section, the Secretary shall  
37 ensure that the aggregate payments made by the Secretary

1 do not exceed the amount which the Secretary would have  
2 paid if the demonstration program under this section was  
3 not implemented.

4 (d) WAIVER AUTHORITY.—The Secretary may waive such  
5 requirements of title XVIII of the Social Security Act (42  
6 U.S.C. 1395 et seq.) as may be necessary for the purpose of  
7 carrying out the demonstration program under this section.

8 (e) REPORT.—Not later than 6 months after the comple-  
9 tion of the demonstration program under this section, the Sec-  
10 retary shall submit to Congress a report on such program, to-  
11 gether with recommendations for such legislation and adminis-  
12 trative action as the Secretary determines to be appropriate.

13 (f) DEFINITIONS.—In this section:

14 (1) RURAL COMMUNITY HOSPITAL DEFINED.—

15 (A) IN GENERAL.—The term “rural community  
16 hospital” means a hospital (as defined in section  
17 1861(e) of the Social Security Act (42 U.S.C.  
18 1395x(e))) that—

19 (i) is located in a rural area (as defined in sec-  
20 tion 1886(d)(2)(D) of such Act (42 U.S.C.  
21 1395ww(d)(2)(D))) or treated as being so located  
22 pursuant to section 1886(d)(8)(E) of such Act (42  
23 U.S.C. 1395ww(d)(8)(E));

24 (ii) subject to paragraph (2), has fewer than  
25 51 acute care inpatient beds, as reported in its  
26 most recent cost report;

27 (iii) makes available 24-hour emergency care  
28 services; and

29 (iv) is not eligible for designation, or has not  
30 been designated, as a critical access hospital under  
31 section 1820.

32 (B) TREATMENT OF PSYCHIATRIC AND REHABILI-  
33 TATION UNITS.—For purposes of paragraph (1)(B),  
34 beds in a psychiatric or rehabilitation unit of the hos-  
35 pital which is a distinct part of the hospital shall not  
36 be counted.

1 (2) COVERED INPATIENT HOSPITAL SERVICES.—The  
2 term “covered inpatient hospital services” means inpatient  
3 hospital services, and includes extended care services fur-  
4 nished under an agreement under section 1883 of the So-  
5 cial Security Act (42 U.S.C. 1395tt).

6 **Subtitle B—Provisions Relating to**  
7 **Part B Only**

8 **SEC. 411. 2-YEAR EXTENSION OF HOLD HARMLESS PRO-**  
9 **VISIONS FOR SMALL RURAL HOSPITALS AND**  
10 **SOLE COMMUNITY HOSPITALS UNDER THE**  
11 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**  
12 **PITAL OUTPATIENT DEPARTMENT SERV-**  
13 **ICES.**

14 (a) HOLD HARMLESS PROVISIONS.—

15 (1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42  
16 U.S.C. 1395l(t)(7)(D)(i)) is amended—

17 (A) in the heading, by striking “SMALL” and in-  
18 serting “CERTAIN”;

19 (B) by inserting “or a sole community hospital (as  
20 defined in section 1886(d)(5)(D)(iii)) located in a rural  
21 area” after “100 beds”; and

22 (C) by striking “2004” and inserting “2006”.

23 (2) EFFECTIVE DATE.—The amendment made by  
24 paragraph (1)(B) shall apply with respect to cost reporting  
25 periods beginning on and after January 1, 2004.

26 (b) STUDY; AUTHORIZATION OF ADJUSTMENT.—Section  
27 1833(t) (42 U.S.C. 1395l(t)) is amended—

28 (1) by redesignating paragraph (13) as paragraph  
29 (16); and

30 (2) by inserting after paragraph (12) the following  
31 new paragraph:

32 “(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL  
33 HOSPITALS.—

34 “(A) STUDY.—The Secretary shall conduct a  
35 study to determine if, under the system under this sub-  
36 section, costs incurred by hospitals located in rural  
37 areas by ambulatory payment classification groups

1 (APCs) exceed those costs incurred by hospitals located  
2 in urban areas.

3 “(B) AUTHORIZATION OF ADJUSTMENT.—Insofar  
4 as the Secretary determines under subparagraph (A)  
5 that costs incurred by hospitals located in rural areas  
6 exceed those costs incurred by hospitals located in  
7 urban areas, the Secretary shall provide for an appro-  
8 priate adjustment under paragraph (2)(E) to reflect  
9 those higher costs by January 1, 2006.”.

10 **SEC. 412. ESTABLISHMENT OF FLOOR ON WORK GEO-**  
11 **GRAPHIC ADJUSTMENT.**

12 Section 1848(e)(1) (42 U.S.C. 1395w-4(e)(1)) is  
13 amended—

14 (1) in subparagraph (A), by striking “subparagraphs  
15 (B) and (C)” and inserting “subparagraphs (B), (C), and  
16 (E)”; and

17 (2) by adding at the end the following new subpara-  
18 graph:

19 “(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC  
20 INDEX.—After calculating the work geographic index in  
21 subparagraph (A)(iii), for purposes of payment for  
22 services furnished on or after January 1, 2004, and be-  
23 fore January 1, 2007, the Secretary shall increase the  
24 work geographic index to 1.00 for any locality for  
25 which such work geographic index is less than 1.00.”.

26 **SEC. 413. MEDICARE INCENTIVE PAYMENT PROGRAM**  
27 **IMPROVEMENTS FOR PHYSICIAN SCARCITY.**

28 (a) ADDITIONAL INCENTIVE PAYMENT FOR CERTAIN PHY-  
29 SICIAN SCARCITY AREAS.—Section 1833 (42 U.S.C. 1395l) is  
30 amended by adding at the end the following new subsection:

31 “(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY  
32 AREAS.—

33 “(1) IN GENERAL.—In the case of physicians’ services  
34 furnished on or after January 1, 2005, and before January  
35 1, 2008—

1           “(A) by a primary care physician in a primary  
2           care scarcity county (identified under paragraph (4));  
3           or

4           “(B) by a physician who is not a primary care  
5           physician in a specialist care scarcity county (as so  
6           identified),

7           in addition to the amount of payment that would otherwise  
8           be made for such services under this part, there also shall  
9           be paid an amount equal to 5 percent of the payment  
10          amount for the service under this part.

11          “(2) DETERMINATION OF RATIOS OF PHYSICIANS TO  
12          MEDICARE BENEFICIARIES IN AREA.—Based upon available  
13          data, the Secretary shall establish for each county or equiv-  
14          alent area in the United States, the following:

15                 “(A) NUMBER OF PHYSICIANS PRACTICING IN THE  
16                 AREA.—The number of physicians who furnish physi-  
17                 cians’ services in the active practice of medicine or os-  
18                 teopathy in that county or area, other than physicians  
19                 whose practice is exclusively for the Federal Govern-  
20                 ment, physicians who are retired, or physicians who  
21                 only provide administrative services. Of such number,  
22                 the number of such physicians who are—

23                         “(i) primary care physicians; or

24                         “(ii) physicians who are not primary care phy-  
25                         sicians.

26                 “(B) NUMBER OF MEDICARE BENEFICIARIES RE-  
27                 SIDING IN THE AREA.—The number of individuals who  
28                 are residing in the county and are entitled to benefits  
29                 under part A or enrolled under this part, or both (in  
30                 this subsection referred to as ‘individuals’).

31                 “(C) DETERMINATION OF RATIOS.—

32                         “(i) PRIMARY CARE RATIO.—The ratio (in this  
33                         paragraph referred to as the ‘primary care ratio’)  
34                         of the number of primary care physicians (deter-  
35                         mined under subparagraph (A)(i)), to the number  
36                         of individuals determined under subparagraph (B).



1                   “(ii) SPECIALIST CARE RATIO.—The ratio (in  
2                   this paragraph referred to as the ‘specialist care  
3                   ratio’) of the number of other physicians (deter-  
4                   mined under subparagraph (A)(ii)), to the number  
5                   of individuals determined under subparagraph (B).

6                   “(3) RANKING OF COUNTIES.—The Secretary shall  
7                   rank each such county or area based separately on its pri-  
8                   mary care ratio and its specialist care ratio.

9                   “(4) IDENTIFICATION OF COUNTIES.—

10                   “(A) IN GENERAL.—The Secretary shall identify—

11                   “(i) those counties and areas (in this para-  
12                   graph referred to as ‘primary care scarcity coun-  
13                   ties’) with the lowest primary care ratios that rep-  
14                   resent, if each such county or area were weighted  
15                   by the number of individuals determined under  
16                   paragraph (2)(B), an aggregate total of 20 percent  
17                   of the total of the individuals determined under  
18                   such paragraph; and

19                   “(ii) those counties and areas (in this sub-  
20                   section referred to as ‘specialist care scarcity coun-  
21                   ties’) with the lowest specialist care ratios that rep-  
22                   resent, if each such county or area were weighted  
23                   by the number of individuals determined under  
24                   paragraph (2)(B), an aggregate total of 20 percent  
25                   of the total of the individuals determined under  
26                   such paragraph.

27                   “(B) PERIODIC REVISIONS.—The Secretary shall  
28                   periodically revise the counties or areas identified in  
29                   subparagraph (A) (but not less often than once every  
30                   three years) unless the Secretary determines that there  
31                   is no new data available on the number of physicians  
32                   practicing in the county or area or the number of indi-  
33                   viduals residing in the county or area, as identified in  
34                   paragraph (2).

35                   “(C) IDENTIFICATION OF COUNTIES WHERE SERV-  
36                   ICE IS FURNISHED.—For purposes of paying the addi-  
37                   tional amount specified in paragraph (1), if the Sec-

1           retary uses the 5-digit postal ZIP Code where the serv-  
2           ice is furnished, the dominant county of the postal ZIP  
3           Code (as determined by the United States Postal Serv-  
4           ice, or otherwise) shall be used to determine whether  
5           the postal ZIP Code is in a scarcity county identified  
6           in subparagraph (A) or revised in subparagraph (B).

7           “(D) JUDICIAL REVIEW.—There shall be no ad-  
8           ministrative or judicial review under section 1869,  
9           1878, or otherwise, respecting—

10           “(i) the identification of a county or area;

11           “(ii) the assignment of a specialty of any phy-  
12           sician under this paragraph;

13           “(iii) the assignment of a physician to a coun-  
14           ty under paragraph (2); or

15           “(iv) the assignment of a postal ZIP Code to  
16           a county or other area under this subsection.

17           “(5) RURAL CENSUS TRACTS.—To the extent feasible,  
18           the Secretary shall treat a rural census tract of a metro-  
19           politan statistical area (as determined under the most re-  
20           cent modification of the Goldsmith Modification, originally  
21           published in the Federal Register on February 27, 1992  
22           (57 Fed. Reg. 6725)), as an equivalent area for purposes  
23           of qualifying as a primary care scarcity county or specialist  
24           care scarcity county under this subsection.

25           “(6) PHYSICIAN DEFINED.—For purposes of this  
26           paragraph, the term ‘physician’ means a physician de-  
27           scribed in section 1861(r)(1) and the term ‘primary care  
28           physician’ means a physician who is identified in the avail-  
29           able data as a general practitioner, family practice practi-  
30           tioner, general internist, or obstetrician or gynecologist.

31           “(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON  
32           WEBSITE.—With respect to a year for which a county or  
33           area is identified or revised under paragraph (4), the Sec-  
34           retary shall identify such counties or areas as part of the  
35           proposed and final rule to implement the physician fee  
36           schedule under section 1848 for the applicable year. The  
37           Secretary shall post the list of counties identified or revised

1 under paragraph (4) on the Internet website of the Centers  
2 for Medicare & Medicaid Services.”.

3 (b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT  
4 PROGRAM.—

5 (1) IN GENERAL.—Section 1833(m) (42 U.S.C.  
6 1395l(m)) is amended—

7 (A) by inserting “(1)” after “(m)”;

8 (B) in paragraph (1), as designated by subpara-  
9 graph (A)—

10 (i) by inserting “in a year” after “In the case  
11 of physicians’ services furnished”; and

12 (ii) by inserting “as identified by the Secretary  
13 prior to the beginning of such year” after “as a  
14 health professional shortage area”; and

15 (C) by adding at the end the following new para-  
16 graphs:

17 “(2) For each health professional shortage area identified  
18 in paragraph (1) that consists of an entire county, the Sec-  
19 retary shall provide for the additional payment under para-  
20 graph (1) without any requirement on the physician to identify  
21 the health professional shortage area involved. The Secretary  
22 may implement the previous sentence using the method speci-  
23 fied in subsection (u)(4)(C).

24 “(3) The Secretary shall post on the Internet website of  
25 the Centers for Medicare & Medicaid Services a list of the  
26 health professional shortage areas identified in paragraph (1)  
27 that consist of a partial county to facilitate the additional pay-  
28 ment under paragraph (1) in such areas.

29 “(4) There shall be no administrative or judicial review  
30 under section 1869, section 1878, or otherwise, respecting—

31 “(A) the identification of a county or area;

32 “(B) the assignment of a specialty of any physician  
33 under this paragraph;

34 “(C) the assignment of a physician to a county under  
35 this subsection; or

36 “(D) the assignment of a postal zip code to a county  
37 or other area under this subsection.”.

1           (2) EFFECTIVE DATE.—The amendments made by  
2           paragraph (1) shall apply to physicians' services furnished  
3           on or after January 1, 2005.

4           (c) GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAY-  
5           MENTS FOR PHYSICIANS' SERVICES.—

6           (1) STUDY.—The Comptroller General of the United  
7           States shall conduct a study of differences in payment  
8           amounts under the physician fee schedule under section  
9           1848 of the Social Security Act (42 U.S.C. 1395w-4) for  
10          physicians' services in different geographic areas. Such  
11          study shall include—

12                (A) an assessment of the validity of the geographic  
13                adjustment factors used for each component of the fee  
14                schedule;

15                (B) an evaluation of the measures used for such  
16                adjustment, including the frequency of revisions;

17                (C) an evaluation of the methods used to deter-  
18                mine professional liability insurance costs used in com-  
19                puting the malpractice component, including a review  
20                of increases in professional liability insurance premiums  
21                and variation in such increases by State and physician  
22                specialty and methods used to update the geographic  
23                cost of practice index and relative weights for the mal-  
24                practice component; and

25                (D) an evaluation of the effect of the adjustment  
26                to the physician work geographic index under section  
27                1848(e)(1)(E) of the Social Security Act, as added by  
28                section 412, on physician location and retention in  
29                areas affected by such adjustment, taking into  
30                account—

31                       (i) differences in recruitment costs and reten-  
32                       tion rates for physicians, including specialists, be-  
33                       tween large urban areas and other areas; and

34                       (ii) the mobility of physicians, including spe-  
35                       cialists, over the last decade.

36          (2) REPORT.—Not later than 1 year after the date of  
37          the enactment of this Act, the Comptroller General shall

1 submit to Congress a report on the study conducted under  
2 paragraph (1). The report shall include recommendations  
3 regarding the use of more current data in computing geo-  
4 graphic cost of practice indices as well as the use of data  
5 directly representative of physicians' costs (rather than  
6 proxy measures of such costs).

7 **SEC. 414. PAYMENT FOR RURAL AND URBAN AMBU-**  
8 **LANCE SERVICES.**

9 (a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE  
10 SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l)  
11 (42 U.S.C. 1395m(l)) is amended—

12 (1) in paragraph (2)(E), by inserting “consistent with  
13 paragraph (11)” after “in an efficient and fair manner”;  
14 and

15 (2) by redesignating paragraph (8), as added by sec-  
16 tion 221(a) of BIPA (114 Stat. 2763A–486), as paragraph  
17 (9); and

18 (3) by adding at the end the following new paragraph:

19 “(10) PHASE-IN PROVIDING FLOOR USING BLEND OF  
20 FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In car-  
21 rying out the phase-in under paragraph (2)(E) for each  
22 level of ground service furnished in a year, the portion of  
23 the payment amount that is based on the fee schedule shall  
24 be the greater of the amount determined under such fee  
25 schedule (without regard to this paragraph) or the fol-  
26 lowing blended rate of the fee schedule under paragraph  
27 (1) and of a regional fee schedule for the region involved:

28 “(A) For 2004 (for services furnished on or after  
29 July 1, 2004), the blended rate shall be based 20 per-  
30 cent on the fee schedule under paragraph (1) and 80  
31 percent on the regional fee schedule.

32 “(B) For 2005, the blended rate shall be based 40  
33 percent on the fee schedule under paragraph (1) and  
34 60 percent on the regional fee schedule.

35 “(C) For 2006, the blended rate shall be based 60  
36 percent on the fee schedule under paragraph (1) and  
37 40 percent on the regional fee schedule.

1           “(D) For 2007, 2008, and 2009, the blended rate  
2 shall be based 80 percent on the fee schedule under  
3 paragraph (1) and 20 percent on the regional fee  
4 schedule.

5           “(E) For 2010 and each succeeding year, the  
6 blended rate shall be based 100 percent on the fee  
7 schedule under paragraph (1).

8 For purposes of this paragraph, the Secretary shall estab-  
9 lish a regional fee schedule for each of the nine census divi-  
10 sions (referred to in section 1886(d)(2)) using the method-  
11 ology (used in establishing the fee schedule under para-  
12 graph (1)) to calculate a regional conversion factor and a  
13 regional mileage payment rate and using the same payment  
14 adjustments and the same relative value units as used in  
15 the fee schedule under such paragraph.”.

16           (b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG  
17 TRIPS.—Section 1834(l), as amended by subsection (a), is  
18 amended by adding at the end the following new paragraph:

19           “(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG  
20 TRIPS.—In the case of ground ambulance services fur-  
21 nished on or after July 1, 2004, and before January 1,  
22 2009, regardless of where the transportation originates, the  
23 fee schedule established under this subsection shall provide  
24 that, with respect to the payment rate for mileage for a  
25 trip above 50 miles the per mile rate otherwise established  
26 shall be increased by  $\frac{1}{4}$  of the payment per mile otherwise  
27 applicable to miles in excess of 50 miles in such trip.”.

28           (c) IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY  
29 CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.—

30           (1) IN GENERAL.—Section 1834(l) (42 U.S.C.  
31 1395m(l)), as amended by subsections (a) and (b), is  
32 amended by adding at the end the following new para-  
33 graph:

34           “(12) ASSISTANCE FOR RURAL PROVIDERS FUR-  
35 NISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

36           “(A) IN GENERAL.—In the case of ground ambu-  
37 lance services furnished on or after July 1, 2004, and

1 before January 1, 2010, for which the transportation  
2 originates in a qualified rural area (identified under  
3 subparagraph (B)(iii)), the Secretary shall provide for  
4 a percent increase in the base rate of the fee schedule  
5 for a trip established under this subsection. In estab-  
6 lishing such percent increase, the Secretary shall esti-  
7 mate the average cost per trip for such services (not  
8 taking into account mileage) in the lowest quartile as  
9 compared to the average cost per trip for such services  
10 (not taking into account mileage) in the highest quar-  
11 tile of all rural county populations.

12 “(B) IDENTIFICATION OF QUALIFIED RURAL  
13 AREAS.—

14 “(i) DETERMINATION OF POPULATION DEN-  
15 SITY IN AREA.—Based upon data from the United  
16 States decennial census for the year 2000, the Sec-  
17 retary shall determine, for each rural area, the pop-  
18 ulation density for that area.

19 “(ii) RANKING OF AREAS.—The Secretary  
20 shall rank each such area based on such population  
21 density.

22 “(iii) IDENTIFICATION OF QUALIFIED RURAL  
23 AREAS.—The Secretary shall identify those areas  
24 (in subparagraph (A) referred to as ‘qualified rural  
25 areas’) with the lowest population densities that  
26 represent, if each such area were weighted by the  
27 population of such area (as used in computing such  
28 population densities), an aggregate total of 25 per-  
29 cent of the total of the population of all such areas.

30 “(iv) RURAL AREA.—For purposes of this  
31 paragraph, the term ‘rural area’ has the meaning  
32 given such term in section 1886(d)(2)(D). If fea-  
33 sible, the Secretary shall treat a rural census tract  
34 of a metropolitan statistical area (as determined  
35 under the most recent modification of the Gold-  
36 smith Modification, originally published in the Fed-  
37 eral Register on February 27, 1992 (57 Fed. Reg.

1           6725) as a rural area for purposes of this para-  
2           graph.

3           “(v) JUDICIAL REVIEW.—There shall be no  
4           administrative or judicial review under section  
5           1869, 1878, or otherwise, respecting the identifica-  
6           tion of an area under this subparagraph.”.

7           (2) USE OF DATA.—In order to promptly implement  
8           section 1834(l)(12) of the Social Security Act, as added by  
9           paragraph (1), the Secretary may use data furnished by the  
10          Comptroller General of the United States.

11          (d) TEMPORARY INCREASE FOR GROUND AMBULANCE  
12          SERVICES.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended  
13          by subsections (a), (b), and (c), is amended by adding at the  
14          end the following new paragraph:

15                 “(13) TEMPORARY INCREASE FOR GROUND AMBU-  
16          LANCE SERVICES.—

17                 “(A) IN GENERAL.—After computing the rates  
18                 with respect to ground ambulance services under the  
19                 other applicable provisions of this subsection, in the  
20                 case of such services furnished on or after July 1,  
21                 2004, and before January 1, 2007, for which the trans-  
22                 portation originates in—

23                 “(i) a rural area described in paragraph (9) or  
24                 in a rural census tract described in such para-  
25                 graph, the fee schedule established under this sec-  
26                 tion shall provide that the rate for the service oth-  
27                 erwise established, after the application of any in-  
28                 crease under paragraphs (11) and (12), shall be in-  
29                 creased by 2 percent; and

30                 “(ii) an area not described in clause (i), the  
31                 fee schedule established under this subsection shall  
32                 provide that the rate for the service otherwise es-  
33                 tablished, after the application of any increase  
34                 under paragraph (11), shall be increased by 1 per-  
35                 cent.

36                 “(B) APPLICATION OF INCREASED PAYMENTS  
37          AFTER 2006.—The increased payments under subpara-



1 graph (A) shall not be taken into account in calculating  
2 payments for services furnished after the period speci-  
3 fied in such subparagraph.”.

4 (e) IMPLEMENTATION.—The Secretary may implement the  
5 amendments made by this section, and revise the conversion  
6 factor applicable under section 1834(l) of the Social Security  
7 Act (42 U.S.C. 1395m(l)) for purposes of implementing such  
8 amendments, on an interim final basis, or by program instruc-  
9 tion.

10 (f) GAO REPORT ON COSTS AND ACCESS.—Not later than  
11 December 31, 2005, the Comptroller General of the United  
12 States shall submit to Congress an initial report on how costs  
13 differ among the types of ambulance providers and on access,  
14 supply, and quality of ambulance services in those regions and  
15 States that have a reduction in payment under the medicare  
16 ambulance fee schedule (under section 1834(l) of the Social Se-  
17 curity Act, as amended by this Act). Not later than December  
18 31, 2007, the Comptroller General shall submit to Congress a  
19 final report on such access and supply.

20 (g) TECHNICAL AMENDMENTS.—(1) Section 221(c) of  
21 BIPA (114 Stat. 2763A–487) is amended by striking “sub-  
22 section (b)(2)” and inserting “subsection (b)(3)”.

23 (2) Section 1861(v)(1) (42 U.S.C. 1395x(v)(1)) is amend-  
24 ed by moving subparagraph (U) 4 ems to the left.

25 **SEC. 415. PROVIDING APPROPRIATE COVERAGE OF**  
26 **RURAL AIR AMBULANCE SERVICES.**

27 (a) COVERAGE.—Section 1834(l) (42 U.S.C. 1395m(l)), as  
28 amended by subsections (a), (b), (c), and (d) of section 414,  
29 is amended by adding at the end the following new paragraph:

30 “(14) PROVIDING APPROPRIATE COVERAGE OF RURAL  
31 AIR AMBULANCE SERVICES.—

32 “(A) IN GENERAL.—The regulations described in  
33 section 1861(s)(7) shall provide, to the extent that any  
34 ambulance services (whether ground or air) may be  
35 covered under such section, that a rural air ambulance  
36 service (as defined in subparagraph (C)) is reimbursed

1 under this subsection at the air ambulance rate if the  
2 air ambulance service—

3 “(i) is reasonable and necessary based on the  
4 health condition of the individual being transported  
5 at or immediately prior to the time of the trans-  
6 port; and

7 “(ii) complies with equipment and crew re-  
8 quirements established by the Secretary.

9 “(B) SATISFACTION OF REQUIREMENT OF MEDI-  
10 CALLY NECESSARY.—The requirement of subparagraph  
11 (A)(i) is deemed to be met for a rural air ambulance  
12 service if—

13 “(i) subject to subparagraph (D), such service  
14 is requested by a physician or other qualified med-  
15 ical personnel (as specified by the Secretary) who  
16 reasonably determines or certifies that the individ-  
17 ual’s condition is such that the time needed to  
18 transport the individual by land or the instability  
19 of transportation by land poses a threat to the indi-  
20 vidual’s survival or seriously endangers the individ-  
21 ual’s health; or

22 “(ii) such service is furnished pursuant to a  
23 protocol that is established by a State or regional  
24 emergency medical service (EMS) agency and rec-  
25 ognized or approved by the Secretary under which  
26 the use of an air ambulance is recommended, if  
27 such agency does not have an ownership interest in  
28 the entity furnishing such service.

29 “(C) RURAL AIR AMBULANCE SERVICE DE-  
30 FINED.—For purposes of this paragraph, the term  
31 ‘rural air ambulance service’ means fixed wing and ro-  
32 tary wing air ambulance service in which the point of  
33 pick up of the individual occurs in a rural area (as de-  
34 fined in section 1886(d)(2)(D)) or in a rural census  
35 tract of a metropolitan statistical area (as determined  
36 under the most recent modification of the Goldsmith

1 Modification, originally published in the Federal Reg-  
2 ister on February 27, 1992 (57 Fed. Reg. 6725)).

3 “(D) LIMITATION.—

4 “(i) IN GENERAL.—Subparagraph (B)(i) shall  
5 not apply if there is a financial or employment rela-  
6 tionship between the person requesting the rural  
7 air ambulance service and the entity furnishing the  
8 ambulance service, or an entity under common  
9 ownership with the entity furnishing the air ambu-  
10 lance service, or a financial relationship between an  
11 immediate family member of such requester and  
12 such an entity.

13 “(ii) EXCEPTION.—Where a hospital and the  
14 entity furnishing rural air ambulance services are  
15 under common ownership, clause (i) shall not apply  
16 to remuneration (through employment or other re-  
17 lationship) by the hospital of the requester or im-  
18 mediate family member if the remuneration is for  
19 provider-based physician services furnished in a  
20 hospital (as described in section 1887) which are  
21 reimbursed under part A and the amount of the re-  
22 muneration is unrelated directly or indirectly to the  
23 provision of rural air ambulance services.”

24 (b) CONFORMING AMENDMENT.—Section 1861(s)(7) (42  
25 U.S.C. 1395x(s)(7)) is amended by inserting “, subject to sec-  
26 tion 1834(l)(14),” after “but”.

27 (c) EFFECTIVE DATE.—The amendments made by this  
28 subsection shall apply to services furnished on or after January  
29 1, 2005.

30 **SEC. 416. TREATMENT OF CERTAIN CLINICAL DIAG-**  
31 **NOSTIC LABORATORY TESTS FURNISHED TO**  
32 **HOSPITAL OUTPATIENTS IN CERTAIN RURAL**  
33 **AREAS.**

34 (a) IN GENERAL.—Notwithstanding subsections (a), (b),  
35 and (h) of section 1833 of the Social Security Act (42 U.S.C.  
36 1395l) and section 1834(d)(1) of such Act (42 U.S.C.  
37 1395m(d)(1)), in the case of a clinical diagnostic laboratory

1 test covered under part B of title XVIII of such Act that is  
2 furnished during a cost reporting period described in subsection  
3 (b) by a hospital with fewer than 50 beds that is located in a  
4 qualified rural area (identified under paragraph (12)(B)(iii) of  
5 section 1834(l) of the Social Security Act (42 U.S.C.  
6 1395m(l)), as added by section 414(c) as part of outpatient  
7 services of the hospital, the amount of payment for such test  
8 shall be 100 percent of the reasonable costs of the hospital in  
9 furnishing such test.

10 (b) APPLICATION.—A cost reporting period described in  
11 this subsection is a cost reporting period beginning during the  
12 2-year period beginning on July 1, 2004.

13 (c) PROVISION AS PART OF OUTPATIENT HOSPITAL SERV-  
14 ICES.—For purposes of subsection (a), in determining whether  
15 clinical diagnostic laboratory services are furnished as part of  
16 outpatient services of a hospital, the Secretary shall apply the  
17 same rules that are used to determine whether clinical diag-  
18 nostic laboratory services are furnished as an outpatient critical  
19 access hospital service under section 1834(g)(4) of the Social  
20 Security Act (42 U.S.C. 1395m(g)(4)).

21 **SEC. 417. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.**  
22

23 Section 4207 of the Balanced Budget Act of 1997 (Public  
24 Law 105–33) is amended—

25 (1) in subsection (a)(4), by striking “4-year” and in-  
26 serting “8-year”; and

27 (2) in subsection (d)(3), by striking “\$30,000,000”  
28 and inserting “\$60,000,000”.

29 **SEC. 418. REPORT ON DEMONSTRATION PROJECT PER-**  
30 **MITTING SKILLED NURSING FACILITIES TO**  
31 **BE ORIGINATING TELEHEALTH SITES; AU-**  
32 **THORITY TO IMPLEMENT.**

33 (a) EVALUATION.—The Secretary, acting through the Ad-  
34 ministrator of the Health Resources and Services Administra-  
35 tion in consultation with the Administrator of the Centers for  
36 Medicare & Medicaid Services, shall evaluate demonstration  
37 projects conducted by the Secretary under which skilled nurs-  
38 ing facilities (as defined in section 1819(a) of the Social Secu-

1 rity Act (42 U.S.C. 1395i-3(a)) are treated as originating sites  
2 for telehealth services.

3 (b) REPORT.—Not later than January 1, 2005, the Sec-  
4 retary shall submit to Congress a report on the evaluation con-  
5 ducted under subsection (a). Such report shall include rec-  
6 ommendations on mechanisms to ensure that permitting a  
7 skilled nursing facility to serve as an originating site for the  
8 use of telehealth services or any other service delivered via a  
9 telecommunications system does not serve as a substitute for  
10 in-person visits furnished by a physician, or for in-person visits  
11 furnished by a physician assistant, nurse practitioner or clinical  
12 nurse specialist, as is otherwise required by the Secretary.

13 (c) AUTHORITY TO EXPAND ORIGINATING TELEHEALTH  
14 SITES TO INCLUDE SKILLED NURSING FACILITIES.—Insofar  
15 as the Secretary concludes in the report required under sub-  
16 section (b) that it is advisable to permit a skilled nursing facil-  
17 ity to be an originating sites for telehealth services under sec-  
18 tion 1834(m) of the Social Security Act (42 U.S.C.  
19 1395m(m)), and that the Secretary can establish the mecha-  
20 nisms to ensure such permission does not serve as a substitute  
21 for in-person visits furnished by a physician, or for in-person  
22 visits furnished by a physician assistant, nurse practitioner or  
23 clinical nurse specialist, the Secretary may deem a skilled nurs-  
24 ing facility to be an originating site under paragraph (4)(C)(ii)  
25 of such section beginning on January 1, 2006.

## 26 **Subtitle C—Provisions Relating to** 27 **Parts A and B**

### 28 **SEC. 421. 1-YEAR INCREASE FOR HOME HEALTH SERV-** 29 **ICES FURNISHED IN A RURAL AREA.**

30 (a) IN GENERAL.—With respect to episodes and visits  
31 ending on or after April 1, 2004, and before April 1, 2005, in  
32 the case of home health services furnished in a rural area (as  
33 defined in section 1886(d)(2)(D) of the Social Security Act (42  
34 U.S.C. 1395ww(d)(2)(D))), the Secretary shall increase the  
35 payment amount otherwise made under section 1895 of such  
36 Act (42 U.S.C. 1395fff) for such services by 5 percent.

1 (b) WAIVING BUDGET NEUTRALITY.—The Secretary shall  
2 not reduce the standard prospective payment amount (or  
3 amounts) under section 1895 of the Social Security Act (42  
4 U.S.C. 1395fff) applicable to home health services furnished  
5 during a period to offset the increase in payments resulting  
6 from the application of subsection (a).

7 (c) NO EFFECT ON SUBSEQUENT PERIODS.—The pay-  
8 ment increase provided under subsection (a) for a period under  
9 such subsection—

10 (1) shall not apply to episodes and visits ending after  
11 such period; and

12 (2) shall not be taken into account in calculating the  
13 payment amounts applicable for episodes and visits occur-  
14 ring after such period.

15 **SEC. 422. REDISTRIBUTION OF UNUSED RESIDENT POSI-**  
16 **TIONS.**

17 (a) IN GENERAL.—Section 1886(h) (42 U.S.C.  
18 1395ww(h)(4)) is amended—

19 (1) in paragraph (4)(F)(i), by inserting “subject to  
20 paragraph (7),” after “October 1, 1997,”;

21 (2) in paragraph (4)(H)(i), by inserting “and subject  
22 to paragraph (7)” after “subparagraphs (F) and (G)”; and

23 (3) by adding at the end the following new paragraph:

24 “(7) REDISTRIBUTION OF UNUSED RESIDENT POSI-  
25 TIONS.—

26 “(A) REDUCTION IN LIMIT BASED ON UNUSED PO-  
27 SITIONS.—

28 “(i) PROGRAMS SUBJECT TO REDUCTION.—

29 “(I) IN GENERAL.—Except as provided in  
30 subclause (II), if a hospital’s reference resident  
31 level (specified in clause (ii)) is less than the  
32 otherwise applicable resident limit (as defined  
33 in subparagraph (C)(ii)), effective for portions  
34 of cost reporting periods occurring on or after  
35 July 1, 2005, the otherwise applicable resident  
36 limit shall be reduced by 75 percent of the dif-

1                   ference between such otherwise applicable resi-  
2                   dent limit and such reference resident level.

3                   “(II) EXCEPTION FOR SMALL RURAL HOS-  
4                   PITALS.—This subparagraph shall not apply to  
5                   a hospital located in a rural area (as defined in  
6                   subsection (d)(2)(D)(ii)) with fewer than 250  
7                   acute care inpatient beds.

8                   “(ii) REFERENCE RESIDENT LEVEL.—

9                   “(I) IN GENERAL.—Except as otherwise  
10                  provided in subclauses (II) and (III), the ref-  
11                  erence resident level specified in this clause for  
12                  a hospital is the resident level for the most re-  
13                  cent cost reporting period of the hospital end-  
14                  ing on or before September 30, 2002, for which  
15                  a cost report has been settled (or, if not, sub-  
16                  mitted (subject to audit)), as determined by the  
17                  Secretary.

18                  “(II) USE OF MOST RECENT ACCOUNTING  
19                  PERIOD TO RECOGNIZE EXPANSION OF EXIST-  
20                  ING PROGRAMS.—If a hospital submits a timely  
21                  request to increase its resident level due to an  
22                  expansion of an existing residency training pro-  
23                  gram that is not reflected on the most recent  
24                  settled cost report, after audit and subject to  
25                  the discretion of the Secretary, the reference  
26                  resident level for such hospital is the resident  
27                  level for the cost reporting period that includes  
28                  July 1, 2003, as determined by the Secretary.

29                  “(III) EXPANSIONS UNDER NEWLY AP-  
30                  PROVED PROGRAMS.—Upon the timely request  
31                  of a hospital, the Secretary shall adjust the ref-  
32                  erence resident level specified under subclause  
33                  (I) or (II) to include the number of medical  
34                  residents that were approved in an application  
35                  for a medical residency training program that  
36                  was approved by an appropriate accrediting or-  
37                  ganization (as determined by the Secretary) be-

1 fore January 1, 2002, but which was not in op-  
2 eration during the cost reporting period used  
3 under subclause (I) or (II), as the case may be,  
4 as determined by the Secretary.

5 “(iii) AFFILIATION.—The provisions of clause  
6 (i) shall be applied to hospitals which are members  
7 of the same affiliated group (as defined by the Sec-  
8 retary under paragraph (4)(H)(ii)) as of July 1,  
9 2003.

10 “(B) REDISTRIBUTION.—

11 “(i) IN GENERAL.—The Secretary is author-  
12 ized to increase the otherwise applicable resident  
13 limit for each qualifying hospital that submits a  
14 timely application under this subparagraph by such  
15 number as the Secretary may approve for portions  
16 of cost reporting periods occurring on or after July  
17 1, 2005. The aggregate number of increases in the  
18 otherwise applicable resident limits under this sub-  
19 paragraph may not exceed the Secretary’s estimate  
20 of the aggregate reduction in such limits attrib-  
21 utable to subparagraph (A).

22 “(ii) CONSIDERATIONS IN REDISTRIBUTION.—  
23 In determining for which hospitals the increase in  
24 the otherwise applicable resident limit is provided  
25 under clause (i), the Secretary shall take into ac-  
26 count the demonstrated likelihood of the hospital  
27 filling the positions within the first 3 cost reporting  
28 periods beginning on or after July 1, 2005, made  
29 available under this subparagraph, as determined  
30 by the Secretary.

31 “(iii) PRIORITY FOR RURAL AND SMALL  
32 URBAN AREAS.—In determining for which hospitals  
33 and residency training programs an increase in the  
34 otherwise applicable resident limit is provided  
35 under clause (i), the Secretary shall distribute the  
36 increase to programs of hospitals located in the fol-  
37 lowing priority order:



1                   “(I) First, to hospitals located in rural  
2                   areas (as defined in subsection (d)(2)(D)(ii)).

3                   “(II) Second, to hospitals located in urban  
4                   areas that are not large urban areas (as de-  
5                   fined for purposes of subsection (d)).

6                   “(III) Third, to other hospitals in a State  
7                   if the residency training program involved is in  
8                   a specialty for which there are not other resi-  
9                   dency training programs in the State.

10                   Increases of residency limits within the same pri-  
11                   ority category under this clause shall be determined  
12                   by the Secretary.

13                   “(iv) LIMITATION.—In no case shall more  
14                   than 25 full-time equivalent additional residency  
15                   positions be made available under this subpara-  
16                   graph with respect to any hospital.

17                   “(v) APPLICATION OF LOCALITY ADJUSTED  
18                   NATIONAL AVERAGE PER RESIDENT AMOUNT.—  
19                   With respect to additional residency positions in a  
20                   hospital attributable to the increase provided under  
21                   this subparagraph, notwithstanding any other pro-  
22                   vision of this subsection, the approved FTE resi-  
23                   dent amount is deemed to be equal to the locality  
24                   adjusted national average per resident amount  
25                   computed under paragraph (4)(E) for that hos-  
26                   pital.

27                   “(vi) CONSTRUCTION.—Nothing in this sub-  
28                   paragraph shall be construed as permitting the re-  
29                   distribution of reductions in residency positions at-  
30                   tributable to voluntary reduction programs under  
31                   paragraph (6), under a demonstration project ap-  
32                   proved as of October 31, 2003, under the authority  
33                   of section 402 of Public Law 90–248, or as affect-  
34                   ing the ability of a hospital to establish new med-  
35                   ical residency training programs under paragraph  
36                   (4)(H).

1                   “(C) RESIDENT LEVEL AND LIMIT DEFINED.—In  
2 this paragraph:

3                   “(i) RESIDENT LEVEL.—The term ‘resident  
4 level’ means, with respect to a hospital, the total  
5 number of full-time equivalent residents, before the  
6 application of weighting factors (as determined  
7 under paragraph (4)), in the fields of allopathic  
8 and osteopathic medicine for the hospital.

9                   “(ii) OTHERWISE APPLICABLE RESIDENT  
10 LIMIT.—The term ‘otherwise applicable resident  
11 limit’ means, with respect to a hospital, the limit  
12 otherwise applicable under subparagraphs (F)(i)  
13 and (H) of paragraph (4) on the resident level for  
14 the hospital determined without regard to this  
15 paragraph.

16                   “(D) JUDICIAL REVIEW.—There shall be no ad-  
17 ministrative or judicial review under section 1869,  
18 1878, or otherwise, with respect to determinations  
19 made under this paragraph.”.

20                   (b) CONFORMING PROVISIONS.—(1) Section  
21 1886(d)(5)(B) (42 U.S.C. 1395ww(d)(5)(B)) is amended—

22                   (A) in the second sentence of clause (ii), by striking  
23 “For discharges” and inserting “Subject to clause (ix), for  
24 discharges”;

25                   (B) in clause (v), by adding at the end the following:  
26 “The provisions of subsection (h)(7) shall apply with re-  
27 spect to the first sentence of this clause in the same man-  
28 ner as it applies with respect to subsection (h)(4)(F)(i).”;  
29 and

30                   (C) by adding at the end the following new clause:

31                   “(ix) For discharges occurring on or after July 1,  
32 2005, insofar as an additional payment amount under this  
33 subparagraph is attributable to resident positions redistrib-  
34 uted to a hospital under subsection (h)(7)(B), in computing  
35 the indirect teaching adjustment factor under clause (ii)  
36 the adjustment shall be computed in a manner as if ‘c’

1           were equal to 0.66 with respect to such resident posi-  
2           tions.”.

3           (2) Chapter 35 of title 44, United States Code, shall not  
4           apply with respect to applications under section 1886(h)(7) of  
5           the Social Security Act, as added by subsection (a)(3).

6           (c) REPORT ON EXTENSION OF APPLICATIONS UNDER  
7           REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the  
8           Secretary shall submit to Congress a report containing rec-  
9           ommendations regarding whether to extend the deadline for ap-  
10          plications for an increase in resident limits under section  
11          1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by  
12          subsection (a)).

### 13                           **Subtitle D—Other Provisions**

#### 14           **SEC. 431. PROVIDING SAFE HARBOR FOR CERTAIN COL-** 15                           **LABORATIVE EFFORTS THAT BENEFIT MEDI-** 16                           **CALLY UNDERSERVED POPULATIONS.**

17           (a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C.  
18          1320a–7(b)(3)), as amended by section 101(e)(2), is  
19          amended—

20                   (1) in subparagraph (F), by striking “and” after the  
21                   semicolon at the end;

22                   (2) in subparagraph (G), by striking the period at the  
23                   end and inserting “; and”; and

24                   (3) by adding at the end the following new subpara-  
25                   graph:

26                           “(H) any remuneration between a health center  
27                           entity described under clause (i) or (ii) of section  
28                           1905(l)(2)(B) and any individual or entity providing  
29                           goods, items, services, donations, loans, or a combina-  
30                           tion thereof, to such health center entity pursuant to  
31                           a contract, lease, grant, loan, or other agreement, if  
32                           such agreement contributes to the ability of the health  
33                           center entity to maintain or increase the availability, or  
34                           enhance the quality, of services provided to a medically  
35                           underserved population served by the health center en-  
36                           tity.”.

1 (b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER  
2 ENTITY ARRANGEMENTS.—

3 (1) ESTABLISHMENT.—

4 (A) IN GENERAL.—The Secretary shall establish,  
5 on an expedited basis, standards relating to the excep-  
6 tion described in section 1128B(b)(3)(H) of the Social  
7 Security Act, as added by subsection (a), for health  
8 center entity arrangements to the antikickback pen-  
9 alties.

10 (B) FACTORS TO CONSIDER.—The Secretary shall  
11 consider the following factors, among others, in estab-  
12 lishing standards relating to the exception for health  
13 center entity arrangements under subparagraph (A):

14 (i) Whether the arrangement between the  
15 health center entity and the other party results in  
16 savings of Federal grant funds or increased reve-  
17 nues to the health center entity.

18 (ii) Whether the arrangement between the  
19 health center entity and the other party restricts or  
20 limits an individual's freedom of choice.

21 (iii) Whether the arrangement between the  
22 health center entity and the other party protects a  
23 health care professional's independent medical  
24 judgment regarding medically appropriate treat-  
25 ment.

26 The Secretary may also include other standards and  
27 criteria that are consistent with the intent of Congress  
28 in enacting the exception established under this section.

29 (2) DEADLINE.—Not later than 1 year after the date  
30 of the enactment of this Act the Secretary shall publish  
31 final regulations establishing the standards described in  
32 paragraph (1).

33 **SEC. 432. OFFICE OF RURAL HEALTH POLICY IMPROVE-**  
34 **MENTS.**

35 Section 711(b) (42 U.S.C. 912(b)) is amended—

36 (1) in paragraph (3), by striking “and” after the  
37 comma at the end;

1 (2) in paragraph (4), by striking the period at the end  
2 and inserting “, and”; and

3 (3) by inserting after paragraph (4) the following new  
4 paragraph:

5 “(5) administer grants, cooperative agreements, and  
6 contracts to provide technical assistance and other activities  
7 as necessary to support activities related to improving  
8 health care in rural areas.”.

9 **SEC. 433. MEDPAC STUDY ON RURAL HOSPITAL PAY-**  
10 **MENT ADJUSTMENTS.**

11 (a) IN GENERAL.—The Medicare Payment Advisory Com-  
12 mission shall conduct a study of the impact of sections 401  
13 through 406, 411, 416, and 505. The Commission shall analyze  
14 the effect on total payments, growth in costs, capital spending,  
15 and such other payment effects under those sections.

16 (b) REPORTS.—

17 (1) INTERIM REPORT.—Not later than 18 months  
18 after the date of the enactment of this Act, the Commission  
19 shall submit to Congress an interim report on the matters  
20 studied under subsection (a) with respect only to changes  
21 to the critical access hospital provisions under section 405.

22 (2) FINAL REPORT.—Not later than 3 years after the  
23 date of the enactment of this Act, the Commission shall  
24 submit to Congress a final report on all matters studied  
25 under subsection (a).

26 **SEC. 434. FRONTIER EXTENDED STAY CLINIC DEM-**  
27 **ONSTRATION PROJECT.**

28 (a) AUTHORITY TO CONDUCT DEMONSTRATION  
29 PROJECT.—The Secretary shall waive such provisions of the  
30 medicare program established under title XVIII of the Social  
31 Security Act (42 U.S.C. 1395 et seq.) as are necessary to con-  
32 duct a demonstration project under which frontier extended  
33 stay clinics described in subsection (b) in isolated rural areas  
34 are treated as providers of items and services under the medi-  
35 care program.

36 (b) CLINICS DESCRIBED.—A frontier extended stay clinic  
37 is described in this subsection if the clinic—

1 (1) is located in a community where the closest short-  
2 term acute care hospital or critical access hospital is at  
3 least 75 miles away from the community or is inaccessible  
4 by public road; and

5 (2) is designed to address the needs of—

6 (A) seriously or critically ill or injured patients  
7 who, due to adverse weather conditions or other rea-  
8 sons, cannot be transferred quickly to acute care refer-  
9 ral centers; or

10 (B) patients who need monitoring and observation  
11 for a limited period of time.

12 (c) SPECIFICATION OF CODES.—The Secretary shall deter-  
13 mine the appropriate life-safety codes for such clinics that treat  
14 patients for needs referred to in subsection (b)(2).

15 (d) FUNDING.—

16 (1) IN GENERAL.—Subject to paragraph (2), there are  
17 authorized to be appropriated, in appropriate part from the  
18 Federal Hospital Insurance Trust Fund and the Federal  
19 Supplementary Medical Insurance Trust Fund, such sums  
20 as are necessary to conduct the demonstration project  
21 under this section.

22 (2) BUDGET NEUTRAL IMPLEMENTATION.—In con-  
23 ducting the demonstration project under this section, the  
24 Secretary shall ensure that the aggregate payments made  
25 by the Secretary under the medicare program do not exceed  
26 the amount which the Secretary would have paid under the  
27 medicare program if the demonstration project under this  
28 section was not implemented.

29 (e) 3-YEAR PERIOD.—The Secretary shall conduct the  
30 demonstration under this section for a 3-year period.

31 (f) REPORT.—Not later than the date that is 1 year after  
32 the date on which the demonstration project concludes, the Sec-  
33 retary shall submit to Congress a report on the demonstration  
34 project, together with such recommendations for legislation or  
35 administrative action as the Secretary determines appropriate.

36 (g) DEFINITIONS.—In this section, the terms “hospital”  
37 and “critical access hospital” have the meanings given such

1 terms in subsections (e) and (mm), respectively, of section  
2 1861 of the Social Security Act (42 U.S.C. 1395x).

3 **TITLE V—PROVISIONS RELATING**  
4 **TO PART A**  
5 **Subtitle A—Inpatient Hospital**  
6 **Services**

7 **SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAY-**  
8 **MENT UPDATES.**

9 (a) IN GENERAL.—Section 1886(b)(3)(B)(i) (42 U.S.C.  
10 1395ww(b)(3)(B)(i)) is amended—

11 (1) by striking “and” at the end of subclause (XVIII);

12 (2) by striking subclause (XIX); and

13 (3) by inserting after subclause (XVIII) the following  
14 new subclauses:

15 “(XIX) for each of fiscal years 2004 through 2007,  
16 subject to clause (vii), the market basket percentage in-  
17 crease for hospitals in all areas; and

18 “(XX) for fiscal year 2008 and each subsequent fiscal  
19 year, the market basket percentage increase for hospitals in  
20 all areas.”.

21 (b) SUBMISSION OF HOSPITAL QUALITY DATA.—Section  
22 1886(b)(3)(B) (42 U.S.C. 1395ww(b)(3)(B)) is amended by  
23 adding at the end the following new clause:

24 “(vii)(I) For purposes of clause (i)(XIX) for each of fiscal  
25 years 2005 through 2007, in a case of a subsection (d) hospital  
26 that does not submit data to the Secretary in accordance with  
27 subclause (II) with respect to such a fiscal year, the applicable  
28 percentage increase under such clause for such fiscal year shall  
29 be reduced by 0.4 percentage points. Such reduction shall apply  
30 only with respect to the fiscal year involved, and the Secretary  
31 shall not take into account such reduction in computing the ap-  
32 plicable percentage increase under clause (i)(XIX) for a subse-  
33 quent fiscal year.

34 “(II) Each subsection (d) hospital shall submit to the Sec-  
35 retary quality data (for a set of 10 indicators established by  
36 the Secretary as of November 1, 2003) that relate to the qual-

1 ity of care furnished by the hospital in inpatient settings in a  
2 form and manner, and at a time, specified by the Secretary for  
3 purposes of this clause, but with respect to fiscal year 2005,  
4 the Secretary shall provide for a 30-day grace period for the  
5 submission of data by a hospital.”.

6 (c) GAO STUDY AND REPORT ON APPROPRIATENESS OF  
7 PAYMENTS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR  
8 INPATIENT HOSPITAL SERVICES.—

9 (1) STUDY.—The Comptroller General of the United  
10 States, using the most current data available, shall conduct  
11 a study to determine—

12 (A) the appropriate level and distribution of pay-  
13 ments in relation to costs under the prospective pay-  
14 ment system under section 1886 of the Social Security  
15 Act (42 U.S.C. 1395ww) for inpatient hospital services  
16 furnished by subsection (d) hospitals (as defined in  
17 subsection (d)(1)(B) of such section); and

18 (B) whether there is a need to adjust such pay-  
19 ments under such system to reflect legitimate dif-  
20 ferences in costs across different geographic areas,  
21 kinds of hospitals, and types of cases.

22 (2) REPORT.—Not later than 24 months after the  
23 date of the enactment of this Act, the Comptroller General  
24 of the United States shall submit to Congress a report on  
25 the study conducted under paragraph (1) together with  
26 such recommendations for legislative and administrative ac-  
27 tion as the Comptroller General determines appropriate.

28 **SEC. 502. REVISION OF THE INDIRECT MEDICAL EDU-**  
29 **CATION (IME) ADJUSTMENT PERCENTAGE.**

30 (a) IN GENERAL.—Section 1886(d)(5)(B)(ii) (42 U.S.C.  
31 1395ww(d)(5)(B)(ii)) is amended—

32 (1) in subclause (VI), by striking “and” after the  
33 semicolon at the end;

34 (2) in subclause (VII)—

35 (A) by inserting “and before April 1, 2004,” after  
36 “on or after October 1, 2002,”; and



1 (B) by striking the period at the end and inserting  
2 a semicolon; and

3 (3) by adding at the end the following new subclauses:

4 “(VIII) on or after April 1, 2004, and before Oc-  
5 tober 1, 2004, ‘c’ is equal to 1.47;

6 “(IX) during fiscal year 2005, ‘c’ is equal to 1.42;

7 “(X) during fiscal year 2006, ‘c’ is equal to 1.37;

8 “(XI) during fiscal year 2007, ‘c’ is equal to 1.32;

9 and

10 “(XII) on or after October 1, 2007, ‘c’ is equal to  
11 1.35.”.

12 (b) CONFORMING AMENDMENT RELATING TO DETER-  
13 MINATION OF STANDARDIZED AMOUNT.—Section  
14 1886(d)(2)(C)(i) (42 U.S.C. 1395ww(d)(2)(C)(i)) is amended—

15 (1) by striking “1999 or” and inserting “1999,”; and

16 (2) by inserting “, or the Medicare Prescription Drug,  
17 Improvement, and Modernization Act of 2003” after  
18 “2000”.

19 (c) EFFECTIVE DATE.—The amendments made by this  
20 section shall apply to discharges occurring on or after April 1,  
21 2004.

22 **SEC. 503. RECOGNITION OF NEW MEDICAL TECH-**  
23 **NOLOGIES UNDER INPATIENT HOSPITAL**  
24 **PROSPECTIVE PAYMENT SYSTEM.**

25 (a) IMPROVING TIMELINESS OF DATA COLLECTION.—Sec-  
26 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended  
27 by adding at the end the following new clause:

28 “(vii) Under the mechanism under this subparagraph, the  
29 Secretary shall provide for the addition of new diagnosis and  
30 procedure codes in April 1 of each year, but the addition of  
31 such codes shall not require the Secretary to adjust the pay-  
32 ment (or diagnosis-related group classification) under this sub-  
33 section until the fiscal year that begins after such date.”.

34 (b) ELIGIBILITY STANDARD FOR TECHNOLOGY  
35 OUTLIERS.—

36 (1) ADJUSTMENT OF THRESHOLD.—Section  
37 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is

1 amended by inserting “(applying a threshold specified by  
2 the Secretary that is the lesser of 75 percent of the stand-  
3 arized amount (increased to reflect the difference between  
4 cost and charges) or 75 percent of one standard deviation  
5 for the diagnosis-related group involved)” after “is inad-  
6 equate”.

7 (2) PROCESS FOR PUBLIC INPUT.—Section  
8 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended  
9 by subsection (a), is amended—

10 (A) in clause (i), by adding at the end the fol-  
11 lowing: “Such mechanism shall be modified to meet the  
12 requirements of clause (viii).”; and

13 (B) by adding at the end the following new clause:  
14 “(viii) The mechanism established pursuant to clause (i)  
15 shall be adjusted to provide, before publication of a proposed  
16 rule, for public input regarding whether a new service or tech-  
17 nology represents an advance in medical technology that sub-  
18 stantially improves the diagnosis or treatment of individuals en-  
19 titled to benefits under part A as follows:

20 “(I) The Secretary shall make public and periodically  
21 update a list of all the services and technologies for which  
22 an application for additional payment under this subpara-  
23 graph is pending.

24 “(II) The Secretary shall accept comments, rec-  
25 ommendations, and data from the public regarding whether  
26 the service or technology represents a substantial improve-  
27 ment.

28 “(III) The Secretary shall provide for a meeting at  
29 which organizations representing hospitals, physicians, such  
30 individuals, manufacturers, and any other interested party  
31 may present comments, recommendations, and data to the  
32 clinical staff of the Centers for Medicare & Medicaid Serv-  
33 ices before publication of a notice of proposed rulemaking  
34 regarding whether service or technology represents a sub-  
35 stantial improvement.”.

36 (c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Sec-  
37 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended

1 by subsections (a) and (b), is amended by adding at the end  
2 the following new clause:

3 “(ix) Before establishing any add-on payment under this  
4 subparagraph with respect to a new technology, the Secretary  
5 shall seek to identify one or more diagnosis-related groups as-  
6 sociated with such technology, based on similar clinical or ana-  
7 tomical characteristics and the cost of the technology. Within  
8 such groups the Secretary shall assign an eligible new tech-  
9 nology into a diagnosis-related group where the average costs  
10 of care most closely approximate the costs of care of using the  
11 new technology. No add-on payment under this subparagraph  
12 shall be made with respect to such new technology and this  
13 clause shall not affect the application of paragraph  
14 (4)(C)(iii).”.

15 (d) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL  
16 INPATIENT TECHNOLOGY.—

17 (1) IN GENERAL.—Section 1886(d)(5)(K)(ii)(III) (42  
18 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking  
19 “subject to paragraph (4)(C)(iii),”.

20 (2) NOT BUDGET NEUTRAL.—There shall be no reduc-  
21 tion or other adjustment in payments under section 1886  
22 of the Social Security Act because an additional payment  
23 is provided under subsection (d)(5)(K)(ii)(III) of such sec-  
24 tion.

25 (e) EFFECTIVE DATE.—

26 (1) IN GENERAL.—The Secretary shall implement the  
27 amendments made by this section so that they apply to  
28 classification for fiscal years beginning with fiscal year  
29 2005.

30 (2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL  
31 YEAR 2004 THAT ARE DENIED.—In the case of an applica-  
32 tion for a classification of a medical service or technology  
33 as a new medical service or technology under section  
34 1886(d)(5)(K) of the Social Security Act (42 U.S.C.  
35 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and  
36 that is denied—

1 (A) the Secretary shall automatically reconsider  
2 the application as an application for fiscal year 2005  
3 under the amendments made by this section; and

4 (B) the maximum time period otherwise permitted  
5 for such classification of the service or technology shall  
6 be extended by 12 months.

7 **SEC. 504. INCREASE IN FEDERAL RATE FOR HOSPITALS**  
8 **IN PUERTO RICO.**

9 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is  
10 amended—

11 (1) in subparagraph (A)—

12 (A) in clause (i), by striking “for discharges begin-  
13 ning on or after October 1, 1997, 50 percent (and for  
14 discharges between October 1, 1987, and September  
15 30, 1997, 75 percent)” and inserting “the applicable  
16 Puerto Rico percentage (specified in subparagraph  
17 (E))”; and

18 (B) in clause (ii), by striking “for discharges be-  
19 ginning in a fiscal year beginning on or after October  
20 1, 1997, 50 percent (and for discharges between Octo-  
21 ber 1, 1987, and September 30, 1997, 25 percent)”  
22 and inserting “the applicable Federal percentage (spec-  
23 ified in subparagraph (E))”; and

24 (2) by adding at the end the following new subpara-  
25 graph:

26 “(E) For purposes of subparagraph (A), for discharges  
27 occurring—

28 “(i) on or after October 1, 1987, and before October  
29 1, 1997, the applicable Puerto Rico percentage is 75 per-  
30 cent and the applicable Federal percentage is 25 percent;

31 “(ii) on or after October 1, 1997, and before April 1,  
32 2004, the applicable Puerto Rico percentage is 50 percent  
33 and the applicable Federal percentage is 50 percent;

34 “(iii) on or after April 1, 2004, and before October 1,  
35 2004, the applicable Puerto Rico percentage is 37.5 percent  
36 and the applicable Federal percentage is 62.5 percent; and

1           “(iv) on or after October 1, 2004, the applicable Puer-  
2           to Rico percentage is 25 percent and the applicable Federal  
3           percentage is 75 percent.”.

4       **SEC. 505. WAGE INDEX ADJUSTMENT RECLASSIFICA-**  
5       **TION REFORM.**

6           (a) IN GENERAL.—Section 1886(d) (42 U.S.C.  
7           1395ww(d)), as amended by section 406, is amended by adding  
8           at the end the following new paragraph:

9           “(13)(A) In order to recognize commuting patterns among  
10          geographic areas, the Secretary shall establish a process  
11          through application or otherwise for an increase of the wage  
12          index applied under paragraph (3)(E) for subsection (d) hos-  
13          pitals located in a qualifying county described in subparagraph  
14          (B) in the amount computed under subparagraph (D) based on  
15          out-migration of hospital employees who reside in that county  
16          to any higher wage index area.

17          “(B) The Secretary shall establish criteria for a qualifying  
18          county under this subparagraph based on the out-migration re-  
19          ferred to in subparagraph (A) and differences in the area wage  
20          indices. Under such criteria the Secretary shall, utilizing such  
21          data as the Secretary determines to be appropriate, establish—

22               “(i) a threshold percentage, established by the Sec-  
23               retary, of the weighted average of the area wage index or  
24               indices for the higher wage index areas involved;

25               “(ii) a threshold (of not less than 10 percent) for min-  
26               imum out-migration to a higher wage index area or areas;  
27               and

28               “(iii) a requirement that the average hourly wage of  
29               the hospitals in the qualifying county equals or exceeds the  
30               average hourly wage of all the hospitals in the area in  
31               which the qualifying county is located.

32          “(C) For purposes of this paragraph, the term ‘higher  
33          wage index area’ means, with respect to a county, an area with  
34          a wage index that exceeds that of the county.

35          “(D) The increase in the wage index under subparagraph  
36          (A) for a qualifying county shall be equal to the percentage of  
37          the hospital employees residing in the qualifying county who

1 are employed in any higher wage index area multiplied by the  
2 sum of the products, for each higher wage index area of—

3 “(i) the difference between—

4 “(I) the wage index for such higher wage index  
5 area, and

6 “(II) the wage index of the qualifying county; and

7 “(ii) the number of hospital employees residing in the  
8 qualifying county who are employed in such higher wage  
9 index area divided by the total number of hospital employ-  
10 ees residing in the qualifying county who are employed in  
11 any higher wage index area.

12 “(E) The process under this paragraph may be based  
13 upon the process used by the Medicare Geographic Classifica-  
14 tion Review Board under paragraph (10). As the Secretary de-  
15 termines to be appropriate to carry out such process, the Sec-  
16 retary may require hospitals (including subsection (d) hospitals  
17 and other hospitals) and critical access hospitals, as required  
18 under section 1866(a)(1)(T), to submit data regarding the lo-  
19 cation of residence, or the Secretary may use data from other  
20 sources.

21 “(F) A wage index increase under this paragraph shall be  
22 effective for a period of 3 fiscal years, except that the Secretary  
23 shall establish procedures under which a subsection (d) hospital  
24 may elect to waive the application of such wage index increase.

25 “(G) A hospital in a county that has a wage index increase  
26 under this paragraph for a period and that has not waived the  
27 application of such an increase under subparagraph (F) is not  
28 eligible for reclassification under paragraph (8) or (10) during  
29 that period.

30 “(H) Any increase in a wage index under this paragraph  
31 for a county shall not be taken into account for purposes of—

32 “(i) computing the wage index for portions of the wage  
33 index area (not including the county) in which the county  
34 is located; or

35 “(ii) applying any budget neutrality adjustment with  
36 respect to such index under paragraph (8)(D).

1           “(I) The thresholds described in subparagraph (B), data  
2 on hospital employees used under this paragraph, and any de-  
3 termination of the Secretary under the process described in  
4 subparagraph (E) shall be final and shall not be subject to ju-  
5 dicial review.”.

6           (b) CONFORMING AMENDMENTS.—Section 1866(a)(1) (42  
7 U.S.C. 1395cc(a)(1)) is amended—

8           (1) in subparagraph (R), by striking “and” at the end;

9           (2) in subparagraph (S), by striking the period at the  
10 end and inserting “, and”; and

11           (3) by inserting after subparagraph (S) the following  
12 new subparagraph:

13           “(T) in the case of hospitals and critical access hos-  
14 pitals, to furnish to the Secretary such data as the Sec-  
15 retary determines appropriate pursuant to subparagraph  
16 (E) of section 1886(d)(12) to carry out such section.”.

17           (c) EFFECTIVE DATE.—The amendments made by this  
18 section shall first apply to the wage index for discharges occur-  
19 ring on or after October 1, 2004. In initially implementing such  
20 amendments, the Secretary may modify the deadlines otherwise  
21 applicable under clauses (ii) and (iii)(I) of section  
22 1886(d)(10)(C) of the Social Security Act (42 U.S.C.  
23 1395ww(d)(10)(C)), for submission of, and actions on, applica-  
24 tions relating to changes in hospital geographic reclassification.

25 **SEC. 506. LIMITATION ON CHARGES FOR INPATIENT**  
26 **HOSPITAL CONTRACT HEALTH SERVICES**  
27 **PROVIDED TO INDIANS BY MEDICARE PAR-**  
28 **TICIPATING HOSPITALS.**

29           (a) IN GENERAL.—Section 1866(a)(1) (42 U.S.C.  
30 1395cc(a)(1)), as amended by section 505(b), is amended—

31           (1) in subparagraph (S), by striking “and” at the end;

32           (2) in subparagraph (T), by striking the period and in-  
33 serting “, and”; and

34           (3) by inserting after subparagraph (T) the following  
35 new subparagraph:

36           “(U) in the case of hospitals which furnish inpatient  
37 hospital services for which payment may be made under

1 this title, to be a participating provider of medical care  
2 both—

3 “(i) under the contract health services program  
4 funded by the Indian Health Service and operated by  
5 the Indian Health Service, an Indian tribe, or tribal or-  
6 ganization (as those terms are defined in section 4 of  
7 the Indian Health Care Improvement Act), with respect  
8 to items and services that are covered under such pro-  
9 gram and furnished to an individual eligible for such  
10 items and services under such program; and

11 “(ii) under any program funded by the Indian  
12 Health Service and operated by an urban Indian orga-  
13 nization with respect to the purchase of items and serv-  
14 ices for an eligible urban Indian (as those terms are de-  
15 fined in such section 4),

16 in accordance with regulations promulgated by the Sec-  
17 retary regarding admission practices, payment method-  
18 ology, and rates of payment (including the acceptance of no  
19 more than such payment rate as payment in full for such  
20 items and services.”.

21 (b) EFFECTIVE DATE.—The amendments made by this  
22 section shall apply as of a date specified by the Secretary of  
23 Health and Human Services (but in no case later than 1 year  
24 after the date of enactment of this Act) to medicare partici-  
25 pation agreements in effect (or entered into) on or after such  
26 date.

27 (c) PROMULGATION OF REGULATIONS.—The Secretary  
28 shall promulgate regulations to carry out the amendments  
29 made by subsection (a).

30 **SEC. 507. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO**  
31 **MEDICARE LIMITS ON PHYSICIAN REFER-**  
32 **RELS.**

33 (a) LIMITS ON PHYSICIAN REFERRALS.—

34 (1) OWNERSHIP AND INVESTMENT INTERESTS IN  
35 WHOLE HOSPITALS.—

36 (A) IN GENERAL.—Section 1877(d)(3) (42 U.S.C.  
37 1395nn(d)(3)) is amended—



1 (i) by striking “, and” at the end of subpara-  
2 graph (A) and inserting a semicolon; and

3 (ii) by redesignating subparagraph (B) as sub-  
4 paragraph (C) and inserting after subparagraph  
5 (A) the following new subparagraph:

6 “(B) effective for the 18-month period beginning  
7 on November 18, 2003, the hospital is not a specialty  
8 hospital (as defined in subsection (h)(7)); and”.

9 (B) DEFINITION.—Section 1877(h) (42 U.S.C.  
10 1395nn(h)) is amended by adding at the end the fol-  
11 lowing:

12 “(7) SPECIALTY HOSPITAL.—

13 “(A) IN GENERAL.—For purposes of this section,  
14 except as provided in subparagraph (B), the term ‘spe-  
15 cialty hospital’ means a subsection (d) hospital that is  
16 primarily or exclusively engaged in the care and treat-  
17 ment of one of the following categories:

18 “(i) Patients with a cardiac condition.

19 “(ii) Patients with an orthopedic condition.

20 “(iii) Patients receiving a surgical procedure.

21 “(iv) Any other specialized category of services  
22 that the Secretary designates as inconsistent with  
23 the purpose of permitting physician ownership and  
24 investment interests in a hospital under this sec-  
25 tion.

26 “(B) EXCEPTION.—For purposes of this section,  
27 the term ‘specialty hospital’ does not include any  
28 hospital—

29 “(i) determined by the Secretary—

30 “(I) to be in operation before November  
31 18, 2003; or

32 “(II) under development as of such date;

33 “(ii) for which the number of physician inves-  
34 tors at any time on or after such date is no greater  
35 than the number of such investors as of such date;

36 “(iii) for which the type of categories de-  
37 scribed in subparagraph (A) at any time on or

1 after such date is no different than the type of  
2 such categories as of such date;

3 “(iv) for which any increase in the number of  
4 beds occurs only in the facilities on the main cam-  
5 pus of the hospital and does not exceed 50 percent  
6 of the number of beds in the hospital as of Novem-  
7 ber 18, 2003, or 5 beds, whichever is greater; and

8 “(v) that meets such other requirements as  
9 the Secretary may specify.”.

10 (2) OWNERSHIP AND INVESTMENT INTERESTS IN A  
11 RURAL PROVIDER.—Section 1877(d)(2) (42 U.S.C.  
12 1395m(d)(2)) is amended to read as follows:

13 “(2) RURAL PROVIDERS.—In the case of designated  
14 health services furnished in a rural area (as defined in sec-  
15 tion 1886(d)(2)(D)) by an entity, if—

16 “(A) substantially all of the designated health  
17 services furnished by the entity are furnished to indi-  
18 viduals residing in such a rural area; and

19 “(B) effective for the 18-month period beginning  
20 on November 18, 2003, the entity is not a specialty  
21 hospital (as defined in subsection (h)(7)).”.

22 (b) APPLICATION OF EXCEPTION FOR HOSPITALS UNDER  
23 DEVELOPMENT.—For purposes of section 1877(h)(7)(B)(i)(II)  
24 of the Social Security Act, as added by subsection (a)(1)(B),  
25 in determining whether a hospital is under development as of  
26 November 18, 2003, the Secretary shall consider—

27 (1) whether architectural plans have been completed,  
28 funding has been received, zoning requirements have been  
29 met, and necessary approvals from appropriate State agen-  
30 cies have been received; and

31 (2) any other evidence the Secretary determines would  
32 indicate whether a hospital is under development as of such  
33 date.

34 (c) STUDIES.—

35 (1) MEDPAC STUDY.—The Medicare Payment Advi-  
36 sory Commission, in consultation with the Comptroller

1 General of the United States, shall conduct a study to  
2 determine—

3 (A) any differences in the costs of health care  
4 services furnished to patients by physician-owned spe-  
5 cialty hospitals and the costs of such services furnished  
6 by local full-service community hospitals within specific  
7 diagnosis-related groups;

8 (B) the extent to which specialty hospitals, relative  
9 to local full-service community hospitals, treat patients  
10 in certain diagnosis-related groups within a category,  
11 such as cardiology, and an analysis of the selection;

12 (C) the financial impact of physician-owned spe-  
13 cialty hospitals on local full-service community hos-  
14 pitals;

15 (D) how the current diagnosis-related group sys-  
16 tem should be updated to better reflect the cost of de-  
17 livering care in a hospital setting; and

18 (E) the proportions of payments received, by type  
19 of payer, between the specialty hospitals and local full-  
20 service community hospitals.

21 (2) HHS STUDY.—The Secretary shall conduct a  
22 study of a representative sample of specialty hospitals—

23 (A) to determine the percentage of patients admit-  
24 ted to physician-owned specialty hospitals who are re-  
25 ferred by physicians with an ownership interest;

26 (B) to determine the referral patterns of physician  
27 owners, including the percentage of patients they re-  
28 ferred to physician-owned specialty hospitals and the  
29 percentage of patients they referred to local full-service  
30 community hospitals for the same condition;

31 (C) to compare the quality of care furnished in  
32 physician-owned specialty hospitals and in local full-  
33 service community hospitals for similar conditions and  
34 patient satisfaction with such care; and

35 (D) to assess the differences in uncompensated  
36 care, as defined by the Secretary, between the specialty  
37 hospital and local full-service community hospitals, and

1 the relative value of any tax exemption available to  
2 such hospitals.

3 (3) REPORTS.—Not later than 15 months after the  
4 date of the enactment of this Act, the Commission and the  
5 Secretary, respectively, shall each submit to Congress a re-  
6 port on the studies conducted under paragraphs (1) and  
7 (2), respectively, and shall include any recommendations  
8 for legislation or administrative changes.

9 **SEC. 508. 1-TIME APPEALS PROCESS FOR HOSPITAL**  
10 **WAGE INDEX CLASSIFICATION.**

11 (a) ESTABLISHMENT OF PROCESS.—

12 (1) IN GENERAL.—The Secretary shall establish by in-  
13 struction or otherwise a process under which a hospital  
14 may appeal the wage index classification otherwise applica-  
15 ble to the hospital and select another area within the State  
16 (or, at the discretion of the Secretary, within a contiguous  
17 State) to which to be reclassified.

18 (2) PROCESS REQUIREMENTS.—The process estab-  
19 lished under paragraph (1) shall be consistent with the fol-  
20 lowing:

21 (A) Such an appeal shall be filed by not later than  
22 April 1, 2004.

23 (B) Such an appeal shall be heard by the Medicare  
24 Geographic Reclassification Review Board.

25 (C) There shall be no further administrative or ju-  
26 dicial review of a decision of such Board.

27 (3) RECLASSIFICATION UPON SUCCESSFUL APPEAL.—  
28 If the Medicare Geographic Reclassification Review Board  
29 determines that the hospital is a qualifying hospital (as de-  
30 fined in subsection (c)), the hospital shall be reclassified to  
31 the area selected under paragraph (1). Such reclassification  
32 shall apply with respect to discharges occurring during the  
33 3-fiscal-year period beginning with fiscal year 2005.

34 (4) INAPPLICABILITY OF CERTAIN PROVISIONS.—Ex-  
35 cept as the Secretary may provide, the provisions of para-  
36 graphs (8) and (10) of section 1886(d) of the Social Secu-

1           rity Act (42 U.S.C. 1395ww(d)) shall not apply to an ap-  
2           peal under this section.

3           (b) APPLICATION OF RECLASSIFICATION.—In the case of  
4           an appeal decided in favor of a qualifying hospital under sub-  
5           section (a), the wage index reclassification shall not affect the  
6           wage index computation for any area or for any other hospital  
7           and shall not be effected in a budget neutral manner. The pro-  
8           visions of this section shall not affect payment for discharges  
9           occurring after the end of the 3-fiscal-year-period referred to  
10          in subsection (a).

11          (c) QUALIFYING HOSPITAL DEFINED.—For purposes of  
12          this section, the term “qualifying hospital” means a subsection  
13          (d) hospital (as defined in section 1886(d)(1)(B) of the Social  
14          Security Act, 42 U.S.C. 1395ww(d)(1)(B)) that—

15               (1) does not qualify for a change in wage index classi-  
16               fication under paragraph (8) or (10) of section 1886(d) of  
17               the Social Security Act (42 U.S.C. 1395ww(d)) on the  
18               basis of requirements relating to distance or commuting;  
19               and

20               (2) meets such other criteria, such as quality, as the  
21               Secretary may specify by instruction or otherwise.

22          The Secretary may modify the wage comparison guidelines pro-  
23          mulgated under section 1886(d)(10)(D) of such Act (42 U.S.C.  
24          1395ww(d)(10)(D)) in carrying out this section.

25          (d) WAGE INDEX CLASSIFICATION.—For purposes of this  
26          section, the term “wage index classification” means the geo-  
27          graphic area in which it is classified for purposes of deter-  
28          mining for a fiscal year the factor used to adjust the DRG pro-  
29          spective payment rate under section 1886(d) of the Social Se-  
30          curity Act (42 U.S.C. 1395ww(d)) for area differences in hos-  
31          pital wage levels that applies to such hospital under paragraph  
32          (3)(E) of such section.

