108TH CONGRESS
1ST SESSION

H. R. 1

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 25, 2003

Mr. HASTERT (for himself, Mr. DELAY, Mr. BLUNT, Ms. PRYCE of Ohio, Mr. THOMAS, Mr. TAUZIN, Mrs. JOHNSON of Connecticut, Mr. BILIRAKIS, Mr. PETERSON of Minnesota, Mrs. CAPITO, Ms. GINNY BROWN-WAITE of Florida, Mr. BRADLEY of New Hampshire, Mr. BURNS, Ms. DUNN, Mr. FLETCHER, Mr. GOSS, Mr. GRAVES, Mr. MCCRERY, Mr. NUNES, Mr. SIMMONS, and Mr. SULLIVAN) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce, and Ways and Means, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Prescription Drug and Modernization Act of 2003''.

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

(c) BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term ''BIPA'' means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION DRUG BENEFIT.

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

(1) by redesignating part D as part F; and

(2) by inserting after part C the following new part:

''PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

''SEC. 1860D–1. BENEFITS; ELIGIBILITY; ENROLLMENT; AND COVERAGE PERIOD.

''(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—Subject to the succeeding provisions of this part, each individual who is entitled to benefits under part A or is enrolled under part B is entitled to obtain qualified prescription drug coverage (described in section 1860D–2(a)) as follows:

''(1) MEDICARE-RELATED PLANS.—

''(A) MEDICARE ADVANTAGE.—If the individual is eligible to enroll in a Medicare Advantage plan that provides qualified prescription

drug coverage under section 1851(j), the individual may enroll in such plan and obtain coverage through such plan.

"(B) EFFS PLANS.—If the individual is eligible to enroll in an EFFS plan that provides qualified prescription drug coverage under part E under section 1860E–2(d), the individual may enroll in such plan and obtain coverage through such plan.

"(C) MA-EFFS PLAN; MA-EFFS RX PLAN.—For purposes of this part, the term 'MA-EFFS plan' means a Medicare Advantage plan under part C and an EFFS plan under part E and the term 'MA-EFFS Rx plan' means a MA-EFFS plan insofar as such plan provides qualified prescription drug coverage.

"(2) PRESCRIPTION DRUG PLAN.—If the individual is not enrolled in a MA-EFFS plan, the individual may enroll under this part in a prescription drug plan (as defined in section 1860D–10(a)(5)).

Such individuals shall have a choice of such plans under section 1860D–5(d).

"(b) GENERAL ELECTION PROCEDURES.—

"(1) IN GENERAL.—An individual eligible to make an election under subsection (a) may elect to

enroll in a prescription drug plan under this part, or elect the option of qualified prescription drug coverage under a MA-EFFS Rx plan under part C or part E, and to change such election only in such manner and form as may be prescribed by regulations of the Administrator of the Medicare Benefits Administration (appointed under section 1809(b)) (in this part referred to as the 'Medicare Benefits Administrator') and only during an election period prescribed in or under this subsection.

''(2) ELECTION PERIODS.—

''(A) IN GENERAL.—Except as provided in this paragraph, the election periods under this subsection shall be the same as the coverage election periods under the Medicare Advantage and EFFS programs under section 1851(e), including—

''(i) annual coordinated election periods; and

''(ii) special election periods.

In applying the last sentence of section 1851(e)(4) (relating to discontinuance of an election during the first year of eligibility) under this subparagraph, in the case of an election described in such section in which the indi-

vidual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug plan under this part at the time of the election of coverage under the original fee-for-service plan.

''(B) INITIAL ELECTION PERIODS.—

''(i) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of October 1, 2005, there shall be an initial election period of 6 months beginning on that date.

''(ii) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

''(C) ADDITIONAL SPECIAL ELECTION PERIODS.—The Administrator shall establish special election periods—

"(i) in cases of individuals who have and involuntarily lose prescription drug coverage described in subsection (c)(2)(C);

"(ii) in cases described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B;

"(iii) in the case of an individual who meets such exceptional conditions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

"(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

"(3) INFORMATION ON PLANS.—Information described in section 1860D–3(b)(1) on prescription drug plans and MA-EFFS Rx plans shall be made available during election periods.

"(4) ADDITIONAL INFORMATION.—In order to promote the efficient marketing of prescription drug plans and MA-EFFS plans, the Administrator may provide information to the sponsors and organiza-

tions offering such plans about individuals eligible to enroll in such plans.

"(c) GUARANTEED ISSUE; COMMUNITY RATING; AND NONDISCRIMINATION.—

"(1) GUARANTEED ISSUE.—

"(A) IN GENERAL.—An eligible individual who is eligible to elect qualified prescription drug coverage under a prescription drug plan or MA-EFFS Rx plan at a time during which elections are accepted under this part with respect to the plan shall not be denied enrollment based on any health status-related factor (described in section 2702(a)(1) of the Public Health Service Act) or any other factor.

"(B) MEDICARE ADVANTAGE LIMITATIONS PERMITTED.—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to PDP sponsors under this subsection.

"(2) COMMUNITY-RATED PREMIUM.—

"(A) IN GENERAL.—In the case of an individual who enrolls under a prescription drug plan or in a MA-EFFS Rx plan during the in-

dividual's initial enrollment period under this part or maintains (as determined under subparagraph (C)) continuous prescription drug coverage since the date the individual first qualifies to elect prescription drug coverage under this part, a PDP sponsor or entity offering a prescription drug plan or MA-EFFS Rx plan and in which the individual is enrolled may not deny, limit, or condition the coverage or provision of covered prescription drug benefits or vary or increase the premium under the plan based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act or any other factor.

''(B) LATE ENROLLMENT PENALTY.—In the case of an individual who does not maintain such continuous prescription drug coverage (as described in subparagraph (C)), a PDP sponsor or an entity offering a MA-EFFS Rx plan may (notwithstanding any provision in this title) adjust the premium otherwise applicable with respect to qualified prescription drug coverage in a manner that reflects additional actuarial risk involved. Such a risk shall be established through an appropriate actuarial opinion of the

type described in subparagraphs (A) through (C) of section 2103(c)(4). The Administrator shall provide a mechanism for assisting such sponsors and entities in identifying eligible individuals who have (or have not) maintained such continuous prescription drug coverage.

''(C) CONTINUOUS PRESCRIPTION DRUG COVERAGE.—An individual is considered for purposes of this part to be maintaining continuous prescription drug coverage on and after the date the individual first qualifies to elect prescription drug coverage under this part if the individual establishes that as of such date the individual is covered under any of the following prescription drug coverage and before the date that is the last day of the 63-day period that begins on the date of termination of the particular prescription drug coverage involved (regardless of whether the individual subsequently obtains any of the following prescription drug coverage):

''(i) COVERAGE UNDER PRESCRIPTION DRUG PLAN OR MA-EFFS RX PLAN.—Qualified prescription drug coverage under a

prescription drug plan or under a MA-EFFS Rx plan.

"(ii) MEDICAID PRESCRIPTION DRUG COVERAGE.—Prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for the Elderly (PACE) under section 1934, or through a demonstration project under part C that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of an interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved.

"(iii) PRESCRIPTION DRUG COVERAGE UNDER GROUP HEALTH PLAN.—Any outpatient prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan as defined in section 1860D–8(f)(1), but only if (subject to subparagraph (E)(ii)) the coverage pro-

vides benefits at least equivalent to the benefits under a qualified prescription drug plan.

''(iv) PRESCRIPTION DRUG COVERAGE UNDER CERTAIN MEDIGAP POLICIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1)), but only if the policy was in effect on January 1, 2006, and if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

''(v) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

''(vi) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescrip-

tion drugs for veterans under chapter 17 of title 38, United States Code, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

''(D) CERTIFICATION.—For purposes of carrying out this paragraph, the certifications of the type described in sections 2701(e) of the Public Health Service Act and in section 9801(e) of the Internal Revenue Code shall also include a statement for the period of coverage of whether the individual involved had prescription drug coverage described in subparagraph (C).

''(E) DISCLOSURE.—

''(i) IN GENERAL.—Each entity that offers coverage of the type described in clause (iii), (iv), (v), or (vi) of subparagraph (C) shall provide for disclosure, consistent with standards established by the Administrator, of whether such coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(ii) WAIVER OF LIMITATIONS.—An individual may apply to the Administrator to waive the requirement that coverage of such type provide benefits at least equivalent to the benefits under a qualified prescription drug plan, if the individual establishes that the individual was not adequately informed that such coverage did not provide such level of benefits.

"(F) CONSTRUCTION.—Nothing in this section shall be construed as preventing the disenrollment of an individual from a prescription drug plan or a MA-EFFS Rx plan based on the termination of an election described in section 1851(g)(3), including for non-payment of premiums or for other reasons specified in subsection (d)(3), which takes into account a grace period described in section 1851(g)(3)(B)(i).

"(3) NONDISCRIMINATION.—A PDP sponsor that offers a prescription drug plan in an area designated under section 1860D–4(b)(5) shall make such plan available to all eligible individuals residing in the area without regard to their health or eco-

nomic status or their place of residence within the area.

''(d) EFFECTIVE DATE OF ELECTIONS.—

''(1) IN GENERAL.—Except as provided in this section, the Administrator shall provide that elections under subsection (b) take effect at the same time as the Administrator provides that similar elections under section 1851(e) take effect under section 1851(f).

''(2) NO ELECTION EFFECTIVE BEFORE 2006.—In no case shall any election take effect before January 1, 2006.

''(3) TERMINATION.—The Administrator shall provide for the termination of an election in the case of—

''(A) termination of coverage under both part A and part B; and

''(B) termination of elections described in section 1851(g)(3) (including failure to pay required premiums).

''SEC. 1860D–2. REQUIREMENTS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

''(a) REQUIREMENTS.—

''(1) IN GENERAL.—For purposes of this part and part C and part E, the term 'qualified prescription drug coverage' means either of the following:

''(A) STANDARD COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

''(B) ACTUARIALLY EQUIVALENT COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Coverage of covered outpatient drugs which meets the alternative coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if it is approved by the Administrator, as provided under subsection (c).

''(2) PERMITTING ADDITIONAL OUTPATIENT PRESCRIPTION DRUG COVERAGE.—

''(A) IN GENERAL.—Subject to subparagraph (B), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered outpatient drugs that exceeds the coverage required under paragraph (1), but any such additional coverage shall be limited to coverage of covered outpatient drugs.

"(B) DISAPPROVAL AUTHORITY.—The Administrator shall review the offering of qualified prescription drug coverage under this part or part C or E. If the Administrator finds, in the case of a qualified prescription drug coverage under a prescription drug plan or a MA-EFFS Rx plan, that the organization or sponsor offering the coverage is engaged in activities intended to discourage enrollment of classes of eligible medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage, the Administrator may terminate the contract with the sponsor or organization under this part or part C or E.

"(3) APPLICATION OF SECONDARY PAYOR PROVISIONS.—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under part C.

"(b) STANDARD COVERAGE.—For purposes of this part, the 'standard coverage' is coverage of covered outpatient drugs (as defined in subsection (f)) that meets the following requirements:

"(1) DEDUCTIBLE.—The coverage has an annual deductible—

''(A) for 2006, that is equal to $250; or

''(B) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(2) 80:20 BENEFIT STRUCTURE.—

''(A) 20 PERCENT COINSURANCE.—The coverage has cost-sharing (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

''(i) equal to 20 percent; or

''(ii) is actuarially equivalent (using processes established under subsection (e)) to an average expected payment of 20 percent of such costs.

''(B) USE OF TIERS.—Nothing in this part shall be construed as preventing a PDP sponsor from applying tiered copayments, so long as such tiered copayments are consistent with subparagraph (A).

''(3) INITIAL COVERAGE LIMIT.—Subject to paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes—

''(A) for 2006, that is equal to $2,000; or

''(B) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $25 shall be rounded to the nearest multiple of $25.

''(4) CATASTROPHIC PROTECTION.—

''(A) IN GENERAL.—Notwithstanding paragraph (3), the coverage provides benefits with no cost-sharing after the individual has incurred costs (as described in subparagraph (C)) for covered outpatient drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B).

''(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

''(i) IN GENERAL.—For purposes of this part, the 'annual out-of-pocket thresh-

old' specified in this subparagraph is equal to $3,500 (subject to adjustment under clause (ii) and subparagraph (D)).

''(ii) INFLATION INCREASE.—For a year after 2006, the dollar amount specified in clause (i) shall be increased by the annual percentage increase described in paragraph (5) for the year involved. Any amount determined under the previous sentence that is not a multiple of $100 shall be rounded to the nearest multiple of $100.

''(C) APPLICATION.—In applying subparagraph (A)—

''(i) incurred costs shall only include costs incurred for the annual deductible (described in paragraph (1)), cost-sharing (described in paragraph (2)), and amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3); and

''(ii) such costs shall be treated as incurred only if they are paid by the individual (or by another individual, such as a family member, on behalf of the indi-

vidual), under section 1860D–7, under title XIX, or under a State pharmaceutical assistance program and the individual (or other individual) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such title or such program) for such costs.

''(D) ADJUSTMENT OF ANNUAL OUT-OF-POCKET THRESHOLDS.—

''(i) IN GENERAL.—Subject to clause (vii), for each enrollee in a prescription drug plan or in a MA-EFFS Rx plan whose adjusted gross income exceeds the income threshold as defined in clause (ii) for a year, the annual out-of-pocket threshold otherwise determined under subparagraph (B) for such year shall be increased by an amount equal to the percentage specified in clause (iii), multiplied by the lesser of—

''(I) the amount of such excess; or

''(II) the amount by which the income threshold limit exceeds the income threshold.

Any amount determined under the previous sentence that is not a multiple of $100 shall be rounded to the nearest multiple of $100.

''(ii) INCOME THRESHOLD.—For purposes of clause (i)—

''(I) IN GENERAL.—Subject to subclause (II), the term 'income threshold' means $60,000 and the term 'income threshold limit' means $200,000.

''(II) INCOME INFLATION ADJUSTMENT.—In the case of a year beginning after 2006, each of the dollar amounts in subclause (I) shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment determined under section 1(f)(3) of the Internal Revenue Code of 1986 for such year, determined by substituting 'calendar year 2005' for 'calendar year 1992'.

If any amount increased under the previous sentence is not a multiple of $100, such amount shall be rounded to the nearest multiple of $100.

"(iii) PERCENTAGE.—The percentage specified in this clause for a year is a fraction (expressed as a percentage) equal to—

"(I) the annual out-of-pocket threshold for a year under subparagraph (B) (determined without regard to this subparagraph), divided by

"(II) the income threshold under clause (ii) for that year.

If any percentage determined under the previous sentence that is not a multiple of 1/10th of 1 percentage point, such percentage shall be rounded to the nearest multiple of 1/10th of 1 percentage point.

"(iv) USE OF MOST RECENT RETURN INFORMATION.—For purposes of clause (i) for an enrollee for a year, except as provided in clause (v), the adjusted gross income of an individual shall be based on the most recent information disclosed to the Secretary under section 6109(l)(19) of the

Internal Revenue Code of 1986 before the beginning of that year.

''(v) INDIVIDUAL ELECTION TO PRESENT MOST RECENT INFORMATION REGARDING INCOME.—The Secretary shall provide, in coordination with the Secretary of the Treasury, a procedure under which, for purposes of applying this subparagraph for a calendar year, instead of using the information described in clause (iv), an enrollee may elect to use more recent information, including information with respect to a taxable year ending in such calendar year. Such process shall—

''(I) require the enrollee to provide the Secretary with a copy of the relevant portion of the more recent return to be used under this clause;

''(II) provide for the Medicare Beneficiary Ombudsman (under section 1810) offering assistance to such enrollees in presenting such information and the toll-free number under such section being a point of contact

for beneficiaries to inquire as to how to present such information;

''(III) provide for the verification of the information in such return by the Secretary of the Treasury under section 6103(l)(19) of the Internal Revenue Code of 1986; and

''(IV) provide for the payment by the Secretary (in a manner specified by the Secretary) to the enrollee of an amount equal to the excess of the benefit payments that would have been payable under the plan if the more recent return information were used, over the benefit payments that were made under the plan.

In the case of a payment under subclause (III) for an enrollee under a prescription drug plan, the PDP sponsor of the plan shall pay to the Secretary the amount so paid, less the applicable reinsurance amount that would have applied under section 1860D–8(c)(1)(B) if such payment had been treated as an allowable cost under such section. Such plan payment

shall be deposited in the Treasury to the credit of the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund (under section 1841).

''(vi) DISSEMINATION OF INFORMATION ON PROCESS.—The Secretary shall provide, through the annual medicare handbook under section 1804(a), for a general description of the adjustment of annual out-of-pocket thresholds provided under this subparagraph, including the process for adjustment based upon more recent information and the confidentiality provisions of subparagraph (F), and shall provide for dissemination of a table for each year that sets forth the amount of the adjustment that is made under clause (i) based on the amount of an enrollee's adjusted gross income.

''(vii) ENROLLEE OPT-OUT.—The Secretary shall provide a procedure whereby, if an enrollee elects to have the maximum annual out-of-pocket threshold applied under this subparagraph for a year, the

Secretary shall not request any information regarding the enrollee under subparagraph (E) for that year.

''(E) REQUESTING INFORMATION ON ENROLLEES.—

''(i) IN GENERAL.—The Secretary shall, periodically as required to carry out subparagraph (D), transmit to the Secretary of the Treasury a list of the names and TINs of enrollees in prescription drug plans (or in MA-EFFS Rx plans) and request that such Secretary disclose to the Secretary information under subparagraph (A) of section 6103(l)(19) of the Internal Revenue Code of 1986 with respect to those enrollees for a specified taxable year for application in a particular calendar year.

''(ii) DISCLOSURE TO PLAN SPONSORS.—In the case of a specified taxpayer (as defined in section 6103(l)(19)(B) of the Internal Revenue Code of 1986) who is enrolled in a prescription drug plan or in an MA-EFFS Rx plan or an individual who makes an election under subparagraph

(D)(vii), the Secretary shall disclose to the entity that offers the plan the annual out-of-pocket threshold applicable to such individual under subparagraph (D).

''(F) MAINTAINING CONFIDENTIALITY OF INFORMATION.—

''(i) IN GENERAL.—The amount of any increase in an annual out-of-pocket threshold under subparagraph (D) may not be disclosed by the Secretary except to a PDP sponsor or entity that offers a MA-EFFS Rx plan to the extent necessary to carry out this part.