33          (e) LIMITATION ON EXPENDITURES.—The aggregate  
34          amount of additional expenditures resulting from the applica-  
35          tion of this section shall not exceed \$500,000,000.

## Subtitle B—Other Provisions

### SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.— Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

“(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

“(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable (determined without regard to any increase under section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, or under section 314(a) of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000), shall be increased by 128 percent to reflect increased costs associated with such residents.

“(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.”.

(b) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2004.

### SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) COVERAGE OF HOSPICE CONSULTATION SERVICES.— Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(1) by striking “and” at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting “; and”; and

(3) by inserting after paragraph (4) the following new paragraph:

1 “(5) for individuals who are terminally ill, have not  
2 made an election under subsection (d)(1), and have not  
3 previously received services under this paragraph, services  
4 that are furnished by a physician (as defined in section  
5 1861(r)(1)) who is either the medical director or an em-  
6 ployee of a hospice program and that—

7 “(A) consist of—

8 “(i) an evaluation of the individual’s need for  
9 pain and symptom management, including the indi-  
10 vidual’s need for hospice care; and

11 “(ii) counseling the individual with respect to  
12 hospice care and other care options; and

13 “(B) may include advising the individual regarding  
14 advanced care planning.”.

15 (b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i)) is  
16 amended by adding at the end the following new paragraph:

17 “(4) The amount paid to a hospice program with respect  
18 to the services under section 1812(a)(5) for which payment  
19 may be made under this part shall be equal to an amount es-  
20 tablished for an office or other outpatient visit for evaluation  
21 and management associated with presenting problems of mod-  
22 erate severity and requiring medical decisionmaking of low  
23 complexity under the fee schedule established under section  
24 1848(b), other than the portion of such amount attributable to  
25 the practice expense component.”.

26 (c) CONFORMING AMENDMENT.—Section  
27 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended  
28 by inserting before the comma at the end the following: “and  
29 services described in section 1812(a)(5)”.

30 (d) EFFECTIVE DATE.—The amendments made by this  
31 section shall apply to services provided by a hospice program  
32 on or after January 1, 2005.

33 **SEC. 513. STUDY ON PORTABLE DIAGNOSTIC**  
34 **ULTRASOUND SERVICES FOR BENE-**  
35 **FIICIARIES IN SKILLED NURSING FACILITIES.**

36 (a) STUDY.—The Comptroller General of the United  
37 States shall conduct a study of portable diagnostic ultrasound

1 services furnished to medicare beneficiaries in skilled nursing  
2 facilities. Such study shall consider the following:

3 (1) TYPES OF EQUIPMENT; TRAINING.—The types of  
4 portable diagnostic ultrasound services furnished to such  
5 beneficiaries, the types of portable ultrasound equipment  
6 used to furnish such services, and the technical skills, or  
7 training, or both, required for technicians to furnish such  
8 services.

9 (2) CLINICAL APPROPRIATENESS.—The clinical appro-  
10 priateness of transporting portable diagnostic ultrasound  
11 diagnostic and technicians to patients in skilled nursing fa-  
12 cilities as opposed to transporting such patients to a hos-  
13 pital or other facility that furnishes diagnostic ultrasound  
14 services.

15 (3) FINANCIAL IMPACT.—The financial impact if  
16 Medicare were make a separate payment for portable  
17 ultrasound diagnostic services, including the impact of sep-  
18 arate payments—

19 (A) for transportation and technician services for  
20 residents during a resident in a part A stay, that would  
21 otherwise be paid for under the prospective payment  
22 system for covered skilled nursing facility services  
23 (under section 1888(e) of the Social Security Act (42  
24 U.S.C. 1395yy(e)); and

25 (B) for such services for residents in a skilled  
26 nursing facility after a part A stay.

27 (4) CREDENTIALING REQUIREMENTS.—Whether the  
28 Secretary should establish credentialing or other require-  
29 ments for technicians that furnish diagnostic ultrasound  
30 services to medicare beneficiaries.

31 (b) REPORT.—Not later than 2 years after the date of the  
32 enactment of this Act, the Comptroller General shall submit to  
33 Congress a report on the study conducted under subsection (a),  
34 and shall include any recommendations for legislation or ad-  
35 ministrative change as the Comptroller General determines ap-  
36 propriate.



1       **TITLE VI—PROVISIONS RELATING**  
2                               **TO PART B**  
3       **Subtitle A—Provisions Relating to**  
4                               **Physicians' Services**

5       **SEC. 601. REVISION OF UPDATES FOR PHYSICIANS'**  
6                               **SERVICES.**

7           (a) UPDATE FOR 2004 AND 2005.—

8               (1) IN GENERAL.—Section 1848(d) (42 U.S.C.  
9               1395w-4(d)) is amended by adding at the end the following  
10              new paragraph:

11              “(5) UPDATE FOR 2004 AND 2005.—The update to the  
12              single conversion factor established in paragraph (1)(C) for  
13              each of 2004 and 2005 shall be not less than 1.5 percent.”.

14              (2) CONFORMING AMENDMENT.—Paragraph (4)(B) of  
15              such section is amended, in the matter before clause (i), by  
16              inserting “and paragraph (5)” after “subparagraph (D)”.

17              (3) NOT TREATED AS CHANGE IN LAW AND REGULA-  
18              TION IN SUSTAINABLE GROWTH RATE DETERMINATION.—  
19              The amendments made by this subsection shall not be  
20              treated as a change in law for purposes of applying section  
21              1848(f)(2)(D) of the Social Security Act (42 U.S.C.  
22              1395w-4(f)(2)(D)).

23           (b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING  
24              GROSS DOMESTIC PRODUCT.—

25               (1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C.  
26               1395w-4(f)(2)(C)) is amended—

27                   (A) by striking “projected” and inserting “annual  
28                   average”; and

29                   (B) by striking “from the previous applicable pe-  
30                   riod to the applicable period involved” and inserting  
31                   “during the 10-year period ending with the applicable  
32                   period involved”.

33               (2) EFFECTIVE DATE.—The amendments made by  
34               paragraph (1) shall apply to computations of the sustain-  
35               able growth rate for years beginning with 2003.

1     **SEC. 602. TREATMENT OF PHYSICIANS' SERVICES FUR-**  
2                   **NISHED IN ALASKA.**

3             Section 1848(e)(1) (42 U.S.C. 1395w-4(e)(1)), as amend-  
4     ed by section 421, is amended—

5             (1) in subparagraph (A), by striking “subpara-  
6             graphs (B), (C), (E), and (F)” and inserting “sub-  
7             paragraphs (B), (C), (E), (F) and (G)”; and

8             (2) by adding at the end the following new sub-  
9     paragraph:

10            “(G) FLOOR FOR PRACTICE EXPENSE,  
11            MALPRACTICE, AND WORK GEOGRAPHIC INDI-  
12            CES FOR SERVICES FURNISHED IN ALASKA.—  
13            For purposes of payment for services furnished  
14            in Alaska on or after January 1, 2004, and be-  
15            fore January 1, 2006, after calculating the  
16            practice expense, malpractice, and work geo-  
17            graphic indices in clauses (i), (ii), and (iii) of  
18            subparagraph (A) and in subparagraph (B), the  
19            Secretary shall increase any such index to 1.67  
20            if such index would otherwise be less than  
21            1.67.”.

22     **SEC. 603. INCLUSION OF PODIATRISTS, DENTISTS, AND OP-**  
23                   **TOMETRISTS UNDER PRIVATE CONTRACTING**  
24                   **AUTHORITY.**

25             Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is  
26     amended by striking “section 1861(r)(1)” and inserting  
27     “paragraphs (1), (2), (3), and (4) of section 1861(r)”.

1 **SEC. 604. GAO STUDY ON ACCESS TO PHYSICIANS' SERV-**  
2 **ICES.**

3 (a) **STUDY.**—The Comptroller General of the United  
4 States shall conduct a study on access of medicare bene-  
5 ficiaries to physicians' services under the medicare pro-  
6 gram. The study shall include—

7 (1) an assessment of the use by beneficiaries of  
8 such services through an analysis of claims sub-  
9 mitted by physicians for such services under part B  
10 of the medicare program;

11 (2) an examination of changes in the use by  
12 beneficiaries of physicians' services over time; and

13 (3) an examination of the extent to which phy-  
14 sicians are not accepting new medicare beneficiaries  
15 as patients.

16 (b) **REPORT.**—Not later than 18 months after the  
17 date of the enactment of this Act, the Comptroller General  
18 shall submit to Congress a report on the study conducted  
19 under subsection (a). The report shall include a deter-  
20 mination whether—

21 (1) data from claims submitted by physicians  
22 under part B of the medicare program indicate po-  
23 tential access problems for medicare beneficiaries in  
24 certain geographic areas; and

1           (2) access by medicare beneficiaries to physi-  
2           cians' services may have improved, remained con-  
3           stant, or deteriorated over time.

4 **SEC. 605. COLLABORATIVE DEMONSTRATION-BASED RE-**  
5 **VIEW OF PHYSICIAN PRACTICE EXPENSE GE-**  
6 **OGRAPHIC ADJUSTMENT DATA.**

7           (a) IN GENERAL.—Not later than January 1, 2005,  
8 the Secretary shall, in collaboration with State and other  
9 appropriate organizations representing physicians, and  
10 other appropriate persons, review and consider alternative  
11 data sources than those currently used in establishing the  
12 geographic index for the practice expense component  
13 under the medicare physician fee schedule under section  
14 1848(e)(1)(A)(i) of the Social Security Act (42 U.S.C.  
15 1395w-4(e)(1)(A)(i)).

16           (b) SITES.—The Secretary shall select two physician  
17 payment localities in which to carry out subsection (a).  
18 One locality shall include rural areas and at least one lo-  
19 cality shall be a statewide locality that includes both urban  
20 and rural areas.

21           (c) REPORT AND RECOMMENDATIONS.—

22           (1) REPORT.—Not later than January 1, 2006,  
23 the Secretary shall submit to Congress a report on  
24 the review and consideration conducted under sub-  
25 section (a). Such report shall include information on

1 the alternative developed data sources considered by  
2 the Secretary under subsection (a), including the ac-  
3 curacy and validity of the data as measures of the  
4 elements of the geographic index for practice ex-  
5 penses under the medicare physician fee schedule as  
6 well as the feasibility of using such alternative data  
7 nationwide in lieu of current proxy data used in such  
8 index, and the estimated impacts of using such al-  
9 ternative data.

10 (2) RECOMMENDATIONS.—The report sub-  
11 mitted under paragraph (1) shall contain rec-  
12 ommendations on which data sources reviewed and  
13 considered under subsection (a) are appropriate for  
14 use in calculating the geographic index for practice  
15 expenses under the medicare physician fee schedule.

16 **SEC. 606. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS'**  
17 **SERVICES.**

18 (a) PRACTICE EXPENSE COMPONENT.—Not later  
19 than 1 year after the date of the enactment of this Act,  
20 the Medicare Payment Advisory Commission shall submit  
21 to Congress a report on the effect of refinements to the  
22 practice expense component of payments for physicians'  
23 services, after the transition to a full resource-based pay-  
24 ment system in 2002, under section 1848 of the Social

1 Security Act (42 U.S.C. 1395w-4). Such report shall ex-  
2 amine the following matters by physician specialty:

3 (1) The effect of such refinements on payment  
4 for physicians' services.

5 (2) The interaction of the practice expense com-  
6 ponent with other components of and adjustments to  
7 payment for physicians' services under such section.

8 (3) The appropriateness of the amount of com-  
9 pensation by reason of such refinements.

10 (4) The effect of such refinements on access to  
11 care by medicare beneficiaries to physicians' serv-  
12 ices.

13 (5) The effect of such refinements on physician  
14 participation under the medicare program.

15 (b) VOLUME OF PHYSICIANS' SERVICES.—Not later  
16 than 1 year after the date of the enactment of this Act,  
17 the Medicare Payment Advisory Commission shall submit  
18 to Congress a report on the extent to which increases in  
19 the volume of physicians' services under part B of the  
20 medicare program are a result of care that improves the  
21 health and well-being of medicare beneficiaries. The study  
22 shall include the following:

23 (1) An analysis of recent and historic growth in  
24 the components that the Secretary includes under

1 the sustainable growth rate (under section 1848(f)  
2 of the Social Security Act (42 U.S.C. 1395w-4(f))).

3 (2) An examination of the relative growth of  
4 volume in physicians' services between medicare  
5 beneficiaries and other populations.

6 (3) An analysis of the degree to which new  
7 technology, including coverage determinations of the  
8 Centers for Medicare & Medicaid Services, has af-  
9 fected the volume of physicians' services.

10 (4) An examination of the impact on volume of  
11 demographic changes.

12 (5) An examination of shifts in the site of serv-  
13 ice or services that influence the number and inten-  
14 sity of services furnished in physicians' offices and  
15 the extent to which changes in reimbursement rates  
16 to other providers have effected these changes.

17 (6) An evaluation of the extent to which the  
18 Centers for Medicare & Medicaid Services takes into  
19 account the impact of law and regulations on the  
20 sustainable growth rate.

## 21 **Subtitle B—Preventive Services**

### 22 **SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYS-** 23 **ICAL EXAMINATION.**

24 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.  
25 1395x(s)(2)) is amended—

1           (1) in subparagraph (U), by striking “and” at  
2           the end;

3           (2) in subparagraph (V)(iii), by inserting “and”  
4           at the end; and

5           (3) by adding at the end the following new sub-  
6           paragraph:

7           “(W) an initial preventive physical examination  
8           (as defined in subsection (ww));”.

9           (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.  
10          1395x) is amended by adding at the end the following new  
11          subsection:

12           “Initial Preventive Physical Examination

13           “(ww)(1) The term ‘initial preventive physical exam-  
14          ination’ means physicians’ services consisting of a physical  
15          examination (including measurement of height, weight,  
16          and blood pressure, and an electrocardiogram) with the  
17          goal of health promotion and disease detection and in-  
18          cludes education, counseling, and referral with respect to  
19          screening and other preventive services described in para-  
20          graph (2), but does not include clinical laboratory tests.

21           “(2) The screening and other preventive services de-  
22          scribed in this paragraph include the following:

23           “(A) Pneumococcal, influenza, and hepatitis B  
24          vaccine and administration under subsection (s)(10).



1           “(B) Screening mammography as defined in  
2           subsection (jj).

3           “(C) Screening pap smear and screening pelvic  
4           exam as defined in subsection (nn).

5           “(D) Prostate cancer screening tests as defined  
6           in subsection (oo).

7           “(E) Colorectal cancer screening tests as de-  
8           fined in subsection (pp).

9           “(F) Diabetes outpatient self-management  
10          training services as defined in subsection (qq)(1).

11          “(G) Bone mass measurement as defined in  
12          subsection (rr).

13          “(H) Screening for glaucoma as defined in sub-  
14          section (uu).

15          “(I) Medical nutrition therapy services as de-  
16          fined in subsection (vv).

17          “(J) Cardiovascular screening blood tests as de-  
18          fined in subsection (xx)(1).

19          “(K) Diabetes screening tests as defined in sub-  
20          section (yy).”.

21          (c) PAYMENT AS PHYSICIANS’ SERVICES.—Section  
22          1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by in-  
23          serting “(2)(W),” after “(2)(S),”.

1 (d) OTHER CONFORMING AMENDMENTS.—(1) Sec-  
2 tion 1862(a) (42 U.S.C. 1395y(a)), as amended by section  
3 303(i)(3)(B), is amended—

4 (A) in paragraph (1)—

5 (i) by striking “and” at the end of sub-  
6 paragraph (I);

7 (ii) by striking the semicolon at the end of  
8 subparagraph (J) and inserting “, and”; and

9 (iii) by adding at the end the following new  
10 subparagraph:

11 “(K) in the case of an initial preventive physical  
12 examination, which is performed not later than 6  
13 months after the date the individual’s first coverage  
14 period begins under part B;” a

15 (B) in paragraph (7), by striking “or (H)” and  
16 inserting “(H), or (K)”.

17 (2) Clauses (i) and (ii) of section 1861(s)(2)(K) (42  
18 U.S.C. 1395x(s)(2)(K)) are each amended by inserting  
19 “and services described in subsection (ww)(1)” after  
20 “services which would be physicians’ services”.

21 (e) EFFECTIVE DATE.—The amendments made by  
22 this section shall apply to services furnished on or after  
23 January 1, 2005, but only for individuals whose coverage  
24 period under part B begins on or after such date.

1 **SEC. 612. COVERAGE OF CARDIOVASCULAR SCREENING**  
2 **BLOOD TESTS.**

3 (a) **COVERAGE.**—Section 1861(s)(2) (42 U.S.C.  
4 1395x(s)(2)), as amended by section 611(a), is amended—

5 (1) in subparagraph (V)(iii), by striking “and”  
6 at the end;

7 (2) in subparagraph (W), by inserting “and” at  
8 the end; and

9 (3) by adding at the end the following new sub-  
10 paragraph:

11 “(X) cardiovascular screening blood tests (as  
12 defined in subsection (xx)(1));”.

13 (b) **SERVICES DESCRIBED.**—Section 1861 (42 U.S.C.  
14 1395x) is amended by adding at the end the following new  
15 subsection:

16 “Cardiovascular Screening Blood Test

17 “(xx)(1) The term ‘cardiovascular screening blood  
18 test’ means a blood test for the early detection of cardio-  
19 vascular disease (or abnormalities associated with an ele-  
20 vated risk of cardiovascular disease) that tests for the fol-  
21 lowing:

22 “(A) Cholesterol levels and other lipid or  
23 triglyceride levels.

24 “(B) Such other indications associated with the  
25 presence of, or an elevated risk for, cardiovascular  
26 disease as the Secretary may approve for all individ-

1 uals (or for some individuals determined by the Sec-  
2 retary to be at risk for cardiovascular disease), in-  
3 cluding indications measured by noninvasive testing.  
4 The Secretary may not approve an indication under sub-  
5 paragraph (B) for any individual unless a blood test for  
6 such is recommended by the United States Preventive  
7 Services Task Force.

8 “(2) The Secretary shall establish standards, in con-  
9 sultation with appropriate organizations, regarding the  
10 frequency for each type of cardiovascular screening blood  
11 tests, except that such frequency may not be more often  
12 than once every 2 years.”.

13 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.  
14 1395y(a)(1)), as amended by section 611(d), is amended—

15 (1) by striking “and” at the end of subparagraph (J);

16 (2) by striking the semicolon at the end of subpara-  
17 graph (K) and inserting “, and”; and

18 (3) by adding at the end the following new subpara-  
19 graph:

20 “(L) in the case of cardiovascular screening blood  
21 tests (as defined in section 1861(xx)(1)), which are per-  
22 formed more frequently than is covered under section  
23 1861(xx)(2);”.

24 (d) EFFECTIVE DATE.—The amendments made by this  
25 section shall apply to tests furnished on or after January 1,  
26 2005.

27 **SEC. 613. COVERAGE OF DIABETES SCREENING TESTS.**

28 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.  
29 1395x(s)(2)), as amended by section 612(a), is amended—

30 (1) in subparagraph (W), by striking “and” at the  
31 end;

1 (2) in subparagraph (X), by adding “and” at the end;  
2 and

3 (3) by adding at the end the following new subpara-  
4 graph:

5 “(Y) diabetes screening tests (as defined in subsection  
6 (yy));”.

7 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.  
8 1395x), as amended by section 612(b), is amended by adding  
9 at the end the following new subsection:

10 “Diabetes Screening Tests

11 “(yy)(1) The term ‘diabetes screening tests’ means testing  
12 furnished to an individual at risk for diabetes (as defined in  
13 paragraph (2)) for the purpose of early detection of diabetes,  
14 including—

15 “(A) a fasting plasma glucose test; and

16 “(B) such other tests, and modifications to tests, as  
17 the Secretary determines appropriate, in consultation with  
18 appropriate organizations.

19 “(2) For purposes of paragraph (1), the term ‘individual  
20 at risk for diabetes’ means an individual who has any of the  
21 following risk factors for diabetes:

22 “(A) Hypertension.

23 “(B) Dyslipidemia.

24 “(C) Obesity, defined as a body mass index greater  
25 than or equal to 30 kg/m<sup>2</sup>.

26 “(D) Previous identification of an elevated impaired  
27 fasting glucose.

28 “(E) Previous identification of impaired glucose toler-  
29 ance.

30 “(F) A risk factor consisting of at least 2 of the fol-  
31 lowing characteristics:

32 “(i) Overweight, defined as a body mass index  
33 greater than 25, but less than 30, kg/m<sup>2</sup>.

34 “(ii) A family history of diabetes.

35 “(iii) A history of gestational diabetes mellitus or  
36 delivery of a baby weighing greater than 9 pounds.

37 “(iv) 65 years of age or older.

1           “(3) The Secretary shall establish standards, in consulta-  
2           tion with appropriate organizations, regarding the frequency of  
3           diabetes screening tests, except that such frequency may not be  
4           more often than twice within the 12-month period following the  
5           date of the most recent diabetes screening test of that indi-  
6           vidual.”.

7           (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.  
8           1395y(a)(1)), as amended by section 612(c), is amended—

9           (1) by striking “and” at the end of subparagraph (K);

10           (2) by striking the semicolon at the end of subpara-  
11           graph (L) and inserting “, and”; and

12           (3) by adding at the end the following new subpara-  
13           graph:

14           “(M) in the case of a diabetes screening test (as de-  
15           fined in section 1861(yy)(1)), which is performed more fre-  
16           quently than is covered under section 1861(yy)(3);”.

17           (d) EFFECTIVE DATE.—The amendments made by this  
18           section shall apply to tests furnished on or after January 1,  
19           2005.

20           **SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**  
21           **RAPHY SERVICES.**

22           (a) EXCLUSION FROM OPD FEE SCHEDULE.—Section  
23           1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by  
24           inserting before the period at the end the following: “and does  
25           not include screening mammography (as defined in section  
26           1861(jj)) and diagnostic mammography”.

27           (b) CONFORMING AMENDMENT.—Section 1833(a)(2)(E)(i)  
28           (42 U.S.C. 1395l(a)(2)(E)(i)) is amended by inserting “and,  
29           for services furnished on or after January 1, 2005, diagnostic  
30           mammography” after “screening mammography”.

31           (c) EFFECTIVE DATE.—The amendments made by this  
32           section shall apply—

33           (1) in the case of screening mammography, to services  
34           furnished on or after the date of the enactment of this Act;  
35           and

36           (2) in the case of diagnostic mammography, to serv-  
37           ices furnished on or after January 1, 2005.

## Subtitle C—Other Provisions

### SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

#### (a) PAYMENT FOR DRUGS.—

(1) SPECIAL RULES FOR CERTAIN DRUGS AND BIOLOGICALS.—Section 1833(t) (42 U.S.C. 1395l(t)), as amended by section 411(b), is amended by inserting after paragraph (13) the following new paragraphs:

#### “(14) DRUG APC PAYMENT RATES.—

“(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

“(i) in 2004, in the case of—

“(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

“(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

“(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

“(ii) in 2005, in the case of—

“(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

“(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

“(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

1                   “(iii) in a subsequent year, shall be equal, sub-  
2                   ject to subparagraph (E)—

3                   “(I) to the average acquisition cost for the  
4                   drug for that year (which, at the option of the  
5                   Secretary, may vary by hospital group (as de-  
6                   fined by the Secretary based on volume of cov-  
7                   ered OPD services or other relevant character-  
8                   istics)), as determined by the Secretary taking  
9                   into account the hospital acquisition cost sur-  
10                  vey data under subparagraph (D); or

11                  “(II) if hospital acquisition cost data are  
12                  not available, the average price for the drug in  
13                  the year established under section 1842(o), sec-  
14                  tion 1847A, or section 1847B, as the case may  
15                  be, as calculated and adjusted by the Secretary  
16                  as necessary for purposes of this paragraph.

17                  “(B) SPECIFIED COVERED OUTPATIENT DRUG DE-  
18                  FINED.—

19                  “(i) IN GENERAL.—In this paragraph, the  
20                  term ‘specified covered outpatient drug’ means,  
21                  subject to clause (ii), a covered outpatient drug (as  
22                  defined in section 1927(k)(2)) for which a separate  
23                  ambulatory payment classification group (APC) has  
24                  been established and that is—

25                  “(I) a radiopharmaceutical; or

26                  “(II) a drug or biological for which pay-  
27                  ment was made under paragraph (6) (relating  
28                  to pass-through payments) on or before Decem-  
29                  ber 31, 2002.

30                  “(ii) EXCEPTION.—Such term does not  
31                  include—

32                  “(I) a drug or biological for which pay-  
33                  ment is first made on or after January 1,  
34                  2003, under paragraph (6);

35                  “(II) a drug or biological for which a tem-  
36                  porary HCPCS code has not been assigned; or



1                   “(III) during 2004 and 2005, an orphan  
2                   drug (as designated by the Secretary).

3                   “(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS  
4                   DURING 2004 AND 2005.—The amount of payment under  
5                   this subsection for an orphan drug designated by the  
6                   Secretary under subparagraph (B)(ii)(III) that is fur-  
7                   nished as part of a covered OPD service (or group of  
8                   services) during 2004 and 2005 shall equal such  
9                   amount as the Secretary may specify.

10                  “(D) ACQUISITION COST SURVEY FOR HOSPITAL  
11                  OUTPATIENT DRUGS.—

12                  “(i) ANNUAL GAO SURVEYS IN 2004 AND  
13                  2005.—

14                  “(I) IN GENERAL.—The Comptroller Gen-  
15                  eral of the United States shall conduct a survey  
16                  in each of 2004 and 2005 to determine the  
17                  hospital acquisition cost for each specified cov-  
18                  ered outpatient drug. Not later than April 1,  
19                  2005, the Comptroller General shall furnish  
20                  data from such surveys to the Secretary for use  
21                  in setting the payment rates under subpara-  
22                  graph (A) for 2006.

23                  “(II) RECOMMENDATIONS.—Upon the  
24                  completion of such surveys, the Comptroller  
25                  General shall recommend to the Secretary the  
26                  frequency and methodology of subsequent sur-  
27                  veys to be conducted by the Secretary under  
28                  clause (ii).

29                  “(ii) SUBSEQUENT SECRETARIAL SURVEYS.—  
30                  The Secretary, taking into account such rec-  
31                  ommendations, shall conduct periodic subsequent  
32                  surveys to determine the hospital acquisition cost  
33                  for each specified covered outpatient drug for use  
34                  in setting the payment rates under subparagraph  
35                  (A).

36                  “(iii) SURVEY REQUIREMENTS.—The surveys  
37                  conducted under clauses (i) and (ii) shall have a

1 large sample of hospitals that is sufficient to gen-  
2 erate a statistically significant estimate of the aver-  
3 age hospital acquisition cost for each specified cov-  
4 ered outpatient drug. With respect to the surveys  
5 conducted under clause (i), the Comptroller Gen-  
6 eral shall report to Congress on the justification for  
7 the size of the sample used in order to assure the  
8 validity of such estimates.

9 “(iv) DIFFERENTIATION IN COST.—In con-  
10 ducting surveys under clause (i), the Comptroller  
11 General shall determine and report to Congress if  
12 there is (and the extent of any) variation in hos-  
13 pital acquisition costs for drugs among hospitals  
14 based on the volume of covered OPD services per-  
15 formed by such hospitals or other relevant charac-  
16 teristics of such hospitals (as defined by the Comp-  
17 troller General).

18 “(v) COMMENT ON PROPOSED RATES.—Not  
19 later than 30 days after the date the Secretary pro-  
20 mulgated proposed rules setting forth the payment  
21 rates under subparagraph (A) for 2006, the Comp-  
22 troller General shall evaluate such proposed rates  
23 and submit to Congress a report regarding the ap-  
24 propriateness of such rates based on the surveys  
25 the Comptroller General has conducted under  
26 clause (i).

27 “(E) ADJUSTMENT IN PAYMENT RATES FOR OVER-  
28 HEAD COSTS.—

29 “(i) MEDPAC REPORT ON DRUG APC DE-  
30 SIGN.—The Medicare Payment Advisory Commis-  
31 sion shall submit to the Secretary, not later than  
32 July 1, 2005, a report on adjustment of payment  
33 for ambulatory payment classifications for specified  
34 covered outpatient drugs to take into account over-  
35 head and related expenses, such as pharmacy serv-  
36 ices and handling costs. Such report shall include—

1                   “(I) a description and analysis of the data  
2                   available with regard to such expenses;

3                   “(II) a recommendation as to whether  
4                   such a payment adjustment should be made;  
5                   and

6                   “(III) if such adjustment should be made,  
7                   a recommendation regarding the methodology  
8                   for making such an adjustment.

9                   “(ii) ADJUSTMENT AUTHORIZED.—The Sec-  
10                   retary may adjust the weights for ambulatory pay-  
11                   ment classifications for specified covered outpatient  
12                   drugs to take into account the recommendations  
13                   contained in the report submitted under clause (i).

14                   “(F) CLASSES OF DRUGS.—For purposes of this  
15                   paragraph:

16                   “(i) SOLE SOURCE DRUGS.—The term ‘sole  
17                   source drug’ means—

18                   “(I) a biological product (as defined under  
19                   section 1861(t)(1)) approved under a biologics  
20                   license application under section 351 of the  
21                   Public Health Service Act; or

22                   “(II) a single source drug (as defined in  
23                   section 1927(k)(7)(A)(iv)).

24                   “(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—  
25                   The term ‘innovator multiple source drug’ has the  
26                   meaning given such term in section  
27                   1927(k)(7)(A)(ii).

28                   “(iii) NONINNOVATOR MULTIPLE SOURCE  
29                   DRUGS.—The term ‘noninnovator multiple source  
30                   drug’ has the meaning given such term in section  
31                   1927(k)(7)(A)(iii).

32                   “(G) REFERENCE AVERAGE WHOLESALE PRICE.—  
33                   The term ‘reference average wholesale price’ means,  
34                   with respect to a specified covered outpatient drug, the  
35                   average wholesale price for the drug as determined  
36                   under section 1842(o) as of May 1, 2003.

1           “(H) INAPPLICABILITY OF EXPENDITURES IN DE-  
2           TERMINING CONVERSION, WEIGHTING, AND OTHER AD-  
3           JUSTMENT FACTORS.—Additional expenditures result-  
4           ing from this paragraph shall not be taken into account  
5           in establishing the conversion, weighting, and other ad-  
6           justment factors for 2004 and 2005 under paragraph  
7           (9), but shall be taken into account for subsequent  
8           years.

9           “(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS  
10          UNTIL HCPCS CODE ASSIGNED.—With respect to payment  
11          under this part for an outpatient drug or biological that is  
12          covered under this part and is furnished as part of covered  
13          OPD services for which a HCPCS code has not been as-  
14          signed, the amount provided for payment for such drug or  
15          biological under this part shall be equal to 95 percent of  
16          the average wholesale price for the drug or biological.”.

17          (2) REDUCTION IN THRESHOLD FOR SEPARATE APCS  
18          FOR DRUGS.—Section 1833(t)(16), as redesignated section  
19          411(b), is amended by adding at the end the following new  
20          subparagraph:

21                 “(B) THRESHOLD FOR ESTABLISHMENT OF SEPA-  
22                 RATE APCS FOR DRUGS.—The Secretary shall reduce  
23                 the threshold for the establishment of separate ambula-  
24                 tory payment classification groups (APCs) with respect  
25                 to drugs or biologicals to \$50 per administration for  
26                 drugs and biologicals furnished in 2005 and 2006.”.

27          (3) EXCLUSION OF SEPARATE DRUG APCS FROM  
28          OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by  
29          adding at the end the following new subparagraph:

30                 “(E) EXCLUSION OF SEPARATE DRUG AND BIO-  
31                 LOGICAL APCS FROM OUTLIER PAYMENTS.—No addi-  
32                 tional payment shall be made under subparagraph (A)  
33                 in the case of ambulatory payment classification groups  
34                 established separately for drugs or biologicals.”.

35          (4) PAYMENT FOR PASS THROUGH DRUGS.—Section  
36          1833(t)(6)(D)(i) (42 U.S.C. 1395l(t)(6)(D)(i)) is amended  
37          by inserting after “under section 1842(o)” the following:

1 “(or if the drug or biological is covered under a competitive  
2 acquisition contract under section 1847B, an amount deter-  
3 mined by the Secretary equal to the average price for the  
4 drug or biological for all competitive acquisition areas and  
5 year established under such section as calculated and ad-  
6 justed by the Secretary for purposes of this paragraph)”.

7 (5) CONFORMING AMENDMENT TO BUDGET NEU-  
8 TRALITY REQUIREMENT.—Section 1833(t)(9)(B) (42  
9 U.S.C. 1395l(t)(9)(B)) is amended by adding at the end  
10 the following: “In determining adjustments under the pre-  
11 ceding sentence for 2004 and 2005, the Secretary shall not  
12 take into account under this subparagraph or paragraph  
13 (2)(E) any expenditures that would not have been made  
14 but for the application of paragraph (14).”.

15 (6) EFFECTIVE DATE.—The amendments made by  
16 this subsection shall apply to items and services furnished  
17 on or after January 1, 2004.

18 (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

19 (1) IN GENERAL.—Section 1833(t)(16), as redesign-  
20 ated by section 411(b) and as amended by subsection  
21 (a)(2), is amended by adding at the end the following new  
22 subparagraph:

23 “(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY  
24 AT CHARGES ADJUSTED TO COST.—Notwithstanding  
25 the preceding provisions of this subsection, for a device  
26 of brachytherapy consisting of a seed or seeds (or ra-  
27 dioactive source) furnished on or after January 1,  
28 2004, and before January 1, 2007, the payment basis  
29 for the device under this subsection shall be equal to  
30 the hospital’s charges for each device furnished, ad-  
31 justed to cost. Charges for such devices shall not be in-  
32 cluded in determining any outlier payment under this  
33 subsection.”.

34 (2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY  
35 DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2)) is  
36 amended—

1 (A) in subparagraph (F), by striking “and” at the  
2 end;

3 (B) in subparagraph (G), by striking the period at  
4 the end and inserting “; and”; and

5 (C) by adding at the end the following new sub-  
6 paragraph:

7 “(H) with respect to devices of brachytherapy con-  
8 sisting of a seed or seeds (or radioactive source), the  
9 Secretary shall create additional groups of covered  
10 OPD services that classify such devices separately from  
11 the other services (or group of services) paid for under  
12 this subsection in a manner reflecting the number, iso-  
13 tope, and radioactive intensity of such devices fur-  
14 nished, including separate groups for palladium-103  
15 and iodine-125 devices.”.

16 (3) GAO REPORT.—The Comptroller General of the  
17 United States shall conduct a study to determine appro-  
18 priate payment amounts under section 1833(t)(16)(C) of  
19 the Social Security Act, as added by paragraph (1), for de-  
20 vices of brachytherapy. Not later than January 1, 2005,  
21 the Comptroller General shall submit to Congress and the  
22 Secretary a report on the study conducted under this para-  
23 graph, and shall include specific recommendations for ap-  
24 propriate payments for such devices.

25 **SEC. 622. LIMITATION OF APPLICATION OF FUNCTIONAL**  
26 **EQUIVALENCE STANDARD.**

27 Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by  
28 adding at the end the following new subparagraph:

29 “(F) LIMITATION OF APPLICATION OF FUNC-  
30 TIONAL EQUIVALENCE STANDARD.—

31 “(i) IN GENERAL.—The Secretary may not  
32 publish regulations that apply a functional equiva-  
33 lence standard to a drug or biological under this  
34 paragraph.

35 “(ii) APPLICATION.—Clause (i) shall apply to  
36 the application of a functional equivalence standard  
37 to a drug or biological on or after the date of en-

1 actment of the Medicare Prescription Drug, Im-  
2 provement, and Modernization Act of 2003  
3 unless—

4 “(I) such application was being made to  
5 such drug or biological prior to such date of en-  
6 actment; and

7 “(II) the Secretary applies such standard  
8 to such drug or biological only for the purpose  
9 of determining eligibility of such drug or bio-  
10 logical for additional payments under this para-  
11 graph and not for the purpose of any other  
12 payments under this title.

13 “(iii) RULE OF CONSTRUCTION.—Nothing in  
14 this subparagraph shall be construed to effect the  
15 Secretary’s authority to deem a particular drug to  
16 be identical to another drug if the 2 products are  
17 pharmaceutically equivalent and bioequivalent, as  
18 determined by the Commissioner of Food and  
19 Drugs.”.

20 **SEC. 623. PAYMENT FOR RENAL DIALYSIS SERVICES.**

21 (a) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR  
22 SERVICES FURNISHED.—The last sentence of section  
23 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended—

24 (1) by striking “and” before “for such services” the  
25 second place it appears;

26 (2) by inserting “and before January 1, 2005,” after  
27 “January 1, 2001,”; and

28 (3) by inserting before the period at the end the fol-  
29 lowing: “, and for such services furnished on or after Janu-  
30 ary 1, 2005, by 1.6 percent above such composite rate pay-  
31 ment amounts for such services furnished on December 31,  
32 2004”.

33 (b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDI-  
34 ATRIC FACILITIES.—

35 (1) IN GENERAL.—Section 422(a)(2) of BIPA is  
36 amended—

1 (A) in subparagraph (A), by striking “and (C)”  
2 and inserting “, (C), and (D)”;

3 (B) in subparagraph (B), by striking “In the  
4 case” and inserting “Subject to subparagraph (D), in  
5 the case”; and

6 (C) by adding at the end the following new sub-  
7 paragraph:

8 “(D) INAPPLICABILITY TO PEDIATRIC FACILI-  
9 TIES.—Subparagraphs (A) and (B) shall not apply, as  
10 of October 1, 2002, to pediatric facilities that do not  
11 have an exception rate described in subparagraph (C)  
12 in effect on such date. For purposes of this subpara-  
13 graph, the term ‘pediatric facility’ means a renal facil-  
14 ity at least 50 percent of whose patients are individuals  
15 under 18 years of age.”.

16 (2) CONFORMING AMENDMENT.—The fourth sentence  
17 of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended  
18 by striking “The Secretary” and inserting “Subject to sec-  
19 tion 422(a)(2) of the Medicare, Medicaid, and SCHIP Ben-  
20 efits Improvement and Protection Act of 2000, the Sec-  
21 retary”.

22 (c) INSPECTOR GENERAL STUDIES ON ESRD DRUGS.—

23 (1) IN GENERAL.—The Inspector General of the De-  
24 partment of Health and Human Services shall conduct two  
25 studies with respect to drugs and biologicals (including  
26 erythropoietin) furnished to end-stage renal disease pa-  
27 tients under the medicare program which are separately  
28 billed by end stage renal disease facilities.

29 (2) STUDIES ON ESRD DRUGS.—

30 (A) EXISTING DRUGS.—The first study under  
31 paragraph (1) shall be conducted with respect to such  
32 drugs and biologicals for which a billing code exists  
33 prior to January 1, 2004.

34 (B) NEW DRUGS.—The second study under para-  
35 graph (1) shall be conducted with respect to such drugs  
36 and biologicals for which a billing code does not exist  
37 prior to January 1, 2004.



1 (3) MATTERS STUDIED.—Under each study conducted  
2 under paragraph (1), the Inspector General shall—

3 (A) determine the difference between the amount  
4 of payment made to end stage renal disease facilities  
5 under title XVIII of the Social Security Act for such  
6 drugs and biologicals and the acquisition costs of such  
7 facilities for such drugs and biologicals and which are  
8 separately billed by end stage renal disease facilities,  
9 and

10 (B) estimate the rates of growth of expenditures  
11 for such drugs and biologicals billed by such facilities.

12 (4) REPORTS.—

13 (A) EXISTING ESRD DRUGS.—Not later than April  
14 1, 2004, the Inspector General shall report to the Sec-  
15 retary on the study described in paragraph (2)(A).

16 (B) NEW ESRD DRUGS.—Not later than April 1,  
17 2006, the Inspector General shall report to the Sec-  
18 retary on the study described in paragraph (2)(B).

19 (d) BASIC CASE-MIX ADJUSTED COMPOSITE RATE FOR  
20 RENAL DIALYSIS FACILITY SERVICES.—(1) Section 1881(b)  
21 (42 U.S.C. 1395rr(b)) is amended by adding at the end the fol-  
22 lowing new paragraphs:

23 “(12)(A) In lieu of payment under paragraph (7) begin-  
24 ning with services furnished on January 1, 2005, the Secretary  
25 shall establish a basic case-mix adjusted prospective payment  
26 system for dialysis services furnished by providers of services  
27 and renal dialysis facilities in a year to individuals in a facility  
28 and to such individuals at home. The case-mix under such sys-  
29 tem shall be for a limited number of patient characteristics.

30 “(B) The system described in subparagraph (A) shall  
31 include—

32 “(i) the services comprising the composite rate estab-  
33 lished under paragraph (7); and

34 “(ii) the difference between payment amounts under  
35 this title for separately billed drugs and biologicals (includ-  
36 ing erythropoietin) and acquisition costs of such drugs and  
37 biologicals, as determined by the Inspector General reports

1 to the Secretary as required by section 623(c) of the Medi-  
2 care Prescription Drug, Improvement, and Modernization  
3 Act of 2003—

4 “(I) beginning with 2005, for such drugs and  
5 biologicals for which a billing code exists prior to Janu-  
6 ary 1, 2004; and

7 “(II) beginning with 2007, for such drugs and  
8 biologicals for which a billing code does not exist prior  
9 to January 1, 2004,

10 adjusted to 2005, or 2007, respectively, as determined to  
11 be appropriate by the Secretary.

12 “(C)(i) In applying subparagraph (B)(ii) for 2005, such  
13 payment amounts under this title shall be determined using the  
14 methodology specified in paragraph (13)(A)(i).

15 “(ii) For 2006, the Secretary shall provide for an adjust-  
16 ment to the payments under clause (i) to reflect the difference  
17 between the payment amounts using the methodology under  
18 paragraph (13)(A)(i) and the payment amount determined  
19 using the methodology applied by the Secretary under para-  
20 graph (13)(A)(iii) of such paragraph, as estimated by the Sec-  
21 retary.

22 “(D) The Secretary shall adjust the payment rates under  
23 such system by a geographic index as the Secretary determines  
24 to be appropriate. If the Secretary applies a geographic index  
25 under this paragraph that differs from the index applied under  
26 paragraph (7) the Secretary shall phase-in the application of  
27 the index under this paragraph over a multiyear period.

28 “(E)(i) Such system shall be designed to result in the  
29 same aggregate amount of expenditures for such services, as  
30 estimated by the Secretary, as would have been made for 2005  
31 if this paragraph did not apply.

32 “(ii) The adjustment made under subparagraph (B)(ii)(II)  
33 shall be done in a manner to result in the same aggregate  
34 amount of expenditures after such adjustment as would other-  
35 wise have been made for such services for 2006 or 2007, re-  
36 spectively, as estimated by the Secretary, if this paragraph did  
37 not apply.

1           “(F) Beginning with 2006, the Secretary shall annually  
2 increase the basic case-mix adjusted payment amounts estab-  
3 lished under this paragraph, by an amount determined by—

4           “(i) applying the estimated growth in expenditures for  
5 drugs and biologicals (including erythropoietin) that are  
6 separately billable to the component of the basic case-mix  
7 adjusted system described in subparagraph (B)(ii); and

8           “(ii) converting the amount determined in clause (i) to  
9 an increase applicable to the basic case-mix adjusted pay-  
10 ment amounts established under subparagraph (B).

11 Nothing in this paragraph shall be construed as providing for  
12 an update to the composite rate component of the basic case-  
13 mix adjusted system under subparagraph (B).

14           “(G) There shall be no administrative or judicial review  
15 under section 1869, section 1878, or otherwise, of the case-mix  
16 system, relative weights, payment amounts, the geographic ad-  
17 justment factor, or the update for the system established under  
18 this paragraph, or the determination of the difference between  
19 medicare payment amounts and acquisition costs for separately  
20 billed drugs and biologicals (including erythropoietin) under  
21 this paragraph and paragraph (13).

22           “(13)(A) The payment amounts under this title for sepa-  
23 rately billed drugs and biologicals furnished in a year, begin-  
24 ning with 2004, are as follows:

25           “(i) For such drugs and biologicals (other than eryth-  
26 ropoietin) furnished in 2004, the amount determined under  
27 section 1842(o)(1)(A)(v) for the drug or biological.

28           “(ii) For such drugs and biologicals (including eryth-  
29 ropoietin) furnished in 2005, the acquisition cost of the  
30 drug or biological, as determined by the Inspector General  
31 reports to the Secretary as required by section 623(c) of  
32 the Medicare Prescription Drug, Improvement, and Mod-  
33 ernization Act of 2003. Insofar as the Inspector General  
34 has not determined the acquisition cost with respect to a  
35 drug or biological, the Secretary shall determine the pay-  
36 ment amount for such drug or biological.

1           “(iii) For such drugs and biologicals (including eryth-  
2           ropoietin) furnished in 2006 and subsequent years, such  
3           acquisition cost or the amount determined under section  
4           1847A for the drug or biological, as the Secretary may  
5           specify.

6           “(B)(i) Drugs and biologicals (including erythropoietin)  
7           which were separately billed under this subsection on the day  
8           before the date of the enactment of the Medicare Prescription  
9           Drug, Improvement, and Modernization Act of 2003 shall con-  
10          tinue to be separately billed on and after such date.

11          “(ii) Nothing in this paragraph, section 1842(o), section  
12          1847A, or section 1847B shall be construed as requiring or au-  
13          thorizing the bundling of payment for drugs and biologicals  
14          into the basic case-mix adjusted payment system under this  
15          paragraph.”.

16          (2) Paragraph (7) of such section is amended in the first  
17          sentence by striking “The Secretary” and inserting “Subject to  
18          paragraph (12), the Secretary”.

19          (3) Paragraph (11)(B) of such section is amended by in-  
20          serting “subject to paragraphs (12) and (13)” before “payment  
21          for such item”.

22          (e) DEMONSTRATION OF BUNDLED CASE-MIX ADJUSTED  
23          PAYMENT SYSTEM FOR ESRD SERVICES.—

24          (1) IN GENERAL.—The Secretary shall establish a  
25          demonstration project of the use of a fully case-mix ad-  
26          justed payment system for end stage renal disease services  
27          under section 1881 of the Social Security Act (42 U.S.C.  
28          1395rr) for patient characteristics identified in the report  
29          under subsection (f) that bundles into such payment rates  
30          amounts for—

31                  (A) drugs and biologicals (including erythro-  
32                  poietin) furnished to end stage renal disease patients  
33                  under the medicare program which are separately billed  
34                  by end stage renal disease facilities (as of the date of  
35                  the enactment of this Act); and

36                  (B) clinical laboratory tests related to such drugs  
37                  and biologicals.

1 (2) FACILITIES INCLUDED IN THE DEMONSTRATION.—

2 In conducting the demonstration under this subsection, the  
3 Secretary shall ensure the participation of a sufficient num-  
4 ber of providers of dialysis services and renal dialysis facili-  
5 ties, but in no case to exceed 500. In selecting such pro-  
6 viders and facilities, the Secretary shall ensure that the fol-  
7 lowing types of providers are included in the demonstra-  
8 tion:

9 (A) Urban providers and facilities.

10 (B) Rural providers and facilities.

11 (C) Not-for-profit providers and facilities.

12 (D) For-profit providers and facilities.

13 (E) Independent providers and facilities.

14 (F) Specialty providers and facilities, including pe-  
15 diatric providers and facilities and small providers and  
16 facilities.

17 (3) TEMPORARY ADD-ON PAYMENT FOR DIALYSIS  
18 SERVICES FURNISHED UNDER THE DEMONSTRATION.—

19 (A) IN GENERAL.—During the period of the dem-  
20 onstration project, the Secretary shall increase payment  
21 rates that would otherwise apply under section 1881(b)  
22 of such Act (42 U.S.C. 1395rr(b)) by 1.6 percent for  
23 dialysis services furnished in facilities in the dem-  
24 onstration site.

25 (B) RULES OF CONSTRUCTION.—Nothing in this  
26 subsection shall be construed as—

27 (i) as an annual update under section 1881(b)  
28 of the Social Security Act (42 U.S.C. 1395rr(b));

29 (ii) as increasing the baseline for payments  
30 under such section; or

31 (iii) requiring the budget neutral implementa-  
32 tion of the demonstration project under this sub-  
33 section.

34 (4) 3-YEAR PERIOD.—The Secretary shall conduct the  
35 demonstration under this subsection for the 3-year period  
36 beginning on January 1, 2006.

37 (5) USE OF ADVISORY BOARD.—

1 (A) IN GENERAL.—In carrying out the demonstra-  
2 tion under this subsection, the Secretary shall establish  
3 an advisory board comprised of representatives de-  
4 scribed in subparagraph (B) to provide advice and rec-  
5 ommendations with respect to the establishment and  
6 operation of such demonstration.

7 (B) REPRESENTATIVES.—Representatives referred  
8 to in subparagraph (A) include representatives of the  
9 following:

10 (i) Patient organizations.

11 (ii) Individuals with expertise in end stage  
12 renal dialysis services, such as clinicians, econo-  
13 mists, and researchers.

14 (iii) The Medicare Payment Advisory Commis-  
15 sion, established under section 1805 of the Social  
16 Security Act (42 U.S.C. 1395b–6).

17 (iv) The National Institutes of Health.

18 (v) Network organizations under section  
19 1881(c) of the Social Security Act (42 U.S.C.  
20 1395rr(c)).

21 (vi) Medicare contractors to monitor quality of  
22 care.

23 (vii) Providers of services and renal dialysis  
24 facilities furnishing end stage renal disease serv-  
25 ices.

26 (C) TERMINATION OF ADVISORY PANEL.—The ad-  
27 visory panel shall terminate on December 31, 2008.

28 (6) AUTHORIZATION OF APPROPRIATIONS.—There are  
29 authorized to be appropriated, in appropriate part from the  
30 Federal Hospital Insurance Trust Fund and the Federal  
31 Supplementary Medical Insurance Trust Fund, \$5,000,000  
32 in fiscal year 2006 to conduct the demonstration under this  
33 subsection.

34 (f) REPORT ON A BUNDLED PROSPECTIVE PAYMENT SYS-  
35 TEM FOR END STAGE RENAL DISEASE SERVICES.—

36 (1) REPORT.—

1 (A) IN GENERAL.—Not later than October 1,  
2 2005, the Secretary shall submit to Congress a report  
3 detailing the elements and features for the design and  
4 implementation of a bundled prospective payment sys-  
5 tem for services furnished by end stage renal disease  
6 facilities including, to the maximum extent feasible,  
7 bundling of drugs, clinical laboratory tests, and other  
8 items that are separately billed by such facilities. The  
9 report shall include a description of the methodology to  
10 be used for the establishment of payment rates, includ-  
11 ing components of the new system described in para-  
12 graph (2).

13 (B) RECOMMENDATIONS.—The Secretary shall in-  
14 clude in such report recommendations on elements, fea-  
15 tures, and methodology for a bundled prospective pay-  
16 ment system or other issues related to such system as  
17 the Secretary determines to be appropriate.

18 (2) ELEMENTS AND FEATURES OF A BUNDLED PRO-  
19 SPECTIVE PAYMENT SYSTEM.—The report required under  
20 paragraph (1) shall include the following elements and fea-  
21 tures of a bundled prospective payment system:

22 (A) BUNDLE OF ITEMS AND SERVICES.—A de-  
23 scription of the bundle of items and services to be in-  
24 cluded under the prospective payment system.

25 (B) CASE MIX.—A description of the case-mix ad-  
26 justment to account for the relative resource use of dif-  
27 ferent types of patients.

28 (C) WAGE INDEX.—A description of an adjust-  
29 ment to account for geographic differences in wages.

30 (D) RURAL AREAS.—The appropriateness of es-  
31 tablishing a specific payment adjustment to account for  
32 additional costs incurred by rural facilities.

33 (E) OTHER ADJUSTMENTS.—Such other adjust-  
34 ments as may be necessary to reflect the variation in  
35 costs incurred by facilities in caring for patients with  
36 end stage renal disease.

1 (F) UPDATE FRAMEWORK.—A methodology for  
2 appropriate updates under the prospective payment  
3 system.

4 (G) ADDITIONAL RECOMMENDATIONS.—Such  
5 other matters as the Secretary determines to be appro-  
6 priate.

7 **SEC. 624. 2-YEAR MORATORIUM ON THERAPY CAPS;**  
8 **PROVISIONS RELATING TO REPORTS.**

9 (a) ADDITIONAL MORATORIUM ON THERAPY CAPS.—

10 (1) 2004 AND 2005.—Section 1833(g)(4) (42 U.S.C.  
11 1395l(g)(4)) is amended by striking “and 2002” and in-  
12 serting “2002, 2004, and 2005”.

13 (2) REMAINDER OF 2003.—For the period beginning  
14 on the date of the enactment of this Act and ending of De-  
15 cember 31, 2003, the Secretary shall not apply the provi-  
16 sions of paragraphs (1), (2), and (3) of section 1833(g) to  
17 expenses incurred with respect to services described in such  
18 paragraphs during such period. Nothing in the preceding  
19 sentence shall be construed as affecting the application of  
20 such paragraphs by the Secretary before the date of the en-  
21 actment of this Act.

22 (b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAY-  
23 MENT AND UTILIZATION OF OUTPATIENT THERAPY SERV-  
24 ICES.—Not later than March 31, 2004, the Secretary shall sub-  
25 mit to Congress the reports required under section 4541(d)(2)  
26 of the Balanced Budget Act of 1997 (Public Law 105–33; 111  
27 Stat. 457) (relating to alternatives to a single annual dollar cap  
28 on outpatient therapy) and under section 221(d) of the Medi-  
29 care, Medicaid, and SCHIP Balanced Budget Refinement Act  
30 of 1999 (Appendix F, 113 Stat. 1501A–352), as enacted into  
31 law by section 1000(a)(6) of Public Law 106–113 (relating to  
32 utilization patterns for outpatient therapy).

33 (c) GAO REPORT IDENTIFYING CONDITIONS AND DIS-  
34 EASES JUSTIFYING WAIVER OF THERAPY CAP.—

35 (1) STUDY.—The Comptroller General of the United  
36 States shall identify conditions or diseases that may justify  
37 waiving the application of the therapy caps under section



1 1833(g) of the Social Security Act (42 U.S.C. 1395l(g))  
2 with respect to such conditions or diseases.

3 (2) REPORT TO CONGRESS.—Not later than October 1,  
4 2004, the Comptroller General shall submit to Congress a  
5 report on the conditions and diseases identified under para-  
6 graph (1), and shall include a recommendation of criteria,  
7 with respect to such conditions and disease, under which a  
8 waiver of the therapy caps would apply.

9 **SEC. 625. WAIVER OF PART B LATE ENROLLMENT PEN-**  
10 **ALTY FOR CERTAIN MILITARY RETIREES;**  
11 **SPECIAL ENROLLMENT PERIOD.**

12 (a) WAIVER OF PENALTY.—

13 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.  
14 1395r(b)) is amended by adding at the end the following  
15 new sentence: “No increase in the premium shall be ef-  
16 fected for a month in the case of an individual who enrolls  
17 under this part during 2001, 2002, 2003, or 2004 and who  
18 demonstrates to the Secretary before December 31, 2004,  
19 that the individual is a covered beneficiary (as defined in  
20 section 1072(5) of title 10, United States Code). The Sec-  
21 retary of Health and Human Services shall consult with the  
22 Secretary of Defense in identifying individuals described in  
23 the previous sentence.”.

24 (2) EFFECTIVE DATE.—The amendment made by  
25 paragraph (1) shall apply to premiums for months begin-  
26 ning with January 2004. The Secretary shall establish a  
27 method for providing rebates of premium penalties paid for  
28 months on or after January 2004 for which a penalty does  
29 not apply under such amendment but for which a penalty  
30 was previously collected.

31 (b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

32 (1) IN GENERAL.—In the case of any individual who,  
33 as of the date of the enactment of this Act, is eligible to  
34 enroll but is not enrolled under part B of title XVIII of the  
35 Social Security Act and is a covered beneficiary (as defined  
36 in section 1072(5) of title 10, United States Code), the  
37 Secretary of Health and Human Services shall provide for

1 a special enrollment period during which the individual may  
2 enroll under such part. Such period shall begin as soon as  
3 possible after the date of the enactment of this Act and  
4 shall end on December 31, 2004.

5 (2) COVERAGE PERIOD.—In the case of an individual  
6 who enrolls during the special enrollment period provided  
7 under paragraph (1), the coverage period under part B of  
8 title XVIII of the Social Security Act shall begin on the  
9 first day of the month following the month in which the in-  
10 dividual enrolls.

11 **SEC. 626. PAYMENT FOR SERVICES FURNISHED IN AM-**  
12 **BULATORY SURGICAL CENTERS.**

13 (a) REDUCTIONS IN PAYMENT UPDATES.—Section  
14 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended to read as  
15 follows:

16 “(C)(i) Notwithstanding the second sentence of each of  
17 subparagraphs (A) and (B), except as otherwise specified in  
18 clauses (ii), (iii), and (iv), if the Secretary has not updated  
19 amounts established under such subparagraphs or under sub-  
20 paragraph (D), with respect to facility services furnished dur-  
21 ing a fiscal year (beginning with fiscal year 1986 or a calendar  
22 year (beginning with 2006)), such amounts shall be increased  
23 by the percentage increase in the Consumer Price Index for all  
24 urban consumers (U.S. city average) as estimated by the Sec-  
25 retary for the 12-month period ending with the midpoint of the  
26 year involved.

27 “(ii) In each of the fiscal years 1998 through 2002, the  
28 increase under this subparagraph shall be reduced (but not  
29 below zero) by 2.0 percentage points.

30 “(iii) In fiscal year 2004, beginning with April 1, 2004,  
31 the increase under this subparagraph shall be the Consumer  
32 Price Index for all urban consumers (U.S. city average) as esti-  
33 mated by the Secretary for the 12-month period ending with  
34 March 31, 2003, minus 3.0 percentage points.

35 “(iv) In fiscal year 2005, the last quarter of calendar year  
36 2005, and each of calendar years 2006 through 2009, the in-  
37 crease under this subparagraph shall be 0 percent.”

1 (b) REPEAL OF SURVEY REQUIREMENT AND IMPLEMEN-  
2 TATION OF NEW SYSTEM.—Section 1833(i)(2) (42 U.S.C.  
3 1395l(i)(2)) is amended—

4 (1) in subparagraph (A)—

5 (A) in the matter preceding clause (i), by striking  
6 “The” and inserting “For services furnished prior to  
7 the implementation of the system described in subpara-  
8 graph (D), the”; and

9 (B) in clause (i), by striking “taken not later than  
10 January 1, 1995, and every 5 years thereafter,”; and

11 (2) by adding at the end the following new subpara-  
12 graph:

13 “(D)(i) Taking into account the recommendations in the  
14 report under section 626(d) of Medicare Prescription Drug,  
15 Improvement, and Modernization Act of 2003, the Secretary  
16 shall implement a revised payment system for payment of sur-  
17 gical services furnished in ambulatory surgical centers.

18 “(ii) In the year the system described in clause (i) is im-  
19 plemented, such system shall be designed to result in the same  
20 aggregate amount of expenditures for such services as would be  
21 made if this subparagraph did not apply, as estimated by the  
22 Secretary.

23 “(iii) The Secretary shall implement the system described  
24 in clause (i) for periods in a manner so that it is first effective  
25 beginning on or after January 1, 2006, and not later than Jan-  
26 uary 1, 2008.

27 “(iv) There shall be no administrative or judicial review  
28 under section 1869, 1878, or otherwise, of the classification  
29 system, the relative weights, payment amounts, and the geo-  
30 graphic adjustment factor, if any, under this subparagraph.”.

31 (c) CONFORMING AMENDMENT.—Section 1833(a)(1) (42  
32 U.S.C. 1395l(a)(1)) is amended by adding the following new  
33 subparagraph:

34 “(G) with respect to facility services furnished in  
35 connection with a surgical procedure specified pursuant  
36 to subsection (i)(1)(A) and furnished to an individual  
37 in an ambulatory surgical center described in such sub-

1 section, for services furnished beginning with the imple-  
2 mentation date of a revised payment system for such  
3 services in such facilities specified in subsection  
4 (i)(2)(D), the amounts paid shall be 80 percent of the  
5 lesser of the actual charge for the services or the  
6 amount determined by the Secretary under such revised  
7 payment system.”.

8 (d) GAO STUDY OF AMBULATORY SURGICAL CENTER  
9 PAYMENTS.—

10 (1) STUDY.—

11 (A) IN GENERAL.—The Comptroller General of  
12 the United States shall conduct a study that compares  
13 the relative costs of procedures furnished in ambulatory  
14 surgical centers to the relative costs of procedures fur-  
15 nished in hospital outpatient departments under section  
16 1833(t) of the Social Security Act (42 U.S.C.  
17 1395l(t)). The study shall also examine how accurately  
18 ambulatory payment categories reflect procedures fur-  
19 nished in ambulatory surgical centers.

20 (B) CONSIDERATION OF ASC DATA.—In con-  
21 ducting the study under paragraph (1), the Comptroller  
22 General shall consider data submitted by ambulatory  
23 surgical centers regarding the matters described in  
24 clauses (i) through (iii) of paragraph (2)(B).

25 (2) REPORT AND RECOMMENDATIONS.—

26 (A) REPORT.—Not later than January 1, 2005,  
27 the Comptroller General shall submit to Congress a re-  
28 port on the study conducted under paragraph (1).

29 (B) RECOMMENDATIONS.—The report submitted  
30 under subparagraph (A) shall include recommendations  
31 on the following matters:

32 (i) The appropriateness of using the groups of  
33 covered services and relative weights established  
34 under the outpatient prospective payment system  
35 as the basis of payment for ambulatory surgical  
36 centers.

1 (ii) If the relative weights under such hospital  
2 outpatient prospective payment system are appro-  
3 priate for such purpose—

4 (I) whether the payment rates for ambula-  
5 tory surgical centers should be based on a uni-  
6 form percentage of the payment rates or  
7 weights under such outpatient system; or

8 (II) whether the payment rates for ambu-  
9 latory surgical centers should vary, or the  
10 weights should be revised, based on specific  
11 procedures or types of services (such as oph-  
12 thalmology and pain management services).

13 (iii) Whether a geographic adjustment should  
14 be used for payment of services furnished in ambu-  
15 latory surgical centers, and if so, the labor and  
16 nonlabor shares of such payment.

17 **SEC. 627. PAYMENT FOR CERTAIN SHOES AND INSERTS**  
18 **UNDER THE FEE SCHEDULE FOR ORTHOTICS**  
19 **AND PROSTHETICS.**

20 (a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o))  
21 is amended—

22 (1) in paragraph (1)(B), by striking “no more than  
23 the limits established under paragraph (2)” and inserting  
24 “no more than the amount of payment applicable under  
25 paragraph (2)”; and

26 (2) in paragraph (2), to read as follows:

27 “(2)(A) Except as provided by the Secretary under sub-  
28 paragraphs (B) and (C), the amount of payment under this  
29 paragraph for custom molded shoes, extra-depth shoes, and in-  
30 serts shall be the amount determined for such items by the  
31 Secretary under section 1834(h).

32 “(B) The Secretary may establish payment amounts for  
33 shoes and inserts that are lower than the amount established  
34 under section 1834(h) if the Secretary finds that shoes and in-  
35 serts of an appropriate quality are readily available at or below  
36 the amount established under such section.

1           “(C) In accordance with procedures established by the  
2 Secretary, an individual entitled to benefits with respect to  
3 shoes described in section 1861(s)(12) may substitute modifica-  
4 tion of such shoes instead of obtaining one (or more, as speci-  
5 fied by the Secretary) pair of inserts (other than the original  
6 pair of inserts with respect to such shoes). In such case, the  
7 Secretary shall substitute, for the payment amount established  
8 under section 1834(h), a payment amount that the Secretary  
9 estimates will assure that there is no net increase in expendi-  
10 tures under this subsection as a result of this subparagraph.”.

11           (b) CONFORMING AMENDMENTS.—(1) Section  
12 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by in-  
13 sserting “(and includes shoes described in section 1861(s)(12))”  
14 after “in section 1861(s)(9)”.

15           (2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amend-  
16 ed by striking subparagraph (C).

17           (c) EFFECTIVE DATE.—The amendments made by this  
18 section shall apply to items furnished on or after January 1,  
19 2005.

20           **SEC. 628. PAYMENT FOR CLINICAL DIAGNOSTIC LAB-**  
21           **ORATORY TESTS.**

22           Section 1833(h)(2)(A)(ii)(IV) (42 U.S.C.  
23 1395l(h)(2)(A)(ii)(IV)) is amended by striking “and 1998  
24 through 2002” and inserting “, 1998 through 2002, and 2004  
25 through 2008”.

26           **SEC. 629. INDEXING PART B DEDUCTIBLE TO INFLA-**  
27           **TION.**

28           The first sentence of section 1833(b) (42 U.S.C. 1395l(b))  
29 is amended by striking “and \$100 for 1991 and subsequent  
30 years” and inserting the following: “, \$100 for 1991 through  
31 2004, \$110 for 2005, and for a subsequent year the amount  
32 of such deductible for the previous year increased by the annual  
33 percentage increase in the monthly actuarial rate under section  
34 1839(a)(1) ending with such subsequent year (rounded to the  
35 nearest \$1)”.

1     **SEC. 630. 5-YEAR AUTHORIZATION OF REIMBURSEMENT**  
2                     **FOR ALL MEDICARE PART B SERVICES FUR-**  
3                     **NISHED BY CERTAIN INDIAN HOSPITALS**  
4                     **AND CLINICS.**

5             Section 1880(e)(1)(A) (42 U.S.C. 1395qq(e)(1)(A)) is  
6     amended by inserting “(and for items and services furnished  
7     during the 5-year period beginning on January 1, 2005, all  
8     items and services for which payment may be made under part  
9     B)” after “for services described in paragraph (2)”.

10     **Subtitle D—Additional Demonstrations,**  
11             **Studies, and Other Provi-**  
12             **sions**

13     **SEC. 641. DEMONSTRATION PROJECT FOR COVERAGE**  
14                     **OF CERTAIN PRESCRIPTION DRUGS AND**  
15                     **BIOLOGICALS.**

16             (a) DEMONSTRATION PROJECT.—The Secretary shall con-  
17     duct a demonstration project under part B of title XVIII of the  
18     Social Security Act under which payment is made for drugs or  
19     biologicals that are prescribed as replacements for drugs and  
20     biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q)  
21     of such Act (42 U.S.C. 1395x(s)(2)(A), 1395x(s)(2)(Q)), or  
22     both, for which payment is made under such part. Such project  
23     shall provide for cost-sharing applicable with respect to such  
24     drugs or biologicals in the same manner as cost-sharing applies  
25     with respect to part D drugs under standard prescription drug  
26     coverage (as defined in section 1860D–2(b) of the Social Secu-  
27     rity Act, as added by section 101(a)).

28             (b) DEMONSTRATION PROJECT SITES.—The project estab-  
29     lished under this section shall be conducted in sites selected by  
30     the Secretary.

31             (c) DURATION.—The Secretary shall conduct the dem-  
32     onstration project for the 2-year period beginning on the date  
33     that is 90 days after the date of the enactment of this Act, but  
34     in no case may the project extend beyond December 31, 2005.

35             (d) LIMITATION.—Under the demonstration project over  
36     the duration of the project, the Secretary may not provide—

37                     (1) coverage for more than 50,000 patients; and

1 (2) more than \$500,000,000 in funding.

2 (e) REPORT.—Not later than July 1, 2006, the Secretary  
3 shall submit to Congress a report on the project. The report  
4 shall include an evaluation of patient access to care and patient  
5 outcomes under the project, as well as an analysis of the cost  
6 effectiveness of the project, including an evaluation of the costs  
7 savings (if any) to the medicare program attributable to re-  
8 duced physicians' services and hospital outpatient departments  
9 services for administration of the biological.

10 **SEC. 642. EXTENSION OF COVERAGE OF INTRAVENOUS**  
11 **IMMUNE GLOBULIN (IVIG) FOR THE TREAT-**  
12 **MENT OF PRIMARY IMMUNE DEFICIENCY**  
13 **DISEASES IN THE HOME.**

14 (a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as  
15 amended by sections 611(a) and 612(a) is amended—

16 (1) in subsection (s)(2)—

17 (A) by striking “and” at the end of subparagraph  
18 (X);

19 (B) by adding “and” at the end of subparagraph  
20 (Y); and

21 (C) by adding at the end the following new sub-  
22 paragraph:

23 “(Z) intravenous immune globulin for the treat-  
24 ment of primary immune deficiency diseases in the  
25 home (as defined in subsection (zz));” and

26 (2) by adding at the end the following new subsection:

27 “Intravenous Immune Globulin

28 “(zz) The term ‘intravenous immune globulin’ means an  
29 approved pooled plasma derivative for the treatment in the pa-  
30 tient’s home of a patient with a diagnosed primary immune de-  
31 ficiency disease, but not including items or services related to  
32 the administration of the derivative, if a physician determines  
33 administration of the derivative in the patient’s home is medi-  
34 cally appropriate.”.

35 (b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section  
36 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by in-  
37 serting “(including intravenous immune globulin (as defined in



1 section 1861(zz)))” after “with respect to drugs and  
2 biologicals”.

3 (c) EFFECTIVE DATE.—The amendments made by this  
4 section shall apply to items furnished administered on or after  
5 January 1, 2004.

6 **SEC. 643. MEDPAC STUDY OF COVERAGE OF SURGICAL**  
7 **FIRST ASSISTING SERVICES OF CERTIFIED**  
8 **REGISTERED NURSE FIRST ASSISTANTS.**

9 (a) STUDY.—The Medicare Payment Advisory Commission  
10 (in this section referred to as the “Commission”) shall conduct  
11 a study on the feasibility and advisability of providing for pay-  
12 ment under part B of title XVIII of the Social Security Act  
13 for surgical first assisting services furnished by a certified reg-  
14 istered nurse first assistant to medicare beneficiaries.

15 (b) REPORT.—Not later than January 1, 2005, the Com-  
16 mission shall submit to Congress a report on the study con-  
17 ducted under subsection (a) together with recommendations for  
18 such legislation or administrative action as the Commission de-  
19 termines to be appropriate.

20 (c) DEFINITIONS.—In this section:

21 (1) SURGICAL FIRST ASSISTING SERVICES.—The term  
22 “surgical first assisting services” means services consisting  
23 of first assisting a physician with surgery and related pre-  
24 operative, intraoperative, and postoperative care (as deter-  
25 mined by the Secretary) furnished by a certified registered  
26 nurse first assistant (as defined in paragraph (2)) which  
27 the certified registered nurse first assistant is legally au-  
28 thorized to perform by the State in which the services are  
29 performed.

30 (2) CERTIFIED REGISTERED NURSE FIRST ASSIST-  
31 ANT.—The term “certified registered nurse first assistant”  
32 means an individual who—

33 (A) is a registered nurse and is licensed to prac-  
34 tice nursing in the State in which the surgical first as-  
35 sisting services are performed;

1 (B) has completed a minimum of 2,000 hours of  
2 first assisting a physician with surgery and related pre-  
3 operative, intraoperative, and postoperative care; and

4 (C) is certified as a registered nurse first assistant  
5 by an organization recognized by the Secretary.

6 **SEC. 644. MEDPAC STUDY OF PAYMENT FOR CARDIO-**  
7 **THORACIC SURGEONS.**

8 (a) STUDY.—The Medicare Payment Advisory Commission  
9 (in this section referred to as the “Commission”) shall conduct  
10 a study on the practice expense relative values established by  
11 the Secretary of Health and Human Services under the medi-  
12 care physician fee schedule under section 1848 of the Social  
13 Security Act (42 U.S.C. 1395w–4) for the specialty of thoracic  
14 surgery to determine whether such values adequately take into  
15 account the attendant costs of nurse assistants at surgery.

16 (b) REPORT.—Not later than January 1, 2005, the Com-  
17 mission shall submit to Congress a report on the study con-  
18 ducted under subsection (a) together with recommendations for  
19 such legislation or administrative action as the Commission de-  
20 termines to be appropriate.

21 **SEC. 645. STUDIES RELATING TO VISION IMPAIRMENTS.**

22 (a) COVERAGE OF OUTPATIENT VISION SERVICES FUR-  
23 NISHED BY VISION REHABILITATION PROFESSIONALS UNDER  
24 PART BK.—

25 (1) STUDY.—The Secretary shall conduct a study to  
26 determine the feasibility and advisability of providing for  
27 payment for vision rehabilitation services furnished by vi-  
28 sion rehabilitation professionals.

29 (2) REPORT.—Not later than January 1, 2005, the  
30 Secretary shall submit to Congress a report on the study  
31 conducted under paragraph (1) together with recommenda-  
32 tions for such legislation or administrative action as the  
33 Secretary determines to be appropriate.

34 (3) VISION REHABILITATION PROFESSIONAL DE-  
35 FINED.—In this subsection, the term “vision rehabilitation  
36 professional” means an orientation and mobility specialist,  
37 a rehabilitation teacher, or a low vision therapist.

1 (b) REPORT ON APPROPRIATENESS OF A DEMONSTRATION  
2 PROJECT TO TEST FEASIBILITY OF USING PPO NETWORKS  
3 TO REDUCE COSTS OF ACQUIRING EYEGLASSES FOR MEDI-  
4 CARE BENEFICIARIES AFTER CATARACT SURGERY.—Not later  
5 than 1 year after the date of the enactment of this Act, the  
6 Secretary shall submit to Congress a report on the feasibility  
7 of establishing a two-year demonstration project under which  
8 the Secretary enters into arrangements with vision care pre-  
9 ferred provider organization networks to furnish and pay for  
10 conventional eyeglasses subsequent to each cataract surgery  
11 with insertion of an intraocular lens on behalf of Medicare  
12 beneficiaries. In such report, the Secretary shall include an es-  
13 timate of potential cost savings to the Medicare program  
14 through the use of such networks, taking into consideration  
15 quality of service and beneficiary access to services offered by  
16 vision care preferred provider organization networks.

17 **SEC. 646. MEDICARE HEALTH CARE QUALITY DEM-**  
18 **ONSTRATION PROGRAMS.**

19 Title XVIII (42 U.S.C. 1395 et seq.) is amended by in-  
20 serting after section 1866B the following new section:

21 “HEALTH CARE QUALITY DEMONSTRATION PROGRAM

22 “SEC. 1866C. (a) DEFINITIONS.—In this section:

23 “(1) BENEFICIARY.—The term ‘beneficiary’ means n  
24 individual who is entitled to benefits under part A and en-  
25 rolled under part B, including any individual who is en-  
26 rolled in a Medicare Advantage plan under part C.

27 “(2) HEALTH CARE GROUP.—

28 “(A) IN GENERAL.—The term ‘health care group’  
29 means—

30 “(i) a group of physicians that is organized at  
31 least in part for the purpose of providing physi-  
32 cian’s services under this title;

33 “(ii) an integrated health care delivery system  
34 that delivers care through coordinated hospitals,  
35 clinics, home health agencies, ambulatory surgery  
36 centers, skilled nursing facilities, rehabilitation fa-

1           ilities and clinics, and employed, independent, or  
2           contracted physicians; or

3                   “(iii) an organization representing regional  
4           coalitions of groups or systems described in clause  
5           (i) or (ii).