''(ii) CRIMINAL AND CIVIL PENALTIES FOR UNAUTHORIZED DISCLOSURE.—A person who makes an unauthorized disclosure of information disclosed under section 6103(l)(19) of the Internal Revenue Code of 1986 (including disclosure of any increase in an annual out-of-pocket threshold under subparagraph (D)) shall be subject to penalty to the extent provided under—

''(I) section 7213 of such Code (relating to criminal penalty for unauthorized disclosure of information);

"(II) section 7213A of such Code (relating to criminal penalty for unauthorized inspection of returns or return information);

"(III) section 7431 of such Code (relating to civil damages for unauthorized inspection or disclosure of returns and return information);

"(IV) any other provision of the Internal Revenue Code of 1986; or

"(V) any other provision of law.

"(iii) APPLICATION OF ADDITIONAL CIVIL MONETARY PENALTY FOR UNAUTHORIZED DISCLOSURES.—In addition to any penalty otherwise provided under law, any person who makes an unauthorized disclosure of such information shall be subject to a civil monetary penalty of not to exceed $10,000 for each such unauthorized disclosure. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

"(G) INFORMATION REGARDING THIRD-PARTY REIMBURSEMENT.—In order to ensure compliance with the requirements of subparagraph (C)(ii), the Administrator is authorized to establish procedures, in coordination with the Secretary of Treasury and the Secretary of Labor, for determining whether costs for individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement, and for alerting the sponsors and organization that offer the plans in which such individuals are enrolled about such reimbursement arrangements. A PDP sponsor or Medicare Advantage or EFFS organization may also periodically ask individuals enrolled in a prescription drug plan or MA-EFFS Rx plan offered by the sponsor or organization whether the individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Administrator and determined through a process established by the Administrator) shall con-

stitute grounds for termination of enrollment under section 1860D–1(d)(3).

''(5) ANNUAL PERCENTAGE INCREASE.—For purposes of this part, the annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as determined by the Administrator for the 12-month period ending in July of the previous year.

''(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A prescription drug plan or MA-EFFS Rx plan may provide a different prescription drug benefit design from the standard coverage described in subsection (b) so long as the Administrator determines (based on an actuarial analysis approved by the Administrator) that the following requirements are met and the plan applies for, and receives, the approval of the Administrator for such benefit design:

''(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

''(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage (as determined under subsection (e)) is at least equal to the actuarial value (as so determined) of standard coverage.

"(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (e)) exceeds the actuarial value of the subsidy payments under section 1860D–8 with respect to such coverage.

"(C) ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization (as determined under subsection (e)), to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3), of an amount equal to at least the product of—

"(i) the amount by which the initial coverage limit described in subsection (b)(3) exceeds the deductible described in subsection (b)(1); and

"(ii) 100 percent minus the cost-sharing percentage specified in subsection (b)(2)(A)(i).

"(2) CATASTROPHIC PROTECTION.—The coverage provides for beneficiaries the catastrophic protection described in subsection (b)(4).

"(d) ACCESS TO NEGOTIATED PRICES.—

"(1) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor or an entity offering a MA-EFFS Rx plan, the sponsor or entity shall provide beneficiaries with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of cost-sharing or an initial coverage limit (described in subsection (b)(3)). Insofar as a State elects to provide medical assistance under title XIX to a beneficiary enrolled under such title and under a prescription drug plan or MA-EFFS Rx plan for a drug based on the prices negotiated by a prescription drug plan or MA-EFFS Rx plan under this part, the requirements of section 1927 shall not apply to such drugs. The prices negotiated by a prescription drug plan under this part, by a MA-EFFS

Rx plan with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

''(2) DISCLOSURE.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall disclose to the Administrator (in a manner specified by the Administrator) the extent to which discounts or rebates or other remuneration or price concessions made available to the sponsor or organization by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Administrator under this paragraph in the same manner as such provisions apply to information disclosed under such section.

''(3) AUDITS AND REPORTS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part, in addition to any protections against fraud and abuse provided under section 1860D–4(b)(3)(C), the Administrator

may periodically audit the financial statements and records of PDP sponsor or entities offering a MA-EFFS Rx plan.

''(e) ACTUARIAL VALUATION; DETERMINATION OF ANNUAL PERCENTAGE INCREASES.—

''(1) PROCESSES.—For purposes of this section, the Administrator shall establish processes and methods—

''(A) for determining the actuarial valuation of prescription drug coverage, including—

''(i) an actuarial valuation of standard coverage and of the reinsurance subsidy payments under section 1860D–8;

''(ii) the use of generally accepted actuarial principles and methodologies; and

''(iii) applying the same methodology for determinations of alternative coverage under subsection (c) as is used with respect to determinations of standard coverage under subsection (b); and

''(B) for determining annual percentage increases described in subsection (b)(5).

Such methods for determining actuarial valuation shall take into account effects of alternative coverage on drug utilization.

''(2) USE OF OUTSIDE ACTUARIES.—Under the processes under paragraph (1)(A), PDP sponsors and entities offering MA-EFFS Rx plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values, but the Administrator shall determine whether such actuarial values meet the requirements under subsection (c)(1).

''(f) COVERED OUTPATIENT DRUGS DEFINED.—

''(1) IN GENERAL.—Except as provided in this subsection, for purposes of this part, the term 'covered outpatient drug' means—

''(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

''(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any

use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

''(2) EXCLUSIONS.—

''(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

''(B) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

''(3) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered under a plan if the plan excludes the drug under a formulary and such exclusion is not successfully appealed under section 1860D–3(f)(2).

''(4) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or MA-EFFS Rx plan may exclude from qualified prescription drug coverage any covered outpatient drug—

''(A) for which payment would not be made if section 1862(a) applied to part D; or

''(B) which are not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860D–3(f).

"SEC. 1860D–3. BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

''(a) GUARANTEED ISSUE, COMMUNITY-RATED PREMIUMS, ACCESS TO NEGOTIATED PRICES, AND NONDISCRIMINATION.—For provisions requiring guaranteed issue, community-rated premiums, access to negotiated prices, and nondiscrimination, see sections 1860D–1(c)(1), 1860D–1(c)(2), 1860D–2(d), and 1860D–6(b), respectively.

''(b) DISSEMINATION OF INFORMATION.—

''(1) GENERAL INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time

of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

"(A) Access to specific covered outpatient drugs, including access through pharmacy networks.

"(B) How any formulary used by the sponsor functions, including the drugs included in the formulary.

"(C) Co-payments and deductible requirements, including the identification of the tiered or other co-payment level applicable to each drug (or class of drugs).

"(D) Grievance and appeals procedures.

Such information shall also be made available upon request to prospective enrollees.

"(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to enroll under a prescription drug plan, the PDP sponsor shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such individual.

''(3) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information to enrollees upon request. The sponsor shall make available on a timely basis, through an Internet website and in writing upon request, information on specific changes in its formulary.

''(4) CLAIMS INFORMATION.—Each PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees an explanation of benefits (in accordance with section 1806(a) or in a comparable manner) and a notice of the benefits in relation to initial coverage limit and the annual out-of-pocket threshold applicable to such enrollee for the current year, whenever prescription drug benefits are provided under this part (except that such notice need not be provided more often than monthly).

''(c) ACCESS TO COVERED BENEFITS.—

''(1) ASSURING PHARMACY ACCESS.—

''(A) PARTICIPATION OF ANY WILLING PHARMACY.—A PDP sponsor and an entity offering a MA-EFFS Rx plan shall permit the participation of any pharmacy that meets terms and conditions that the plan has established.

"(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—A prescription drug plan and a MA-EFFS Rx plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for its enrolled beneficiaries below the level otherwise provided for covered outpatient drugs dispensed through in-network pharmacies, but in no case shall such a reduction result in an increase in payments made by the Administrator under section 1860D–8 to a plan.

"(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—The PDP sponsor of the prescription drug plan and the entity offering a MA-EFFS Rx plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules of the Administrator). The Administrator shall establish convenient access rules under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies of the Secretary of Defense established as of June 1, 2003, for purposes of the

TRICARE Retail Pharmacy (TRRx) program. Such rules shall include adequate emergency access for enrolled beneficiaries.

''(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order, with any differential in charge paid by such enrollees.

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

''(2) USE OF STANDARDIZED TECHNOLOGY.—

''(A) IN GENERAL.—The PDP sponsor of a prescription drug plan and an entity offering a MA-EFFS Rx plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d) for the purchase of prescription drugs for which coverage is not otherwise provided under the plan.

''(B) STANDARDS.—

''(i) DEVELOPMENT.—The Administrator shall provide for the development or utilization of uniform standards relating to a standardized format for the card or other technology referred to in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

''(ii) APPLICATION OF ADVISORY TASK FORCE.—The advisory task force established under subsection (d)(3)(B)(ii) shall provide recommendations to the Administrator under such subsection regarding the standards developed under clause (i).

''(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan or an entity offering a MA-EFFS Rx plan uses a formulary, the following requirements must be met:

''(A) PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—The sponsor or entity must establish a pharmacy and therapeutic committee that develops and reviews the formulary. Such committee shall include at least one practicing physician and at least one practicing phar-

macist independent and free of conflict with respect to the committee both with expertise in the care of elderly or disabled persons and a majority of its members shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

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

''(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

''(ii) shall take into account whether including in the formulary particular covered outpatient drugs has therapeutic advantages in terms of safety and efficacy.

''(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (although

not necessarily for all drugs within such categories and classes). In establishing such classes, the committee shall take into account the standards published in the United States Pharmacopeia-Drug Information. The committee shall make available to the enrollees under the plan through the Internet or otherwise the bases for the exclusion of coverage of any drug from the formulary.

''(D) PROVIDER AND PATIENT EDUCATION.—The committee shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

''(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY FOR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered outpatient drug from a formulary and any change in the preferred or tier cost-sharing status of such a drug shall take effect only after appropriate notice is made available to beneficiaries and physicians.

''(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, a prescription drug plan shall provide for the peri-

odic evaluation and analysis of treatment protocols and procedures.

''(G) GRIEVANCES AND APPEALS RELATING TO APPLICATION OF FORMULARIES.—For provisions relating to grievances and appeals of coverage, see subsections (e) and (f).

''(d) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

''(1) IN GENERAL.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall have in place, directly or through appropriate arrangements, with respect to covered outpatient drugs—

''(A) an effective cost and drug utilization management program, including medically appropriate incentives to use generic drugs and therapeutic interchange, when appropriate;

''(B) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including side-effects, and improve medication use, including a medication therapy management program described in paragraph (2) and for years beginning with 2007, an electronic prescription program described in paragraph (3); and

"(C) a program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor or entity from utilizing cost management tools (including differential payments) under all methods of operation.

"(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

"(A) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management and medication administration that may be furnished by a pharmacy provider and that is designed to assure, with respect to beneficiaries at risk for potential medication problems, such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that covered outpatient drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use and reduce the risk of adverse events, including adverse drug interactions. Such programs may

distinguish between services in ambulatory and institutional settings.

''(B) ELEMENTS.—Such program may include—

''(i) enhanced beneficiary understanding to promote the appropriate use of medications by beneficiaries and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, case management, disease state management programs, and other appropriate means;

''(ii) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

''(iii) detection of patterns of overuse and underuse of prescription drugs.

''(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

"(D) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug program and an entity offering a MA-EFFS Rx plan shall take into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program. Each such sponsor or entity shall disclose to the Administrator upon request the amount of any such management or dispensing fees and such fees shall be confidential in the same manner as provided under section 1927(b)(3)(D) for information disclosed under section 1927(b)(3)(A).

"(3) ELECTRONIC PRESCRIPTION PROGRAM.—

"(A) IN GENERAL.—An electronic prescription drug program described in this paragraph is a program that includes at least the following components, consistent with uniform standards established under subparagraph (B):

"(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions must be written and transmitted electronically (other than by facsimile), except in emergency cases and other exceptional cir-

cumstances recognized by the Administrator.

''(ii) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL.—The program provides for the electronic transmittal to the prescribing health care professional of information that includes—

''(I) information (to the extent available and feasible) on the drug or drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

''(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

''(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related

information on an interactive, real-time basis.

''(B) STANDARDS.—

''(i) DEVELOPMENT.—The Administrator shall provide for the development of uniform standards relating to the electronic prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

''(ii) ADVISORY TASK FORCE.—In developing such standards and the standards described in subsection (c)(2)(B)(i) the Administrator shall establish a task force that includes representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, individuals with expertise in information technology, and pharmacy benefit experts of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Administrator on such standards, including recommendations relating to the following:

''(I) The range of available computerized prescribing software and hardware and their costs to develop and implement.

''(II) The extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals.

''(III) Efforts to develop uniform standards and a common software platform for the secure electronic communication of medication history, eligibility, benefit, and prescription information.

''(IV) Efforts to develop and promote universal connectivity and interoperability for the secure electronic exchange of such information.

''(V) The cost of implementing such systems in the range of hospital and physician office settings and pharmacies, including hardware, software, and training costs.

''(VI) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

''(iii) DEADLINES.—

''(I) The Administrator shall constitute the task force under clause (ii) by not later than April 1, 2004.

''(II) Such task force shall submit recommendations to Administrator by not later than January 1, 2005.

''(III) The Administrator shall provide for the development and promulgation, by not later than January 1, 2006, of national standards relating to the electronic prescription drug program described in clause (ii). Such standards shall be issued by a standards organization accredited by the American National Standards Institute (ANSI) and shall be compatible

with standards established under part C of title XI.

''(4) TREATMENT OF ACCREDITATION.—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to prescription drug plans under this part with respect to the following requirements, in the same manner as they apply to plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

''(A) Paragraph (1) (including quality assurance), including medication therapy management program under paragraph (2).

''(B) Subsection (c)(1) (relating to access to covered benefits).

''(C) Subsection (g) (relating to confidentiality and accuracy of enrollee records).

''(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—Each PDP sponsor and each entity offering a MA-EFFS Rx plan shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug shall inform the beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost available generic drug

covered under the plan that is therapeutically equivalent and bioequivalent.

''(e) GRIEVANCE MECHANISM, COVERAGE DETERMINATIONS, AND RECONSIDERATIONS.—

''(1) IN GENERAL.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

''(2) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an organization with respect to benefits it offers under a plan under part C.

''(3) REQUEST FOR REVIEW OF TIERED FORMULARY DETERMINATIONS.—In the case of a prescription drug plan offered by a PDP sponsor or a MA-EFFS Rx plan that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs in-

cluded within the formulary, an individual who is enrolled in the plan may request coverage of a nonpreferred drug under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both.

''(f) APPEALS.—

''(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to drugs (including a determination related to the application of tiered cost-sharing described in subsection (e)(3)) in the same manner as such requirements apply to an organization with respect to benefits it offers under a plan under part C.

''(2) FORMULARY DETERMINATIONS.—An individual who is enrolled in a prescription drug plan offered by a PDP sponsor or in a MA-EFFS Rx plan may appeal to obtain coverage for a covered outpatient drug that is not on a formulary of the sponsor or entity offering the plan if the prescribing physician determines that the formulary drug for treatment of the same condition either would not be as

effective for the individual or would have adverse effects for the individual or both.

''(g) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—A PDP sponsor that offers a prescription drug plan shall meet the requirements of section 1852(h) with respect to enrollees under the plan in the same manner as such requirements apply to an organization with respect to enrollees under part C. A PDP sponsor shall be treated as a business associate for purposes of the provisions of subpart E of part 164 of title 45, Code of Federal Regulations, adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2 note).

''SEC. 1860D–4. REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS.

''(a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

''(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

''(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

''(A) IN GENERAL.—Subject to subparagraph (B) and section 1860D–5(d)(2), the entity assumes full financial risk on a prospective basis for qualified prescription drug coverage that it offers under a prescription drug plan and that is not covered under section 1860D–8.

''(B) REINSURANCE PERMITTED.—The entity may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee.

''(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a sponsor that is not described in paragraph (1), the sponsor shall meet solvency standards established by the Administrator under subsection (d).

''(b) CONTRACT REQUIREMENTS.—

''(1) IN GENERAL.—The Administrator shall not permit the election under section 1860D–1 of a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D–7 or 1860D–8, unless the Administrator has entered into a contract

under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

''(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—The Administrator shall have the same authority to negotiate the terms and conditions of prescription drug plans under this part as the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. In negotiating the terms and conditions regarding premiums for which information is submitted under section 1860D–6(a)(2), the Administrator shall take into account the subsidy payments under section 1860D–8.

''(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—The following provisions of section 1857 shall apply, subject to subsection (c)(5), to contracts under this section in the same manner as they apply to contracts under section 1857(a):

"(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b), except that the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

"(B) CONTRACT PERIOD AND EFFECTIVENESS.—Paragraphs (1) through (3) and (5) of section 1857(c).

"(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

"(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that in applying section 1857(e)(2) under this part—

"(i) such section shall be applied separately to costs relating to this part (from costs under part C and part E);

"(ii) in no case shall the amount of the fee established under this subparagraph for a plan exceed 20 percent of the maximum amount of the fee that may be established under subparagraph (B) of such section; and

"(iii) no fees shall be applied under this subparagraph with respect to MA-EFFS Rx plans.

"(E) INTERMEDIATE SANCTIONS.—Section 1857(g).

"(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

"(4) RULES OF APPLICATION FOR INTERMEDIATE SANCTIONS.—In applying paragraph (3)(E)—

"(A) the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part; and

"(B) the reference in section 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall not be applied.

"(5) SERVICE AREA REQUIREMENT.—For purposes of this part, the Administrator shall designate at least 10 areas covering the entire United States and to the extent practicable shall be consistent with EFFS regions established under section 1860E–1(a)(2).

"(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

"(1) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Administrator shall waive the requirement of subsection (a)(1) that the entity be licensed in

that State if the Administrator determines, based on the application and other evidence presented to the Administrator, that any of the grounds for approval of the application described in paragraph (2) have been met.

''(2) GROUNDS FOR APPROVAL.—The grounds for approval under this paragraph are the grounds for approval described in subparagraph (B), (C), and (D) of section 1855(a)(2), and also include the application by a State of any grounds other than those required under Federal law.

''(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply.

''(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that an entity is licensed in accordance with subsection (a)(1) does not deem the entity to meet other requirements imposed under this part for a PDP sponsor.

''(5) REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying provi-

sions of section 1855(a)(2) under this subsection to prescription drug plans and PDP sponsors—

"(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1); and

"(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d).