6                   “(B) INCLUSION.—As the Secretary determines  
7           appropriate, a health care group may include a hospital  
8           or any other individual or entity furnishing items or  
9           services for which payment may be made under this  
10          title that is affiliated with the health care group under  
11          an arrangement structured so that such hospital, indi-  
12          vidual, or entity participates in a demonstration project  
13          under this section.

14                   “(3) PHYSICIAN.—Except as otherwise provided for by  
15          the Secretary, the term ‘physician’ means any individual  
16          who furnishes services that may be paid for as physicians’  
17          services under this title.

18                   “(b) DEMONSTRATION PROJECTS.—The Secretary shall  
19          establish a 5-year demonstration program under which the Sec-  
20          retary shall approve demonstration projects that examine  
21          health delivery factors that encourage the delivery of improved  
22          quality in patient care, including—

23                           “(1) the provision of incentives to improve the safety  
24          of care provided to beneficiaries;

25                           “(2) the appropriate use of best practice guidelines by  
26          providers and services by beneficiaries;

27                           “(3) reduced scientific uncertainty in the delivery of  
28          care through the examination of variations in the utiliza-  
29          tion and allocation of services, and outcomes measurement  
30          and research;

31                           “(4) encourage shared decision making between pro-  
32          viders and patients;

33                           “(5) the provision of incentives for improving the qual-  
34          ity and safety of care and achieving the efficient allocation  
35          of resources;

36                           “(6) the appropriate use of culturally and ethnically  
37          sensitive health care delivery; and

1           “(7) the financial effects on the health care market-  
2           place of altering the incentives for care delivery and chang-  
3           ing the allocation of resources.

4           “(c) ADMINISTRATION BY CONTRACT.—

5           “(1) IN GENERAL.—Except as otherwise provided in  
6           this section, the Secretary may administer the demonstra-  
7           tion program established under this section in a manner  
8           that is similar to the manner in which the demonstration  
9           program established under section 1866A is administered  
10          in accordance with section 1866B.

11          “(2) ALTERNATIVE PAYMENT SYSTEMS.—A health  
12          care group that receives assistance under this section may,  
13          with respect to the demonstration project to be carried out  
14          with such assistance, include proposals for the use of alter-  
15          native payment systems for items and services provided to  
16          beneficiaries by the group that are designed to—

17                 “(A) encourage the delivery of high quality care  
18                 while accomplishing the objectives described in sub-  
19                 section (b); and

20                 “(B) streamline documentation and reporting re-  
21                 quirements otherwise required under this title.

22          “(3) BENEFITS.—A health care group that receives  
23          assistance under this section may, with respect to the dem-  
24          onstration project to be carried out with such assistance,  
25          include modifications to the package of benefits available  
26          under the original medicare fee-for-service program under  
27          parts A and B or the package of benefits available through  
28          a Medicare Advantage plan under part C. The criteria em-  
29          ployed under the demonstration program under this section  
30          to evaluate outcomes and determine best practice guidelines  
31          and incentives shall not be used as a basis for the denial  
32          of medicare benefits under the demonstration program to  
33          patients against their wishes (or if the patient is incom-  
34          petent, against the wishes of the patient’s surrogate) on the  
35          basis of the patient’s age or expected length of life or of  
36          the patient’s present or predicted disability, degree of med-  
37          ical dependency, or quality of life.

1           “(d) ELIGIBILITY CRITERIA.—To be eligible to receive as-  
2           sistance under this section, an entity shall—

3                   “(1) be a health care group;

4                   “(2) meet quality standards established by the Sec-  
5           retary, including—

6                           “(A) the implementation of continuous quality im-  
7                           provement mechanisms that are aimed at integrating  
8                           community-based support services, primary care, and  
9                           referral care;

10                           “(B) the implementation of activities to increase  
11                           the delivery of effective care to beneficiaries;

12                           “(C) encouraging patient participation in pref-  
13                           erence-based decisions;

14                           “(D) the implementation of activities to encourage  
15                           the coordination and integration of medical service de-  
16                           livery; and

17                           “(E) the implementation of activities to measure  
18                           and document the financial impact on the health care  
19                           marketplace of altering the incentives of health care de-  
20                           livery and changing the allocation of resources; and

21                   “(3) meet such other requirements as the Secretary  
22           may establish.

23           “(e) WAIVER AUTHORITY.—The Secretary may waive such  
24           requirements of titles XI and XVIII as may be necessary to  
25           carry out the purposes of the demonstration program estab-  
26           lished under this section.

27           “(f) BUDGET NEUTRALITY.—With respect to the 5-year  
28           period of the demonstration program under subsection (b), the  
29           aggregate expenditures under this title for such period shall not  
30           exceed the aggregate expenditures that would have been ex-  
31           pended under this title if the program established under this  
32           section had not been implemented.

33           “(g) NOTICE REQUIREMENTS.—In the case of an indi-  
34           vidual that receives health care items or services under a dem-  
35           onstration program carried out under this section, the Sec-  
36           retary shall ensure that such individual is notified of any waiv-  
37           ers of coverage or payment rules that are applicable to such in-

1 individual under this title as a result of the participation of the  
2 individual in such program.

3 “(h) PARTICIPATION AND SUPPORT BY FEDERAL AGEN-  
4 CIES.—In carrying out the demonstration program under this  
5 section, the Secretary may direct—

6 “(1) the Director of the National Institutes of Health  
7 to expand the efforts of the Institutes to evaluate current  
8 medical technologies and improve the foundation for evi-  
9 dence-based practice;

10 “(2) the Administrator of the Agency for Healthcare  
11 Research and Quality to, where possible and appropriate,  
12 use the program under this section as a laboratory for the  
13 study of quality improvement strategies and to evaluate,  
14 monitor, and disseminate information relevant to such pro-  
15 gram; and

16 “(3) the Administrator of the Centers for Medicare &  
17 Medicaid Services and the Administrator of the Center for  
18 Medicare Choices to support linkages of relevant medicare  
19 data to registry information from participating health care  
20 groups for the beneficiary populations served by the partici-  
21 pating groups, for analysis supporting the purposes of the  
22 demonstration program, consistent with the applicable pro-  
23 visions of the Health Insurance Portability and Account-  
24 ability Act of 1996.”.

25 **SEC. 647. MEDPAC STUDY ON DIRECT ACCESS TO PHYS-**  
26 **ICAL THERAPY SERVICES.**

27 (a) STUDY.—The Medicare Payment Advisory Commission  
28 (in this section referred to as the “Commission”) shall conduct  
29 a study on the feasibility and advisability of allowing medicare  
30 fee-for-service beneficiaries direct access to outpatient physical  
31 therapy services and physical therapy services furnished as  
32 comprehensive rehabilitation facility services.

33 (b) REPORT.—Not later than January 1, 2005, the Com-  
34 mission shall submit to Congress a report on the study con-  
35 ducted under subsection (a) together with recommendations for  
36 such legislation or administrative action as the Commission de-  
37 termines to be appropriate.

1 (c) DIRECT ACCESS DEFINED.—The term “direct access”  
2 means, with respect to outpatient physical therapy services and  
3 physical therapy services furnished as comprehensive outpatient  
4 rehabilitation facility services, coverage of and payment for  
5 such services in accordance with the provisions of title XVIII  
6 of the Social Security Act, except that sections 1835(a)(2),  
7 1861(p), and 1861(cc) of such Act (42 U.S.C. 1395n(a)(2),  
8 1395x(p), and 1395x(cc), respectively) shall be applied—

9 (1) without regard to any requirement that—

10 (A) an individual be under the care of (or referred  
11 by) a physician; or

12 (B) services be provided under the supervision of  
13 a physician; and

14 (2) by allowing a physician or a qualified physical  
15 therapist to satisfy any requirement for—

16 (A) certification and recertification; and

17 (B) establishment and periodic review of a plan of  
18 care.

19 **SEC. 648. DEMONSTRATION PROJECT FOR CONSUMER-**  
20 **DIRECTED CHRONIC OUTPATIENT SERVICES.**

21 (a) ESTABLISHMENT.—

22 (1) IN GENERAL.—Subject to the succeeding provi-  
23 sions of this section, the Secretary shall establish dem-  
24 onstration projects (in this section referred to as “dem-  
25 onstration projects”) under which the Secretary shall evalu-  
26 ate methods that improve the quality of care provided to  
27 individuals with chronic conditions and that reduce expend-  
28 itures that would otherwise be made under the medicare  
29 program on behalf of such individuals for such chronic con-  
30 ditions, such methods to include permitting those bene-  
31 ficiaries to direct their own health care needs and services.

32 (2) INDIVIDUALS WITH CHRONIC CONDITIONS DE-  
33 FINED.—In this section, the term “individuals with chronic  
34 conditions” means an individual entitled to benefits under  
35 part A of title XVIII of the Social Security Act, and en-  
36 rolled under part B of such title, but who is not enrolled  
37 under part C of such title who is diagnosed as having one



1 or more chronic conditions (as defined by the Secretary),  
2 such as diabetes.

3 (b) DESIGN OF PROJECTS.—

4 (1) EVALUATION BEFORE IMPLEMENTATION OF  
5 PROJECT.—

6 (A) IN GENERAL.—In establishing the demonstra-  
7 tion projects under this section, the Secretary shall  
8 evaluate best practices employed by group health plans  
9 and practices under State plans for medical assistance  
10 under the medicaid program under title XIX of the So-  
11 cial Security Act, as well as best practices in the pri-  
12 vate sector or other areas, of methods that permit pa-  
13 tients to self-direct the provision of personal care serv-  
14 ices. The Secretary shall evaluate such practices for a  
15 1-year period and, based on such evaluation, shall de-  
16 sign the demonstration project.

17 (B) REQUIREMENT FOR ESTIMATE OF BUDGET  
18 NEUTRAL COSTS.—As part of the evaluation under sub-  
19 paragraph (A), the Secretary shall evaluate the costs of  
20 furnishing care under the projects. The Secretary may  
21 not implement the demonstration projects under this  
22 section unless the Secretary determines that the costs  
23 of providing care to individuals with chronic conditions  
24 under the project will not exceed the costs, in the ag-  
25 gregate, of furnishing care to such individuals under  
26 title XVIII of the Social Security Act, that would other-  
27 wise be paid without regard to the demonstration  
28 projects for the period of the project.

29 (2) SCOPE OF SERVICES.—The Secretary shall deter-  
30 mine the appropriate scope of personal care services that  
31 would apply under the demonstration projects.

32 (c) VOLUNTARY PARTICIPATION.—Participation of pro-  
33 viders of services and suppliers, and of individuals with chronic  
34 conditions, in the demonstration projects shall be voluntary.

35 (d) DEMONSTRATION PROJECTS SITES.—Not later than 2  
36 years after the date of the enactment of this Act, the Secretary  
37 shall conduct at least one area that the Secretary determines

1 has a population of individuals entitled to benefits under part  
2 A of title XVIII of the Social Security Act, and enrolled under  
3 part B of such title, with a rate of incidence of diabetes that  
4 significantly exceeds the national average rate of all areas.

5 (e) EVALUATION AND REPORT.—

6 (1) EVALUATIONS.—The Secretary shall conduct eval-  
7 uations of the clinical and cost effectiveness of the dem-  
8 onstration projects.

9 (2) REPORTS.—Not later than 2 years after the com-  
10 mencement of the demonstration projects, and biannually  
11 thereafter, the Secretary shall submit to Congress a report  
12 on the evaluation, and shall include in the report the fol-  
13 lowing:

14 (A) An analysis of the patient outcomes and costs  
15 of furnishing care to the individuals with chronic condi-  
16 tions participating in the projects as compared to such  
17 outcomes and costs to other individuals for the same  
18 health conditions.

19 (B) Evaluation of patient satisfaction under the  
20 demonstration projects.

21 (C) Such recommendations regarding the exten-  
22 sion, expansion, or termination of the projects as the  
23 Secretary determines appropriate.

24 (f) WAIVER AUTHORITY.—The Secretary shall waive com-  
25 pliance with the requirements of title XVIII of the Social Secu-  
26 rity Act (42 U.S.C. 1395 et seq.) to such extent and for such  
27 period as the Secretary determines is necessary to conduct  
28 demonstration projects.

29 (g) AUTHORIZATION OF APPROPRIATIONS.—(1) Payments  
30 for the costs of carrying out the demonstration project under  
31 this section shall be made from the Federal Supplementary  
32 Medical Insurance Trust Fund under section 1841 of such Act  
33 (42 U.S.C. 1395t).

34 (2) There are authorized to be appropriated from such  
35 Trust Fund such sums as may be necessary for the Secretary  
36 to enter into contracts with appropriate organizations for the

1 deign, implementation, and evaluation of the demonstration  
2 project.

3 (3) In no case may expenditures under this section exceed  
4 the aggregate expenditures that would otherwise have been  
5 made for the provision of personal care services.

6 **SEC. 649. MEDICARE CARE MANAGEMENT PERFORM-**  
7 **ANCE DEMONSTRATION.**

8 (a) ESTABLISHMENT.—

9 (1) IN GENERAL.—The Secretary shall establish a  
10 pay-for-performance demonstration program with physi-  
11 cians to meet the needs of eligible beneficiaries through the  
12 adoption and use of health information technology and evi-  
13 dence-based outcomes measures for—

14 (A) promoting continuity of care;

15 (B) helping stabilize medical conditions;

16 (C) preventing or minimizing acute exacerbations  
17 of chronic conditions; and

18 (D) reducing adverse health outcomes, such as ad-  
19 verse drug interactions related to polypharmacy.

20 (2) SITES.—The Secretary shall designate no more  
21 than 4 sites at which to conduct the demonstration pro-  
22 gram under this section, of which—

23 (A) 2 shall be in an urban area;

24 (B) 1 shall be in a rural area; and

25 (C) 1 shall be in a State with a medical school  
26 with a Department of Geriatrics that manages rural  
27 outreach sites and is capable of managing patients with  
28 multiple chronic conditions, one of which is dementia.

29 (3) DURATION.—The Secretary shall conduct the dem-  
30 onstration program under this section for a 3-year period.

31 (4) CONSULTATION.—In carrying out the demonstra-  
32 tion program under this section, the Secretary shall consult  
33 with private sector and non-profit groups that are under-  
34 taking similar efforts to improve quality and reduce avoid-  
35 able hospitalizations for chronically ill patients.

36 (b) PARTICIPATION.—

1           (1) IN GENERAL.—A physician who provides care for  
2 a minimum number of eligible beneficiaries (as specified by  
3 the Secretary) may participate in the demonstration pro-  
4 gram under this section if such physician agrees, to phase-  
5 in over the course of the 3-year demonstration period and  
6 with the assistance provided under subsection (d)(2)—

7           (A) the use of health information technology to  
8 manage the clinical care of eligible beneficiaries con-  
9 sistent with paragraph (3); and

10          (B) the electronic reporting of clinical quality and  
11 outcomes measures in accordance with requirements es-  
12 tablished by the Secretary under the demonstration  
13 program.

14          (2) SPECIAL RULE.—In the case of the sites referred  
15 to in subparagraphs (B) and (C) of subsection (a)(2), a  
16 physician who provides care for a minimum number of  
17 beneficiaries with two or more chronic conditions, including  
18 dementia (as specified by the Secretary), may participate in  
19 the program under this section if such physician agrees to  
20 the requirements in subparagraphs (A) and (B) of para-  
21 graph (1).

22          (3) PRACTICE STANDARDS.—Each physician partici-  
23 pating in the demonstration program under this section  
24 must demonstrate the ability—

25           (A) to assess each eligible beneficiary for condi-  
26 tions other than chronic conditions, such as impaired  
27 cognitive ability and co-morbidities, for the purposes of  
28 developing care management requirements;

29           (B) to serve as the primary contact of eligible  
30 beneficiaries in accessing items and services for which  
31 payment may be made under the medicare program;

32           (C) to establish and maintain health care informa-  
33 tion system for such beneficiaries;

34           (D) to promote continuity of care across providers  
35 and settings;

1 (E) to use evidence-based guidelines and meet  
2 such clinical quality and outcome measures as the Sec-  
3 retary shall require;

4 (F) to promote self-care through the provision of  
5 patient education and support for patients or, where  
6 appropriate, family caregivers;

7 (G) when appropriate, to refer such beneficiaries  
8 to community service organizations; and

9 (H) to meet such other complex care management  
10 requirements as the Secretary may specify.

11 The guidelines and measures required under subparagraph  
12 (E) shall be designed to take into account beneficiaries with  
13 multiple chronic conditions.

14 (c) PAYMENT METHODOLOGY.—Under the demonstration  
15 program under this section the Secretary shall pay a per bene-  
16 ficiary amount to each participating physician who meets or ex-  
17 ceeds specific performance standards established by the Sec-  
18 retary with respect to the clinical quality and outcome meas-  
19 ures reported under subsection (b)(1)(B). Such amount may  
20 vary based on different levels of performance or improvement.

21 (d) ADMINISTRATION.—

22 (1) USE OF QUALITY IMPROVEMENT ORGANIZA-  
23 TIONS.—The Secretary shall contract with quality improve-  
24 ment organizations or such other entities as the Secretary  
25 deems appropriate to enroll physicians and evaluate their  
26 performance under the demonstration program under this  
27 section.

28 (2) TECHNICAL ASSISTANCE.—The Secretary shall re-  
29 quire in such contracts that the contractor be responsible  
30 for technical assistance and education as needed to physi-  
31 cians enrolled in the demonstration program under this sec-  
32 tion for the purpose of aiding their adoption of health in-  
33 formation technology, meeting practice standards, and im-  
34 plementing required clinical and outcomes measures.

35 (e) FUNDING.—

36 (1) IN GENERAL.—The Secretary shall provide for the  
37 transfer from the Federal Supplementary Medical Insur-

1           ance Trust Fund established under section 1841 of the So-  
2           cial Security Act (42 U.S.C. 1395t) of such funds as are  
3           necessary for the costs of carrying out the demonstration  
4           program under this section.

5           (2) BUDGET NEUTRALITY.—In conducting the dem-  
6           onstration program under this section, the Secretary shall  
7           ensure that the aggregate payments made by the Secretary  
8           do not exceed the amount which the Secretary estimates  
9           would have been paid if the demonstration program under  
10          this section was not implemented.

11          (f) WAIVER AUTHORITY.—The Secretary may waive such  
12          requirements of titles XI and XVIII of the Social Security Act  
13          (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary for  
14          the purpose of carrying out the demonstration program under  
15          this section.

16          (g) REPORT.—Not later than 12 months after the date of  
17          completion of the demonstration program under this section,  
18          the Secretary shall submit to Congress a report on such pro-  
19          gram, together with recommendations for such legislation and  
20          administrative action as the Secretary determines to be appro-  
21          priate.

22          (h) DEFINITIONS.—In this section:

23           (1) ELIGIBLE BENEFICIARY.—The term “eligible bene-  
24           ficiary” means any individual who—

25           (A) is entitled to benefits under part A and en-  
26           rolled for benefits under part B of title XVIII of the  
27           Social Security Act and is not enrolled in a plan under  
28           part C of such title; and

29           (B) has one or more chronic medical conditions  
30           specified by the Secretary (one of which may be cog-  
31           nitive impairment).

32           (2) HEALTH INFORMATION TECHNOLOGY.—The term  
33           “health information technology” means email communica-  
34           tion, clinical alerts and reminders, and other information  
35           technology that meets such functionality, interoperability,  
36           and other standards as prescribed by the Secretary.

1     **SEC. 650. GAO STUDY AND REPORT ON THE PROPAGA-**  
2                   **TION OF CONCIERGE CARE.**

3           (a) STUDY.—

4           (1) IN GENERAL.—The Comptroller General of the  
5     United States shall conduct a study on concierge care (as  
6     defined in paragraph (2)) to determine the extent to which  
7     such care—

8           (A) is used by medicare beneficiaries (as defined  
9     in section 1802(b)(5)(A) of the Social Security Act (42  
10    U.S.C. 1395a(b)(5)(A))); and

11          (B) has impacted upon the access of medicare  
12    beneficiaries (as so defined) to items and services for  
13    which reimbursement is provided under the medicare  
14    program under title XVIII of the Social Security Act  
15    (42 U.S.C. 1395 et seq.).

16          (2) CONCIERGE CARE.—In this section, the term “con-  
17    cierge care” means an arrangement under which, as a pre-  
18    requisite for the provision of a health care item or service  
19    to an individual, a physician, practitioner (as described in  
20    section 1842(b)(18)(C) of the Social Security Act (42  
21    U.S.C. 1395u(b)(18)(C))), or other individual—

22          (A) charges a membership fee or another inci-  
23    dental fee to an individual desiring to receive the health  
24    care item or service from such physician, practitioner,  
25    or other individual; or

26          (B) requires the individual desiring to receive the  
27    health care item or service from such physician, practi-  
28    tioner, or other individual to purchase an item or serv-  
29    ice.

30          (b) REPORT.—Not later than the date that is 12 months  
31    after the date of enactment of this Act, the Comptroller Gen-  
32    eral of the United States shall submit to Congress a report on  
33    the study conducted under subsection (a)(1) together with such  
34    recommendations for legislative or administrative action as the  
35    Comptroller General determines to be appropriate.

1     **SEC. 651. DEMONSTRATION OF COVERAGE OF CHIRO-**  
2                   **PRACTIC SERVICES UNDER MEDICARE.**

3           (a) DEFINITIONS.—In this section:

4               (1) CHIROPRACTIC SERVICES.—The term “chiropractic  
5 services” has the meaning given that term by the Secretary  
6 for purposes of the demonstration projects, but shall in-  
7 clude, at a minimum—

8                   (A) care for neuromusculoskeletal conditions typ-  
9 ical among eligible beneficiaries; and

10                  (B) diagnostic and other services that a chiro-  
11 practor is legally authorized to perform by the State or  
12 jurisdiction in which such treatment is provided.

13               (2) DEMONSTRATION PROJECT.—The term “dem-  
14 onstration project” means a demonstration project estab-  
15 lished by the Secretary under subsection (b)(1).

16               (3) ELIGIBLE BENEFICIARY.—The term “eligible bene-  
17 ficiary” means an individual who is enrolled under part B  
18 of the medicare program.

19               (4) MEDICARE PROGRAM.—The term “medicare pro-  
20 gram” means the health benefits program under title  
21 XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

22           (b) DEMONSTRATION OF COVERAGE OF CHIROPRACTIC  
23 SERVICES UNDER MEDICARE.—

24               (1) ESTABLISHMENT.—The Secretary shall establish  
25 demonstration projects in accordance with the provisions of  
26 this section for the purpose of evaluating the feasibility and  
27 advisability of covering chiropractic services under the  
28 medicare program (in addition to the coverage provided for  
29 services consisting of treatment by means of manual ma-  
30 nipulation of the spine to correct a subluxation described  
31 in section 1861(r)(5) of the Social Security Act (42 U.S.C.  
32 1395x(r)(5))).

33               (2) NO PHYSICIAN APPROVAL REQUIRED.—In estab-  
34 lishing the demonstration projects, the Secretary shall en-  
35 sure that an eligible beneficiary who participates in a dem-  
36 onstration project, including an eligible beneficiary who is  
37 enrolled for coverage under a Medicare+Choice plan (or,



1 on and after January 1, 2006, under a Medicare Advan-  
2 tage plan), is not required to receive approval from a physi-  
3 cian or other health care provider in order to receive a  
4 chiropractic service under a demonstration project.

5 (3) CONSULTATION.—In establishing the demonstra-  
6 tion projects, the Secretary shall consult with chiropractors,  
7 organizations representing chiropractors, eligible bene-  
8 ficiaries, and organizations representing eligible bene-  
9 ficiaries.

10 (4) PARTICIPATION.—Any eligible beneficiary may  
11 participate in the demonstration projects on a voluntary  
12 basis.

13 (c) CONDUCT OF DEMONSTRATION PROJECTS.—

14 (1) DEMONSTRATION SITES.—

15 (A) SELECTION OF DEMONSTRATION SITES.—The  
16 Secretary shall conduct demonstration projects at 4  
17 demonstration sites.

18 (B) GEOGRAPHIC DIVERSITY.—Of the sites de-  
19 scribed in subparagraph (A)—

20 (i) 2 shall be in rural areas; and

21 (ii) 2 shall be in urban areas.

22 (C) SITES LOCATED IN HPSAS.—At least 1 site de-  
23 scribed in clause (i) of subparagraph (B) and at least  
24 1 site described in clause (ii) of such subparagraph  
25 shall be located in an area that is designated under sec-  
26 tion 332(a)(1)(A) of the Public Health Service Act (42  
27 U.S.C. 254e(a)(1)(A)) as a health professional shortage  
28 area.

29 (2) IMPLEMENTATION; DURATION.—

30 (A) IMPLEMENTATION.—The Secretary shall not  
31 implement the demonstration projects before October 1,  
32 2004.

33 (B) DURATION.—The Secretary shall complete the  
34 demonstration projects by the date that is 2 years after  
35 the date on which the first demonstration project is im-  
36 plemented.

37 (d) EVALUATION AND REPORT.—

1           (1) EVALUATION.—The Secretary shall conduct an  
2 evaluation of the demonstration projects—

3           (A) to determine whether eligible beneficiaries who  
4 use chiropractic services use a lesser overall amount of  
5 items and services for which payment is made under  
6 the medicare program than eligible beneficiaries who do  
7 not use such services;

8           (B) to determine the cost of providing payment for  
9 chiropractic services under the medicare program;

10          (C) to determine the satisfaction of eligible bene-  
11 ficiaries participating in the demonstration projects and  
12 the quality of care received by such beneficiaries; and

13          (D) to evaluate such other matters as the Sec-  
14 retary determines is appropriate.

15          (2) REPORT.—Not later than the date that is 1 year  
16 after the date on which the demonstration projects con-  
17 clude, the Secretary shall submit to Congress a report on  
18 the evaluation conducted under paragraph (1) together  
19 with such recommendations for legislation or administrative  
20 action as the Secretary determines is appropriate.

21          (e) WAIVER OF MEDICARE REQUIREMENTS.—The Sec-  
22 retary shall waive compliance with such requirements of the  
23 medicare program to the extent and for the period the Sec-  
24 retary finds necessary to conduct the demonstration projects.

25          (f) FUNDING.—

26           (1) DEMONSTRATION PROJECTS.—

27           (A) IN GENERAL.—Subject to subparagraph (B)  
28 and paragraph (2), the Secretary shall provide for the  
29 transfer from the Federal Supplementary Insurance  
30 Trust Fund under section 1841 of the Social Security  
31 Act (42 U.S.C. 1395t) of such funds as are necessary  
32 for the costs of carrying out the demonstration projects  
33 under this section.

34           (B) LIMITATION.—In conducting the demonstra-  
35 tion projects under this section, the Secretary shall en-  
36 sure that the aggregate payments made by the Sec-  
37 retary under the medicare program do not exceed the

1 amount which the Secretary would have paid under the  
2 medicare program if the demonstration projects under  
3 this section were not implemented.

4 (2) EVALUATION AND REPORT.—There are authorized  
5 to be appropriated such sums as are necessary for the pur-  
6 pose of developing and submitting the report to Congress  
7 under subsection (d).

8 **TITLE VII—PROVISIONS RELATING**  
9 **TO PARTS A AND B**  
10 **Subtitle A—Home Health Services**

11 **SEC. 701. UPDATE IN HOME HEALTH SERVICES.**

12 (a) CHANGE TO CALENDAR YEAR UPDATE.—Section  
13 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

14 (1) in paragraph (3)(B)(i)—

15 (A) by striking “each fiscal year (beginning with  
16 fiscal year 2002)” and inserting “fiscal year 2002 and  
17 for fiscal year 2003 and for each subsequent year (be-  
18 ginning with 2004)”; and

19 (B) by inserting “or year” after “the fiscal year”;

20 (2) in paragraph (3)(B)(ii)—

21 (A) in subclause (I), by striking “or” at the end;

22 (B) by redesignating subclause (II) as subclause  
23 (III);

24 (C) in subclause (III), as so redesignated, by strik-  
25 ing “any subsequent fiscal year” and inserting “2004  
26 and any subsequent year”; and

27 (D) by inserting after subclause (I) the following  
28 new subclause:

29 “(II) for the last calendar quarter of 2003  
30 and the first calendar quarter of 2004, the  
31 home health market basket percentage in-  
32 crease; or”;

33 (3) in paragraph (3)(B)(iii), by inserting “or year”  
34 after “fiscal year” each place it appears; and

35 (4) in paragraph (3)(B)(iv)—

1 (A) by inserting “or year” after “fiscal year” each  
2 place it appears; and

3 (B) by inserting “or years” after “fiscal years”;  
4 and

5 (5) in paragraph (5), by inserting “or year” after “fis-  
6 cal year”.

7 (b) ADJUSTMENT TO UPDATES FOR 2004, 2005, AND  
8 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C.  
9 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(2), is  
10 amended—

11 (1) by striking “or” at the end of subclause (II);

12 (2) by redesignating subclause (III) as subclause (IV);

13 (3) in subclause (IV), as so redesignated, by striking  
14 “2004” and inserting “2007”; and

15 (4) by inserting after subclause (II) the following new  
16 subclause:

17 “(III) the last 3 calendar quarters of  
18 2004, and each of 2005 and 2006 the home  
19 health market basket percentage increase  
20 minus 0.8 percentage points; or”.

21 **SEC. 702. DEMONSTRATION PROJECT TO CLARIFY THE**  
22 **DEFINITION OF HOMEBOUND.**

23 (a) DEMONSTRATION PROJECT.—Not later than 180 days  
24 after the date of the enactment of this Act, the Secretary shall  
25 conduct a 2-year demonstration project under part B of title  
26 XVIII of the Social Security Act under which medicare bene-  
27 ficiaries with chronic conditions described in subsection (b) are  
28 deemed to be homebound for purposes of receiving home health  
29 services under the medicare program.

30 (b) MEDICARE BENEFICIARY DESCRIBED.—For purposes  
31 of subsection (a), a medicare beneficiary is eligible to be  
32 deemed to be homebound, without regard to the purpose, fre-  
33 quency, or duration of absences from the home, if—

34 (1) the beneficiary has been certified by one physician  
35 as an individual who has a permanent and severe, disabling  
36 condition that is not expected to improve;

1           (2) the beneficiary is dependent upon assistance from  
2 another individual with at least 3 out of the 5 activities of  
3 daily living for the rest of the beneficiary's life;

4           (3) the beneficiary requires skilled nursing services for  
5 the rest of the beneficiary's life and the skilled nursing is  
6 more than medication management;

7           (4) an attendant is required to visit the beneficiary on  
8 a daily basis to monitor and treat the beneficiary's medical  
9 condition or to assist the beneficiary with activities of daily  
10 living;

11           (5) the beneficiary requires technological assistance or  
12 the assistance of another person to leave the home; and

13           (6) the beneficiary does not regularly work in a paid  
14 position full-time or part-time outside the home.

15           (c) DEMONSTRATION PROJECT SITES.—The demonstra-  
16 tion project established under this section shall be conducted in  
17 3 States selected by the Secretary to represent the Northeast,  
18 Midwest, and Western regions of the United States.

19           (d) LIMITATION ON NUMBER OF PARTICIPANTS.—The ag-  
20 gregate number of such beneficiaries that may participate in  
21 the project may not exceed 15,000.

22           (e) DATA.—The Secretary shall collect such data on the  
23 demonstration project with respect to the provision of home  
24 health services to medicare beneficiaries that relates to quality  
25 of care, patient outcomes, and additional costs, if any, to the  
26 medicare program.

27           (f) REPORT TO CONGRESS.—Not later than 1 year after  
28 the date of the completion of the demonstration project under  
29 this section, the Secretary shall submit to Congress a report on  
30 the project using the data collected under subsection (e). The  
31 report shall include the following:

32           (1) An examination of whether the provision of home  
33 health services to medicare beneficiaries under the project  
34 has had any of the following effects:

35           (A) Has adversely affected the provision of home  
36 health services under the medicare program.

1           (B) Has directly caused an increase of expendi-  
2           tures under the medicare program for the provision of  
3           such services that is directly attributable to such clari-  
4           fication.

5           (2) The specific data evidencing the amount of any in-  
6           crease in expenditures that is directly attributable to the  
7           demonstration project (expressed both in absolute dollar  
8           terms and as a percentage) above expenditures that would  
9           otherwise have been incurred for home health services  
10          under the medicare program.

11          (3) Specific recommendations to exempt permanently  
12          and severely disabled homebound beneficiaries from restric-  
13          tions on the length, frequency, and purpose of their ab-  
14          sences from the home to qualify for home health services  
15          without incurring additional costs to the medicare program.

16          (g) WAIVER AUTHORITY.—The Secretary shall waive com-  
17          pliance with the requirements of title XVIII of the Social Secu-  
18          rity Act (42 U.S.C. 1395 et seq.) to such extent and for such  
19          period as the Secretary determines is necessary to conduct  
20          demonstration projects.

21          (h) CONSTRUCTION.—Nothing in this section shall be con-  
22          strued as waiving any applicable civil monetary penalty, crimi-  
23          nal penalty, or other remedy available to the Secretary under  
24          title XI or title XVIII of the Social Security Act for acts pro-  
25          hibited under such titles, including penalties for false certifi-  
26          cations for purposes of receipt of items or services under the  
27          medicare program.

28          (i) AUTHORIZATION OF APPROPRIATIONS.—Payments for  
29          the costs of carrying out the demonstration project under this  
30          section shall be made from the Federal Supplementary Medical  
31          Insurance Trust Fund under section 1841 of such Act (42  
32          U.S.C. 1395t).

33          (j) DEFINITIONS.—In this section:

34               (1) MEDICARE BENEFICIARY.—The term “medicare  
35               beneficiary” means an individual who is enrolled under part  
36               B of title XVIII of the Social Security Act.

1           (2) HOME HEALTH SERVICES.—The term “home  
2 health services” has the meaning given such term in section  
3 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

4           (3) ACTIVITIES OF DAILY LIVING DEFINED.—The  
5 term “activities of daily living” means eating, toileting,  
6 transferring, bathing, and dressing.

7 **SEC. 703. DEMONSTRATION PROJECT FOR MEDICAL**  
8 **ADULT DAY-CARE SERVICES.**

9           (a) ESTABLISHMENT.—Subject to the succeeding provi-  
10 sions of this section, the Secretary shall establish a demonstra-  
11 tion project (in this section referred to as the “demonstration  
12 project”) under which the Secretary shall, as part of a plan of  
13 an episode of care for home health services established for a  
14 medicare beneficiary, permit a home health agency, directly or  
15 under arrangements with a medical adult day-care facility, to  
16 provide medical adult day-care services as a substitute for a  
17 portion of home health services that would otherwise be pro-  
18 vided in the beneficiary’s home.

19           (b) PAYMENT.—

20           (1) IN GENERAL.—Subject to paragraph (2), the  
21 amount of payment for an episode of care for home health  
22 services, a portion of which consists of substitute medical  
23 adult day-care services, under the demonstration project  
24 shall be made at a rate equal to 95 percent of the amount  
25 that would otherwise apply for such home health services  
26 under section 1895 of the Social Security Act (42 U.S.C.  
27 1395fff). In no case may a home health agency, or a med-  
28 ical adult day-care facility under arrangements with a home  
29 health agency, separately charge a beneficiary for medical  
30 adult day-care services furnished under the plan of care.

31           (2) ADJUSTMENT IN CASE OF OVERUTILIZATION OF  
32 SUBSTITUTE ADULT DAY-CARE SERVICES TO ENSURE  
33 BUDGET NEUTRALITY.—The Secretary shall monitor the  
34 expenditures under the demonstration project and under  
35 title XVIII of the Social Security Act for home health serv-  
36 ices. If the Secretary estimates that the total expenditures  
37 under the demonstration project and under such title

1 XVIII for home health services for a period determined by  
2 the Secretary exceed expenditures that would have been  
3 made under such title XVIII for home health services for  
4 such period if the demonstration project had not been con-  
5 ducted, the Secretary shall adjust the rate of payment to  
6 medical adult day-care facilities under paragraph (1) in  
7 order to eliminate such excess.

8 (c) DEMONSTRATION PROJECT SITES.—The demonstra-  
9 tion project established under this section shall be conducted in  
10 not more than 5 sites in States selected by the Secretary that  
11 license or certify providers of services that furnish medical  
12 adult day-care services.

13 (d) DURATION.—The Secretary shall conduct the dem-  
14 onstration project for a period of 3 years.

15 (e) VOLUNTARY PARTICIPATION.—Participation of medi-  
16 care beneficiaries in the demonstration project shall be vol-  
17 untary. The total number of such beneficiaries that may par-  
18 ticipate in the project at any given time may not exceed  
19 15,000.

20 (f) PREFERENCE IN SELECTING AGENCIES.—In selecting  
21 home health agencies to participate under the demonstration  
22 project, the Secretary shall give preference to those agencies  
23 that are currently licensed or certified through common owner-  
24 ship and control to furnish medical adult day-care services.

25 (g) WAIVER AUTHORITY.—The Secretary may waive such  
26 requirements of title XVIII of the Social Security Act as may  
27 be necessary for the purposes of carrying out the demonstra-  
28 tion project, other than waiving the requirement that an indi-  
29 vidual be homebound in order to be eligible for benefits for  
30 home health services.

31 (h) EVALUATION AND REPORT.—The Secretary shall con-  
32 duct an evaluation of the clinical and cost-effectiveness of the  
33 demonstration project. Not later than 6 months after the com-  
34 pletion of the project, the Secretary shall submit to Congress  
35 a report on the evaluation, and shall include in the report the  
36 following:



1           (1) An analysis of the patient outcomes and costs of  
2           furnishing care to the medicare beneficiaries participating  
3           in the project as compared to such outcomes and costs to  
4           beneficiaries receiving only home health services for the  
5           same health conditions.

6           (2) Such recommendations regarding the extension,  
7           expansion, or termination of the project as the Secretary  
8           determines appropriate.

9           (i) DEFINITIONS.—In this section:

10           (1) HOME HEALTH AGENCY.—The term “home health  
11           agency” has the meaning given such term in section  
12           1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

13           (2) MEDICAL ADULT DAY-CARE FACILITY.—The term  
14           “medical adult day-care facility” means a facility that—

15           (A) has been licensed or certified by a State to  
16           furnish medical adult day-care services in the State for  
17           a continuous 2-year period;

18           (B) is engaged in providing skilled nursing serv-  
19           ices and other therapeutic services directly or under ar-  
20           rangement with a home health agency;

21           (C) is licensed and certified by the State in which  
22           it operates or meets such standards established by the  
23           Secretary to assure quality of care and such other re-  
24           quirements as the Secretary finds necessary in the in-  
25           terest of the health and safety of individuals who are  
26           furnished services in the facility; and

27           (D) provides medical adult day-care services.

28           (3) MEDICAL ADULT DAY-CARE SERVICES.—The term  
29           “medical adult day-care services” means—

30           (A) home health service items and services de-  
31           scribed in paragraphs (1) through (7) of section  
32           1861(m) furnished in a medical adult day-care facility;

33           (B) a program of supervised activities furnished in  
34           a group setting in the facility that—

35           (i) meet such criteria as the Secretary deter-  
36           mines appropriate; and

1 (ii) is designed to promote physical and mental  
2 health of the individuals; and

3 (C) such other services as the Secretary may  
4 specify.

5 (4) MEDICARE BENEFICIARY.—The term “medicare  
6 beneficiary” means an individual entitled to benefits under  
7 part A of this title, enrolled under part B of this title, or  
8 both.

9 **SEC. 704. TEMPORARY SUSPENSION OF OASIS REQUIRE-**  
10 **MENT FOR COLLECTION OF DATA ON NON-**  
11 **MEDICARE AND NON-MEDICAID PATIENTS.**

12 (a) IN GENERAL.—During the period described in sub-  
13 section (b), the Secretary may not require, under section  
14 4602(e) of the Balanced Budget Act of 1997 (Public Law 105–  
15 33; 111 Stat. 467) or otherwise under OASIS, a home health  
16 agency to gather or submit information that relates to an indi-  
17 vidual who is not eligible for benefits under either title XVIII  
18 or title XIX of the Social Security Act (such information in  
19 this section referred to as “non-medicare/medicaid OASIS in-  
20 formation”).

21 (b) PERIOD OF SUSPENSION.—The period described in  
22 this subsection—

23 (1) begins on the date of the enactment of this Act;  
24 and

25 (2) ends on the last day of the second month begin-  
26 ning after the date as of which the Secretary has published  
27 final regulations regarding the collection and use by the  
28 Centers for Medicare & Medicaid Services of non-medicare/  
29 medicaid OASIS information following the submission of  
30 the report required under subsection (c).

31 (c) REPORT.—

32 (1) STUDY.—The Secretary shall conduct a study on  
33 how non-medicare/medicaid OASIS information is and can  
34 be used by large home health agencies. Such study shall  
35 examine—

36 (A) whether there are unique benefits from the  
37 analysis of such information that cannot be derived

1 from other information available to, or collected by,  
2 such agencies; and

3 (B) the value of collecting such information by  
4 small home health agencies compared to the adminis-  
5 trative burden related to such collection.

6 In conducting the study the Secretary shall obtain rec-  
7 ommendations from quality assessment experts in the use  
8 of such information and the necessity of small, as well as  
9 large, home health agencies collecting such information.

10 (2) REPORT.—The Secretary shall submit to Congress  
11 a report on the study conducted under paragraph (1) by  
12 not later than 18 months after the date of the enactment  
13 of this Act.

14 (d) CONSTRUCTION.—Nothing in this section shall be con-  
15 strued as preventing home health agencies from collecting non-  
16 medicare/medicaid OASIS information for their own use.

17 **SEC. 705. MEDPAC STUDY ON MEDICARE MARGINS OF**  
18 **HOME HEALTH AGENCIES.**

19 (a) STUDY.—The Medicare Payment Advisory Commission  
20 shall conduct a study of payment margins of home health agen-  
21 cies under the home health prospective payment system under  
22 section 1895 of the Social Security Act (42 U.S.C. 1395fff).  
23 Such study shall examine whether systematic differences in  
24 payment margins are related to differences in case mix (as  
25 measured by home health resource groups (HHRGs)) among  
26 such agencies. The study shall use the partial or full-year cost  
27 reports filed by home health agencies.

28 (b) REPORT.—Not later than 2 years after the date of the  
29 enactment of this Act, the Commission shall submit to Con-  
30 gress a report on the study under subsection (a).

31 **SEC. 706. COVERAGE OF RELIGIOUS NONMEDICAL**  
32 **HEALTH CARE INSTITUTION SERVICES FUR-**  
33 **NISHED IN THE HOME.**

34 (a) IN GENERAL.—Section 1821(a) (42 U.S.C. 1395i-  
35 5(a)) is amended—

36 (1) in the matter preceding paragraph (1), by insert-  
37 ing “and for home health services furnished an individual

1 by a religious nonmedical health care institution” after “re-  
2 religious nonmedical health care institution”; and

3 (2) in paragraph (2)—

4 (A) by striking “or extended care services” and in-  
5 serting “, extended care services, or home health serv-  
6 ices”; and

7 (B) by inserting “, or receiving services from a  
8 home health agency,” after “skilled nursing facility”.

9 (b) DEFINITION.—Section 1861 (42 U.S.C. 1395x), as  
10 amended by section 642, is amended by adding at the end the  
11 following new section:

12 “Extended Care in Religious Nonmedical Health Care  
13 Institutions

14 “(aaa)(1) The term ‘home health agency’ also includes a  
15 religious nonmedical health care institution (as defined in sub-  
16 section (ss)(1)), but only with respect to items and services or-  
17 dinarily furnished by such an institution to individuals in their  
18 homes, and that are comparable to items and services furnished  
19 to individuals by a home health agency that is not religious  
20 nonmedical health care institution.

21 “(2)(A) Subject to subparagraphs (B), payment may be  
22 made with respect to services provided by such an institution  
23 only to such extent and under such conditions, limitations, and  
24 requirements (in addition to or in lieu of the conditions, limita-  
25 tions, and requirements otherwise applicable) as may be pro-  
26 vided in regulations consistent with section 1821.

27 “(B) Notwithstanding any other provision of this title,  
28 payment may not be made under subparagraph (A)—

29 “(i) in a year insofar as such payments exceed  
30 \$700,000; and

31 “(ii) after December 31, 2006.”.

32 **Subtitle B—Graduate Medical**  
33 **Education**

34 **SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH**  
35 **COST PROGRAMS.**

36 Section 1886(h)(2)(D)(iv) (42 U.S.C.  
37 1395ww(h)(2)(D)(iv)) is amended—

- 1 (1) in subclause (I)—  
2 (A) by inserting “AND 2004 THROUGH 2013” after  
3 “AND 2002”; and  
4 (B) by inserting “or during the period beginning  
5 with fiscal year 2004 and ending with fiscal year 2013”  
6 after “during fiscal year 2001 or fiscal year 2002”;  
7 and  
8 (2) in subclause (II)—  
9 (A) by striking “fiscal year 2004, or fiscal year  
10 2005,” and  
11 (B) by striking “For a” and inserting “For the”.

12 **SEC. 712. EXCEPTION TO INITIAL RESIDENCY PERIOD**  
13 **FOR GERIATRIC RESIDENCY OR FELLOW-**  
14 **SHIP PROGRAMS.**

15 (a) CLARIFICATION OF CONGRESSIONAL INTENT.—Con-  
16 gress intended section 1886(h)(5)(F)(ii) of the Social Security  
17 Act (42 U.S.C. 1395ww(h)(5)(F)(ii)), as added by section 9202  
18 of the Consolidated Omnibus Budget Reconciliation Act of  
19 1985 (Public Law 99–272), to provide an exception to the ini-  
20 tial residency period for geriatric residency or fellowship pro-  
21 grams such that, where a particular approved geriatric training  
22 program requires a resident to complete 2 years of training to  
23 initially become board eligible in the geriatric specialty, the 2  
24 years spent in the geriatric training program are treated as  
25 part of the resident’s initial residency period, but are not  
26 counted against any limitation on the initial residency period.

27 (b) INTERIM FINAL REGULATORY AUTHORITY AND EF-  
28 FECTIVE DATE.—The Secretary shall promulgate interim final  
29 regulations consistent with the congressional intent expressed  
30 in this section after notice and pending opportunity for public  
31 comment to be effective for cost reporting periods beginning on  
32 or after October 1, 2003.

33 **SEC. 713. TREATMENT OF VOLUNTEER SUPERVISION.**

34 (a) MORATORIUM ON CHANGES IN TREATMENT.—During  
35 the 1-year period beginning on January 1, 2004, for purposes  
36 of applying subsections (d)(5)(B) and (h) of section 1886 of  
37 the Social Security Act (42 U.S.C. 1395ww), the Secretary

1 shall allow all hospitals to count residents in osteopathic and  
2 allopathic family practice programs in existence as of January  
3 1, 2002, who are training in non-hospital sites, without regard  
4 to the financial arrangement between the hospital and the  
5 teaching physician practicing in the non-hospital site to which  
6 the resident has been assigned.

7 (b) STUDY AND REPORT.—

8 (1) STUDY.—The Inspector General of the Depart-  
9 ment of Health and Human Services shall conduct a study  
10 of the appropriateness of alternative payment methodolo-  
11 gies under such sections for the costs of training residents  
12 in non-hospital settings.

13 (2) REPORT.—Not later than 1 year after the date of  
14 the enactment of this Act, the Inspector General shall sub-  
15 mit to Congress a report on the study conducted under  
16 paragraph (1), together with such recommendations as the  
17 Inspector General determines appropriate.

## 18 **Subtitle C—Chronic Care** 19 **Improvement**

### 20 **SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT** 21 **UNDER TRADITIONAL FEE-FOR-SERVICE.**

22 (a) IN GENERAL.—Title XVIII is amended by inserting  
23 after section 1806 the following new section:

24 “CHRONIC CARE IMPROVEMENT

25 “SEC. 1807. (a) IMPLEMENTATION OF CHRONIC CARE IM-  
26 PROVEMENT PROGRAMS.—

27 “(1) IN GENERAL.—The Secretary shall provide for  
28 the phased-in development, testing, evaluation, and imple-  
29 mentation of chronic care improvement programs in accord-  
30 ance with this section. Each such program shall be de-  
31 signed to improve clinical quality and beneficiary satisfac-  
32 tion and achieve spending targets with respect to expendi-  
33 tures under this title for targeted beneficiaries with one or  
34 more threshold conditions.

35 “(2) DEFINITIONS.—For purposes of this section:

36 “(A) CHRONIC CARE IMPROVEMENT PROGRAM.—  
37 The term ‘chronic care improvement program’ means a

1 program described in paragraph (1) that is offered  
2 under an agreement under subsection (b) or (c).

3 “(B) CHRONIC CARE IMPROVEMENT ORGANIZA-  
4 TION.—The term ‘chronic care improvement organiza-  
5 tion’ means an entity that has entered into an agree-  
6 ment under subsection (b) or (c) to provide, directly or  
7 through contracts with subcontractors, a chronic care  
8 improvement program under this section. Such an enti-  
9 ty may be a disease management organization, health  
10 insurer, integrated delivery system, physician group  
11 practice, a consortium of such entities, or any other  
12 legal entity that the Secretary determines appropriate  
13 to carry out a chronic care improvement program  
14 under this section.

15 “(C) CARE MANAGEMENT PLAN.—The term ‘care  
16 management plan’ means a plan established under sub-  
17 section (d) for a participant in a chronic care improve-  
18 ment program.

19 “(D) THRESHOLD CONDITION.—The term ‘thresh-  
20 old condition’ means a chronic condition, such as con-  
21 gestive heart failure, diabetes, chronic obstructive pul-  
22 monary disease (COPD), or other diseases or condi-  
23 tions, as selected by the Secretary as appropriate for  
24 the establishment of a chronic care improvement pro-  
25 gram.

26 “(E) TARGETED BENEFICIARY.—The term ‘tar-  
27 geted beneficiary’ means, with respect to a chronic care  
28 improvement program, an individual who—

29 “(i) is entitled to benefits under part A and  
30 enrolled under part B, but not enrolled in a plan  
31 under part C;

32 “(ii) has one or more threshold conditions cov-  
33 ered under such program; and

34 “(iii) has been identified under subsection  
35 (d)(1) as a potential participant in such program.

36 “(3) CONSTRUCTION.—Nothing in this section shall be  
37 construed as—

1           “(A) expanding the amount, duration, or scope of  
2 benefits under this title;

3           “(B) providing an entitlement to participate in a  
4 chronic care improvement program under this section;

5           “(C) providing for any hearing or appeal rights  
6 under section 1869, 1878, or otherwise, with respect to  
7 a chronic care improvement program under this sec-  
8 tion; or

9           “(D) providing benefits under a chronic care im-  
10 provement program for which a claim may be sub-  
11 mitted to the Secretary by any provider of services or  
12 supplier (as defined in section 1861(d)).

13       “(b) DEVELOPMENTAL PHASE (PHASE I).—

14           “(1) IN GENERAL.—In carrying out this section, the  
15 Secretary shall enter into agreements consistent with sub-  
16 section (f) with chronic care improvement organizations for  
17 the development, testing, and evaluation of chronic care im-  
18 provement programs using randomized controlled trials.  
19 The first such agreement shall be entered into not later  
20 than 12 months after the date of the enactment of this sec-  
21 tion.

22           “(2) AGREEMENT PERIOD.—The period of an agree-  
23 ment under this subsection shall be for 3 years.

24           “(3) MINIMUM PARTICIPATION.—

25           “(A) IN GENERAL.—The Secretary shall enter into  
26 agreements under this subsection in a manner so that  
27 chronic care improvement programs offered under this  
28 section are offered in geographic areas that, in the ag-  
29 gregate, consist of areas in which at least 10 percent  
30 of the aggregate number of medicare beneficiaries re-  
31 side.

32           “(B) MEDICARE BENEFICIARY DEFINED.—In this  
33 paragraph, the term ‘medicare beneficiary’ means an  
34 individual who is entitled to benefits under part A, en-  
35 rolled under part B, or both, and who resides in the  
36 United States.



1           “(4) SITE SELECTION.—In selecting geographic areas  
2           in which agreements are entered into under this subsection,  
3           the Secretary shall ensure that each chronic care improve-  
4           ment program is conducted in a geographic area in which  
5           at least 10,000 targeted beneficiaries reside among other  
6           individuals entitled to benefits under part A, enrolled under  
7           part B, or both to serve as a control population.

8           “(5) INDEPENDENT EVALUATIONS OF PHASE I PRO-  
9           GRAMS.—The Secretary shall contract for an independent  
10          evaluation of the programs conducted under this sub-  
11          section. Such evaluation shall be done by a contractor with  
12          knowledge of chronic care management programs and dem-  
13          onstrated experience in the evaluation of such programs.  
14          Each evaluation shall include an assessment of the fol-  
15          lowing factors of the programs:

16               “(A) Quality improvement measures, such as ad-  
17               herence to evidence-based guidelines and rehospitaliza-  
18               tion rates.

19               “(B) Beneficiary and provider satisfaction.

20               “(C) Health outcomes.

21               “(D) Financial outcomes, including any cost sav-  
22               ings to the program under this title.

23          “(c) EXPANDED IMPLEMENTATION PHASE (PHASE II).—

24               “(1) IN GENERAL.—With respect to chronic care im-  
25               provement programs conducted under subsection (b), if the  
26               Secretary finds that the results of the independent evalua-  
27               tion conducted under subsection (b)(6) indicate that the  
28               conditions specified in paragraph (2) have been met by a  
29               program (or components of such program), the Secretary  
30               shall enter into agreements consistent with subsection (f) to  
31               expand the implementation of the program (or components)  
32               to additional geographic areas not covered under the pro-  
33               gram as conducted under subsection (b), which may include  
34               the implementation of the program on a national basis.  
35               Such expansion shall begin not earlier than 2 years after  
36               the program is implemented under subsection (b) and not

1 later than 6 months after the date of completion of such  
2 program.

3 “(2) CONDITIONS FOR EXPANSION OF PROGRAMS.—  
4 The conditions specified in this paragraph are, with respect  
5 to a chronic care improvement program conducted under  
6 subsection (b) for a threshold condition, that the program  
7 is expected to—

8 “(A) improve the clinical quality of care;

9 “(B) improve beneficiary satisfaction; and

10 “(C) achieve targets for savings to the program  
11 under this title specified by the Secretary in the agree-  
12 ment within a range determined to be appropriate by  
13 the Secretary, subject to the application of budget neu-  
14 trality with respect to the program and not taking into  
15 account any payments by the organization under the  
16 agreement under the program for risk under subsection  
17 (f)(3)(B).

18 “(3) INDEPENDENT EVALUATIONS OF PHASE II PRO-  
19 GRAMS.—The Secretary shall carry out evaluations of pro-  
20 grams expanded under this subsection as the Secretary de-  
21 termines appropriate. Such evaluations shall be carried out  
22 in the similar manner as is provided under subsection  
23 (b)(5).

24 “(d) IDENTIFICATION AND ENROLLMENT OF PROSPEC-  
25 TIVE PROGRAM PARTICIPANTS.—

26 “(1) IDENTIFICATION OF PROSPECTIVE PROGRAM PAR-  
27 TICIPANTS.—The Secretary shall establish a method for  
28 identifying targeted beneficiaries who may benefit from  
29 participation in a chronic care improvement program.

30 “(2) INITIAL CONTACT BY SECRETARY.—The Sec-  
31 retary shall communicate with each targeted beneficiary  
32 concerning participation in a chronic care improvement  
33 program. Such communication may be made by the Sec-  
34 retary and shall include information on the following:

35 “(A) A description of the advantages to the bene-  
36 fiary in participating in a program.

1           “(B) Notification that the organization offering a  
2           program may contact the beneficiary directly con-  
3           cerning such participation.

4           “(C) Notification that participation in a program  
5           is voluntary.

6           “(D) A description of the method for the bene-  
7           ficiary to participate or for declining to participate and  
8           the method for obtaining additional information con-  
9           cerning such participation.

10          “(3) VOLUNTARY PARTICIPATION.—A targeted bene-  
11          ficiary may participate in a chronic care improvement pro-  
12          gram on a voluntary basis and may terminate participation  
13          at any time.

14          “(e) CHRONIC CARE IMPROVEMENT PROGRAMS.—

15          “(1) IN GENERAL.—Each chronic care improvement  
16          program shall—

17                 “(A) have a process to screen each targeted bene-  
18                 ficiary for conditions other than threshold conditions,  
19                 such as impaired cognitive ability and co-morbidities,  
20                 for the purposes of developing an individualized, goal-  
21                 oriented care management plan under paragraph (2);

22                 “(B) provide each targeted beneficiary partici-  
23                 pating in the program with such plan; and

24                 “(C) carry out such plan and other chronic care  
25                 improvement activities in accordance with paragraph  
26                 (3).

27          “(2) ELEMENTS OF CARE MANAGEMENT PLANS.—A  
28          care management plan for a targeted beneficiary shall be  
29          developed with the beneficiary and shall, to the extent ap-  
30          propriate, include the following:

31                 “(A) A designated point of contact responsible for  
32                 communications with the beneficiary and for facili-  
33                 tating communications with other health care providers  
34                 under the plan.

35                 “(B) Self-care education for the beneficiary  
36                 (through approaches such as disease management or

1 medical nutrition therapy) and education for primary  
2 caregivers and family members.

3 “(C) Education for physicians and other providers  
4 and collaboration to enhance communication of relevant  
5 clinical information.

6 “(D) The use of monitoring technologies that en-  
7 able patient guidance through the exchange of perti-  
8 nent clinical information, such as vital signs, sympto-  
9 matic information, and health self-assessment.

10 “(E) The provision of information about hospice  
11 care, pain and palliative care, and end-of-life care.

12 “(3) CONDUCT OF PROGRAMS.—In carrying out para-  
13 graph (1)(C) with respect to a participant, the chronic care  
14 improvement organization shall—

15 “(A) guide the participant in managing the par-  
16 ticipant’s health (including all co-morbidities, relevant  
17 health care services, and pharmaceutical needs) and in  
18 performing activities as specified under the elements of  
19 the care management plan of the participant;

20 “(B) use decision-support tools such as evidence-  
21 based practice guidelines or other criteria as deter-  
22 mined by the Secretary; and

23 “(C) develop a clinical information database to  
24 track and monitor each participant across settings and  
25 to evaluate outcomes.

26 “(4) ADDITIONAL RESPONSIBILITIES.—

27 “(A) OUTCOMES REPORT.—Each chronic care im-  
28 provement organization offering a chronic care im-  
29 provement program shall monitor and report to the  
30 Secretary, in a manner specified by the Secretary, on  
31 health care quality, cost, and outcomes.

32 “(B) ADDITIONAL REQUIREMENTS.—Each such  
33 organization and program shall comply with such addi-  
34 tional requirements as the Secretary may specify.

35 “(5) ACCREDITATION.—The Secretary may provide  
36 that chronic care improvement programs and chronic care  
37 improvement organizations that are accredited by qualified

1 organizations (as defined by the Secretary) may be deemed  
2 to meet such requirements under this section as the Sec-  
3 retary may specify.

4 “(f) TERMS OF AGREEMENTS.—

5 “(1) TERMS AND CONDITIONS.—

6 “(A) IN GENERAL.—An agreement under this sec-  
7 tion with a chronic care improvement organization shall  
8 contain such terms and conditions as the Secretary  
9 may specify consistent with this section.

10 “(B) CLINICAL, QUALITY IMPROVEMENT, AND FI-  
11 NANCIAL REQUIREMENTS.—The Secretary may not  
12 enter into an agreement with such an organization  
13 under this section for the operation of a chronic care  
14 improvement program unless—

15 “(i) the program and organization meet the  
16 requirements of subsection (e) and such clinical,  
17 quality improvement, financial, and other require-  
18 ments as the Secretary deems to be appropriate for  
19 the targeted beneficiaries to be served; and

20 “(ii) the organization demonstrates to the sat-  
21 isfaction of the Secretary that the organization is  
22 able to assume financial risk for performance under  
23 the agreement (as applied under paragraph (3)(B))  
24 with respect to payments made to the organization  
25 under such agreement through available reserves,  
26 reinsurance, withholds, or such other means as the  
27 Secretary determines appropriate.

28 “(2) MANNER OF PAYMENT.—Subject to paragraph  
29 (3)(B), the payment under an agreement under—

30 “(A) subsection (b) shall be computed on a per-  
31 member per-month basis; or

32 “(B) subsection (c) may be on a per-member per-  
33 month basis or such other basis as the Secretary and  
34 organization may agree.

35 “(3) APPLICATION OF PERFORMANCE STANDARDS.—

36 “(A) SPECIFICATION OF PERFORMANCE STAND-  
37 ARDS.—Each agreement under this section with a

1 chronic care improvement organization shall specify  
2 performance standards for each of the factors specified  
3 in subsection (c)(2), including clinical quality and  
4 spending targets under this title, against which the per-  
5 formance of the chronic care improvement organization  
6 under the agreement is measured.

7 “(B) ADJUSTMENT OF PAYMENT BASED ON PER-  
8 FORMANCE.—

9 “(i) IN GENERAL.—Each such agreement shall  
10 provide for adjustments in payment rates to an or-  
11 ganization under the agreement insofar as the Sec-  
12 retary determines that the organization failed to  
13 meet the performance standards specified in the  
14 agreement under subparagraph (A).

15 “(ii) FINANCIAL RISK FOR PERFORMANCE.—  
16 In the case of an agreement under subsection (b)  
17 or (c), the agreement shall provide for a full recov-  
18 ery for any amount by which the fees paid to the  
19 organization under the agreement exceed the esti-  
20 mated savings to the programs under this title at-  
21 tributable to implementation of such agreement.

22 “(4) BUDGET NEUTRAL PAYMENT CONDITION.—Under  
23 this section, the Secretary shall ensure that the aggregate  
24 sum of medicare program benefit expenditures for bene-  
25 ficiaries participating in chronic care improvement pro-  
26 grams and funds paid to chronic care improvement organi-  
27 zations under this section, shall not exceed the medicare  
28 program benefit expenditures that the Secretary estimates  
29 would have been made for such targeted beneficiaries in the  
30 absence of such programs.

31 “(g) FUNDING.—(1) Subject to paragraph (2), there are  
32 appropriated to the Secretary, in appropriate part from the  
33 Federal Hospital Insurance Trust Fund and the Federal Sup-  
34 plementary Medical Insurance Trust Fund, such sums as may  
35 be necessary to provide for agreements with chronic care im-  
36 provement programs under this section.

1           “(2) In no case shall the funding under this section exceed  
2 \$100,000,000 in aggregate increased expenditures under this  
3 title (after taking into account any savings attributable to the  
4 operation of this section) over the 3-fiscal-year period beginning  
5 on October 1, 2003.”.

6           (b) REPORTS.—The Secretary shall submit to Congress re-  
7 ports on the operation of section 1807 of the Social Security  
8 Act, as added by subsection (a), as follows:

9           (1) Not later than 2 years after the date of the imple-  
10 mentation of such section, the Secretary shall submit to  
11 Congress an interim report on the scope of implementation  
12 of the programs under subsection (b) of such section, the  
13 design of the programs, and preliminary cost and quality  
14 findings with respect to those programs based on the fol-  
15 lowing measures of the programs:

16           (A) Quality improvement measures, such as adher-  
17 ence to evidence-based guidelines and rehospitalization  
18 rates.

19           (B) Beneficiary and provider satisfaction.

20           (C) Health outcomes.

21           (D) Financial outcomes.

22           (2) Not later than 3 years and 6 months after the  
23 date of the implementation of such section the Secretary  
24 shall submit to Congress an update to the report required  
25 under paragraph (1) on the results of such programs.

26           (3) The Secretary shall submit to Congress 2 addi-  
27 tional biennial reports on the chronic care improvement  
28 programs conducted under such section. The first such re-  
29 port shall be submitted not later than 2 years after the re-  
30 port is submitted under paragraph (2). Each such report  
31 shall include information on—

32           (A) the scope of implementation (in terms of both  
33 regions and chronic conditions) of the chronic care im-  
34 provement programs;

35           (B) the design of the programs; and

1 (C) the improvements in health outcomes and fi-  
2 nancial efficiencies that result from such implementa-  
3 tion.

4 **SEC. 722. MEDICARE ADVANTAGE QUALITY IMPROVE-**  
5 **MENT PROGRAMS.**

6 (a) IN GENERAL.—Section 1852(e) (42 U.S.C. 1395w-  
7 22(e)) is amended—

8 (1) in the heading, by striking “ASSURANCE” and in-  
9 serting “IMPROVEMENT”;

10 (2) by amending paragraphs (1) through (3) to read  
11 as follows:

12 “(1) IN GENERAL.—Each MA organization shall have  
13 an ongoing quality improvement program for the purpose  
14 of improving the quality of care provided to enrollees in  
15 each MA plan offered by such organization (other than an  
16 MA private fee-for-service plan or an MSA plan).

17 “(2) CHRONIC CARE IMPROVEMENT PROGRAMS.—As  
18 part of the quality improvement program under paragraph  
19 (1), each MA organization shall have a chronic care im-  
20 provement program. Each chronic care improvement pro-  
21 gram shall have a method for monitoring and identifying  
22 enrollees with multiple or sufficiently severe chronic condi-  
23 tions that meet criteria established by the organization for  
24 participation under the program.

25 “(3) DATA.—

26 “(A) COLLECTION, ANALYSIS, AND REPORTING.—

27 “(i) IN GENERAL.—Except as provided in  
28 clauses (ii) and (iii) with respect to plans described  
29 in such clauses and subject to subparagraph (B),  
30 as part of the quality improvement program under  
31 paragraph (1), each MA organization shall provide  
32 for the collection, analysis, and reporting of data  
33 that permits the measurement of health outcomes  
34 and other indices of quality.

35 “(ii) APPLICATION TO MA REGIONAL PLANS.—  
36 The Secretary shall establish as appropriate by reg-  
37 ulation requirements for the collection, analysis,



1 and reporting of data that permits the measure-  
2 ment of health outcomes and other indices of qual-  
3 ity for MA organizations with respect to MA re-  
4 gional plans. Such requirements may not exceed  
5 the requirements under this subparagraph with re-  
6 spect to MA local plans that are preferred provider  
7 organization plans.

8 “(iii) APPLICATION TO PREFERRED PROVIDER  
9 ORGANIZATIONS.—Clause (i) shall apply to MA or-  
10 ganizations with respect to MA local plans that are  
11 preferred provider organization plans only insofar  
12 as services are furnished by providers or services,  
13 physicians, and other health care practitioners and  
14 suppliers that have contracts with such organiza-  
15 tion to furnish services under such plans.

16 “(iv) DEFINITION OF PREFERRED PROVIDER  
17 ORGANIZATION PLAN.—In this subparagraph, the  
18 term ‘preferred provider organization plan’ means  
19 an MA plan that—

20 “(I) has a network of providers that have  
21 agreed to a contractually specified reimburse-  
22 ment for covered benefits with the organization  
23 offering the plan;

24 “(II) provides for reimbursement for all  
25 covered benefits regardless of whether such  
26 benefits are provided within such network of  
27 providers; and

28 “(III) is offered by an organization that is  
29 not licensed or organized under State law as a  
30 health maintenance organization.

31 “(B) LIMITATIONS.—

32 “(i) TYPES OF DATA.—The Secretary shall not  
33 collect under subparagraph (A) data on quality,  
34 outcomes, and beneficiary satisfaction to facilitate  
35 consumer choice and program administration other  
36 than the types of data that were collected by the  
37 Secretary as of November 1, 2003.

1                   “(ii) CHANGES IN TYPES OF DATA.—Subject  
2                   to subclause (iii), the Secretary may only change  
3                   the types of data that are required to be submitted  
4                   under subparagraph (A) after submitting to Con-  
5                   gress a report on the reasons for such changes that  
6                   was prepared in consultation with MA organiza-  
7                   tions and private accrediting bodies.

8                   “(iii) CONSTRUCTION.—Nothing in the sub-  
9                   section shall be construed as restricting the ability  
10                  of the Secretary to carry out the duties under sec-  
11                  tion 1851(d)(4)(D).”;

12               (3) in paragraph (4)(B)—

13                   (A) by amending clause (i) to read as follows:

14                   “(i) Paragraphs (1) through (3) of this sub-  
15                   section (relating to quality improvement pro-  
16                   grams).”; and

17                   (B) by adding at the end the following new clause:

18                   “(vii) The requirements described in section  
19                   1860D–4(j), to the extent such requirements apply  
20                   under section 1860D–21(c).”; and

21               (4) by striking paragraph (5).

22               (b) CONFORMING AMENDMENT.—Section 1852(c)(1)(I)  
23               (42 U.S.C. 1395w–22(c)(1)(I)) is amended to read as follows:

24                   “(I) QUALITY IMPROVEMENT PROGRAM.—A de-  
25                   scription of the organization’s quality improvement pro-  
26                   gram under subsection (e).”.

27               (c) EFFECTIVE DATE.—The amendments made by this  
28               section shall apply with respect to contract years beginning on  
29               and after January 1, 2006.

30               **SEC. 723. CHRONICALLY ILL MEDICARE BENEFICIARY**  
31                   **RESEARCH, DATA, DEMONSTRATION STRAT-**  
32                   **EGY.**

33               (a) DEVELOPMENT OF PLAN.—Not later than 6 months  
34               after the date of the enactment of this Act, the Secretary shall  
35               develop a plan to improve quality of care and reduce the cost  
36               of care for chronically ill medicare beneficiaries.

1 (b) PLAN REQUIREMENTS.—The plan will utilize existing  
2 data and identify data gaps, develop research initiatives, and  
3 propose intervention demonstration programs to provide better  
4 health care for chronically ill medicare beneficiaries. The plan  
5 shall—

6 (1) integrate existing data sets including, the Medicare  
7 Current Beneficiary Survey (MCBS), Minimum Data Set  
8 (MDS), Outcome and Assessment Information Set  
9 (OASIS), data from Quality Improvement Organizations  
10 (QIO), and claims data;

11 (2) identify any new data needs and a methodology to  
12 address new data needs;

13 (3) plan for the collection of such data in a data ware-  
14 house; and

15 (4) develop a research agenda using such data.

16 (c) CONSULTATION.—In developing the plan under this  
17 section, the Secretary shall consult with experts in the fields of  
18 care for the chronically ill (including clinicians).

19 (d) IMPLEMENTATION.—Not later than 2 years after the  
20 date of the enactment of this Act, the Secretary shall imple-  
21 ment the plan developed under this section. The Secretary may  
22 contract with appropriate entities to implement such plan.

23 (e) AUTHORIZATION OF APPROPRIATIONS.—There are au-  
24 thorized to be appropriated to the Secretary such sums as may  
25 be necessary in fiscal years 2004 and 2005 to carry out this  
26 section.

## 27 **Subtitle D—Other Provisions**

### 28 **SEC. 731. IMPROVEMENTS IN NATIONAL AND LOCAL** 29 **COVERAGE DETERMINATION PROCESS TO** 30 **RESPOND TO CHANGES IN TECHNOLOGY.**

31 (a) NATIONAL AND LOCAL COVERAGE DETERMINATION  
32 PROCESS.—

33 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y),  
34 as amended by sections 948 and 950, is amended—

35 (A) in the third sentence of subsection (a), by in-  
36 serting “consistent with subsection (l)” after “the Sec-  
37 retary shall ensure”; and

1 (B) by adding at the end the following new sub-  
2 section:

3 “(I) NATIONAL AND LOCAL COVERAGE DETERMINATION  
4 PROCESS.—

5 “(1) FACTORS AND EVIDENCE USED IN MAKING NA-  
6 TIONAL COVERAGE DETERMINATIONS.—The Secretary shall  
7 make available to the public the factors considered in mak-  
8 ing national coverage determinations of whether an item or  
9 service is reasonable and necessary. The Secretary shall de-  
10 velop guidance documents to carry out this paragraph in a  
11 manner similar to the development of guidance documents  
12 under section 701(h) of the Federal Food, Drug, and Cos-  
13 metic Act (21 U.S.C. 371(h)).

14 “(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR  
15 NATIONAL COVERAGE DETERMINATIONS.—In the case of a  
16 request for a national coverage determination that—

17 “(A) does not require a technology assessment  
18 from an outside entity or deliberation from the Medi-  
19 care Coverage Advisory Committee, the decision on the  
20 request shall be made not later than 6 months after the  
21 date of the request; or

22 “(B) requires such an assessment or deliberation  
23 and in which a clinical trial is not requested, the deci-  
24 sion on the request shall be made not later than 9  
25 months after the date of the request.

26 “(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL  
27 COVERAGE DETERMINATIONS.—

28 “(A) PERIOD FOR PROPOSED DECISION.—Not  
29 later than the end of the 6-month period (or 9-month  
30 period for requests described in paragraph (2)(B)) that  
31 begins on the date a request for a national coverage de-  
32 termination is made, the Secretary shall make a draft  
33 of proposed decision on the request available to the  
34 public through the Internet website of the Centers for  
35 Medicare & Medicaid Services or other appropriate  
36 means.

1           “(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Be-  
2           ginning on the date the Secretary makes a draft of the  
3           proposed decision available under subparagraph (A),  
4           the Secretary shall provide a 30-day period for public  
5           comment on such draft.

6           “(C) 60-DAY PERIOD FOR FINAL DECISION.—Not  
7           later than 60 days after the conclusion of the 30-day  
8           period referred to under subparagraph (B), the Sec-  
9           retary shall—

10           “(i) make a final decision on the request;

11           “(ii) include in such final decision summaries  
12           of the public comments received and responses to  
13           such comments;

14           “(iii) make available to the public the clinical  
15           evidence and other data used in making such a de-  
16           cision when the decision differs from the rec-  
17           ommendations of the Medicare Coverage Advisory  
18           Committee; and

19           “(iv) in the case of a final decision under  
20           clause (i) to grant the request for the national cov-  
21           erage determination, the Secretary shall assign a  
22           temporary or permanent code (whether existing or  
23           unclassified) and implement the coding change.

24           “(4) CONSULTATION WITH OUTSIDE EXPERTS IN CER-  
25           TAIN NATIONAL COVERAGE DETERMINATIONS.—With re-  
26           spect to a request for a national coverage determination for  
27           which there is not a review by the Medicare Coverage Advi-  
28           sory Committee, the Secretary shall consult with appro-  
29           priate outside clinical experts.

30           “(5) LOCAL COVERAGE DETERMINATION PROCESS.—

31           “(A) PLAN TO PROMOTE CONSISTENCY OF COV-  
32           ERAGE DETERMINATIONS.—The Secretary shall develop  
33           a plan to evaluate new local coverage determinations to  
34           determine which determinations should be adopted na-  
35           tionally and to what extent greater consistency can be  
36           achieved among local coverage determinations.

1           “(B) CONSULTATION.—The Secretary shall re-  
2           quire the fiscal intermediaries or carriers providing  
3           services within the same area to consult on all new  
4           local coverage determinations within the area.

5           “(C) DISSEMINATION OF INFORMATION.—The  
6           Secretary should serve as a center to disseminate infor-  
7           mation on local coverage determinations among fiscal  
8           intermediaries and carriers to reduce duplication of ef-  
9           fort.

10          “(6) NATIONAL AND LOCAL COVERAGE DETERMINA-  
11          TION DEFINED.—For purposes of this subsection—

12           “(A) NATIONAL COVERAGE DETERMINATION.—  
13           The term ‘national coverage determination’ means a  
14           determination by the Secretary with respect to whether  
15           or not a particular item or service is covered nationally  
16           under this title.

17           “(B) LOCAL COVERAGE DETERMINATION.—The  
18           term ‘local coverage determination’ has the meaning  
19           given that in section 1869(f)(2)(B).”.