"(d) SOLVENCY STANDARDS FOR NON-LICENSED SPONSORS.—

"(1) ESTABLISHMENT.—The Administrator shall establish, by not later than October 1, 2004, financial solvency and capital adequacy standards that an entity that does not meet the requirements of subsection (a)(1) must meet to qualify as a PDP sponsor under this part.

"(2) COMPLIANCE WITH STANDARDS.—Each PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Administrator shall establish certification procedures for such PDP sponsors

with respect to such solvency standards in the manner described in section 1855(c)(2).

''(e) RELATION TO STATE LAWS.—

''(1) IN GENERAL.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency, except as provided in subsection (d)) with respect to prescription drug plans which are offered by PDP sponsors under this part.

''(2) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.—No State may impose a premium tax or similar tax with respect to premiums paid to PDP sponsors for prescription drug plans under this part, or with respect to any payments made to such a sponsor by the Administrator under this part.

''SEC. 1860D–5. PROCESS FOR BENEFICIARIES TO SELECT QUALIFIED PRESCRIPTION DRUG COVERAGE.

''(a) IN GENERAL.—The Administrator shall establish a process for the selection of the prescription drug plan or MA-EFFS Rx plan through which eligible individuals elect qualified prescription drug coverage under this part.

''(b) ELEMENTS.—Such process shall include the following:

''(1) Annual, coordinated election periods, in which such individuals can change the qualifying plans through which they obtain coverage, in accordance with section 1860D–1(b)(2).

''(2) Active dissemination of information to promote an informed selection among qualifying plans based upon price, quality, and other features, in the manner described in (and in coordination with) section 1851(d), including the provision of annual comparative information, maintenance of a toll-free hotline, and the use of non-Federal entities.

''(3) Coordination of elections through filing with the entity offering a MA-EFFS Rx plan or a PDP sponsor, in the manner described in (and in coordination with) section 1851(c)(2).

''(4) Informing each enrollee before the beginning of each year of the annual out-of-pocket threshold applicable to the enrollee for that year under section 1860D–2(b)(4) at such time.

''(c) MA-EFFS RX ENROLLEE MAY ONLY OBTAIN BENEFITS THROUGH THE PLAN.—An individual who is enrolled under a MA-EFFS Rx plan may only elect to receive qualified prescription drug coverage under this part through such plan.

"(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

"(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—

"(A) IN GENERAL.—The Administrator shall assure that each individual who is entitled to benefits under part A or enrolled under part B and who is residing in an area in the United States has available, consistent with subparagraph (B), a choice of enrollment in at least two qualifying plans (as defined in paragraph (5)) in the area in which the individual resides, at least one of which is a prescription drug plan.

"(B) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in subparagraph (A) is not satisfied with respect to an area if only one PDP sponsor or one entity that offers a MA-EFFS Rx plan offers all the qualifying plans in the area.

"(2) GUARANTEEING ACCESS TO COVERAGE.—In order to assure access under paragraph (1) and consistent with paragraph (3), the Administrator may provide partial underwriting of risk for a PDP sponsor to expand the service area under an existing

prescription drug plan to adjoining or additional areas or to establish such a plan (including offering such a plan on a regional or nationwide basis), but only so long as (and to the extent) necessary to assure the access guaranteed under paragraph (1).

''(3) LIMITATION ON AUTHORITY.—In exercising authority under this subsection, the Administrator—

''(A) shall not provide for the full underwriting of financial risk for any PDP sponsor; and

''(B) shall seek to maximize the assumption of financial risk by PDP sponsors or entities offering a MA-EFFS Rx plan.

''(4) REPORTS.—The Administrator shall, in each annual report to Congress under section 1809(f), include information on the exercise of authority under this subsection. The Administrator also shall include such recommendations as may be appropriate to minimize the exercise of such authority, including minimizing the assumption of financial risk.

''(5) QUALIFYING PLAN DEFINED.—For purposes of this subsection, the term 'qualifying plan'

means a prescription drug plan or a MA-EFFS Rx plan.

"SEC. 1860D–6. SUBMISSION OF BIDS AND PREMIUMS.

"(a) SUBMISSION OF BIDS, PREMIUMS, AND RELATED INFORMATION.—

"(1) IN GENERAL.—Each PDP sponsor shall submit to the Administrator the information described in paragraph (2) in the same manner as information is submitted by an organization under section 1854(a)(1).

"(2) INFORMATION SUBMITTED.—The information described in this paragraph is the following:

"(A) COVERAGE PROVIDED.—Information on the qualified prescription drug coverage to be provided.

"(B) ACTUARIAL VALUE.—Information on the actuarial value of the coverage.

"(C) BID AND PREMIUM.—Information on the bid and the premium for the coverage, including an actuarial certification of—

"(i) the actuarial basis for such bid and premium;

"(ii) the portion of such bid and premium attributable to benefits in excess of standard coverage;

"(iii) the reduction in such bid resulting from the reinsurance subsidy payments provided under section 1860D–8(a)(2); and

"(iv) the reduction in such premium resulting from the direct and reinsurance subsidy payments provided under section 1860D–8.

"(D) ADDITIONAL INFORMATION.—Such other information as the Administrator may require to carry out this part.

"(3) REVIEW OF INFORMATION; NEGOTIATION AND APPROVAL OF PREMIUMS.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Administrator shall review the information filed under paragraph (2) for the purpose of conducting negotiations under section 1860D–4(b)(2) (relating to using OPM-like authority under the FEHBP). The Administrator, using the information provided (including the actuarial certification under paragraph (2)(C)) shall approve the premium submitted under this subsection only if the premium accurately reflects both (i) the actuarial value of the benefits provided, and (ii) the 73 percent aver-

age subsidy provided under section 1860D–8 for the standard benefit. The Administrator shall apply actuarial principles to approval of a premium under this part in a manner similar to the manner in which those principles are applied in establishing the monthly part B premium under section 1839.

''(B) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of subparagraph (A) shall not apply and the provisions of paragraph (5)(B) of section 1854(a), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and proportion referred to in subparagraph (A).

''(b) UNIFORM BID AND PREMIUM.—

''(1) IN GENERAL.—The bid and premium for a prescription drug plan under this section may not vary among enrollees in the plan in the same service area.

''(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing the imposition of a late enrollment penalty under section 1860D–1(c)(2)(B).

''(c) COLLECTION.—

''(1) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a PDP sponsor shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the sponsor through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph shall be credited to the Medicare Prescription Drug Trust Fund and shall be paid to the PDP sponsor involved.

''(2) OFFSETTING.—Reductions in premiums for coverage under parts A and B as a result of a selection of a MA-EFFS Rx plan may be used to reduce the premium otherwise imposed under paragraph (1).

''(d) ACCEPTANCE OF REFERENCE PREMIUM AMOUNT AS FULL PREMIUM FOR SUBSIDIZED LOW-IN-

come Individuals if No Standard (or Equivalent) Coverage in an Area.—

''(1) In general.—If there is no standard prescription drug coverage (as defined in paragraph (2)) offered in an area, in the case of an individual who is eligible for a premium subsidy under section 1860D–7 and resides in the area, the PDP sponsor of any prescription drug plan offered in the area (and any entity offering a MA-EFFS Rx plan in the area) shall accept the reference premium amount (under paragraph (3)) as payment in full for the premium charge for qualified prescription drug coverage.

''(2) Standard prescription drug coverage defined.—For purposes of this subsection, the term 'standard prescription drug coverage' means qualified prescription drug coverage that is standard coverage or that has an actuarial value equivalent to the actuarial value for standard coverage.

''(3) Reference premium amount defined.—For purposes of this subsection, the term 'reference premium amount' means, with respect to qualified prescription drug coverage offered under—

''(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value is equivalent to that of standard coverage), the plan's PDP premium; or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the plan's PDP premium multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage;

"(B) an EFFS plan, the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)); or

"(C) a Medicare Advantage, the Medicare Advantage monthly prescription drug beneficiary premium (as defined in section 1854(b)(2)(B)).

For purposes of subparagraph (A), the term 'PDP premium' means, with respect to a prescription drug plan, the premium amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or

any late enrollment penalty under section 1860D–1(c)(2)(B)).

"SEC. 1860D–7. PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS.

"(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY LEVEL.—

"(1) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR INDIVIDUALS WITH INCOME BELOW 135 PERCENT OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual (as defined in paragraph (4)) who is determined to have income that does not exceed 135 percent of the Federal poverty level, the individual is entitled under this section—

"(A) to an income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1); and

"(B) subject to subsection (c), to the substitution for the beneficiary cost-sharing described in paragraphs (1) and (2) of section 1860D–2(b) (up to the initial coverage limit specified in paragraph (3) of such section) of amounts that do not exceed $2 for a multiple source or generic drug (as described in section

1927(k)(7)(A)) and $5 for a non-preferred drug.

''(2) SLIDING SCALE PREMIUM SUBSIDY FOR INDIVIDUALS WITH INCOME ABOVE 135, BUT BELOW 150 PERCENT, OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual who is determined to have income that exceeds 135 percent, but does not exceed 150 percent, of the Federal poverty level, the individual is entitled under this section to an income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in subsection (b)(1) for individuals with incomes at 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

''(3) CONSTRUCTION.—Nothing in this section shall be construed as preventing a PDP sponsor or entity offering a MA-EFFS Rx plan from reducing to 0 the cost-sharing otherwise applicable to generic drugs.

''(4) DETERMINATION OF ELIGIBILITY.—

''(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, subject to subparagraph (D), the term 'subsidy eligible individual' means an individual who—

"(i) is eligible to elect, and has elected, to obtain qualified prescription drug coverage under this part;

"(ii) has income below 150 percent of the Federal poverty line; and

"(iii) meets the resources requirement described in subparagraph (D).

"(B) DETERMINATIONS.—The determination of whether an individual residing in a State is a subsidy eligible individual and the amount of such individual's income shall be determined under the State medicaid plan for the State under section 1935(a) or by the Social Security Administration. In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

"(C) INCOME DETERMINATIONS.—For purposes of applying this section—

"(i) income shall be determined in the manner described in section 1905(p)(1)(B); and

"(ii) the term 'Federal poverty line' means the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

"(D) RESOURCE STANDARD APPLIED TO BE BASED ON THREE TIMES SSI RESOURCE STANDARD.—The resource requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed—

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

"(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the con-

sumer price index (all items; U.S. city average) as of September of such previous year.

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

''(E) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of an individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual but may be eligible for financial assistance with prescription drug expenses under section 1935(e).

''(F) TREATMENT OF CONFORMING MEDIGAP POLICIES.—For purposes of this section, the term 'qualified prescription drug coverage' includes a medicare supplemental policy described in section 1860D–8(b)(4).

''(5) INDEXING DOLLAR AMOUNTS.—

''(A) FOR 2007.—The dollar amounts applied under paragraphs (1)(B) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase described in section 1860D–2(b)(5) for 2007.

''(B) FOR SUBSEQUENT YEARS.—The dollar amounts applied under paragraph (1)(B) for a year after 2007 shall be the amounts (under this paragraph) applied under paragraph (1)(B) for the preceding year increased by the annual percentage increase described in section 1860D–2(b)(5) (relating to growth in medicare prescription drug costs per beneficiary) for the year involved.

''(b) PREMIUM SUBSIDY AMOUNT.—

''(1) IN GENERAL.—The premium subsidy amount described in this subsection for an individual residing in an area is the benchmark premium amount (as defined in paragraph (2)) for qualified prescription drug coverage offered by the prescription drug plan or the MA-EFFS Rx plan in which the individual is enrolled.

''(2) BENCHMARK PREMIUM AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark premium amount' means, with respect to qualified prescription drug coverage offered under—

''(A) a prescription drug plan that—

''(i) provides standard coverage (or alternative prescription drug coverage the

actuarial value of which is equivalent to that of standard coverage), the premium amount for enrollment under the plan under this part (determined without regard to any subsidy under this section or any late enrollment penalty under section 1860D–1(c)(2)(B)); or

''(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the premium amount described in clause (i) multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

''(B) a MA-EFFS Rx plan, the portion of the premium amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

''(c) RULES IN APPLYING COST-SHARING SUBSIDIES.—

''(1) IN GENERAL.—In applying subsection (a)(1)(B), nothing in this part shall be construed as preventing a plan or provider from waiving or reducing the amount of cost-sharing otherwise applicable.

''(2) LIMITATION ON CHARGES.—In the case of an individual receiving cost-sharing subsidies under subsection (a)(1)(B), the PDP sponsor or entity offering a MA-EFFS Rx plan may not charge more than $5 per prescription.

''(3) APPLICATION OF INDEXING RULES.—The provisions of subsection (a)(5) shall apply to the dollar amount specified in paragraph (2) in the same manner as they apply to the dollar amounts specified in subsections (a)(1)(B).

''(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The Administrator shall provide a process whereby, in the case of an individual who is determined to be a subsidy eligible individual and who is enrolled in prescription drug plan or is enrolled in a MA-EFFS Rx plan—

''(1) the Administrator provides for a notification of the PDP sponsor or the entity offering the MA-EFFS Rx plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

''(2) the sponsor or entity involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Administrator information on the amount of such reduction; and

''(3) the Administrator periodically and on a timely basis reimburses the sponsor or entity for the amount of such reductions.

The reimbursement under paragraph (3) with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

''(e) RELATION TO MEDICAID PROGRAM.—

''(1) IN GENERAL.—For provisions providing for eligibility determinations, and additional financing, under the medicaid program, see section 1935.

''(2) MEDICAID PROVIDING WRAP AROUND BENEFITS.—The coverage provided under this part is primary payor to benefits for prescribed drugs provided under the medicaid program under title XIX consistent with section 1935(d)(1).

''(3) COORDINATION.—The Administrator shall develop and implement a plan for the coordination of prescription drug benefits under this part with the benefits provided under the medicaid program under title XIX, with particular attention to insuring coordination of payments and prevention of fraud and abuse. In developing and implementing such plan, the Administrator shall involve the Sec-

retary, the States, the data processing industry, pharmacists, and pharmaceutical manufacturers, and other experts.

"SEC. 1860D–8. SUBSIDIES FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

''(a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for all medicare beneficiaries consistent with an overall subsidy level of 73 percent, to reduce adverse selection among prescription drug plans and MA-EFFS Rx plans, and to promote the participation of PDP sponsors under this part, the Administrator shall provide in accordance with this section for payment to a qualifying entity (as defined in subsection (b)) of the following subsidies:

''(1) DIRECT SUBSIDY.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, a direct subsidy equal to 43 percent of the national average monthly bid amount (computed under subsection (g)) for that month.

''(2) SUBSIDY THROUGH REINSURANCE.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, the reinsurance payment amount (as defined in subsection

(c)), which in the aggregate is 30 percent of the total payments made by qualifying entities for standard coverage under the respective plan, for excess costs incurred in providing qualified prescription drug coverage—

"(A) for enrollees with a prescription drug plan under this part; and

"(B) for enrollees with a MA-EFFS Rx plan.

"(3) EMPLOYER AND UNION FLEXIBILITY.—In the case of an individual who is a participant or beneficiary in a qualified retiree prescription drug plan (as defined in subsection (f)(1)) and who is not enrolled in a prescription drug plan or in a MA-EFFS Rx plan, the special subsidy payments under subsection (f)(3).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Administrator to provide for the payment of amounts provided under this section.

"(b) QUALIFYING ENTITY DEFINED.—For purposes of this section, the term 'qualifying entity' means any of the following that has entered into an agreement with the Administrator to provide the Administrator with such information as may be required to carry out this section:

''(1) A PDP sponsor offering a prescription drug plan under this part.

''(2) An entity that offers a MA-EFFS Rx plan.

''(3) The sponsor of a qualified retiree prescription drug plan (as defined in subsection (f)).

''(c) REINSURANCE PAYMENT AMOUNT.—

''(1) IN GENERAL.—Subject to subsection (d)(1)(B) and paragraph (4), the reinsurance payment amount under this subsection for a qualifying covered individual (as defined in paragraph (5)) for a coverage year (as defined in subsection (h)(2)) is equal to the sum of the following:

''(A) REINSURANCE BETWEEN INITIAL REINSURANCE THRESHOLD AND THE INITIAL COVERAGE LIMIT.—For the portion of the individual's gross covered prescription drug costs (as defined in paragraph (3)) for the year that exceeds the initial reinsurance threshold specified in paragraph (4), but does not exceed the initial coverage limit specified in section 1860D–2(b)(3), an amount equal to 20 percent of the allowable costs (as defined in paragraph (2)) attributable to such gross covered prescription drug costs.

''(B) REINSURANCE ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—For the portion of the individual's gross covered prescription drug costs for the year that exceeds the annual out-of-pocket threshold specified in 1860D–2(b)(4)(B), an amount equal to 80 percent of the allowable costs attributable to such gross covered prescription drug costs.

''(2) ALLOWABLE COSTS.—For purposes of this section, the term 'allowable costs' means, with respect to gross covered prescription drug costs under a plan described in subsection (b) offered by a qualifying entity, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were standard coverage.

''(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered prescription drug costs' means, with respect to an enrollee with a qualifying entity under a plan described in subsection (b) during a coverage year, the costs incurred under the plan (including costs attributable to administrative costs) for cov-

ered prescription drugs dispensed during the year, including costs relating to the deductible, whether paid by the enrollee or under the plan, regardless of whether the coverage under the plan exceeds standard coverage and regardless of when the payment for such drugs is made.

''(4) INITIAL REINSURANCE THRESHOLD.—The initial reinsurance threshold specified in this paragraph—

''(A) for 2006, is equal to $1,000; or

''(B) for a subsequent year, is equal to the payment threshold specified in this paragraph for the previous year, increased by the annual percentage increase described in section 1860D–2(b)(5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(5) QUALIFYING COVERED INDIVIDUAL DEFINED.—For purposes of this subsection, the term 'qualifying covered individual' means an individual who—

''(A) is enrolled with a prescription drug plan under this part; or

''(B) is enrolled with a MA-EFFS Rx plan.

''(d) ADJUSTMENT OF PAYMENTS.—

''(1) ADJUSTMENT OF REINSURANCE PAYMENTS TO ASSURE 30 PERCENT LEVEL OF SUBSIDY THROUGH REINSURANCE.—

''(A) ESTIMATION OF PAYMENTS.—The Administrator shall estimate—

''(i) the total payments to be made (without regard to this subsection) during a year under subsections (a)(2) and (c); and

''(ii) the total payments to be made by qualifying entities for standard coverage under plans described in subsection (b) during the year.

''(B) ADJUSTMENT.—The Administrator shall proportionally adjust the payments made under subsections (a)(2) and (c) for a coverage year in such manner so that the total of the payments made under such subsections for the year is equal to 30 percent of the total payments described in subparagraph (A)(ii).

''(2) RISK ADJUSTMENT FOR DIRECT SUBSIDIES.—To the extent the Administrator determines it appropriate to avoid risk selection, the payments made for direct subsidies under subsection

(a)(1) are subject to adjustment based upon risk factors specified by the Administrator. Any such risk adjustment shall be designed in a manner as to not result in a change in the aggregate payments made under such subsection.

''(e) PAYMENT METHODS.—

''(1) IN GENERAL.—Payments under this section shall be based on such a method as the Administrator determines. The Administrator may establish a payment method by which interim payments of amounts under this section are made during a year based on the Administrator's best estimate of amounts that will be payable after obtaining all of the information.

''(2) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Trust Fund.

''(f) RULES RELATING TO QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—

''(1) DEFINITION.—For purposes of this section, the term 'qualified retiree prescription drug plan' means employment-based retiree health coverage (as defined in paragraph (4)(A)) if, with respect to an individual who is a participant or beneficiary under such coverage and is eligible to be en-

rolled in a prescription drug plan or a MA-EFFS Rx plan under this part, the following requirements are met:

"(A) ACTUARIAL EQUIVALENCE TO STANDARD COVERAGE.—The Administrator determines (based on an actuarial analysis approved by the Administrator) that coverage provides at least the same actuarial value as standard coverage. Such determination may be made on an annual basis.

"(B) AUDITS.—The sponsor (or the administrator, if designated by the sponsor) and the plan shall maintain, and afford the Administrator access to, such records as the Administrator may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made.

"(C) PROVISION OF CERTIFICATION OF PRESCRIPTION DRUG COVERAGE.—The sponsor of the plan shall provide for issuance of certifications of the type described in section 1860D–1(c)(2)(D).

"(2) LIMITATION ON BENEFIT ELIGIBILITY.—No payment shall be provided under this section

with respect to a participant or beneficiary in a qualified retiree prescription drug plan unless the individual is—

"(A) is covered under the plan; and

"(B) is eligible to obtain qualified prescription drug coverage under section 1860D–1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan).

"(3) EMPLOYER AND UNION SPECIAL SUBSIDY AMOUNTS.—

"(A) IN GENERAL.—For purposes of subsection (a), the special subsidy payment amount under this paragraph for a qualifying covered retiree(as defined in paragraph (6)) for a coverage year (as defined in subsection (h)) enrolled in a qualifying entity described in subsection (b)(3) under a qualified retiree prescription drug plan is, for the portion of the individual's gross covered prescription drug costs for the year that exceeds the deductible amount specified in subparagraph (B), an amount equal to, subject to subparagraph (D), 28 percent of the allowable costs attributable to such gross covered prescription drug costs, but only to the

extent such costs exceed the deductible under subparagraph (B) and do not exceed the cost limit under such subparagraph in the case of any such individual for the plan year.

''(B) DEDUCTIBLE AND COST LIMIT APPLICABLE.—Subject to subparagraph (C)—

''(i) the deductible under this subparagraph is equal to $250 for plan years that end in 2006; and

''(ii) the cost limit under this subparagraph is equal to $5,000 for plan years that end in 2006.

''(C) INDEXING.—The deductible and cost limit amounts specified in subparagraphs (B) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible under section 1860D–2(b)(1) is annually adjusted under such section.

''(4) RELATED DEFINITIONS.—As used in this section:

''(A) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs for individuals eligible to enroll in a prescription

drug plan or MA-EFFS Rx plan under this part (or for such individuals and their spouses and dependents) under a group health plan (including such a plan that is established or maintained under or pursuant to one or more collective bargaining agreements or that is offered under chapter 89 of title 5, United States Code) based on their status as retired participants in such plan.

''(B) QUALIFYING COVERED RETIREE.—The term 'qualifying covered retiree' means an individual who is eligible to obtain qualified prescription drug coverage under section 1860D–1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan) but is covered under a qualified retiree prescription drug plan.

''(C) SPONSOR.—The term 'sponsor' means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

''(5) CONSTRUCTION.—Nothing in this subsection shall be construed as—

''(A) precluding an individual who is covered under employment-based retiree health

coverage from enrolling in a prescription drug plan or in a MA-EFFS plan;

''(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under such a prescription drug plan or MA-EFFS plan on behalf of such an individual; or

''(C) preventing such employment-based retiree health coverage from providing coverage for retirees—

''(i) who are covered under a qualified retiree prescription plan that is better than standard coverage; or

''(ii) who are not covered under a qualified retiree prescription plan but who are enrolled in a prescription drug plan or a MA-EFFS Rx plan, that is supplemental to the benefits provided under such prescription drug plan or MA-EFFS Rx plan, except that any such supplemental coverage (not including payment of any premium referred to in subparagraph (B)) shall be treated as primary coverage to

which section 1862(b)(2)(A)(i) is deemed to apply.

''(g) COMPUTATION OF NATIONAL AVERAGE MONTHLY BID AMOUNT.—

''(1) IN GENERAL.—For each year (beginning with 2006) the Administrator shall compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each prescription drug plan and for each MA-EFFS Rx plan (as computed under paragraph (2), but excluding plans described in section 1851(a)(2)(C))) adjusted under paragraph (4) to take into account reinsurance payments.

''(2) BENCHMARK BID AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark bid amount' means, with respect to qualified prescription drug coverage offered under—

''(A) a prescription drug plan that—

''(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard coverage), the PDP bid; or

''(ii) provides alternative prescription drug coverage the actuarial value of which

is greater than that of standard coverage, the PDP bid multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

''(B) a MA-EFFS Rx plan, the portion of the bid amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

For purposes of subparagraph (A), the term 'PDP bid' means, with respect to a prescription drug plan, the bid amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or any late enrollment penalty under section 1860D–1(c)(2)(B)).

''(3) WEIGHTED AVERAGE.—

''(A) IN GENERAL.—The monthly national average monthly bid amount computed under paragraph (1) shall be a weighted average, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the previous year.

''(B) SPECIAL RULE FOR 2006.—For purposes of applying this subsection for 2006, the Administrator shall establish procedures for de-

termining the weighted average under subparagraph (A) for 2005.

''(4) ADJUSTMENT TO ADD BACK IN VALUE OF REINSURANCE SUBSIDIES.—The adjustment under this paragraph, to take into account reinsurance payments under subsection (c) making up 30 percent of total payments, is such an adjustment as will make the national average monthly bid amount represent represent 100 percent, instead of representing 70 percent, of average payments under this part.

''(h) COVERAGE YEAR DEFINED.—For purposes of this section, the term 'coverage year' means a calendar year in which covered outpatient drugs are dispensed if a claim for payment is made under the plan for such drugs, regardless of when the claim is paid.

"SEC. 1860D–9. MEDICARE PRESCRIPTION DRUG TRUST FUND.

''(a) IN GENERAL.—There is created on the books of the Treasury of the United States a trust fund to be known as the 'Medicare Prescription Drug Trust Fund' (in this section referred to as the 'Trust Fund'). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, such fund as provided in this part. Except as otherwise pro-

vided in this section, the provisions of subsections (b) through (i) of section 1841 shall apply to the Trust Fund in the same manner as they apply to the Federal Supplementary Medical Insurance Trust Fund under such section.

''(b) PAYMENTS FROM TRUST FUND.—

''(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Administrator certifies are necessary to make—

''(A) payments under section 1860D–7 (relating to low-income subsidy payments);

''(B) payments under section 1860D–8 (relating to subsidy payments); and

''(C) payments with respect to administrative expenses under this part in accordance with section 201(g).

''(2) TRANSFERS TO MEDICAID ACCOUNT FOR INCREASED ADMINISTRATIVE COSTS.—The Managing Trustee shall transfer from time to time from the Trust Fund to the Grants to States for Medicaid account amounts the Administrator certifies are attributable to increases in payment resulting from the application of a higher Federal matching percentage under section 1935(b).

''(c) DEPOSITS INTO TRUST FUND.—

''(1) LOW-INCOME TRANSFER.—There is hereby transferred to the Trust Fund, from amounts appropriated for Grants to States for Medicaid, amounts equivalent to the aggregate amount of the reductions in payments under section 1903(a)(1) attributable to the application of section 1935(c).

''(2) APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Trust Fund, an amount equivalent to the amount of payments made from the Trust Fund under subsection (b), reduced by the amount transferred to the Trust Fund under paragraph (1).

''(d) RELATION TO SOLVENCY REQUIREMENTS.—Any provision of law that relates to the solvency of the Trust Fund under this part shall take into account the Trust Fund and amounts receivable by, or payable from, the Trust Fund.

"SEC. 1860D–10. DEFINITIONS; APPLICATION TO MEDICARE ADVANTAGE AND EFFS PROGRAMS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C.

''(a) DEFINITIONS.—For purposes of this part:

''(1) COVERED OUTPATIENT DRUGS.—The term 'covered outpatient drugs' is defined in section 1860D–2(f).

''(2) INITIAL COVERAGE LIMIT.—The term 'initial coverage limit' means such limit as established under section 1860D–2(b)(3), or, in the case of coverage that is not standard coverage, the comparable limit (if any) established under the coverage.

''(3) MEDICARE PRESCRIPTION DRUG TRUST FUND.—The term 'Medicare Prescription Drug Trust Fund' means the Trust Fund created under section 1860D–9(a).

''(4) PDP SPONSOR.—The term 'PDP sponsor' means an entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

''(5) PRESCRIPTION DRUG PLAN.—The term 'prescription drug plan' means health benefits coverage that—

''(A) is offered under a policy, contract, or plan by a PDP sponsor pursuant to, and in accordance with, a contract between the Administrator and the sponsor under section 1860D–4(b);

"(B) provides qualified prescription drug coverage; and

"(C) meets the applicable requirements of the section 1860D–3 for a prescription drug plan.

"(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' is defined in section 1860D–2(a).

"(7) STANDARD COVERAGE.—The term 'standard coverage' is defined in section 1860D–2(b).

"(8) INSURANCE RISK.—The term 'insurance risk' means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

"(b) OFFER OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE ADVANTAGE AND EFFS PROGRAMS.—

"(1) AS PART OF MEDICARE ADVANTAGE PLAN.—Medicare Advantage organizations are required to offer Medicare Advantage plans that in-

clude qualified prescription drug coverage under part C pursuant to section 1851(j).

''(2) AS PART OF EFFS PLAN.—EFFS organizations are required to offer EFFS plans that include qualified prescription drug coverage under part E pursuant to section 1860E–2(d).

''(c) APPLICATION OF PART C PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

''(1) any reference to a Medicare Advantage or other plan included a reference to a prescription drug plan;

''(2) any reference to a provider-sponsored organization included a reference to a PDP sponsor;

''(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D–4(b); and

''(4) any reference to part C included a reference to this part.

''(d) REPORT ON PHARMACY SERVICES PROVIDED TO LONG-TERM CARE FACILITY PATIENTS.—

''(1) REVIEW.—Within 6 months after the date of the enactment of this section, the Secretary shall

review the current standards of practice for pharmacy services provided to patients in nursing facilities and other long-term care facilities.

''(2) EVALUATIONS AND RECOMMENDATIONS.—Specifically in the review under paragraph (1), the Secretary shall—

''(A) assess the current standards of practice, clinical services, and other service requirements generally utilized for pharmacy services in the long-term care setting;

''(B) evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care; and

''(C) recommend (in the Secretary's report under paragraph (3)) necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to medicare beneficiaries residing in nursing facilities and other long-term care facilities in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

''(3) REPORT.—The Secretary shall submit a report to the Congress on the Secretary's findings and recommendations under this subsection, includ-

ing a detailed description of the Secretary's plans to implement this part in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of patients of nursing facilities and other long-term care facilities.''.

(b) ADDITIONAL CONFORMING CHANGES.—

(1) CONFORMING REFERENCES TO PREVIOUS PART D.—Any reference in law (in effect before the date of the enactment of this Act) to part D of title XVIII of the Social Security Act is deemed a reference to part F of such title (as in effect after such date).

(2) CONFORMING AMENDMENT PERMITTING WAIVER OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)) is amended—

(A) by striking ''and'' at the end of subparagraph (E);

(B) by striking the period at the end of subparagraph (F) and inserting ''; and''; and

(C) by adding at the end the following new subparagraph:

''(G) the waiver or reduction of any cost-sharing imposed under part D of title XVIII.''.

(3) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enact-

ment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this subtitle.

(c) STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE.—Not later than January 1, 2005, the Medicare Benefits Administrator shall submit a report to Congress that makes recommendations regarding methods for providing benefits under part D of title XVIII of the Social Security Act for outpatient prescription drugs for which benefits are provided under part B of such title.

SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM.

(a) MEDICARE ADVANTAGE.—Section 1851 (42 U.S.C. 1395w–21) is amended by adding at the end the following new subsection:

''(j) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS AND SUBSIDIES.—

''(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—A Medicare Advantage organization on and after January 1, 2006—

''(A) may not offer a Medicare Advantage plan described in section 1851(a)(2)(A) in an area unless either that plan (or another Medicare Advantage plan offered by the organization in that area) includes qualified prescription drug coverage; and

''(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under a Medicare Advantage plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

''(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D–1(b) shall be treated as being ineligible to enroll in a Medicare Advantage plan under this part that offers such coverage.

''(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by a Medicare

Advantage organization under this part on and after January 1, 2006, the organization and plan shall meet the requirements of subsections (a) through (d) of section 1860D–3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D–6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

''(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in a Medicare Advantage plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

''(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—Medicare Advantage organizations are provided direct and reinsurance subsidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

''(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of a Medicare Advantage plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

''(7) TRANSITION IN INITIAL ENROLLMENT PERIOD.—Notwithstanding any other provision of this part, the annual, coordinated election period under subsection (e)(3)(B) for 2006 shall be the 6-month period beginning with November 2005.

''(8) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.

''(9) SPECIAL RULES FOR PRIVATE FEE-FOR-SERVICE PLANS.— With respect to a Medicare Advantage plan described in section 1851(a)(2)(C) that offers qualified prescription drug coverage—

''(A) REQUIREMENTS REGARDING NEGOTIATED PRICES.—Subsections (a)(1) and (d)(1) of section 1860D–2 shall not be construed to require the plan to negotiate prices or discounts but shall apply to the extent the plan does so.

"(B) MODIFICATION OF PHARMACY PARTICIPATION REQUIREMENT.—If the plan provides access, without charging additional copayments, to all pharmacies without regard to whether they are participating pharmacies in a network, section 1860D-3(c)(1)(A)(iii) shall not apply to the plan.

"(C) DRUG UTILIZATION MANAGEMENT PROGRAM NOT REQUIRED.—The requirements of section 1860D-3(d)(1)(A) shall not apply to the plan.

"(D) NON-PARTICIPATING PHARMACY DISCLOSURE EXCEPTION.—If the plan provides coverage for drugs purchased from all pharmacies, without entering into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, section 1860D-3(d)(5) shall not apply to the plan.".

(b) APPLICATION TO EFFS PLANS.—Subsection (d) of section 1860E–2, as added by section 201(a), is amended to read as follows:

"(d) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS AND SUBSIDIES.—

"(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—An EFFS organization—

''(A) may not offer an EFFS plan in an area unless either that plan (or another EFFS plan offered by the organization in that area) includes qualified prescription drug coverage; and

''(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under an EFFS plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

''(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D–1(b) shall be treated as being ineligible to enroll in an EFFS plan under this part that offers such coverage.

''(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by an EFFS organization under this part, the organization and plan shall meet the requirements of subsections (a)

through (d) of section 1860D–3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D–6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

''(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in an EFFS plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

''(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—EFFS organizations are provided direct and reinsurance subsidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

''(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of an EFFS plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a sin-

gle premium for both drug and non-drug coverage provided under the plan.

''(7) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.''.

(c) CONFORMING AMENDMENTS.—Section 1851 (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)—

(A) by inserting ''(other than qualified prescription drug benefits)'' after ''benefits'';

(B) by striking the period at the end of subparagraph (B) and inserting a comma; and

(C) by adding after and below subparagraph (B) the following:

''and may elect qualified prescription drug coverage in accordance with section 1860D–1.''; and

(2) in subsection (g)(1), by inserting ''and section 1860D–1(c)(2)(B)'' after ''in this subsection''.

(d) EFFECTIVE DATE.—The amendments made by this section apply to coverage provided on or after January 1, 2006.

SEC. 103. MEDICAID AMENDMENTS.

(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—

(1) REQUIREMENT.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

(A) by striking ''and'' at the end of paragraph (64);

(B) by striking the period at the end of paragraph (65) and inserting ''; and''; and

(C) by inserting after paragraph (65) the following new paragraph:

''(66) provide for making eligibility determinations under section 1935(a).''.

(2) NEW SECTION.—Title XIX is further amended—

(A) by redesignating section 1935 as section 1936; and

(B) by inserting after section 1934 the following new section:

''SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

''SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a), a State shall—

''(1) make determinations of eligibility for premium and cost-sharing subsidies under (and in accordance with) section 1860D–7;

''(2) inform the Administrator of the Medicare Benefits Administration of such determinations in cases in which such eligibility is established; and

''(3) otherwise provide such Administrator with such information as may be required to carry out part D of title XVIII (including section 1860D–7).

''(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE COSTS.—

''(1) IN GENERAL.—The amounts expended by a State in carrying out subsection (a) are, subject to paragraph (2), expenditures reimbursable under the appropriate paragraph of section 1903(a); except that, notwithstanding any other provision of such section, the applicable Federal matching rates with respect to such expenditures under such section shall be increased as follows (but in no case shall the rate as so increased exceed 100 percent):

''(A) For expenditures attributable to costs incurred during 2005, the otherwise applicable Federal matching rate shall be increased by 6-⅔ percent of the percentage otherwise payable (but for this subsection) by the State.

"(B)(i) For expenditures attributable to costs incurred during 2006 and each subsequent year through 2018, the otherwise applicable Federal matching rate shall be increased by the applicable percent (as defined in clause (ii)) of the percentage otherwise payable (but for this subsection) by the State.

"(ii) For purposes of clause (i), the 'applicable percent' for—

"(I) 2006 is 13-⅓ percent; or

"(II) a subsequent year is the applicable percent under this clause for the previous year increased by 6-⅔ percentage points.