20          “(2) EFFECTIVE DATE.—The amendments made by  
21          paragraph (1) shall apply to national coverage determina-  
22          tions as of January 1, 2004, and section 1862(l)(5) of the  
23          Social Security Act, as added by such paragraph, shall  
24          apply to local coverage determinations made on or after  
25          July 1, 2004.

26          “(b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCI-  
27          ATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DE-  
28          VICES.—

29           “(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y),  
30           as amended by subsection (a), is amended by adding at the  
31           end the following new subsection:

32           “(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH  
33           CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

34           “(1) IN GENERAL.—In the case of an individual enti-  
35           tled to benefits under part A, or enrolled under part B, or  
36           both who participates in a category A clinical trial, the Sec-  
37           retary shall not exclude under subsection (a)(1) payment

1 for coverage of routine costs of care (as defined by the Sec-  
2 retary) furnished to such individual in the trial.

3 “(2) CATEGORY A CLINICAL TRIAL.—For purposes of  
4 paragraph (1), a ‘category A clinical trial’ means a trial of  
5 a medical device if—

6 “(A) the trial is of an experimental/investigational  
7 (category A) medical device (as defined in regulations  
8 under section 405.201(b) of title 42, Code of Federal  
9 Regulations (as in effect as of September 1, 2003));

10 “(B) the trial meets criteria established by the  
11 Secretary to ensure that the trial conforms to appro-  
12 priate scientific and ethical standards; and

13 “(C) in the case of a trial initiated before January  
14 1, 2010, the device involved in the trial has been deter-  
15 mined by the Secretary to be intended for use in the  
16 diagnosis, monitoring, or treatment of an immediately  
17 life-threatening disease or condition.”.

18 (2) EFFECTIVE DATE.—The amendment made by  
19 paragraph (1) shall apply to routine costs incurred on and  
20 after January 1, 2005, and, as of such date, section  
21 411.15(o) of title 42, Code of Federal Regulations, is su-  
22 perseded to the extent inconsistent with section 1862(m) of  
23 the Social Security Act, as added by such paragraph.

24 (3) RULE OF CONSTRUCTION.—Nothing in the amend-  
25 ment made by paragraph (1) shall be construed as applying  
26 to, or affecting, coverage or payment for a nonexperi-  
27 mental/investigational (category B) device.

28 (c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not  
29 later than July 1, 2004, the Secretary shall implement revised  
30 procedures for the issuance of temporary national HCPCS  
31 codes under part B of title XVIII of the Social Security Act.

32 **SEC. 732. EXTENSION OF TREATMENT OF CERTAIN PHY-**  
33 **SICIAN PATHOLOGY SERVICES UNDER MEDI-**  
34 **CARE.**

35 Section 542(c) of BIPA (114 Stat. 2763A–551) is amend-  
36 ed by inserting “, and for services furnished during 2005 and  
37 2006” before the period at the end.

1     **SEC. 733. PAYMENT FOR PANCREATIC ISLET CELL IN-**  
2                   **VESTIGATIONAL TRANSPLANTS FOR MEDI-**  
3                   **CARE BENEFICIARIES IN CLINICAL TRIALS.**

4             (a) CLINICAL TRIAL.—

5                 (1) IN GENERAL.—The Secretary, acting through the  
6             National Institute of Diabetes and Digestive and Kidney  
7             Disorders, shall conduct a clinical investigation of pan-  
8             creatic islet cell transplantation which includes medicare  
9             beneficiaries.

10                (2) AUTHORIZATION OF APPROPRIATIONS.—There are  
11             authorized to be appropriated to the Secretary such sums  
12             as may be necessary to conduct the clinical investigation  
13             under paragraph (1).

14                (b) MEDICARE PAYMENT.—Not earlier than October 1,  
15             2004, the Secretary shall pay for the routine costs as well as  
16             transplantation and appropriate related items and services (as  
17             described in subsection (c)) in the case of medicare bene-  
18             ficiaries who are participating in a clinical trial described in  
19             subsection (a) as if such transplantation were covered under  
20             title XVIII of such Act and as would be paid under part A or  
21             part B of such title for such beneficiary.

22                (c) SCOPE OF PAYMENT.—For purposes of subsection (b):

23                 (1) The term “routine costs” means reasonable and  
24             necessary routine patient care costs (as defined in the Cen-  
25             ters for Medicare & Medicaid Services Coverage Issues  
26             Manual, section 30–1), including immunosuppressive drugs  
27             and other followup care.

28                 (2) The term “transplantation and appropriate related  
29             items and services” means items and services related to the  
30             acquisition and delivery of the pancreatic islet cell trans-  
31             plantation, notwithstanding any national noncoverage de-  
32             termination contained in the Centers for Medicare & Med-  
33             icaid Services Coverage Issues Manual.

34                 (3) The term “medicare beneficiary” means an indi-  
35             vidual who is entitled to benefits under part A of title  
36             XVIII of the Social Security Act, or enrolled under part B  
37             of such title, or both.



1 (d) CONSTRUCTION.—The provisions of this section shall  
2 not be construed—

3 (1) to permit payment for partial pancreatic tissue or  
4 islet cell transplantation under title XVIII of the Social Se-  
5 curity Act other than payment as described in subsection  
6 (b); or

7 (2) as authorizing or requiring coverage or payment  
8 conveying—

9 (A) benefits under part A of such title to a bene-  
10 ficiary not entitled to such part A; or

11 (B) benefits under part B of such title to a bene-  
12 ficiary not enrolled in such part B.

13 **SEC. 734. RESTORATION OF MEDICARE TRUST FUNDS.**

14 (a) DEFINITIONS.—In this section:

15 (1) CLERICAL ERROR.—The term “clerical error”  
16 means a failure that occurs on or after April 15, 2001, to  
17 have transferred the correct amount from the general fund  
18 of the Treasury to a Trust Fund.

19 (2) TRUST FUND.—The term “Trust Fund” means  
20 the Federal Hospital Insurance Trust Fund established  
21 under section 1817 of the Social Security Act (42 U.S.C.  
22 1395i) and the Federal Supplementary Medical Insurance  
23 Trust Fund established under section 1841 of such Act (42  
24 U.S.C. 1395t).

25 (b) CORRECTION OF TRUST FUND HOLDINGS.—

26 (1) IN GENERAL.—The Secretary of the Treasury  
27 shall take the actions described in paragraph (2) with re-  
28 spect to the Trust Fund with the goal being that, after  
29 such actions are taken, the holdings of the Trust Fund will  
30 replicate, to the extent practicable in the judgment of the  
31 Secretary of the Treasury, in consultation with the Sec-  
32 retary, the holdings that would have been held by the Trust  
33 Fund if the clerical error involved had not occurred.

34 (2) OBLIGATIONS ISSUED AND REDEEMED.—The Sec-  
35 retary of the Treasury shall—

36 (A) issue to the Trust Fund obligations under  
37 chapter 31 of title 31, United States Code, that bear

1 issue dates, interest rates, and maturity dates that are  
2 the same as those for the obligations that—

3 (i) would have been issued to the Trust Fund  
4 if the clerical error involved had not occurred; or

5 (ii) were issued to the Trust Fund and were  
6 redeemed by reason of the clerical error involved;  
7 and

8 (B) redeem from the Trust Fund obligations that  
9 would have been redeemed from the Trust Fund if the  
10 clerical error involved had not occurred.

11 (c) APPROPRIATION.—There is appropriated to the Trust  
12 Fund, out of any money in the Treasury not otherwise appro-  
13 priated, an amount determined by the Secretary of the Treas-  
14 ury, in consultation with the Secretary, to be equal to the inter-  
15 est income lost by the Trust Fund through the date on which  
16 the appropriation is being made as a result of the clerical error  
17 involved.

18 (d) CONGRESSIONAL NOTICE.—In the case of a clerical  
19 error that occurs after April 15, 2001, the Secretary of the  
20 Treasury, before taking action to correct the error under this  
21 section, shall notify the appropriate committees of Congress  
22 concerning such error and the actions to be taken under this  
23 section in response to such error.

24 (e) DEADLINE.—With respect to the clerical error that oc-  
25 curred on April 15, 2001, not later than 120 days after the  
26 date of the enactment of this Act—

27 (1) the Secretary of the Treasury shall take the ac-  
28 tions under subsection (b)(1); and

29 (2) the appropriation under subsection (c) shall be  
30 made.

31 **SEC. 735. MODIFICATIONS TO MEDICARE PAYMENT AD-**  
32 **VISORY COMMISSION (MEDPAC).**

33 (a) EXAMINATION OF BUDGET CONSEQUENCES.—Section  
34 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the  
35 end the following new paragraph:

36 “(8) EXAMINATION OF BUDGET CONSEQUENCES.—Be-  
37 fore making any recommendations, the Commission shall

1 examine the budget consequences of such recommendations,  
2 directly or through consultation with appropriate expert en-  
3 tities.”.

4 (b) CONSIDERATION OF EFFICIENT PROVISION OF SERV-  
5 ICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b-  
6 6(b)(2)(B)(i)) is amended by inserting “the efficient provision  
7 of” after “expenditures for”.

8 (c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

9 (1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C.  
10 1395b-6(c)(2)(D)) is amended by adding at the end the  
11 following: “Members of the Commission shall be treated as  
12 employees of Congress for purposes of applying title I of  
13 the Ethics in Government Act of 1978 (Public Law 95-  
14 521).”.

15 (2) EFFECTIVE DATE.—The amendment made by  
16 paragraph (1) shall take effect on January 1, 2004.

17 (d) ADDITIONAL REPORTS.—

18 (1) DATA NEEDS AND SOURCES.—The Medicare Pay-  
19 ment Advisory Commission shall conduct a study, and sub-  
20 mit a report to Congress by not later than June 1, 2004,  
21 on the need for current data, and sources of current data  
22 available, to determine the solvency and financial cir-  
23 cumstances of hospitals and other medicare providers of  
24 services.

25 (2) USE OF TAX-RELATED RETURNS.—Using return  
26 information provided under Form 990 of the Internal Rev-  
27 enue Service, the Commission shall submit to Congress, by  
28 not later than June 1, 2004, a report on the following:

29 (A) Investments, endowments, and fundraising of  
30 hospitals participating under the medicare program and  
31 related foundations.

32 (B) Access to capital financing for private and for  
33 not-for-profit hospitals.

34 (e) REPRESENTATION OF EXPERTS IN PRESCRIPTION  
35 DRUGS.—

36 (1) IN GENERAL.—Section 1805(c)(2)(B) (42 U.S.C.  
37 1395b-6(c)(2)(B)) is amended by inserting “experts in the

1 area of pharmaco-economics or prescription drug benefit  
2 programs,” after “other health professionals,”.

3 (2) APPOINTMENT.—The Comptroller General of the  
4 United States shall ensure that the membership of the  
5 Commission complies with the amendment made by para-  
6 graph (1) with respect to appointments made on or after  
7 the date of the enactment of this Act.

8 **SEC. 736. TECHNICAL AMENDMENTS.**

9 (a) PART A.—(1) Section 1814(a) (42 U.S.C. 1395f(a)) is  
10 amended—

11 (A) by striking the seventh sentence, as added by sec-  
12 tion 322(a)(1) of BIPA (114 Stat. 2763A–501); and

13 (B) in paragraph (7)(A)—

14 (i) in clause (i), by inserting before the comma at  
15 the end the following: “based on the physician’s or  
16 medical director’s clinical judgment regarding the nor-  
17 mal course of the individual’s illness”; and

18 (ii) in clause (ii), by inserting before the semicolon  
19 at the end the following: “based on such clinical judg-  
20 ment”.

21 (2) Section 1814(b) (42 U.S.C. 1395f(b)), in the matter  
22 preceding paragraph (1), is amended by inserting a comma  
23 after “1813”.

24 (3) Section 1815(e)(1)(B) (42 U.S.C. 1395g(e)(1)(B)), in  
25 the matter preceding clause (i), is amended by striking “of hos-  
26 pital” and inserting “of a hospital”.

27 (4) Section 1816(c)(2)(B)(ii) (42 U.S.C.  
28 1395h(c)(2)(B)(ii)) is amended—

29 (A) by striking “and” at the end of subclause (III);  
30 and

31 (B) by striking the period at the end of subclause (IV)  
32 and inserting “, and”.

33 (5) Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is  
34 amended—

35 (A) in clause (i)(I), by striking the comma at the end  
36 and inserting a semicolon; and

1 (B) in clause (ii), by striking “the Medicare and med-  
2 icaid programs” and inserting “the programs under this  
3 title and title XIX”.

4 (6) Section 1817(k)(6)(B) (42 U.S.C. 1395i(k)(6)(B)) is  
5 amended by striking “Medicare program under title XVIII”  
6 and inserting “program under this title”.

7 (7) Section 1818 (42 U.S.C. 1395i-2) is amended—

8 (A) in subsection (d)(6)(A) is amended by inserting  
9 “of such Code” after “3111(b)”; and

10 (B) in subsection (g)(2)(B) is amended by striking  
11 “subsection (b).” and inserting “subsection (b)”.

12 (8) Section 1819 (42 U.S.C. 1395i-3) is amended—

13 (A) in subsection (b)(4)(C)(i), by striking “at least at  
14 least” and inserting “at least”;

15 (B) in subsection (d)(1)(A), by striking “physical men-  
16 tal” and inserting “physical, mental”; and

17 (C) in subsection (f)(2)(B)(iii), by moving the last sen-  
18 tence 2 ems to the left.

19 (9) Section 1886(b)(3)(I)(i)(I) (42 U.S.C.  
20 1395ww(b)(3)(I)(i)(I)) is amended by striking “the the” and  
21 inserting “the”.

22 (10) The heading of subsection (mm) of section 1861 (42  
23 U.S.C. 1395x) is amended to read as follows:

24 “Critical Access Hospital; Critical Access Hospital Services”.

25 (11) Paragraphs (1) and (2) of section 1861(tt) (42  
26 U.S.C. 1395x(tt)) are each amended by striking “rural primary  
27 care” and inserting “critical access”.

28 (12) Section 1865(b)(3)(B) (42 U.S.C. 1395bb(b)(3)(B))  
29 is amended by striking “section 1819 and 1861(j)” and insert-  
30 ing “sections 1819 and 1861(j)”.

31 (13) Section 1866(b)(2) (42 U.S.C. 1395cc(b)(2)) is  
32 amended by moving subparagraph (D) 2 ems to the left.

33 (14) Section 1867 (42 U.S.C. 1395dd) is amended—

34 (A) in the matter following clause (ii) of subsection  
35 (d)(1)(B), by striking “is is” and inserting “is”;

36 (B) in subsection (e)(1)(B), by striking “a pregnant  
37 women” and inserting “a pregnant woman”; and

1 (C) in subsection (e)(2), by striking “means hospital”  
2 and inserting “means a hospital”.

3 (15) Section 1886(g)(3)(B) (42 U.S.C. 1395ww(g)(3)(B))  
4 is amended by striking “(as defined in subsection  
5 (d)(5)(D)(iii)” and inserting “(as defined in subsection  
6 (d)(5)(D)(iii))”.

7 (b) PART B.—(1) Section 1833(h)(5)(D) (42 U.S.C.  
8 1395l(h)(5)(D)) is amended by striking “clinic,,” and inserting  
9 “clinic,”.

10 (2) Section 1833(t)(3)(C)(ii) (42 U.S.C.  
11 1395l(t)(3)(C)(ii)) is amended by striking “clause (iii)” and in-  
12 serting “clause (iv)”.

13 (3) Section 1861(v)(1)(S)(ii)(III) (42 U.S.C.  
14 1395x(v)(1)(S)(ii)(III)) is amended by striking “(as defined in  
15 section 1886(d)(5)(D)(iii)” and inserting “(as defined in sec-  
16 tion 1886(d)(5)(D)(iii))”.

17 (4) Section 1834(b)(4)(D)(iv) (42 U.S.C.  
18 1395m(b)(4)(D)(iv)) is amended by striking “clauses (vi)” and  
19 inserting “clause (vi)”.

20 (5) Section 1834(m)(4)(C)(ii)(III) (42 U.S.C.  
21 1395m(m)(4)(C)(ii)(III)) is amended by striking “1861(aa)(s)”  
22 and inserting “1861(aa)(2)”.

23 (6) Section 1838(a)(1) (42 U.S.C. 1395q(a)(1)) is amend-  
24 ed by inserting a comma after “1966”.

25 (7) The second sentence of section 1839(a)(4) (42 U.S.C.  
26 1395r(a)(4)) is amended by striking “which will” and inserting  
27 “will”.

28 (8) Section 1842(c)(2)(B)(ii) (42 U.S.C.  
29 1395u(c)(2)(B)(ii)) is amended—

30 (A) by striking “and” at the end of subclause (III);  
31 and

32 (B) by striking the period at the end of subclause (IV)  
33 and inserting “, and”.

34 (9) Section 1842(i)(2) (42 U.S.C. 1395u(i)(2)) is amended  
35 by striking “services, a physician” and inserting “services, to  
36 a physician”.

1           (10) Section 1848(i)(3)(A) (42 U.S.C. 1395w-4(i)(3)(A))  
2 is amended by striking “a comparable services” and inserting  
3 “comparable services”.

4           (11) Section 1861(s)(2)(K)(i) (42 U.S.C.  
5 1395x(s)(2)(K)(i)) is amended by striking “; and but” and in-  
6 serting “, but”.

7           (12) Section 1861(aa)(1)(B) (42 U.S.C. 1395x(aa)(1)(B))  
8 is amended by striking “,” and inserting a comma.

9           (13) Section 128(b)(2) of BIPA (114 Stat. 2763A-480) is  
10 amended by striking “Not later that” and inserting “Not later  
11 than” each place it appears.

12           (c) PARTS A AND B.—(1) Section 1812(a)(3) (42 U.S.C.  
13 1395d(a)(3)) is amended—

14               (A) by striking “for individuals not” and inserting “in  
15 the case of individuals not”; and

16               (B) by striking “for individuals so” and inserting “in  
17 the case of individuals so”.

18           (2)(A) Section 1814(a) (42 U.S.C. 1395f(a)) is amended  
19 in the sixth sentence by striking “leave home,” and inserting  
20 “leave home and”.

21           (B) Section 1835(a) (42 U.S.C. 1395n(a)) is amended in  
22 the seventh sentence by striking “leave home,” and inserting  
23 “leave home and”.

24           (3) Section 1891(d)(1) (42 U.S.C. 1395bbb(d)(1)) is  
25 amended by striking “subsection (c)(2)(C)(I)” and inserting  
26 “subsection (c)(2)(C)(i)(I)”.

27           (4) Section 1861(v) (42 U.S.C. 1395x(v)) is amended by  
28 moving paragraph (8) (including clauses (i) through (v) of such  
29 paragraph) 2 ems to the left.

30           (5) Section 1866B(b)(7)(D) (42 U.S.C. 1395cc-  
31 2(b)(7)(D)) is amended by striking “(c)(2)(A)(ii)” and insert-  
32 ing “(c)(2)(B)”.

33           (6) Section 1886(h)(3)(D)(ii)(III) (42 U.S.C.  
34 1395ww(h)(3)(D)(ii)(III)) is amended by striking “and” after  
35 the comma at the end.

1           (7) Section 1893(a) (42 U.S.C. 1395ddd(a)) is amended  
2 by striking “Medicare program” and inserting “medicare pro-  
3 gram”.

4           (8) Section 1896(b)(4) (42 U.S.C. 1395ggg(b)(4)) is  
5 amended by striking “701(f)” and inserting “712(f)”.

6           (d) PART C.—(1) Section 1853 (42 U.S.C. 1395w-23), as  
7 amended by section 607 of BIPA (114 Stat. 2763A-558), is  
8 amended—

9           (A) in subsection (a)(3)(C)(ii), by striking “clause  
10 (iii)” and inserting “clause (iv)”;

11           (B) in subsection (a)(3)(C), by redesignating the  
12 clause (iii) added by such section 607 as clause (iv); and

13           (C) in subsection (c)(5), by striking “(a)(3)(C)(iii)”  
14 and inserting “(a)(3)(C)(iv)”.

15           (2) Section 1876 (42 U.S.C. 1395mm) is amended—

16           (A) in subsection (c)(2)(B), by striking “significant”  
17 and inserting “significant”; and

18           (B) in subsection (j)(2), by striking “this setion” and  
19 inserting “this section”.

20           (e) MEDIGAP.—Section 1882 (42 U.S.C. 1395ss) is  
21 amended—

22           (1) in subsection (d)(3)(A)(i)(II), by striking “plan a  
23 medicare supplemental policy” and inserting “plan, a medi-  
24 care supplemental policy”;

25           (2) in subsection (d)(3)(B)(iii)(II), by striking “to the  
26 best of the issuer or seller’s knowledge” and inserting “to  
27 the best of the issuer’s or seller’s knowledge”;

28           (3) in subsection (g)(2)(A), by striking “medicare sup-  
29 plement policies” and inserting “medicare supplemental  
30 policies”;

31           (4) in subsection (p)(2)(B), by striking “, and” and  
32 inserting “; and”; and

33           (5) in subsection (s)(3)(A)(iii), by striking “pre-exist-  
34 ing” and inserting “preexisting”.



1           **TITLE VIII—COST CONTAINMENT**  
2           **Subtitle A—Cost Containment**

3           **SEC. 801. INCLUSION IN ANNUAL REPORT OF MEDICARE**  
4           **TRUSTEES OF INFORMATION ON STATUS OF**  
5           **MEDICARE TRUST FUNDS.**

6           (a) DETERMINATIONS OF EXCESS GENERAL REVENUE  
7           MEDICARE FUNDING.—

8           (1) IN GENERAL.—The Board of Trustees of each  
9           medicare trust fund shall include in the annual reports sub-  
10          mitted under subsection (b)(2) of sections 1817 and 1841  
11          of the Social Security Act (42 U.S.C. 1395i and 1395t)—

12           (A) the information described in subsection (b);

13           and

14           (B) a determination as to whether there is pro-  
15          jected to be excess general revenue medicare funding  
16          (as defined in subsection (c)) for the fiscal year in  
17          which the report is submitted or for any of the suc-  
18          ceeding 6 fiscal years.

19          (2) MEDICARE FUNDING WARNING.—For purposes of  
20          section 1105(h) of title 31, United States Code, and this  
21          subtitle, an affirmative determination under paragraph  
22          (1)(B) in 2 consecutive annual reports shall be treated as  
23          a medicare funding warning in the year in which the sec-  
24          ond such report is made.

25          (3) 7-FISCAL-YEAR REPORTING PERIOD.—For pur-  
26          poses of this subtitle, the term “7-fiscal-year reporting pe-  
27          riod” means, with respect to a year in which an annual re-  
28          port described in paragraph (1) is made, the period of 7  
29          consecutive fiscal years beginning with the fiscal year in  
30          which the report is submitted.

31          (b) INFORMATION.—The information described in this sub-  
32          section for an annual report in a year is as follows:

33           (1) PROJECTIONS OF GROWTH OF GENERAL REVENUE  
34          SPENDING.—A statement of the general revenue medicare  
35          funding as a percentage of the total medicare outlays for  
36          each of the following:

1 (A) Each fiscal year within the 7-fiscal-year re-  
2 porting period.

3 (B) Previous fiscal years and as of 10, 50, and 75  
4 years after such year.

5 (2) COMPARISON WITH OTHER GROWTH TRENDS.—A  
6 comparison of the trend of such percentages with the an-  
7 nual growth rate in the following:

8 (A) The gross domestic product.

9 (B) Private health costs.

10 (C) National health expenditures.

11 (D) Other appropriate measures.

12 (3) PART D SPENDING.—Expenditures, including  
13 trends in expenditures, under part D of title XVIII of the  
14 Social Security Act, as added by section 101.

15 (4) COMBINED MEDICARE TRUST FUND ANALYSIS.—A  
16 financial analysis of the combined medicare trust funds if  
17 general revenue medicare funding were limited to the per-  
18 centage specified in subsection (c)(1)(B) of total medicare  
19 outlays.

20 (c) DEFINITIONS.—For purposes of this section:

21 (1) EXCESS GENERAL REVENUE MEDICARE FUND-  
22 ING.—The term “excess general revenue medicare funding”  
23 means, with respect to a fiscal year, that—

24 (A) general revenue medicare funding (as defined  
25 in paragraph (2)), expressed as a percentage of total  
26 medicare outlays (as defined in paragraph (4)) for the  
27 fiscal year; exceeds

28 (B) 45 percent.

29 (2) GENERAL REVENUE MEDICARE FUNDING.—The  
30 term “general revenue medicare funding” means for a  
31 year—

32 (A) the total medicare outlays (as defined in para-  
33 graph (4)) for the year; minus

34 (B) the dedicated medicare financing sources (as  
35 defined in paragraph (3))) for the year.

1           (3) DEDICATED MEDICARE FINANCING SOURCES.—  
2           The term “dedicated medicare financing sources” means  
3           the following:

4           (A) HOSPITAL INSURANCE TAX.—Amounts appro-  
5           priated to the Hospital Insurance Trust Fund under  
6           the third sentence of section 1817(a) of the Social Se-  
7           curity Act (42 U.S.C. 1395i(a)) and amounts trans-  
8           ferred to such Trust Fund under section 7(c)(2) of the  
9           Railroad Retirement Act of 1974 (45 U.S.C.  
10          231f(c)(2)).

11          (B) TAXATION OF CERTAIN OASDI BENEFITS.—  
12          Amounts appropriated to the Hospital Insurance Trust  
13          Fund under section 121(e)(1)(B) of the Social Security  
14          Amendments of 1983 (Public Law 98–21), as inserted  
15          by section 13215(c) of the Omnibus Budget Reconcili-  
16          ation Act of 1993 (Public Law 103–66).

17          (C) STATE TRANSFERS.—The State share of  
18          amounts paid to the Federal Government by a State  
19          under section 1843 of the Social Security Act (42  
20          U.S.C. 1395v) or pursuant to section 1935(c) of such  
21          Act.

22          (D) PREMIUMS.—The following premiums:

23           (i) PART A.—Premiums paid by non-Federal  
24           sources under sections 1818 and section 1818A (42  
25           U.S.C. 1395i–2 and 1395i–2a) of such Act.

26           (ii) PART B.—Premiums paid by non-Federal  
27           sources under section 1839 of such Act (42 U.S.C.  
28           1395r), including any adjustments in premiums  
29           under such section.

30           (iii) PART D.—Monthly beneficiary premiums  
31           paid under part D of title XVIII of such Act, as  
32           added by section 101, and MA monthly prescription  
33           drug beneficiary premiums paid under part C of  
34           such title insofar as they are attributable to basic  
35           prescription drug coverage.

36          Premiums under clauses (ii) and (iii) shall be determined  
37          without regard to any reduction in such premiums attrib-

1           utable to a beneficiary rebate under section 1854(b)(1)(C)  
2           of such title, as amended by section 222(b)(1), and pre-  
3           miums under clause (iii) are deemed to include any  
4           amounts paid under section 1860D–13(b) of such title, as  
5           added by section 101.

6           (E) GIFTS.—Amounts received by the medicare  
7           trust funds under section 201(i) of the Social Security  
8           Act (42 U.S.C. 401(i)).

9           (4) TOTAL MEDICARE OUTLAYS.—The term “total  
10          medicare outlays” means total outlays from the medicare  
11          trust funds and shall—

12          (A) include payments made to plans under part C  
13          of title XVIII of the Social Security Act that are attrib-  
14          utable to any rebates under section 1854(b)(1)(C) of  
15          such Act (42 U.S.C. 1395w–24(b)(1)(C)), as amended  
16          by section 222(b)(1);

17          (B) include administrative expenditures made in  
18          carrying out title XVIII of such Act and Federal out-  
19          lays under section 1935(b) of such Act, as added by  
20          section 103(a)(2); and

21          (C) offset outlays by the amount of fraud and  
22          abuse collections insofar as they are applied or depos-  
23          ited into a medicare trust fund.

24          (5) MEDICARE TRUST FUND.—The term “medicare  
25          trust fund” means—

26          (A) the Federal Hospital Insurance Trust Fund  
27          established under section 1817 of the Social Security  
28          Act (42 U.S.C. 1395i); and

29          (B) the Federal Supplementary Medical Insurance  
30          Trust Fund established under section 1841 of such Act  
31          (42 U.S.C. 1395t), including the Medicare Prescription  
32          Drug Account under such Trust Fund.

33          (d) CONFORMING AMENDMENTS.—

34          (1) FEDERAL HOSPITAL INSURANCE TRUST FUND.—  
35          Section 1817(b)(2) (42 U.S.C. 1395i(b)(2)) is amended by  
36          adding at the end the following: “Each report provided  
37          under paragraph (2) beginning with the report in 2005

1 shall include the information specified in section 801(a) of  
2 Medicare Prescription Drug, Improvement, and Moderniza-  
3 tion Act of 2003.”.

4 (2) FEDERAL SUPPLEMENTARY MEDICAL INSURANCE  
5 TRUST FUND.—Section 1841(b)(2) (42 U.S.C. 1395t(b)(2))  
6 is amended by adding at the end the following: “Each re-  
7 port provided under paragraph (2) beginning with the re-  
8 port in 2005 shall include the information specified in sec-  
9 tion 801(a) of Medicare Prescription Drug, Improvement,  
10 and Modernization Act of 2003.”.

11 (e) NOTICE OF MEDICARE FUNDING WARNING.—When-  
12 ever any report described in subsection (a) contains a deter-  
13 mination that for any fiscal year within the 7-fiscal-year report-  
14 ing period there will be excess general revenue medicare fund-  
15 ing, Congress and the President should address the matter  
16 under existing rules and procedures.

17 **SEC. 802. PRESIDENTIAL SUBMISSION OF LEGISLATION.**

18 (a) IN GENERAL.—Section 1105 of title 31, United States  
19 Code, is amended by adding at the end the following new sub-  
20 section:

21 “(h)(1) If there is a medicare funding warning under sec-  
22 tion 801(a)(2) of the Medicare Prescription Drug, Improve-  
23 ment, and Modernization Act of 2003 made in a year, the  
24 President shall submit to Congress, within the 15-day period  
25 beginning on the date of the budget submission to Congress  
26 under subsection (a) for the succeeding year, proposed legisla-  
27 tion to respond to such warning.

28 “(2) Paragraph (1) does not apply if, during the year in  
29 which the warning is made, legislation is enacted which elimi-  
30 nates excess general revenue medicare funding (as defined in  
31 section 801(c) of the Medicare Prescription Drug, Improve-  
32 ment, and Modernization Act of 2003) for the 7-fiscal-year re-  
33 porting period, as certified by the Board of Trustees of each  
34 medicare trust fund (as defined in section 801(c)(5) of such  
35 Act) not later than 30 days after the date of the enactment of  
36 such legislation.”.

1 (b) SENSE OF CONGRESS.—It is the sense of Congress  
2 that legislation submitted pursuant to section 1105(h) of title  
3 31, United States Code, in a year should be designed to elimi-  
4 nate excess general revenue medicare funding (as defined in  
5 section 801(c)) for the 7-fiscal-year period that begins in such  
6 year.

7 **SEC. 803. PROCEDURES IN THE HOUSE OF REPRESENTA-**  
8 **TIVES.**

9 (a) INTRODUCTION AND REFERRAL OF PRESIDENT'S LEG-  
10 ISLATIVE PROPOSAL.—

11 (1) INTRODUCTION.—In the case of a legislative pro-  
12 posal submitted by the President pursuant to section  
13 1105(h) of title 31, United States Code, within the 15-day  
14 period specified in paragraph (1) of such section, the Ma-  
15 jority Leader of the House of Representatives (or his des-  
16 ignee) and the Minority Leader of the House of Represent-  
17 atives (or his designee) shall introduce such proposal (by  
18 request), the title of which is as follows: “A bill to respond  
19 to a medicare funding warning.” Such bill shall be intro-  
20 duced within 3 legislative days after Congress receives such  
21 proposal.

22 (2) REFERRAL.—Any legislation introduced pursuant  
23 to paragraph (1) shall be referred to the appropriate com-  
24 mittees of the House of Representatives.

25 (b) DIRECTION TO THE APPROPRIATE HOUSE COMMIT-  
26 TEES.—

27 (1) IN GENERAL.—In the House, in any year during  
28 which the President is required to submit proposed legisla-  
29 tion to Congress under section 1105(h) of title 31, United  
30 States Code, the appropriate committees shall report medi-  
31 care funding legislation by not later than June 30 of such  
32 year.

33 (2) MEDICARE FUNDING LEGISLATION.—For purposes  
34 of this section, the term “medicare funding legislation”  
35 means—

36 (A) legislation introduced pursuant to subsection  
37 (a)(1), but only if the legislative proposal upon which

1 the legislation is based was submitted within the 15-  
2 day period referred to in such subsection; or

3 (B) any bill the title of which is as follows: “A bill  
4 to respond to a medicare funding warning.”.

5 (3) CERTIFICATION.—With respect to any medicare  
6 funding legislation or any amendment to such legislation to  
7 respond to a medicare funding warning, the chairman of  
8 the Committee on the Budget of the House shall certify—

9 (A) whether or not such legislation eliminates ex-  
10 cess general revenue medicare funding (as defined in  
11 section 801(c)) for each fiscal year in the 7-fiscal-year  
12 reporting period; and

13 (B) with respect to such an amendment, whether  
14 the legislation, as amended, would eliminate excess gen-  
15 eral revenue medicare funding (as defined in section  
16 801(c)) for each fiscal year in such 7-fiscal-year report-  
17 ing period.

18 (c) FALLBACK PROCEDURE FOR FLOOR CONSIDERATION  
19 IF THE HOUSE FAILS TO VOTE ON FINAL PASSAGE BY JULY  
20 30.—

21 (1) After July 30 of any year during which the Presi-  
22 dent is required to submit proposed legislation to Congress  
23 under section 1105(h) of title 31, United States Code, un-  
24 less the House of Representatives has voted on final pas-  
25 sage of any medicare funding legislation for which there is  
26 an affirmative certification under subsection (b)(3)(A),  
27 then, after the expiration of not less than 30 calendar days  
28 (and concurrently 5 legislative days), it is in order to move  
29 to discharge any committee to which medicare funding leg-  
30 islation which has such a certification and which has been  
31 referred to such committee for 30 calendar days from fur-  
32 ther consideration of the legislation.

33 (2) A motion to discharge may be made only by an in-  
34 dividual favoring the legislation, may be made only if sup-  
35 ported by one-fifth of the total membership of the House  
36 (a quorum being present), and is highly privileged in the  
37 House. Debate thereon shall be limited to not more than

1 one hour, the time to be divided in the House equally be-  
2 tween those favoring and those opposing the motion. An  
3 amendment to the motion is not in order, and it is not in  
4 order to move to reconsider the vote by which the motion  
5 is agreed to or disagreed to.

6 (3) Only one motion to discharge a particular com-  
7 mittee may be adopted under this subsection in any session  
8 of a Congress.

9 (4) Notwithstanding paragraph (1), it shall not be in  
10 order to move to discharge a committee from further con-  
11 sideration of medicare funding legislation pursuant to this  
12 subsection during a session of a Congress if, during the  
13 previous session of the Congress, the House passed medi-  
14 care funding legislation for which there is an affirmative  
15 certification under subsection (b)(3)(A).

16 (d) FLOOR CONSIDERATION IN THE HOUSE OF DIS-  
17 CHARGED LEGISLATION.—

18 (1) In the House, not later than 3 legislative days  
19 after any committee has been discharged from further con-  
20 sideration of legislation under subsection (c), the Speaker  
21 shall resolve the House into the Committee of the Whole  
22 for consideration of the legislation.

23 (2) The first reading of the legislation shall be dis-  
24 pensed with. All points of order against consideration of the  
25 legislation are waived. General debate shall be confined to  
26 the legislation and shall not exceed five hours, which shall  
27 be divided equally between those favoring and those oppos-  
28 ing the legislation. After general debate the legislation shall  
29 be considered for amendment under the five-minute rule.  
30 During consideration of the legislation, no amendments  
31 shall be in order in the House or in the Committee of the  
32 Whole except those for which there has been an affirmative  
33 certification under subsection (b)(3)(B). All points of order  
34 against consideration of any such amendment in the Com-  
35 mittee of the Whole are waived. The legislation, together  
36 with any amendments which shall be in order, shall be con-  
37 sidered as read. During the consideration of the bill for



1 amendment, the Chairman of the Committee of the Whole  
2 may accord priority in recognition on the basis of whether  
3 the Member offering an amendment has caused it to be  
4 printed in the portion of the Congressional Record des-  
5 ignated for that purpose in clause 8 of Rule XVIII of the  
6 Rules of the House of Representatives. Debate on any  
7 amendment shall not exceed one hour, which shall be di-  
8 vided equally between those favoring and those opposing  
9 the amendment, and no pro forma amendments shall be of-  
10 fered during the debate. The total time for debate on all  
11 amendments shall not exceed 10 hours. At the conclusion  
12 of consideration of the legislation for amendment, the Com-  
13 mittee shall rise and report the legislation to the House  
14 with such amendments as may have been adopted. The pre-  
15 vious question shall be considered as ordered on the legisla-  
16 tion and amendments thereto to final passage without in-  
17 tervening motion except one motion to recommit with or  
18 without instructions. If the Committee of the Whole rises  
19 and reports that it has come to no resolution on the bill,  
20 then on the next legislative day the House shall, imme-  
21 diately after the third daily order of business under clause  
22 1 of Rule XIV of the Rules of the House of Representa-  
23 tives, resolve into the Committee of the Whole for further  
24 consideration of the bill.

25 (3) All appeals from the decisions of the Chair relating  
26 to the application of the Rules of the House of Representa-  
27 tives to the procedure relating to any such legislation shall  
28 be decided without debate.

29 (4) Except to the extent specifically provided in the  
30 preceding provisions of this subsection, consideration of any  
31 such legislation and amendments thereto (or any con-  
32 ference report thereon) shall be governed by the Rules of  
33 the House of Representatives applicable to other bills and  
34 resolutions, amendments, and conference reports in similar  
35 circumstances.

1 (e) LEGISLATIVE DAY DEFINED.—As used in this section,  
2 the term “legislative day” means a day on which the House of  
3 Representatives is in session.

4 (f) RESTRICTION ON WAIVER.—In the House, the provi-  
5 sions of this section may be waived only by a rule or order pro-  
6 posing only to waive such provisions.

7 (g) RULEMAKING POWER.—The provisions of this section  
8 are enacted by the Congress—

9 (1) as an exercise of the rulemaking power of the  
10 House of Representatives and, as such, shall be considered  
11 as part of the rules of that House and shall supersede  
12 other rules only to the extent that they are inconsistent  
13 therewith; and

14 (2) with full recognition of the constitutional right of  
15 that House to change the rules (so far as they relate to the  
16 procedures of that House) at any time, in the same man-  
17 ner, and to the same extent as in the case of any other rule  
18 of that House.

19 **SEC. 804. PROCEDURES IN THE SENATE.**

20 (a) INTRODUCTION AND REFERRAL OF PRESIDENT’S LEG-  
21 ISLATIVE PROPOSAL.—

22 (1) INTRODUCTION.—In the case of a legislative pro-  
23 posal submitted by the President pursuant to section  
24 1105(h) of title 31, United States Code, within the 15-day  
25 period specified in paragraph (1) of such section, the Ma-  
26 jority Leader and Minority Leader of the Senate (or their  
27 designees) shall introduce such proposal (by request), the  
28 title of which is as follows: “A bill to respond to a medicare  
29 funding warning.” Such bill shall be introduced within 3  
30 days of session after Congress receives such proposal.

31 (2) REFERRAL.—Any legislation introduced pursuant  
32 to paragraph (1) shall be referred to the Committee on Fi-  
33 nance.

34 (b) MEDICARE FUNDING LEGISLATION.—For purposes of  
35 this section, the term “medicare funding legislation” means—

36 (1) legislation introduced pursuant to subsection  
37 (a)(1), but only if the legislative proposal upon which the

1 legislation is based was submitted within the 15-day period  
2 referred to in such subsection; or

3 (2) any bill the title of which is as follows: “A bill to  
4 respond to a medicare funding warning.”.

5 (c) QUALIFICATION FOR SPECIAL PROCEDURES.—

6 (1) IN GENERAL.—The special procedures set forth in  
7 subsections (d) and (e) shall apply to medicare funding leg-  
8 islation, as described in subsection (b), only if the  
9 legislation—

10 (A) is medicare funding legislation that is passed  
11 by the House of Representatives; or

12 (B) contains matter within the jurisdiction of the  
13 Committee on Finance in the Senate.

14 (2) FAILURE TO QUALIFY FOR SPECIAL PROCE-  
15 DURES.—If the medicare funding legislation does not sat-  
16 isfy paragraph (1), then the legislation shall be considered  
17 under the ordinary procedures of the Standing Rules of the  
18 Senate.

19 (d) DISCHARGE.—

20 (1) IN GENERAL.—If the Committee on Finance has  
21 not reported medicare funding legislation described in sub-  
22 section (c)(1) by June 30 of a year in which the President  
23 is required to submit medicare funding legislation to Con-  
24 gress under section 1105(h) of title 31, United States  
25 Code, then any Senator may move to discharge the Com-  
26 mittee of any single medicare funding legislation measure.  
27 Only one such motion shall be in order in any session of  
28 Congress.

29 (2) DEBATE LIMITS.—Debate in the Senate on any  
30 such motion to discharge, and all appeals in connection  
31 therewith, shall be limited to not more than 2 hours. The  
32 time shall be equally divided between, and controlled by,  
33 the maker of the motion and the Majority Leader, or their  
34 designees, except that in the event the Majority Leader is  
35 in favor of such motion, the time in opposition thereto shall  
36 be controlled by the Minority Leader or the Minority Lead-  
37 er’s designee. A point of order under this subsection may

1 be made at any time. It is not in order to move to proceed  
2 to another measure or matter while such motion (or the  
3 motion to reconsider such motion) is pending.

4 (3) AMENDMENTS.—No amendment to the motion to  
5 discharge shall be in order.

6 (4) EXCEPTION IF CERTIFIED LEGISLATION EN-  
7 ACTED.—Notwithstanding paragraph (1), it shall not be in  
8 order to discharge the Committee from further consider-  
9 ation of medicare funding legislation pursuant to this sub-  
10 section during a session of a Congress if the chairman of  
11 the Committee on the Budget of the Senate certifies that  
12 medicare funding legislation has been enacted that elimi-  
13 nates excess general revenue medicare funding (as defined  
14 in section 801(c)) for each fiscal year in the 7-fiscal-year  
15 reporting period.

16 (e) CONSIDERATION.—After the date on which the Com-  
17 mittee on Finance has reported medicare funding legislation  
18 described in subsection (c)(1), or has been discharged (under  
19 subsection (d)) from further consideration of, such legislation,  
20 it is in order (even though a previous motion to the same effect  
21 has been disagreed to) for any Member of the Senate to move  
22 to proceed to the consideration of such legislation.

23 (f) RULES OF THE SENATE.—This section is enacted by  
24 the Senate—

25 (1) as an exercise of the rulemaking power of the Sen-  
26 ate and as such it is deemed a part of the rules of the Sen-  
27 ate, but applicable only with respect to the procedure to be  
28 followed in the Senate in the case of a bill described in this  
29 paragraph, and it supersedes other rules only to the extent  
30 that it is inconsistent with such rules; and

31 (2) with full recognition of the constitutional right of  
32 the Senate to change the rules (so far as relating to the  
33 procedure of the Senate) at any time, in the same manner,  
34 and to the same extent as in the case of any other rule of  
35 the Senate.

1     **Subtitle B—Income-Related Reduc-**  
2     **tion in Part B Premium Subsidy**

3     **SEC. 811. INCOME-RELATED REDUCTION IN PART B PRE-**  
4     **MIUM SUBSIDY.**

5           (a) IN GENERAL.—Section 1839 (42 U.S.C. 1395r), as  
6     amended by section 241(c), is amended by adding at the end  
7     the following:

8           “(i) REDUCTION IN PREMIUM SUBSIDY BASED ON IN-  
9     COME.—

10           “(1) IN GENERAL.—In the case of an individual whose  
11     modified adjusted gross income exceeds the threshold  
12     amount under paragraph (2), the monthly amount of the  
13     premium subsidy applicable to the premium under this sec-  
14     tion for a month after December 2006 shall be reduced  
15     (and the monthly premium shall be increased) by the  
16     monthly adjustment amount specified in paragraph (3).

17           “(2) THRESHOLD AMOUNT.—For purposes of this sub-  
18     section, the threshold amount is—

19           “(A) except as provided in subparagraph (B),  
20     \$80,000, and

21           “(B) in the case of a joint return, twice the  
22     amount applicable under subparagraph (A) for the cal-  
23     endar year.

24           “(3) MONTHLY ADJUSTMENT AMOUNT.—

25           “(A) IN GENERAL.—Subject to subparagraph (B),  
26     the monthly adjustment amount specified in this para-  
27     graph for an individual for a month in a year is equal  
28     to the product of the following:

29           “(i) SLIDING SCALE PERCENTAGE.—The ap-  
30     plicable percentage specified in the table in sub-  
31     paragraph (C) for the individual minus 25 percent-  
32     age points.

33           “(ii) UNSUBSIDIZED PART B PREMIUM  
34     AMOUNT.—200 percent of the monthly actuarial  
35     rate for enrollees age 65 and over (as determined  
36     under subsection (a)(1) for the year).

1                   “(B) 5-YEAR PHASE IN.—The monthly adjustment  
 2                   amount specified in this paragraph for an individual for  
 3                   a month in a year before 2011 is equal to the following  
 4                   percentage of the monthly adjustment amount specified  
 5                   in subparagraph (A):

- 6                   “(i) For 2007, 20 percent.
- 7                   “(ii) For 2008, 40 percent.
- 8                   “(iii) For 2009, 60 percent.
- 9                   “(iv) for 2010, 80 percent.

10                   “(C) APPLICABLE PERCENTAGE.—

11                   “(i) IN GENERAL.—

<b>“If the modified adjusted gross income is:</b>	<b>The applicable percentage is:</b>
More than \$80,000 but not more than \$100,000 .....	35 percent
More than \$100,000 but not more than \$150,000 .....	50 percent
More than \$150,000 but not more than \$200,000 .....	65 percent
More than \$200,000 .....	80 percent.

12                   “(ii) JOINT RETURNS.—In the case of a joint  
 13                   return, clause (i) shall be applied by substituting  
 14                   dollar amounts which are twice the dollar amounts  
 15                   otherwise applicable under clause (i) for the cal-  
 16                   endar year.

17                   “(iii) MARRIED INDIVIDUALS FILING SEPA-  
 18                   RATE RETURNS.—In the case of an individual  
 19                   who—

20                   “(I) is married as of the close of the tax-  
 21                   able year (within the meaning of section 7703  
 22                   of the Internal Revenue Code of 1986) but does  
 23                   not file a joint return for such year, and

24                   “(II) does not live apart from such indi-  
 25                   vidual’s spouse at all times during the taxable  
 26                   year,

27                   clause (i) shall be applied by reducing each of the  
 28                   dollar amounts otherwise applicable under such  
 29                   clause for the calendar year by the threshold

1 amount for such year applicable to an unmarried  
2 individual.

3 “(4) MODIFIED ADJUSTED GROSS INCOME.—

4 “(A) IN GENERAL.—For purposes of this sub-  
5 section, the term ‘modified adjusted gross income’  
6 means adjusted gross income (as defined in section 62  
7 of the Internal Revenue Code of 1986)—

8 “(i) determined without regard to sections  
9 135, 911, 931, and 933 of such Code; and

10 “(ii) increased by the amount of interest re-  
11 ceived or accrued during the taxable year which is  
12 exempt from tax under such Code.

13 In the case of an individual filing a joint return, any  
14 reference in this subsection to the modified adjusted  
15 gross income of such individual shall be to such re-  
16 turn’s modified adjusted gross income.

17 “(B) TAXABLE YEAR TO BE USED IN DETER-  
18 MINING MODIFIED ADJUSTED GROSS INCOME.—

19 “(i) IN GENERAL.—In applying this subsection  
20 for an individual’s premiums in a month in a year,  
21 subject to clause (ii) and subparagraph (C), the in-  
22 dividual’s modified adjusted gross income shall be  
23 such income determined for the individual’s last  
24 taxable year beginning in the second calendar year  
25 preceding the year involved.

26 “(ii) TEMPORARY USE OF OTHER DATA.—If,  
27 as of October 15 before a calendar year, the Sec-  
28 retary of the Treasury does not have adequate data  
29 for an individual in appropriate electronic form for  
30 the taxable year referred to in clause (i), the indi-  
31 vidual’s modified adjusted gross income shall be de-  
32 termined using the data in such form from the pre-  
33 vious taxable year. Except as provided in regula-  
34 tions prescribed by the Commissioner of Social Se-  
35 curity in consultation with the Secretary, the pre-  
36 ceding sentence shall cease to apply when adequate  
37 data in appropriate electronic form are available for

1 the individual for the taxable year referred to in  
2 clause (i), and proper adjustments shall be made to  
3 the extent that the premium adjustments deter-  
4 mined under the preceding sentence were incon-  
5 sistent with those determined using such taxable  
6 year.

7 “(iii) NON-FILERS.—In the case of individuals  
8 with respect to whom the Secretary of the Treasury  
9 does not have adequate data in appropriate elec-  
10 tronic form for either taxable year referred to in  
11 clause (i) or clause (ii), the Commissioner of Social  
12 Security, in consultation with the Secretary, shall  
13 prescribe regulations which provide for the treat-  
14 ment of the premium adjustment with respect to  
15 such individual under this subsection, including  
16 regulations which provide for—

17 “(I) the application of the highest applica-  
18 ble percentage under paragraph (3)(C) to such  
19 individual if the Commissioner has information  
20 which indicates that such individual’s modified  
21 adjusted gross income might exceed the thresh-  
22 old amount for the taxable year referred to in  
23 clause (i), and

24 “(II) proper adjustments in the case of the  
25 application of an applicable percentage under  
26 subclause (I) to such individual which is incon-  
27 sistent with such individual’s modified adjusted  
28 gross income for such taxable year.

29 “(C) USE OF MORE RECENT TAXABLE YEAR.—

30 “(i) IN GENERAL.—The Commissioner of So-  
31 cial Security in consultation with the Secretary of  
32 the Treasury shall establish a procedures under  
33 which an individual’s modified adjusted gross in-  
34 come shall, at the request of such individual, be de-  
35 termined under this subsection—



1                   “(I) for a more recent taxable year than  
2                   the taxable year otherwise used under subpara-  
3                   graph (B), or

4                   “(II) by such methodology as the Commis-  
5                   sioner, in consultation with such Secretary, de-  
6                   termines to be appropriate, which may include  
7                   a methodology for aggregating or  
8                   disaggregating information from tax returns in  
9                   the case of marriage or divorce.

10                   “(ii) STANDARD FOR GRANTING REQUESTS.—  
11                   A request under clause (i)(I) to use a more recent  
12                   taxable year may be granted only if—

13                   “(I) the individual furnishes to such Com-  
14                   missioner with respect to such year such docu-  
15                   mentation, such as a copy of a filed Federal in-  
16                   come tax return or an equivalent document, as  
17                   the Commissioner specifies for purposes of de-  
18                   termining the premium adjustment (if any)  
19                   under this subsection; and

20                   “(II) the individual’s modified adjusted  
21                   gross income for such year is significantly less  
22                   than such income for the taxable year deter-  
23                   mined under subparagraph (B) by reason of  
24                   the death of such individual’s spouse, the mar-  
25                   riage or divorce of such individual, or other  
26                   major life changing events specified in regula-  
27                   tions prescribed by the Commissioner in con-  
28                   sultation with the Secretary.

29                   “(5) INFLATION ADJUSTMENT.—

30                   “(A) IN GENERAL.—In the case of any calendar  
31                   year beginning after 2007, each dollar amount in para-  
32                   graph (2) or (3) shall be increased by an amount equal  
33                   to—

34                   “(i) such dollar amount, multiplied by

35                   “(ii) the percentage (if any) by which the aver-  
36                   age of the Consumer Price Index for all urban con-  
37                   sumers (United States city average) for the 12-

1 month period ending with August of the preceding  
2 calendar year exceeds such average for the 12-  
3 month period ending with August 2006.

4 “(B) ROUNDING.—If any dollar amount after  
5 being increased under subparagraph (A) is not a mul-  
6 tiple of \$1,000, such dollar amount shall be rounded to  
7 the nearest multiple of \$1,000.

8 “(6) JOINT RETURN DEFINED.—For purposes of this  
9 subsection, the term ‘joint return’ has the meaning given  
10 to such term by section 7701(a)(38) of the Internal Rev-  
11 enue Code of 1986.”.

12 (b) CONFORMING AMENDMENTS.—

13 (1) Section 1839 (42 U.S.C. 1395r) is amended—

14 (A) in subsection (a)(2), by striking “and (f)” and  
15 inserting “(f), and (i)”;

16 (B) in subsection (b), inserting “(without regard  
17 to any adjustment under subsection (i))” after “sub-  
18 section (a)”;

19 (C) in subsection (f)—

20 (i) by striking “and if” and inserting “if”; and

21 (ii) by inserting “and if the amount of the in-  
22 dividual’s premium is not adjusted for such Janu-  
23 ary under subsection (i),” after “section  
24 1840(b)(1),”.

25 (2) Section 1844 (42 U.S.C. 1395w) is amended—

26 (A) in subsection (a)(1)—

27 (i) in subparagraph (B), by striking “plus” at  
28 the end and inserting “minus”; and

29 (ii) by adding at the end the following new  
30 subparagraph:

31 “(C) the aggregate amount of additional premium pay-  
32 ments attributable to the application of section 1839(i);  
33 plus”; and

34 (B) in subsection (c), by inserting before the pe-  
35 riod at the end the following: “and without regard to  
36 any premium adjustment under section 1839(i)”.

1 (c) REPORTING REQUIREMENTS FOR SECRETARY OF THE  
2 TREASURY.—

3 (1) IN GENERAL.—Subsection (l) of section 6103 of  
4 the Internal Revenue Code of 1986 (relating to disclosure  
5 of returns and return information for purposes other than  
6 tax administration), as amended by section 105(f), is  
7 amended by adding at the end the following new para-  
8 graph:

9 “(20) DISCLOSURE OF RETURN INFORMATION TO  
10 CARRY OUT MEDICARE PART B PREMIUM SUBSIDY ADJUST-  
11 MENT.—

12 “(A) IN GENERAL.—The Secretary shall, upon  
13 written request from the Commissioner of Social Secu-  
14 rity, disclose to officers, employees, and contractors of  
15 the Social Security Administration return information  
16 of a taxpayer whose premium (according to the records  
17 of the Secretary) may be subject to adjustment under  
18 section 1839(i) of the Social Security Act. Such return  
19 information shall be limited to—

20 “(i) taxpayer identity information with respect  
21 to such taxpayer,

22 “(ii) the filing status of such taxpayer,

23 “(iii) the adjusted gross income of such tax-  
24 payer,

25 “(iv) the amounts excluded from such tax-  
26 payer’s gross income under sections 135 and 911  
27 to the extent such information is available,

28 “(v) the interest received or accrued during  
29 the taxable year which is exempt from the tax im-  
30 posed by chapter 1 to the extent such information  
31 is available,

32 “(vi) the amounts excluded from such tax-  
33 payer’s gross income by sections 931 and 933 to  
34 the extent such information is available,

35 “(vii) such other information relating to the li-  
36 ability of the taxpayer as is prescribed by the Sec-  
37 retary by regulation as might indicate in the case

1 of a taxpayer who is an individual described in sub-  
2 section (i)(4)(B)(iii) of section 1839 of the Social  
3 Security Act that the amount of the premium of  
4 the taxpayer under such section may be subject to  
5 adjustment under subsection (i) of such section and  
6 the amount of such adjustment, and

7 “(viii) the taxable year with respect to which  
8 the preceding information relates.

9 “(B) RESTRICTION ON USE OF DISCLOSED INFOR-  
10 MATION.—Return information disclosed under subpara-  
11 graph (A) may be used by officers, employees, and con-  
12 tractors of the Social Security Administration only for  
13 the purposes of, and to the extent necessary in, estab-  
14 lishing the appropriate amount of any premium adjust-  
15 ment under such section 1839(i).”

16 (2) CONFORMING AMENDMENTS.—

17 (A) Paragraph (3) of section 6103(a) of such  
18 Code, as amended by section 105(f)(2), is amended by  
19 striking “or (19)” and inserting “(19), or (20)”.

20 (B) Paragraph (4) of section 6103(p) of such  
21 Code, as amended by section 105(f)(3), is amended by  
22 striking “(l)(16), (17), or (19)” each place it appears  
23 and inserting “(l)(16), (17), (19), or (20)”.

24 (C) Paragraph (2) of section 7213(a) of such  
25 Code, as amended by section 105(f)(4), is amended by  
26 striking “or (19)” and inserting “(19), or (20)”.

27 **TITLE IX—ADMINISTRATIVE IM-**  
28 **PROVEMENTS, REGULATORY RE-**  
29 **DUCTION, AND CONTRACTING**  
30 **REFORM**

31 **SEC. 900. ADMINISTRATIVE IMPROVEMENTS WITHIN**  
32 **THE CENTERS FOR MEDICARE & MEDICAID**  
33 **SERVICES (CMS).**

34 (a) COORDINATED ADMINISTRATION OF MEDICARE PRE-  
35 SCRIPTIION DRUG AND MEDICARE ADVANTAGE PROGRAMS.—  
36 Title XVIII (42 U.S.C. 1395 et seq.), as amended by section

1 721, is amended by inserting after 1807 the following new sec-  
2 tion:

3 “PROVISIONS RELATING TO ADMINISTRATION

4 “SEC. 1808. (a) COORDINATED ADMINISTRATION OF  
5 MEDICARE PRESCRIPTION DRUG AND MEDICARE ADVANTAGE  
6 PROGRAMS.—

7 “(1) IN GENERAL.—There is within the Centers for  
8 Medicare & Medicaid Services a center to carry out the du-  
9 ties described in paragraph (3).

10 “(2) DIRECTOR.—Such center shall be headed by a di-  
11 rector who shall report directly to the Administrator of the  
12 Centers for Medicare & Medicaid Services.

13 “(3) DUTIES.—The duties described in this paragraph  
14 are the following:

15 “(A) The administration of parts C and D.

16 “(B) The provision of notice and information  
17 under section 1804.

18 “(C) Such other duties as the Secretary may  
19 specify.

20 “(4) DEADLINE.—The Secretary shall ensure that the  
21 center is carrying out the duties described in paragraph (3)  
22 by not later than January 1, 2008.”.

23 (b) MANAGEMENT STAFF FOR THE CENTERS FOR MEDI-  
24 CARE & MEDICAID SERVICES.—Such section is further amend-  
25 ed by adding at the end the following new subsection:

26 “(b) EMPLOYMENT OF MANAGEMENT STAFF.—

27 “(1) IN GENERAL.—The Secretary may employ, within  
28 the Centers for Medicare & Medicaid Services, such individ-  
29 uals as management staff as the Secretary determines to  
30 be appropriate. With respect to the administration of parts  
31 C and D, such individuals shall include individuals with pri-  
32 vate sector expertise in negotiations with health benefits  
33 plans.

34 “(2) ELIGIBILITY.—To be eligible for employment  
35 under paragraph (1) an individual shall be required to have  
36 demonstrated, by their education and experience (either in

1 the public or private sector), superior expertise in at least  
2 one of the following areas:

3 “(A) The review, negotiation, and administration of  
4 health care contracts.

5 “(B) The design of health care benefit plans.

6 “(C) Actuarial sciences.

7 “(D) Compliance with health plan contracts.

8 “(E) Consumer education and decision making.

9 “(F) Any other area specified by the Secretary that  
10 requires specialized management or other expertise.

11 “(3) RATES OF PAYMENT.—

12 “(A) PERFORMANCE-RELATED PAY.—Subject to  
13 subparagraph (B), the Secretary shall establish the  
14 rate of pay for an individual employed under paragraph  
15 (1). Such rate shall take into account expertise, experi-  
16 ence, and performance.

17 “(B) LIMITATION.—In no case may the rate of  
18 compensation determined under subparagraph (A) ex-  
19 ceed the highest rate of basic pay for the Senior Execu-  
20 tive Service under section 5382(b) of title 5, United  
21 States Code.”.

22 (c) REQUIREMENT FOR DEDICATED ACTUARY FOR PRI-  
23 VATE HEALTH PLANS.—Section 1117(b) (42 U.S.C. 1317(b))  
24 is amended by adding at the end the following new paragraph:

25 “(3) In the office of the Chief Actuary there shall be an  
26 actuary whose duties relate exclusively to the programs under  
27 parts C and D of title XVIII and related provisions of such  
28 title.”.

29 (d) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR  
30 THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE &  
31 MEDICAID SERVICES.—

32 (1) IN GENERAL.—Section 5314 of title 5, United  
33 States Code, is amended by adding at the end the fol-  
34 lowing:

35 “Administrator of the Centers for Medicare & Med-  
36 icaid Services.”.

1           (2) CONFORMING AMENDMENT.—Section 5315 of such  
2 title is amended by striking “Administrator of the Health  
3 Care Financing Administration.”.

4           (3) EFFECTIVE DATE.—The amendments made by  
5 this subsection take effect on January 1, 2004.

6           (e) CONFORMING AMENDMENTS RELATING TO HEALTH  
7 CARE FINANCING ADMINISTRATION.—

8           (1) AMENDMENTS TO THE SOCIAL SECURITY ACT.—

9           The Social Security Act is amended—

10           (A) in section 1117 (42 U.S.C. 1317)—

11           (i) in the heading to read as follows:

12           “APPOINTMENT OF THE ADMINISTRATOR AND CHIEF ACTUARY  
13           OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES”;

14           (ii) in subsection (a), by striking “Health Care  
15           Financing Administration” and inserting “Centers  
16           for Medicare & Medicaid Services”; and

17           (iii) in subsection (b)(1)—

18           (I) by striking “Health Care Financing  
19           Administration” and inserting “Centers for  
20           Medicare & Medicaid Services”; and

21           (II) by striking “Administration” and in-  
22           serting “Centers”;

23           (B) in section 1140(a) (42 U.S.C. 1320b–10(a))—

24           (i) in paragraph (1), by striking “Health Care  
25           Financing Administration” both places it appears  
26           in the matter following subparagraph (B) and in-  
27           serting “Centers for Medicare & Medicaid Serv-  
28           ices”;

29           (ii) in paragraph (1)(A)—

30           (I) by striking “Health Care Financing  
31           Administration” and inserting “Centers for  
32           Medicare & Medicaid Services”; and

33           (II) by striking “HCFA” and inserting  
34           “CMS”; and

35           (iii) in paragraph (1)(B), by striking “Health  
36           Care Financing Administration” both places it ap-

1                   pears and inserting “Centers for Medicare & Med-  
2                   icaid Services”;

3                   (C) in section 1142(b)(3) (42 U.S.C. 1320b-  
4                   12(b)(3)), by striking “Health Care Financing Admin-  
5                   istration” and inserting “Centers for Medicare & Med-  
6                   icaid Services”;

7                   (D) in section 1817(b) (42 U.S.C. 1395i(b))—

8                   (i) by striking “Health Care Financing Ad-  
9                   ministration”, both in the fifth sentence of the  
10                  matter preceding paragraph (1) and in the second  
11                  sentence of the matter following paragraph (4), and  
12                  inserting “Centers for Medicare & Medicaid Serv-  
13                  ices”; and

14                  (ii) by striking “Chief Actuarial Officer” in  
15                  the second sentence of the matter following para-  
16                  graph (4) and inserting “Chief Actuary”;

17                  (E) in section 1841(b) (42 U.S.C. 1395t(b))—

18                  (i) by striking “Health Care Financing Ad-  
19                  ministration”, both in the fifth sentence of the  
20                  matter preceding paragraph (1) and in the second  
21                  sentence of the matter following paragraph (4), and  
22                  inserting “Centers for Medicare & Medicaid Serv-  
23                  ices”; and

24                  (ii) by striking “Chief Actuarial Officer” in  
25                  the second sentence of the matter following para-  
26                  graph (4) and inserting “Chief Actuary”;

27                  (F) in section 1852(a)(5) (42 U.S.C. 1395w-  
28                  22(a)(5)), by striking “Health Care Financing Admin-  
29                  istration” in the matter following subparagraph (B)  
30                  and inserting “Centers for Medicare & Medicaid Serv-  
31                  ices”;

32                  (G) in section 1853 (42 U.S.C. 1395w-23)—

33                  (i) in subsection (b)(4), by striking “Health  
34                  Care Financing Administration” in the first sen-  
35                  tence and inserting “Centers for Medicare & Med-  
36                  icaid Services”; and



1 (ii) in subsection (c)(7), by striking “Health  
2 Care Financing Administration” in the last sen-  
3 tence and inserting “Centers for Medicare & Med-  
4 icaid Services”;

5 (H) in section 1854(a)(5)(A) (42 U.S.C. 1395w-  
6 24(a)(5)(A)), by striking “Health Care Financing  
7 Administration” and inserting “Centers for Medicare &  
8 Medicaid Services”;

9 (I) in section 1857(d)(4)(A)(ii) (42 U.S.C.  
10 1395w-27(d)(4)(A)(ii)), by striking “Health Care Fi-  
11 nancing Administration” and inserting “Secretary”;

12 (J) in section 1862(b)(5)(A)(ii) (42 U.S.C.  
13 1395y(b)(5)(A)(ii)), by striking “Health Care Financ-  
14 ing Administration” and inserting “Centers for Medi-  
15 care & Medicaid Services”;

16 (K) in section 1927(e)(4) (42 U.S.C. 1396r-  
17 8(e)(4)), by striking “HCFA” and inserting “The Sec-  
18 retary”;

19 (L) in section 1927(f)(2) (42 U.S.C. 1396r-  
20 8(f)(2)), by striking “HCFA” and inserting “The Sec-  
21 retary”; and

22 (M) in section 2104(g)(3) (42 U.S.C.  
23 1397dd(g)(3)) by inserting “or CMS Form 64 or CMS  
24 Form 21, as the case may be,” after “HCFA Form 64  
25 or HCFA Form 21”.

26 (2) AMENDMENTS TO THE PUBLIC HEALTH SERVICE  
27 ACT.—The Public Health Service Act is amended—

28 (A) in section 501(d)(18) (42 U.S.C.  
29 290aa(d)(18)), by striking “Health Care Financing Ad-  
30 ministration” and inserting “Centers for Medicare &  
31 Medicaid Services”;

32 (B) in section 507(b)(6) (42 U.S.C. 290bb(b)(6)),  
33 by striking “Health Care Financing Administration”  
34 and inserting “Centers for Medicare & Medicaid Serv-  
35 ices”;

36 (C) in section 916 (42 U.S.C. 299b-5)—

1 (i) in subsection (b)(2), by striking “Health  
2 Care Financing Administration” and inserting  
3 “Centers for Medicare & Medicaid Services”; and

4 (ii) in subsection (c)(2), by striking “Health  
5 Care Financing Administration” and inserting  
6 “Centers for Medicare & Medicaid Services”;

7 (D) in section 921(c)(3)(A) (42 U.S.C.  
8 299c(c)(3)(A)), by striking “Health Care Financing  
9 Administration” and inserting “Centers for Medicare &  
10 Medicaid Services”;

11 (E) in section 1318(a)(2) (42 U.S.C. 300e-  
12 17(a)(2)), by striking “Health Care Financing Admin-  
13 istration” and inserting “Centers for Medicare & Med-  
14 icaid Services”;

15 (F) in section 2102(a)(7) (42 U.S.C. 300aa-  
16 2(a)(7)), by striking “Health Care Financing Adminis-  
17 tration” and inserting “Centers for Medicare & Med-  
18 icaid Services”; and

19 (G) in section 2675(a) (42 U.S.C. 300ff-75(a)),  
20 by striking “Health Care Financing Administration” in  
21 the first sentence and inserting “Centers for Medicare  
22 & Medicaid Services”.

23 (3) AMENDMENTS TO THE INTERNAL REVENUE CODE  
24 OF 1986.—Section 6103(l)(12) of the Internal Revenue  
25 Code of 1986 is amended—

26 (A) in subparagraph (B), by striking “Health  
27 Care Financing Administration” in the matter pre-  
28 ceding clause (i) and inserting “Centers for Medicare  
29 & Medicaid Services”; and

30 (B) in subparagraph (C)—

31 (i) by striking “HEALTH CARE FINANCING AD-  
32 MINISTRATION” in the heading and inserting “CEN-  
33 TERS FOR MEDICARE & MEDICAID SERVICES”; and

34 (ii) by striking “Health Care Financing Ad-  
35 ministration” in the matter preceding clause (i)  
36 and inserting “Centers for Medicare & Medicaid  
37 Services”.

1 (4) AMENDMENTS TO TITLE 10, UNITED STATES  
2 CODE.—Title 10, United States Code, is amended—

3 (A) in section 1086(d)(4), by striking “adminis-  
4 trator of the Health Care Financing Administration” in  
5 the last sentence and inserting “Administrator of the  
6 Centers for Medicare & Medicaid Services”; and

7 (B) in section 1095(k)(2), by striking “Health  
8 Care Financing Administration” in the second sentence  
9 and inserting “Centers for Medicare & Medicaid Serv-  
10 ices”.

11 (5) AMENDMENTS TO THE ALZHEIMER’S DISEASE AND  
12 RELATED DEMENTIAS SERVICES RESEARCH ACT OF 1992.—  
13 The Alzheimer’s Disease and Related Dementias Research  
14 Act of 1992 (42 U.S.C. 11271 et seq.) is amended—

15 (A) in the heading of subpart 3 of part D to read  
16 as follows:

17 “Subpart 3—Responsibilities of the Centers for Medicare &  
18 Medicaid Services”;

19 (B) in section 937 (42 U.S.C. 11271)—

20 (i) in subsection (a), by striking “National  
21 Health Care Financing Administration” and insert-  
22 ing “Centers for Medicare & Medicaid Services”;

23 (ii) in subsection (b)(1), by striking “Health  
24 Care Financing Administration” and inserting  
25 “Centers for Medicare & Medicaid Services”;

26 (iii) in subsection (b)(2), by striking “Health  
27 Care Financing Administration” and inserting  
28 “Centers for Medicare & Medicaid Services”; and

29 (iv) in subsection (c), by striking “Health  
30 Care Financing Administration” and inserting  
31 “Centers for Medicare & Medicaid Services”; and

32 (C) in section 938 (42 U.S.C. 11272), by striking  
33 “Health Care Financing Administration” and inserting  
34 “Centers for Medicare & Medicaid Services”.

35 (6) MISCELLANEOUS AMENDMENTS.—

36 (A) REHABILITATION ACT OF 1973.—Section  
37 202(b)(8) of the Rehabilitation Act of 1973 (29 U.S.C.

1           762(b)(8)) is amended by striking “Health Care Fi-  
2           nancing Administration” and inserting “Centers for  
3           Medicare & Medicaid Services”.

4           (B) INDIAN HEALTH CARE IMPROVEMENT ACT.—  
5           Section 405(d)(1) of the Indian Health Care Improve-  
6           ment Act (25 U.S.C. 1645(d)(1)) is amended by strik-  
7           ing “Health Care Financing Administration” in the  
8           matter preceding subparagraph (A) and inserting  
9           “Centers for Medicare & Medicaid Services”.

10          (C) INDIVIDUALS WITH DISABILITIES EDUCATION  
11          ACT.—Section 644(b)(5) of the Individuals with Dis-  
12          abilities Education Act (20 U.S.C. 1444(b)(5)) is  
13          amended by striking “Health Care Financing Adminis-  
14          tration” and inserting “Centers for Medicare & Med-  
15          icaid Services”.

16          (D) THE HOME HEALTH CARE AND ALZHEIMER’S  
17          DISEASE AMENDMENTS OF 1990.—Section 302(a)(9) of  
18          the Home Health Care and Alzheimer’s Disease  
19          Amendments of 1990 (42 U.S.C. 242q–1(a)(9)) is  
20          amended by striking “Health Care Financing Adminis-  
21          tration” and inserting “Centers for Medicare & Med-  
22          icaid Services”.

23          (E) THE CHILDREN’S HEALTH ACT OF 2000.—Sec-  
24          tion 2503(a) of the Children’s Health Act of 2000 (42  
25          U.S.C. 247b–3a(a)) is amended by striking “Health  
26          Care Financing Administration” and inserting “Cen-  
27          ters for Medicare & Medicaid Services”.

28          (F) THE NATIONAL INSTITUTES OF HEALTH REVI-  
29          TALIZATION ACT OF 1993.—Section 1909 of the Na-  
30          tional Institutes of Health Revitalization Act of 1993  
31          (42 U.S.C. 299a note) is amended by striking “Health  
32          Care Financing Administration” and inserting “Cen-  
33          ters for Medicare & Medicaid Services”.

34          (G) THE OMNIBUS BUDGET RECONCILIATION ACT  
35          OF 1990.—Section 4359(d) of the Omnibus Budget  
36          Reconciliation Act of 1990 (42 U.S.C. 1395b–3(d)) is  
37          amended by striking “Health Care Financing Adminis-

1           tration” and inserting “Centers for Medicare & Med-  
2           icaid Services”.

3           (H) THE MEDICARE, MEDICAID, AND SCHIP BENE-  
4           FITS IMPROVEMENT AND PROTECTION ACT OF 2000.—  
5           Section 104(d)(4) of the Medicare, Medicaid, and  
6           SCHIP Benefits Improvement and Protection Act of  
7           2000 (42 U.S.C. 1395m note) is amended by striking  
8           “Health Care Financing Administration” and inserting  
9           “Health Care”.

10          (7) ADDITIONAL AMENDMENT.—Section 403 of the  
11          Act entitled, “An Act to authorize certain appropriations  
12          for the territories of the United States, to amend certain  
13          Acts relating thereto, and for other purposes”, enacted Oc-  
14          tober 15, 1977 (48 U.S.C. 1574–1; 48 U.S.C. 1421q–1),  
15          is amended by striking “Health Care Financing Adminis-  
16          tration” and inserting “Centers for Medicare & Medicaid  
17          Services”.

## 18                   **Subtitle A—Regulatory Reform**

### 19           **SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.**

20          (a) CONSTRUCTION.—Nothing in this title shall be  
21          construed—

22               (1) to compromise or affect existing legal remedies for  
23               addressing fraud or abuse, whether it be criminal prosecu-  
24               tion, civil enforcement, or administrative remedies, includ-  
25               ing under sections 3729 through 3733 of title 31, United  
26               States Code (commonly known as the “False Claims Act”);

27               or

28               (2) to prevent or impede the Department of Health  
29               and Human Services in any way from its ongoing efforts  
30               to eliminate waste, fraud, and abuse in the medicare pro-  
31               gram.

32          Furthermore, the consolidation of medicare administrative con-  
33          tracting set forth in this division does not constitute consolida-  
34          tion of the Federal Hospital Insurance Trust Fund and the  
35          Federal Supplementary Medical Insurance Trust Fund or re-  
36          flect any position on that issue.

1 (b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C.  
2 1395x) is amended by inserting after subsection (c) the fol-  
3 lowing new subsection:

4 “Supplier

5 “(d) The term ‘supplier’ means, unless the context other-  
6 wise requires, a physician or other practitioner, a facility, or  
7 other entity (other than a provider of services) that furnishes  
8 items or services under this title.”.