"(C) For expenditures attributable to costs incurred after 2018, the otherwise applicable Federal matching rate shall be increased to 100 percent.

"(2) COORDINATION.—The State shall provide the Administrator with such information as may be necessary to properly allocate administrative expenditures described in paragraph (1) that may otherwise be made for similar eligibility determinations.".

(b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RESPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES FOR DUALLY ELIGIBLE INDIVIDUALS.—

(1) IN GENERAL.—Section 1903(a)(1) (42 U.S.C. 1396b(a)(1)) is amended by inserting before the semicolon the following: ", reduced by the amount computed under section 1935(c)(1) for the State and the quarter".

(2) AMOUNT DESCRIBED.—Section 1935, as inserted by subsection (a)(2), is amended by adding at the end the following new subsection:

"(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALLY-ELIGIBLE BENEFICIARIES.—

"(1) IN GENERAL.—For purposes of section 1903(a)(1), for a State that is one of the 50 States or the District of Columbia for a calendar quarter in a year (beginning with 2005) the amount computed under this subsection is equal to the product of the following:

"(A) MEDICARE SUBSIDIES.—The total amount of payments made in the quarter under section 1860D–7 (relating to premium and cost-sharing prescription drug subsidies for low-income medicare beneficiaries) that are attrib-

utable to individuals who are residents of the State and are entitled to benefits with respect to prescribed drugs under the State plan under this title (including such a plan operating under a waiver under section 1115).

"(B) STATE MATCHING RATE.—A proportion computed by subtracting from 100 percent the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State and the quarter.

"(C) PHASE-OUT PROPORTION.—The phase-out proportion (as defined in paragraph (2)) for the quarter.

"(2) PHASE-OUT PROPORTION.—For purposes of paragraph (1)(C), the 'phase-out proportion' for a calendar quarter in—

"(A) 2006 is 93-⅓ percent;

"(B) a subsequent year before 2021, is the phase-out proportion for calendar quarters in the previous year decreased by 6-⅔ percentage points; or

"(C) a year after 2020 is 0 percent.".

(c) MEDICAID PROVIDING WRAP-AROUND BENEFITS.—Section 1935, as so inserted and amended, is fur-

ther amended by adding at the end the following new subsection:

''(d) ADDITIONAL PROVISIONS.—

''(1) MEDICAID AS SECONDARY PAYOR.—In the case of an individual who is entitled to qualified prescription drug coverage under a prescription drug plan under part D of title XVIII (or under a MA-EFFS Rx plan under part C or E of such title) and medical assistance for prescribed drugs under this title, medical assistance shall continue to be provided under this title (other than for copayment amounts specified in section 1860D–7(a)(1)(B), notwithstanding section 1916) for prescribed drugs to the extent payment is not made under the prescription drug plan or MA-EFFS Rx plan selected by the individual.

''(2) CONDITION.—A State may require, as a condition for the receipt of medical assistance under this title with respect to prescription drug benefits for an individual eligible to obtain qualified prescription drug coverage described in paragraph (1), that the individual elect qualified prescription drug coverage under section 1860D–1.''.

(d) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—Section 1935, as so inserted and amended, is further amended—

(A) in subsection (a) in the matter preceding paragraph (1), by inserting ''subject to subsection (e)'' after ''section 1903(a)'';

(B) in subsection (c)(1), by inserting ''subject to subsection (e)'' after ''1903(a)(1)''; and

(C) by adding at the end the following new subsection:

''(e) TREATMENT OF TERRITORIES.—

''(1) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia—

''(A) the previous provisions of this section shall not apply to residents of such State; and

''(B) if the State establishes a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in paragraph (3).

''(2) PLAN.—The plan described in this paragraph is a plan that—

''(A) provides medical assistance with respect to the provision of covered outpatient drugs (as defined in section 1860D–2(f)) to low-income medicare beneficiaries; and

''(B) assures that additional amounts received by the State that are attributable to the operation of this subsection are used only for such assistance.

''(3) INCREASED AMOUNT.—

''(A) IN GENERAL.—The amount specified in this paragraph for a State for a year is equal to the product of—

''(i) the aggregate amount specified in subparagraph (B); and

''(ii) the amount specified in section 1108(g)(1) for that State, divided by the sum of the amounts specified in such section for all such States.

''(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for—

''(i) 2006, is equal to $25,000,000; or

''(ii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased

by annual percentage increase specified in section 1860D–2(b)(5) for the year involved.

''(4) REPORT.—The Administrator shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Administrator deems appropriate.''.

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting ''and section 1935(e)(1)(B)'' after ''Subject to subsection (g)''.

(e) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(1) by striking ''and'' at the end of subclause (III);

(2) by striking the period at the end of subclause (IV) and inserting ''; and''; and

(3) by adding at the end the following new subclause:

''(V) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by a MA-EFFS Rx plan under part C or

E of such title with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.''.

SEC. 104. MEDIGAP TRANSITION.

(a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

''(v) COVERAGE OF PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, except as provided in paragraph (3) no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under this section on or after January 1, 2006, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs. Nothing in this subsection shall be construed as preventing the policy holder of a medicare supplemental policy issued before Janu-

ary 1, 2006, from continuing to receive benefits under such policy on and after such date.

''(2) ISSUANCE OF SUBSTITUTE POLICIES FOR BENEFICIARIES ENROLLED WITH A PLAN UNDER PART D.—

''(A) IN GENERAL.—The issuer of a medicare supplemental policy—

''(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as 'A', 'B', 'C', 'D', 'E', 'F', or 'G' (under the standards established under subsection (p)(2)) and that is offered and is available for issuance to new enrollees by such issuer;

''(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

''(iii) may not impose an exclusion of benefits based on a pre-existing condition under such policy,

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the date of

the termination of enrollment described in such paragraph and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

''(B) INDIVIDUAL COVERED.—An individual described in this subparagraph is an individual who—

''(i) enrolls in a prescription drug plan under part D; and

''(ii) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as 'H', 'I', or 'J' under the standards referred to in subparagraph (A)(i) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

''(C) ENFORCEMENT.—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of this paragraph in the same manner as they apply to the requirements of such subsection.

"(3) NEW STANDARDS.—In applying subsection (p)(1)(E) (including permitting the NAIC to revise its model regulations in response to changes in law) with respect to the change in benefits resulting from title I of the Medicare Prescription Drug and Modernization Act of 2003, with respect to policies issued to individuals who are enrolled in a plan under part D, the changes in standards shall only provide for substituting (for the benefit packages described in paragraph (2)(B)(ii) that included coverage for prescription drugs) two benefit packages that may provide for coverage of cost-sharing (other than the prescription drug deductible) with respect to qualified prescription drug coverage under such part. The two benefit packages shall be consistent with the following:

"(A) FIRST NEW POLICY.—The policy described in this subparagraph has the following benefits, notwithstanding any other provision of this section relating to a core benefit package:

"(i) Coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B, except coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

"(ii) No coverage of the part B deductible.

"(iii) Coverage for all hospital coinsurance for long stays (as in the current core benefit package).

"(iv) A limitation on annual out-of-pocket expenditures under parts A and B to $4,000 in 2005 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

"(B) SECOND NEW POLICY.—The policy described in this subparagraph has the same benefits as the policy described in subparagraph (A), except as follows:

"(i) Substitute '75 percent' for '50 percent' in clause (i) of such subparagraph.

"(ii) Substitute '$2,000' for '$4,000' in clause (iv) of such subparagraph.

"(4) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met through the offering of other coverage under this subsection.".

(b) NAIC REPORT TO CONGRESS ON MEDIGAP MODERNIZATION.—The Secretary shall request the National Association of Insurance Commissioners to submit to Congress, not later than 18 months after the date of the enactment of this Act, a report that includes recommendations on the modernization of coverage under the medigap program under section 1882 of the Social Security Act (42 U.S.C. 1395ss).

SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND ASSISTANCE PROGRAM.

(a) IN GENERAL.—Title XVIII is amended by inserting after section 1806 the following new sections:

''MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT AND ASSISTANCE PROGRAM

''SEC. 1807. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—The Secretary shall establish a program—

''(A) to endorse prescription drug discount card programs (each such program referred to as an 'endorsed program') that meet the requirements of this section in order to provide access to prescription drug discounts through eligible entities for medicare beneficiaries throughout the United States; and

''(B) to provide for prescription drug accounts and public contributions into such accounts.

The Secretary shall make available to medicare beneficiaries information regarding endorsed programs and accounts under this section.

''(2) LIMITED PERIOD OF OPERATION.—The Secretary shall begin—

''(A) the card endorsement part of the program under paragraph (1)(A) as soon as possible, but in no case later than 90 days after the date of the enactment of this section; and

''(B) the prescription drug account part of the program under paragraph (1)(B) as soon as possible, but in no case later than September 2004.

''(3) TRANSITION.—The program under this section shall continue through 2005 throughout the United States. The Secretary shall provide for an appropriate transition and termination of such program on January 1, 2006.

''(4) VOLUNTARY NATURE OF PROGRAM.—Nothing in this section shall be construed as requiring an eligible beneficiary to enroll in the program under this section.

''(b) ELIGIBLE BENEFICIARY; ELIGIBLE ENTITY; PRESCRIPTION DRUG ACCOUNT.—For purposes of this section:

''(1) ELIGIBLE BENEFICIARY.—The term 'eligible beneficiary' means an individual who is eligible for benefits under part A or enrolled under part B and who is not enrolled in a Medicare Advantage plan that offers qualified prescription drug coverage.

''(2) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity that the Secretary determines to be appropriate to provide the benefits under this section, including—

''(A) pharmaceutical benefit management companies;

''(B) wholesale and retail pharmacy delivery systems;

''(C) insurers;

''(D) Medicare Advantage organizations;

''(E) other entities; or

''(F) any combination of the entities described in subparagraphs (A) through (E).

''(3) PRESCRIPTION DRUG ACCOUNT.—The term 'prescription drug account' means, with respect to an eligible beneficiary, an account established for the benefit of that beneficiary under section 1807A.

"(c) ENROLLMENT IN ENDORSED PLAN.—

"(1) ESTABLISHMENT OF PROCESS.—

"(A) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary may make an election to enroll under this section with an endorsed program.

"(B) REQUIREMENT OF ENROLLMENT.—An eligible beneficiary must enroll under this section for a year in order to be eligible to receive the benefits under this section for that year.

"(C) LIMITATION ON ENROLLMENT.—

"(i) IN GENERAL.—Except as provided under this subparagraph and under such exceptional circumstances as the Secretary may provide, an eligible individual shall have the opportunity to enroll under this section during an initial, general enrollment period as soon as possible after the date of the enactment of this section and annually thereafter. The Secretary shall specify the form, manner, and timing of such election but shall permit the exercise of such election at the time the individual is eligible to enroll. The annual open

enrollment periods shall be coordinated with those provided under the Medicare Advantage program under part C.

''(ii) REELECTION AFTER TERMINATION OF ENROLLMENT IN A MEDICARE ADVANTAGE PLAN.—In the case of an individual who is enrolled under this section and who subsequently enrolls in a Medicare Advantage plan that provides qualified prescription drug coverage under part C, the individual shall be given the opportunity to reenroll under this section at the time the individual discontinues the enrollment under such part.

''(iii) LATE ENROLLMENT.—The Secretary shall permit individuals to elect to enroll under this section at times other than as permitted under the previous provisions of this paragraph.

''(D) TERMINATION OF ENROLLMENT.—An enrollee under this section shall be disenrolled—

''(i) upon enrollment in a Medicare Advantage plan under part C that provides qualified prescription drug coverage;

"(ii) upon failure to pay the applicable enrollment fee under subsection (f);

"(iii) upon termination of coverage under part A or part B; or

"(iv) upon notice submitted to the Secretary in such form, manner, and time as the Secretary shall provide.

Terminations of enrollment under this subparagraph shall be effective as specified by the Secretary in regulations.

"(2) ENROLLMENT PERIODS.—

"(A) IN GENERAL.—Except as provided under this paragraph, an eligible beneficiary may not enroll in the program under this part during any period after the beneficiary's initial enrollment period under part B (as determined under section 1837).

"(B) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES.—The Secretary shall establish a period, which shall begin on the date on which the Secretary first begins to accept elections for enrollment under this section and shall end not earlier than 3 months later, during which any eligible beneficiary may enroll under this section.

"(C) SPECIAL ENROLLMENT PERIOD IN CASE OF TERMINATION OF COVERAGE UNDER A GROUP HEALTH PLAN.—The Secretary shall provide for a special enrollment period under this section in the same manner as is provided under section 1837(i) with respect to part B, except that for purposes of this subparagraph any reference to 'by reason of the individual's (or the individual's spouse's) current employment status' shall be treated as being deleted.

"(3) PERIOD OF COVERAGE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subject to subparagraph (C), an eligible beneficiary's coverage under the program under this section shall be effective for the period provided under section 1838, as if that section applied to the program under this section.

"(B) ENROLLMENT DURING OPEN AND SPECIAL ENROLLMENT.—Subject to subparagraph (C), an eligible beneficiary who enrolls under the program under this section under subparagraph (B) or (C) of paragraph (2) shall be entitled to the benefits under this section be-

ginning on the first day of the month following the month in which such enrollment occurs.

''(d) SELECTION OF AN ELIGIBLE ENTITY FOR ACCESS TO NEGOTIATED PRICES.—

''(1) PROCESS.—

''(A) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary who is enrolled under this section shall select any eligible entity, that has been awarded a contract under this section and serves the State in which the beneficiary resides, to provide access to negotiated prices under subsection (i).

''(B) RULES.—In establishing the process under subparagraph (A), the Secretary shall use rules similar to the rules for enrollment and disenrollment with a Medicare Advantage plan under section 1851 (including the special election periods under subsection (e)(4) of such section), including that—

''(i) an individual may not select more than one eligible entity at any time; and

''(ii) an individual shall only be permitted (except for unusual circumstances)

to change the selection of the entity once a year.

In carrying out clause (ii), the Secretary may consider a change in residential setting (such as placement in a nursing facility) to be an unusual circumstance.

''(C) DEFAULT SELECTION.—In establishing such process, the Secretary shall provide an equitable method for selecting an eligible entity for individuals who enroll under this section and fail to make such a selection.

''(2) COMPETITION.—Eligible entities with a contract under this section shall compete for beneficiaries on the basis of discounts, formularies, pharmacy networks, and other services provided for under the contract.

''(e) PROVIDING ENROLLMENT, SELECTION, AND COVERAGE INFORMATION TO BENEFICIARIES.—

''(1) ACTIVITIES.—The Secretary shall provide for activities under this section to broadly disseminate information to eligible beneficiaries (and prospective eligible beneficiaries) regarding enrollment under this section, the selection of eligible entities, and the prescription drug coverage made available by eligible entities with a contract under this section.

''(2) SPECIAL RULE FOR FIRST ENROLLMENT UNDER THE PROGRAM.—To the extent practicable, the activities described in paragraph (1) shall ensure that eligible beneficiaries are provided with such information at least 60 days prior to the first enrollment period described in subsection (c).

''(f) ENROLLMENT FEE.—

''(1) AMOUNT.—Except as provided in paragraph (3), enrollment under the program under this section is conditioned upon payment of an annual enrollment fee of $30. Such fee for 2004 shall include any portion of 2003 in which the program is implemented under this section.

''(2) COLLECTION OF ENROLLMENT FEE.—The annual enrollment fee shall be collected and credited to the Federal Supplementary Medical Insurance Trust Fund in the same manner as the monthly premium determined under section 1839 is collected and credited to such Trust Fund under section 1840, except that it shall be collected only 1 time per year.

''(3) PAYMENT OF ENROLLMENT FEE BY STATE FOR CERTAIN BENEFICIARIES.—

''(A) IN GENERAL.—The Secretary shall establish an arrangement under which a State

may provide for payment of some or all of the enrollment fee for some or all low income enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State and shall not be collected under paragraph (2). In carrying out this paragraph, the Secretary may apply procedures similar to that applied under state agreements under section 1843.

''(B) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State described in subparagraph (A) shall not be treated as State expenditures for purposes of Federal matching payments under titles XIX and XXI insofar as such expenditures are for an enrollment fee under this subsection.

''(4) DISTRIBUTION OF PORTION OF ENROLLMENT FEE.—Of the enrollment fee collected by the Secretary under this subsection with respect to a beneficiary, ⅔ of that fee shall be made available to the eligible entity selected by the eligible beneficiary.

''(g) ISSUANCE OF CARD AND COORDINATION.—Each eligible entity shall—

''(1) issue, in a uniform standard format specified by the Secretary, to each enrolled beneficiary a card and an enrollment number that establishes proof of enrollment and that can be used in a coordinated manner—

''(A) to identify the eligible entity selected to provide access to negotiated prices under subsection (i); and

''(B) to make deposits to and withdrawals from a prescription drug account under section 1807A; and

''(2) provide for electronic methods to coordinate with the accounts established under section 1807A.

''(h) ENROLLEE PROTECTIONS.—

''(1) GUARANTEED ISSUE AND NONDISCRIMINATION.—

''(A) GUARANTEED ISSUE.—

''(i) IN GENERAL.—An eligible beneficiary who is eligible to select an eligible entity under subsection (b) for prescription drug coverage under this section at a time during which selections are accepted under

this section with respect to the coverage shall not be denied selection based on any health status-related factor (described in section 2702(a)(1) of the Public Health Service Act) or any other factor and may not be charged any selection or other fee as a condition of such acceptance.

''(ii) MEDICARE ADVANTAGE LIMITATIONS PERMITTED.—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to selection of eligible entities under this paragraph.

''(B) NONDISCRIMINATION.—An eligible entity offering prescription drug coverage under this section shall not establish a service area in a manner that would discriminate based on health or economic status of potential enrollees.

''(C) COVERAGE OF ALL PORTIONS OF A STATE.—If an eligible entity with a contract under this section serves any part of a State it shall serve the entire State.

''(2) DISSEMINATION OF INFORMATION.—

"(A) GENERAL INFORMATION.—An eligible entity with a contract under this section shall disclose, in a clear, accurate, and standardized form to each eligible beneficiary who has selected the entity to provide access to negotiated prices under this section at the time of selection and at least annually thereafter, the information described in section 1852(c)(1) relating to such prescription drug coverage. Such information includes the following (in a manner designed to permit and promote competition among eligible entities):

"(i) Summary information regarding negotiated prices (including discounts) for covered outpatient drugs.

"(ii) Access to such prices through pharmacy networks.