9 **SEC. 902. ISSUANCE OF REGULATIONS.**

10 (a) REGULAR TIMELINE FOR PUBLICATION OF FINAL  
11 RULES.—

12 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.  
13 1395hh(a)) is amended by adding at the end the following  
14 new paragraph:

15 “(3)(A) The Secretary, in consultation with the Director  
16 of the Office of Management and Budget, shall establish and  
17 publish a regular timeline for the publication of final regula-  
18 tions based on the previous publication of a proposed regulation  
19 or an interim final regulation.

20 “(B) Such timeline may vary among different regulations  
21 based on differences in the complexity of the regulation, the  
22 number and scope of comments received, and other relevant  
23 factors, but shall not be longer than 3 years except under ex-  
24 ceptional circumstances. If the Secretary intends to vary such  
25 timeline with respect to the publication of a final regulation,  
26 the Secretary shall cause to have published in the Federal Reg-  
27 ister notice of the different timeline by not later than the  
28 timeline previously established with respect to such regulation.  
29 Such notice shall include a brief explanation of the justification  
30 for such variation.

31 “(C) In the case of interim final regulations, upon the ex-  
32 piration of the regular timeline established under this para-  
33 graph for the publication of a final regulation after opportunity  
34 for public comment, the interim final regulation shall not con-  
35 tinue in effect unless the Secretary publishes (at the end of the  
36 regular timeline and, if applicable, at the end of each suc-  
37 ceeding 1-year period) a notice of continuation of the regulation

1 that includes an explanation of why the regular timeline (and  
2 any subsequent 1-year extension) was not complied with. If  
3 such a notice is published, the regular timeline (or such  
4 timeline as previously extended under this paragraph) for publi-  
5 cation of the final regulation shall be treated as having been  
6 extended for 1 additional year.

7 “(D) The Secretary shall annually submit to Congress a  
8 report that describes the instances in which the Secretary failed  
9 to publish a final regulation within the applicable regular  
10 timeline under this paragraph and that provides an explanation  
11 for such failures.”.

12 (2) EFFECTIVE DATE.—The amendment made by  
13 paragraph (1) shall take effect on the date of the enact-  
14 ment of this Act. The Secretary shall provide for an appro-  
15 priate transition to take into account the backlog of pre-  
16 viously published interim final regulations.

17 (b) LIMITATIONS ON NEW MATTER IN FINAL REGULA-  
18 TIONS.—

19 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.  
20 1395hh(a)), as amended by subsection (a), is amended by  
21 adding at the end the following new paragraph:

22 “(4) If the Secretary publishes a final regulation that in-  
23 cludes a provision that is not a logical outgrowth of a pre-  
24 viously published notice of proposed rulemaking or interim final  
25 rule, such provision shall be treated as a proposed regulation  
26 and shall not take effect until there is the further opportunity  
27 for public comment and a publication of the provision again as  
28 a final regulation.”.

29 (2) EFFECTIVE DATE.—The amendment made by  
30 paragraph (1) shall apply to final regulations published on  
31 or after the date of the enactment of this Act.

32 **SEC. 903. COMPLIANCE WITH CHANGES IN REGULA-**  
33 **TIONS AND POLICIES.**

34 (a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE  
35 CHANGES.—

1 (1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh),  
2 as amended by section 902(a), is amended by adding at the  
3 end the following new subsection:

4 “(e)(1)(A) A substantive change in regulations, manual in-  
5 structions, interpretative rules, statements of policy, or guide-  
6 lines of general applicability under this title shall not be applied  
7 (by extrapolation or otherwise) retroactively to items and serv-  
8 ices furnished before the effective date of the change, unless  
9 the Secretary determines that—

10 “(i) such retroactive application is necessary to comply  
11 with statutory requirements; or

12 “(ii) failure to apply the change retroactively would be  
13 contrary to the public interest.”.

14 (2) EFFECTIVE DATE.—The amendment made by  
15 paragraph (1) shall apply to substantive changes issued on  
16 or after the date of the enactment of this Act.

17 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE  
18 CHANGES AFTER NOTICE.—

19 (1) IN GENERAL.—Section 1871(e)(1), as added by  
20 subsection (a), is amended by adding at the end the fol-  
21 lowing:

22 “(B)(i) Except as provided in clause (ii), a substantive  
23 change referred to in subparagraph (A) shall not become effec-  
24 tive before the end of the 30-day period that begins on the date  
25 that the Secretary has issued or published, as the case may be,  
26 the substantive change.

27 “(ii) The Secretary may provide for such a substantive  
28 change to take effect on a date that precedes the end of the  
29 30-day period under clause (i) if the Secretary finds that waiv-  
30 er of such 30-day period is necessary to comply with statutory  
31 requirements or that the application of such 30-day period is  
32 contrary to the public interest. If the Secretary provides for an  
33 earlier effective date pursuant to this clause, the Secretary  
34 shall include in the issuance or publication of the substantive  
35 change a finding described in the first sentence, and a brief  
36 statement of the reasons for such finding.



1           “(C) No action shall be taken against a provider of serv-  
2           ices or supplier with respect to noncompliance with such a sub-  
3           stantive change for items and services furnished before the ef-  
4           fective date of such a change.”.

5           (2) EFFECTIVE DATE.—The amendment made by  
6           paragraph (1) shall apply to compliance actions undertaken  
7           on or after the date of the enactment of this Act.

8           (c) RELIANCE ON GUIDANCE.—

9           (1) IN GENERAL.—Section 1871(e), as added by sub-  
10          section (a), is further amended by adding at the end the  
11          following new paragraph:

12          “(2)(A) If—

13               “(i) a provider of services or supplier follows the writ-  
14               ten guidance (which may be transmitted electronically) pro-  
15               vided by the Secretary or by a medicare contractor (as de-  
16               fined in section 1889(g)) acting within the scope of the  
17               contractor’s contract authority, with respect to the fur-  
18               nishing of items or services and submission of a claim for  
19               benefits for such items or services with respect to such pro-  
20               vider or supplier;

21               “(ii) the Secretary determines that the provider of  
22               services or supplier has accurately presented the cir-  
23               cumstances relating to such items, services, and claim to  
24               the contractor in writing; and

25               “(iii) the guidance was in error;

26          the provider of services or supplier shall not be subject to any  
27          penalty or interest under this title or the provisions of title XI  
28          insofar as they relate to this title (including interest under a  
29          repayment plan under section 1893 or otherwise) relating to  
30          the provision of such items or service or such claim if the pro-  
31          vider of services or supplier reasonably relied on such guidance.

32          “(B) Subparagraph (A) shall not be construed as pre-  
33          venting the recoupment or repayment (without any additional  
34          penalty) relating to an overpayment insofar as the overpayment  
35          was solely the result of a clerical or technical operational  
36          error.”.

1           (2) EFFECTIVE DATE.—The amendment made by  
2           paragraph (1) shall take effect on the date of the enact-  
3           ment of this Act and shall only apply to a penalty or inter-  
4           est imposed with respect to guidance provided on or after  
5           July 24, 2003.

6           **SEC. 904. REPORTS AND STUDIES RELATING TO REGU-**  
7           **LATORY REFORM.**

8           (a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

9           (1) STUDY.—The Comptroller General of the United  
10          States shall conduct a study to determine the feasibility  
11          and appropriateness of establishing in the Secretary au-  
12          thority to provide legally binding advisory opinions on ap-  
13          propriate interpretation and application of regulations to  
14          carry out the medicare program under title XVIII of the  
15          Social Security Act. Such study shall examine the appro-  
16          priate timeframe for issuing such advisory opinions, as well  
17          as the need for additional staff and funding to provide such  
18          opinions.

19          (2) REPORT.—The Comptroller General shall submit  
20          to Congress a report on the study conducted under para-  
21          graph (1) by not later than 1 year after the date of the  
22          enactment of this Act.

23          (b) REPORT ON LEGAL AND REGULATORY INCONSIST-  
24          ENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by  
25          section 903(a)(1), is amended by adding at the end the fol-  
26          lowing new subsection:

27                 “(f)(1) Not later than 2 years after the date of the enact-  
28                 ment of this subsection, and every 3 years thereafter, the Sec-  
29                 retary shall submit to Congress a report with respect to the ad-  
30                 ministration of this title and areas of inconsistency or conflict  
31                 among the various provisions under law and regulation.

32                 “(2) In preparing a report under paragraph (1), the Sec-  
33                 retary shall collect—

34                         “(A) information from individuals entitled to benefits  
35                         under part A or enrolled under part B, or both, providers  
36                         of services, and suppliers and from the Medicare Bene-

1           ficiary Ombudsman with respect to such areas of inconsis-  
2           tency and conflict; and

3           “(B) information from medicare contractors that  
4           tracks the nature of written and telephone inquiries.

5           “(3) A report under paragraph (1) shall include a descrip-  
6           tion of efforts by the Secretary to reduce such inconsistency or  
7           conflicts, and recommendations for legislation or administrative  
8           action that the Secretary determines appropriate to further re-  
9           duce such inconsistency or conflicts.”.

## 10           **Subtitle B—Contracting Reform**

### 11           **SEC. 911. INCREASED FLEXIBILITY IN MEDICARE AD-** 12           **MINISTRATION.**

13           (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE AD-  
14           MINISTRATION.—

15           (1) IN GENERAL.—Title XVIII is amended by insert-  
16           ing after section 1874 the following new section:

17           “CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

18           “SEC. 1874A. (a) AUTHORITY.—

19           “(1) AUTHORITY TO ENTER INTO CONTRACTS.—The  
20           Secretary may enter into contracts with any eligible entity  
21           to serve as a medicare administrative contractor with re-  
22           spect to the performance of any or all of the functions de-  
23           scribed in paragraph (4) or parts of those functions (or, to  
24           the extent provided in a contract, to secure performance  
25           thereof by other entities).

26           “(2) ELIGIBILITY OF ENTITIES.—An entity is eligible  
27           to enter into a contract with respect to the performance of  
28           a particular function described in paragraph (4) only if—

29           “(A) the entity has demonstrated capability to  
30           carry out such function;

31           “(B) the entity complies with such conflict of in-  
32           terest standards as are generally applicable to Federal  
33           acquisition and procurement;

34           “(C) the entity has sufficient assets to financially  
35           support the performance of such function; and

36           “(D) the entity meets such other requirements as  
37           the Secretary may impose.

1           “(3) MEDICARE ADMINISTRATIVE CONTRACTOR DE-  
2           FINED.—For purposes of this title and title XI—

3           “(A) IN GENERAL.—The term ‘medicare adminis-  
4           trative contractor’ means an agency, organization, or  
5           other person with a contract under this section.

6           “(B) APPROPRIATE MEDICARE ADMINISTRATIVE  
7           CONTRACTOR.—With respect to the performance of a  
8           particular function in relation to an individual entitled  
9           to benefits under part A or enrolled under part B, or  
10          both, a specific provider of services or supplier (or class  
11          of such providers of services or suppliers), the ‘appro-  
12          priate’ medicare administrative contractor is the medi-  
13          care administrative contractor that has a contract  
14          under this section with respect to the performance of  
15          that function in relation to that individual, provider of  
16          services or supplier or class of provider of services or  
17          supplier.

18          “(4) FUNCTIONS DESCRIBED.—The functions referred  
19          to in paragraphs (1) and (2) are payment functions (in-  
20          cluding the function of developing local coverage determina-  
21          tions, as defined in section 1869(f)(2)(B)), provider serv-  
22          ices functions, and functions relating to services furnished  
23          to individuals entitled to benefits under part A or enrolled  
24          under part B, or both, as follows:

25          “(A) DETERMINATION OF PAYMENT AMOUNTS.—  
26          Determining (subject to the provisions of section 1878  
27          and to such review by the Secretary as may be provided  
28          for by the contracts) the amount of the payments re-  
29          quired pursuant to this title to be made to providers of  
30          services, suppliers and individuals.

31          “(B) MAKING PAYMENTS.—Making payments de-  
32          scribed in subparagraph (A) (including receipt, dis-  
33          bursement, and accounting for funds in making such  
34          payments).

35          “(C) BENEFICIARY EDUCATION AND ASSIST-  
36          ANCE.—Providing education and outreach to individ-  
37          uals entitled to benefits under part A or enrolled under

1 part B, or both, and providing assistance to those indi-  
2 viduals with specific issues, concerns, or problems.

3 “(D) PROVIDER CONSULTATIVE SERVICES.—Pro-  
4 viding consultative services to institutions, agencies,  
5 and other persons to enable them to establish and  
6 maintain fiscal records necessary for purposes of this  
7 title and otherwise to qualify as providers of services or  
8 suppliers.

9 “(E) COMMUNICATION WITH PROVIDERS.—Com-  
10 municating to providers of services and suppliers any  
11 information or instructions furnished to the medicare  
12 administrative contractor by the Secretary, and facili-  
13 tating communication between such providers and sup-  
14 pliers and the Secretary.

15 “(F) PROVIDER EDUCATION AND TECHNICAL AS-  
16 SISTANCE.—Performing the functions relating to pro-  
17 vider education, training, and technical assistance.

18 “(G) ADDITIONAL FUNCTIONS.—Performing such  
19 other functions, including (subject to paragraph (5))  
20 functions under the Medicare Integrity Program under  
21 section 1893, as are necessary to carry out the pur-  
22 poses of this title.

23 “(5) RELATIONSHIP TO MIP CONTRACTS.—

24 “(A) NONDUPLICATION OF DUTIES.—In entering  
25 into contracts under this section, the Secretary shall  
26 assure that functions of medicare administrative con-  
27 tractors in carrying out activities under parts A and B  
28 do not duplicate activities carried out under a contract  
29 entered into under the Medicare Integrity Program  
30 under section 1893. The previous sentence shall not  
31 apply with respect to the activity described in section  
32 1893(b)(5) (relating to prior authorization of certain  
33 items of durable medical equipment under section  
34 1834(a)(15)).

35 “(B) CONSTRUCTION.—An entity shall not be  
36 treated as a medicare administrative contractor merely

1           by reason of having entered into a contract with the  
2           Secretary under section 1893.

3           “(6) APPLICATION OF FEDERAL ACQUISITION REGULA-  
4           TION.—Except to the extent inconsistent with a specific re-  
5           quirement of this section, the Federal Acquisition Regula-  
6           tion applies to contracts under this section.

7           “(b) CONTRACTING REQUIREMENTS.—

8           “(1) USE OF COMPETITIVE PROCEDURES.—

9           “(A) IN GENERAL.—Except as provided in laws  
10          with general applicability to Federal acquisition and  
11          procurement or in subparagraph (B), the Secretary  
12          shall use competitive procedures when entering into  
13          contracts with medicare administrative contractors  
14          under this section, taking into account performance  
15          quality as well as price and other factors.

16          “(B) RENEWAL OF CONTRACTS.—The Secretary  
17          may renew a contract with a medicare administrative  
18          contractor under this section from term to term with-  
19          out regard to section 5 of title 41, United States Code,  
20          or any other provision of law requiring competition, if  
21          the medicare administrative contractor has met or ex-  
22          ceeded the performance requirements applicable with  
23          respect to the contract and contractor, except that the  
24          Secretary shall provide for the application of competi-  
25          tive procedures under such a contract not less fre-  
26          quently than once every 5 years.

27          “(C) TRANSFER OF FUNCTIONS.—The Secretary  
28          may transfer functions among medicare administrative  
29          contractors consistent with the provisions of this para-  
30          graph. The Secretary shall ensure that performance  
31          quality is considered in such transfers. The Secretary  
32          shall provide public notice (whether in the Federal Reg-  
33          ister or otherwise) of any such transfer (including a de-  
34          scription of the functions so transferred, a description  
35          of the providers of services and suppliers affected by  
36          such transfer, and contact information for the contrac-  
37          tors involved).

1           “(D) INCENTIVES FOR QUALITY.—The Secretary  
2           shall provide incentives for medicare administrative  
3           contractors to provide quality service and to promote  
4           efficiency.

5           “(2) COMPLIANCE WITH REQUIREMENTS.—No con-  
6           tract under this section shall be entered into with any  
7           medicare administrative contractor unless the Secretary  
8           finds that such medicare administrative contractor will per-  
9           form its obligations under the contract efficiently and effec-  
10          tively and will meet such requirements as to financial re-  
11          sponsibility, legal authority, quality of services provided,  
12          and other matters as the Secretary finds pertinent.

13          “(3) PERFORMANCE REQUIREMENTS.—

14                 “(A) DEVELOPMENT OF SPECIFIC PERFORMANCE  
15                 REQUIREMENTS.—

16                         “(i) IN GENERAL.—The Secretary shall de-  
17                         velop contract performance requirements to carry  
18                         out the specific requirements applicable under this  
19                         title to a function described in subsection (a)(4)  
20                         and shall develop standards for measuring the ex-  
21                         tent to which a contractor has met such require-  
22                         ments.

23                         “(ii) CONSULTATION.—In developing such per-  
24                         formance requirements and standards for measure-  
25                         ment, the Secretary shall consult with providers of  
26                         services, organizations representative of bene-  
27                         ficiaries under this title, and organizations and  
28                         agencies performing functions necessary to carry  
29                         out the purposes of this section with respect to  
30                         such performance requirements.

31                         “(iii) PUBLICATION OF STANDARDS.—The  
32                         Secretary shall make such performance require-  
33                         ments and measurement standards available to the  
34                         public.

35                         “(B) CONSIDERATIONS.—The Secretary shall in-  
36                         clude, as one of the standards developed under sub-

1 paragraph (A), provider and beneficiary satisfaction  
2 levels.

3 “(C) INCLUSION IN CONTRACTS.—All contractor  
4 performance requirements shall be set forth in the con-  
5 tract between the Secretary and the appropriate medi-  
6 care administrative contractor. Such performance  
7 requirements—

8 “(i) shall reflect the performance requirements  
9 published under subparagraph (A), but may include  
10 additional performance requirements;

11 “(ii) shall be used for evaluating contractor  
12 performance under the contract; and

13 “(iii) shall be consistent with the written state-  
14 ment of work provided under the contract.

15 “(4) INFORMATION REQUIREMENTS.—The Secretary  
16 shall not enter into a contract with a medicare administra-  
17 tive contractor under this section unless the contractor  
18 agrees—

19 “(A) to furnish to the Secretary such timely infor-  
20 mation and reports as the Secretary may find nec-  
21 essary in performing his functions under this title; and

22 “(B) to maintain such records and afford such ac-  
23 cess thereto as the Secretary finds necessary to assure  
24 the correctness and verification of the information and  
25 reports under subparagraph (A) and otherwise to carry  
26 out the purposes of this title.

27 “(5) SURETY BOND.—A contract with a medicare ad-  
28 ministrative contractor under this section may require the  
29 medicare administrative contractor, and any of its officers  
30 or employees certifying payments or disbursing funds pur-  
31 suant to the contract, or otherwise participating in carrying  
32 out the contract, to give surety bond to the United States  
33 in such amount as the Secretary may deem appropriate.

34 “(c) TERMS AND CONDITIONS.—

35 “(1) IN GENERAL.—A contract with any medicare ad-  
36 ministrative contractor under this section may contain such  
37 terms and conditions as the Secretary finds necessary or



1 appropriate and may provide for advances of funds to the  
2 medicare administrative contractor for the making of pay-  
3 ments by it under subsection (a)(4)(B).

4 “(2) PROHIBITION ON MANDATES FOR CERTAIN DATA  
5 COLLECTION.—The Secretary may not require, as a condi-  
6 tion of entering into, or renewing, a contract under this  
7 section, that the medicare administrative contractor match  
8 data obtained other than in its activities under this title  
9 with data used in the administration of this title for pur-  
10 poses of identifying situations in which the provisions of  
11 section 1862(b) may apply.

12 “(d) LIMITATION ON LIABILITY OF MEDICARE ADMINIS-  
13 TRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

14 “(1) CERTIFYING OFFICER.—No individual designated  
15 pursuant to a contract under this section as a certifying of-  
16 ficer shall, in the absence of the reckless disregard of the  
17 individual’s obligations or the intent by that individual to  
18 defraud the United States, be liable with respect to any  
19 payments certified by the individual under this section.

20 “(2) DISBURSING OFFICER.—No disbursing officer  
21 shall, in the absence of the reckless disregard of the offi-  
22 cer’s obligations or the intent by that officer to defraud the  
23 United States, be liable with respect to any payment by  
24 such officer under this section if it was based upon an au-  
25 thorization (which meets the applicable requirements for  
26 such internal controls established by the Comptroller Gen-  
27 eral of the United States) of a certifying officer designated  
28 as provided in paragraph (1) of this subsection.

29 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE CON-  
30 TRACTOR.—

31 “(A) IN GENERAL.—No medicare administrative  
32 contractor shall be liable to the United States for a  
33 payment by a certifying or disbursing officer unless, in  
34 connection with such payment, the medicare adminis-  
35 trative contractor acted with reckless disregard of its  
36 obligations under its medicare administrative contract  
37 or with intent to defraud the United States.

1           “(B) RELATIONSHIP TO FALSE CLAIMS ACT.—  
2           Nothing in this subsection shall be construed to limit  
3           liability for conduct that would constitute a violation of  
4           sections 3729 through 3731 of title 31, United States  
5           Code.

6           “(4) INDEMNIFICATION BY SECRETARY.—

7           “(A) IN GENERAL.—Subject to subparagraphs (B)  
8           and (D), in the case of a medicare administrative con-  
9           tractor (or a person who is a director, officer, or em-  
10          ployee of such a contractor or who is engaged by the  
11          contractor to participate directly in the claims adminis-  
12          tration process) who is made a party to any judicial or  
13          administrative proceeding arising from or relating di-  
14          rectly to the claims administration process under this  
15          title, the Secretary may, to the extent the Secretary de-  
16          termines to be appropriate and as specified in the con-  
17          tract with the contractor, indemnify the contractor and  
18          such persons.

19          “(B) CONDITIONS.—The Secretary may not pro-  
20          vide indemnification under subparagraph (A) insofar as  
21          the liability for such costs arises directly from conduct  
22          that is determined by the judicial proceeding or by the  
23          Secretary to be criminal in nature, fraudulent, or  
24          grossly negligent. If indemnification is provided by the  
25          Secretary with respect to a contractor before a deter-  
26          mination that such costs arose directly from such con-  
27          duct, the contractor shall reimburse the Secretary for  
28          costs of indemnification.

29          “(C) SCOPE OF INDEMNIFICATION.—Indemnifica-  
30          tion by the Secretary under subparagraph (A) may in-  
31          clude payment of judgments, settlements (subject to  
32          subparagraph (D)), awards, and costs (including rea-  
33          sonable legal expenses).

34          “(D) WRITTEN APPROVAL FOR SETTLEMENTS OR  
35          COMPROMISES.—A contractor or other person described  
36          in subparagraph (A) may not propose to negotiate a  
37          settlement or compromise of a proceeding described in

1 such subparagraph without the prior written approval  
2 of the Secretary to negotiate such settlement or com-  
3 promise. Any indemnification under subparagraph (A)  
4 with respect to amounts paid under a settlement or  
5 compromise of a proceeding described in such subpara-  
6 graph are conditioned upon prior written approval by  
7 the Secretary of the final settlement or compromise.

8 “(E) CONSTRUCTION.—Nothing in this paragraph  
9 shall be construed—

10 “(i) to change any common law immunity that  
11 may be available to a medicare administrative con-  
12 tractor or person described in subparagraph (A); or

13 “(ii) to permit the payment of costs not other-  
14 wise allowable, reasonable, or allocable under the  
15 Federal Acquisition Regulation.”.

16 (2) CONSIDERATION OF INCORPORATION OF CURRENT  
17 LAW STANDARDS.—In developing contract performance re-  
18 quirements under section 1874A(b) of the Social Security  
19 Act, as inserted by paragraph (1), the Secretary shall con-  
20 sider inclusion of the performance standards described in  
21 sections 1816(f)(2) of such Act (relating to timely proc-  
22 essing of reconsiderations and applications for exemptions)  
23 and section 1842(b)(2)(B) of such Act (relating to timely  
24 review of determinations and fair hearing requests), as  
25 such sections were in effect before the date of the enact-  
26 ment of this Act.

27 (b) CONFORMING AMENDMENTS TO SECTION 1816 (RE-  
28 LATING TO FISCAL INTERMEDIARIES).—Section 1816 (42  
29 U.S.C. 1395h) is amended as follows:

30 (1) The heading is amended to read as follows:

31 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

32 (2) Subsection (a) is amended to read as follows:

33 “(a) The administration of this part shall be conducted  
34 through contracts with medicare administrative contractors  
35 under section 1874A.”.

36 (3) Subsection (b) is repealed.

37 (4) Subsection (c) is amended—

1 (A) by striking paragraph (1); and

2 (B) in each of paragraphs (2)(A) and (3)(A), by  
3 striking “agreement under this section” and inserting  
4 “contract under section 1874A that provides for mak-  
5 ing payments under this part”.

6 (5) Subsections (d) through (i) are repealed.

7 (6) Subsections (j) and (k) are each amended—

8 (A) by striking “An agreement with an agency or  
9 organization under this section” and inserting “A con-  
10 tract with a medicare administrative contractor under  
11 section 1874A with respect to the administration of  
12 this part”; and

13 (B) by striking “such agency or organization” and  
14 inserting “such medicare administrative contractor”  
15 each place it appears.

16 (7) Subsection (l) is repealed.

17 (c) CONFORMING AMENDMENTS TO SECTION 1842 (RE-  
18 LATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is  
19 amended as follows:

20 (1) The heading is amended to read as follows:

21 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.

22 (2) Subsection (a) is amended to read as follows:

23 “(a) The administration of this part shall be conducted  
24 through contracts with medicare administrative contractors  
25 under section 1874A.”.

26 (3) Subsection (b) is amended—

27 (A) by striking paragraph (1);

28 (B) in paragraph (2)—

29 (i) by striking subparagraphs (A) and (B);

30 (ii) in subparagraph (C), by striking “car-  
31 riers” and inserting “medicare administrative con-  
32 tractors”; and

33 (iii) by striking subparagraphs (D) and (E);

34 (C) in paragraph (3)—

35 (i) in the matter before subparagraph (A), by  
36 striking “Each such contract shall provide that the  
37 carrier” and inserting “The Secretary”;

1 (ii) by striking “will” the first place it appears  
2 in each of subparagraphs (A), (B), (F), (G), (H),  
3 and (L) and inserting “shall”;

4 (iii) in subparagraph (B), in the matter before  
5 clause (i), by striking “to the policyholders and  
6 subscribers of the carrier” and inserting “to the  
7 policyholders and subscribers of the medicare ad-  
8 ministrative contractor”;

9 (iv) by striking subparagraphs (C), (D), and  
10 (E);

11 (v) in subparagraph (H)—

12 (I) by striking “if it makes determinations  
13 or payments with respect to physicians’ serv-  
14 ices,” in the matter preceding clause (i); and

15 (II) by striking “carrier” and inserting  
16 “medicare administrative contractor” in clause  
17 (i);

18 (vi) by striking subparagraph (I);

19 (vii) in subparagraph (L), by striking the  
20 semicolon and inserting a period;

21 (viii) in the first sentence, after subparagraph  
22 (L), by striking “and shall contain” and all that  
23 follows through the period; and

24 (ix) in the seventh sentence, by inserting  
25 “medicare administrative contractor,” after “car-  
26 rier,”;

27 (D) by striking paragraph (5);

28 (E) in paragraph (6)(D)(iv), by striking “carrier”  
29 and inserting “medicare administrative contractor”;  
30 and

31 (F) in paragraph (7), by striking “the carrier”  
32 and inserting “the Secretary” each place it appears.

33 (4) Subsection (c) is amended—

34 (A) by striking paragraph (1);

35 (B) in paragraph (2)(A), by striking “contract  
36 under this section which provides for the disbursement  
37 of funds, as described in subsection (a)(1)(B),” and in-

1           serting “contract under section 1874A that provides for  
2           making payments under this part”;

3           (C) in paragraph (3)(A), by striking “subsection  
4           (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;

5           (D) in paragraph (4), in the matter preceding sub-  
6           paragraph (A), by striking “carrier” and inserting  
7           “medicare administrative contractor”; and

8           (E) by striking paragraphs (5) and (6).

9           (5) Subsections (d), (e), and (f) are repealed.

10          (6) Subsection (g) is amended by striking “carrier or  
11          carriers” and inserting “medicare administrative contractor  
12          or contractors”.

13          (7) Subsection (h) is amended—

14           (A) in paragraph (2)—

15           (i) by striking “Each carrier having an agree-  
16           ment with the Secretary under subsection (a)” and  
17           inserting “The Secretary”; and

18           (ii) by striking “Each such carrier” and in-  
19           serting “The Secretary”;

20           (B) in paragraph (3)(A)—

21           (i) by striking “a carrier having an agreement  
22           with the Secretary under subsection (a)” and in-  
23           serting “medicare administrative contractor having  
24           a contract under section 1874A that provides for  
25           making payments under this part”; and

26           (ii) by striking “such carrier” and inserting  
27           “such contractor”;

28           (C) in paragraph (3)(B)—

29           (i) by striking “a carrier” and inserting “a  
30           medicare administrative contractor” each place it  
31           appears; and

32           (ii) by striking “the carrier” and inserting  
33           “the contractor” each place it appears; and

34           (D) in paragraphs (5)(A) and (5)(B)(iii), by strik-  
35           ing “carriers” and inserting “medicare administrative  
36           contractors” each place it appears.

37          (8) Subsection (l) is amended—

1 (A) in paragraph (1)(A)(iii), by striking “carrier”  
2 and inserting “medicare administrative contractor”;  
3 and

4 (B) in paragraph (2), by striking “carrier” and in-  
5 serting “medicare administrative contractor”.

6 (9) Subsection (p)(3)(A) is amended by striking “car-  
7 rier” and inserting “medicare administrative contractor”.

8 (10) Subsection (q)(1)(A) is amended by striking “car-  
9 rier”.

10 (d) EFFECTIVE DATE; TRANSITION RULE.—

11 (1) EFFECTIVE DATE.—

12 (A) IN GENERAL.—Except as otherwise provided  
13 in this subsection, the amendments made by this sec-  
14 tion shall take effect on October 1, 2005, and the Sec-  
15 retary is authorized to take such steps before such date  
16 as may be necessary to implement such amendments on  
17 a timely basis.

18 (B) CONSTRUCTION FOR CURRENT CONTRACTS.—  
19 Such amendments shall not apply to contracts in effect  
20 before the date specified under subparagraph (A) that  
21 continue to retain the terms and conditions in effect on  
22 such date (except as otherwise provided under this Act,  
23 other than under this section) until such date as the  
24 contract is let out for competitive bidding under such  
25 amendments.

26 (C) DEADLINE FOR COMPETITIVE BIDDING.—The  
27 Secretary shall provide for the letting by competitive  
28 bidding of all contracts for functions of medicare ad-  
29 ministrative contractors for annual contract periods  
30 that begin on or after October 1, 2011.

31 (2) GENERAL TRANSITION RULES.—

32 (A) AUTHORITY TO CONTINUE TO ENTER INTO  
33 NEW AGREEMENTS AND CONTRACTS AND WAIVER OF  
34 PROVIDER NOMINATION PROVISIONS DURING TRANSI-  
35 TION.—Prior to October 1, 2005, the Secretary may,  
36 consistent with subparagraph (B), continue to enter  
37 into agreements under section 1816 and contracts

1           under section 1842 of the Social Security Act (42  
2           U.S.C. 1395h, 1395u). The Secretary may enter into  
3           new agreements under section 1816 prior to October 1,  
4           2005, without regard to any of the provider nomination  
5           provisions of such section.

6           (B) APPROPRIATE TRANSITION.—The Secretary  
7           shall take such steps as are necessary to provide for an  
8           appropriate transition from agreements under section  
9           1816 and contracts under section 1842 of the Social  
10          Security Act (42 U.S.C. 1395h, 1395u) to contracts  
11          under section 1874A, as added by subsection (a)(1).

12          (3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS  
13          UNDER CURRENT CONTRACTS AND AGREEMENTS AND  
14          UNDER TRANSITION CONTRACTS.—Notwithstanding the  
15          amendments made by this section, the provisions contained  
16          in the exception in section 1893(d)(2) of the Social Secu-  
17          rity Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply  
18          during the period that begins on the date of the enactment  
19          of this Act and ends on October 1, 2011, and any reference  
20          in such provisions to an agreement or contract shall be  
21          deemed to include a contract under section 1874A of such  
22          Act, as inserted by subsection (a)(1), that continues the ac-  
23          tivities referred to in such provisions.

24          (e) REFERENCES.—On and after the effective date pro-  
25          vided under subsection (d)(1), any reference to a fiscal inter-  
26          mediary or carrier under title XI or XVIII of the Social Secu-  
27          rity Act (or any regulation, manual instruction, interpretative  
28          rule, statement of policy, or guideline issued to carry out such  
29          titles) shall be deemed a reference to a medicare administrative  
30          contractor (as provided under section 1874A of the Social Se-  
31          curity Act).

32          (f) SECRETARIAL SUBMISSION OF LEGISLATIVE PRO-  
33          POSAL.—Not later than 6 months after the date of the enact-  
34          ment of this Act, the Secretary shall submit to the appropriate  
35          committees of Congress a legislative proposal providing for  
36          such technical and conforming amendments in the law as are  
37          required by the provisions of this section.



1 (g) REPORTS ON IMPLEMENTATION.—

2 (1) PLAN FOR IMPLEMENTATION.—By not later than  
3 October 1, 2004, the Secretary shall submit a report to  
4 Congress and the Comptroller General of the United States  
5 that describes the plan for implementation of the amend-  
6 ments made by this section. The Comptroller General shall  
7 conduct an evaluation of such plan and shall submit to  
8 Congress, not later than 6 months after the date the report  
9 is received, a report on such evaluation and shall include  
10 in such report such recommendations as the Comptroller  
11 General deems appropriate.

12 (2) STATUS OF IMPLEMENTATION.—The Secretary  
13 shall submit a report to Congress not later than October  
14 1, 2008, that describes the status of implementation of  
15 such amendments and that includes a description of the  
16 following:

17 (A) The number of contracts that have been com-  
18 petitively bid as of such date.

19 (B) The distribution of functions among contracts  
20 and contractors.

21 (C) A timeline for complete transition to full com-  
22 petition.

23 (D) A detailed description of how the Secretary  
24 has modified oversight and management of medicare  
25 contractors to adapt to full competition.

26 **SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY**  
27 **FOR MEDICARE ADMINISTRATIVE CONTRAC-**  
28 **TORS.**

29 (a) IN GENERAL.—Section 1874A, as added by section  
30 911(a)(1), is amended by adding at the end the following new  
31 subsection:

32 “(e) REQUIREMENTS FOR INFORMATION SECURITY.—

33 “(1) DEVELOPMENT OF INFORMATION SECURITY PRO-  
34 GRAM.—A medicare administrative contractor that per-  
35 forms the functions referred to in subparagraphs (A) and  
36 (B) of subsection (a)(4) (relating to determining and mak-  
37 ing payments) shall implement a contractor-wide informa-

1           tion security program to provide information security for  
2           the operation and assets of the contractor with respect to  
3           such functions under this title. An information security  
4           program under this paragraph shall meet the requirements  
5           for information security programs imposed on Federal  
6           agencies under paragraphs (1) through (8) of section  
7           3544(b) of title 44, United States Code (other than the re-  
8           quirements under paragraphs (2)(D)(i), (5)(A), and (5)(B)  
9           of such section).

10           “(2) INDEPENDENT AUDITS.—

11           “(A) PERFORMANCE OF ANNUAL EVALUATIONS.—

12           Each year a medicare administrative contractor that  
13           performs the functions referred to in subparagraphs  
14           (A) and (B) of subsection (a)(4) (relating to deter-  
15           mining and making payments) shall undergo an evalua-  
16           tion of the information security of the contractor with  
17           respect to such functions under this title. The evalua-  
18           tion shall—

19           “(i) be performed by an entity that meets such  
20           requirements for independence as the Inspector  
21           General of the Department of Health and Human  
22           Services may establish; and

23           “(ii) test the effectiveness of information secu-  
24           rity control techniques of an appropriate subset of  
25           the contractor’s information systems (as defined in  
26           section 3502(8) of title 44, United States Code) re-  
27           lating to such functions under this title and an as-  
28           sessment of compliance with the requirements of  
29           this subsection and related information security  
30           policies, procedures, standards and guidelines, in-  
31           cluding policies and procedures as may be pre-  
32           scribed by the Director of the Office of Manage-  
33           ment and Budget and applicable information secu-  
34           rity standards promulgated under section 11331 of  
35           title 40, United States Code.

36           “(B) DEADLINE FOR INITIAL EVALUATION.—

1           “(i) NEW CONTRACTORS.—In the case of a  
2 medicare administrative contractor covered by this  
3 subsection that has not previously performed the  
4 functions referred to in subparagraphs (A) and (B)  
5 of subsection (a)(4) (relating to determining and  
6 making payments) as a fiscal intermediary or car-  
7 rier under section 1816 or 1842, the first inde-  
8 pendent evaluation conducted pursuant to subpara-  
9 graph (A) shall be completed prior to commencing  
10 such functions.

11           “(ii) OTHER CONTRACTORS.—In the case of a  
12 medicare administrative contractor covered by this  
13 subsection that is not described in clause (i), the  
14 first independent evaluation conducted pursuant to  
15 subparagraph (A) shall be completed within 1 year  
16 after the date the contractor commences functions  
17 referred to in clause (i) under this section.

18           “(C) REPORTS ON EVALUATIONS.—

19           “(i) TO THE DEPARTMENT OF HEALTH AND  
20 HUMAN SERVICES.—The results of independent  
21 evaluations under subparagraph (A) shall be sub-  
22 mitted promptly to the Inspector General of the  
23 Department of Health and Human Services and to  
24 the Secretary.

25           “(ii) TO CONGRESS.—The Inspector General  
26 of the Department of Health and Human Services  
27 shall submit to Congress annual reports on the re-  
28 sults of such evaluations, including assessments of  
29 the scope and sufficiency of such evaluations.

30           “(iii) AGENCY REPORTING.—The Secretary  
31 shall address the results of such evaluations in re-  
32 ports required under section 3544(c) of title 44,  
33 United States Code.”.

34           (b) APPLICATION OF REQUIREMENTS TO FISCAL INTER-  
35 MEDIARIES AND CARRIERS.—

36           (1) IN GENERAL.—The provisions of section  
37 1874A(e)(2) of the Social Security Act (other than sub-

1 paragraph (B)), as added by subsection (a), shall apply to  
2 each fiscal intermediary under section 1816 of the Social  
3 Security Act (42 U.S.C. 1395h) and each carrier under  
4 section 1842 of such Act (42 U.S.C. 1395u) in the same  
5 manner as they apply to medicare administrative contrac-  
6 tors under such provisions.

7 (2) DEADLINE FOR INITIAL EVALUATION.—In the case  
8 of such a fiscal intermediary or carrier with an agreement  
9 or contract under such respective section in effect as of the  
10 date of the enactment of this Act, the first evaluation  
11 under section 1874A(e)(2)(A) of the Social Security Act  
12 (as added by subsection (a)), pursuant to paragraph (1),  
13 shall be completed (and a report on the evaluation sub-  
14 mitted to the Secretary) by not later than 1 year after such  
15 date.

## 16 **Subtitle C—Education and Outreach**

### 17 **SEC. 921. PROVIDER EDUCATION AND TECHNICAL AS-** 18 **SISTANCE.**

19 (a) COORDINATION OF EDUCATION FUNDING.—

20 (1) IN GENERAL.—Title XVIII is amended by insert-  
21 ing after section 1888 the following new section:

22 “PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

23 “SEC. 1889. (a) COORDINATION OF EDUCATION FUND-  
24 ING.—The Secretary shall coordinate the educational activities  
25 provided through medicare contractors (as defined in sub-  
26 section (g), including under section 1893) in order to maximize  
27 the effectiveness of Federal education efforts for providers of  
28 services and suppliers.”.

29 (2) EFFECTIVE DATE.—The amendment made by  
30 paragraph (1) shall take effect on the date of the enact-  
31 ment of this Act.

32 (3) REPORT.—Not later than October 1, 2004, the  
33 Secretary shall submit to Congress a report that includes  
34 a description and evaluation of the steps taken to coordi-  
35 nate the funding of provider education under section  
36 1889(a) of the Social Security Act, as added by paragraph  
37 (1).

1 (b) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-  
2 ANCE.—

3 (1) IN GENERAL.—Section 1874A, as added by section  
4 911(a)(1) and as amended by section 912(a), is amended  
5 by adding at the end the following new subsection:

6 “(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-  
7 ANCE IN PROVIDER EDUCATION AND OUTREACH.—The Sec-  
8 retary shall use specific claims payment error rates or similar  
9 methodology of medicare administrative contractors in the  
10 processing or reviewing of medicare claims in order to give such  
11 contractors an incentive to implement effective education and  
12 outreach programs for providers of services and suppliers.”.

13 (2) APPLICATION TO FISCAL INTERMEDIARIES AND  
14 CARRIERS.—The provisions of section 1874A(f) of the So-  
15 cial Security Act, as added by paragraph (1), shall apply  
16 to each fiscal intermediary under section 1816 of the Social  
17 Security Act (42 U.S.C. 1395h) and each carrier under  
18 section 1842 of such Act (42 U.S.C. 1395u) in the same  
19 manner as they apply to medicare administrative contrac-  
20 tors under such provisions.

21 (3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—  
22 Not later than October 1, 2004, the Comptroller General  
23 of the United States shall submit to Congress and to the  
24 Secretary a report on the adequacy of the methodology  
25 under section 1874A(f) of the Social Security Act, as added  
26 by paragraph (1), and shall include in the report such rec-  
27 ommendations as the Comptroller General determines ap-  
28 propriate with respect to the methodology.

29 (4) REPORT ON USE OF METHODOLOGY IN ASSESSING  
30 CONTRACTOR PERFORMANCE.—Not later than October 1,  
31 2004, the Secretary shall submit to Congress a report that  
32 describes how the Secretary intends to use such method-  
33 ology in assessing medicare contractor performance in im-  
34 plementing effective education and outreach programs, in-  
35 cluding whether to use such methodology as a basis for per-  
36 formance bonuses. The report shall include an analysis of  
37 the sources of identified errors and potential changes in

1 systems of contractors and rules of the Secretary that could  
2 reduce claims error rates.

3 (c) PROVISION OF ACCESS TO AND PROMPT RESPONSES  
4 FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

5 (1) IN GENERAL.—Section 1874A, as added by section  
6 911(a)(1) and as amended by section 912(a) and sub-  
7 section (b), is further amended by adding at the end the  
8 following new subsection:

9 “(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS  
10 OF SERVICES AND SUPPLIERS.—

11 “(1) COMMUNICATION STRATEGY.—The Secretary  
12 shall develop a strategy for communications with individ-  
13 uals entitled to benefits under part A or enrolled under  
14 part B, or both, and with providers of services and sup-  
15 pliers under this title.

16 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each medi-  
17 care administrative contractor shall, for those providers of  
18 services and suppliers which submit claims to the con-  
19 tractor for claims processing and for those individuals enti-  
20 tled to benefits under part A or enrolled under part B, or  
21 both, with respect to whom claims are submitted for claims  
22 processing, provide general written responses (which may  
23 be through electronic transmission) in a clear, concise, and  
24 accurate manner to inquiries of providers of services, sup-  
25 pliers, and individuals entitled to benefits under part A or  
26 enrolled under part B, or both, concerning the programs  
27 under this title within 45 business days of the date of re-  
28 ceipt of such inquiries.

29 “(3) RESPONSE TO TOLL-FREE LINES.—The Secretary  
30 shall ensure that each medicare administrative contractor  
31 shall provide, for those providers of services and suppliers  
32 which submit claims to the contractor for claims processing  
33 and for those individuals entitled to benefits under part A  
34 or enrolled under part B, or both, with respect to whom  
35 claims are submitted for claims processing, a toll-free tele-  
36 phone number at which such individuals, providers of serv-  
37 ices, and suppliers may obtain information regarding bill-

1 ing, coding, claims, coverage, and other appropriate infor-  
2 mation under this title.

3 “(4) MONITORING OF CONTRACTOR RESPONSES.—

4 “(A) IN GENERAL.—Each medicare administrative  
5 contractor shall, consistent with standards developed by  
6 the Secretary under subparagraph (B)—

7 “(i) maintain a system for identifying who  
8 provides the information referred to in paragraphs  
9 (2) and (3); and

10 “(ii) monitor the accuracy, consistency, and  
11 timeliness of the information so provided.

12 “(B) DEVELOPMENT OF STANDARDS.—

13 “(i) IN GENERAL.—The Secretary shall estab-  
14 lish and make public standards to monitor the ac-  
15 curacy, consistency, and timeliness of the informa-  
16 tion provided in response to written and telephone  
17 inquiries under this subsection. Such standards  
18 shall be consistent with the performance require-  
19 ments established under subsection (b)(3).

20 “(ii) EVALUATION.—In conducting evaluations  
21 of individual medicare administrative contractors,  
22 the Secretary shall take into account the results of  
23 the monitoring conducted under subparagraph (A)  
24 taking into account as performance requirements  
25 the standards established under clause (i). The  
26 Secretary shall, in consultation with organizations  
27 representing providers of services, suppliers, and  
28 individuals entitled to benefits under part A or en-  
29 rolled under part B, or both, establish standards  
30 relating to the accuracy, consistency, and timeliness  
31 of the information so provided.

32 “(C) DIRECT MONITORING.—Nothing in this para-  
33 graph shall be construed as preventing the Secretary  
34 from directly monitoring the accuracy, consistency, and  
35 timeliness of the information so provided.

1           “(5) AUTHORIZATION OF APPROPRIATIONS.—There  
2           are authorized to be appropriated such sums as are nec-  
3           essary to carry out this subsection.”.

4           (2) EFFECTIVE DATE.—The amendment made by  
5           paragraph (1) shall take effect October 1, 2004.

6           (3) APPLICATION TO FISCAL INTERMEDIARIES AND  
7           CARRIERS.—The provisions of section 1874A(g) of the So-  
8           cial Security Act, as added by paragraph (1), shall apply  
9           to each fiscal intermediary under section 1816 of the Social  
10          Security Act (42 U.S.C. 1395h) and each carrier under  
11          section 1842 of such Act (42 U.S.C. 1395u) in the same  
12          manner as they apply to medicare administrative contrac-  
13          tors under such provisions.

14          (d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

15           (1) IN GENERAL.—Section 1889, as added by sub-  
16           section (a), is amended by adding at the end the following  
17           new subsections:

18           “(b) ENHANCED EDUCATION AND TRAINING.—

19           “(1) ADDITIONAL RESOURCES.—There are authorized  
20           to be appropriated to the Secretary (in appropriate part  
21           from the Federal Hospital Insurance Trust Fund and the  
22           Federal Supplementary Medical Insurance Trust Fund)  
23           such sums as may be necessary for fiscal years beginning  
24           with fiscal year 2005.

25           “(2) USE.—The funds made available under para-  
26           graph (1) shall be used to increase the conduct by medicare  
27           contractors of education and training of providers of serv-  
28           ices and suppliers regarding billing, coding, and other ap-  
29           propriate items and may also be used to improve the accu-  
30           racy, consistency, and timeliness of contractor responses.

31           “(c) TAILORING EDUCATION AND TRAINING ACTIVITIES  
32           FOR SMALL PROVIDERS OR SUPPLIERS.—

33           “(1) IN GENERAL.—Insofar as a medicare contractor  
34           conducts education and training activities, it shall tailor  
35           such activities to meet the special needs of small providers  
36           of services or suppliers (as defined in paragraph (2)). Such  
37           education and training activities for small providers of serv-



1           ices and suppliers may include the provision of technical as-  
2           sistance (such as review of billing systems and internal con-  
3           trols to determine program compliance and to suggest more  
4           efficient and effective means of achieving such compliance).

5           “(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—

6           In this subsection, the term ‘small provider of services or  
7           supplier’ means—

8           “(A) a provider of services with fewer than 25 full-  
9           time-equivalent employees; or

10           “(B) a supplier with fewer than 10 full-time-equiv-  
11           alent employees.”.

12           (2) EFFECTIVE DATE.—The amendment made by  
13           paragraph (1) shall take effect on October 1, 2004.

14           (e) REQUIREMENT TO MAINTAIN INTERNET WEBSITES.—

15           (1) IN GENERAL.—Section 1889, as added by sub-  
16           section (a) and as amended by subsection (d), is further  
17           amended by adding at the end the following new sub-  
18           section:

19           “(d) INTERNET WEBSITES; FAQs.—The Secretary, and  
20           each medicare contractor insofar as it provides services (includ-  
21           ing claims processing) for providers of services or suppliers,  
22           shall maintain an Internet website which—

23           “(1) provides answers in an easily accessible format to  
24           frequently asked questions, and

25           “(2) includes other published materials of the con-  
26           tractor,

27           that relate to providers of services and suppliers under the pro-  
28           grams under this title (and title XI insofar as it relates to such  
29           programs).”.

30           (2) EFFECTIVE DATE.—The amendment made by  
31           paragraph (1) shall take effect on October 1, 2004.

32           (f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

33           (1) IN GENERAL.—Section 1889, as added by sub-  
34           section (a) and as amended by subsections (d) and (e), is  
35           further amended by adding at the end the following new  
36           subsections:

1           “(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION  
2 PROGRAM ACTIVITIES.—A medicare contractor may not use a  
3 record of attendance at (or failure to attend) educational activi-  
4 ties or other information gathered during an educational pro-  
5 gram conducted under this section or otherwise by the Sec-  
6 retary to select or track providers of services or suppliers for  
7 the purpose of conducting any type of audit or prepayment re-  
8 view.

9           “(f) CONSTRUCTION.—Nothing in this section or section  
10 1893(g) shall be construed as providing for disclosure by a  
11 medicare contractor—

12           “(1) of the screens used for identifying claims that will  
13 be subject to medical review; or

14           “(2) of information that would compromise pending  
15 law enforcement activities or reveal findings of law enforce-  
16 ment-related audits.

17           “(g) DEFINITIONS.—For purposes of this section, the  
18 term ‘medicare contractor’ includes the following:

19           “(1) A medicare administrative contractor with a con-  
20 tract under section 1874A, including a fiscal intermediary  
21 with a contract under section 1816 and a carrier with a  
22 contract under section 1842.

23           “(2) An eligible entity with a contract under section  
24 1893.

25 Such term does not include, with respect to activities of a spe-  
26 cific provider of services or supplier an entity that has no au-  
27 thority under this title or title IX with respect to such activities  
28 and such provider of services or supplier.”.

29           “(2) EFFECTIVE DATE.—The amendment made by  
30 paragraph (1) shall take effect on the date of the enact-  
31 ment of this Act.

32 **SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE**  
33 **DEMONSTRATION PROGRAM.**

34           “(a) ESTABLISHMENT.—

35           “(1) IN GENERAL.—The Secretary shall establish a  
36 demonstration program (in this section referred to as the  
37 “demonstration program”) under which technical assist-

1           ance described in paragraph (2) is made available, upon re-  
2           quest and on a voluntary basis, to small providers of serv-  
3           ices or suppliers in order to improve compliance with the  
4           applicable requirements of the programs under medicare  
5           program under title XVIII of the Social Security Act (in-  
6           cluding provisions of title XI of such Act insofar as they  
7           relate to such title and are not administered by the Office  
8           of the Inspector General of the Department of Health and  
9           Human Services).

10           (2) FORMS OF TECHNICAL ASSISTANCE.—The tech-  
11           nical assistance described in this paragraph is—

12                   (A) evaluation and recommendations regarding  
13                   billing and related systems; and

14                   (B) information and assistance regarding policies  
15                   and procedures under the medicare program, including  
16                   coding and reimbursement.

17           (3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—  
18           In this section, the term “small providers of services or  
19           suppliers” means—

20                   (A) a provider of services with fewer than 25 full-  
21                   time-equivalent employees; or

22                   (B) a supplier with fewer than 10 full-time-equa-  
23                   lent employees.

24           (b) QUALIFICATION OF CONTRACTORS.—In conducting the  
25           demonstration program, the Secretary shall enter into contracts  
26           with qualified organizations (such as peer review organizations  
27           or entities described in section 1889(g)(2) of the Social Secu-  
28           rity Act, as inserted by section 921(f)(1)) with appropriate ex-  
29           pertise with billing systems of the full range of providers of  
30           services and suppliers to provide the technical assistance. In  
31           awarding such contracts, the Secretary shall consider any prior  
32           investigations of the entity’s work by the Inspector General of  
33           Department of Health and Human Services or the Comptroller  
34           General of the United States.

35           (c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The tech-  
36           nical assistance provided under the demonstration program  
37           shall include a direct and in-person examination of billing sys-

1    tems and internal controls of small providers of services or sup-  
2    pliers to determine program compliance and to suggest more  
3    efficient or effective means of achieving such compliance.

4           (d) GAO EVALUATION.—Not later than 2 years after the  
5    date the demonstration program is first implemented, the  
6    Comptroller General, in consultation with the Inspector General  
7    of the Department of Health and Human Services, shall con-  
8    duct an evaluation of the demonstration program. The evalua-  
9    tion shall include a determination of whether claims error rates  
10   are reduced for small providers of services or suppliers who  
11   participated in the program and the extent of improper pay-  
12   ments made as a result of the demonstration program. The  
13   Comptroller General shall submit a report to the Secretary and  
14   the Congress on such evaluation and shall include in such re-  
15   port recommendations regarding the continuation or extension  
16   of the demonstration program.

17           (e) FINANCIAL PARTICIPATION BY PROVIDERS.—The pro-  
18   vision of technical assistance to a small provider of services or  
19   supplier under the demonstration program is conditioned upon  
20   the small provider of services or supplier paying an amount es-  
21   timated (and disclosed in advance of a provider’s or supplier’s  
22   participation in the program) to be equal to 25 percent of the  
23   cost of the technical assistance.

24           (f) AUTHORIZATION OF APPROPRIATIONS.—There are au-  
25   thorized to be appropriated, from amounts not otherwise appro-  
26   priated in the Treasury, such sums as may be necessary to  
27   carry out this section.

28   **SEC. 923. MEDICARE BENEFICIARY OMBUDSMAN.**

29           (a) IN GENERAL.—Section 1808, as added and amended  
30   by section 900, is amended by adding at the end the following  
31   new subsection:

32           “(c) MEDICARE BENEFICIARY OMBUDSMAN.—

33           “(1) IN GENERAL.—The Secretary shall appoint with-  
34   in the Department of Health and Human Services a Medi-  
35   care Beneficiary Ombudsman who shall have expertise and  
36   experience in the fields of health care and education of

1 (and assistance to) individuals entitled to benefits under  
2 this title.

3 “(2) DUTIES.—The Medicare Beneficiary Ombudsman  
4 shall—

5 “(A) receive complaints, grievances, and requests  
6 for information submitted by individuals entitled to  
7 benefits under part A or enrolled under part B, or  
8 both, with respect to any aspect of the medicare pro-  
9 gram;

10 “(B) provide assistance with respect to complaints,  
11 grievances, and requests referred to in subparagraph  
12 (A), including—

13 “(i) assistance in collecting relevant informa-  
14 tion for such individuals, to seek an appeal of a de-  
15 cision or determination made by a fiscal inter-  
16 mediary, carrier, MA organization, or the Sec-  
17 retary;

18 “(ii) assistance to such individuals with any  
19 problems arising from disenrollment from an MA  
20 plan under part C; and

21 “(iii) assistance to such individuals in pre-  
22 senting information under section 1839(i)(4)(C)  
23 (relating to income-related premium adjustment;  
24 and

25 “(C) submit annual reports to Congress and the  
26 Secretary that describe the activities of the Office and  
27 that include such recommendations for improvement in  
28 the administration of this title as the Ombudsman de-  
29 termines appropriate.

30 The Ombudsman shall not serve as an advocate for any in-  
31 creases in payments or new coverage of services, but may  
32 identify issues and problems in payment or coverage poli-  
33 cies.

34 “(3) WORKING WITH HEALTH INSURANCE COUN-  
35 SELING PROGRAMS.—To the extent possible, the Ombuds-  
36 man shall work with health insurance counseling programs  
37 (receiving funding under section 4360 of Omnibus Budget

1 Reconciliation Act of 1990) to facilitate the provision of in-  
2 formation to individuals entitled to benefits under part A  
3 or enrolled under part B, or both regarding MA plans and  
4 changes to those plans. Nothing in this paragraph shall  
5 preclude further collaboration between the Ombudsman and  
6 such programs.”.

7 (b) DEADLINE FOR APPOINTMENT.—By not later than 1  
8 year after the date of the enactment of this Act, the Secretary  
9 shall appoint the Medicare Beneficiary Ombudsman under sec-  
10 tion 1808(c) of the Social Security Act, as added by subsection  
11 (a).

12 (c) FUNDING.—There are authorized to be appropriated to  
13 the Secretary (in appropriate part from the Federal Hospital  
14 Insurance Trust Fund, established under section 1817 of the  
15 Social Security Act (42 U.S.C. 1395i), and the Federal Supple-  
16 mentary Medical Insurance Trust Fund, established under sec-  
17 tion 1841 of such Act (42 U.S.C. 1395t)) to carry out section  
18 1808(c) of such Act (relating to the Medicare Beneficiary Om-  
19 budsman), as added by subsection (a), such sums as are nec-  
20 essary for fiscal year 2004 and each succeeding fiscal year.

21 (d) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-  
22 MEDICARE).—

23 (1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE  
24 HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—  
25 Section 1804(b) (42 U.S.C. 1395b-2(b)) is amended by  
26 adding at the end the following: “The Secretary shall pro-  
27 vide, through the toll-free telephone number 1-800-MEDI-  
28 CARE, for a means by which individuals seeking informa-  
29 tion about, or assistance with, such programs who phone  
30 such toll-free number are transferred (without charge) to  
31 appropriate entities for the provision of such information or  
32 assistance. Such toll-free number shall be the toll-free num-  
33 ber listed for general information and assistance in the an-  
34 nual notice under subsection (a) instead of the listing of  
35 numbers of individual contractors.”.

36 (2) MONITORING ACCURACY.—

1 (A) STUDY.—The Comptroller General of the  
2 United States shall conduct a study to monitor the ac-  
3 curacy and consistency of information provided to indi-  
4 viduals entitled to benefits under part A or enrolled  
5 under part B, or both, through the toll-free telephone  
6 number 1-800-MEDICARE, including an assessment  
7 of whether the information provided is sufficient to an-  
8 swer questions of such individuals. In conducting the  
9 study, the Comptroller General shall examine the edu-  
10 cation and training of the individuals providing infor-  
11 mation through such number.

12 (B) REPORT.—Not later than 1 year after the  
13 date of the enactment of this Act, the Comptroller Gen-  
14 eral shall submit to Congress a report on the study  
15 conducted under subparagraph (A).

16 **SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION**  
17 **PROGRAM.**

18 (a) IN GENERAL.—The Secretary shall establish a dem-  
19 onstration program (in this section referred to as the “dem-  
20 onstration program”) under which medicare specialists em-  
21 ployed by the Department of Health and Human Services pro-  
22 vide advice and assistance to individuals entitled to benefits  
23 under part A of title XVIII of the Social Security Act, or en-  
24 rolled under part B of such title, or both, regarding the medi-  
25 care program at the location of existing local offices of the So-  
26 cial Security Administration.

27 (b) LOCATIONS.—

28 (1) IN GENERAL.—The demonstration program shall  
29 be conducted in at least 6 offices or areas. Subject to para-  
30 graph (2), in selecting such offices and areas, the Secretary  
31 shall provide preference for offices with a high volume of  
32 visits by individuals referred to in subsection (a).

33 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—The  
34 Secretary shall provide for the selection of at least 2 rural  
35 areas to participate in the demonstration program. In con-  
36 ducting the demonstration program in such rural areas, the

1 Secretary shall provide for medicare specialists to travel  
2 among local offices in a rural area on a scheduled basis.

3 (c) DURATION.—The demonstration program shall be con-  
4 ducted over a 3-year period.

5 (d) EVALUATION AND REPORT.—

6 (1) EVALUATION.—The Secretary shall provide for an  
7 evaluation of the demonstration program. Such evaluation  
8 shall include an analysis of—

9 (A) utilization of, and satisfaction of those individ-  
10 uals referred to in subsection (a) with, the assistance  
11 provided under the program; and

12 (B) the cost-effectiveness of providing beneficiary  
13 assistance through out-stationing medicare specialists  
14 at local offices of the Social Security Administration.

15 (2) REPORT.—The Secretary shall submit to Congress  
16 a report on such evaluation and shall include in such report  
17 recommendations regarding the feasibility of permanently  
18 out-stationing medicare specialists at local offices of the So-  
19 cial Security Administration.

20 **SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN**  
21 **NOTICES TO BENEFICIARIES ABOUT**  
22 **SKILLED NURSING FACILITY BENEFITS.**

23 (a) IN GENERAL.—The Secretary shall provide that in  
24 medicare beneficiary notices provided (under section 1806(a) of  
25 the Social Security Act, 42 U.S.C. 1395b-7(a)) with respect to  
26 the provision of post-hospital extended care services under part  
27 A of title XVIII of the Social Security Act, there shall be in-  
28 cluded information on the number of days of coverage of such  
29 services remaining under such part for the medicare beneficiary  
30 and spell of illness involved.

31 (b) EFFECTIVE DATE.—Subsection (a) shall apply to no-  
32 tices provided during calendar quarters beginning more than 6  
33 months after the date of the enactment of this Act.

34 **SEC. 926. INFORMATION ON MEDICARE-CERTIFIED**  
35 **SKILLED NURSING FACILITIES IN HOSPITAL**  
36 **DISCHARGE PLANS.**

37 (a) AVAILABILITY OF DATA.—The Secretary shall publicly  
38 provide information that enables hospital discharge planners,



1 medicare beneficiaries, and the public to identify skilled nursing  
2 facilities that are participating in the medicare program.

3 (b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL  
4 DISCHARGE PLANS.—

5 (1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C.  
6 1395x(ee)(2)(D)) is amended—

7 (A) by striking “hospice services” and inserting  
8 “hospice care and post-hospital extended care services”;  
9 and

10 (B) by inserting before the period at the end the  
11 following: “and, in the case of individuals who are like-  
12 ly to need post-hospital extended care services, the  
13 availability of such services through facilities that par-  
14 ticipate in the program under this title and that serve  
15 the area in which the patient resides”.

16 (2) EFFECTIVE DATE.—The amendments made by  
17 paragraph (1) shall apply to discharge plans made on or  
18 after such date as the Secretary shall specify, but not later  
19 than 6 months after the date the Secretary provides for  
20 availability of information under subsection (a).

## 21 **Subtitle D—Appeals and Recovery**

### 22 **SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDI-** 23 **CARE APPEALS.**

24 (a) TRANSITION PLAN.—

25 (1) IN GENERAL.—Not later than April 1, 2004, the  
26 Commissioner of Social Security and the Secretary shall de-  
27 velop and transmit to Congress and the Comptroller Gen-  
28 eral of the United States a plan under which the functions  
29 of administrative law judges responsible for hearing cases  
30 under title XVIII of the Social Security Act (and related  
31 provisions in title XI of such Act) are transferred from the  
32 responsibility of the Commissioner and the Social Security  
33 Administration to the Secretary and the Department of  
34 Health and Human Services.

35 (2) CONTENTS.—The plan shall include information  
36 on the following:

1 (A) WORKLOAD.—The number of such administra-  
2 tive law judges and support staff required now and in  
3 the future to hear and decide such cases in a timely  
4 manner, taking into account the current and antici-  
5 pated claims volume, appeals, number of beneficiaries,  
6 and statutory changes.

7 (B) COST PROJECTIONS AND FINANCING.—Fund-  
8 ing levels required for fiscal year 2005 and subsequent  
9 fiscal years to carry out the functions transferred  
10 under the plan.

11 (C) TRANSITION TIMETABLE.—A timetable for the  
12 transition.

13 (D) REGULATIONS.—The establishment of specific  
14 regulations to govern the appeals process.

15 (E) CASE TRACKING.—The development of a uni-  
16 fied case tracking system that will facilitate the mainte-  
17 nance and transfer of case specific data across both the  
18 fee-for-service and managed care components of the  
19 medicare program.

20 (F) FEASIBILITY OF PRECEDENTIAL AUTHOR-  
21 ITY.—The feasibility of developing a process to give de-  
22 cisions of the Departmental Appeals Board in the De-  
23 partment of Health and Human Services addressing  
24 broad legal issues binding, precedential authority.

25 (G) ACCESS TO ADMINISTRATIVE LAW JUDGES.—  
26 The feasibility of—

27 (i) filing appeals with administrative law  
28 judges electronically; and

29 (ii) conducting hearings using tele- or video-  
30 conference technologies.

31 (H) INDEPENDENCE OF ADMINISTRATIVE LAW  
32 JUDGES.—The steps that should be taken to ensure the  
33 independence of administrative law judges consistent  
34 with the requirements of subsection (b)(2).

35 (I) GEOGRAPHIC DISTRIBUTION.—The steps that  
36 should be taken to provide for an appropriate geo-  
37 graphic distribution of administrative law judges

1 throughout the United States to carry out subsection  
2 (b)(3).

3 (J) HIRING.—The steps that should be taken to  
4 hire administrative law judges (and support staff) to  
5 carry out subsection (b)(4).

6 (K) PERFORMANCE STANDARDS.—The appro-  
7 priateness of establishing performance standards for  
8 administrative law judges with respect to timelines for  
9 decisions in cases under title XVIII of the Social Secu-  
10 rity Act taking into account requirements under sub-  
11 section (b)(2) for the independence of such judges and  
12 consistent with the applicable provisions of title 5,  
13 United States Code relating to impartiality.

14 (L) SHARED RESOURCES.—The steps that should  
15 be taken to carry out subsection (b)(6) (relating to the  
16 arrangements with the Commissioner of Social Security  
17 to share office space, support staff, and other re-  
18 sources, with appropriate reimbursement).

19 (M) TRAINING.—The training that should be pro-  
20 vided to administrative law judges with respect to laws  
21 and regulations under title XVIII of the Social Security  
22 Act.

23 (3) ADDITIONAL INFORMATION.—The plan may also  
24 include recommendations for further congressional action,  
25 including modifications to the requirements and deadlines  
26 established under section 1869 of the Social Security Act  
27 (42 U.S.C. 1395ff) (as amended by this Act).

28 (4) GAO EVALUATION.—The Comptroller General of  
29 the United States shall evaluate the plan and, not later  
30 than the date that is 6 months after the date on which the  
31 plan is received by the Comptroller General, shall submit  
32 to Congress a report on such evaluation.

33 (b) TRANSFER OF ADJUDICATION AUTHORITY.—

34 (1) IN GENERAL.—Not earlier than July 1, 2005, and  
35 not later than October 1, 2005, the Commissioner of Social  
36 Security and the Secretary shall implement the transition  
37 plan under subsection (a) and transfer the administrative

1 law judge functions described in such subsection from the  
2 Social Security Administration to the Secretary.

3 (2) ASSURING INDEPENDENCE OF JUDGES.—The Sec-  
4 retary shall assure the independence of administrative law  
5 judges performing the administrative law judge functions  
6 transferred under paragraph (1) from the Centers for  
7 Medicare & Medicaid Services and its contractors. In order  
8 to assure such independence, the Secretary shall place such  
9 judges in an administrative office that is organizationally  
10 and functionally separate from such Centers. Such judges  
11 shall report to, and be under the general supervision of, the  
12 Secretary, but shall not report to, or be subject to super-  
13 vision by, another officer of the Department of Health and  
14 Human Services.

15 (3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall  
16 provide for an appropriate geographic distribution of ad-  
17 ministrative law judges performing the administrative law  
18 judge functions transferred under paragraph (1) through-  
19 out the United States to ensure timely access to such  
20 judges.

21 (4) HIRING AUTHORITY.—Subject to the amounts pro-  
22 vided in advance in appropriations Acts, the Secretary shall  
23 have authority to hire administrative law judges to hear  
24 such cases, taking into consideration those judges with ex-  
25 pertise in handling medicare appeals and in a manner con-  
26 sistent with paragraph (3), and to hire support staff for  
27 such judges.

28 (5) FINANCING.—Amounts payable under law to the  
29 Commissioner for administrative law judges performing the  
30 administrative law judge functions transferred under para-  
31 graph (1) from the Federal Hospital Insurance Trust Fund  
32 and the Federal Supplementary Medical Insurance Trust  
33 Fund shall become payable to the Secretary for the func-  
34 tions so transferred.

35 (6) SHARED RESOURCES.—The Secretary shall enter  
36 into such arrangements with the Commissioner as may be  
37 appropriate with respect to transferred functions of admin-

1            administrative law judges to share office space, support staff, and  
2            other resources, with appropriate reimbursement from the  
3            Trust Funds described in paragraph (5).

4            (c) INCREASED FINANCIAL SUPPORT.—In addition to any  
5            amounts otherwise appropriated, to ensure timely action on ap-  
6            peals before administrative law judges and the Departmental  
7            Appeals Board consistent with section 1869 of the Social Secu-  
8            rity Act (42 U.S.C. 1395ff) (as amended by this Act), there are  
9            authorized to be appropriated (in appropriate part from the  
10           Federal Hospital Insurance Trust Fund, established under sec-  
11           tion 1817 of the Social Security Act (42 U.S.C. 1395i), and  
12           the Federal Supplementary Medical Insurance Trust Fund, es-  
13           tablished under section 1841 of such Act (42 U.S.C. 1395t))  
14           to the Secretary such sums as are necessary for fiscal year  
15           2005 and each subsequent fiscal year to—

16                (1) increase the number of administrative law judges  
17                (and their staffs) under subsection (b)(4);

18                (2) improve education and training opportunities for  
19                administrative law judges (and their staffs); and

20                (3) increase the staff of the Departmental Appeals  
21                Board.

22            (d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i)  
23            (42 U.S.C. 1395ff(f)(2)(A)(i)) is amended by striking “of the  
24            Social Security Administration”.

25            **SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.**

26            (a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

27                (1) IN GENERAL.—Section 1869(b) (42 U.S.C.  
28                1395ff(b)) is amended—

29                        (A) in paragraph (1)(A), by inserting “, subject to  
30                        paragraph (2),” before “to judicial review of the Sec-  
31                        retary’s final decision”; and

32                        (B) by adding at the end the following new para-  
33                        graph:

34                                “(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

35                                        “(A) IN GENERAL.—The Secretary shall establish  
36                                        a process under which a provider of services or supplier  
37                                        that furnishes an item or service or an individual enti-

1           tled to benefits under part A or enrolled under part B,  
2           or both, who has filed an appeal under paragraph (1)  
3           (other than an appeal filed under paragraph (1)(F)(i))  
4           may obtain access to judicial review when a review enti-  
5           ty (described in subparagraph (D)), on its own motion  
6           or at the request of the appellant, determines that the  
7           Departmental Appeals Board does not have the author-  
8           ity to decide the question of law or regulation relevant  
9           to the matters in controversy and that there is no ma-  
10          terial issue of fact in dispute. The appellant may make  
11          such request only once with respect to a question of law  
12          or regulation for a specific matter in dispute in a case  
13          of an appeal.

14                 “(B) PROMPT DETERMINATIONS.—If, after or co-  
15                 incident with appropriately filing a request for an ad-  
16                 ministrative hearing, the appellant requests a deter-  
17                 mination by the appropriate review entity that the De-  
18                 partmental Appeals Board does not have the authority  
19                 to decide the question of law or regulations relevant to  
20                 the matters in controversy and that there is no mate-  
21                 rial issue of fact in dispute, and if such request is ac-  
22                 companied by the documents and materials as the ap-  
23                 propriate review entity shall require for purposes of  
24                 making such determination, such review entity shall  
25                 make a determination on the request in writing within  
26                 60 days after the date such review entity receives the  
27                 request and such accompanying documents and mate-  
28                 rials. Such a determination by such review entity shall  
29                 be considered a final decision and not subject to review  
30                 by the Secretary.

31                 “(C) ACCESS TO JUDICIAL REVIEW.—

32                         “(i) IN GENERAL.—If the appropriate review  
33                         entity—

34                                 “(I) determines that there are no material  
35                                 issues of fact in dispute and that the only  
36                                 issues to be adjudicated are ones of law or reg-

1                   ulation that the Departmental Appeals Board  
2                   does not have authority to decide; or

3                   “(II) fails to make such determination  
4                   within the period provided under subparagraph  
5                   (B),

6                   then the appellant may bring a civil action as de-  
7                   scribed in this subparagraph.

8                   “(ii) DEADLINE FOR FILING.—Such action  
9                   shall be filed, in the case described in—

10                   “(I) clause (i)(I), within 60 days of the  
11                   date of the determination described in such  
12                   clause; or

13                   “(II) clause (i)(II), within 60 days of the  
14                   end of the period provided under subparagraph  
15                   (B) for the determination.

16                   “(iii) VENUE.—Such action shall be brought  
17                   in the district court of the United States for the ju-  
18                   dicial district in which the appellant is located (or,  
19                   in the case of an action brought jointly by more  
20                   than one applicant, the judicial district in which  
21                   the greatest number of applicants are located) or in  
22                   the District Court for the District of Columbia.

23                   “(iv) INTEREST ON ANY AMOUNTS IN CON-  
24                   TROVERSY.—Where a provider of services or sup-  
25                   plier is granted judicial review pursuant to this  
26                   paragraph, the amount in controversy (if any) shall  
27                   be subject to annual interest beginning on the first  
28                   day of the first month beginning after the 60-day  
29                   period as determined pursuant to clause (ii) and  
30                   equal to the rate of interest on obligations issued  
31                   for purchase by the Federal Supplementary Med-  
32                   ical Insurance Trust Fund for the month in which  
33                   the civil action authorized under this paragraph is  
34                   commenced, to be awarded by the reviewing court  
35                   in favor of the prevailing party. No interest award-  
36                   ed pursuant to the preceding sentence shall be  
37                   deemed income or cost for the purposes of deter-

1 mining reimbursement due providers of services or  
2 suppliers under this title.

3 “(D) REVIEW ENTITY DEFINED.—For purposes of  
4 this subsection, the term ‘review entity’ means an enti-  
5 ty of up to three reviewers who are administrative law  
6 judges or members of the Departmental Appeals Board  
7 selected for purposes of making determinations under  
8 this paragraph.”.

9 (2) CONFORMING AMENDMENT.—Section  
10 1869(b)(1)(F)(ii) (42 U.S.C. 1395ff(b)(1)(F)(ii)) is amend-  
11 ed to read as follows:

12 “(ii) REFERENCE TO EXPEDITED ACCESS TO  
13 JUDICIAL REVIEW.—For the provision relating to  
14 expedited access to judicial review, see paragraph  
15 (2).”.

16 (b) APPLICATION TO PROVIDER AGREEMENT DETERMINA-  
17 TIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is  
18 amended—

19 (1) by inserting “(A)” after “(h)(1)”; and

20 (2) by adding at the end the following new subpara-  
21 graph:

22 “(B) An institution or agency described in subparagraph  
23 (A) that has filed for a hearing under subparagraph (A) shall  
24 have expedited access to judicial review under this subpara-  
25 graph in the same manner as providers of services, suppliers,  
26 and individuals entitled to benefits under part A or enrolled  
27 under part B, or both, may obtain expedited access to judicial  
28 review under the process established under section 1869(b)(2).  
29 Nothing in this subparagraph shall be construed to affect the  
30 application of any remedy imposed under section 1819 during  
31 the pendency of an appeal under this subparagraph.”.

32 (c) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREE-  
33 MENT DETERMINATIONS.—

34 (1) TERMINATION AND CERTAIN OTHER IMMEDIATE  
35 REMEDIES.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)),  
36 as amended by subsection (b), is amended by adding at the  
37 end the following new subparagraph:



1 “(C)(i) The Secretary shall develop and implement a pro-  
2 cess to expedite proceedings under this subsection in which—

3 “(I) the remedy of termination of participation has  
4 been imposed;

5 “(II) a remedy described in clause (i) or (iii) of section  
6 1819(h)(2)(B) has been imposed, but only if such remedy  
7 has been imposed on an immediate basis; or

8 “(III) a determination has been made as to a finding  
9 of substandard quality of care that results in the loss of ap-  
10 proval of a skilled nursing facility’s nurse aide training pro-  
11 gram.

12 “(ii) Under such process under clause (i), priority shall be  
13 provided in cases of termination described in clause (i)(I).

14 “(iii) Nothing in this subparagraph shall be construed to  
15 affect the application of any remedy imposed under section  
16 1819 during the pendency of an appeal under this subpara-  
17 graph.”.

18 (2) WAIVER OF DISAPPROVAL OF NURSE-AIDE TRAIN-  
19 ING PROGRAMS.—Sections 1819(f)(2) and section  
20 1919(f)(2) (42 U.S.C. 1395i–3(f)(2) and 1396r(f)(2)) are  
21 each amended—

22 (A) in subparagraph (B)(iii), by striking “sub-  
23 paragraph (C)” and inserting “subparagraphs (C) and  
24 (D)”; and

25 (B) by adding at the end the following new sub-  
26 paragraph:

27 “(D) WAIVER OF DISAPPROVAL OF NURSE-AIDE  
28 TRAINING PROGRAMS.—Upon application of a nursing  
29 facility, the Secretary may waive the application of sub-  
30 paragraph (B)(iii)(I)(e) if the imposition of the civil  
31 monetary penalty was not related to the quality of care  
32 provided to residents of the facility. Nothing in this  
33 subparagraph shall be construed as eliminating any re-  
34 quirement upon a facility to pay a civil monetary pen-  
35 alty described in the preceding sentence.”.

36 (3) INCREASED FINANCIAL SUPPORT.—In addition to  
37 any amounts otherwise appropriated, to reduce by 50 per-

1 cent the average time for administrative determinations on  
2 appeals under section 1866(h) of the Social Security Act  
3 (42 U.S.C. 1395cc(h)), there are authorized to be appro-  
4 priated (in appropriate part from the Federal Hospital In-  
5 surance Trust Fund, established under section 1817 of the  
6 Social Security Act (42 U.S.C. 1395i), and the Federal  
7 Supplementary Medical Insurance Trust Fund, established  
8 under section 1841 of such Act (42 U.S.C. 1395t)) to the  
9 Secretary such additional sums for fiscal year 2004 and  
10 each subsequent fiscal year as may be necessary. The pur-  
11 poses for which such amounts are available include increas-  
12 ing the number of administrative law judges (and their  
13 staffs) and the appellate level staff at the Departmental  
14 Appeals Board of the Department of Health and Human  
15 Services and educating such judges and staffs on long-term  
16 care issues.

17 (d) EFFECTIVE DATE.—The amendments made by this  
18 section shall apply to appeals filed on or after October 1, 2004.

19 **SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.**

20 (a) REQUIRING FULL AND EARLY PRESENTATION OF EVI-  
21 DENCE.—

22 (1) IN GENERAL.—Section 1869(b) (42 U.S.C.  
23 1395ff(b)), as amended by section 932(a), is further  
24 amended by adding at the end the following new para-  
25 graph:

26 “(3) REQUIRING FULL AND EARLY PRESENTATION OF  
27 EVIDENCE BY PROVIDERS.—A provider of services or sup-  
28 plier may not introduce evidence in any appeal under this  
29 section that was not presented at the reconsideration con-  
30 ducted by the qualified independent contractor under sub-  
31 section (c), unless there is good cause which precluded the  
32 introduction of such evidence at or before that reconsider-  
33 ation.”.

34 (2) EFFECTIVE DATE.—The amendment made by  
35 paragraph (1) shall take effect on October 1, 2004.

36 (b) USE OF PATIENTS’ MEDICAL RECORDS.—Section  
37 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)) is amended by

1 inserting “(including the medical records of the individual in-  
2 volved)” after “clinical experience”.

3 (c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

4 (1) INITIAL DETERMINATIONS AND REDETERMINA-  
5 TIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)) is amended  
6 by adding at the end the following new paragraphs:

7 “(4) REQUIREMENTS OF NOTICE OF DETERMINA-  
8 TIONS.—With respect to an initial determination insofar as  
9 it results in a denial of a claim for benefits—

10 “(A) the written notice on the determination shall  
11 include—

12 “(i) the reasons for the determination, includ-  
13 ing whether a local medical review policy or a local  
14 coverage determination was used;

15 “(ii) the procedures for obtaining additional  
16 information concerning the determination, includ-  
17 ing the information described in subparagraph (B);  
18 and

19 “(iii) notification of the right to seek a rede-  
20 termination or otherwise appeal the determination  
21 and instructions on how to initiate such a redeter-  
22 mination under this section;

23 “(B) such written notice shall be provided in  
24 printed form and written in a manner calculated to be  
25 understood by the individual entitled to benefits under  
26 part A or enrolled under part B, or both; and

27 “(C) the individual provided such written notice  
28 may obtain, upon request, information on the specific  
29 provision of the policy, manual, or regulation used in  
30 making the redetermination.

31 “(5) REQUIREMENTS OF NOTICE OF REDETERMINA-  
32 TIONS.—With respect to a redetermination insofar as it re-  
33 sults in a denial of a claim for benefits—

34 “(A) the written notice on the redetermination  
35 shall include—

36 “(i) the specific reasons for the redetermina-  
37 tion;

1                   “(ii) as appropriate, a summary of the clinical  
2                   or scientific evidence used in making the redeter-  
3                   mination;

4                   “(iii) a description of the procedures for ob-  
5                   taining additional information concerning the rede-  
6                   termination; and

7                   “(iv) notification of the right to appeal the re-  
8                   determination and instructions on how to initiate  
9                   such an appeal under this section;

10                  “(B) such written notice shall be provided in  
11                  printed form and written in a manner calculated to be  
12                  understood by the individual entitled to benefits under  
13                  part A or enrolled under part B, or both; and

14                  “(C) the individual provided such written notice  
15                  may obtain, upon request, information on the specific  
16                  provision of the policy, manual, or regulation used in  
17                  making the redetermination.”.

18                  (2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42  
19                  U.S.C. 1395ff(c)(3)(E)) is amended—

20                  (A) by inserting “be written in a manner cal-  
21                  culated to be understood by the individual entitled to  
22                  benefits under part A or enrolled under part B, or  
23                  both, and shall include (to the extent appropriate)”  
24                  after “in writing,”; and

25                  (B) by inserting “and a notification of the right to  
26                  appeal such determination and instructions on how to  
27                  initiate such appeal under this section” after “such de-  
28                  cision,”.

29                  (3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d))  
30                  is amended—

31                  (A) in the heading, by inserting “; NOTICE” after  
32                  “SECRETARY”; and

33                  (B) by adding at the end the following new para-  
34                  graph:

35                  “(4) NOTICE.—Notice of the decision of an adminis-  
36                  trative law judge shall be in writing in a manner calculated  
37                  to be understood by the individual entitled to benefits

1 under part A or enrolled under part B, or both, and shall  
2 include—

3 “(A) the specific reasons for the determination (in-  
4 cluding, to the extent appropriate, a summary of the  
5 clinical or scientific evidence used in making the deter-  
6 mination);

7 “(B) the procedures for obtaining additional infor-  
8 mation concerning the decision; and

9 “(C) notification of the right to appeal the deci-  
10 sion and instructions on how to initiate such an appeal  
11 under this section.”.

12 (4) SUBMISSION OF RECORD FOR APPEAL.—Section  
13 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) is amended  
14 by striking “prepare” and inserting “submit” and by strik-  
15 ing “with respect to” and all that follows through “and rel-  
16 evant policies”.

17 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

18 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDE-  
19 PENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C.  
20 1395ff(c)(3)) is amended—

21 (A) in subparagraph (A), by striking “sufficient  
22 training and expertise in medical science and legal mat-  
23 ters” and inserting “sufficient medical, legal, and other  
24 expertise (including knowledge of the program under  
25 this title) and sufficient staffing”; and

26 (B) by adding at the end the following new sub-  
27 paragraph:

28 “(K) INDEPENDENCE REQUIREMENTS.—

29 “(i) IN GENERAL.—Subject to clause (ii), a  
30 qualified independent contractor shall not conduct  
31 any activities in a case unless the entity—

32 “(I) is not a related party (as defined in  
33 subsection (g)(5));

34 “(II) does not have a material familial, fi-  
35 nancial, or professional relationship with such a  
36 party in relation to such case; and

1 “(III) does not otherwise have a conflict of  
2 interest with such a party.

3 “(ii) EXCEPTION FOR REASONABLE COM-  
4 PENSATION.—Nothing in clause (i) shall be con-  
5 strued to prohibit receipt by a qualified inde-  
6 pendent contractor of compensation from the Sec-  
7 retary for the conduct of activities under this sec-  
8 tion if the compensation is provided consistent with  
9 clause (iii).

10 “(iii) LIMITATIONS ON ENTITY COMPENSA-  
11 TION.—Compensation provided by the Secretary to  
12 a qualified independent contractor in connection  
13 with reviews under this section shall not be contin-  
14 gent on any decision rendered by the contractor or  
15 by any reviewing professional.”.

16 (2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—  
17 Section 1869 (42 U.S.C. 1395ff) is amended—

18 (A) by amending subsection (c)(3)(D) to read as  
19 follows:

20 “(D) QUALIFICATIONS FOR REVIEWERS.—The re-  
21 quirements of subsection (g) shall be met (relating to  
22 qualifications of reviewing professionals).”; and

23 (B) by adding at the end the following new sub-  
24 section:

25 “(g) QUALIFICATIONS OF REVIEWERS.—

26 “(1) IN GENERAL.—In reviewing determinations under  
27 this section, a qualified independent contractor shall assure  
28 that—

29 “(A) each individual conducting a review shall  
30 meet the qualifications of paragraph (2);

31 “(B) compensation provided by the contractor to  
32 each such reviewer is consistent with paragraph (3);  
33 and

34 “(C) in the case of a review by a panel described  
35 in subsection (c)(3)(B) composed of physicians or other  
36 health care professionals (each in this subsection re-  
37 ferred to as a ‘reviewing professional’), a reviewing pro-

1           fessional meets the qualifications described in para-  
2           graph (4) and, where a claim is regarding the fur-  
3           nishing of treatment by a physician (allopathic or os-  
4           teopathic) or the provision of items or services by a  
5           physician (allopathic or osteopathic), a reviewing pro-  
6           fessional shall be a physician (allopathic or osteo-  
7           pathic).

8           “(2) INDEPENDENCE.—

9           “(A) IN GENERAL.—Subject to subparagraph (B),  
10          each individual conducting a review in a case shall—

11           “(i) not be a related party (as defined in para-  
12          graph (5));

13           “(ii) not have a material familial, financial, or  
14          professional relationship with such a party in the  
15          case under review; and

16           “(iii) not otherwise have a conflict of interest  
17          with such a party.

18          “(B) EXCEPTION.—Nothing in subparagraph (A)  
19          shall be construed to—

20           “(i) prohibit an individual, solely on the basis  
21          of a participation agreement with a fiscal inter-  
22          mediary, carrier, or other contractor, from serving  
23          as a reviewing professional if—

24           “(I) the individual is not involved in the  
25          provision of items or services in the case under  
26          review;

27           “(II) the fact of such an agreement is dis-  
28          closed to the Secretary and the individual enti-  
29          tled to benefits under part A or enrolled under  
30          part B, or both, or such individual’s authorized  
31          representative, and neither party objects; and

32           “(III) the individual is not an employee of  
33          the intermediary, carrier, or contractor and  
34          does not provide services exclusively or pri-  
35          marily to or on behalf of such intermediary,  
36          carrier, or contractor;

1                   “(ii) prohibit an individual who has staff privi-  
2                   leges at the institution where the treatment in-  
3                   volved takes place from serving as a reviewer mere-  
4                   ly on the basis of having such staff privileges if the  
5                   existence of such privileges is disclosed to the Sec-  
6                   retary and such individual (or authorized represent-  
7                   ative), and neither party objects; or

8                   “(iii) prohibit receipt of compensation by a re-  
9                   viewing professional from a contractor if the com-  
10                  pensation is provided consistent with paragraph  
11                  (3).

12                 For purposes of this paragraph, the term ‘participation  
13                 agreement’ means an agreement relating to the provi-  
14                 sion of health care services by the individual and does  
15                 not include the provision of services as a reviewer  
16                 under this subsection.

17                 “(3) LIMITATIONS ON REVIEWER COMPENSATION.—  
18                 Compensation provided by a qualified independent con-  
19                 tractor to a reviewer in connection with a review under this  
20                 section shall not be contingent on the decision rendered by  
21                 the reviewer.

22                 “(4) LICENSURE AND EXPERTISE.—Each reviewing  
23                 professional shall be—

24                         “(A) a physician (allopathic or osteopathic) who is  
25                         appropriately credentialed or licensed in one or more  
26                         States to deliver health care services and has medical  
27                         expertise in the field of practice that is appropriate for  
28                         the items or services at issue; or

29                         “(B) a health care professional who is legally au-  
30                         thorized in one or more States (in accordance with  
31                         State law or the State regulatory mechanism provided  
32                         by State law) to furnish the health care items or serv-  
33                         ices at issue and has medical expertise in the field of  
34                         practice that is appropriate for such items or services.

35                 “(5) RELATED PARTY DEFINED.—For purposes of this  
36                 section, the term ‘related party’ means, with respect to a  
37                 case under this title involving a specific individual entitled



1 to benefits under part A or enrolled under part B, or both,  
2 any of the following:

3 “(A) The Secretary, the medicare administrative  
4 contractor involved, or any fiduciary, officer, director,  
5 or employee of the Department of Health and Human  
6 Services, or of such contractor.

7 “(B) The individual (or authorized representative).

8 “(C) The health care professional that provides  
9 the items or services involved in the case.

10 “(D) The institution at which the items or services  
11 (or treatment) involved in the case are provided.

12 “(E) The manufacturer of any drug or other item  
13 that is included in the items or services involved in the  
14 case.

15 “(F) Any other party determined under any regu-  
16 lations to have a substantial interest in the case in-  
17 volved.”.

18 (3) REDUCING MINIMUM NUMBER OF QUALIFIED  
19 INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42  
20 U.S.C. 1395ff(c)(4)) is amended by striking “not fewer  
21 than 12 qualified independent contractors under this sub-  
22 section” and inserting “a sufficient number of qualified  
23 independent contractors (but not fewer than 4 such con-  
24 tractors) to conduct reconsiderations consistent with the  
25 timeframes applicable under this subsection”.

26 (4) EFFECTIVE DATE.—The amendments made by  
27 paragraphs (1) and (2) shall be effective as if included in  
28 the enactment of the respective provisions of subtitle C of  
29 title V of BIPA (114 Stat. 2763A–534).

30 (5) TRANSITION.—In applying section 1869(g) of the  
31 Social Security Act (as added by paragraph (2)), any ref-  
32 erence to a medicare administrative contractor shall be  
33 deemed to include a reference to a fiscal intermediary  
34 under section 1816 of the Social Security Act (42 U.S.C.  
35 1395h) and a carrier under section 1842 of such Act (42  
36 U.S.C. 1395u).

1     **SEC. 934. PREPAYMENT REVIEW.**

2           (a) IN GENERAL.—Section 1874A, as added by section  
3 911(a)(1) and as amended by sections 912(b), 921(b)(1), and  
4 921(e)(1), is further amended by adding at the end the fol-  
5 lowing new subsection:

6           “(h) CONDUCT OF PREPAYMENT REVIEW.—

7           “(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

8           “(A) IN GENERAL.—A medicare administrative  
9 contractor may conduct random prepayment review  
10 only to develop a contractor-wide or program-wide  
11 claims payment error rates or under such additional  
12 circumstances as may be provided under regulations,  
13 developed in consultation with providers of services and  
14 suppliers.

15           “(B) USE OF STANDARD PROTOCOLS WHEN CON-  
16 DUCTING PREPAYMENT REVIEWS.—When a medicare  
17 administrative contractor conducts a random prepay-  
18 ment review, the contractor may conduct such review  
19 only in accordance with a standard protocol for random  
20 prepayment audits developed by the Secretary.

21           “(C) CONSTRUCTION.—Nothing in this paragraph  
22 shall be construed as preventing the denial of payments  
23 for claims actually reviewed under a random prepay-  
24 ment review.

25           “(D) RANDOM PREPAYMENT REVIEW.—For pur-  
26 poses of this subsection, the term ‘random prepayment  
27 review’ means a demand for the production of records  
28 or documentation absent cause with respect to a claim.

29           “(2) LIMITATIONS ON NON-RANDOM PREPAYMENT RE-  
30 VIEW.—

31           “(A) LIMITATIONS ON INITIATION OF NON-RAN-  
32 DOM PREPAYMENT REVIEW.—A medicare administra-  
33 tive contractor may not initiate non-random prepay-  
34 ment review of a provider of services or supplier based  
35 on the initial identification by that provider of services  
36 or supplier of an improper billing practice unless there

1 is a likelihood of sustained or high level of payment  
2 error under section 1893(f)(3)(A).

3 “(B) TERMINATION OF NON-RANDOM PREPAY-  
4 MENT REVIEW.—The Secretary shall issue regulations  
5 relating to the termination, including termination  
6 dates, of non-random prepayment review. Such regula-  
7 tions may vary such a termination date based upon the  
8 differences in the circumstances triggering prepayment  
9 review.”.

10 (b) EFFECTIVE DATE.—

11 (1) IN GENERAL.—Except as provided in this sub-  
12 section, the amendment made by subsection (a) shall take  
13 effect 1 year after the date of the enactment of this Act.

14 (2) DEADLINE FOR PROMULGATION OF CERTAIN REG-  
15 ULATIONS.—The Secretary shall first issue regulations  
16 under section 1874A(h) of the Social Security Act, as  
17 added by subsection (a), by not later than 1 year after the  
18 date of the enactment of this Act.

19 (3) APPLICATION OF STANDARD PROTOCOLS FOR RAN-  
20 DOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of  
21 the Social Security Act, as added by subsection (a), shall  
22 apply to random prepayment reviews conducted on or after  
23 such date (not later than 1 year after the date of the enact-  
24 ment of this Act) as the Secretary shall specify.

25 (c) APPLICATION TO FISCAL INTERMEDIARIES AND CAR-  
26 RRIERS.—The provisions of section 1874A(h) of the Social Secu-  
27 rity Act, as added by subsection (a), shall apply to each fiscal  
28 intermediary under section 1816 of the Social Security Act (42  
29 U.S.C. 1395h) and each carrier under section 1842 of such Act  
30 (42 U.S.C. 1395u) in the same manner as they apply to medi-  
31 care administrative contractors under such provisions.

32 **SEC. 935. RECOVERY OF OVERPAYMENTS.**

33 (a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is  
34 amended by adding at the end the following new subsection:

35 “(f) RECOVERY OF OVERPAYMENTS.—

36 “(1) USE OF REPAYMENT PLANS.—

1           “(A) IN GENERAL.—If the repayment, within 30  
2           days by a provider of services or supplier, of an over-  
3           payment under this title would constitute a hardship  
4           (as described in subparagraph (B)), subject to subpara-  
5           graph (C), upon request of the provider of services or  
6           supplier the Secretary shall enter into a plan with the  
7           provider of services or supplier for the repayment  
8           (through offset or otherwise) of such overpayment over  
9           a period of at least 6 months but not longer than 3  
10          years (or not longer than 5 years in the case of extreme  
11          hardship, as determined by the Secretary). Interest  
12          shall accrue on the balance through the period of re-  
13          payment. Such plan shall meet terms and conditions  
14          determined to be appropriate by the Secretary.

15           “(B) HARDSHIP.—

16           “(i) IN GENERAL.—For purposes of subpara-  
17          graph (A), the repayment of an overpayment (or  
18          overpayments) within 30 days is deemed to con-  
19          stitute a hardship if—

20           “(I) in the case of a provider of services  
21          that files cost reports, the aggregate amount of  
22          the overpayments exceeds 10 percent of the  
23          amount paid under this title to the provider of  
24          services for the cost reporting period covered by  
25          the most recently submitted cost report; or

26           “(II) in the case of another provider of  
27          services or supplier, the aggregate amount of  
28          the overpayments exceeds 10 percent of the  
29          amount paid under this title to the provider of  
30          services or supplier for the previous calendar  
31          year.

32           “(ii) RULE OF APPLICATION.—The Secretary  
33          shall establish rules for the application of this sub-  
34          paragraph in the case of a provider of services or  
35          supplier that was not paid under this title during  
36          the previous year or was paid under this title only  
37          during a portion of that year.

1                   “(iii) TREATMENT OF PREVIOUS OVERPAY-  
2                   MENTS.—If a provider of services or supplier has  
3                   entered into a repayment plan under subparagraph  
4                   (A) with respect to a specific overpayment amount,  
5                   such payment amount under the repayment plan  
6                   shall not be taken into account under clause (i)  
7                   with respect to subsequent overpayment amounts.

8                   “(C) EXCEPTIONS.—Subparagraph (A) shall not  
9                   apply if—

10                   “(i) the Secretary has reason to suspect that  
11                   the provider of services or supplier may file for  
12                   bankruptcy or otherwise cease to do business or  
13                   discontinue participation in the program under this  
14                   title; or

15                   “(ii) there is an indication of fraud or abuse  
16                   committed against the program.

17                   “(D) IMMEDIATE COLLECTION IF VIOLATION OF  
18                   REPAYMENT PLAN.—If a provider of services or sup-  
19                   plier fails to make a payment in accordance with a re-  
20                   payment plan under this paragraph, the Secretary may  
21                   immediately seek to offset or otherwise recover the  
22                   total balance outstanding (including applicable interest)  
23                   under the repayment plan.

24                   “(E) RELATION TO NO FAULT PROVISION.—Noth-  
25                   ing in this paragraph shall be construed as affecting  
26                   the application of section 1870(c) (relating to no ad-  
27                   justment in the cases of certain overpayments).

28                   “(2) LIMITATION ON RECOUPMENT.—

29                   “(A) IN GENERAL.—In the case of a provider of  
30                   services or supplier that is determined to have received  
31                   an overpayment under this title and that seeks a recon-  
32                   sideration by a qualified independent contractor on  
33                   such determination under section 1869(b)(1), the Sec-  
34                   retary may not take any action (or authorize any other  
35                   person, including any medicare contractor, as defined  
36                   in subparagraph (C)) to recoup the overpayment until  
37                   the date the decision on the reconsideration has been

1 rendered. If the provisions of section 1869(b)(1) (pro-  
2 viding for such a reconsideration by a qualified inde-  
3 pendent contractor) are not in effect, in applying the  
4 previous sentence any reference to such a reconsider-  
5 ation shall be treated as a reference to a redetermina-  
6 tion by the fiscal intermediary or carrier involved.

7 “(B) COLLECTION WITH INTEREST.—Insofar as  
8 the determination on such appeal is against the pro-  
9 vider of services or supplier, interest on the overpay-  
10 ment shall accrue on and after the date of the original  
11 notice of overpayment. Insofar as such determination  
12 against the provider of services or supplier is later re-  
13 versed, the Secretary shall provide for repayment of the  
14 amount recouped plus interest at the same rate as  
15 would apply under the previous sentence for the period  
16 in which the amount was recouped.

17 “(C) MEDICARE CONTRACTOR DEFINED.—For  
18 purposes of this subsection, the term ‘medicare con-  
19 tractor’ has the meaning given such term in section  
20 1889(g).

21 “(3) LIMITATION ON USE OF EXTRAPOLATION.—A  
22 medicare contractor may not use extrapolation to determine  
23 overpayment amounts to be recovered by recoupment, off-  
24 set, or otherwise unless the Secretary determines that—

25 “(A) there is a sustained or high level of payment  
26 error; or

27 “(B) documented educational intervention has  
28 failed to correct the payment error.

29 There shall be no administrative or judicial review under sec-  
30 tion 1869, section 1878, or otherwise, of determinations by the  
31 Secretary of sustained or high levels of payment errors under  
32 this paragraph.

33 “(4) PROVISION OF SUPPORTING DOCUMENTATION.—  
34 In the case of a provider of services or supplier with respect  
35 to which amounts were previously overpaid, a medicare con-  
36 tractor may request the periodic production of records or  
37 supporting documentation for a limited sample of sub-

1           mitted claims to ensure that the previous practice is not  
2           continuing.

3           “(5) CONSENT SETTLEMENT REFORMS.—

4           “(A) IN GENERAL.—The Secretary may use a con-  
5           sent settlement (as defined in subparagraph (D)) to  
6           settle a projected overpayment.

7           “(B) OPPORTUNITY TO SUBMIT ADDITIONAL IN-  
8           FORMATION BEFORE CONSENT SETTLEMENT OFFER.—  
9           Before offering a provider of services or supplier a con-  
10          sent settlement, the Secretary shall—

11          “(i) communicate to the provider of services or  
12          supplier—

13               “(I) that, based on a review of the medical  
14               records requested by the Secretary, a prelimi-  
15               nary evaluation of those records indicates that  
16               there would be an overpayment;

17               “(II) the nature of the problems identified  
18               in such evaluation; and

19               “(III) the steps that the provider of serv-  
20               ices or supplier should take to address the  
21               problems; and

22          “(ii) provide for a 45-day period during which  
23          the provider of services or supplier may furnish ad-  
24          ditional information concerning the medical records  
25          for the claims that had been reviewed.

26          “(C) CONSENT SETTLEMENT OFFER.—The Sec-  
27          retary shall review any additional information furnished  
28          by the provider of services or supplier under subpara-  
29          graph (B)(ii). Taking into consideration such informa-  
30          tion, the Secretary shall determine if there still appears  
31          to be an overpayment. If so, the Secretary—

32               “(i) shall provide notice of such determination  
33               to the provider of services or supplier, including an  
34               explanation of the reason for such determination;  
35               and

36               “(ii) in order to resolve the overpayment, may  
37               offer the provider of services or supplier—

1                   “(I) the opportunity for a statistically  
2                   valid random sample; or

3                   “(II) a consent settlement.

4                   The opportunity provided under clause (ii)(I) does not  
5                   waive any appeal rights with respect to the alleged  
6                   overpayment involved.

7                   “(D) CONSENT SETTLEMENT DEFINED.—For pur-  
8                   poses of this paragraph, the term ‘consent settlement’  
9                   means an agreement between the Secretary and a pro-  
10                  vider of services or supplier whereby both parties agree  
11                  to settle a projected overpayment based on less than a  
12                  statistically valid sample of claims and the provider of  
13                  services or supplier agrees not to appeal the claims in-  
14                  volved.

15                  “(6) NOTICE OF OVER-UTILIZATION OF CODES.—The  
16                  Secretary shall establish, in consultation with organizations  
17                  representing the classes of providers of services and sup-  
18                  pliers, a process under which the Secretary provides for no-  
19                  tice to classes of providers of services and suppliers served  
20                  by the contractor in cases in which the contractor has iden-  
21                  tified that particular billing codes may be overutilized by  
22                  that class of providers of services or suppliers under the  
23                  programs under this title (or provisions of title XI insofar  
24                  as they relate to such programs).

25                  “(7) PAYMENT AUDITS.—

26                  “(A) WRITTEN NOTICE FOR POST-PAYMENT AU-  
27                  DITS.—Subject to subparagraph (C), if a medicare con-  
28                  tractor decides to conduct a post-payment audit of a  
29                  provider of services or supplier under this title, the con-  
30                  tractor shall provide the provider of services or supplier  
31                  with written notice (which may be in electronic form)  
32                  of the intent to conduct such an audit.

33                  “(B) EXPLANATION OF FINDINGS FOR ALL AU-  
34                  DITS.—Subject to subparagraph (C), if a medicare con-  
35                  tractor audits a provider of services or supplier under  
36                  this title, the contractor shall—



1 “(i) give the provider of services or supplier a  
2 full review and explanation of the findings of the  
3 audit in a manner that is understandable to the  
4 provider of services or supplier and permits the de-  
5 velopment of an appropriate corrective action plan;

6 “(ii) inform the provider of services or supplier  
7 of the appeal rights under this title as well as con-  
8 sent settlement options (which are at the discretion  
9 of the Secretary);

10 “(iii) give the provider of services or supplier  
11 an opportunity to provide additional information to  
12 the contractor; and

13 “(iv) take into account information provided,  
14 on a timely basis, by the provider of services or  
15 supplier under clause (iii).

16 “(C) EXCEPTION.—Subparagraphs (A) and (B)  
17 shall not apply if the provision of notice or findings  
18 would compromise pending law enforcement activities,  
19 whether civil or criminal, or reveal findings of law en-  
20 forcement-related audits.

21 “(8) STANDARD METHODOLOGY FOR PROBE SAM-  
22 PLING.—The Secretary shall establish a standard method-  
23 ology for medicare contractors to use in selecting a sample  
24 of claims for review in the case of an abnormal billing pat-  
25 tern.”.

26 (b) EFFECTIVE DATES AND DEADLINES.—

27 (1) USE OF REPAYMENT PLANS.—Section 1893(f)(1)  
28 of the Social Security Act, as added by subsection (a), shall  
29 apply to requests for repayment plans made after the date  
30 of the enactment of this Act.

31 (2) LIMITATION ON RECOUPMENT.—Section  
32 1893(f)(2) of the Social Security Act, as added by sub-  
33 section (a), shall apply to actions taken after the date of  
34 the enactment of this Act.

35 (3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of  
36 the Social Security Act, as added by subsection (a), shall  
37 apply to statistically valid random samples initiated after

1 the date that is 1 year after the date of the enactment of  
2 this Act.

3 (4) PROVISION OF SUPPORTING DOCUMENTATION.—  
4 Section 1893(f)(4) of the Social Security Act, as added by  
5 subsection (a), shall take effect on the date of the enact-  
6 ment of this Act.

7 (5) CONSENT SETTLEMENT.—Section 1893(f)(5) of  
8 the Social Security Act, as added by subsection (a), shall  
9 apply to consent settlements entered into after the date of  
10 the enactment of this Act.

11 (6) NOTICE OF OVERUTILIZATION.—Not later than 1  
12 year after the date of the enactment of this Act, the Sec-  
13 retary shall first establish the process for notice of over-  
14 utilization of billing codes under section 1893A(f)(6) of the  
15 Social Security Act, as added by subsection (a).

16 (7) PAYMENT AUDITS.—Section 1893A(f)(7) of the  
17 Social Security Act, as added by subsection (a), shall apply  
18 to audits initiated after the date of the enactment of this  
19 Act.

20 (8) STANDARD FOR ABNORMAL BILLING PATTERNS.—  
21 Not later than 1 year after the date of the enactment of  
22 this Act, the Secretary shall first establish a standard  
23 methodology for selection of sample claims for abnormal  
24 billing patterns under section 1893(f)(8) of the Social Se-  
25 curity Act, as added by subsection (a).

26 **SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF**  
27 **APPEAL.**

28 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is  
29 amended—

30 (1) by adding at the end of the heading the following:

31 “; ENROLLMENT PROCESSES”; and

32 (2) by adding at the end the following new subsection:

33 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERV-  
34 ICES AND SUPPLIERS.—

35 “(1) ENROLLMENT PROCESS.—

1           “(A) IN GENERAL.—The Secretary shall establish  
2           by regulation a process for the enrollment of providers  
3           of services and suppliers under this title.

4           “(B) DEADLINES.—The Secretary shall establish  
5           by regulation procedures under which there are dead-  
6           lines for actions on applications for enrollment (and, if  
7           applicable, renewal of enrollment). The Secretary shall  
8           monitor the performance of medicare administrative  
9           contractors in meeting the deadlines established under  
10          this subparagraph.

11          “(C) CONSULTATION BEFORE CHANGING PRO-  
12          VIDER ENROLLMENT FORMS.—The Secretary shall con-  
13          sult with providers of services and suppliers before  
14          making changes in the provider enrollment forms re-  
15          quired of such providers and suppliers to be eligible to  
16          submit claims for which payment may be made under  
17          this title.

18          “(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-  
19          RENEWAL.—A provider of services or supplier whose appli-  
20          cation to enroll (or, if applicable, to renew enrollment)  
21          under this title is denied may have a hearing and judicial  
22          review of such denial under the procedures that apply  
23          under subsection (h)(1)(A) to a provider of services that is  
24          dissatisfied with a determination by the Secretary.”.

25          (b) EFFECTIVE DATES.—

26                (1) ENROLLMENT PROCESS.—The Secretary shall pro-  
27                vide for the establishment of the enrollment process under  
28                section 1866(j)(1) of the Social Security Act, as added by  
29                subsection (a)(2), within 6 months after the date of the en-  
30                actment of this Act.

31                (2) CONSULTATION.—Section 1866(j)(1)(C) of the So-  
32                cial Security Act, as added by subsection (a)(2), shall apply  
33                with respect to changes in provider enrollment forms made  
34                on or after January 1, 2004.

35                (3) HEARING RIGHTS.—Section 1866(j)(2) of the So-  
36                cial Security Act, as added by subsection (a)(2), shall apply  
37                to denials occurring on or after such date (not later than

1 1 year after the date of the enactment of this Act) as the  
2 Secretary specifies.

3 **SEC. 937. PROCESS FOR CORRECTION OF MINOR ER-**  
4 **RORS AND OMISSIONS WITHOUT PURSUING**  
5 **APPEALS PROCESS.**

6 (a) CLAIMS.—The Secretary shall develop, in consultation  
7 with appropriate medicare contractors (as defined in section  
8 1889(g) of the Social Security Act, as inserted by section  
9 301(a)(1)) and representatives of providers of services and sup-  
10 pliers, a process whereby, in the case of minor errors or omis-  
11 sions (as defined by the Secretary) that are detected in the sub-  
12 mission of claims under the programs under title XVIII of such  
13 Act, a provider of services or supplier is given an opportunity  
14 to correct such an error or omission without the need to initiate  
15 an appeal. Such process shall include the ability to resubmit  
16 corrected claims.

17 (b) DEADLINE.—Not later than 1 year after the date of  
18 the enactment of this Act, the Secretary shall first develop the  
19 process under subsection (a).

20 **SEC. 938. PRIOR DETERMINATION PROCESS FOR CER-**  
21 **TAIN ITEMS AND SERVICES; ADVANCE BENE-**  
22 **FICIARY NOTICES.**

23 (a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as  
24 amended by section 933(d)(2)(B), is further amended by add-  
25 ing at the end the following new subsection:

26 “(h) PRIOR DETERMINATION PROCESS FOR CERTAIN  
27 ITEMS AND SERVICES.—

28 “(1) ESTABLISHMENT OF PROCESS.—

29 “(A) IN GENERAL.—With respect to a medicare  
30 administrative contractor that has a contract under  
31 section 1874A that provides for making payments  
32 under this title with respect to physicians’ services (as  
33 defined in section 1848(j)(3)), the Secretary shall es-  
34 tablish a prior determination process that meets the re-  
35 quirements of this subsection and that shall be applied  
36 by such contractor in the case of eligible requesters.

1           “(B) ELIGIBLE REQUESTER.—For purposes of  
2 this subsection, each of the following shall be an eligi-  
3 ble requester:

4           “(i) A participating physician, but only with  
5 respect to physicians’ services to be furnished to an  
6 individual who is entitled to benefits under this title  
7 and who has consented to the physician making the  
8 request under this subsection for those physicians’  
9 services.

10          “(ii) An individual entitled to benefits under  
11 this title, but only with respect to a physicians’  
12 service for which the individual receives, from a  
13 physician, an advance beneficiary notice under sec-  
14 tion 1879(a).

15          “(2) SECRETARIAL FLEXIBILITY.—The Secretary shall  
16 establish by regulation reasonable limits on the physicians’  
17 services for which a prior determination of coverage may be  
18 requested under this subsection. In establishing such limits,  
19 the Secretary may consider the dollar amount involved with  
20 respect to the physicians’ service, administrative costs and  
21 burdens, and other relevant factors.

22          “(3) REQUEST FOR PRIOR DETERMINATION.—

23          “(A) IN GENERAL.—Subject to paragraph (2),  
24 under the process established under this subsection an  
25 eligible requester may submit to the contractor a re-  
26 quest for a determination, before the furnishing of a  
27 physicians’ service, as to whether the physicians’ serv-  
28 ice is covered under this title consistent with the appli-  
29 cable requirements of section 1862(a)(1)(A) (relating  
30 to medical necessity).

31          “(B) ACCOMPANYING DOCUMENTATION.—The Sec-  
32 retary may require that the request be accompanied by  
33 a description of the physicians’ service, supporting doc-  
34 umentation relating to the medical necessity for the  
35 physicians’ service, and any other appropriate docu-  
36 mentation. In the case of a request submitted by an eli-  
37 gible requester who is described in paragraph

1 (1)(B)(ii), the Secretary may require that the request  
2 also be accompanied by a copy of the advance bene-  
3 ficiary notice involved.

4 “(4) RESPONSE TO REQUEST.—

5 “(A) IN GENERAL.—Under such process, the con-  
6 tractor shall provide the eligible requester with written  
7 notice of a determination as to whether—

8 “(i) the physicians’ service is so covered;

9 “(ii) the physicians’ service is not so covered;

10 or

11 “(iii) the contractor lacks sufficient informa-  
12 tion to make a coverage determination with respect  
13 to the physicians’ service.

14 “(B) CONTENTS OF NOTICE FOR CERTAIN DETER-  
15 MINATIONS.—

16 “(i) NONCOVERAGE.—If the contractor makes  
17 the determination described in subparagraph  
18 (A)(ii), the contractor shall include in the notice a  
19 brief explanation of the basis for the determination,  
20 including on what national or local coverage or  
21 noncoverage determination (if any) the determina-  
22 tion is based, and a description of any applicable  
23 rights under subsection (a).

24 “(ii) INSUFFICIENT INFORMATION.—If the  
25 contractor makes the determination described in  
26 subparagraph (A)(iii), the contractor shall include  
27 in the notice a description of the additional infor-  
28 mation required to make the coverage determina-  
29 tion.

30 “(C) DEADLINE TO RESPOND.—Such notice shall  
31 be provided within the same time period as the time pe-  
32 riod applicable to the contractor providing notice of ini-  
33 tial determinations on a claim for benefits under sub-  
34 section (a)(2)(A).

35 “(D) INFORMING BENEFICIARY IN CASE OF PHYSI-  
36 CIAN REQUEST.—In the case of a request by a partici-  
37 pating physician under paragraph (1)(B)(i), the process

1 shall provide that the individual to whom the physi-  
2 cians' service is proposed to be furnished shall be in-  
3 formed of any determination described in subparagraph  
4 (A)(ii) (relating to a determination of non-coverage)  
5 and the right (referred to in paragraph (6)(B)) to ob-  
6 tain the physicians' service and have a claim submitted  
7 for the physicians' service.

8 “(5) BINDING NATURE OF POSITIVE DETERMINA-  
9 TION.—If the contractor makes the determination described  
10 in paragraph (4)(A)(i), such determination shall be binding  
11 on the contractor in the absence of fraud or evidence of  
12 misrepresentation of facts presented to the contractor.

13 “(6) LIMITATION ON FURTHER REVIEW.—

14 “(A) IN GENERAL.—Contractor determinations de-  
15 scribed in paragraph (4)(A)(ii) or (4)(A)(iii) (relating  
16 to pre-service claims) are not subject to further admin-  
17 istrative appeal or judicial review under this section or  
18 otherwise.

19 “(B) DECISION NOT TO SEEK PRIOR DETERMINA-  
20 TION OR NEGATIVE DETERMINATION DOES NOT IMPACT  
21 RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT,  
22 OR APPEAL RIGHTS.—Nothing in this subsection shall  
23 be construed as affecting the right of an individual  
24 who—

25 “(i) decides not to seek a prior determination  
26 under this subsection with respect to physicians'  
27 services; or

28 “(ii) seeks such a determination and has re-  
29 ceived a determination described in paragraph  
30 (4)(A)(ii),

31 from receiving (and submitting a claim for) such physi-  
32 cians' services and from obtaining administrative or ju-  
33 dicial review respecting such claim under the other ap-  
34 plicable provisions of this section. Failure to seek a  
35 prior determination under this subsection with respect  
36 to physicians' service shall not be taken into account in  
37 such administrative or judicial review.

1                   “(C) NO PRIOR DETERMINATION AFTER RECEIPT  
2                   OF SERVICES.—Once an individual is provided physi-  
3                   cians’ services, there shall be no prior determination  
4                   under this subsection with respect to such physicians’  
5                   services.”.

6                   (b) EFFECTIVE DATE; SUNSET; TRANSITION.—

7                   (1) EFFECTIVE DATE.—The Secretary shall establish  
8                   the prior determination process under the amendment  
9                   made by subsection (a) in such a manner as to provide for  
10                  the acceptance of requests for determinations under such  
11                  process filed not later than 18 months after the date of the  
12                  enactment of this Act.

13                  (2) SUNSET.—Such prior determination process shall  
14                  not apply to requests filed after the end of the 5-year pe-  
15                  riod beginning on the first date on which requests for de-  
16                  terminations under such process are accepted.

17                  (3) TRANSITION.—During the period in which the  
18                  amendment made by subsection (a) has become effective  
19                  but contracts are not provided under section 1874A of the  
20                  Social Security Act with medicare administrative contrac-  
21                  tors, any reference in section 1869(g) of such Act (as  
22                  added by such amendment) to such a contractor is deemed  
23                  a reference to a fiscal intermediary or carrier with an  
24                  agreement under section 1816, or contract under section  
25                  1842, respectively, of such Act.

26                  (4) LIMITATION ON APPLICATION TO SGR.—For pur-  
27                  poses of applying section 1848(f)(2)(D) of the Social Secu-  
28                  rity Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment  
29                  made by subsection (a) shall not be considered to be a  
30                  change in law or regulation.

31                  (c) PROVISIONS RELATING TO ADVANCE BENEFICIARY  
32                  NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

33                  (1) DATA COLLECTION.—The Secretary shall establish  
34                  a process for the collection of information on the instances  
35                  in which an advance beneficiary notice (as defined in para-  
36                  graph (5)) has been provided and on instances in which a  
37                  beneficiary indicates on such a notice that the beneficiary



1 does not intend to seek to have the item or service that is  
2 the subject of the notice furnished.

3 (2) OUTREACH AND EDUCATION.—The Secretary shall  
4 establish a program of outreach and education for bene-  
5 ficiaries and providers of services and other persons on the  
6 appropriate use of advance beneficiary notices and coverage  
7 policies under the medicare program.

8 (3) GAO REPORT ON USE OF ADVANCE BENEFICIARY  
9 NOTICES.—Not later than 18 months after the date on  
10 which section 1869(h) of the Social Security Act (as added  
11 by subsection (a)) takes effect, the Comptroller General of  
12 the United States shall submit to Congress a report on the  
13 use of advance beneficiary notices under title XVIII of such  
14 Act. Such report shall include information concerning the  
15 providers of services and other persons that have provided  
16 such notices and the response of beneficiaries to such no-  
17 tices.

18 (4) GAO REPORT ON USE OF PRIOR DETERMINATION  
19 PROCESS.—Not later than 36 months after the date on  
20 which section 1869(h) of the Social Security Act (as added  
21 by subsection (a)) takes effect, the Comptroller General of  
22 the United States shall submit to Congress a report on the  
23 use of the prior determination process under such section.  
24 Such report shall include—

25 (A) information concerning—  
26 (i) the number and types of procedures for  
27 which a prior determination has been sought;  
28 (ii) determinations made under the process;  
29 (iii) the percentage of beneficiaries prevailing;  
30 (iv) in those cases in which the beneficiaries  
31 do not prevail, the reasons why such beneficiaries  
32 did not prevail; and  
33 (v) changes in receipt of services resulting  
34 from the application of such process;

35 (B) an evaluation of whether the process was use-  
36 ful for physicians (and other suppliers) and bene-  
37 ficiaries, whether it was timely, and whether the

1 amount of information required was burdensome to  
2 physicians and beneficiaries; and

3 (C) recommendations for improvements or con-  
4 tinuation of such process.

5 (5) ADVANCE BENEFICIARY NOTICE DEFINED.—In  
6 this subsection, the term “advance beneficiary notice”  
7 means a written notice provided under section 1879(a) of  
8 the Social Security Act (42 U.S.C. 1395pp(a)) to an indi-  
9 vidual entitled to benefits under part A or enrolled under  
10 part B of title XVIII of such Act before items or services  
11 are furnished under such part in cases where a provider of  
12 services or other person that would furnish the item or  
13 service believes that payment will not be made for some or  
14 all of such items or services under such title.

15 **SEC. 939. APPEALS BY PROVIDERS WHEN THERE IS NO**  
16 **OTHER PARTY AVAILABLE.**

17 (a) IN GENERAL.—Section 1870 (42 U.S.C. 1395gg) is  
18 amended by adding at the end the following new subsection:

19 “(h) Notwithstanding subsection (f) or any other provision  
20 of law, the Secretary shall permit a provider of services or sup-  
21 plier to appeal any determination of the Secretary under this  
22 title relating to services rendered under this title to an indi-  
23 vidual who subsequently dies if there is no other party available  
24 to appeal such determination.”.

25 (b) EFFECTIVE DATE.—The amendment made by sub-  
26 section (a) shall take effect on the date of the enactment of this  
27 Act and shall apply to items and services furnished on or after  
28 such date.

29 **SEC. 940. REVISIONS TO APPEALS TIMEFRAMES AND**  
30 **AMOUNTS.**

31 (a) TIMEFRAMES.—Section 1869 (42 U.S.C. 1395ff) is  
32 amended—

33 (1) in subsection (a)(3)(C)(ii), by striking “30-day pe-  
34 riod” each place it appears and inserting “60-day period”;  
35 and

36 (2) in subsection (c)(3)(C)(i), by striking “30-day pe-  
37 riod” and inserting “60-day period”.

1 (b) AMOUNTS.—

2 (1) IN GENERAL.—Section 1869(b)(1)(E) (42 U.S.C.  
3 1395ff(b)(1)(E)) is amended by adding at the end the fol-  
4 lowing new clause:

5 “(iii) ADJUSTMENT OF DOLLAR AMOUNTS.—

6 For requests for hearings or judicial review made  
7 in a year after 2004, the dollar amounts specified  
8 in clause (i) shall be equal to such dollar amounts  
9 increased by the percentage increase in the medical  
10 care component of the consumer price index for all  
11 urban consumers (U.S. city average) for July 2003  
12 to the July preceding the year involved. Any  
13 amount determined under the previous sentence  
14 that is not a multiple of \$10 shall be rounded to  
15 the nearest multiple of \$10.”

16 (2) CONFORMING AMENDMENTS.—(A) Section  
17 1852(g)(5) (42 U.S.C. 1395w-22(g)(5)) is amended by  
18 adding at the end the following: “The provisions of section  
19 1869(b)(1)(E)(iii) shall apply with respect to dollar  
20 amounts specified in the first 2 sentences of this paragraph  
21 in the same manner as they apply to the dollar amounts  
22 specified in section 1869(b)(1)(E)(i).”

23 (B) Section 1876(b)(5)(B) (42 U.S.C. 1395mm(b)(5)(B))  
24 is amended by adding at the end the following: “The provisions  
25 of section 1869(b)(1)(E)(iii) shall apply with respect to dollar  
26 amounts specified in the first 2 sentences of this subparagraph  
27 in the same manner as they apply to the dollar amounts speci-  
28 fied in section 1869(b)(1)(E)(i).”

29 **SEC. 940A. MEDIATION PROCESS FOR LOCAL COV-**  
30 **ERAGE DETERMINATIONS.**

31 (a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff), as  
32 amended by section 938(a), is amended by adding at the end  
33 the following new subsection:

34 “(i) MEDIATION PROCESS FOR LOCAL COVERAGE DETER-  
35 MINATIONS.—

36 “(1) ESTABLISHMENT OF PROCESS.—The Secretary  
37 shall establish a mediation process under this subsection

1 through the use of a physician trained in mediation and  
2 employed by the Centers for Medicare & Medicaid Services.

3 “(2) RESPONSIBILITY OF MEDIATOR.—Under the  
4 process established in paragraph (1), such a mediator shall  
5 mediate in disputes between groups representing providers  
6 of services, suppliers (as defined in section 1861(d)), and  
7 the medical director for a medicare administrative con-  
8 tractor whenever the regional administrator (as defined by  
9 the Secretary) involved determines that there was a system-  
10 atic pattern and a large volume of complaints from such  
11 groups regarding decisions of such director or there is a  
12 complaint from the co-chair of the advisory committee for  
13 that contractor to such regional administrator regarding  
14 such dispute.”

15 (b) INCLUSION IN MAC CONTRACTS.—Section  
16 1874A(b)(3)(A)(i), as added by section 911(a)(1), is amended  
17 by adding at the end the following: “Such requirements shall  
18 include specific performance duties expected of a medical direc-  
19 tor of a medicare administrative contractor, including require-  
20 ments relating to professional relations and the availability of  
21 such director to conduct medical determination activities within  
22 the jurisdiction of such a contractor.”

## 23 **Subtitle E—Miscellaneous Provisions**

### 24 **SEC. 941. POLICY DEVELOPMENT REGARDING EVALUA-** 25 **TION AND MANAGEMENT (E & M) DOCU-** 26 **MENTATION GUIDELINES.**

27 (a) IN GENERAL.—The Secretary may not implement any  
28 new or modified documentation guidelines (which for purposes  
29 of this section includes clinical examples) for evaluation and  
30 management physician services under the title XVIII of the So-  
31 cial Security Act on or after the date of the enactment of this  
32 Act unless the Secretary—

33 (1) has developed the guidelines in collaboration with  
34 practicing physicians (including both generalists and spe-  
35 cialists) and provided for an assessment of the proposed  
36 guidelines by the physician community;

1 (2) has established a plan that contains specific goals,  
2 including a schedule, for improving the use of such guide-  
3 lines;

4 (3) has conducted appropriate and representative pilot  
5 projects under subsection (b) to test such guidelines;

6 (4) finds, based on reports submitted under subsection  
7 (b)(5) with respect to pilot projects conducted for such or  
8 related guidelines, that the objectives described in sub-  
9 section (c) will be met in the implementation of such guide-  
10 lines; and

11 (5) has established, and is implementing, a program to  
12 educate physicians on the use of such guidelines and that  
13 includes appropriate outreach.

14 The Secretary shall make changes to the manner in which ex-  
15 isting evaluation and management documentation guidelines  
16 are implemented to reduce paperwork burdens on physicians.

17 (b) PILOT PROJECTS TO TEST MODIFIED OR NEW EVAL-  
18 UATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

19 (1) IN GENERAL.—With respect to proposed new or  
20 modified documentation guidelines referred to in subsection  
21 (a), the Secretary shall conduct under this subsection ap-  
22 propriate and representative pilot projects to test the pro-  
23 posed guidelines.

24 (2) LENGTH AND CONSULTATION.—Each pilot project  
25 under this subsection shall—

26 (A) be voluntary;

27 (B) be of sufficient length as determined by the  
28 Secretary (but in no case to exceed 1 year) to allow for  
29 preparatory physician and medicare contractor edu-  
30 cation, analysis, and use and assessment of potential  
31 evaluation and management guidelines; and

32 (C) be conducted, in development and throughout  
33 the planning and operational stages of the project, in  
34 consultation with practicing physicians (including both  
35 generalists and specialists).

1 (3) RANGE OF PILOT PROJECTS.—Of the pilot projects  
2 conducted under this subsection with respect to proposed  
3 new or modified documentation guidelines—

4 (A) at least one shall focus on a peer review meth-  
5 od by physicians (not employed by a medicare con-  
6 tractor) which evaluates medical record information for  
7 claims submitted by physicians identified as statistical  
8 outliers relative to codes used for billing purposes for  
9 such services;

10 (B) at least one shall focus on an alternative  
11 method to detailed guidelines based on physician docu-  
12 mentation of face to face encounter time with a patient;

13 (C) at least one shall be conducted for services  
14 furnished in a rural area and at least one for services  
15 furnished outside such an area; and

16 (D) at least one shall be conducted in a setting  
17 where physicians bill under physicians' services in  
18 teaching settings and at least one shall be conducted in  
19 a setting other than a teaching setting.

20 (4) STUDY OF IMPACT.—Each pilot project shall ex-  
21 amine the effect of the proposed guidelines on—

22 (A) different types of physician practices, includ-  
23 ing those with fewer than 10 full-time-equivalent em-  
24 ployees (including physicians); and

25 (B) the costs of physician compliance, including  
26 education, implementation, auditing, and monitoring.

27 (5) REPORT ON PILOT PROJECTS.—Not later than 6  
28 months after the date of completion of pilot projects carried  
29 out under this subsection with respect to a proposed guide-  
30 line described in paragraph (1), the Secretary shall submit  
31 to Congress a report on the pilot projects. Each such report  
32 shall include a finding by the Secretary of whether the ob-  
33 jectives described in subsection (c) will be met in the imple-  
34 mentation of such proposed guideline.

35 (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT  
36 GUIDELINES.—The objectives for modified evaluation and man-

1     agement documentation guidelines developed by the Secretary  
2     shall be to—

3             (1) identify clinically relevant documentation needed to  
4             code accurately and assess coding levels accurately;

5             (2) decrease the level of non-clinically pertinent and  
6             burdensome documentation time and content in the physi-  
7             cian's medical record;

8             (3) increase accuracy by reviewers; and

9             (4) educate both physicians and reviewers.

10            (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOC-  
11     UMENTATION FOR PHYSICIAN CLAIMS.—

12             (1) STUDY.—The Secretary shall carry out a study of  
13             the matters described in paragraph (2).

14             (2) MATTERS DESCRIBED.—The matters referred to in  
15             paragraph (1) are—

16                 (A) the development of a simpler, alternative sys-  
17                 tem of requirements for documentation accompanying  
18                 claims for evaluation and management physician serv-  
19                 ices for which payment is made under title XVIII of  
20                 the Social Security Act; and

21                 (B) consideration of systems other than current  
22                 coding and documentation requirements for payment  
23                 for such physician services.

24             (3) CONSULTATION WITH PRACTICING PHYSICIANS.—  
25             In designing and carrying out the study under paragraph  
26             (1), the Secretary shall consult with practicing physicians,  
27             including physicians who are part of group practices and  
28             including both generalists and specialists.

29             (4) APPLICATION OF HIPAA UNIFORM CODING RE-  
30             QUIREMENTS.—In developing an alternative system under  
31             paragraph (2), the Secretary shall consider requirements of  
32             administrative simplification under part C of title XI of the  
33             Social Security Act.

34             (5) REPORT TO CONGRESS.—(A) Not later than Octo-  
35             ber 1, 2005, the Secretary shall submit to Congress a re-  
36             port on the results of the study conducted under paragraph  
37             (1).

1 (B) The Medicare Payment Advisory Commission shall  
2 conduct an analysis of the results of the study included in  
3 the report under subparagraph (A) and shall submit a re-  
4 port on such analysis to Congress.

5 (e) STUDY ON APPROPRIATE CODING OF CERTAIN EX-  
6 TENDED OFFICE VISITS.—The Secretary shall conduct a study  
7 of the appropriateness of coding in cases of extended office vis-  
8 its in which there is no diagnosis made. Not later than October  
9 1, 2005, the Secretary shall submit a report to Congress on  
10 such study and shall include recommendations on how to code  
11 appropriately for such visits in a manner that takes into ac-  
12 count the amount of time the physician spent with the patient.

13 (f) DEFINITIONS.—In this section—

14 (1) the term “rural area” has the meaning given that  
15 term in section 1886(d)(2)(D) of the Social Security Act  
16 (42 U.S.C. 1395ww(d)(2)(D)); and

17 (2) the term “teaching settings” are those settings de-  
18 scribed in section 415.150 of title 42, Code of Federal Reg-  
19 ulations.

20 **SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECH-**  
21 **NOLOGY AND COVERAGE.**

22 (a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Sec-  
23 tion 1868 (42 U.S.C. 1395ee) is amended—

24 (1) by adding at the end of the heading the following:  
25 “; COUNCIL FOR TECHNOLOGY AND INNOVATION”;

26 (2) by inserting “PRACTICING PHYSICIANS ADVISORY  
27 COUNCIL.—(1)” after “(a)”;

28 (3) in paragraph (1), as so redesignated under para-  
29 graph (2), by striking “in this section” and inserting “in  
30 this subsection”;

31 (4) by redesignating subsections (b) and (c) as para-  
32 graphs (2) and (3), respectively; and

33 (5) by adding at the end the following new subsection:  
34 “(b) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

35 “(1) ESTABLISHMENT.—The Secretary shall establish  
36 a Council for Technology and Innovation within the Cen-



1           ters for Medicare & Medicaid Services (in this section re-  
2           ferred to as ‘CMS’).

3           “(2) COMPOSITION.—The Council shall be composed  
4           of senior CMS staff and clinicians and shall be chaired by  
5           the Executive Coordinator for Technology and Innovation  
6           (appointed or designated under paragraph (4)).

7           “(3) DUTIES.—The Council shall coordinate the activi-  
8           ties of coverage, coding, and payment processes under this  
9           title with respect to new technologies and procedures, in-  
10          cluding new drug therapies, and shall coordinate the ex-  
11          change of information on new technologies between CMS  
12          and other entities that make similar decisions.

13          “(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY  
14          AND INNOVATION.—The Secretary shall appoint (or des-  
15          ignate) a noncareer appointee (as defined in section  
16          3132(a)(7) of title 5, United States Code) who shall serve  
17          as the Executive Coordinator for Technology and Innova-  
18          tion. Such executive coordinator shall report to the Admin-  
19          istrator of CMS, shall chair the Council, shall oversee the  
20          execution of its duties, and shall serve as a single point of  
21          contact for outside groups and entities regarding the cov-  
22          erage, coding, and payment processes under this title.”.

23          (b) METHODS FOR DETERMINING PAYMENT BASIS FOR  
24          NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is  
25          amended by adding at the end the following:

26          “(8)(A) The Secretary shall establish by regulation proce-  
27          dures for determining the basis for, and amount of, payment  
28          under this subsection for any clinical diagnostic laboratory test  
29          with respect to which a new or substantially revised HCPCS  
30          code is assigned on or after January 1, 2005 (in this para-  
31          graph referred to as ‘new tests’).

32          “(B) Determinations under subparagraph (A) shall be  
33          made only after the Secretary—

34                  “(i) makes available to the public (through an Internet  
35                  website and other appropriate mechanisms) a list that in-  
36                  cludes any such test for which establishment of a payment

1 amount under this subsection is being considered for a  
2 year;

3 “(ii) on the same day such list is made available,  
4 causes to have published in the Federal Register notice of  
5 a meeting to receive comments and recommendations (and  
6 data on which recommendations are based) from the public  
7 on the appropriate basis under this subsection for estab-  
8 lishing payment amounts for the tests on such list;

9 “(iii) not less than 30 days after publication of such  
10 notice convenes a meeting, that includes representatives of  
11 officials of the Centers for Medicare & Medicaid Services  
12 involved in determining payment amounts, to receive such  
13 comments and recommendations (and data on which the  
14 recommendations are based);

15 “(iv) taking into account the comments and rec-  
16 ommendations (and accompanying data) received at such  
17 meeting, develops and makes available to the public  
18 (through an Internet website and other appropriate mecha-  
19 nisms) a list of proposed determinations with respect to the  
20 appropriate basis for establishing a payment amount under  
21 this subsection for each such code, together with an expla-  
22 nation of the reasons for each such determination, the data  
23 on which the determinations are based, and a request for  
24 public written comments on the proposed determination;  
25 and

26 “(v) taking into account the comments received during  
27 the public comment period, develops and makes available to  
28 the public (through an Internet website and other appro-  
29 priate mechanisms) a list of final determinations of the  
30 payment amounts for such tests under this subsection, to-  
31 gether with the rationale for each such determination, the  
32 data on which the determinations are based, and responses  
33 to comments and suggestions received from the public.

34 “(C) Under the procedures established pursuant to sub-  
35 paragraph (A), the Secretary shall—

36 “(i) set forth the criteria for making determinations  
37 under subparagraph (A); and

1           “(ii) make available to the public the data (other than  
2           proprietary data) considered in making such determina-  
3           tions.

4           “(D) The Secretary may convene such further public meet-  
5           ings to receive public comments on payment amounts for new  
6           tests under this subsection as the Secretary deems appropriate.

7           “(E) For purposes of this paragraph:

8           “(i) The term ‘HCPCS’ refers to the Health Care Pro-  
9           cedure Coding System.

10           “(ii) A code shall be considered to be ‘substantially re-  
11           vised’ if there is a substantive change to the definition of  
12           the test or procedure to which the code applies (such as a  
13           new analyte or a new methodology for measuring an exist-  
14           ing analyte-specific test).”.

15           (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA  
16           COLLECTION FOR USE IN THE MEDICARE INPATIENT PAY-  
17           MENT SYSTEM.—

18           (1) STUDY.—The Comptroller General of the United  
19           States shall conduct a study that analyzes which external  
20           data can be collected in a shorter timeframe by the Centers  
21           for Medicare & Medicaid Services for use in computing pay-  
22           ments for inpatient hospital services. The study may in-  
23           clude an evaluation of the feasibility and appropriateness of  
24           using quarterly samples or special surveys or any other  
25           methods. The study shall include an analysis of whether  
26           other executive agencies, such as the Bureau of Labor Sta-  
27           tistics in the Department of Commerce, are best suited to  
28           collect this information.

29           (2) REPORT.—By not later than October 1, 2004, the  
30           Comptroller General shall submit a report to Congress on  
31           the study under paragraph (1).

32           **SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN**  
33           **SERVICES UNDER MEDICARE SECONDARY**  
34           **PAYOR (MSP) PROVISIONS.**

35           (a) IN GENERAL.—The Secretary shall not require a hos-  
36           pital (including a critical access hospital) to ask questions (or  
37           obtain information) relating to the application of section

1 1862(b) of the Social Security Act (relating to medicare sec-  
2 ondary payor provisions) in the case of reference laboratory  
3 services described in subsection (b), if the Secretary does not  
4 impose such requirement in the case of such services furnished  
5 by an independent laboratory.

6 (b) REFERENCE LABORATORY SERVICES DESCRIBED.—  
7 Reference laboratory services described in this subsection are  
8 clinical laboratory diagnostic tests (or the interpretation of  
9 such tests, or both) furnished without a face-to-face encounter  
10 between the individual entitled to benefits under part A or en-  
11 rolled under part B, or both, and the hospital involved and in  
12 which the hospital submits a claim only for such test or inter-  
13 pretation.

14 **SEC. 944. EMTALA IMPROVEMENTS.**

15 (a) PAYMENT FOR EMTALA-MANDATED SCREENING AND  
16 STABILIZATION SERVICES.—

17 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is  
18 amended by inserting after subsection (c) the following new  
19 subsection:

20 “(d) For purposes of subsection (a)(1)(A), in the case of  
21 any item or service that is required to be provided pursuant to  
22 section 1867 to an individual who is entitled to benefits under  
23 this title, determinations as to whether the item or service is  
24 reasonable and necessary shall be made on the basis of the in-  
25 formation available to the treating physician or practitioner (in-  
26 cluding the patient’s presenting symptoms or complaint) at the  
27 time the item or service was ordered or furnished by the physi-  
28 cian or practitioner (and not on the patient’s principal diag-  
29 nosis). When making such determinations with respect to such  
30 an item or service, the Secretary shall not consider the fre-  
31 quency with which the item or service was provided to the pa-  
32 tient before or after the time of the admission or visit.”

33 (2) EFFECTIVE DATE.—The amendment made by  
34 paragraph (1) shall apply to items and services furnished  
35 on or after January 1, 2004.

36 (b) NOTIFICATION OF PROVIDERS WHEN EMTALA IN-  
37 VESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C.

1 1395dd(d)) is amended by adding at the end the following new  
2 paragraph:

3 “(4) NOTICE UPON CLOSING AN INVESTIGATION.—The  
4 Secretary shall establish a procedure to notify hospitals and  
5 physicians when an investigation under this section is  
6 closed.”.

7 (c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN  
8 EMTALA CASES INVOLVING TERMINATION OF PARTICIPA-  
9 TION.—

10 (1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C.  
11 1395dd(d)(3)) is amended—

12 (A) in the first sentence, by inserting “or in termi-  
13 nating a hospital’s participation under this title” after  
14 “in imposing sanctions under paragraph (1)”; and

15 (B) by adding at the end the following new sen-  
16 tences: “Except in the case in which a delay would  
17 jeopardize the health or safety of individuals, the Sec-  
18 retary shall also request such a review before making  
19 a compliance determination as part of the process of  
20 terminating a hospital’s participation under this title  
21 for violations related to the appropriateness of a med-  
22 ical screening examination, stabilizing treatment, or an  
23 appropriate transfer as required by this section, and  
24 shall provide a period of 5 days for such review. The  
25 Secretary shall provide a copy of the organization’s re-  
26 port to the hospital or physician consistent with con-  
27 fidentiality requirements imposed on the organization  
28 under such part B.”.

29 (2) EFFECTIVE DATE.—The amendments made by  
30 paragraph (1) shall apply to terminations of participation  
31 initiated on or after the date of the enactment of this Act.

32 **SEC. 945. EMERGENCY MEDICAL TREATMENT AND**  
33 **LABOR ACT (EMTALA) TECHNICAL ADVISORY**  
34 **GROUP.**

35 (a) ESTABLISHMENT.—The Secretary shall establish a  
36 Technical Advisory Group (in this section referred to as the  
37 “Advisory Group”) to review issues related to the Emergency

1 Medical Treatment and Labor Act (EMTALA) and its imple-  
2 mentation. In this section, the term “EMTALA” refers to the  
3 provisions of section 1867 of the Social Security Act (42 U.S.C.  
4 1395dd).

5 (b) MEMBERSHIP.—The Advisory Group shall be com-  
6 posed of 19 members, including the Administrator of the Cen-  
7 ters for Medicare & Medicaid Services and the Inspector Gen-  
8 eral of the Department of Health and Human Services and of  
9 which—

10 (1) 4 shall be representatives of hospitals, including at  
11 least one public hospital, that have experience with the ap-  
12 plication of EMTALA and at least 2 of which have not  
13 been cited for EMTALA violations;

14 (2) 7 shall be practicing physicians drawn from the  
15 fields of emergency medicine, cardiology or cardiothoracic  
16 surgery, orthopedic surgery, neurosurgery, pediatrics or a  
17 pediatric subspecialty, obstetrics-gynecology, and psychi-  
18 atry, with not more than one physician from any particular  
19 field;

20 (3) 2 shall represent patients;

21 (4) 2 shall be staff involved in EMTALA investiga-  
22 tions from different regional offices of the Centers for  
23 Medicare & Medicaid Services; and

24 (5) 1 shall be from a State survey office involved in  
25 EMTALA investigations and 1 shall be from a peer review  
26 organization, both of whom shall be from areas other than  
27 the regions represented under paragraph (4).

28 In selecting members described in paragraphs (1) through (3),  
29 the Secretary shall consider qualified individuals nominated by  
30 organizations representing providers and patients.

31 (c) GENERAL RESPONSIBILITIES.—The Advisory Group—

32 (1) shall review EMTALA regulations;

33 (2) may provide advice and recommendations to the  
34 Secretary with respect to those regulations and their appli-  
35 cation to hospitals and physicians;

1 (3) shall solicit comments and recommendations from  
2 hospitals, physicians, and the public regarding the imple-  
3 mentation of such regulations; and

4 (4) may disseminate information on the application of  
5 such regulations to hospitals, physicians, and the public.

6 (d) ADMINISTRATIVE MATTERS.—

7 (1) CHAIRPERSON.—The members of the Advisory  
8 Group shall elect a member to serve as chairperson of the  
9 Advisory Group for the life of the Advisory Group.

10 (2) MEETINGS.—The Advisory Group shall first meet  
11 at the direction of the Secretary. The Advisory Group shall  
12 then meet twice per year and at such other times as the  
13 Advisory Group may provide.

14 (e) TERMINATION.—The Advisory Group shall terminate  
15 30 months after the date of its first meeting.

16 (f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Sec-  
17 retary shall establish the Advisory Group notwithstanding any  
18 limitation that may apply to the number of advisory committees  
19 that may be established (within the Department of Health and  
20 Human Services or otherwise).

21 **SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO**  
22 **PROVIDE CORE HOSPICE SERVICES IN CER-**  
23 **TAIN CIRCUMSTANCES.**

24 (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.  
25 1395x(dd)(5)) is amended by adding at the end the following:

26 “(D) In extraordinary, exigent, or other non-routine cir-  
27 cumstances, such as unanticipated periods of high patient  
28 loads, staffing shortages due to illness or other events, or tem-  
29 porary travel of a patient outside a hospice program’s service  
30 area, a hospice program may enter into arrangements with an-  
31 other hospice program for the provision by that other program  
32 of services described in paragraph (2)(A)(ii)(I). The provisions  
33 of paragraph (2)(A)(ii)(II) shall apply with respect to the serv-  
34 ices provided under such arrangements.

35 “(E) A hospice program may provide services described in  
36 paragraph (1)(A) other than directly by the program if the  
37 services are highly specialized services of a registered profes-

1 sional nurse and are provided non-routinely and so infrequently  
2 so that the provision of such services directly would be imprac-  
3 ticable and prohibitively expensive.”.

4 (b) CONFORMING PAYMENT PROVISION.—Section 1814(i)  
5 (42 U.S.C. 1395f(i)), as amended by section 512(b), is amend-  
6 ed by adding at the end the following new paragraph:

7 “(5) In the case of hospice care provided by a hospice pro-  
8 gram under arrangements under section 1861(dd)(5)(D) made  
9 by another hospice program, the hospice program that made  
10 the arrangements shall bill and be paid for the hospice care.”.

11 (c) EFFECTIVE DATE.—The amendments made by this  
12 section shall apply to hospice care provided on or after the date  
13 of the enactment of this Act.

14 **SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHO-**  
15 **GENS STANDARD TO CERTAIN HOSPITALS.**

16 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc), as  
17 amended by section 506, is amended—

18 (1) in subsection (a)(1)—

19 (A) in subparagraph (T), by striking “and” at the  
20 end;

21 (B) in subparagraph (U), by striking the period at  
22 the end and inserting “, and”; and

23 (C) by inserting after subparagraph (U) the fol-  
24 lowing new subparagraph:

25 “(V) in the case of hospitals that are not otherwise  
26 subject to the Occupational Safety and Health Act of 1970  
27 (or a State occupational safety and health plan that is ap-  
28 proved under 18(b) of such Act), to comply with the  
29 Bloodborne Pathogens standard under section 1910.1030  
30 of title 29 of the Code of Federal Regulations (or as subse-  
31 quently redesignated).”; and

32 (2) by adding at the end of subsection (b) the fol-  
33 lowing new paragraph:

34 “(4)(A) A hospital that fails to comply with the require-  
35 ment of subsection (a)(1)(V) (relating to the Bloodborne  
36 Pathogens standard) is subject to a civil money penalty in an



1 amount described in subparagraph (B), but is not subject to  
2 termination of an agreement under this section.

3 “(B) The amount referred to in subparagraph (A) is an  
4 amount that is similar to the amount of civil penalties that may  
5 be imposed under section 17 of the Occupational Safety and  
6 Health Act of 1970 for a violation of the Bloodborne Pathogens  
7 standard referred to in subsection (a)(1)(U) by a hospital that  
8 is subject to the provisions of such Act.

9 “(C) A civil money penalty under this paragraph shall be  
10 imposed and collected in the same manner as civil money pen-  
11 alties under subsection (a) of section 1128A are imposed and  
12 collected under that section.”

13 (b) EFFECTIVE DATE.—The amendments made by this  
14 subsection (a) shall apply to hospitals as of July 1, 2004.

15 **SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND**  
16 **CORRECTIONS.**

17 (a) TECHNICAL AMENDMENTS RELATING TO ADVISORY  
18 COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i)  
19 of section 1114 (42 U.S.C. 1314)—

20 (A) is transferred to section 1862 and added at the  
21 end of such section; and

22 (B) is redesignated as subsection (j).

23 (2) Section 1862 (42 U.S.C. 1395y) is amended—

24 (A) in the last sentence of subsection (a), by striking  
25 “established under section 1114(f)”; and

26 (B) in subsection (j), as so transferred and  
27 redesignated—

28 (i) by striking “under subsection (f)”; and

29 (ii) by striking “section 1862(a)(1)” and inserting  
30 “subsection (a)(1)”.

31 (b) TERMINOLOGY CORRECTIONS.—(1) Section  
32 1869(e)(3)(I)(ii) (42 U.S.C. 1395ff(e)(3)(I)(ii)) is amended—

33 (A) in subclause (III), by striking “policy” and insert-  
34 ing “determination”; and

35 (B) in subclause (IV), by striking “medical review  
36 policies” and inserting “coverage determinations”.

1           (2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C))  
2 is amended by striking “policy” and “POLICY” and inserting  
3 “determination” each place it appears and “DETERMINATION”,  
4 respectively.

5           (c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42  
6 U.S.C. 1395ff(f)(4)) is amended—

7           (1) in subparagraph (A)(iv), by striking “subclause  
8 (I), (II), or (III)” and inserting “clause (i), (ii), or (iii)”;

9           (2) in subparagraph (B), by striking “clause (i)(IV)”  
10 and “clause (i)(III)” and inserting “subparagraph (A)(iv)”  
11 and “subparagraph (A)(iii)”, respectively; and

12           (3) in subparagraph (C), by striking “clause (i)”,  
13 “subclause (IV)” and “subparagraph (A)” and inserting  
14 “subparagraph (A)”, “clause (iv)” and “paragraph  
15 (1)(A)”, respectively each place it appears.

16           (d) OTHER CORRECTIONS.—Effective as if included in the  
17 enactment of section 521(c) of BIPA, section 1154(e) (42  
18 U.S.C. 1320c-3(e)) is amended by striking paragraph (5).

19           (e) EFFECTIVE DATE.—Except as otherwise provided, the  
20 amendments made by this section shall be effective as if in-  
21 cluded in the enactment of BIPA.

22           **SEC. 949. CONFORMING AUTHORITY TO WAIVE A PRO-**  
23           **GRAM EXCLUSION.**

24           The first sentence of section 1128(c)(3)(B) (42 U.S.C.  
25 1320a-7(c)(3)(B)) is amended to read as follows: “Subject to  
26 subparagraph (G), in the case of an exclusion under subsection  
27 (a), the minimum period of exclusion shall be not less than five  
28 years, except that, upon the request of the administrator of a  
29 Federal health care program (as defined in section 1128B(f))  
30 who determines that the exclusion would impose a hardship on  
31 individuals entitled to benefits under part A of title XVIII or  
32 enrolled under part B of such title, or both, the Secretary may,  
33 after consulting with the Inspector General of the Department  
34 of Health and Human Services, waive the exclusion under sub-  
35 section (a)(1), (a)(3), or (a)(4) with respect to that program  
36 in the case of an individual or entity that is the sole community

1 physician or sole source of essential specialized services in a  
2 community.”.