"(iii) How any formulary used by the eligible entity functions.

"(B) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an eligible beneficiary, the eligible entity shall provide the information described in section 1852(c)(2)

(other than subparagraph (D)) to such beneficiary.

''(C) RESPONSE TO BENEFICIARY QUESTIONS.—Each eligible entity offering prescription drug coverage under this section shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices, including discounts) to individuals who have selected the entity. The entity shall make available, through an Internet website and in writing upon request, information on specific changes in its formulary.

''(D) COORDINATION WITH PRESCRIPTION DRUG ACCOUNT BENEFITS.—Each such eligible entity shall provide for coordination of such information as the Secretary may specify to carry out section 1807A.

''(3) ACCESS TO COVERED BENEFITS.—

''(A) ENSURING PHARMACY ACCESS.—The provisions of subsection (c)(1) of section 1860D–3 (other than payment provisions under section 1860D–8 with respect to sponsors under such subsection) shall apply to an eligible entity

under this section in the same manner as they apply to a PDP sponsor under such section.

''(B) ACCESS TO NEGOTIATED PRICES FOR PRESCRIPTION DRUGS.—For requirements relating to the access of an eligible beneficiary to negotiated prices (including applicable discounts), see subsection (i).

''(C) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—Insofar as an eligible entity with a contract under this part uses a formulary, the entity shall comply with the requirements of section 1860D–3(c)(3), insofar as the Secretary determines that such requirements can be implemented on a timely basis.

''(4) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

''(A) IN GENERAL.—For purposes of providing access to negotiated benefits under subsection (i), the eligible entity shall have in place the programs and measure described in section 1860D–3(d), including an effective cost and drug utilization management program, quality assurance measures and systems, and a pro-

gram to control fraud, abuse, and waste, insofar as the Secretary determines that such provisions can be implemented on a timely basis.

''(B) TREATMENT OF ACCREDITATION.—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to the requirements for an endorsed program under this section with respect to the following requirements, in the same manner as they apply to Medicare Advantage plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

''(i) Paragraph (3)(A) (relating to access to covered benefits).

''(ii) Paragraph (7) (relating to confidentiality and accuracy of enrollee records).

''(5) GRIEVANCE MECHANISM.—Each eligible entity shall provide meaningful procedures for hearing and resolving grievances between the organization consistent with the requirements of section 1860D–3(e) insofar as they relate to PDP sponsors of prescription drug plans.

''(6) BENEFICIARY SERVICES.—An eligible entity shall provide for its enrollees pharmaceutical sup-

port services, such as education and counseling, and services to prevent adverse drug interactions.

''(7) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—An eligible entity shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug coverage it offers under this section in the same manner as such requirements apply to a Medicare Advantage organization with respect to benefits it offers under a Medicare Advantage plan under part C.

''(8) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—An eligible entity shall meet the requirements of section 1852(h) with respect to enrollees under this section in the same manner as such requirements apply to a Medicare Advantage organization with respect to enrollees under part C. The eligible entity shall implement policies and procedures to safeguard the use and disclosure of enrollees' individually identifiable health information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. The eligible entity shall be

treated as a covered entity for purposes of the provisions of subpart E of part 164 of title 45, Code of Federal Regulations, adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2 note).

''(9) PERIODIC REPORTS AND OVERSIGHT.—The eligible entity shall submit to the Secretary periodic reports on performance, utilization, finances, and such other matters as the Secretary may specify. The Secretary shall provide appropriate oversight to ensure compliance of eligible entities with the requirements of this subsection, including verification of the discounts and services provided.

''(10) ADDITIONAL BENEFICIARY PROTECTIONS.—The eligible entity meets such additional requirements as the Secretary identifies to protect and promote the interest of enrollees, including requirements that ensure that enrollees are not charged more than the lower of the negotiated retail price or the usual and customary price.

''(i) BENEFITS UNDER THE PROGRAM THROUGH SAVINGS TO ENROLLEES THROUGH NEGOTIATED PRICES.—

''(1) IN GENERAL.—Subject to paragraph (2), each eligible entity with a contract under this section shall provide each eligible beneficiary enrolled with the entity with access to negotiated prices (including applicable discounts). For purposes of this paragraph, the term 'prescription drugs' is not limited to covered outpatient drugs, but does not include any over-the-counter drug that is not a covered outpatient drug. The prices negotiated by an eligible entity under this paragraph shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

''(2) FORMULARY RESTRICTIONS.—Insofar as an eligible entity with a contract under this part uses a formulary, the negotiated prices (including applicable discounts) for prescription drugs shall only be available for drugs included in such formulary.

''(3) PROHIBITION ON APPLICATION ONLY TO MAIL ORDER.—The negotiated prices under this subsection shall apply to prescription drugs that are available other than solely through mail order.

''(4) PROHIBITION ON CHARGES FOR REQUIRED SERVICES.—An eligible entity (and any pharmacy

contracting with such entity for the provision of a discount under this section) may not charge a beneficiary any amount for any services required to be provided by the entity under this section.

''(5) DISCLOSURE.—The eligible entity offering the endorsed program shall disclose to the Secretary (in a manner specified by the Secretary) the extent to which discounts or rebates or other remuneration or price concessions made available to the entity by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Secretary under this paragraph in the same manner as such provisions apply to information disclosed under such section.

''(6) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—Each eligible entity shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug in connection with its endorsed program shall inform the enrollee in that program at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost available ge-

neric drug covered under the program that is therapeutically equivalent and bioequivalent.

''(j) CONTRIBUTION INTO PRESCRIPTION DRUG ACCOUNT.—

''(1) IN GENERAL.—In the case of an individual enrolled under this section, the Secretary shall—

''(A) establish a prescription drug account for the individual under section 1807A; and

''(B) subject to paragraph (5), deposit into such account on a monthly or other periodic basis an amount that, on an annual basis, is equivalent to the annual Federal contribution amount specified in paragraph (2) for the enrollee involved.

''(2) ANNUAL FEDERAL CONTRIBUTION AMOUNT.—Subject to paragraph (3), in the case of an accountholder whose income is—

''(A) not more than 135 percent of the poverty line, the annual Federal contribution amount for a year is $800;

''(B) more than 135 percent, but not more than 150 percent, of the poverty line, the annual Federal contribution amount for a year is $500; or

"(C) more than 150 percent of the poverty line, the annual Federal contribution amount for a year is $100.

"(3) INCOME ELIGIBILITY DETERMINATIONS.—The determination of whether an individual residing in a State is a eligible for a contribution under paragraph (1) shall be determined under the State medicaid plan for the State under section 1935(a) or by the Social Security Administration. In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Secretary. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this paragraph.

"(4) PARTIAL YEAR.—Insofar as the provisions of this subsection and section 1807A are not implemented for all months in 2004, the annual contribution amount under this subsection for 2004 shall be prorated to reflect the portion of that year in which such provisions are in effect.

"(5) RESTRICTION ON CONTRIBUTIONS.—There shall only be an annual Federal contribution under

paragraph (1) for an individual if the individual is not eligible for coverage of, or assistance for, outpatient prescription drugs under any of the following:

"(A) A medicaid plan under title XIX (including under any waiver approved under section 1115).

"(B) Enrollment under a group health plan or health insurance coverage.

"(C) Enrollment under a medicare supplemental insurance policy.

"(D) Chapter 55 of title 10, United States Code (relating to medical and dental care for members of the uniformed services).

"(E) Chapter 17 of title 38, United States Code (relating to Veterans' medical care).

"(F) Enrollment under a plan under chapter 89 of title 5, United States Code (relating to the Federal employees' health benefits program).

"(G) The Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

"(6) APPROPRIATION TO COVER NET PROGRAM EXPENDITURES.—There are authorized to be appropriated from time to time, out of any moneys in the

Treasury not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund established under section 1841, an amount equal to the amount by which the benefits and administrative costs of providing the benefits under this section exceed the sum of the portion of the enrollment fees retained by the Secretary.

''(k) DEFINITIONS.—In this part and section 1807A:

''(1) COVERED OUTPATIENT DRUG.—

''(A) IN GENERAL.—Except as provided in this paragraph, for purposes of this section, the term 'covered outpatient drug' means—

''(i) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

''(ii) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 351 of the Public Health Service Act

and any use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

"(B) EXCLUSIONS.—

"(i) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

"(ii) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this section shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

"(C) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this section shall not be so considered under an endorsed program if the el-

igible entity offering the program excludes the drug under a formulary and a review of such exclusion is not successfully resolved under subsection (h)(5).

''(D) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—An eligible entity offering an endorsed program may exclude from qualified prescription drug coverage any covered outpatient drug—

''(i) for which payment would not be made if section 1862(a) applied to part D; or

''(ii) which are not prescribed in accordance with the program or this section.

Such exclusions are determinations subject to review pursuant to subsection (h)(5).

''(2) POVERTY LINE.—The term 'poverty line' means the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

''(l) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section and section 1807A.

''(e) INTERIM, FINAL REGULATORY AUTHORITY.—In order to carry out this section and section 1807A in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

''PRESCRIPTION DRUG ACCOUNTS

''SEC. 1807A. ''(a) ESTABLISHMENT OF ACCOUNTS.—

''(1) IN GENERAL.—The Secretary shall establish and maintain for each eligible beneficiary who is enrolled under section 1807 at the time of enrollment a prescription drug account (in this section and section 1807 referred to as an 'account').

''(2) RESERVE ACCOUNTS.—In cases described in subsections (b)(3)(A), (b)(3)(B)(i), and (b)(3)(B)(ii)(I), the Secretary shall establish and maintain for each surviving spouse who is not enrolled under section 1807 a reserve prescription drug account (in this section referred to as an 'reserve account').

''(3) ACCOUNTHOLDER DEFINED.—In this section and section 1807A, the term 'accountholder' means an individual for whom an account or reserve account has been established under this section.

''(4) EXPENDITURES FROM ACCOUNT.—Nothing in this section shall be construed as requiring

the Federal Government to obligate funds for amounts in any account until such time as a withdrawal from such account is authorized under this section.

''(b) USE OF ACCOUNTS.—

''(1) APPLICATION OF ACCOUNT.—Except as provided in this subsection, amounts credited to an account shall only be used for the purchase of covered outpatient drugs for the accountholder. Any amounts remaining at the end of a year remain available for expenditures in succeeding years.

''(2) ACCOUNT RULES FOR PUBLIC AND PRIVATE CONTRIBUTIONS.—The Secretary shall establish a ongoing process for the determination of the amount in each account that is attributable to public and private contributions (including spousal rollover contributions) based on the following rules:

''(A) TREATMENT OF EXPENDITURES.—Expenditures from the account shall—

''(i) first be counted against any public contribution; and

''(ii) next be counted against private contributions.

''(B) TREATMENT OF SPOUSAL ROLLOVER CONTRIBUTIONS.—With respect to any spousal

rollover contribution, the portions of such contribution that were attributable to public and private contributions at the time of its distribution under subsection (b)(3) shall be treated under this paragraph as if it were a direct public or private contribution, respectively, into the account of the spouse.

''(3) DEATH OF ACCOUNTHOLDER.—In the case of the death of an accountholder, the balance in any account (taking into account liabilities accrued before the time of death) shall be distributed as follows:

''(A) TREATMENT OF PUBLIC CONTRIBUTIONS.—If the accountholder is married at the time of death, the amount in the account that is attributable to public contributions shall be credited to the account (if any) of the surviving spouse of the accountholder (or, if the surviving spouse is not an eligible beneficiary, into a reserve account to be held for when that spouse becomes an eligible beneficiary).

''(B) TREATMENT OF PRIVATE CONTRIBUTIONS.—The amount in the account that is attributable to private contributions shall be distributed as follows:

"(i) DESIGNATION OF DISTRIBUTEE.—If the accountholder has made a designation, in a form and manner specified by the Secretary, for the distribution of some or all of such amount, such amount shall be distributed in accordance with the designation. Such designation may provide for the distribution into an account (including a reserve account) of a surviving spouse.

"(ii) ABSENCE OF DESIGNATION.—Insofar as the accountholder has not made such a designation—

"(I) SURVIVING SPOUSE.—If the accountholder was married at the time of death, the remainder shall be credited to an account (including a reserve account) of the accountholder's surviving spouse.

"(II) NO SURVIVING SPOUSE.—If the accountholder was not so married, the remainder shall be distributed to the estate of the accountholder and distributed as provided by law.

"(4) USE OF ACCOUNT FOR PREMIUMS FOR ENROLLMENT IN A MEDICARE ADVANTAGE PLAN.—During any period in which an accountholder is enrolled in a Medicare Advantage plan under part C, the balance in the account may be used and applied only to reimburse the amount of the premium (if any) established for enrollment under the plan.

"(5) APPLICATION TO MEDICAID EXPENSES IN CERTAIN CASES.—

"(A) IN GENERAL.—Except as provided in this paragraph, an account shall be treated as an asset for purposes of establishing eligibility for medical assistance under title XIX.

"(B) APPLICATION TOWARDS SPENDDOWN.—In the case of an accountholder who is applying for such medical assistance and who would, but for the application of subparagraph (A), be eligible for such assistance—

"(i) subparagraph (A) shall not apply; and

"(ii) the account shall be available (in accordance with a procedure established by the Secretary) to the State to reimburse the State for any expenditures made under the plan for such medical assistance.

''(c) AMOUNTS CREDITED IN ACCOUNT.—The Secretary shall credit to a prescription drug account of an eligible beneficiary the following amounts:

''(1) PUBLIC CONTRIBUTIONS.—The following contributions (each referred to in this section as a 'public contribution'):

''(A) FEDERAL CONTRIBUTIONS.—Federal contributions provided under subsection (d).

''(B) STATE CONTRIBUTIONS.—Contributions made by a State under subsection (f).

''(2) SPOUSAL ROLLOVER CONTRIBUTION.—A distribution from a deceased spouse under subsection (b)(3) (referred to in this section as a 'spousal rollover contribution').

''(3) PRIVATE CONTRIBUTIONS.—The following contributions (each referred to in this section as a 'private contribution'):

''(A) EMPLOYER AND INDIVIDUAL CONTRIBUTIONS.—Contributions made under subsection (e).

''(B) OTHER INDIVIDUAL CONTRIBUTIONS.—Contributions made by accountholder other than under subsection (e).

''(C) CONTRIBUTIONS BY NONPROFIT ORGANIZATIONS.—Contributions made by a chari-

table, not-for-profit organization (that may be a religious organization).

Except as provided in this subsection, no amounts may be contributed to, or credited to, a prescription drug account.

''(d) FEDERAL CONTRIBUTION.—For Federal contributions in the case of accountholders, see section 1807(j).

''(e) EMPLOYER AND INDIVIDUAL CONTRIBUTIONS.—

''(1) EMPLOYMENT-RELATED CONTRIBUTION.—

''(A) IN GENERAL.—In the case of any accountholder who is a beneficiary or participant in a group health plan (including a multiemployer plan), whether as an employee, former employee or otherwise, including as a dependent of an employee or former employee, the plan may make a contribution into the accountholder's account (but not into a reserve account of the accountholder).

''(B) LIMITATION.—The total amount that may be contributed under subparagraph (A) under a plan to an account during any year may not exceed $5,000.

"(C) CONDITION.—A group health plan may condition a contribution with respect to an accountholder under this paragraph on the accountholder's enrollment under section 1807 with an eligible entity that is recognized or approved by that plan.

"(2) OTHER INDIVIDUALS.—

"(A) IN GENERAL.—Any individual may also contribute to the account of that individual or the account of any other individual under this subsection.

"(B) LIMITATION.—The total amount that may be contributed to an account under subparagraph (A) during any year may not exceed $5,000, regardless of who makes such contribution.

"(3) NO CONTRIBUTION PERMITTED TO RESERVE ACCOUNT.—No contribution may be made under this subsection to a reserve account.

"(4) FORM AND MANNER OF CONTRIBUTION.—The Secretary shall specify the form and manner of contributions under this subsection.

"(f) STATE CONTRIBUTIONS.—

''(1) IN GENERAL.—A State may enter into arrangements with the Secretary for the crediting of amounts for accountholders.

''(2) FORM AND MANNER OF CONTRIBUTION.—The Secretary shall specify the form and manner of contributions under this subsection.

''(3) MEDICAID TREATMENT.—Amounts credited under this subsection shall not be treated as medical assistance for purposes of title XIX or child health assistance for purposes of title XXI for individuals who are not qualifying low income enrollees.''.

(b) EXCLUSION OF COSTS FROM DETERMINATION OF PART B MONTHLY PREMIUM.—Section 1839(g) (42 U.S.C. 1395r(g)) is amended—

(1) by striking ''attributable to the application of section'' and inserting ''attributable to—

''(1) the application of section'';

(2) by striking the period and inserting ''; and''; and

(3) by adding at the end the following new paragraph:

''(2) the Voluntary Medicare Outpatient Prescription Drug Discount and Security Program under sections 1807 and 1807A.''.

(c) STATE ELIGIBILITY DETERMINATIONS.—Section 1935, as added by section 103(a)(2), is amended—

(1) in subsection (a)(1), by inserting ''and of eligibility for an annual Federal contribution amount under section 1807A(j)(2)'' before the semicolon; and

(2) in subsection (a)(3), by inserting ''and sections 1807 and 1807A'' after ''1860D–7)''.

(d) REPORT ON PROGRESS IN IMPLEMENTATION OF PRESCRIPTION DRUG BENEFIT.—Not later than March 1, 2005, the Administrator shall submit a report to Congress on the progress that has been made in implementing the prescription drug benefit under this title. The Administrator shall include in the report specific steps that have been taken, and that need to be taken, to ensure a timely start of the program on January 1, 2006.

SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.

(a) DISCLOSURE.—

(1) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for

purposes other than tax administration) is amended by adding at the end the following new paragraph:

"(19) DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.—

"(A) IN GENERAL.—The Secretary may, upon written request from the Secretary of Health and Human Services under section 1860D–2(b)(4)(E)(i) of the Social Security Act, disclose to officers and employees of the Department of Health and Human Services with respect to a specified taxpayer for the taxable year specified by the Secretary of Health and Human Services in such request—

"(i) the taxpayer identity information with respect to such taxpayer, and

"(ii) the adjusted gross income of such taxpayer for the taxable year (or, if less, the income threshold limit specified in section 1860D–2(b)(4)(D)(ii) for the calendar year specified by such Secretary in such request).

"(B) SPECIFIED TAXPAYER.—For purposes of this paragraph, the term 'specified taxpayer' means any taxpayer who—

"(i) is identified by the Secretary of Health and Human Services in the request referred to in subparagraph (A), and

"(ii) either—

"(I) has an adjusted gross income for the taxable year referred to in subparagraph (A) in excess of the income threshold specified in section 1860D–2(b)(4)(D)(ii) of such Act for the calendar year referred to in such subparagraph, or

"(II) is identified by such Secretary under subparagraph (A) as being an individual who elected to use more recent information under section 1860D–2(b)(4)(D)(v) of such Act.

"(C) JOINT RETURNS.—In the case of a joint return, the Secretary shall, for purposes of applying this paragraph, treat each spouse as a separate taxpayer having an adjusted gross income equal to one-half of the adjusted gross income determined with respect to such return.

"(D) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under subparagraph (A) may be used by offi-

cers and employees of the Department of Health and Human Services only for the purpose of administering the prescription drug benefit under title XVIII of the Social Security Act. Such officers and employees may disclose the annual out-of-pocket threshold which applies to an individual under such part to the entity that offers the plan referred to in section 1860D–2(b)(4)(E)(ii) of such Act in which such individual is enrolled. Such sponsor may use such information only for purposes of administering such benefit.''.

(2) JOINT RETURN PERMITTED IN CASE OF SURVIVING SPOUSES.—Under section 6103(a)(3) of the Internal Revenue Code of 1986, a surviving spouse may file a joint return for the taxable year in which one spouse dies.

(b) CONFIDENTIALITY.—Paragraph (3) of section 6103(a) of such Code is amended by striking ''or (16)'' and inserting ''(16), or (19)''.

(c) PROCEDURES AND RECORDKEEPING RELATED TO DISCLOSURES.—Subsection (p)(4) of section 6103 of such Code is amended by striking ''any other person described in subsection (l)(16) or (17)'' each place it appears

and inserting ''any other person described in subsection (l)(16), (17), or (19)''.

(d) UNAUTHORIZED DISCLOSURE.—Paragraph (2) of section 7213(a) of such Code is amended by striking ''or (16)'' and inserting ''(16), or (19)''.

(e) UNAUTHORIZED INSPECTION.—Subparagraph (B) of section 7213A(a)(1) of such Code is amended by inserting ''or (19)'' after ''subsection (l)(18)''.

SEC. 107. STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act, a State Pharmaceutical Assistance Transition Commission (in this section referred to as the ''Commission'') to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the medicare prescription drug program under part D of title XVIII of the Social Security Act.

(2) DEFINITIONS.—For purposes of this section:

(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term ''State pharmaceutical assistance program'' means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act assistance to low-income medicare beneficiaries for the purchase of prescription drugs.

(B) PROGRAM PARTICIPANT.—The term ''program participant'' means a low-income medicare beneficiary who is a participant in a State pharmaceutical assistance program.

(b) COMPOSITION.—The Commission shall include the following:

(1) A representative of each governor of each State that the Secretary identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under part D of title XVIII of the Social Security Act.

(2) Representatives from other States that the Secretary identifies have in operation other State

pharmaceutical assistance programs, as appointed by the Secretary.

(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

(4) Representatives of Medicare Advantage organizations and other private health insurance plans, as appointed by the Secretary.

(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify

The Secretary shall designate a member to serve as chair of the Commission and the Commission shall meet at the call of the chair.

(c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title.

(3) Principles of medicare modernization provided under title II of this Act.

(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

SEC. 108. ADDITIONAL REQUIREMENTS FOR ANNUAL FINANCIAL REPORT AND OVERSIGHT ON MEDICARE PROGRAM, INCLUDING PRESCRIPTION DRUG SPENDING.

(a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i) is amended by adding at the end the following new subsection:

''(l) COMBINED REPORT ON OPERATION AND STATUS OF THE TRUST FUND, THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND, AND MEDICARE PRESCRIPTION DRUG TRUST FUND.—

''(1) IN GENERAL.—In addition to the duty of the Board of Trustees to report to Congress under subsection (b), on the date the Board submits the report required under subsection (b)(2), the Board shall submit to Congress a report on the operation and status of the Trust Fund, the Federal Supplementary Medical Insurance Trust Fund established under section 1841, and the Medicare Prescription Drug Trust Fund under section 1860D–9(a) (in this subsection collectively referred to as the 'Trust Funds'). Such report shall included the following information:

''(A) OVERALL SPENDING FROM THE GENERAL FUND OF THE TREASURY.—A statement of total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury to the Trust Funds for payment for benefits covered under this title, stated in terms of the total amount and in terms of the percentage such amount bears to all other amounts

obligated from such General Revenues during such fiscal year.

''(B) HISTORICAL OVERVIEW OF SPENDING.—From the date of the inception of the program of insurance under this title through the fiscal year involved, a statement of the total amounts referred to in subparagraph (A).

''(C) 10-YEAR AND 75-YEAR PROJECTIONS.—An estimate of total amounts referred to in subparagraph (A) required to be obligated for payment for benefits covered under this title for each of the 10 fiscal years succeeding the fiscal year involved and for the 75-year period beginning with the succeeding fiscal year.

''(D) RELATION TO GDP GROWTH.—A comparison of the rate of growth of the total amounts referred to in subparagraph (A) to the rate of growth in the gross domestic product for the same period.

''(2) PUBLICATION.—Each report submitted under paragraph (1) shall be published jointly by the Committee on Ways and Means and the Committee on Energy and Commerce as a public document and shall be made available by such Committees on the Internet.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to fiscal years beginning on or after the date of the enactment of this Act.

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

SEC. 200. MEDICARE MODERNIZATION AND REVITALIZATION.

This title provides for—

(1) establishment of the medicare enhanced fee-for-service (EFFS) program under which medicare beneficiaries are provided access to a range of enhanced fee-for-service (EFFS) plans that may use preferred provider networks to offer an enhanced range of benefits;

(2) establishment of a Medicare Advantage program that offers improved managed care plans with coordinated care; and

(3) competitive bidding, in the style of the Federal Employees Health Benefits program (FEHBP), among enhanced fee-for-service plans and Medicare Advantage plans in order to promote greater efficiency and responsiveness to medicare beneficiaries.

Subtitle A—Medicare Enhanced Fee-for-Service Program

SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM UNDER MEDICARE.

(a) IN GENERAL.—Title XVIII, as amended by section 101(a), is amended—

(1) by redesignating part E as part F; and

(2) by inserting after part D the following new part:

''PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

''OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS THROUGHOUT THE UNITED STATES

''SEC. 1860E–1. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—The Administrator shall establish under this part beginning January 1, 2006, an enhanced fee-for-service program under which enhanced fee-for-service plans (as defined in subsection (b)) are offered to EFFS-eligible individuals (as so defined) in EFFS regions throughout the United States.

''(2) EFFS REGIONS.—For purposes of this part the Administrator shall establish EFFS regions throughout the United States by dividing the entire United States into at least 10 such regions. Before

establishing such regions, the Administrator shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established. The regions shall be established in a manner to take into consideration maximizing full access for all EFFS-eligible individuals, especially those residing in rural areas.

''(b) DEFINITIONS.—For purposes of this part:

''(1) EFFS ORGANIZATION.—The 'EFFS organization' means an entity that the Administrator certifies as meeting the requirements and standards applicable to such organization under this part.

''(2) ENHANCED FEE-FOR-SERVICE PLAN; EFFS PLAN.—The terms 'enhanced fee-for-service plan' and 'EFFS plan' mean health benefits coverage offered under a policy, contract, or plan by an EFFS organization pursuant to and in accordance with a contract pursuant to section 1860E–4(c), but only if the plan provides either fee-for-service coverage described in the following subparagraph (A) or preferred provider coverage described in the following subparagraph (B):

''(A) FEE-FOR-SERVICE COVERAGE.—The plan—

"(i) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

"(ii) does not vary such rates for such a provider based on utilization relating to such provider; and

"(iii) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

"(B) PREFERRED PROVIDER COVERAGE.—The plan—

"(i) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; and

"(ii) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers.

"(3) EFFS ELIGIBLE INDIVIDUAL.—The term 'EFFS eligible individual' means an eligible individual described in section 1851(a)(3).

''(4) EFFS REGION.—The term 'EFFS region' means a region established under subsection (a)(2).

''(c) APPLICATION OF CERTAIN ELIGIBILITY, ENROLLMENT, ETC. REQUIREMENTS.—The provisions of section 1851 (other than subsection (h)(4)(A)) shall apply to EFFS plans offered by an EFFS organization in an EFFS region, including subsection (g) (relating to guaranteed issue and renewal).

''OFFERING OF ENHANCED FEE-FOR-SERVICE (EFFS) PLANS

''SEC. 1860E–2. (a) PLAN REQUIREMENTS.—No EFFS plan may be offered under this part in an EFFS region unless the requirements of this part are met with respect to the plan and EFFS organization offering the plan.

''(b) AVAILABLE TO ALL EFFS BENEFICIARIES IN THE ENTIRE REGION.—With respect to an EFFS plan offered in an EFFS region—

''(1) IN GENERAL.—The plan must be offered to all EFFS-eligible individuals residing in the region.

''(2) ASSURING ACCESS TO SERVICES.—The plan shall comply with the requirements of section 1852(d)(4).

''(c) BENEFITS.—

''(1) IN GENERAL.—Each EFFS plan shall provide to members enrolled in the plan under this part benefits, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

''(A) for the items and services described in section 1852(a)(1);

''(B) that are uniform for the plan for all EFFS eligible individuals residing in the same EFFS region;

''(C) that include a single deductible applicable to benefits under parts A and B and include a catastrophic limit on out-of-pocket expenditures for such covered benefits; and

''(D) that include benefits for prescription drug coverage for each enrollee who elects under part D to be provided qualified prescription drug coverage through the plan.

''(2) DISAPPROVAL AUTHORITY.—The Administrator shall not approve a plan of an EFFS organization if the Administrator determines (pursuant to the last sentence of section 1852(b)(1)(A)) that the benefits are designed to substantially discourage enrollment by certain EFFS eligible individuals with the organization.

''(d) OUTPATIENT PRESCRIPTION DRUG COVERAGE.—For rules concerning the offering of prescription drug coverage under EFFS plans, see the amendment made by section 102(b) of the Medicare Prescription Drug and Modernization Act of 2003.

''(e) OTHER ADDITIONAL PROVISIONS.—The provisions of section 1852 (other than subsection (a)(1)) shall apply under this part to EFFS plans. For the application of chronic care improvement provisions, see the amendment made by section 722(b).

''SUBMISSION OF BIDS; BENEFICIARY SAVINGS; PAYMENT OF PLANS

''SEC. 1860E–3. (a) SUBMISSION OF BIDS.—

''(1) REQUIREMENT.—

''(A) EFFS MONTHLY BID AMOUNT.—For each year (beginning with 2006), an EFFS organization shall submit to the Administrator an EFFS monthly bid amount for each EFFS plan offered in each region. Each such bid is referred to in this section as the 'EFFS monthly bid amount'.

''(B) FORM.—Such bid amounts shall be submitted for each such plan and region in a form and manner and time specified by the Administrator, and shall include information described in paragraph (3)(A).

''(2) UNIFORM BID AMOUNTS.—Each EFFS monthly bid amount submitted under paragraph (1) by an EFFS organization under this part for an EFFS plan in an EFFS region may not vary among EFFS eligible individuals residing in the EFFS region involved.

''(3) SUBMISSION OF BID AMOUNT INFORMATION BY EFFS ORGANIZATIONS.—

''(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

''(i) The EFFS monthly bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the region, and the actuarial basis for determining such amount.

''(ii) The proportions of such bid amount that are attributable to—

''(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted EFFS statutory non-drug monthly bid amount');

"(II) the provision of statutory prescription drug benefits; and

"(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

"(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

"(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

"(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

"(ii) The term 'statutory prescription drug benefits' means benefits under part D.

"(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

"(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—The Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A)

(and the proportion described in subparagraph (A)(ii)), and for such purpose, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. The Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

''(D) CONTRACT AUTHORITY.—The Administrator may, taking into account the unadjusted EFFS statutory non-drug monthly bid amounts accepted under subparagraph (C), enter into contracts for the offering of EFFS plans by up to 3 EFFS organizations in any region.

''(b) PROVISION OF BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

''(1) BENEFICIARY REBATE RULE.—

''(A) REQUIREMENT.—The EFFS plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita

savings (if any) described in paragraph (2) applicable to the plan and year involved.

''(B) FORM OF REBATE.—A rebate required under this paragraph shall be provided—

''(i) through the crediting of the amount of the rebate towards the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)) and the EFFS monthly supplemental beneficiary premium (as defined in section 1860E–4(a)(3)(C));

''(ii) through a direct monthly payment (through electronic funds transfer or otherwise); or

''(iii) through other means approved by the Medicare Benefits Administrator,

or any combination thereof.

''(2) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes of paragraph (1)(A), the average per capita monthly savings referred to in such paragraph for an EFFS plan and year is computed as follows:

''(A) DETERMINATION OF REGION-WIDE AVERAGE RISK ADJUSTMENT.—

"(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each EFFS region the average of the risk adjustment factors described in subsection (c)(3) to be applied to enrollees under this part in that region. In the case of an EFFS region in which an EFFS plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied under subsection (c)(3) in that region in a previous year.

"(ii) TREATMENT OF NEW REGIONS.—In the case of a region in which no EFFS plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable EFFS regions or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For

each EFFS plan offered in an EFFS region, the Administrator shall—

"(i) adjust the EFFS region-specific non-drug monthly benchmark amount (as defined in paragraph (3)) by the applicable average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted EFFS statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(3) COMPUTATION OF EFFS REGION-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'EFFS region-specific non-drug monthly benchmark amount' means,

with respect to an EFFS region for a month in a year, an amount equal to 1/12 of the average (weighted by number of EFFS eligible individuals in each payment area described in section 1853(d)) of the annual capitation rate as calculated under section 1853(c)(1) for that area.

''(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

''(1) NON-DRUG BENEFITS.—Under a contract under section 1860E–4(c) and subject to section 1853(g) (as made applicable under subsection (d)), the Administrator shall make monthly payments under this subsection in advance to each EFFS organization, with respect to coverage of an individual under this part in an EFFS region for a month, in an amount determined as follows:

''(A) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in subsection (b)(2)(C), the payment under this subsection is equal to the unadjusted EFFS statutory non-drug monthly bid amount, adjusted under paragraphs (3) and (4), plus the amount of the monthly rebate computed under subsection (b)(1)(A) for that plan and year.

"(B) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in subsection (b)(2)(C), the payment amount under this subsection is equal to the EFFS region-specific non-drug monthly benchmark amount, adjusted under paragraphs (3) and (4).

"(2) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the EFFS organization offering such plan also is entitled—

"(A) to direct subsidy payment under section 1860D–8(a)(1);

"(B) to reinsurance subsidy payments under section 1860D–8(a)(2); and

"(C) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–7(c)(3).

"(3) DEMOGRAPHIC RISK ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust under paragraph (1)(A) the unadjusted EFFS statutory non-drug monthly bid amount and under paragraph (1)(B) the EFFS

region-specific non-drug monthly benchmark amount for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under section 1853(a)(3) (as applied under subsection (d)), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

''(4) ADJUSTMENT FOR INTRA-REGIONAL GEOGRAPHIC VARIATIONS.—The Administrator shall also adjust such amounts in a manner to take into account variations in payments rates under part C among the different payment areas under such part included in each EFFS region.

''(d) APPLICATION OF ADDITIONAL PAYMENT RULES.—The provisions of section 1853 (other than subsections (a)(1)(A), (d), and (e)) shall apply to an EFFS plan under this part, except as otherwise provided in this section.

''PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIREMENTS; ESTABLISHMENT OF STANDARDS; CONTRACTS WITH EFFS ORGANIZATIONS

''SEC. 1860E–4. (a) PREMIUMS.—

''(1) IN GENERAL.—The provisions of section 1854 (other than subsections (a)(6)(C) and (h)), including subsection (b)(5) relating to the consolidation of drug and non-drug beneficiary premiums and subsection (c) relating to uniform bids and premiums, shall apply to an EFFS plan under this part, subject to paragraph (2).

''(2) CROSS-WALK.—In applying paragraph (1), any reference in section 1854(b)(1)(A) or 1854(d) to—

''(A) a Medicare Advantage monthly basic beneficiary premium is deemed a reference to the EFFS monthly basic beneficiary premium (as defined in paragraph (3)(A));

''(B) a Medicare Advantage monthly prescription drug beneficiary premium is deemed a reference to the EFFS monthly prescription drug beneficiary premium (as defined in paragraph (3)(B)); and

''(C) a Medicare Advantage monthly supplemental beneficiary premium is deemed a reference to the EFFS monthly supplemental beneficiary premium (as defined in paragraph (3)(C)).

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

"(A) EFFS MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'EFFS monthly basic beneficiary premium' means, with respect to an EFFS plan—

"(i) described in section 1860E–3(c)(1)(A) (relating to plans providing rebates), zero; or

"(ii) described in section 1860E–3(c)(1)(B), the amount (if any) by which the unadjusted EFFS statutory non-drug monthly bid amount exceeds the EFFS region-specific non-drug monthly benchmark amount (as defined in section 1860E–3(b)(3)).

"(B) EFFS MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'EFFS monthly prescription drug beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount submitted under clause (i) of section 1860E–3(a)(3)(A) for the year that is attributable under such section to the provision of statutory prescription drug benefits.

"(C) EFFS MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'EFFS

monthly supplemental beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount submitted under clause (i) of section 1860E–3(a)(3)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.

''(b) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS.—The provisions of section 1855 shall apply to an EFFS plan offered by an EFFS organization under this part.

''(c) STANDARDS.—The provisions of paragraphs (1), (3), and (4) of section 1856(b) shall apply to an EFFS plan offered by an EFFS organization under this part.

''(d) CONTRACTS WITH EFFS ORGANIZATIONS.—The provisions of section 1857 shall apply to an EFFS plan offered by an EFFS organization under this part, except that any reference in such section to part C is deemed a reference to this part.''.

(b) APPLICATION OF MEDIGAP PROVISIONS TO EFFS PLANS.—Section 1882 of the Social Security Act (42 U.S.C. 1395ss) shall be administered as if any reference to a Medicare+Choice organization offering a Medicare+Choice plan under part C of title XVIII of such Act were a reference both to a Medicare Advantage orga-

nization offering a Medicare Advantage plan under such part and an EFFS organization offering an EFFS plan under part E of such title.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

SEC. 211. IMPLEMENTATION OF MEDICARE ADVANTAGE PROGRAM.