3 **SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.**

4 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is  
5 amended by adding at the end, after the subsection transferred  
6 and redesignated by section 948(a), the following new sub-  
7 section:

8 “(k)(1) Subject to paragraph (2), a group health plan (as  
9 defined in subsection (a)(1)(A)(v)) providing supplemental or  
10 secondary coverage to individuals also entitled to services under  
11 this title shall not require a medicare claims determination  
12 under this title for dental benefits specifically excluded under  
13 subsection (a)(12) as a condition of making a claims deter-  
14 mination for such benefits under the group health plan.

15 “(2) A group health plan may require a claims determina-  
16 tion under this title in cases involving or appearing to involve  
17 inpatient dental hospital services or dental services expressly  
18 covered under this title pursuant to actions taken by the Sec-  
19 retary.”.

20 (b) EFFECTIVE DATE.—The amendment made by sub-  
21 section (a) shall take effect on the date that is 60 days after  
22 the date of the enactment of this Act.

23 **SEC. 951. FURNISHING HOSPITALS WITH INFORMATION**  
24 **TO COMPUTE DSH FORMULA.**

25 Beginning not later than 1 year after the date of the en-  
26 actment of this Act, the Secretary shall arrange to furnish to  
27 subsection (d) hospitals (as defined in section 1886(d)(1)(B) of  
28 the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data  
29 necessary for such hospitals to compute the number of patient  
30 days used in computing the disproportionate patient percentage  
31 under such section for that hospital for the current cost report-  
32 ing year. Such data shall also be furnished to other hospitals  
33 which would qualify for additional payments under part A of  
34 title XVIII of the Social Security Act on the basis of such data.

35 **SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.**

36 (a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C.  
37 1395u(b)(6)(A)) is amended by striking “or (ii) (where the

1 service was provided in a hospital, critical access hospital, clinic,  
2 ic, or other facility) to the facility in which the service was provided  
3 if there is a contractual arrangement between such physician or other person  
4 and such facility under which such facility submits the bill for such service,”  
5 and inserting “or (ii) where the service was provided under a contractual  
6 arrangement between such physician or other person and an entity, to the  
7 entity if, under the contractual arrangement, the entity submits the bill  
8 for the service and the contractual arrangement meets such program integrity  
9 and other safeguards as the Secretary may determine to be appropriate.”

12 (b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6)  
13 (42 U.S.C. 1395u(b)(6)) is amended by striking “except to an employer  
14 or facility as described in clause (A)” and inserting “except to an employer  
15 or entity as described in subparagraph (A)”.

17 (c) EFFECTIVE DATE.—The amendments made by this section shall apply  
18 to payments made on or after the date of the enactment of this Act.

20 **SEC. 953. OTHER PROVISIONS.**

21 (a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

22 (1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 months  
23 after the date of the enactment of this Act, the Comptroller General of  
24 the United States shall submit to Congress a report on the appropriateness  
25 of the updates in the conversion factor under subsection (d)(3) of section  
26 1848 of the Social Security Act (42 U.S.C. 1395w-4), including the  
27 appropriateness of the sustainable growth rate formula under subsection  
28 (f) of such section for 2002 and succeeding years. Such report shall  
29 examine the stability and predictability of such updates and rate and  
30 alternatives for the use of such rate in the updates.

31 (2) PHYSICIAN COMPENSATION GENERALLY.—Not later than 12 months  
32 after the date of the enactment of this Act, the Comptroller General  
33 shall submit to Congress a report on all aspects of physician compensation  
34 for services furnished under title XVIII of the Social Security Act,  
35  
36  
37

1 and how those aspects interact and the effect on appro-  
2 priate compensation for physician services. Such report  
3 shall review alternatives for the physician fee schedule  
4 under section 1848 of such title (42 U.S.C. 1395w-4).

5 (b) ANNUAL PUBLICATION OF LIST OF NATIONAL COV-  
6 ERAGE DETERMINATIONS.—The Secretary shall provide, in an  
7 appropriate annual publication available to the public, a list of  
8 national coverage determinations made under title XVIII of the  
9 Social Security Act in the previous year and information on  
10 how to get more information with respect to such determina-  
11 tions.

12 (c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME  
13 HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO  
14 ARE NOT MEDICARE BENEFICIARIES.—Not later than 6  
15 months after the date of the enactment of this Act, the Comp-  
16 troller General of the United States shall submit to Congress  
17 a report on the implications if there were flexibility in the ap-  
18 plication of the medicare conditions of participation for home  
19 health agencies with respect to groups or types of patients who  
20 are not medicare beneficiaries. The report shall include an  
21 analysis of the potential impact of such flexible application on  
22 clinical operations and the recipients of such services and an  
23 analysis of methods for monitoring the quality of care provided  
24 to such recipients.

25 (d) OIG REPORT ON NOTICES RELATING TO USE OF  
26 HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year  
27 after the date of the enactment of this Act, the Inspector Gen-  
28 eral of the Department of Health and Human Services shall  
29 submit a report to Congress on—

30 (1) the extent to which hospitals provide notice to  
31 medicare beneficiaries in accordance with applicable re-  
32 quirements before they use the 60 lifetime reserve days de-  
33 scribed in section 1812(a)(1) of the Social Security Act (42  
34 U.S.C. 1395d(a)(1)); and

35 (2) the appropriateness and feasibility of hospitals pro-  
36 viding a notice to such beneficiaries before they completely  
37 exhaust such lifetime reserve days.

1                   **TITLE X—MEDICAID AND**  
2                   **MISCELLANEOUS PROVISIONS**  
3                   **Subtitle A—Medicaid Provisions**

4                   **SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOS-**  
5                   **PITAL (DSH) PAYMENTS.**

6                   (a) TEMPORARY INCREASE.—Section 1923(f)(3) (42  
7 U.S.C. 1396r-4(f)(3)) is amended—

8                   (1) in subparagraph (A), by striking “subparagraph  
9 (B)” and inserting “subparagraphs (B) and (C)”; and

10                   (2) by adding at the end the following new subpara-  
11 graphs:

12                   “(C) SPECIAL, TEMPORARY INCREASE IN ALLOT-  
13 MENTS ON A ONE-TIME, NON-CUMULATIVE BASIS.—The  
14 DSH allotment for any State (other than a State with  
15 a DSH allotment determined under paragraph (5))—

16                   “(i) for fiscal year 2004 is equal to 116 per-  
17 cent of the DSH allotment for the State for fiscal  
18 year 2003 under this paragraph, notwithstanding  
19 subparagraph (B); and

20                   “(ii) for each succeeding fiscal year is equal to  
21 the DSH allotment for the State for fiscal year  
22 2004 or, in the case of fiscal years beginning with  
23 the fiscal year specified in subparagraph (D) for  
24 that State, the DSH allotment for the State for the  
25 previous fiscal year increased by the percentage  
26 change in the consumer price index for all urban  
27 consumers (all items; U.S. city average), for the  
28 previous fiscal year.

29                   “(D) FISCAL YEAR SPECIFIED.—For purposes of  
30 subparagraph (C)(ii), the fiscal year specified in this  
31 subparagraph for a State is the first fiscal year for  
32 which the Secretary estimates that the DSH allotment  
33 for that State will equal (or no longer exceed) the DSH  
34 allotment for that State under the law as in effect be-  
35 fore the date of the enactment of this subparagraph.”.

1 (b) INCREASE IN FLOOR FOR TREATMENT AS A LOW DSH  
2 STATE.—Section 1923(f)(5) (42 U.S.C. 1396r-4(f)(5)) is  
3 amended—

4 (1) in the paragraph heading, by striking “EX-  
5 TREMELY”;

6 (2) by striking “In the case of” and inserting the fol-  
7 lowing:

8 “(A) FOR FISCAL YEARS 2001 THROUGH 2003 FOR  
9 EXTREMELY LOW DSH STATES.—In the case of”;

10 (3) by inserting “before fiscal year 2004” after “In  
11 subsequent years”; and

12 (4) by adding at the end the following:

13 “(B) FOR FISCAL YEAR 2004 AND SUBSEQUENT  
14 FISCAL YEARS.—In the case of a State in which the  
15 total expenditures under the State plan (including Fed-  
16 eral and State shares) for disproportionate share hos-  
17 pital adjustments under this section for fiscal year  
18 2000, as reported to the Administrator of the Centers  
19 for Medicare & Medicaid Services as of August 31,  
20 2003, is greater than 0 but less than 3 percent of the  
21 State’s total amount of expenditures under the State  
22 plan for medical assistance during the fiscal year, the  
23 DSH allotment for the State with respect to—

24 “(i) fiscal year 2004 shall be the DSH allot-  
25 ment for the State for fiscal year 2003 increased  
26 by 16 percent;

27 “(ii) each succeeding fiscal year before fiscal  
28 year 2009 shall be the DSH allotment for the State  
29 for the previous fiscal year increased by 16 percent;  
30 and

31 “(iii) fiscal year 2009 and any subsequent fis-  
32 cal year, shall be the DSH allotment for the State  
33 for the previous year subject to an increase for in-  
34 flation as provided in paragraph (3)(A).”.

35 (1) IN GENERAL.—Section 1923(f)(5) (42 U.S.C.  
36 1396r-4(f)(5)) is amended to read as follows:

1           “(5) SPECIAL RULE FOR LOW DSH STATES.—In the  
2 case of a State in which the total expenditures under the  
3 State plan (including Federal and State shares) for dis-  
4 proportionate share hospital adjustments under this section  
5 for fiscal year 2000, as reported to the Administrator of  
6 the Centers for Medicare & Medicaid Services as of August  
7 31, 2003, is greater than 0 but less than 3 percent of the  
8 State’s total amount of expenditures under the State plan  
9 for medical assistance during the fiscal year, the DSH al-  
10 lotment for the State with respect to—

11           “(A) fiscal year 2004 shall be the DSH allotment  
12 for the State for fiscal year 2003 increased by 16 per-  
13 cent;

14           “(B) each succeeding fiscal year before fiscal year  
15 2009 shall be the DSH allotment for the State for the  
16 previous fiscal year increased by 16 percent; and

17           “(C) fiscal year 2009 and any subsequent fiscal  
18 year, shall be the DSH allotment for the State for the  
19 previous year subject to an increase for inflation as  
20 provided in paragraph (3)(A).”.

21           (c) ALLOTMENT ADJUSTMENT.—Section 1923(f) of the  
22 Social Security Act (42 U.S.C. 1396r–4(f)) is amended—

23           (1) in paragraph (3)(A), by striking “The DSH” and  
24 inserting “Except as provided in paragraph (6), the DSH”;

25           (2) by redesignating paragraph (6) as paragraph (7);  
26 and

27           (3) by inserting after paragraph (5) the following:

28           “(6) ALLOTMENT ADJUSTMENT.—Only with respect to  
29 fiscal year 2004 or 2005, if a statewide waiver under sec-  
30 tion 1115 is revoked or terminated before the end of either  
31 such fiscal year and there is no DSH allotment for the  
32 State, the Secretary shall—

33           “(A) permit the State whose waiver was revoked  
34 or terminated to submit an amendment to its State  
35 plan that would describe the methodology to be used by  
36 the State (after the effective date of such revocation or  
37 termination) to identify and make payments to dis-



1 proportionate share hospitals, including children's hos-  
2 pitals and institutions for mental diseases or other  
3 mental health facilities (other than State-owned institu-  
4 tions or facilities), on the basis of the proportion of pa-  
5 tients served by such hospitals that are low-income pa-  
6 tients with special needs; and

7 “(B) provide for purposes of this subsection for  
8 computation of an appropriate DSH allotment for the  
9 State for fiscal year 2004 or 2005 (or both) that would  
10 not exceed the amount allowed under paragraph  
11 (3)(B)(ii) and that does not result in greater expendi-  
12 tures under this title than would have been made if  
13 such waiver had not been revoked or terminated.

14 In determining the amount of an appropriate DSH allot-  
15 ment under subparagraph (B) for a State, the Secretary  
16 shall take into account the level of DSH expenditures for  
17 the State for the fiscal year preceding the fiscal year in  
18 which the waiver commenced.”.

19 (d) INCREASED REPORTING AND OTHER REQUIREMENTS  
20 TO ENSURE THE APPROPRIATE USE OF MEDICAID DSH PAY-  
21 MENT ADJUSTMENTS.—Section 1923 (42 U.S.C. 1396r-4) is  
22 amended by adding at the end the following new subsection:

23 “(j) ANNUAL REPORTS AND OTHER REQUIREMENTS RE-  
24 GARDING PAYMENT ADJUSTMENTS.—With respect to fiscal  
25 year 2004 and each fiscal year thereafter, the Secretary shall  
26 require a State, as a condition of receiving a payment under  
27 section 1903(a)(1) with respect to a payment adjustment made  
28 under this section, to do the following:

29 “(1) REPORT.—The State shall submit an annual re-  
30 port that includes the following:

31 “(A) An identification of each disproportionate  
32 share hospital that received a payment adjustment  
33 under this section for the preceding fiscal year and the  
34 amount of the payment adjustment made to such hos-  
35 pital for the preceding fiscal year.

36 “(B) Such other information as the Secretary de-  
37 termines necessary to ensure the appropriateness of the

1 payment adjustments made under this section for the  
2 preceding fiscal year.

3 “(2) INDEPENDENT CERTIFIED AUDIT.—The State  
4 shall annually submit to the Secretary an independent cer-  
5 tified audit that verifies each of the following:

6 “(A) The extent to which hospitals in the State  
7 have reduced their uncompensated care costs to reflect  
8 the total amount of payment adjustments under this  
9 section.

10 “(B) Payments under this section to hospitals that  
11 comply with the requirements of subsection (g).

12 “(C) Only the uncompensated care costs of pro-  
13 viding inpatient hospital and outpatient hospital serv-  
14 ices to individuals described in paragraph (1)(A) of  
15 such subsection are included in the calculation of the  
16 hospital-specific limits under such subsection.

17 “(D) The State included all payments under this  
18 title, including supplemental payments, in the calcula-  
19 tion of such hospital-specific limits.

20 “(E) The State has separately documented and re-  
21 tained a record of all of its costs under this title,  
22 claimed expenditures under this title, uninsured costs  
23 in determining payment adjustments under this section,  
24 and any payments made on behalf of the uninsured  
25 from payment adjustments under this section.”.

26 **SEC. 1002. CLARIFICATION OF INCLUSION OF INPA-**  
27 **TIENT DRUG PRICES CHARGED TO CERTAIN**  
28 **PUBLIC HOSPITALS IN THE BEST PRICE EX-**  
29 **EMPTIONS FOR THE MEDICAID DRUG RE-**  
30 **BATE PROGRAM.**

31 (a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C.  
32 1396r-8(c)(1)(C)(i)(I)) is amended by inserting before the  
33 semicolon the following: “(including inpatient prices charged to  
34 hospitals described in section 340B(a)(4)(L) of the Public  
35 Health Service Act)”.

36 (b) ANTI-DIVERSION PROTECTION.—Section  
37 1927(c)(1)(C) (42 U.S.C. 1396r-8(c)(1)(C)) is amended by  
38 adding at the end the following:

1                   “(iii) APPLICATION OF AUDITING AND REC-  
2                   ORDKEEPING REQUIREMENTS.—With respect to a  
3                   covered entity described in section 340B(a)(4)(L)  
4                   of the Public Health Service Act, any drug pur-  
5                   chased for inpatient use shall be subject to the au-  
6                   diting and recordkeeping requirements described in  
7                   section 340B(a)(5)(C) of the Public Health Service  
8                   Act.”.

9                   **SEC. 1003. EXTENSION OF MORATORIUM.**

10                   (a) IN GENERAL.—Section 6408(a)(3) of the Omnibus  
11                   Budget Reconciliation Act of 1989, as amended by section  
12                   13642 of the Omnibus Budget Reconciliation Act of 1993 and  
13                   section 4758 of the Balanced Budget Act of 1997, is  
14                   amended—

15                   (1) by striking “until December 31, 2002”, and

16                   (2) by striking “Kent Community Hospital Complex in  
17                   Michigan or.”

18                   (b) EFFECTIVE DATES.—

19                   (1) PERMANENT EXTENSION.—The amendment made  
20                   by subsection (a)(1) shall take effect as if included in the  
21                   amendment made by section 4758 of the Balanced Budget  
22                   Act of 1997.

23                   (2) MODIFICATION.—The amendment made by sub-  
24                   section (a)(2) shall take effect on the date of enactment of  
25                   this Act.

26                   **Subtitle B—Miscellaneous Provisions**

27                   **SEC. 1011. FEDERAL REIMBURSEMENT OF EMERGENCY**  
28                   **HEALTH SERVICES FURNISHED TO UNDOCU-**  
29                   **MENTED ALIENS.**

30                   (a) TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—

31                   (1) IN GENERAL.—Out of any funds in the Treasury  
32                   not otherwise appropriated, there are appropriated to the  
33                   Secretary \$250,000,000 for each of fiscal years 2005  
34                   through 2008 for the purpose of making allotments under  
35                   this section for payments to eligible providers in States de-  
36                   scribed in paragraph (1) or (2) of subsection (b).

1 (2) AVAILABILITY.—Funds appropriated under para-  
2 graph (1) shall remain available until expended.

3 (b) STATE ALLOTMENTS.—

4 (1) BASED ON PERCENTAGE OF UNDOCUMENTED  
5 ALIENS.—

6 (A) IN GENERAL.—Out of the amount appro-  
7 priated under subsection (a) for a fiscal year, the Sec-  
8 retary shall use \$167,000,000 of such amount to make  
9 allotments for such fiscal year in accordance with sub-  
10 paragraph (B).

11 (B) FORMULA.—The amount of the allotment for  
12 payments to eligible providers in each State for a fiscal  
13 year shall be equal to the product of—

14 (i) the total amount available for allotments  
15 under this paragraph for the fiscal year; and

16 (ii) the percentage of undocumented aliens re-  
17 siding in the State as compared to the total num-  
18 ber of such aliens residing in all States, as deter-  
19 mined by the Statistics Division of the Immigration  
20 and Naturalization Service, as of January 2003,  
21 based on the 2000 decennial census.

22 (2) BASED ON NUMBER OF UNDOCUMENTED ALIEN  
23 APPREHENSION STATES.—

24 (A) IN GENERAL.—Out of the amount appro-  
25 priated under subsection (a) for a fiscal year, the Sec-  
26 retary shall use \$83,000,000 of such amount to make  
27 allotments, in addition to amounts allotted under para-  
28 graph (1), for such fiscal year for each of the 6 States  
29 with the highest number of undocumented alien appre-  
30 hensions for such fiscal year.

31 (B) DETERMINATION OF ALLOTMENTS.—The  
32 amount of the allotment for each State described in  
33 subparagraph (A) for a fiscal year shall be equal to the  
34 product of—

35 (i) the total amount available for allotments  
36 under this paragraph for the fiscal year; and

1 (ii) the percentage of undocumented alien ap-  
2 prehensions in the State in that fiscal year as com-  
3 pared to the total of such apprehensions for all  
4 such States for the preceding fiscal year.

5 (C) DATA.—For purposes of this paragraph, the  
6 highest number of undocumented alien apprehensions  
7 for a fiscal year shall be based on the apprehension  
8 rates for the 4-consecutive-quarter period ending before  
9 the beginning of the fiscal year for which information  
10 is available for undocumented aliens in such States, as  
11 reported by the Department of Homeland Security.

12 (c) USE OF FUNDS.—

13 (1) AUTHORITY TO MAKE PAYMENTS.—From the allot-  
14 ments made for a State under subsection (b) for a fiscal  
15 year, the Secretary shall pay the amount (subject to the  
16 total amount available from such allotments) determined  
17 under paragraph (2) directly to eligible providers located in  
18 the State for the provision of eligible services to aliens de-  
19 scribed in paragraph (5) to the extent that the eligible pro-  
20 vider was not otherwise reimbursed (through insurance or  
21 otherwise) for such services during that fiscal year.

22 (2) DETERMINATION OF PAYMENT AMOUNTS.—

23 (A) IN GENERAL.—Subject to subparagraph (B),  
24 the payment amount determined under this paragraph  
25 shall be an amount determined by the Secretary that  
26 is equal to the lesser of—

27 (i) the amount that the provider demonstrates  
28 was incurred for the provision of such services; or

29 (ii) amounts determined under a methodology  
30 established by the Secretary for purposes of this  
31 subsection.

32 (B) PRO-RATA REDUCTION.—If the amount of  
33 funds allotted to a State under subsection (b) for a fis-  
34 cal year is insufficient to ensure that each eligible pro-  
35 vider in that State receives the amount of payment cal-  
36 culated under subparagraph (A), the Secretary shall re-  
37 duce that amount of payment with respect to each eli-

1           gible provider to ensure that the entire amount allotted  
2           to the State for that fiscal year is paid to such eligible  
3           providers.

4           (3) METHODOLOGY.—In establishing a methodology  
5           under paragraph (2)(A)(ii), the Secretary—

6                 (A) may establish different methodologies for  
7                 types of eligible providers;

8                 (B) may base payments for hospital services on es-  
9                 timated hospital charges, adjusted to estimated cost,  
10                through the application of hospital-specific cost-to-  
11                charge ratios;

12               (C) shall provide for the election by a hospital to  
13                receive either payments to the hospital for—

14                     (i) hospital and physician services; or

15                     (ii) hospital services and for a portion of the  
16                    on-call payments made by the hospital to physi-  
17                    cians; and

18               (D) shall make quarterly payments under this sec-  
19                tion to eligible providers.

20           If a hospital makes the election under subparagraph (C)(i),  
21           the hospital shall pass on payments for services of a physi-  
22           cian to the physician and may not charge any administra-  
23           tive or other fee with respect to such payments.

24           (4) LIMITATION ON USE OF FUNDS.—Payments made  
25           to eligible providers in a State from allotments made under  
26           subsection (b) for a fiscal year may only be used for costs  
27           incurred in providing eligible services to aliens described in  
28           paragraph (5).

29           (5) ALIENS DESCRIBED.—For purposes of paragraphs  
30           (1) and (2), aliens described in this paragraph are any of  
31           the following:

32                 (A) Undocumented aliens.

33                 (B) Aliens who have been paroled into the United  
34                 States at a United States port of entry for the purpose  
35                 of receiving eligible services.

36                 (C) Mexican citizens permitted to enter the United  
37                 States for not more than 72 hours under the authority

1 of a biometric machine readable border crossing identi-  
2 fication card (also referred to as a “laser visa”) issued  
3 in accordance with the requirements of regulations pre-  
4 scribed under section 101(a)(6) of the Immigration and  
5 Nationality Act (8 U.S.C. 1101(a)(6)).

6 (d) APPLICATIONS; ADVANCE PAYMENTS.—

7 (1) DEADLINE FOR ESTABLISHMENT OF APPLICATION  
8 PROCESS.—

9 (A) IN GENERAL.—Not later than September 1,  
10 2004, the Secretary shall establish a process under  
11 which eligible providers located in a State may request  
12 payments under subsection (c).

13 (B) INCLUSION OF MEASURES TO COMBAT FRAUD  
14 AND ABUSE.—The Secretary shall include in the proc-  
15 ess established under subparagraph (A) measures to  
16 ensure that inappropriate, excessive, or fraudulent pay-  
17 ments are not made from the allotments determined  
18 under subsection (b), including certification by the eli-  
19 gible provider of the veracity of the payment request.

20 (2) ADVANCE PAYMENT; RETROSPECTIVE ADJUST-  
21 MENT.—The process established under paragraph (1) may  
22 provide for making payments under this section for each  
23 quarter of a fiscal year on the basis of advance estimates  
24 of expenditures submitted by applicants for such payments  
25 and such other investigation as the Secretary may find nec-  
26 essary, and for making reductions or increases in the pay-  
27 ments as necessary to adjust for any overpayment or un-  
28 derpayment for prior quarters of such fiscal year.

29 (e) DEFINITIONS.—In this section:

30 (1) ELIGIBLE PROVIDER.—The term “eligible pro-  
31 vider” means a hospital, physician, or provider of ambu-  
32 lance services (including an Indian Health Service facility  
33 whether operated by the Indian Health Service or by an In-  
34 dian tribe or tribal organization).

35 (2) ELIGIBLE SERVICES.—The term “eligible services”  
36 means health care services required by the application of  
37 section 1867 of the Social Security Act (42 U.S.C.

1 1395dd), and related hospital inpatient and outpatient  
2 services and ambulance services (as defined by the Sec-  
3 retary).

4 (3) HOSPITAL.—The term “hospital” has the meaning  
5 given such term in section 1861(e) of the Social Security  
6 Act (42 U.S.C. 1395x(e)), except that such term shall in-  
7 clude a critical access hospital (as defined in section  
8 1861(mm)(1) of such Act (42 U.S.C. 1395x(mm)(1))).

9 (4) PHYSICIAN.—The term “physician” has the mean-  
10 ing given that term in section 1861(r) of the Social Secu-  
11 rity Act (42 U.S.C. 1395x(r)).

12 (5) INDIAN TRIBE; TRIBAL ORGANIZATION.—The  
13 terms “Indian tribe” and “tribal organization” have the  
14 meanings given such terms in section 4 of the Indian  
15 Health Care Improvement Act (25 U.S.C. 1603).

16 (6) STATE.—The term “State” means the 50 States  
17 and the District of Columbia.

18 **SEC. 1012. COMMISSION ON SYSTEMIC INTEROPER-**  
19 **ABILITY.**

20 (a) ESTABLISHMENT.—The Secretary shall establish a  
21 commission to be known as the “Commission on Systemic  
22 Interoperability” (in this section referred to as the “Commis-  
23 sion”).

24 (b) DUTIES.—

25 (1) IN GENERAL.—The Commission shall develop a  
26 comprehensive strategy for the adoption and implementa-  
27 tion of health care information technology standards, that  
28 includes a timeline and prioritization for such adoption and  
29 implementation.

30 (2) CONSIDERATIONS.—In developing the comprehen-  
31 sive health care information technology strategy under  
32 paragraph (1), the Commission shall consider—

33 (A) the costs and benefits of the standards, both  
34 financial impact and quality improvement;

35 (B) the current demand on industry resources to  
36 implement this Act and other electronic standards, in-  
37 cluding HIPAA standards; and



1 (C) the most cost-effective and efficient means for  
2 industry to implement the standards.

3 (3) NONINTERFERENCE.—In carrying out this section,  
4 the Commission shall not interfere with any standards de-  
5 velopment of adoption processes underway in the private or  
6 public sector and shall not replicate activities related to  
7 such standards or the national health information infra-  
8 structure underway within the Department of Health and  
9 Human Services.

10 (4) REPORT.—Not later than October 31, 2005, the  
11 Commission shall submit to the Secretary and to Congress  
12 a report describing the strategy developed under paragraph  
13 (1), including an analysis of the matters considered under  
14 paragraph (2).

15 (c) MEMBERSHIP.—

16 (1) NUMBER AND APPOINTMENT.—The Commission  
17 shall be composed of 11 members appointed as follows:

18 (A) The President shall appoint 3 members, one of  
19 whom the President shall designate as Chairperson.

20 (B) The Majority Leader of the Senate shall ap-  
21 point 2 members.

22 (C) The Minority Leader of the Senate shall ap-  
23 point 2 members.

24 (D) The Speaker of the House of Representatives  
25 shall appoint 2 members.

26 (E) The Minority Leader of the House of Rep-  
27 resentatives shall appoint 2 members.

28 (2) QUALIFICATIONS.—The membership of the Com-  
29 mission shall include individuals with national recognition  
30 for their expertise in health finance and economics, health  
31 plans and integrated delivery systems, reimbursement of  
32 health facilities, practicing physicians, practicing phar-  
33 macists, and other providers of health services, health care  
34 technology and information systems, and other related  
35 fields, who provide a mix of different professionals, broad  
36 geographic representation, and a balance between urban  
37 and rural representatives.

1 (d) TERMS.—Each member shall be appointed for the life  
2 of the Commission.

3 (e) COMPENSATION.—

4 (1) RATES OF PAY.—Members shall each be paid at a  
5 rate not to exceed the daily equivalent of the rate of basic  
6 pay for level IV of the Executive Schedule for each day (in-  
7 cluding travel time) during which they are engaged in the  
8 actual performance of duties vested in the Commission.

9 (2) PROHIBITION OF COMPENSATION OF FEDERAL EM-  
10 PLOYEES.—Members of the Commission who are full-time  
11 officers or employees of the United States or Members of  
12 Congress may not receive additional pay, allowances, or  
13 benefits by reason of their service on the Commission.

14 (3) TRAVEL EXPENSES.—Each member shall receive  
15 travel expenses, including per diem in lieu of subsistence,  
16 in accordance with applicable provisions under subchapter  
17 I of chapter 57 of title 5, United States Code.

18 (f) QUORUM.—A majority of the members of the Commis-  
19 sion shall constitute a quorum but a lesser number may hold  
20 hearings.

21 (g) DIRECTOR AND STAFF OF COMMISSION; EXPERTS AND  
22 CONSULTANTS.—

23 (1) DIRECTOR.—The Commission shall have a Direc-  
24 tor who shall be appointed by the Chairperson. The Direc-  
25 tor shall be paid at a rate not to exceed the rate of basic  
26 pay for level IV of the Executive Schedule.

27 (2) STAFF.—With the approval of the Commission,  
28 the Director may appoint and fix the pay of such additional  
29 personnel as the Director considers appropriate.

30 (3) APPLICABILITY OF CERTAIN CIVIL SERVICE  
31 LAWS.—The Director and staff of the Commission may be  
32 appointed without regard to the provisions of title 5,  
33 United States Code, governing appointments in the com-  
34 petitive service, and may be paid without regard to the pro-  
35 visions of chapter 51 and subchapter III of chapter 53 of  
36 that title relating to classification and General Schedule

1 pay rates, except that an individual so appointed may not  
2 receive pay in excess of level IV of the Executive Schedule.

3 (4) EXPERTS AND CONSULTANTS.—With the approval  
4 of the Commission, the Director may procure temporary  
5 and intermittent services under section 3109(b) of title 5,  
6 United States Code.

7 (5) STAFF OF FEDERAL AGENCIES.—Upon request of  
8 the Chairperson, the head of any Federal department or  
9 agency may detail, on a reimbursable basis, any of the per-  
10 sonnel of that department or agency to the Commission to  
11 assist it in carrying out its duties under this Act.

12 (h) POWERS OF COMMISSION.—

13 (1) HEARINGS AND SESSIONS.—The Commission may,  
14 for the purpose of carrying out this Act, hold hearings, sit  
15 and act at times and places, take testimony, and receive  
16 evidence as the Commission considers appropriate.

17 (2) POWERS OF MEMBERS AND AGENTS.—Any mem-  
18 ber or agent of the Commission may, if authorized by the  
19 Commission, take any action which the Commission is au-  
20 thorized to take by this section.

21 (3) OBTAINING OFFICIAL DATA.—The Commission  
22 may secure directly from any department or agency of the  
23 United States information necessary to enable it to carry  
24 out this Act. Upon request of the Chairperson of the Com-  
25 mission, the head of that department or agency shall fur-  
26 nish that information to the Commission.

27 (4) GIFTS, BEQUESTS, AND DEVICES.—The Commis-  
28 sion may accept, use, and dispose of gifts, bequests, or de-  
29 vices of services or property, both real and personal, for the  
30 purpose of aiding or facilitating the work of the Commis-  
31 sion. Gifts, bequests, or devices of money and proceeds  
32 from sales of other property received as gifts, bequests, or  
33 devices shall be deposited in the Treasury and shall be  
34 available for disbursement upon order of the Commission.  
35 For purposes of Federal income, estate, and gift taxes,  
36 property accepted under this subsection shall be considered  
37 as a gift, bequest, or devise to the United States.

1           (5) **MAILS.**—The Commission may use the United  
2 States mails in the same manner and under the same con-  
3 ditions as other departments and agencies of the United  
4 States.

5           (6) **ADMINISTRATIVE SUPPORT SERVICES.**—Upon the  
6 request of the Commission, the Administrator of General  
7 Services shall provide to the Commission, on a reimburs-  
8 able basis, the administrative support services necessary for  
9 the Commission to carry out its responsibilities under this  
10 Act.

11           (7) **CONTRACT AUTHORITY.**—The Commission may  
12 enter into contracts or make other arrangements, as may  
13 be necessary for the conduct of the work of the Commission  
14 (without regard to section 3709 of the Revised Statutes (41  
15 U.S.C. 5)).

16           (i) **TERMINATION.**—The Commission shall terminate on 30  
17 days after submitting its report pursuant to subsection (b)(3).

18           (j) **AUTHORIZATION OF APPROPRIATIONS.**—There is au-  
19 thorized to be appropriated such sums as may be necessary to  
20 carry out this section.

21 **SEC. 1013. RESEARCH ON OUTCOMES OF HEALTH CARE**  
22 **ITEMS AND SERVICES.**

23           (a) **RESEARCH, DEMONSTRATIONS, AND EVALUATIONS.**—

24           (1) **IMPROVEMENT OF EFFECTIVENESS AND EFFI-**  
25 **CIENCY.**—

26           (A) **IN GENERAL.**—To improve the quality, effec-  
27 tiveness, and efficiency of health care delivered pursu-  
28 ant to the programs established under titles XVIII,  
29 XIX, and XXI of the Social Security Act, the Secretary  
30 acting through the Director of the Agency for  
31 Healthcare Research and Quality (in this section re-  
32 ferred to as the “Director”), shall conduct and support  
33 research to meet the priorities and requests for sci-  
34 entific evidence and information identified by such pro-  
35 grams with respect to—

1 (i) the outcomes, comparative clinical effective-  
2 ness, and appropriateness of health care items and  
3 services (including prescription drugs); and

4 (ii) strategies for improving the efficiency and  
5 effectiveness of such programs, including the ways  
6 in which such items and services are organized,  
7 managed, and delivered under such programs.

8 (B) SPECIFICATION.—To respond to priorities and  
9 information requests in subparagraph (A), the Sec-  
10 retary may conduct or support, by grant, contract, or  
11 interagency agreement, research, demonstrations, eval-  
12 uations, technology assessments, or other activities, in-  
13 cluding the provision of technical assistance, scientific  
14 expertise, or methodological assistance.

15 (2) PRIORITIES.—

16 (A) IN GENERAL.—The Secretary shall establish a  
17 process to develop priorities that will guide the re-  
18 search, demonstrations, and evaluation activities under-  
19 taken pursuant to this section.

20 (B) INITIAL LIST.—Not later than 6 months after  
21 the date of the enactment of this Act, the Secretary  
22 shall establish an initial list of priorities for research  
23 related to health care items and services (including pre-  
24 scription drugs).

25 (C) PROCESS.—In carrying out subparagraph (A),  
26 the Secretary—

27 (i) shall ensure that there is broad and ongoing  
28 consultation with relevant stakeholders in iden-  
29 tifying the highest priorities for research, dem-  
30 onstrations, and evaluations to support and im-  
31 prove the programs established under titles XVIII,  
32 XIX, and XXI of the Social Security Act;

33 (ii) may include health care items and services  
34 which impose a high cost on such programs, as well  
35 as those which may be underutilized or overutilized  
36 and which may significantly improve the preven-  
37 tion, treatment, or cure of diseases and conditions

1 (including chronic conditions) which impose high  
2 direct or indirect costs on patients or society; and  
3 (iii) shall ensure that the research and activi-  
4 ties undertaken pursuant to this section are re-  
5 sponsive to the specified priorities and are con-  
6 ducted in a timely manner.

7 (3) EVALUATION AND SYNTHESIS OF SCIENTIFIC EVI-  
8 DENCE.—

9 (A) IN GENERAL.—The Secretary shall—

10 (i) evaluate and synthesize available scientific  
11 evidence related to health care items and services  
12 (including prescription drugs) identified as prior-  
13 ities in accordance with paragraph (2) with respect  
14 to the comparative clinical effectiveness, outcomes,  
15 appropriateness, and provision of such items and  
16 services (including prescription drugs);

17 (ii) identify issues for which existing scientific  
18 evidence is insufficient with respect to such health  
19 care items and services (including prescription  
20 drugs);

21 (iii) disseminate to prescription drug plans  
22 and MA–PD plans under part D of title XVIII of  
23 the Social Security Act, other health plans, and the  
24 public the findings made under clauses (i) and (ii);  
25 and

26 (iv) work in voluntary collaboration with public  
27 and private sector entities to facilitate the develop-  
28 ment of new scientific knowledge regarding health  
29 care items and services (including prescription  
30 drugs).

31 (B) INITIAL RESEARCH.—The Secretary shall  
32 complete the evaluation and synthesis of the initial re-  
33 search required by the priority list developed under  
34 paragraph (2)(B) not later than 18 months after the  
35 development of such list.

36 (C) DISSEMINATION.—

1 (i) IN GENERAL.—To enhance patient safety  
2 and the quality of health care, the Secretary shall  
3 make available and disseminate in appropriate for-  
4 mats to prescription drugs plans under part D, and  
5 MA–PD plans under part C, of title XVIII of the  
6 Social Security Act, other health plans, and the  
7 public the evaluations and syntheses prepared pur-  
8 suant to subparagraph (A) and the findings of re-  
9 search conducted pursuant to paragraph (1). In  
10 carrying out this clause the Secretary, in order to  
11 facilitate the availability of such evaluations and  
12 syntheses or findings at every decision point in the  
13 health care system, shall—

14 (I) present such evaluations and syntheses  
15 or findings in a form that is easily understood  
16 by the individuals receiving health care items  
17 and services (including prescription drugs)  
18 under such plans and periodically assess that  
19 the requirements of this subclause have been  
20 met; and

21 (II) provide such evaluations and syn-  
22 theses or findings and other relevant informa-  
23 tion through easily accessible and searchable  
24 electronic mechanisms, and in hard copy for-  
25 mats as appropriate.

26 (ii) RULE OF CONSTRUCTION.—Nothing in  
27 this section shall be construed as—

28 (I) affecting the authority of the Secretary  
29 or the Commissioner of Food and Drugs under  
30 the Federal Food, Drug, and Cosmetic Act or  
31 the Public Health Service Act; or

32 (II) conferring any authority referred to in  
33 subclause (I) to the Director.

34 (D) ACCOUNTABILITY.—In carrying out this para-  
35 graph, the Secretary shall implement activities in a  
36 manner that—

1 (i) makes publicly available all scientific evi-  
2 dence relied upon and the methodologies employed,  
3 provided such evidence and method are not pro-  
4 tected from public disclosure by section 1905 of  
5 title 18, United States Code, or other applicable  
6 law so that the results of the research, analyses, or  
7 syntheses can be evaluated or replicated; and

8 (ii) ensures that any information needs and  
9 unresolved issues identified in subparagraph (A)(ii)  
10 are taken into account in priority-setting for future  
11 research conducted by the Secretary.

12 (4) CONFIDENTIALITY.—

13 (A) IN GENERAL.—In making use of administra-  
14 tive, clinical, and program data and information devel-  
15 oped or collected with respect to the programs estab-  
16 lished under titles XVIII, XIX, and XXI of the Social  
17 Security Act, for purposes of carrying out the require-  
18 ments of this section or the activities authorized under  
19 title IX of the Public Health Service Act (42 U.S.C.  
20 299 et seq.), such data and information shall be pro-  
21 tected in accordance with the confidentiality require-  
22 ments of title IX of the Public Health Service Act.

23 (B) RULE OF CONSTRUCTION.—Nothing in this  
24 section shall be construed to require or permit the dis-  
25 closure of data provided to the Secretary that is other-  
26 wise protected from disclosure under the Federal Food,  
27 Drug, and Cosmetic Act, section 1905 of title 18,  
28 United States Code, or other applicable law.

29 (5) EVALUATIONS.—The Secretary shall conduct and  
30 support evaluations of the activities carried out under this  
31 section to determine the extent to which such activities  
32 have had an effect on outcomes and utilization of health  
33 care items and services.

34 (6) IMPROVING INFORMATION AVAILABLE TO HEALTH  
35 CARE PROVIDERS, PATIENTS, AND POLICYMAKERS.—Not  
36 later than 18 months after the date of enactment of this  
37 Act, the Secretary shall identify options that could be un-



1           dertaken in voluntary collaboration with private and public  
2           entities (as appropriate) for the—

3           (A) provision of more timely information through  
4           the programs established under titles XVIII, XIX, and  
5           XXI of the Social Security Act, regarding the outcomes  
6           and quality of patient care, including clinical and pa-  
7           tient-reported outcomes, especially with respect to  
8           interventions and conditions for which clinical trials  
9           would not be feasible or raise ethical concerns that are  
10          difficult to address;

11          (B) acceleration of the adoption of innovation and  
12          quality improvement under such programs; and

13          (C) development of management tools for the pro-  
14          grams established under titles XIX and XXI of the So-  
15          cial Security Act, and with respect to the programs es-  
16          tablished under such titles, assess the feasibility of  
17          using administrative or claims data, to—

18               (i) improve oversight by State officials;

19               (ii) support Federal and State initiatives to  
20               improve the quality, safety, and efficiency of serv-  
21               ices provided under such programs; and

22               (iii) provide a basis for estimating the fiscal  
23               and coverage impact of Federal or State program  
24               and policy changes.

25          (b) RECOMMENDATIONS.—

26               (1) DISCLAIMER.—In carrying out this section, the Di-  
27               rector shall—

28                   (A) not mandate national standards of clinical  
29                   practice or quality health care standards; and

30                   (B) include in any recommendations resulting  
31                   from projects funded and published by the Director, a  
32                   corresponding reference to the prohibition described in  
33                   subparagraph (A).

34               (2) REQUIREMENT FOR IMPLEMENTATION.—Research,  
35               evaluation, and communication activities performed pursu-  
36               ant to this section shall reflect the principle that clinicians  
37               and patients should have the best available evidence upon

1 which to make choices in health care items and services, in  
2 providers, and in health care delivery systems, recognizing  
3 that patient subpopulations and patient and physician pref-  
4 erences may vary.

5 (3) RULE OF CONSTRUCTION.—Nothing in this section  
6 shall be construed to provide the Director with authority to  
7 mandate a national standard or require a specific approach  
8 to quality measurement and reporting.

9 (c) RESEARCH WITH RESPECT TO DISSEMINATION.—The  
10 Secretary, acting through the Director, may conduct or support  
11 research with respect to improving methods of disseminating  
12 information in accordance with subsection (a)(3)(C).

13 (d) LIMITATION ON CMS.—The Administrator of the Cen-  
14 ters for Medicare & Medicaid Services may not use data ob-  
15 tained in accordance with this section to withhold coverage of  
16 a prescription drug.

17 (e) AUTHORIZATION OF APPROPRIATIONS.—There is au-  
18 thorized to be appropriated to carry out this section,  
19 \$50,000,000 for fiscal year 2004, and such sums as may be  
20 necessary for each fiscal year thereafter.

21 **SEC. 1014. HEALTH CARE THAT WORKS FOR ALL AMERI-**  
22 **CANS: CITIZENS HEALTH CARE WORKING**  
23 **GROUP.**

24 (a) FINDINGS.—Congress finds the following:

25 (1) In order to improve the health care system, the  
26 American public must engage in an informed national pub-  
27 lic debate to make choices about the services they want cov-  
28 ered, what health care coverage they want, and how they  
29 are willing to pay for coverage.

30 (2) More than a trillion dollars annually is spent on  
31 the health care system, yet—

32 (A) 41,000,000 Americans are uninsured;

33 (B) insured individuals do not always have access  
34 to essential, effective services to improve and maintain  
35 their health; and

36 (C) employers, who cover over 170,000,000 Ameri-  
37 cans, find providing coverage increasingly difficult be-

1           cause of rising costs and double digit premium in-  
2           creases.

3           (3) Despite increases in medical care spending that  
4           are greater than the rate of inflation, population growth,  
5           and Gross Domestic Product growth, there has not been a  
6           commensurate improvement in our health status as a na-  
7           tion.

8           (4) Health care costs for even just 1 member of a  
9           family can be catastrophic, resulting in medical bills poten-  
10          tially harming the economic stability of the entire family.

11          (5) Common life occurrences can jeopardize the ability  
12          of a family to retain private coverage or jeopardize access  
13          to public coverage.

14          (6) Innovations in health care access, coverage, and  
15          quality of care, including the use of technology, have often  
16          come from States, local communities, and private sector or-  
17          ganizations, but more creative policies could tap this poten-  
18          tial.

19          (7) Despite our Nation's wealth, the health care sys-  
20          tem does not provide coverage to all Americans who want  
21          it.

22          (b) PURPOSES.—The purposes of this section are—

23           (1) to provide for a nationwide public debate about im-  
24           proving the health care system to provide every American  
25           with the ability to obtain quality, affordable health care  
26           coverage; and

27           (2) to provide for a vote by Congress on the rec-  
28           ommendations that result from the debate.

29          (c) ESTABLISHMENT.—The Secretary, acting through the  
30          Agency for Healthcare Research and Quality, shall establish an  
31          entity to be known as the Citizens' Health Care Working  
32          Group (referred to in this section as the "Working Group").

33          (d) MEMBERSHIP.—

34           (1) NUMBER AND APPOINTMENT.—The Working  
35           Group shall be composed of 15 members. One member shall  
36           be the Secretary. The Comptroller General of the United  
37           States shall appoint 14 members.

1 (2) QUALIFICATIONS.—

2 (A) IN GENERAL.—The membership of the Work-  
3 ing Group shall include—

4 (i) consumers of health services that represent  
5 those individuals who have not had insurance with-  
6 in 2 years of appointment, that have had chronic  
7 illnesses, including mental illness, are disabled, and  
8 those who receive insurance coverage through medi-  
9 care and medicaid; and

10 (ii) individuals with expertise in financing and  
11 paying for benefits and access to care, business and  
12 labor perspectives, and providers of health care.

13 The membership shall reflect a broad geographic rep-  
14 resentation and a balance between urban and rural rep-  
15 resentatives.

16 (B) PROHIBITED APPOINTMENTS.—Members of  
17 the Working Group shall not include Members of Con-  
18 gress or other elected government officials (Federal,  
19 State, or local). Individuals appointed to the Working  
20 Group shall not be paid employees or representatives of  
21 associations or advocacy organizations involved in the  
22 health care system.

23 (e) PERIOD OF APPOINTMENT.—Members of the Working  
24 Group shall be appointed for a life of the Working Group. Any  
25 vacancies shall not affect the power and duties of the Working  
26 Group but shall be filled in the same manner as the original  
27 appointment.

28 (f) DESIGNATION OF THE CHAIRPERSON.—Not later than  
29 15 days after the date on which all members of the Working  
30 Group have been appointed under subsection (d)(1), the Comp-  
31 troller General shall designate the chairperson of the Working  
32 Group.

33 (g) SUBCOMMITTEES.—The Working Group may establish  
34 subcommittees if doing so increases the efficiency of the Work-  
35 ing Group in completing its tasks.

36 (h) DUTIES.—

1 (1) HEARINGS.—Not later than 90 days after the date  
2 of the designation of the chairperson under subsection (f),  
3 the Working Group shall hold hearings to examine—

4 (A) the capacity of the public and private health  
5 care systems to expand coverage options;

6 (B) the cost of health care and the effectiveness  
7 of care provided at all stages of disease;

8 (C) innovative State strategies used to expand  
9 health care coverage and lower health care costs;

10 (D) local community solutions to accessing health  
11 care coverage;

12 (E) efforts to enroll individuals currently eligible  
13 for public or private health care coverage;

14 (F) the role of evidence-based medical practices  
15 that can be documented as restoring, maintaining, or  
16 improving a patient's health, and the use of technology  
17 in supporting providers in improving quality of care  
18 and lowering costs; and

19 (G) strategies to assist purchasers of health care,  
20 including consumers, to become more aware of the im-  
21 pact of costs, and to lower the costs of health care.

22 (2) ADDITIONAL HEARINGS.—The Working Group  
23 may hold additional hearings on subjects other than those  
24 listed in paragraph (1) so long as such hearings are deter-  
25 mined to be necessary by the Working Group in carrying  
26 out the purposes of this section. Such additional hearings  
27 do not have to be completed within the time period speci-  
28 fied in paragraph (1) but shall not delay the other activities  
29 of the Working Group under this section.

30 (3) THE HEALTH REPORT TO THE AMERICAN PEO-  
31 PLE.—Not later than 90 days after the hearings described  
32 in paragraphs (1) and (2) are completed, the Working  
33 Group shall prepare and make available to health care con-  
34 sumers through the Internet and other appropriate public  
35 channels, a report to be entitled, “The Health Report to  
36 the American People”. Such report shall be understandable  
37 to the general public and include—

- 1 (A) a summary of—
- 2 (i) health care and related services that may
- 3 be used by individuals throughout their life span;
- 4 (ii) the cost of health care services and their
- 5 medical effectiveness in providing better quality of
- 6 care for different age groups;
- 7 (iii) the source of coverage and payment, in-
- 8 cluding reimbursement, for health care services;
- 9 (iv) the reasons people are uninsured or
- 10 underinsured and the cost to taxpayers, purchasers
- 11 of health services, and communities when Ameri-
- 12 cans are uninsured or underinsured;
- 13 (v) the impact on health care outcomes and
- 14 costs when individuals are treated in all stages of
- 15 disease;
- 16 (vi) health care cost containment strategies;
- 17 and
- 18 (vii) information on health care needs that
- 19 need to be addressed;
- 20 (B) examples of community strategies to provide
- 21 health care coverage or access;
- 22 (C) information on geographic-specific issues relat-
- 23 ing to health care;
- 24 (D) information concerning the cost of care in dif-
- 25 ferent settings, including institutional-based care and
- 26 home and community-based care;
- 27 (E) a summary of ways to finance health care cov-
- 28 erage; and
- 29 (F) the role of technology in providing future
- 30 health care including ways to support the information
- 31 needs of patients and providers.
- 32 (4) COMMUNITY MEETINGS.—
- 33 (A) IN GENERAL.—Not later than 1 year after the
- 34 date of enactment of this Act, the Working Group shall
- 35 initiate health care community meetings throughout the
- 36 United States (in this paragraph referred to as “com-
- 37 munity meetings”). Such community meetings may be

1 geographically or regionally based and shall be com-  
2 pleted within 180 days after the initiation of the first  
3 meeting.

4 (B) NUMBER OF MEETINGS.—The Working Group  
5 shall hold a sufficient number of community meetings  
6 in order to receive information that reflects—

7 (i) the geographic differences throughout the  
8 United States;

9 (ii) diverse populations; and

10 (iii) a balance among urban and rural popu-  
11 lations.

12 (C) MEETING REQUIREMENTS.—

13 (i) FACILITATOR.—A State health officer may  
14 be the facilitator at the community meetings.

15 (ii) ATTENDANCE.—At least 1 member of the  
16 Working Group shall attend and serve as chair of  
17 each community meeting. Other members may par-  
18 ticipate through interactive technology.

19 (iii) TOPICS.—The community meetings shall,  
20 at a minimum, address the following questions:

21 (I) What health care benefits and services  
22 should be provided?

23 (II) How does the American public want  
24 health care delivered?

25 (III) How should health care coverage be  
26 financed?

27 (IV) What trade-offs are the American  
28 public willing to make in either benefits or fi-  
29 nancing to ensure access to affordable, high  
30 quality health care coverage and services?

31 (iv) INTERACTIVE TECHNOLOGY.—The Work-  
32 ing Group may encourage public participation in  
33 community meetings through interactive technology  
34 and other means as determined appropriate by the  
35 Working Group.

36 (D) INTERIM REQUIREMENTS.—Not later than  
37 180 days after the date of completion of the community

1 meetings, the Working Group shall prepare and make  
2 available to the public through the Internet and other  
3 appropriate public channels, an interim set of rec-  
4 ommendations on health care coverage and ways to im-  
5 prove and strengthen the health care system based on  
6 the information and preferences expressed at the com-  
7 munity meetings. There shall be a 90-day public com-  
8 ment period on such recommendations.

9 (i) RECOMMENDATIONS.—Not later than 120 days after  
10 the expiration of the public comment period described in sub-  
11 section (h)(4)(D), the Working Group shall submit to Congress  
12 and the President a final set of recommendations.

13 (j) ADMINISTRATION.—

14 (1) EXECUTIVE DIRECTOR.—There shall be an Execu-  
15 tive Director of the Working Group who shall be appointed  
16 by the chairperson of the Working Group in consultation  
17 with the members of the Working Group.

18 (2) COMPENSATION.—While serving on the business of  
19 the Working Group (including travel time), a member of  
20 the Working Group shall be entitled to compensation at the  
21 per diem equivalent of the rate provided for level IV of the  
22 Executive Schedule under section 5315 of title 5, United  
23 States Code, and while so serving away from home and the  
24 member's regular place of business, a member may be al-  
25 lowed travel expenses, as authorized by the chairperson of  
26 the Working Group. For purposes of pay and employment  
27 benefits, rights, and privileges, all personnel of the Working  
28 Group shall be treated as if they were employees of the  
29 Senate.

30 (3) INFORMATION FROM FEDERAL AGENCIES.—The  
31 Working Group may secure directly from any Federal de-  
32 partment or agency such information as the Working  
33 Group considers necessary to carry out this section. Upon  
34 request of the Working Group, the head of such depart-  
35 ment or agency shall furnish such information.

36 (4) POSTAL SERVICES.—The Working Group may use  
37 the United States mails in the same manner and under the



1 same conditions as other departments and agencies of the  
2 Federal Government.

3 (k) **DETAIL.**—Not more than 10 Federal Government em-  
4 ployees employed by the Department of Labor and 10 Federal  
5 Government employees employed by the Department of Health  
6 and Human Services may be detailed to the Working Group  
7 under this section without further reimbursement. Any detail of  
8 an employee shall be without interruption or loss of civil service  
9 status or privilege.

10 (l) **TEMPORARY AND INTERMITTENT SERVICES.**—The  
11 chairperson of the Working Group may procure temporary and  
12 intermittent services under section 3109(b) of title 5, United  
13 States Code, at rates for individuals which do not exceed the  
14 daily equivalent of the annual rate of basic pay prescribed for  
15 level V of the Executive Schedule under section 5316 of such  
16 title.

17 (m) **ANNUAL REPORT.**—Not later than 1 year after the  
18 date of enactment of this Act, and annually thereafter during  
19 the existence of the Working Group, the Working Group shall  
20 report to Congress and make public a detailed description of  
21 the expenditures of the Working Group used to carry out its  
22 duties under this section.

23 (n) **SUNSET OF WORKING GROUP.**—The Working Group  
24 shall terminate on the date that is 2 years after the date on  
25 which all the members of the Working Group have been ap-  
26 pointed under subsection (d)(1).

27 (o) **ADMINISTRATION REVIEW AND COMMENTS.**—Not later  
28 than 45 days after receiving the final recommendations of the  
29 Working Group under subsection (i), the President shall submit  
30 a report to Congress which shall contain—

31 (1) additional views and comments on such rec-  
32 ommendations; and

33 (2) recommendations for such legislation and adminis-  
34 trative actions as the President considers appropriate.

35 (p) **REQUIRED CONGRESSIONAL ACTION.**—Not later than  
36 45 days after receiving the report submitted by the President  
37 under subsection (o), each committee of jurisdiction of Con-

1 gress, the Committee on Finance of the Senate, the Committee  
2 on Health, Education, Labor, and Pensions of the Senate, the  
3 Committee on Ways and Means of the House of Representa-  
4 tives, the Committee on Energy and Commerce of the House  
5 of Representatives, Committee on Education and the Workforce  
6 of the House of Representatives, shall hold at least 1 hearing  
7 on such report and on the final recommendations of the Work-  
8 ing Group submitted under subsection (i).

9 (q) AUTHORIZATION OF APPROPRIATIONS.—

10 (1) IN GENERAL.—There are authorized to be appro-  
11 priated to carry out this section, other than subsection  
12 (h)(3), \$3,000,000 for each of fiscal years 2005 and 2006.

13 (2) HEALTH REPORT TO THE AMERICAN PEOPLE.—  
14 There are authorized to be appropriated for the preparation  
15 and dissemination of the Health Report to the American  
16 People described in subsection (h)(3), such sums as may be  
17 necessary for the fiscal year in which the report is required  
18 to be submitted.

19 **SEC. 1015. FUNDING START-UP ADMINISTRATIVE COSTS**  
20 **FOR MEDICARE REFORM.**

21 (a) IN GENERAL.—There are appropriated to carry out  
22 this Act (including the amendments made by this Act), to be  
23 transferred from the Federal Hospital Insurance Trust Fund  
24 and the Federal Supplementary Medical Insurance Trust  
25 Fund—

26 (1) not to exceed \$1,000,000,000 for the Centers for  
27 Medicare & Medicaid Services; and

28 (2) not to exceed \$500,000,000 for the Social Security  
29 Administration.

30 (b) AVAILABILITY.—Amounts provided under subsection  
31 (a) shall remain available until September 30, 2005.

32 (c) APPLICATION.—From amounts provided under sub-  
33 section (a)(2), the Social Security Administration may reim-  
34 burse the Internal Revenue Service for expenses in carrying out  
35 this Act (and the amendments made by this Act).

36 (d) TRANSFER.—The President may transfer amounts  
37 provided under subsection (a) between the Centers for Medicare

1 & Medicaid Services and the Social Security Administration.  
2 Notice of such transfers shall be transmitted within 15 days to  
3 the authorizing committees of the House of Representatives  
4 and of the Senate.

5 **SEC. 1016. HEALTH CARE INFRASTRUCTURE IMPROVE-**  
6 **MENT PROGRAM.**

7 Title XVIII is amended by adding at the end the following  
8 new section:

9 “HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

10 “SEC. 1897. (a) ESTABLISHMENT.—The Secretary shall  
11 establish a loan program that provides loans to qualifying hos-  
12 pitals for payment of the capital costs of projects described in  
13 subsection (d).

14 “(b) APPLICATION.—No loan may be provided under this  
15 section to a qualifying hospital except pursuant to an applica-  
16 tion that is submitted and approved in a time, manner, and  
17 form specified by the Secretary. A loan under this section shall  
18 be on such terms and conditions and meet such requirements  
19 as the Secretary determines appropriate.

20 “(c) SELECTION CRITERIA.—

21 “(1) IN GENERAL.—The Secretary shall establish cri-  
22 teria for selecting among qualifying hospitals that apply for  
23 a loan under this section. Such criteria shall consider the  
24 extent to which the project for which loan is sought is na-  
25 tionally or regionally significant, in terms of expanding or  
26 improving the health care infrastructure of the United  
27 States or the region or in terms of the medical benefit that  
28 the project will have.

29 “(2) QUALIFYING HOSPITAL DEFINED.—For purposes  
30 of this section, the term ‘qualifying hospital’ means a hos-  
31 pital that—

32 “(A) is engaged in research in the causes, preven-  
33 tion, and treatment of cancer; and

34 “(B) is designated as a cancer center for the Na-  
35 tional Cancer Institute or is designated by the State as  
36 the official cancer institute of the State.

1           “(d) PROJECTS.—A project described in this subsection is  
2 a project of a qualifying hospital that is designed to improve  
3 the health care infrastructure of the hospital, including con-  
4 struction, renovation, or other capital improvements.

5           “(e) STATE AND LOCAL PERMITS.—The provision of a  
6 loan under this section with respect to a project shall not—

7           “(1) relieve any recipient of the loan of any obligation  
8 to obtain any required State or local permit or approval  
9 with respect to the project;

10           “(2) limit the right of any unit of State or local gov-  
11 ernment to approve or regulate any rate of return on pri-  
12 vate equity invested in the project; or

13           “(3) otherwise supersede any State or local law (in-  
14 cluding any regulation) applicable to the construction or  
15 operation of the project.

16           “(f) FORGIVENESS OF INDEBTEDNESS.—The Secretary  
17 may forgive a loan provided to a qualifying hospital under this  
18 section under terms and conditions that are analogous to the  
19 loan forgiveness provision for student loans under part D of  
20 title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a  
21 et seq.), except that the Secretary shall condition such forgive-  
22 ness on the establishment by the hospital of—

23           “(A) an outreach program for cancer prevention,  
24 early diagnosis, and treatment that provides services to  
25 a substantial majority of the residents of a State or re-  
26 gion, including residents of rural areas;

27           “(B) an outreach program for cancer prevention,  
28 early diagnosis, and treatment that provides services to  
29 multiple Indian tribes; and

30           “(C)(i) unique research resources (such as popu-  
31 lation databases); or

32           “(ii) an affiliation with an entity that has unique  
33 research resources.

34           “(g) FUNDING.—

35           “(1) IN GENERAL.—There are appropriated, out of  
36 amounts in the Treasury not otherwise appropriated, to  
37 carry out this section, \$200,000,000, to remain available

1 during the period beginning on July 1, 2004, and ending  
2 on September 30, 2008.

3 “(2) ADMINISTRATIVE COSTS.—From funds made  
4 available under paragraph (1), the Secretary may use, for  
5 the administration of this section, not more than  
6 \$2,000,000 for each of fiscal years 2004 through 2008.

7 “(3) AVAILABILITY.—Amounts appropriated under  
8 this section shall be available for obligation on July 1,  
9 2004.

10 “(h) REPORT TO CONGRESS.—Not later than 4 years after  
11 the date of the enactment of this section, the Secretary shall  
12 submit to Congress a report on the projects for which loans are  
13 provided under this section and a recommendation as to wheth-  
14 er the Congress should authorize the Secretary to continue  
15 loans under this section beyond fiscal year 2008.”.

16 **TITLE XI—ACCESS TO**  
17 **AFFORDABLE PHARMACEUTICALS**  
18 **Subtitle A—Access to Affordable**  
19 **Pharmaceuticals**

20 **SEC. 1101. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

21 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Section  
22 505(j) of the Federal Food, Drug, and Cosmetic Act (21  
23 U.S.C. 355(j)) is amended—

24 (1) in paragraph (2)—

25 (A) by striking subparagraph (B) and inserting  
26 the following:

27 “(B) NOTICE OF OPINION THAT PATENT IS INVALID OR  
28 WILL NOT BE INFRINGED.—

29 “(i) AGREEMENT TO GIVE NOTICE.—An applicant that  
30 makes a certification described in subparagraph  
31 (A)(vii)(IV) shall include in the application a statement  
32 that the applicant will give notice as required by this sub-  
33 paragraph.

34 “(ii) TIMING OF NOTICE.—An applicant that makes a  
35 certification described in subparagraph (A)(vii)(IV) shall  
36 give notice as required under this subparagraph—

1           “(I) if the certification is in the application, not  
2 later than 20 days after the date of the postmark on  
3 the notice with which the Secretary informs the appli-  
4 cant that the application has been filed; or

5           “(II) if the certification is in an amendment or  
6 supplement to the application, at the time at which the  
7 applicant submits the amendment or supplement, re-  
8 gardless of whether the applicant has already given no-  
9 tice with respect to another such certification contained  
10 in the application or in an amendment or supplement  
11 to the application.

12           “(iii) RECIPIENTS OF NOTICE.—An applicant required  
13 under this subparagraph to give notice shall give notice  
14 to—

15           “(I) each owner of the patent that is the subject  
16 of the certification (or a representative of the owner  
17 designated to receive such a notice); and

18           “(II) the holder of the approved application under  
19 subsection (b) for the drug that is claimed by the pat-  
20 ent or a use of which is claimed by the patent (or a  
21 representative of the holder designated to receive such  
22 a notice).

23           “(iv) CONTENTS OF NOTICE.—A notice required under  
24 this subparagraph shall—

25           “(I) state that an application that contains data  
26 from bioavailability or bioequivalence studies has been  
27 submitted under this subsection for the drug with re-  
28 spect to which the certification is made to obtain ap-  
29 proval to engage in the commercial manufacture, use,  
30 or sale of the drug before the expiration of the patent  
31 referred to in the certification; and

32           “(II) include a detailed statement of the factual  
33 and legal basis of the opinion of the applicant that the  
34 patent is invalid or will not be infringed.”; and

35           (B) by adding at the end the following subpara-  
36 graph:

1           “(D)(i) An applicant may not amend or supplement an ap-  
2     plication to seek approval of a drug referring to a different list-  
3     ed drug from the listed drug identified in the application as  
4     submitted to the Secretary.

5           “(ii) With respect to the drug for which an application is  
6     submitted, nothing in this subsection prohibits an applicant  
7     from amending or supplementing the application to seek ap-  
8     proval of a different strength.

9           “(iii) Within 60 days after the date of the enactment of  
10    the Medicare Prescription Drug, Improvement, and Moderniza-  
11    tion Act of 2003, the Secretary shall issue guidance defining  
12    the term ‘listed drug’ for purposes of this subparagraph.”; and

13           (2) in paragraph (5)—

14           (A) in subparagraph (B)—

15           (i) by striking “under the following” and in-  
16     serting “by applying the following to each certifi-  
17     cation made under paragraph (2)(A)(vii)”;

18           (ii) in clause (iii)—

19           (I) in the first sentence, by striking “un-  
20     less” and all that follows and inserting “unless,  
21     before the expiration of 45 days after the date  
22     on which the notice described in paragraph  
23     (2)(B) is received, an action is brought for in-  
24     fringement of the patent that is the subject of  
25     the certification and for which information was  
26     submitted to the Secretary under subsection  
27     (b)(1) or (c)(2) before the date on which the  
28     application (excluding an amendment or sup-  
29     plement to the application), which the Sec-  
30     retary later determines to be substantially com-  
31     plete, was submitted.”; and

32           (II) in the second sentence—

33           (aa) by striking subclause (I) and in-  
34     serting the following:

35           “(I) if before the expiration of such period the dis-  
36     trict court decides that the patent is invalid or not in-  
37     fringed (including any substantive determination that

1           there is no cause of action for patent infringement or  
2           invalidity), the approval shall be made effective on—

3                   “(aa) the date on which the court enters judg-  
4                   ment reflecting the decision; or

5                   “(bb) the date of a settlement order or consent  
6                   decree signed and entered by the court stating that  
7                   the patent that is the subject of the certification is  
8                   invalid or not infringed;”;

9                           (bb) by striking subclause (II) and in-  
10                           serting the following:

11                   “(II) if before the expiration of such period the  
12                   district court decides that the patent has been  
13                   infringed—

14                           “(aa) if the judgment of the district court is  
15                           appealed, the approval shall be made effective on—

16                                   “(AA) the date on which the court of ap-  
17                                   peals decides that the patent is invalid or not  
18                                   infringed (including any substantive determina-  
19                                   tion that there is no cause of action for patent  
20                                   infringement or invalidity); or

21                                   “(BB) the date of a settlement order or  
22                                   consent decree signed and entered by the court  
23                                   of appeals stating that the patent that is the  
24                                   subject of the certification is invalid or not in-  
25                                   fringed; or

26                                   “(bb) if the judgment of the district court is  
27                                   not appealed or is affirmed, the approval shall be  
28                                   made effective on the date specified by the district  
29                                   court in a court order under section 271(e)(4)(A)  
30                                   of title 35, United States Code;”;

31   (cc) in subclause (III), by striking “on  
32   the date of such court decision.” and in-  
33   serting “as provided in subclause (I); or”;

34   (dd) by inserting after subclause (III)  
35   the following:

36                                   “(IV) if before the expiration of such period the  
37                                   court grants a preliminary injunction prohibiting the



1 applicant from engaging in the commercial manufac-  
2 ture or sale of the drug until the court decides the  
3 issues of patent validity and infringement and if the  
4 court decides that such patent has been infringed, the  
5 approval shall be made effective as provided in sub-  
6 clause (II).”; and

7 (ee) in the matter after and below sub-  
8 clause (IV) (as added by item (dd)), by  
9 striking “Until the expiration” and all that  
10 follows;

11 (B) by redesignating subparagraphs (C) and (D)  
12 as subparagraphs (E) and (F), respectively; and

13 (C) by inserting after subparagraph (B) the fol-  
14 lowing:

15 “(C) CIVIL ACTION TO OBTAIN PATENT CER-  
16 TAINTY.—

17 “(i) DECLARATORY JUDGMENT ABSENT IN-  
18 FRINGEMENT ACTION.—

19 “(I) IN GENERAL.—No action may be  
20 brought under section 2201 of title 28, United  
21 States Code, by an applicant under paragraph  
22 (2) for a declaratory judgment with respect to  
23 a patent which is the subject of the certifi-  
24 cation referred to in subparagraph (B)(iii)  
25 unless—

26 “(aa) the forty-five day period referred  
27 to in such subparagraph has expired;

28 “(bb) neither the owner of such patent  
29 nor the holder of the approved application  
30 under subsection (b) for the drug that is  
31 claimed by the patent or a use of which is  
32 claimed by the patent brought a civil action  
33 against the applicant for infringement of  
34 the patent before the expiration of such pe-  
35 riod; and

36 “(cc) in any case in which the notice  
37 provided under paragraph (2)(B) relates to

1 noninfringement, the notice was accom-  
2 panied by a document described in sub-  
3 clause (III).

4 “(II) FILING OF CIVIL ACTION.—If the  
5 conditions described in items (aa), (bb), and as  
6 applicable, (cc) of subclause (I) have been met,  
7 the applicant referred to in such subclause  
8 may, in accordance with section 2201 of title  
9 28, United States Code, bring a civil action  
10 under such section against the owner or holder  
11 referred to in such subclause (but not against  
12 any owner or holder that has brought such a  
13 civil action against the applicant, unless that  
14 civil action was dismissed without prejudice)  
15 for a declaratory judgment that the patent is  
16 invalid or will not be infringed by the drug for  
17 which the applicant seeks approval, except that  
18 such civil action may be brought for a declara-  
19 tory judgment that the patent will not be in-  
20 fringed only in a case in which the condition  
21 described in subclause (I)(cc) is applicable. A  
22 civil action referred to in this subclause shall be  
23 brought in the judicial district where the de-  
24 fendant has its principal place of business or a  
25 regular and established place of business.

26 “(III) OFFER OF CONFIDENTIAL ACCESS  
27 TO APPLICATION.—For purposes of subclause  
28 (I)(cc), the document described in this sub-  
29 clause is a document providing an offer of con-  
30 fidential access to the application that is in the  
31 custody of the applicant under paragraph (2)  
32 for the purpose of determining whether an ac-  
33 tion referred to in subparagraph (B)(iii) should  
34 be brought. The document providing the offer  
35 of confidential access shall contain such restric-  
36 tions as to persons entitled to access, and on  
37 the use and disposition of any information

1 accessed, as would apply had a protective order  
2 been entered for the purpose of protecting  
3 trade secrets and other confidential business in-  
4 formation. A request for access to an applica-  
5 tion under an offer of confidential access shall  
6 be considered acceptance of the offer of con-  
7 fidential access with the restrictions as to per-  
8 sons entitled to access, and on the use and dis-  
9 position of any information accessed, contained  
10 in the offer of confidential access, and those re-  
11 strictions and other terms of the offer of con-  
12 fidential access shall be considered terms of an  
13 enforceable contract. Any person provided an  
14 offer of confidential access shall review the ap-  
15 plication for the sole and limited purpose of  
16 evaluating possible infringement of the patent  
17 that is the subject of the certification under  
18 paragraph (2)(A)(vii)(IV) and for no other pur-  
19 pose, and may not disclose information of no  
20 relevance to any issue of patent infringement to  
21 any person other than a person provided an  
22 offer of confidential access. Further, the appli-  
23 cation may be redacted by the applicant to re-  
24 move any information of no relevance to any  
25 issue of patent infringement.

26 “(ii) COUNTERCLAIM TO INFRINGEMENT AC-  
27 TION.—

28 “(I) IN GENERAL.—If an owner of the  
29 patent or the holder of the approved applica-  
30 tion under subsection (b) for the drug that is  
31 claimed by the patent or a use of which is  
32 claimed by the patent brings a patent infringe-  
33 ment action against the applicant, the appli-  
34 cant may assert a counterclaim seeking an  
35 order requiring the holder to correct or delete  
36 the patent information submitted by the holder

1 under subsection (b) or (c) on the ground that  
2 the patent does not claim either—

3 “(aa) the drug for which the applica-  
4 tion was approved; or

5 “(bb) an approved method of using  
6 the drug.

7 “(II) NO INDEPENDENT CAUSE OF AC-  
8 TION.—Subclause (I) does not authorize the as-  
9 sertion of a claim described in subclause (I) in  
10 any civil action or proceeding other than a  
11 counterclaim described in subclause (I).

12 “(iii) NO DAMAGES.—An applicant shall not  
13 be entitled to damages in a civil action under sub-  
14 paragraph (i) or a counterclaim under subpara-  
15 graph (ii).”.

16 (b) APPLICATIONS GENERALLY.—Section 505 of the Fed-  
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) is  
18 amended—

19 (1) in subsection (b)—

20 (A) by striking paragraph (3) and inserting the  
21 following:

22 “(3) NOTICE OF OPINION THAT PATENT IS INVALID OR  
23 WILL NOT BE INFRINGED.—

24 “(A) AGREEMENT TO GIVE NOTICE.—An applicant  
25 that makes a certification described in paragraph (2)(A)(iv)  
26 shall include in the application a statement that the appli-  
27 cant will give notice as required by this paragraph.

28 “(B) TIMING OF NOTICE.—An applicant that makes a  
29 certification described in paragraph (2)(A)(iv) shall give  
30 notice as required under this paragraph—

31 “(i) if the certification is in the application, not  
32 later than 20 days after the date of the postmark on  
33 the notice with which the Secretary informs the appli-  
34 cant that the application has been filed; or

35 “(ii) if the certification is in an amendment or  
36 supplement to the application, at the time at which the  
37 applicant submits the amendment or supplement, re-

1            regardless of whether the applicant has already given no-  
2            tice with respect to another such certification contained  
3            in the application or in an amendment or supplement  
4            to the application.

5            “(C) RECIPIENTS OF NOTICE.—An applicant required  
6            under this paragraph to give notice shall give notice to—

7            “(i) each owner of the patent that is the subject  
8            of the certification (or a representative of the owner  
9            designated to receive such a notice); and

10           “(ii) the holder of the approved application under  
11           this subsection for the drug that is claimed by the pat-  
12           ent or a use of which is claimed by the patent (or a  
13           representative of the holder designated to receive such  
14           a notice).

15           “(D) CONTENTS OF NOTICE.—A notice required under  
16           this paragraph shall—

17           “(i) state that an application that contains data  
18           from bioavailability or bioequivalence studies has been  
19           submitted under this subsection for the drug with re-  
20           spect to which the certification is made to obtain ap-  
21           proval to engage in the commercial manufacture, use,  
22           or sale of the drug before the expiration of the patent  
23           referred to in the certification; and

24           “(ii) include a detailed statement of the factual  
25           and legal basis of the opinion of the applicant that the  
26           patent is invalid or will not be infringed.”; and

27           (B)(i) by redesignating paragraph (4) as para-  
28           graph (5); and

29           (ii) by inserting after paragraph (3) the following  
30           paragraph:

31           “(4)(A) An applicant may not amend or supplement an  
32           application referred to in paragraph (2) to seek approval of a  
33           drug that is a different drug than the drug identified in the  
34           application as submitted to the Secretary.

35           “(B) With respect to the drug for which such an applica-  
36           tion is submitted, nothing in this subsection or subsection

1 (c)(3) prohibits an applicant from amending or supplementing  
2 the application to seek approval of a different strength.”; and

3 (2) in subsection (c)(3)—

4 (A) in the first sentence, by striking “under the  
5 following” and inserting “by applying the following to  
6 each certification made under subsection (b)(2)(A)(iv)”;

7 (B) in subparagraph (C)—

8 (i) in the first sentence, by striking “unless”  
9 and all that follows and inserting “unless, before  
10 the expiration of 45 days after the date on which  
11 the notice described in subsection (b)(3) is received,  
12 an action is brought for infringement of the patent  
13 that is the subject of the certification and for which  
14 information was submitted to the Secretary under  
15 paragraph (2) or subsection (b)(1) before the date  
16 on which the application (excluding an amendment  
17 or supplement to the application) was submitted.”;

18 (ii) in the second sentence—

19 (I) by striking “paragraph (3)(B)” and in-  
20 serting “subsection (b)(3)”;

21 (II) by striking clause (i) and inserting the  
22 following:

23 “(i) if before the expiration of such period the dis-  
24 trict court decides that the patent is invalid or not in-  
25 fringed (including any substantive determination that  
26 there is no cause of action for patent infringement or  
27 invalidity), the approval shall be made effective on—

28 “(I) the date on which the court enters judg-  
29 ment reflecting the decision; or

30 “(II) the date of a settlement order or consent  
31 decree signed and entered by the court stating that  
32 the patent that is the subject of the certification is  
33 invalid or not infringed;”;

34 (III) by striking clause (ii) and inserting  
35 the following:

36 “(ii) if before the expiration of such period the dis-  
37 trict court decides that the patent has been infringed—

1                   “(I) if the judgment of the district court is ap-  
2 pealed, the approval shall be made effective on—

3                   “(aa) the date on which the court of ap-  
4 peals decides that the patent is invalid or not  
5 infringed (including any substantive determina-  
6 tion that there is no cause of action for patent  
7 infringement or invalidity); or

8                   “(bb) the date of a settlement order or  
9 consent decree signed and entered by the court  
10 of appeals stating that the patent that is the  
11 subject of the certification is invalid or not in-  
12 fringed; or

13                   “(II) if the judgment of the district court is  
14 not appealed or is affirmed, the approval shall be  
15 made effective on the date specified by the district  
16 court in a court order under section 271(e)(4)(A)  
17 of title 35, United States Code;”;

18                   (IV) in clause (iii), by striking “on the  
19 date of such court decision.” and inserting “as  
20 provided in clause (i); or”;

21                   (V) by inserting after clause (iii), the fol-  
22 lowing:

23                   “(iv) if before the expiration of such period the  
24 court grants a preliminary injunction prohibiting the  
25 applicant from engaging in the commercial manufac-  
26 ture or sale of the drug until the court decides the  
27 issues of patent validity and infringement and if the  
28 court decides that such patent has been infringed, the  
29 approval shall be made effective as provided in clause  
30 (ii).”; and

31                   (VI) in the matter after and below clause  
32 (iv) (as added by subclause (V)), by striking  
33 “Until the expiration” and all that follows; and

34                   (iii) in the third sentence, by striking “para-  
35 graph (3)(B)” and inserting “subsection (b)(3)”;

36                   (C) by redesignating subparagraph (D) as sub-  
37 paragraph (E); and

1 (D) by inserting after subparagraph (C) the fol-  
2 lowing:

3 “(D) CIVIL ACTION TO OBTAIN PATENT CER-  
4 TAINTY.—

5 “(i) DECLARATORY JUDGMENT ABSENT IN-  
6 FRINGEMENT ACTION.—

7 “(I) IN GENERAL.—No action may be  
8 brought under section 2201 of title 28, United  
9 States Code, by an applicant referred to in sub-  
10 section (b)(2) for a declaratory judgment with  
11 respect to a patent which is the subject of the  
12 certification referred to in subparagraph (C)  
13 unless—

14 “(aa) the forty-five day period referred  
15 to in such subparagraph has expired;

16 “(bb) neither the owner of such patent  
17 nor the holder of the approved application  
18 under subsection (b) for the drug that is  
19 claimed by the patent or a use of which is  
20 claimed by the patent brought a civil action  
21 against the applicant for infringement of  
22 the patent before the expiration of such pe-  
23 riod; and

24 “(cc) in any case in which the notice  
25 provided under paragraph (2)(B) relates to  
26 noninfringement, the notice was accom-  
27 panied by a document described in sub-  
28 clause (III).

29 “(II) FILING OF CIVIL ACTION.—If the  
30 conditions described in items (aa), (bb), and as  
31 applicable, (cc) of subclause (I) have been met,  
32 the applicant referred to in such subclause  
33 may, in accordance with section 2201 of title  
34 28, United States Code, bring a civil action  
35 under such section against the owner or holder  
36 referred to in such subclause (but not against  
37 any owner or holder that has brought such a



1 civil action against the applicant, unless that  
2 civil action was dismissed without prejudice)  
3 for a declaratory judgment that the patent is  
4 invalid or will not be infringed by the drug for  
5 which the applicant seeks approval, except that  
6 such civil action may be brought for a declara-  
7 tory judgment that the patent will not be in-  
8 fringed only in a case in which the condition  
9 described in subclause (I)(cc) is applicable. A  
10 civil action referred to in this subclause shall be  
11 brought in the judicial district where the de-  
12 fendant has its principal place of business or a  
13 regular and established place of business.

14 “(III) OFFER OF CONFIDENTIAL ACCESS  
15 TO APPLICATION.—For purposes of subclause  
16 (I)(cc), the document described in this sub-  
17 clause is a document providing an offer of con-  
18 fidential access to the application that is in the  
19 custody of the applicant referred to in sub-  
20 section (b)(2) for the purpose of determining  
21 whether an action referred to in subparagraph  
22 (C) should be brought. The document providing  
23 the offer of confidential access shall contain  
24 such restrictions as to persons entitled to ac-  
25 cess, and on the use and disposition of any in-  
26 formation accessed, as would apply had a pro-  
27 tective order been entered for the purpose of  
28 protecting trade secrets and other confidential  
29 business information. A request for access to  
30 an application under an offer of confidential ac-  
31 cess shall be considered acceptance of the offer  
32 of confidential access with the restrictions as to  
33 persons entitled to access, and on the use and  
34 disposition of any information accessed, con-  
35 tained in the offer of confidential access, and  
36 those restrictions and other terms of the offer  
37 of confidential access shall be considered terms

1 of an enforceable contract. Any person provided  
2 an offer of confidential access shall review the  
3 application for the sole and limited purpose of  
4 evaluating possible infringement of the patent  
5 that is the subject of the certification under  
6 subsection (b)(2)(A)(iv) and for no other pur-  
7 pose, and may not disclose information of no  
8 relevance to any issue of patent infringement to  
9 any person other than a person provided an  
10 offer of confidential access. Further, the appli-  
11 cation may be redacted by the applicant to re-  
12 move any information of no relevance to any  
13 issue of patent infringement.

14 “(ii) COUNTERCLAIM TO INFRINGEMENT AC-  
15 TION.—

16 “(I) IN GENERAL.—If an owner of the  
17 patent or the holder of the approved applica-  
18 tion under subsection (b) for the drug that is  
19 claimed by the patent or a use of which is  
20 claimed by the patent brings a patent infringe-  
21 ment action against the applicant, the appli-  
22 cant may assert a counterclaim seeking an  
23 order requiring the holder to correct or delete  
24 the patent information submitted by the holder  
25 under subsection (b) or this subsection on the  
26 ground that the patent does not claim either—

27 “(aa) the drug for which the applica-  
28 tion was approved; or

29 “(bb) an approved method of using  
30 the drug.

31 “(II) NO INDEPENDENT CAUSE OF AC-  
32 TION.—Subclause (I) does not authorize the as-  
33 sertion of a claim described in subclause (I) in  
34 any civil action or proceeding other than a  
35 counterclaim described in subclause (I).

1                   “(iii) NO DAMAGES.—An applicant shall not  
2                   be entitled to damages in a civil action under  
3                   clause (i) or a counterclaim under clause (ii).”.

4                   (c) APPLICABILITY.—

5                   (1) IN GENERAL.—Except as provided in paragraphs  
6                   (2) and (3), the amendments made by subsections (a), (b),  
7                   and (c) apply to any proceeding under section 505 of the  
8                   Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
9                   that is pending on or after the date of the enactment of  
10                  this Act regardless of the date on which the proceeding was  
11                  commenced or is commenced.

12                  (2) NOTICE OF OPINION THAT PATENT IS INVALID OR  
13                  WILL NOT BE INFRINGED.—The amendments made by sub-  
14                  sections (a)(1) and (b)(1) apply with respect to any certifi-  
15                  cation under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)  
16                  of section 505 of the Federal Food, Drug, and Cosmetic  
17                  Act (21 U.S.C. 355) submitted on or after August 18,  
18                  2003, in an application filed under subsection (b) or (j) of  
19                  that section or in an amendment or supplement to an ap-  
20                  plication filed under subsection (b) or (j) of that section.

21                  (3) EFFECTIVE DATE OF APPROVAL.—The amend-  
22                  ments made by subsections (a)(2)(A)(ii)(I) and (b)(2)(B)(i)  
23                  apply with respect to any patent information submitted  
24                  under subsection (b)(1) or (c)(2) of section 505 of the Fed-  
25                  eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) on or  
26                  after August 18, 2003.

27                  (d) INFRINGEMENT ACTIONS.—Section 271(e) of title 35,  
28                  United States Code, is amended by adding at the end the fol-  
29                  lowing:

30                  “(5) Where a person has filed an application described in  
31                  paragraph (2) that includes a certification under subsection  
32                  (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal  
33                  Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither  
34                  the owner of the patent that is the subject of the certification  
35                  nor the holder of the approved application under subsection (b)  
36                  of such section for the drug that is claimed by the patent or  
37                  a use of which is claimed by the patent brought an action for

1 infringement of such patent before the expiration of 45 days  
2 after the date on which the notice given under subsection (b)(3)  
3 or (j)(2)(B) of such section was received, the courts of the  
4 United States shall, to the extent consistent with the Constitu-  
5 tion, have subject matter jurisdiction in any action brought by  
6 such person under section 2201 of title 28 for a declaratory  
7 judgment that such patent is invalid or not infringed.”.

8 **SEC. 1102. FORFEITURE OF 180-DAY EXCLUSIVITY PE-**  
9 **RIOD.**

10 (a) IN GENERAL.—Section 505(j)(5) of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by  
12 section 1101) is amended—

13 (1) in subparagraph (B), by striking clause (iv) and  
14 inserting the following:

15 “(iv) 180-DAY EXCLUSIVITY PERIOD.—

16 “(I) EFFECTIVENESS OF APPLICATION.—Subject  
17 to subparagraph (D), if the application contains a cer-  
18 tification described in paragraph (2)(A)(vii)(IV) and is  
19 for a drug for which a first applicant has submitted an  
20 application containing such a certification, the applica-  
21 tion shall be made effective on the date that is 180  
22 days after the date of the first commercial marketing  
23 of the drug (including the commercial marketing of the  
24 listed drug) by any first applicant.

25 “(II) DEFINITIONS.—In this paragraph:

26 “(aa) 180-DAY EXCLUSIVITY PERIOD.—The  
27 term ‘180-day exclusivity period’ means the 180-  
28 day period ending on the day before the date on  
29 which an application submitted by an applicant  
30 other than a first applicant could become effective  
31 under this clause.

32 “(bb) FIRST APPLICANT.—As used in this sub-  
33 section, the term ‘first applicant’ means an appli-  
34 cant that, on the first day on which a substantially  
35 complete application containing a certification de-  
36 scribed in paragraph (2)(A)(vii)(IV) is submitted  
37 for approval of a drug, submits a substantially

1 complete application that contains and lawfully  
2 maintains a certification described in paragraph  
3 (2)(A)(vii)(IV) for the drug.

4 “(cc) SUBSTANTIALLY COMPLETE APPLICA-  
5 TION.—As used in this subsection, the term ‘sub-  
6 stantially complete application’ means an applica-  
7 tion under this subsection that on its face is suffi-  
8 ciently complete to permit a substantive review and  
9 contains all the information required by paragraph  
10 (2)(A).

11 “(dd) TENTATIVE APPROVAL.—

12 “(AA) IN GENERAL.—The term ‘tentative  
13 approval’ means notification to an applicant by  
14 the Secretary that an application under this  
15 subsection meets the requirements of para-  
16 graph (2)(A), but cannot receive effective ap-  
17 proval because the application does not meet  
18 the requirements of this subparagraph, there is  
19 a period of exclusivity for the listed drug under  
20 subparagraph (E) or section 505A, or there is  
21 a 7-year period of exclusivity for the listed drug  
22 under section 527.

23 “(BB) LIMITATION.—A drug that is  
24 granted tentative approval by the Secretary is  
25 not an approved drug and shall not have an ef-  
26 fective approval until the Secretary issues an  
27 approval after any necessary additional review  
28 of the application.”; and

29 (2) by inserting after subparagraph (C) the following:

30 “(D) FORFEITURE OF 180-DAY EXCLUSIVITY PE-  
31 RIOD.—

32 “(i) DEFINITION OF FORFEITURE EVENT.—In  
33 this subparagraph, the term ‘forfeiture event’, with  
34 respect to an application under this subsection,  
35 means the occurrence of any of the following:

1                   “(I) FAILURE TO MARKET.—The first ap-  
2                   plicant fails to market the drug by the later  
3                   of—

4                   “(aa) the earlier of the date that is—

5                   “(AA) 75 days after the date on  
6                   which the approval of the application of  
7                   the first applicant is made effective  
8                   under subparagraph (B)(iii); or

9                   “(BB) 30 months after the date of  
10                  submission of the application of the  
11                  first applicant; or

12                  “(bb) with respect to the first appli-  
13                  cant or any other applicant (which other  
14                  applicant has received tentative approval),  
15                  the date that is 75 days after the date as  
16                  of which, as to each of the patents with re-  
17                  spect to which the first applicant submitted  
18                  and lawfully maintained a certification  
19                  qualifying the first applicant for the 180-  
20                  day exclusivity period under subparagraph  
21                  (B)(iv), at least 1 of the following has oc-  
22                  curred:

23                  “(AA) In an infringement action  
24                  brought against that applicant with re-  
25                  spect to the patent or in a declaratory  
26                  judgment action brought by that appli-  
27                  cant with respect to the patent, a court  
28                  enters a final decision from which no  
29                  appeal (other than a petition to the Su-  
30                  preme Court for a writ of certiorari)  
31                  has been or can be taken that the pat-  
32                  ent is invalid or not infringed.

33                  “(BB) In an infringement action  
34                  or a declaratory judgment action de-  
35                  scribed in subitem (AA), a court signs  
36                  a settlement order or consent decree  
37                  that enters a final judgment that in-

1 includes a finding that the patent is in-  
2 valid or not infringed.

3 “(CC) The patent information  
4 submitted under subsection (b) or (c) is  
5 withdrawn by the holder of the applica-  
6 tion approved under subsection (b).

7 “(II) WITHDRAWAL OF APPLICATION.—  
8 The first applicant withdraws the application  
9 or the Secretary considers the application to  
10 have been withdrawn as a result of a deter-  
11 mination by the Secretary that the application  
12 does not meet the requirements for approval  
13 under paragraph (4).

14 “(III) AMENDMENT OF CERTIFICATION.—  
15 The first applicant amends or withdraws the  
16 certification for all of the patents with respect  
17 to which that applicant submitted a certifi-  
18 cation qualifying the applicant for the 180-day  
19 exclusivity period.

20 “(IV) FAILURE TO OBTAIN TENTATIVE AP-  
21 PROVAL.—The first applicant fails to obtain  
22 tentative approval of the application within 30  
23 months after the date on which the application  
24 is filed, unless the failure is caused by a change  
25 in or a review of the requirements for approval  
26 of the application imposed after the date on  
27 which the application is filed.

28 “(V) AGREEMENT WITH ANOTHER APPLI-  
29 CANT, THE LISTED DRUG APPLICATION HOLD-  
30 ER, OR A PATENT OWNER.—The first applicant  
31 enters into an agreement with another appli-  
32 cant under this subsection for the drug, the  
33 holder of the application for the listed drug, or  
34 an owner of the patent that is the subject of  
35 the certification under paragraph  
36 (2)(A)(vii)(IV), the Federal Trade Commission  
37 or the Attorney General files a complaint, and

1           there is a final decision of the Federal Trade  
2           Commission or the court with regard to the  
3           complaint from which no appeal (other than a  
4           petition to the Supreme Court for a writ of cer-  
5           tiorari) has been or can be taken that the  
6           agreement has violated the antitrust laws (as  
7           defined in section 1 of the Clayton Act (15  
8           U.S.C. 12), except that the term includes sec-  
9           tion 5 of the Federal Trade Commission Act  
10          (15 U.S.C. 45) to the extent that that section  
11          applies to unfair methods of competition).

12           “(VI) EXPIRATION OF ALL PATENTS.—All  
13          of the patents as to which the applicant sub-  
14          mitted a certification qualifying it for the 180-  
15          day exclusivity period have expired.

16           “(ii) FORFEITURE.—The 180-day exclusivity  
17          period described in subparagraph (B)(iv) shall be  
18          forfeited by a first applicant if a forfeiture event  
19          occurs with respect to that first applicant.

20           “(iii) SUBSEQUENT APPLICANT.—If all first  
21          applicants forfeit the 180-day exclusivity period  
22          under clause (ii)—

23           “(I) approval of any application containing  
24          a certification described in paragraph  
25          (2)(A)(vii)(IV) shall be made effective in ac-  
26          cordance with subparagraph (B)(iii); and

27           “(II) no applicant shall be eligible for a  
28          180-day exclusivity period.”.

29          (b) EFFECTIVE DATE.—

30           (1) IN GENERAL.—Except as provided in paragraph  
31          (2), the amendment made by subsection (a) shall be effec-  
32          tive only with respect to an application filed under section  
33          505(j) of the Federal Food, Drug, and Cosmetic Act (21  
34          U.S.C. 355(j)) after the date of the enactment of this Act  
35          for a listed drug for which no certification under section  
36          505(j)(2)(A)(vii)(IV) of that Act was made before the date  
37          of the enactment of this Act.



1           (2) COLLUSIVE AGREEMENTS.—If a forfeiture event  
2 described in section 505(j)(5)(D)(i)(V) of that Act occurs  
3 in the case of an applicant, the applicant shall forfeit the  
4 180-day period under section 505(j)(5)(B)(iv) of that Act  
5 without regard to when the first certification under section  
6 505(j)(2)(A)(vii)(IV) of that Act for the listed drug was  
7 made.

8           (3) DECISION OF A COURT WHEN THE 180-DAY EXCLU-  
9 SIVITY PERIOD HAS NOT BEEN TRIGGERED.—With respect  
10 to an application filed before, on, or after the date of the  
11 enactment of this Act for a listed drug for which a certifi-  
12 cation under section 505(j)(2)(A)(vii)(IV) of that Act was  
13 made before the date of the enactment of this Act and for  
14 which neither of the events described in subclause (I) or  
15 (II) of section 505(j)(5)(B)(iv) of that Act (as in effect on  
16 the day before the date of the enactment of this Act) has  
17 occurred on or before the date of the enactment of this Act,  
18 the term “decision of a court” as used in clause (iv) of sec-  
19 tion 505(j)(5)(B) of that Act means a final decision of a  
20 court from which no appeal (other than a petition to the  
21 Supreme Court for a writ of certiorari) has been or can be  
22 taken.

23 **SEC. 1103. BIOAVAILABILITY AND BIOEQUIVALENCE.**

24           (a) IN GENERAL.—Section 505(j)(8) of the Federal Food,  
25 Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

26           (1) by striking subparagraph (A) and inserting the fol-  
27 lowing:

28           “(A)(i) The term ‘bioavailability’ means the rate and  
29 extent to which the active ingredient or therapeutic ingre-  
30 dient is absorbed from a drug and becomes available at the  
31 site of drug action.

32           “(ii) For a drug that is not intended to be absorbed  
33 into the bloodstream, the Secretary may assess bio-  
34 availability by scientifically valid measurements intended to  
35 reflect the rate and extent to which the active ingredient  
36 or therapeutic ingredient becomes available at the site of  
37 drug action.”; and

1 (2) by adding at the end the following:

2 “(C) For a drug that is not intended to be absorbed  
3 into the bloodstream, the Secretary may establish alter-  
4 native, scientifically valid methods to show bioequivalence if  
5 the alternative methods are expected to detect a significant  
6 difference between the drug and the listed drug in safety  
7 and therapeutic effect.”.

8 (b) EFFECT OF AMENDMENT.—The amendment made by  
9 subsection (a) does not alter the standards for approval of  
10 drugs under section 505(j) of the Federal Food, Drug, and  
11 Cosmetic Act (21 U.S.C. 355(j)).

12 **SEC. 1104. CONFORMING AMENDMENTS.**

13 Section 505A of the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 355a) is amended—

15 (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by  
16 striking “(j)(5)(D)(ii)” each place it appears and inserting  
17 “(j)(5)(F)(ii)”;

18 (2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by  
19 striking “(j)(5)(D)” each place it appears and inserting  
20 “(j)(5)(F)”;

21 (3) in subsections (e) and (l), by striking  
22 “505(j)(5)(D)” each place it appears and inserting  
23 “505(j)(5)(F)”.

24 **Subtitle B—Federal Trade**  
25 **Commission Review**

26 **SEC. 1111. DEFINITIONS.**

27 In this subtitle:

28 (1) ANDA.—The term “ANDA” means an abbrevi-  
29 ated drug application, as defined under section 201(aa) of  
30 the Federal Food, Drug, and Cosmetic Act.

31 (2) ASSISTANT ATTORNEY GENERAL.—The term “As-  
32 sistant Attorney General” means the Assistant Attorney  
33 General in charge of the Antitrust Division of the Depart-  
34 ment of Justice.

35 (3) BRAND NAME DRUG.—The term “brand name  
36 drug” means a drug for which an application is approved

1 under section 505(c) of the Federal Food, Drug, and Cos-  
2 metic Act, including an application referred to in section  
3 505(b)(2) of such Act.

4 (4) BRAND NAME DRUG COMPANY.—The term “brand  
5 name drug company” means the party that holds the ap-  
6 proved application referred to in paragraph (2) for a brand  
7 name drug that is a listed drug in an ANDA, or a party  
8 that is the owner of a patent for which information is sub-  
9 mitted for such drug under subsection (b) or (c) of section  
10 505 of the Federal Food, Drug, and Cosmetic Act.

11 (5) COMMISSION.—The term “Commission” means the  
12 Federal Trade Commission.

13 (6) GENERIC DRUG.—The term “generic drug” means  
14 a drug for which an application under section 505(j) of the  
15 Federal Food, Drug, and Cosmetic Act is approved.

16 (7) GENERIC DRUG APPLICANT.—The term “generic  
17 drug applicant” means a person who has filed or received  
18 approval for an ANDA under section 505(j) of the Federal  
19 Food, Drug, and Cosmetic Act.

20 (8) LISTED DRUG.—The term “listed drug” means a  
21 brand name drug that is listed under section 505(j)(7) of  
22 the Federal Food, Drug, and Cosmetic Act.

23 **SEC. 1112. NOTIFICATION OF AGREEMENTS.**

24 (a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

25 (1) REQUIREMENT.—A generic drug applicant that  
26 has submitted an ANDA containing a certification under  
27 section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug,  
28 and Cosmetic Act and a brand name drug company that  
29 enter into an agreement described in paragraph (2) shall  
30 each file the agreement in accordance with subsection (c).  
31 The agreement shall be filed prior to the date of the first  
32 commercial marketing of the generic drug that is the sub-  
33 ject of the ANDA.

34 (2) SUBJECT MATTER OF AGREEMENT.—An agree-  
35 ment described in this paragraph between a generic drug  
36 applicant and a brand name drug company is an agreement  
37 regarding—

1 (A) the manufacture, marketing or sale of the  
2 brand name drug that is the listed drug in the ANDA  
3 involved;

4 (B) the manufacture, marketing, or sale of the ge-  
5 neric drug for which the ANDA was submitted; or

6 (C) the 180-day period referred to in section  
7 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cos-  
8 metic Act as it applies to such ANDA or to any other  
9 ANDA based on the same brand name drug.

10 (b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLI-  
11 CANT.—

12 (1) REQUIREMENT.—A generic drug applicant that  
13 has submitted an ANDA containing a certification under  
14 section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug,  
15 and Cosmetic Act with respect to a listed drug and another  
16 generic drug applicant that has submitted an ANDA con-  
17 taining such a certification for the same listed drug shall  
18 each file the agreement in accordance with subsection (c).  
19 The agreement shall be filed prior to the date of the first  
20 commercial marketing of either of the generic drugs for  
21 which such ANDAs were submitted.

22 (2) SUBJECT MATTER OF AGREEMENT.—An agree-  
23 ment described in this paragraph between two generic drug  
24 applicants is an agreement regarding the 180-day period  
25 referred to in section 505(j)(5)(B)(iv) of the Federal Food,  
26 Drug, and Cosmetic Act as it applies to the ANDAs with  
27 which the agreement is concerned.

28 (c) FILING.—

29 (1) AGREEMENT.—The parties that are required in  
30 subsection (a) or (b) to file an agreement in accordance  
31 with this subsection shall file with the Assistant Attorney  
32 General and the Commission the text of any such agree-  
33 ment, except that such parties are not required to file an  
34 agreement that solely concerns—

35 (A) purchase orders for raw material supplies;

36 (B) equipment and facility contracts;

37 (C) employment or consulting contracts; or

1 (D) packaging and labeling contracts.

2 (2) OTHER AGREEMENTS.—The parties that are re-  
3 quired in subsection (a) or (b) to file an agreement in ac-  
4 cordance with this subsection shall file with the Assistant  
5 Attorney General and the Commission the text of any  
6 agreements between the parties that are not described in  
7 such subsections and are contingent upon, provide a contin-  
8 gent condition for, or are otherwise related to an agreement  
9 that is required in subsection (a) or (b) to be filed in ac-  
10 cordance with this subsection.

11 (3) DESCRIPTION.—In the event that any agreement  
12 required in subsection (a) or (b) to be filed in accordance  
13 with this subsection has not been reduced to text, each of  
14 the parties involved shall file written descriptions of such  
15 agreement that are sufficient to disclose all the terms and  
16 conditions of the agreement.

17 **SEC. 1113. FILING DEADLINES.**

18 Any filing required under section 1112 shall be filed with  
19 the Assistant Attorney General and the Commission not later  
20 than 10 business days after the date the agreements are exe-  
21 cuted.

22 **SEC. 1114. DISCLOSURE EXEMPTION.**

23 Any information or documentary material filed with the  
24 Assistant Attorney General or the Commission pursuant to this  
25 subtitle shall be exempt from disclosure under section 552 of  
26 title 5, United States Code, and no such information or docu-  
27 mentary material may be made public, except as may be rel-  
28 evant to any administrative or judicial action or proceeding.  
29 Nothing in this section is intended to prevent disclosure to ei-  
30 ther body of the Congress or to any duly authorized committee  
31 or subcommittee of the Congress.

32 **SEC. 1115. ENFORCEMENT.**

33 (a) CIVIL PENALTY.—Any brand name drug company or  
34 generic drug applicant which fails to comply with any provision  
35 of this subtitle shall be liable for a civil penalty of not more  
36 than \$11,000, for each day during which such entity is in viola-  
37 tion of this subtitle. Such penalty may be recovered in a civil

1 action brought by the United States, or brought by the Com-  
2 mission in accordance with the procedures established in sec-  
3 tion 16(a)(1) of the Federal Trade Commission Act (15 U.S.C.  
4 56(a)).

5 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand  
6 name drug company or generic drug applicant fails to comply  
7 with any provision of this subtitle, the United States district  
8 court may order compliance, and may grant such other equi-  
9 table relief as the court in its discretion determines necessary  
10 or appropriate, upon application of the Assistant Attorney Gen-  
11 eral or the Commission.

12 **SEC. 1116. RULEMAKING.**

13 The Commission, with the concurrence of the Assistant  
14 Attorney General and by rule in accordance with section 553  
15 of title 5, United States Code, consistent with the purposes of  
16 this subtitle—

- 17 (1) may define the terms used in this subtitle;  
18 (2) may exempt classes of persons or agreements from  
19 the requirements of this subtitle; and  
20 (3) may prescribe such other rules as may be nec-  
21 essary and appropriate to carry out the purposes of this  
22 subtitle.

23 **SEC. 1117. SAVINGS CLAUSE.**

24 Any action taken by the Assistant Attorney General or the  
25 Commission, or any failure of the Assistant Attorney General  
26 or the Commission to take action, under this subtitle shall not  
27 at any time bar any proceeding or any action with respect to  
28 any agreement between a brand name drug company and a ge-  
29 neric drug applicant, or any agreement between generic drug  
30 applicants, under any other provision of law, nor shall any fil-  
31 ing under this subtitle constitute or create a presumption of  
32 any violation of any competition laws.

33 **SEC. 1118. EFFECTIVE DATE.**

34 This subtitle shall—

- 35 (1) take effect 30 days after the date of the enactment  
36 of this Act; and

1 (2) shall apply to agreements described in section  
2 1112 that are entered into 30 days after the date of the  
3 enactment of this Act.

## 4 **Subtitle C—Importation of** 5 **Prescription Drugs**

### 6 **SEC. 1121. IMPORTATION OF PRESCRIPTION DRUGS.**

7 (a) IN GENERAL.—Chapter VIII of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended  
9 by striking section 804 and inserting the following:

#### 10 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

11 “(a) DEFINITIONS.—In this section:

12 “(1) IMPORTER.—The term ‘importer’ means a phar-  
13 macist or wholesaler.

14 “(2) PHARMACIST.—The term ‘pharmacist’ means a  
15 person licensed by a State to practice pharmacy, including  
16 the dispensing and selling of prescription drugs.

17 “(3) PRESCRIPTION DRUG.—The term ‘prescription  
18 drug’ means a drug subject to section 503(b), other than—

19 “(A) a controlled substance (as defined in section  
20 102 of the Controlled Substances Act (21 U.S.C. 802));

21 “(B) a biological product (as defined in section  
22 351 of the Public Health Service Act (42 U.S.C. 262));

23 “(C) an infused drug (including a peritoneal dialy-  
24 sis solution);

25 “(D) an intravenously injected drug;

26 “(E) a drug that is inhaled during surgery; or

27 “(F) a drug which is a parenteral drug, the impor-  
28 tation of which pursuant to subsection (b) is deter-  
29 mined by the Secretary to pose a threat to the public  
30 health, in which case section 801(d)(1) shall continue  
31 to apply.

32 “(4) QUALIFYING LABORATORY.—The term ‘qualifying  
33 laboratory’ means a laboratory in the United States that  
34 has been approved by the Secretary for the purposes of this  
35 section.

36 “(5) WHOLESALER.—

1           “(A) IN GENERAL.—The term ‘wholesaler’ means  
2           a person licensed as a wholesaler or distributor of pre-  
3           scription drugs in the United States under section  
4           503(e)(2)(A).

5           “(B) EXCLUSION.—The term ‘wholesaler’ does not  
6           include a person authorized to import drugs under sec-  
7           tion 801(d)(1).

8           “(b) REGULATIONS.—The Secretary, after consultation  
9           with the United States Trade Representative and the Commis-  
10          sioner of Customs, shall promulgate regulations permitting  
11          pharmacists and wholesalers to import prescription drugs from  
12          Canada into the United States.

13          “(c) LIMITATION.—The regulations under subsection (b)  
14          shall—

15               “(1) require that safeguards be in place to ensure that  
16               each prescription drug imported under the regulations complies with section 505 (including with respect to being safe  
17               and effective for the intended use of the prescription drug),  
18               with sections 501 and 502, and with other applicable re-  
19               quirements of this Act;

20               “(2) require that an importer of a prescription drug  
21               under the regulations comply with subsections (d)(1) and  
22               (e); and  
23               “(3) contain any additional provisions determined by

24               the Secretary to be appropriate as a safeguard to protect  
25               the public health or as a means to facilitate the importation  
26               of prescription drugs.  
27               “(d) INFORMATION AND RECORDS.—

28               “(1) IN GENERAL.—The regulations under subsection

29               (b) shall require an importer of a prescription drug under  
30               subsection (b) to submit to the Secretary the following in-  
31               formation and documentation:  
32               “(A) The name and quantity of the active ingre-

33               dient of the prescription drug.  
34               “(B) A description of the dosage form of the pre-

35               scription drug.  
36



1           “(C) The date on which the prescription drug is  
2 shipped.

3           “(D) The quantity of the prescription drug that is  
4 shipped.

5           “(E) The point of origin and destination of the  
6 prescription drug.

7           “(F) The price paid by the importer for the pre-  
8 scription drug.

9           “(G) Documentation from the foreign seller  
10 specifying—

11           “(i) the original source of the prescription  
12 drug; and

13           “(ii) the quantity of each lot of the prescrip-  
14 tion drug originally received by the seller from that  
15 source.

16           “(H) The lot or control number assigned to the  
17 prescription drug by the manufacturer of the prescrip-  
18 tion drug.

19           “(I) The name, address, telephone number, and  
20 professional license number (if any) of the importer.

21           “(J)(i) In the case of a prescription drug that is  
22 shipped directly from the first foreign recipient of the  
23 prescription drug from the manufacturer:

24           “(I) Documentation demonstrating that the  
25 prescription drug was received by the recipient  
26 from the manufacturer and subsequently shipped  
27 by the first foreign recipient to the importer.

28           “(II) Documentation of the quantity of each  
29 lot of the prescription drug received by the first  
30 foreign recipient demonstrating that the quantity  
31 being imported into the United States is not more  
32 than the quantity that was received by the first for-  
33 eign recipient.

34           “(III)(aa) In the case of an initial imported  
35 shipment, documentation demonstrating that each  
36 batch of the prescription drug in the shipment was

1 statistically sampled and tested for authenticity  
2 and degradation.

3 “(bb) In the case of any subsequent shipment,  
4 documentation demonstrating that a statistically  
5 valid sample of the shipment was tested for authen-  
6 ticity and degradation.

7 “(ii) In the case of a prescription drug that is not  
8 shipped directly from the first foreign recipient of the  
9 prescription drug from the manufacturer, documenta-  
10 tion demonstrating that each batch in each shipment  
11 offered for importation into the United States was sta-  
12 tistically sampled and tested for authenticity and deg-  
13 radation.

14 “(K) Certification from the importer or manufac-  
15 turer of the prescription drug that the prescription  
16 drug—

17 “(i) is approved for marketing in the United  
18 States and is not adulterated or misbranded; and

19 “(ii) meets all labeling requirements under this  
20 Act.

21 “(L) Laboratory records, including complete data  
22 derived from all tests necessary to ensure that the pre-  
23 scription drug is in compliance with established speci-  
24 fications and standards.

25 “(M) Documentation demonstrating that the test-  
26 ing required by subparagraphs (J) and (L) was con-  
27 ducted at a qualifying laboratory.

28 “(N) Any other information that the Secretary de-  
29 termines is necessary to ensure the protection of the  
30 public health.

31 “(2) MAINTENANCE BY THE SECRETARY.—The Sec-  
32 retary shall maintain information and documentation sub-  
33 mitted under paragraph (1) for such period of time as the  
34 Secretary determines to be necessary.

35 “(e) TESTING.—The regulations under subsection (b) shall  
36 require—

1           “(1) that testing described in subparagraphs (J) and  
2           (L) of subsection (d)(1) be conducted by the importer or  
3           by the manufacturer of the prescription drug at a qualified  
4           laboratory;

5           “(2) if the tests are conducted by the importer—

6           “(A) that information needed to—

7           “(i) authenticate the prescription drug being  
8           tested; and

9           “(ii) confirm that the labeling of the prescrip-  
10           tion drug complies with labeling requirements  
11           under this Act;

12           be supplied by the manufacturer of the prescription  
13           drug to the pharmacist or wholesaler; and

14           “(B) that the information supplied under subpara-  
15           graph (A) be kept in strict confidence and used only for  
16           purposes of testing or otherwise complying with this  
17           Act; and

18           “(3) may include such additional provisions as the  
19           Secretary determines to be appropriate to provide for the  
20           protection of trade secrets and commercial or financial in-  
21           formation that is privileged or confidential.

22           “(f) REGISTRATION OF FOREIGN SELLERS.—Any estab-  
23           lishment within Canada engaged in the distribution of a pre-  
24           scription drug that is imported or offered for importation into  
25           the United States shall register with the Secretary the name  
26           and place of business of the establishment and the name of the  
27           United States agent for the establishment.

28           “(g) SUSPENSION OF IMPORTATION.—The Secretary shall  
29           require that importations of a specific prescription drug or im-  
30           portations by a specific importer under subsection (b) be imme-  
31           diately suspended on discovery of a pattern of importation of  
32           that specific prescription drug or by that specific importer of  
33           drugs that are counterfeit or in violation of any requirement  
34           under this section, until an investigation is completed and the  
35           Secretary determines that the public is adequately protected  
36           from counterfeit and violative prescription drugs being im-  
37           ported under subsection (b).

1           “(h) APPROVED LABELING.—The manufacturer of a pre-  
2       scription drug shall provide an importer written authorization  
3       for the importer to use, at no cost, the approved labeling for  
4       the prescription drug.

5           “(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any  
6       other provision of this section, section 801(d)(1) continues to  
7       apply to a prescription drug that is donated or otherwise sup-  
8       plied at no charge by the manufacturer of the drug to a chari-  
9       table or humanitarian organization (including the United Na-  
10      tions and affiliates) or to a government of a foreign country.

11          “(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVID-  
12      UALS.—

13           “(1) DECLARATIONS.—Congress declares that in the  
14      enforcement against individuals of the prohibition of impor-  
15      tation of prescription drugs and devices, the Secretary  
16      should—

17           “(A) focus enforcement on cases in which the im-  
18      portation by an individual poses a significant threat to  
19      public health; and

20           “(B) exercise discretion to permit individuals to  
21      make such importations in circumstances in which—

22           “(i) the importation is clearly for personal use;  
23      and

24           “(ii) the prescription drug or device imported  
25      does not appear to present an unreasonable risk to  
26      the individual.

27          “(2) WAIVER AUTHORITY.—

28           “(A) IN GENERAL.—The Secretary may grant to  
29      individuals, by regulation or on a case-by-case basis, a  
30      waiver of the prohibition of importation of a prescrip-  
31      tion drug or device or class of prescription drugs or de-  
32      vices, under such conditions as the Secretary deter-  
33      mines to be appropriate.

34           “(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The  
35      Secretary shall publish, and update as necessary, guid-  
36      ance that accurately describes circumstances in which  
37      the Secretary will consistently grant waivers on a case-

1 by-case basis under subparagraph (A), so that individ-  
2 uals may know with the greatest practicable degree of  
3 certainty whether a particular importation for personal  
4 use will be permitted.

5 “(3) DRUGS IMPORTED FROM CANADA.—In particular,  
6 the Secretary shall by regulation grant individuals a waiver  
7 to permit individuals to import into the United States a  
8 prescription drug that—

9 “(A) is imported from a licensed pharmacy for  
10 personal use by an individual, not for resale, in quan-  
11 tities that do not exceed a 90-day supply;

12 “(B) is accompanied by a copy of a valid prescrip-  
13 tion;

14 “(C) is imported from Canada, from a seller reg-  
15 istered with the Secretary;

16 “(D) is a prescription drug approved by the Sec-  
17 retary under chapter V;

18 “(E) is in the form of a final finished dosage that  
19 was manufactured in an establishment registered under  
20 section 510; and

21 “(F) is imported under such other conditions as  
22 the Secretary determines to be necessary to ensure  
23 public safety.

24 “(k) CONSTRUCTION.—Nothing in this section limits the  
25 authority of the Secretary relating to the importation of pre-  
26 scription drugs, other than with respect to section 801(d)(1) as  
27 provided in this section.

28 “(l) EFFECTIVENESS OF SECTION.—

29 “(1) COMMENCEMENT OF PROGRAM.—This section  
30 shall become effective only if the Secretary certifies to the  
31 Congress that the implementation of this section will—

32 (A) pose no additional risk to the public’s health  
33 and safety; and

34 (B) result in a significant reduction in the cost of  
35 covered products to the American consumer.

36 “(2) TERMINATION OF PROGRAM.—

1           “(A) IN GENERAL.—If, after the date that is 1  
2 year after the effective date of the regulations under  
3 subsection (b) and before the date that is 18 months  
4 after the effective date, the Secretary submits to Con-  
5 gress a certification that, in the opinion of the Sec-  
6 retary, based on substantial evidence obtained after the  
7 effective date, the benefits of implementation of this  
8 section do not outweigh any detriment of implementa-  
9 tion of this section, this section shall cease to be effec-  
10 tive as of the date that is 30 days after the date on  
11 which the Secretary submits the certification.

12           “(B) PROCEDURE.—The Secretary shall not sub-  
13 mit a certification under subparagraph (A) unless,  
14 after a hearing on the record under sections 556 and  
15 557 of title 5, United States Code, the Secretary—

16           “(i)(I) determines that it is more likely than  
17 not that implementation of this section would result  
18 in an increase in the risk to the public health and  
19 safety;

20           “(II) identifies specifically, in qualitative and  
21 quantitative terms, the nature of the increased risk;

22           “(III) identifies specifically the causes of the  
23 increased risk; and

24           “(IV)(aa) considers whether any measures can  
25 be taken to avoid, reduce, or mitigate the increased  
26 risk; and

27           “(bb) if the Secretary determines that any  
28 measures described in item (aa) would require ad-  
29 ditional statutory authority, submits to Congress a  
30 report describing the legislation that would be re-  
31 quired;

32           “(ii) identifies specifically, in qualitative and  
33 quantitative terms, the benefits that would result  
34 from implementation of this section (including the  
35 benefit of reductions in the cost of covered products  
36 to consumers in the United States, allowing con-  
37 sumers to procure needed medication that con-

1           sumers might not otherwise be able to procure  
2           without foregoing other necessities of life); and

3           “(iii)(I) compares in specific terms the det-  
4           riment identified under clause (i) with the benefits  
5           identified under clause (ii); and

6           “(II) determines that the benefits do not out-  
7           weigh the detriment.

8           “(m) AUTHORIZATION OF APPROPRIATIONS.—There are  
9           authorized to be appropriated such sums as are necessary to  
10          carry out this section.”.

11          (b) CONFORMING AMENDMENTS.—The Federal Food,  
12          Drug, and Cosmetic Act is amended—

13                 (1) in section 301(aa) (21 U.S.C. 331(aa)), by striking  
14                 “covered product in violation of section 804” and inserting  
15                 “prescription drug in violation of section 804”; and

16                 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by  
17                 striking “covered product pursuant to section 804(a)” and  
18                 inserting “prescription drug under section 804(b)”.

19          **SEC. 1122. STUDY AND REPORT ON IMPORTATION OF**  
20          **DRUGS.**

21                 The Secretary, in consultation with appropriate govern-  
22                 ment agencies, shall conduct a study on the importation of  
23                 drugs into the United States pursuant to section 804 of the  
24                 Federal Food, Drug, and Cosmetic Act (as added by section  
25                 1121 of this Act). Not later than 12 months after the date of  
26                 the enactment of this Act, the Secretary shall submit to the ap-  
27                 propriate committees of the Congress a report providing the  
28                 findings of such study.

29          **SEC. 1123. STUDY AND REPORT ON TRADE IN PHARMA-**  
30          **CEUTICALS.**

31                 The President’s designees shall conduct a study and report  
32                 on issues related to trade and pharmaceuticals.

1 **TITLE XII—TAX INCENTIVES FOR**  
2 **HEALTH AND RETIREMENT SE-**  
3 **CURITY**

4 **SEC. 1201. HEALTH SAVINGS ACCOUNTS.**

5 (a) IN GENERAL.—Part VII of subchapter B of chapter 1  
6 of the Internal Revenue Code of 1986 (relating to additional  
7 itemized deductions for individuals) is amended by redesignig-  
8 nating section 223 as section 224 and by inserting after section  
9 222 the following new section:

10 **“SEC. 223. HEALTH SAVINGS ACCOUNTS.**

11 “(a) DEDUCTION ALLOWED.—In the case of an individual  
12 who is an eligible individual for any month during the taxable  
13 year, there shall be allowed as a deduction for the taxable year  
14 an amount equal to the aggregate amount paid in cash during  
15 such taxable year by or on behalf of such individual to a health  
16 savings account of such individual.

17 “(b) LIMITATIONS.—

18 “(1) IN GENERAL.—The amount allowable as a deduc-  
19 tion under subsection (a) to an individual for the taxable  
20 year shall not exceed the sum of the monthly limitations for  
21 months during such taxable year that the individual is an  
22 eligible individual.

23 “(2) MONTHLY LIMITATION.—The monthly limitation  
24 for any month is  $\frac{1}{12}$  of—

25 “(A) in the case of an eligible individual who has  
26 self-only coverage under a high deductible health plan  
27 as of the first day of such month, the lesser of—

28 “(i) the annual deductible under such cov-  
29 erage, or

30 “(ii) \$2,250, or

31 “(B) in the case of an eligible individual who has  
32 family coverage under a high deductible health plan as  
33 of the first day of such month, the lesser of—

34 “(i) the annual deductible under such cov-  
35 erage, or

36 “(ii) \$4,500.



1           “(3) ADDITIONAL CONTRIBUTIONS FOR INDIVIDUALS  
2           55 OR OLDER.—

3           “(A) IN GENERAL.—In the case of an individual  
4           who has attained age 55 before the close of the taxable  
5           year, the applicable limitation under subparagraphs (A)  
6           and (B) of paragraph (2) shall be increased by the ad-  
7           ditional contribution amount.

8           “(B) ADDITIONAL CONTRIBUTION AMOUNT.—For  
9           purposes of this section, the additional contribution  
10          amount is the amount determined in accordance with  
11          the following table:

<b>“For taxable years beginning in:</b>	<b>The additional contribution amount is:</b>
2004 .....	\$500
2005 .....	\$600
2006 .....	\$700
2007 .....	\$800
2008 .....	\$900
2009 and thereafter .....	\$1,000.

12          “(4) COORDINATION WITH OTHER CONTRIBUTIONS.—  
13          The limitation which would (but for this paragraph) apply  
14          under this subsection to an individual for any taxable year  
15          shall be reduced (but not below zero) by the sum of—

16                 “(A) the aggregate amount paid for such taxable  
17                 year to Archer MSAs of such individual, and

18                 “(B) the aggregate amount contributed to health  
19                 savings accounts of such individual which is excludable  
20                 from the taxpayer’s gross income for such taxable year  
21                 under section 106(d) (and such amount shall not be al-  
22                 lowed as a deduction under subsection (a)).

23          Subparagraph (A) shall not apply with respect to any indi-  
24          vidual to whom paragraph (5) applies.

25          “(5) SPECIAL RULE FOR MARRIED INDIVIDUALS.—In  
26          the case of individuals who are married to each other, if  
27          either spouse has family coverage—

28                 “(A) both spouses shall be treated as having only  
29                 such family coverage (and if such spouses each have

1 family coverage under different plans, as having the  
2 family coverage with the lowest annual deductible), and

3 “(B) the limitation under paragraph (1) (after the  
4 application of subparagraph (A) and without regard to  
5 any additional contribution amount under paragraph  
6 (3))—

7 “(i) shall be reduced by the aggregate amount  
8 paid to Archer MSAs of such spouses for the tax-  
9 able year, and

10 “(ii) after such reduction, shall be divided  
11 equally between them unless they agree on a dif-  
12 ferent division.

13 “(6) DENIAL OF DEDUCTION TO DEPENDENTS.—No  
14 deduction shall be allowed under this section to any indi-  
15 vidual with respect to whom a deduction under section 151  
16 is allowable to another taxpayer for a taxable year begin-  
17 ning in the calendar year in which such individual’s taxable  
18 year begins.

19 “(7) MEDICARE ELIGIBLE INDIVIDUALS.—The limita-  
20 tion under this subsection for any month with respect to  
21 an individual shall be zero for the first month such indi-  
22 vidual is entitled to benefits under title XVIII of the Social  
23 Security Act and for each month thereafter.

24 “(c) DEFINITIONS AND SPECIAL RULES.—For purposes of  
25 this section—

26 “(1) ELIGIBLE INDIVIDUAL.—

27 “(A) IN GENERAL.—The term ‘eligible individual’  
28 means, with respect to any month, any individual if—

29 “(i) such individual is covered under a high  
30 deductible health plan as of the 1st day of such  
31 month, and

32 “(ii) such individual is not, while covered  
33 under a high deductible health plan, covered under  
34 any health plan—

35 “(I) which is not a high deductible health  
36 plan, and

1 “(II) which provides coverage for any ben-  
2 efit which is covered under the high deductible  
3 health plan.

4 “(B) CERTAIN COVERAGE DISREGARDED.—Sub-  
5 paragraph (A)(ii) shall be applied without regard to—

6 “(i) coverage for any benefit provided by per-  
7 mitted insurance, and

8 “(ii) coverage (whether through insurance or  
9 otherwise) for accidents, disability, dental care, vi-  
10 sion care, or long-term care.

11 “(2) HIGH DEDUCTIBLE HEALTH PLAN.—

12 “(A) IN GENERAL.—The term ‘high deductible  
13 health plan’ means a health plan—

14 “(i) which has an annual deductible which is  
15 not less than—

16 “(I) \$1,000 for self-only coverage, and

17 “(II) twice the dollar amount in subclause  
18 (I) for family coverage, and

19 “(ii) the sum of the annual deductible and the  
20 other annual out-of-pocket expenses required to be  
21 paid under the plan (other than for premiums) for  
22 covered benefits does not exceed—

23 “(I) \$5,000 for self-only coverage, and

24 “(II) twice the dollar amount in subclause  
25 (I) for family coverage.

26 “(B) EXCLUSION OF CERTAIN PLANS.—Such term  
27 does not include a health plan if substantially all of its  
28 coverage is coverage described in paragraph (1)(B).

29 “(C) SAFE HARBOR FOR ABSENCE OF PREVENTIVE  
30 CARE DEDUCTIBLE.—A plan shall not fail to be treated  
31 as a high deductible health plan by reason of failing to  
32 have a deductible for preventive care (within the mean-  
33 ing of section 1871 of the Social Security Act, except  
34 as otherwise provided by the Secretary).

35 “(D) SPECIAL RULES FOR NETWORK PLANS.—In  
36 the case of a plan using a network of providers—

1                   “(i) ANNUAL OUT-OF-POCKET LIMITATION.—  
2                   Such plan shall not fail to be treated as a high de-  
3                   ductible health plan by reason of having an out-of-  
4                   pocket limitation for services provided outside of  
5                   such network which exceeds the applicable limita-  
6                   tion under subparagraph (A)(ii).

7                   “(ii) ANNUAL DEDUCTIBLE.—Such plan’s an-  
8                   nual deductible for services provided outside of  
9                   such network shall not be taken into account for  
10                  purposes of subsection (b)(2).

11                 “(3) PERMITTED INSURANCE.—The term ‘permitted  
12                 insurance’ means—

13                         “(A) insurance if substantially all of the coverage  
14                         provided under such insurance relates to—

15                                 “(i) liabilities incurred under workers’ com-  
16                                 pensation laws,

17                                 “(ii) tort liabilities,

18                                 “(iii) liabilities relating to ownership or use of  
19                                 property, or

20                                 “(iv) such other similar liabilities as the Sec-  
21                                 retary may specify by regulations,

22                                 “(B) insurance for a specified disease or illness,  
23                                 and

24                                 “(C) insurance paying a fixed amount per day (or  
25                                 other period) of hospitalization.

26                 “(4) FAMILY COVERAGE.—The term ‘family coverage’  
27                 means any coverage other than self-only coverage.

28                 “(5) ARCHER MSA.—The term ‘Archer MSA’ has the  
29                 meaning given such term in section 220(d).

30                 “(d) HEALTH SAVINGS ACCOUNT.—For purposes of this  
31                 section—

32                         “(1) IN GENERAL.—The term ‘health savings account’  
33                         means a trust created or organized in the United States as  
34                         a health savings account exclusively for the purpose of pay-  
35                         ing the qualified medical expenses of the account bene-  
36                         ficiary, but only if the written governing instrument cre-  
37                         ating the trust meets the following requirements:

1           “(A) Except in the case of a rollover contribution  
2 described in subsection (f)(5) or section 220(f)(5), no  
3 contribution will be accepted—

4                   “(i) unless it is in cash, or

5                   “(ii) to the extent such contribution, when  
6 added to previous contributions to the trust for the  
7 calendar year, exceeds the sum of—

8                           “(I) the dollar amount in effect under sub-  
9 section (b)(2)(B)(ii), and

10                           “(II) the dollar amount in effect under  
11 subsection (b)(3)(B).

12           “(B) The trustee is a bank (as defined in section  
13 408(n)), an insurance company (as defined in section  
14 816), or another person who demonstrates to the satis-  
15 faction of the Secretary that the manner in which such  
16 person will administer the trust will be consistent with  
17 the requirements of this section.

18           “(C) No part of the trust assets will be invested  
19 in life insurance contracts.

20           “(D) The assets of the trust will not be commin-  
21 gled with other property except in a common trust fund  
22 or common investment fund.

23           “(E) The interest of an individual in the balance  
24 in his account is nonforfeitable.

25           “(2) QUALIFIED MEDICAL EXPENSES.—

26                   “(A) IN GENERAL.—The term ‘qualified medical  
27 expenses’ means, with respect to an account bene-  
28 ficiary, amounts paid by such beneficiary for medical  
29 care (as defined in section 213(d) for such individual,  
30 the spouse of such individual, and any dependent (as  
31 defined in section 152) of such individual, but only to  
32 the extent such amounts are not compensated for by  
33 insurance or otherwise.

34                   “(B) HEALTH INSURANCE MAY NOT BE PUR-  
35 CHASED FROM ACCOUNT.—Subparagraph (A) shall not  
36 apply to any payment for insurance.

1           “(C) EXCEPTIONS.—Subparagraph (B) shall not  
2 apply to any expense for coverage under—

3           “(i) a health plan during any period of con-  
4 tinuation coverage required under any Federal law,

5           “(ii) a qualified long-term care insurance con-  
6 tract (as defined in section 7702B(b)),

7           “(iii) a health plan during a period in which  
8 the individual is receiving unemployment compensa-  
9 tion under any Federal or State law, or

10           “(iv) in the case of an account beneficiary who  
11 has attained the age specified in section 1811 of  
12 the Social Security Act, any health insurance other  
13 than a medicare supplemental policy (as defined in  
14 section 1882 of the Social Security Act).

15           “(3) ACCOUNT BENEFICIARY.—The term ‘account  
16 beneficiary’ means the individual on whose behalf the  
17 health savings account was established.

18           “(4) CERTAIN RULES TO APPLY.—Rules similar to the  
19 following rules shall apply for purposes of this section:

20           “(A) Section 219(d)(2) (relating to no deduction  
21 for rollovers).

22           “(B) Section 219(f)(3) (relating to time when con-  
23 tributions deemed made).

24           “(C) Except as provided in section 106(d), section  
25 219(f)(5) (relating to employer payments).

26           “(D) Section 408(g) (relating to community prop-  
27 erty laws).

28           “(E) Section 408(h) (relating to custodial ac-  
29 counts).

30           “(e) TAX TREATMENT OF ACCOUNTS.—

31           “(1) IN GENERAL.—A health savings account is ex-  
32 empt from taxation under this subtitle unless such account  
33 has ceased to be a health savings account. Notwithstanding  
34 the preceding sentence, any such account is subject to the  
35 taxes imposed by section 511 (relating to imposition of tax  
36 on unrelated business income of charitable, etc. organiza-  
37 tions).

1           “(2) ACCOUNT TERMINATIONS.—Rules similar to the  
2 rules of paragraphs (2) and (4) of section 408(e) shall  
3 apply to health savings accounts, and any amount treated  
4 as distributed under such rules shall be treated as not used  
5 to pay qualified medical expenses.

6           “(f) TAX TREATMENT OF DISTRIBUTIONS.—

7           “(1) AMOUNTS USED FOR QUALIFIED MEDICAL EX-  
8 PENSES.—Any amount paid or distributed out of a health  
9 savings account which is used exclusively to pay qualified  
10 medical expenses of any account beneficiary shall not be in-  
11 cludible in gross income.

12           “(2) INCLUSION OF AMOUNTS NOT USED FOR QUALI-  
13 FIED MEDICAL EXPENSES.—Any amount paid or distrib-  
14 uted out of a health savings account which is not used ex-  
15 clusively to pay the qualified medical expenses of the ac-  
16 count beneficiary shall be included in the gross income of  
17 such beneficiary.

18           “(3) EXCESS CONTRIBUTIONS RETURNED BEFORE  
19 DUE DATE OF RETURN.—

20           “(A) IN GENERAL.—If any excess contribution is  
21 contributed for a taxable year to any health savings ac-  
22 count of an individual, paragraph (2) shall not apply  
23 to distributions from the health savings accounts of  
24 such individual (to the extent such distributions do not  
25 exceed the aggregate excess contributions to all such  
26 accounts of such individual for such year) if—

27           “(i) such distribution is received by the indi-  
28 vidual on or before the last day prescribed by law  
29 (including extensions of time) for filing such indi-  
30 vidual’s return for such taxable year, and

31           “(ii) such distribution is accompanied by the  
32 amount of net income attributable to such excess  
33 contribution.

34 Any net income described in clause (ii) shall be in-  
35 cluded in the gross income of the individual for the tax-  
36 able year in which it is received.

1           “(B) EXCESS CONTRIBUTION.—For purposes of  
2           subparagraph (A), the term ‘excess contribution’ means  
3           any contribution (other than a rollover contribution de-  
4           scribed in paragraph (5) or section 220(f)(5)) which is  
5           neither excludable from gross income under section  
6           106(d) nor deductible under this section.

7           “(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED  
8           FOR QUALIFIED MEDICAL EXPENSES.—

9           “(A) IN GENERAL.—The tax imposed by this  
10          chapter on the account beneficiary for any taxable year  
11          in which there is a payment or distribution from a  
12          health savings account of such beneficiary which is in-  
13          cludible in gross income under paragraph (2) shall be  
14          increased by 10 percent of the amount which is so in-  
15          cludible.

16          “(B) EXCEPTION FOR DISABILITY OR DEATH.—  
17          Subparagraph (A) shall not apply if the payment or  
18          distribution is made after the account beneficiary be-  
19          comes disabled within the meaning of section 72(m)(7)  
20          or dies.

21          “(C) EXCEPTION FOR DISTRIBUTIONS AFTER  
22          MEDICARE ELIGIBILITY.—Subparagraph (A) shall not  
23          apply to any payment or distribution after the date on  
24          which the account beneficiary attains the age specified  
25          in section 1811 of the Social Security Act.

26          “(5) ROLLOVER CONTRIBUTION.—An amount is de-  
27          scribed in this paragraph as a rollover contribution if it  
28          meets the requirements of subparagraphs (A) and (B).

29          “(A) IN GENERAL.—Paragraph (2) shall not apply  
30          to any amount paid or distributed from a health sav-  
31          ings account to the account beneficiary to the extent  
32          the amount received is paid into a health savings ac-  
33          count for the benefit of such beneficiary not later than  
34          the 60th day after the day on which the beneficiary re-  
35          ceives the payment or distribution.

36          “(B) LIMITATION.—This paragraph shall not  
37          apply to any amount described in subparagraph (A) re-



1           ceived by an individual from a health savings account  
2           if, at any time during the 1-year period ending on the  
3           day of such receipt, such individual received any other  
4           amount described in subparagraph (A) from a health  
5           savings account which was not includible in the individ-  
6           ual's gross income because of the application of this  
7           paragraph.

8           “(6) COORDINATION WITH MEDICAL EXPENSE DEDUC-  
9           TION.—For purposes of determining the amount of the deduc-  
10          tion under section 213, any payment or distribution out  
11          of a health savings account for qualified medical expenses  
12          shall not be treated as an expense paid for medical care.

13          “(7) TRANSFER OF ACCOUNT INCIDENT TO DI-  
14          VORCE.—The transfer of an individual's interest in a health  
15          savings account to an individual's spouse or former spouse  
16          under a divorce or separation instrument described in sub-  
17          paragraph (A) of section 71(b)(2) shall not be considered  
18          a taxable transfer made by such individual notwithstanding  
19          any other provision of this subtitle, and such interest shall,  
20          after such transfer, be treated as a health savings account  
21          with respect to which such spouse is the account bene-  
22          ficiary.

23          “(8) TREATMENT AFTER DEATH OF ACCOUNT BENE-  
24          FICIARY.—

25                 “(A) TREATMENT IF DESIGNATED BENEFICIARY  
26                 IS SPOUSE.—If the account beneficiary's surviving  
27                 spouse acquires such beneficiary's interest in a health  
28                 savings account by reason of being the designated bene-  
29                 ficiary of such account at the death of the account ben-  
30                 eficiary, such health savings account shall be treated as  
31                 if the spouse were the account beneficiary.

32                 “(B) OTHER CASES.—

33                         “(i) IN GENERAL.— If, by reason of the death  
34                         of the account beneficiary, any person acquires the  
35                         account beneficiary's interest in a health savings  
36                         account in a case to which subparagraph (A) does  
37                         not apply—

1                   “(I) such account shall cease to be a  
2                   health savings account as of the date of death,  
3                   and

4                   “(II) an amount equal to the fair market  
5                   value of the assets in such account on such  
6                   date shall be includible if such person is not the  
7                   estate of such beneficiary, in such person’s  
8                   gross income for the taxable year which in-  
9                   cludes such date, or if such person is the estate  
10                  of such beneficiary, in such beneficiary’s gross  
11                  income for the last taxable year of such bene-  
12                  ficiary.

13                  “(ii) SPECIAL RULES.—

14                  “(I) REDUCTION OF INCLUSION FOR  
15                  PREDEATH EXPENSES.—The amount includible  
16                  in gross income under clause (i) by any person  
17                  (other than the estate) shall be reduced by the  
18                  amount of qualified medical expenses which  
19                  were incurred by the decedent before the date  
20                  of the decedent’s death and paid by such per-  
21                  son within 1 year after such date.

22                  “(II) DEDUCTION FOR ESTATE TAXES.—  
23                  An appropriate deduction shall be allowed  
24                  under section 691(c) to any person (other than  
25                  the decedent or the decedent’s spouse) with re-  
26                  spect to amounts included in gross income  
27                  under clause (i) by such person.

28                  “(g) COST-OF-LIVING ADJUSTMENT.—

29                  “(1) IN GENERAL.—Each dollar amount in subsections  
30                  (b)(2) and (c)(2)(A) shall be increased by an amount equal  
31                  to—

32                          “(A) such dollar amount, multiplied by

33                          “(B) the cost-of-living adjustment determined  
34                          under section 1(f)(3) for the calendar year in which  
35                          such taxable year begins determined by substituting for  
36                          ‘calendar year 1992’ in subparagraph (B) thereof—

1 “(i) except as provided in clause (ii), ‘calendar  
2 year 1997’, and

3 “(ii) in the case of each dollar amount in sub-  
4 section (c)(2)(A), ‘calendar year 2003’.

5 “(2) ROUNDING.—If any increase under paragraph (1)  
6 is not a multiple of \$50, such increase shall be rounded to  
7 the nearest multiple of \$50.

8 “(h) REPORTS.—The Secretary may require—

9 “(1) the trustee of a health savings account to make  
10 such reports regarding such account to the Secretary and  
11 to the account beneficiary with respect to contributions,  
12 distributions, the return of excess contributions, and such  
13 other matters as the Secretary determines appropriate, and

14 “(2) any person who provides an individual with a  
15 high deductible health plan to make such reports to the  
16 Secretary and to the account beneficiary with respect to  
17 such plan as the Secretary determines appropriate.

18 The reports required by this subsection shall be filed at such  
19 time and in such manner and furnished to such individuals at  
20 such time and in such manner as may be required by the Sec-  
21 retary.”.

22 (b) DEDUCTION ALLOWED WHETHER OR NOT INDI-  
23 VIDUAL ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of  
24 section 62 of such Code is amended by inserting after para-  
25 graph (18) the following new paragraph:

26 “(19) HEALTH SAVINGS ACCOUNTS.—The deduction  
27 allowed by section 223.”.

28 (c) ROLLOVERS FROM ARCHER MSAS PERMITTED.—Sub-  
29 paragraph (A) of section 220(f)(5) of such Code (relating to  
30 rollover contribution) is amended by inserting “or a health sav-  
31 ings account (as defined in section 223(d))” after “paid into  
32 an Archer MSA”.

33 (d) EXCLUSIONS FOR EMPLOYER CONTRIBUTIONS TO  
34 HEALTH SAVINGS ACCOUNTS.—

35 (1) EXCLUSION FROM INCOME TAX.—Section 106 of  
36 such Code (relating to contributions by employer to acci-

1 dent and health plans) is amended by adding at the end  
2 the following new subsection:

3 “(d) CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—

4 “(1) IN GENERAL.—In the case of an employee who is  
5 an eligible individual (as defined in section 223(c)(1)),  
6 amounts contributed by such employee’s employer to any  
7 health savings account (as defined in section 223(d)) of  
8 such employee shall be treated as employer-provided cov-  
9 erage for medical expenses under an accident or health  
10 plan to the extent such amounts do not exceed the limita-  
11 tion under section 223(b) (determined without regard to  
12 this subsection) which is applicable to such employee for  
13 such taxable year.

14 “(2) SPECIAL RULES.—Rules similar to the rules of  
15 paragraphs (2), (3), (4), and (5) of subsection (b) shall  
16 apply for purposes of this subsection.

17 “(3) CROSS REFERENCE.—

“**For penalty on failure by employer to make  
comparable contributions to the health savings  
accounts of comparable employees, see section  
4980G.**”.

18 (2) EXCLUSION FROM EMPLOYMENT TAXES.—

19 (A) RAILROAD RETIREMENT TAX.—Subsection (e)  
20 of section 3231 of such Code is amended by adding at  
21 the end the following new paragraph:

22 “(11) HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—  
23 The term ‘compensation’ shall not include any payment  
24 made to or for the benefit of an employee if at the time  
25 of such payment it is reasonable to believe that the em-  
26 ployee will be able to exclude such payment from income  
27 under section 106(d).”.

28 (B) UNEMPLOYMENT TAX.—Subsection (b) of sec-  
29 tion 3306 of such Code is amended by striking “or” at  
30 the end of paragraph (16), by striking the period at the  
31 end of paragraph (17) and inserting “; or”, and by in-  
32 serting after paragraph (17) the following new para-  
33 graph:

1           “(18) any payment made to or for the benefit of an  
2           employee if at the time of such payment it is reasonable  
3           to believe that the employee will be able to exclude such  
4           payment from income under section 106(d).”.

5           (C) WITHHOLDING TAX.—Subsection (a) of sec-  
6           tion 3401 of such Code is amended by striking “or” at  
7           the end of paragraph (20), by striking the period at the  
8           end of paragraph (21) and inserting “; or”, and by in-  
9           serting after paragraph (21) the following new para-  
10          graph:

11          “(22) any payment made to or for the benefit of an  
12          employee if at the time of such payment it is reasonable  
13          to believe that the employee will be able to exclude such  
14          payment from income under section 106(d).”.

15          (3) EMPLOYER CONTRIBUTIONS REQUIRED TO BE  
16          SHOWN ON W-2.—Subsection (a) of section 6051 of such  
17          Code is amended by striking “and” at the end of para-  
18          graph (10), by striking the period at the end of paragraph  
19          (11) and inserting “, and”, and by inserting after para-  
20          graph (11) the following new paragraph:

21          “(12) the amount contributed to any health savings  
22          account (as defined in section 223(d)) of such employee or  
23          such employee’s spouse.”.

24          (4) PENALTY FOR FAILURE OF EMPLOYER TO MAKE  
25          COMPARABLE HEALTH SAVINGS ACCOUNT CONTRIBU-  
26          TIONS.—

27          (A) IN GENERAL.—Chapter 43 of such Code is  
28          amended by adding after section 4980F the following  
29          new section:

30          **“SEC. 4980G. FAILURE OF EMPLOYER TO MAKE COM-**  
31                   **PARABLE HEALTH SAVINGS ACCOUNT CON-**  
32                   **TRIBUTIONS.**

33          “(a) GENERAL RULE.—In the case of an employer who  
34          makes a contribution to the health savings account of any em-  
35          ployee during a calendar year, there is hereby imposed a tax  
36          on the failure of such employer to meet the requirements of  
37          subsection (b) for such calendar year.

1           “(b) RULES AND REQUIREMENTS.—Rules and require-  
2           ments similar to the rules and requirements of section 4980E  
3           shall apply for purposes of this section.

4           “(c) REGULATIONS.—The Secretary shall issue regulations  
5           to carry out the purposes of this section, including regulations  
6           providing special rules for employers who make contributions to  
7           Archer MSAs and health savings accounts during the calendar  
8           year.”.

9                       (B) CLERICAL AMENDMENT.—The table of sec-  
10           tions for chapter 43 of such Code is amended by add-  
11           ing after the item relating to section 4980F the fol-  
12           lowing new item:

          “Sec. 4980G. Failure of employer to make comparable health savings ac-  
          count contributions.”.

13           (e) TAX ON EXCESS CONTRIBUTIONS.—Section 4973 of  
14           such Code (relating to tax on excess contributions to certain  
15           tax-favored accounts and annuities) is amended—

16                       (1) by striking “or” at the end of subsection (a)(3),  
17                       by inserting “or” at the end of subsection (a)(4), and by  
18                       inserting after subsection (a)(4) the following new para-  
19                       graph:

20                               “(5) a health savings account (within the meaning of  
21                               section 223(d)),”, and

22                       (2) by adding at the end the following new subsection:

23                               “(g) EXCESS CONTRIBUTIONS TO HEALTH SAVINGS AC-  
24           COUNTS.—For purposes of this section, in the case of health  
25           savings accounts (within the meaning of section 223(d)), the  
26           term ‘excess contributions’ means the sum of—

27                               “(1) the aggregate amount contributed for the taxable  
28           year to the accounts (other than a rollover contribution de-  
29           scribed in section 220(f)(5) or 223(f)(5)) which is neither  
30           excludable from gross income under section 106(d) nor al-  
31           lowable as a deduction under section 223 for such year,  
32           and

33                               “(2) the amount determined under this subsection for  
34           the preceding taxable year, reduced by the sum of—

1                   “(A) the distributions out of the accounts which  
2                   were included in gross income under section 223(f)(2),  
3                   and

4                   “(B) the excess (if any) of—

5                   “(i) the maximum amount allowable as a de-  
6                   duction under section 223(b) (determined without  
7                   regard to section 106(d)) for the taxable year, over

8                   “(ii) the amount contributed to the accounts  
9                   for the taxable year.

10                   For purposes of this subsection, any contribution which is dis-  
11                   tributed out of the health savings account in a distribution to  
12                   which section 223(f)(3) applies shall be treated as an amount  
13                   not contributed.”.

14                   (f) TAX ON PROHIBITED TRANSACTIONS.—

15                   (1) Section 4975 of such Code (relating to tax on pro-  
16                   hibited transactions) is amended by adding at the end of  
17                   subsection (c) the following new paragraph:

18                   “(6) SPECIAL RULE FOR HEALTH SAVINGS AC-  
19                   COUNTS.—An individual for whose benefit a health savings  
20                   account (within the meaning of section 223(d)) is estab-  
21                   lished shall be exempt from the tax imposed by this section  
22                   with respect to any transaction concerning such account  
23                   (which would otherwise be taxable under this section) if,  
24                   with respect to such transaction, the account ceases to be  
25                   a health savings account by reason of the application of  
26                   section 223(e)(2) to such account.”.

27                   (2) Paragraph (1) of section 4975(e) of such Code is  
28                   amended by redesignating subparagraphs (E) and (F) as  
29                   subparagraphs (F) and (G), respectively, and by inserting  
30                   after subparagraph (D) the following new subparagraph:

31                   “(E) a health savings account described in section  
32                   223(d),”.

33                   (g) FAILURE TO PROVIDE REPORTS ON HEALTH SAVINGS  
34                   ACCOUNTS.—Paragraph (2) of section 6693(a) of such Code  
35                   (relating to reports) is amended by redesignating subpara-  
36                   graphs (C) and (D) as subparagraphs (D) and (E), respec-

1 tively, and by inserting after subparagraph (B) the following  
2 new subparagraph:

3 “(C) section 223(h) (relating to health savings ac-  
4 counts),”.

5 (h) EXCEPTION FROM CAPITALIZATION OF POLICY ACQUI-  
6 SITION EXPENSES.—Subparagraph (B) of section 848(e)(1) of  
7 such Code (defining specified insurance contract) is amended  
8 by striking “and” at the end of clause (iii), by striking the pe-  
9 riod at the end of clause (iv) and inserting “, and”, and by  
10 adding at the end the following new clause:

11 “(v) any contract which is a health savings ac-  
12 count (as defined in section 223(d)).”.

13 (i) HEALTH SAVINGS ACCOUNTS MAY BE OFFERED  
14 UNDER CAFETERIA PLANS.—Paragraph (2) of section 125(d)  
15 (relating to cafeteria plan defined) is amended by adding at the  
16 end the following new subparagraph:

17 “(D) EXCEPTION FOR HEALTH SAVINGS AC-  
18 COUNTS.—Subparagraph (A) shall not apply to a plan  
19 to the extent of amounts which a covered employee may  
20 elect to have the employer pay as contributions to a  
21 health savings account established on behalf of the em-  
22 ployee.”.

23 (j) CLERICAL AMENDMENT.—The table of sections for  
24 part VII of subchapter B of chapter 1 of such Code is amended  
25 by striking the last item and inserting the following:

“Sec. 223. Health savings accounts.

“Sec. 224. Cross reference.”.

26 (k) EFFECTIVE DATE.—The amendments made by this  
27 section shall apply to taxable years beginning after December  
28 31, 2003.

29 **SEC. 1202. EXCLUSION FROM GROSS INCOME OF CER-**  
30 **TAIN FEDERAL SUBSIDIES FOR PRESCRIP-**  
31 **TION DRUG PLANS.**

32 (a) IN GENERAL.—Part III of subchapter B of chapter 1  
33 of the Internal Revenue Code of 1986 is amended by inserting  
34 after section 139 the following new section:



1     **“SEC. 139A. FEDERAL SUBSIDIES FOR PRESCRIPTION**  
2                     **DRUG PLANS.**

3             “Gross income shall not include any special subsidy pay-  
4     ment received under section 1860D–22 of the Social Security  
5     Act. This section shall not be taken into account for purposes  
6     of determining whether any deduction is allowable with respect  
7     to any cost taken into account in determining such payment.”.

8             (b) ALTERNATIVE MINIMUM TAX RELIEF.—Section  
9     56(g)(4)(B) of such Code is amended by inserting “or 139A”  
10    after “section 114”.

11            (c) CONFORMING AMENDMENT.—The table of sections for  
12    part III of subchapter B of chapter 1 of such Code is amended  
13    by inserting after the item relating to section 139 the following  
14    new item:

                  “Sec. 139A. Federal subsidies for prescription drug plans.”.

15            (d) EFFECTIVE DATE.—The amendments made by this  
16    section shall apply to taxable years ending after the date of the  
17    enactment of this Act.

18     **SEC. 1203. EXCEPTION TO INFORMATION REPORTING**  
19                     **REQUIREMENTS RELATED TO CERTAIN**  
20                     **HEALTH ARRANGEMENTS.**

21            (a) IN GENERAL.—Section 6041 of the Internal Revenue  
22    Code of 1986 (relating to information at source) is amended  
23    by adding at the end the following new subsection:

24            “(f) SECTION DOES NOT APPLY TO CERTAIN HEALTH  
25    ARRANGEMENTS.—This section shall not apply to any payment  
26    for medical care (as defined in section 213(d)) made under—

27            “(1) a flexible spending arrangement (as defined in  
28            section 106(c)(2)), or

29            “(2) a health reimbursement arrangement which is  
30            treated as employer-provided coverage under an accident or  
31            health plan for purposes of section 106.”.

32            (b) EFFECTIVE DATE.—The amendment made by this sec-  
33    tion shall apply to payments made after December 31, 2002.