(a) IN GENERAL.—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title XVIII of the Social Security Act, as amended by this title.

(b) REFERENCES.—Any reference to the program under part C of title XVIII of the Social Security Act shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to ''Medicare+Choice'' is deemed a reference to ''Medicare Advantage''.

SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.

(a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended by adding at the end the following:

"(D) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

"(i) IN GENERAL.—For 2004, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare Advantage payment area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in a Medicare Advantage under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(ii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department

of Veterans Affairs or the Department of Defense.''.

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking ''or (C)'' and inserting ''(C), or (D)''.

(b) CHANGE IN BUDGET NEUTRALITY FOR BLEND.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

(1) in paragraph (1)(A), by inserting ''(for a year other than 2004)'' after ''multiplied''; and

(2) in paragraph (5), by inserting ''(other than 2004)'' after ''for each year''.

(c) INCREASING MINIMUM PERCENTAGE INCREASE TO NATIONAL GROWTH RATE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended—

(A) in subparagraph (A), by striking ''The sum'' and inserting ''For a year before 2005, the sum'';

(B) in subparagraph (B)(iv), by striking ''and each succeeding year'' and inserting '', 2003, and 2004'';

(C) in subparagraph (C)(iv), by striking ''and each succeeding year'' and inserting ''and 2003''; and

(D) by adding at the end of subparagraph (C) the following new clause:

''(v) For 2004 and each succeeding year, the greater of—

''(I) 102 percent of the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year; or

''(II) the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year increased by the national per capita Medicare Advantage growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before 2004.''.

(2) CONFORMING AMENDMENT.—Section 1853(c)(6)(C) (42 U.S.C. 1395w–23(c)(6)(C)) is amended by inserting before the period at the end the following: '', except that for purposes of para-

graph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004''.

(d) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (E)'', and

(2) by adding at the end the following new subparagraph:

''(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2004), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from

facilities of the Department of Defense or the Department of Veterans Affairs.''.

(e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT HOSPITAL STAYS TO REHABILITATION HOSPITALS.—

(1) IN GENERAL.—Section 1853(g) (42 U.S.C. 1395w–23(g)) is amended—

(A) by inserting ''or from a rehabilitation facility (as defined in section 1886(j)(1)(A))'' after ''1886(d)(1)(B))''; and

(B) in paragraph (2)(B), by inserting ''or section 1886(j), as the case may be,'' after ''1886(d)''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to contract years beginning on or after January 1, 2004.

(f) MEDPAC STUDY OF AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)) as applied under section 1853(c)(1)(A) of such Act (as amended by sub-

section (a)). Such study shall include an examination of—

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment under the Medicare Advantage program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1).

(g) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than July 1, 2006, the Medicare Benefits Administrator shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and BIPA) on the availability of Medicare Advantage plans in different

areas and its impact on lowering premiums and increasing benefits under such plans.

(h) ANNOUNCEMENT OF REVISED MEDICARE ADVANTAGE PAYMENT RATES.—Within 6 weeks after the date of the enactment of this Act, the Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties) Medicare Advantage capitation rates under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for 2004, revised in accordance with the provisions of this section.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

SEC. 221. COMPETITION PROGRAM BEGINNING IN 2006.

(a) SUBMISSION OF EFFS-LIKE BIDDING INFORMATION BEGINNING IN 2006.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(1) by amending the section heading to read as follows:

''PREMIUMS AND BID AMOUNT'';

(2) in subsection (a)(1)(A)—

(A) by striking ''(A)'' and inserting ''(A)(i) if the following year is before 2006,''; and

(B) by inserting before the semicolon at the end the following: ''or (ii) if the following year is 2006 or later, the information described

in paragraph (3) or (6)(A) for the type of plan involved''; and

(3) by adding at the end of subsection (a) the following:

''(6) SUBMISSION OF BID AMOUNTS BY MEDICARE ADVANTAGE ORGANIZATIONS.—

''(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

''(i) The monthly aggregate bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the area, and the actuarial basis for determining such amount.

''(ii) The proportions of such bid amount that are attributable to—

''(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted Medicare Advantage statutory non-drug monthly bid amount');

''(II) the provision of statutory prescription drug benefits; and

''(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

''(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

''(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

''(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

''(ii) The term 'statutory prescription drug benefits' means benefits under part D.

''(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

''(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—

''(i) IN GENERAL.—Subject to clause (ii)—

''(I) the Administrator has the authority to negotiate regarding

monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)), and for such purpose and subject to such clause, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code; and

''(II) the Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

''(ii) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of clause (i) shall not apply and the provisions of paragraph (5)(B), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts

and proportion referred to in subparagraph (A).''.

(b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

(1) IN GENERAL.—Section 1854(b) (42 U.S.C. 1395w–24(b)) is amended—

(A) by adding at the end of paragraph (1) the following new subparagraph:

''(C) BENEFICIARY REBATE RULE.—

''(i) REQUIREMENT.—The Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3) applicable to the plan and year involved.

''(iii) FORM OF REBATE.—A rebate required under this subparagraph shall be provided—

''(I) through the crediting of the amount of the rebate towards the Medicare Advantage monthly supplementary beneficiary premium or the premium imposed for prescription drug coverage under part D;

''(II) through a direct monthly payment (through electronic funds transfer or otherwise); or

''(III) through other means approved by the Medicare Benefits Administrator,

or any combination thereof.''; and

(B) by adding at the end the following new paragraphs:

''(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for a Medicare Advantage plan and year is computed as follows:

''(A) DETERMINATION OF STATE-WIDE AVERAGE RISK ADJUSTMENT.—

''(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each State the average of the risk adjustment factors to be applied under section 1853(a)(1)(A) to payment for enrollees in that State. In the case of a State in which a Medicare Advantage plan was of-

fered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied in that State in a previous year.

"(ii) TREATMENT OF NEW STATES.—In the case of a State in which no Medicare Advantage plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable States or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each Medicare Advantage plan offered in a State, the Administrator shall—

"(i) adjust the Medicare Advantage area-specific non-drug monthly benchmark amount (as defined in subsection (j)) by the applicable average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted Medicare Advantage statutory non-drug monthly bid

amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(D) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Administrator may provide for the determination and application of risk adjustment factors under this paragraph on the basis of areas other than States.

"(4) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a Medicare Advantage organization shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the organization in-

directly through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph that are credited to the Federal Supplementary Medical Insurance Drug Trust Fund shall be paid to the Medicare Advantage organization involved.''.

(2) PROVISION OF SINGLE CONSOLIDATED PREMIUM.—Section 1854(b) (42 U.S.C. 1395w–24(b)), as amended by paragraph (1), is further amended by adding at the end the following new paragraph:

''(5) SINGLE CONSOLIDATED PREMIUM.—In the case of an enrollee in a Medicare Advantage plan who elects under part D to be provided qualified prescription drug coverage through the plan, the Administrator shall provide a mechanism for the consolidation of the beneficiary premium amount for non-drug benefits under this part with the premium amount for prescription drug coverage under part D provided through the plan.''.

(3) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w–23) is amended by adding at the end the following new subsection:

''(j) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'Medicare Advantage area-specific non-drug monthly benchmark amount' means, with respect to a Medicare Advantage payment area for a month in a year, an amount equal to 1/12 of the annual Medicare Advantage capitation rate under section 1853(c)(1) for the area for the year.''.

(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C. 1395w–23) is amended by striking ''in an amount'' and all that follows and inserting the following: ''in an amount determined as follows:

''(i) PAYMENT BEFORE 2006.—For years before 2006, the payment amount shall be equal to 1/12 of the annual Medicare Advantage capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, reduced by the amount of any reduction

elected under section 1854(f)(1)(E) and adjusted under clause (iv).

"(ii) PAYMENT FOR STATUTORY NON-DRUG BENEFITS BEGINNING WITH 2006.—For years beginning with 2006—

"(I) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C), the payment under this subsection is equal to the unadjusted Medicare Advantage statutory non-drug monthly bid amount, adjusted under clause (iv), plus the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year.

"(II) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C), the payment amount under this subsection is equal to the Medicare Advantage area-spe-

cific non-drug monthly benchmark amount, adjusted under clause (iv).

''(iii) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the Medicare Advantage organization offering such plan also is entitled—

''(I) to direct subsidy payment under section 1860D–8(a)(1);

''(II) to reinsurance subsidy payments under section 1860D–8(a)(2); and

''(III) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–7(c)(3).

''(iv) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust the payment amount under clause (i), the unadjusted Medicare Advantage statutory non-drug monthly bid amount under clause (ii)(I), and the Medicare Advantage area-

specific non-drug monthly benchmark amount under clause (ii)(II) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.''.

(d) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: ''The Administrator shall not approve a plan of an organization if the Administrator determines that the benefits are designed to substantially discourage enrollment by certain Medicare Advantage eligible individuals with the organization.''.

(2) CONFORMING AMENDMENT TO PREMIUM TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) is amended by redesignating subparagraph (C) as subparagraph (D) and by striking

subparagraphs (A) and (B) and inserting the following:

"(A) MEDICARE ADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly basic beneficiary premium' means, with respect to a Medicare Advantage plan—

"(i) described in section 1853(a)(1)(A)(ii)(I) (relating to plans providing rebates), zero; or

"(ii) described in section 1853(a)(1)(A)(ii)(II), the amount (if any) by which the unadjusted Medicare Advantage statutory non-drug monthly bid amount exceeds the Medicare Advantage area-specific non-drug monthly benchmark amount.

"(B) MEDICARE ADVANTAGE MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly prescription drug beneficiary premium' means, with respect to a Medicare Advantage plan, that portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the

provision of statutory prescription drug benefits.

''(C) MEDICARE ADVANTAGE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly supplemental beneficiary premium' means, with respect to a Medicare Advantage plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.''.

(3) REQUIREMENT FOR UNIFORM PREMIUM AND BID AMOUNTS.—Section 1854(c) (42 U.S.C. 1395w–24(c)) is amended to read as follows:

''(c) UNIFORM PREMIUM AND BID AMOUNTS.—The Medicare Advantage monthly bid amount submitted under subsection (a)(6), the Medicare Advantage monthly basic, prescription drug, and supplemental beneficiary premiums, and the Medicare Advantage monthly MSA premium charged under subsection (b) of a Medicare Advantage organization under this part may not vary among individuals enrolled in the plan.''.

(4) PERMITTING BENEFICIARY REBATES.—

(A) Section 1851(h)(4)(A) (42 U.S.C. 1395w–21(h)(4)(A)) is amended by inserting

''except as provided under section 1854(b)(1)(C)'' after ''or otherwise''.

(B) Section 1854(d) (42 U.S.C. 1395w–24(d)) is amended by inserting '', except as provided under subsection (b)(1)(C),'' after ''and may not provide''.

(5) OTHER CONFORMING AMENDMENTS RELATING TO BIDS.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) in the heading of subsection (a), by inserting ''AND BID AMOUNTS'' after ''PREMIUMS''; and

(B) in subsection (a)(5)(A), by inserting ''paragraphs (2), (3), and (4) of'' after ''filed under''.

(e) ADDITIONAL CONFORMING AMENDMENTS.—

(1) ANNUAL DETERMINATION AND ANNOUNCEMENT OF CERTAIN FACTORS.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)) is amended by striking ''the respective calendar year'' and all that follows and inserting the following: ''the calendar year concerned with respect to each Medicare Advantage payment area, the following:

''(A) PRE-COMPETITION INFORMATION.—For years before 2006, the following:

"(i) MEDICARE ADVANTAGE CAPITATION RATES.—The annual Medicare Advantage capitation rate for each Medicare Advantage payment area for the year.

"(ii) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(A) for payments for months in that year.

"(B) COMPETITION INFORMATION.—For years beginning with 2006, the following:

"(i) BENCHMARK.—The Medicare Advantage area-specific non-drug benchmark under section 1853(j).

"(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment).".

(2) REPEAL OF PROVISIONS RELATING TO ADJUSTED COMMUNITY RATE (ACR).—

(A) IN GENERAL.—Subsections (e) and (f) of section 1854 (42 U.S.C. 1395w–24) are repealed.

(B) CONFORMING AMENDMENTS.—(i) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking ", and to reflect" and all that follows and inserting a period.

(ii) Section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)) is amended by striking "title XI" and all that follows and inserting the following: "title XI those items and services (other than hospice care) for which benefits are available under parts A and B to individuals residing in the area served by the plan.".

(iii) Section 1857(d)(1) (42 U.S.C. 1395w–27(d)(1)) is amended by striking ", costs, and computation of the adjusted community rate" and inserting "and costs".

(f) REFERENCES UNDER PART E.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

"(f) APPLICATION UNDER PART E.—In the case of any reference under part E to a requirement or provision of this part in the relation to an EFFS plan or organization under such part, except as otherwise specified any such requirement or provision shall be applied to such organization or plan in the same manner as such requirement or provision applies to a Medicare Advantage private

fee-for-service plan (and the Medicare Advantage organization that offers such plan) under this part.''.

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to payments and premiums for months beginning with January 2006.

CHAPTER 3—ADDITIONAL REFORMS

SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE ADVANTAGE REPORTING DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD.

(a) CHANGE IN REPORTING DEADLINE.—Section 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by section 532(b)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking ''2002, 2003, and 2004 (or July 1 of each other year)'' and inserting ''2002 and each subsequent year''.

(b) DELAY IN ANNUAL, COORDINATED ELECTION PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)), as amended by section 532(c)(1)(A) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended—

(1) by striking ''and after 2005''; and

(2) by striking '', 2004, and 2005'' and inserting ''and any subsequent year''.

(c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)), as amended by section 532(d)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended—

(1) by striking ''and after 2005''; and

(2) by striking ''and 2005'' and inserting ''and each subsequent year''.

(d) REQUIRING PROVISION OF AVAILABLE INFORMATION COMPARING PLAN OPTIONS.—The first sentence of section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w–21(d)(2)(A)(ii)) is amended by inserting before the period the following: ''to the extent such information is available at the time of preparation of materials for the mailing''.

SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.

(a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–26(b)(3)) is amended to read as follows:

''(3) RELATION TO STATE LAWS.—The standards established under this subsection shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to Medicare Advantage plans which are offered by Medicare Advantage organizations under this part.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by adding at the end the following new sentence: ''Specialized Medicare Advantage plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.''.

(b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraph:

''(4) SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

''(A) IN GENERAL.—The term 'specialized Medicare Advantage plan for special needs beneficiaries' means a Medicare Advantage plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

''(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare Advantage 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 Medicare Advantage plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.''.

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

''(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare Advantage plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2007, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.''.

(d) AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MEDICARE ADVANTAGE PLANS.—In promulgating regulations to carry out the last sentence of sec-

tion 1851(a)(2)(A) of the Social Security Act (as added by subsection (a)) and section 1859(b)(4) of such Act (as added by subsection (b)), the Secretary may provide (notwithstanding section 1859(b)(4)(A) of such Act) for the offering of specialized Medicare Advantage plans by Medicare Advantage plans that disproportionately serve special needs beneficiaries who are frail, elderly medicare beneficiaries.

(e) REPORT TO CONGRESS.—Not later than December 31, 2005, the Medicare Benefits Administrator shall submit to Congress a report that assesses the impact of specialized Medicare Advantage plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(f) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later than 6 months after the date of the enactment of this Act, the Secretary shall issue interim final regulations to establish requirements

for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 234. MEDICARE MSAS.

(a) EXEMPTION FROM REPORTING ENROLLEE ENCOUNTER DATA.—

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w–22(e)(1)) is amended by inserting ''(other than MSA plans)'' after ''plans''.

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: ''if required under such section''; and

(B) in subparagraphs (A) and (B) of subsection (e)(2), by striking '', a non-network MSA plan,'' and '', NON-NETWORK MSA PLANS,'' each place it appears.

(b) MAKING PROGRAM PERMANENT AND ELIMINATING CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is amended—

(1) in the heading, by striking ''ON A DEMONSTRATION BASIS'';

(2) by striking the first sentence of subparagraph (A); and

(3) by striking the second sentence of subparagraph (C).

(c) APPLYING LIMITATIONS ON BALANCE BILLING.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amended by inserting ''or with an organization offering a MSA plan'' after ''section 1851(a)(2)(A)''.

(d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A) (42 U.S.C. 1395w–21(e)(5)(A)) is amended—

(1) by adding ''or'' at the end of clause (i);

(2) by striking '', or'' at the end of clause (ii) and inserting a semicolon; and

(3) by striking clause (iii).

SEC. 235. EXTENSION OF REASONABLE COST CONTRACTS.

Subparagraph (C) of section 1876(h)(5) (42 U.S.C. 1395mm(h)(5)) is amended to read as follows:

''(C)(i) Subject to clause (ii), may be extended or renewed under this subsection indefinitely.

''(ii) For any period beginning on or after January 1, 2008, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area, during the entire previous year, was within the service area of 2 or more plans which were coordinated care Medicare Advantage plans under part C or 2 or more enhanced fee-for-service plans under

part E and each of which plan for that previous year for the area involved meets the following minimum enrollment requirements:

''(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area, 5,000 individuals.

''(II) With respect to any other portion of such area, 1,500 individuals.''.

SEC. 236. EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.

Section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as amended by section 6135 of the Omnibus Budget Reconciliation Act of 1989, section 13557 of the Omnibus Budget Reconciliation Act of 1993, section 4017 of BBA, section 534 of BBRA (113 Stat. 1501A–390), and section 633 of BIPA, is amended by striking ''December 31, 2004'' and inserting ''December 31, 2009''.

SEC. 237. STUDY OF PERFORMANCE-BASED PAYMENT SYSTEMS.

(a) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to—

(1) conduct a study that reviews and evaluates public and private sector experiences in establishing performance measures and payment incentives under the medicare program and linking performance to payment; and

(2) submit a report to the Secretary and Congress, not later than 18 months after the date of the enactment of this Act, regarding such study.

(b) STUDY.—The study under subsection (a)(1) shall—

(1) include a review and evaluation of incentives that have been or could be used to encourage quality performance, including those aimed at health plans and their enrollees, providers and their patients, and other incentives that encourage quality-based health care purchasing and collaborative efforts to improve performance; and

(2) examine how these measures and incentives might be applied in the Medicare Advantage program, the Enhanced Fee-For-Service (EFFS) program, and traditional fee-for-service programs.

(c) REPORT RECOMMENDATIONS.—The report under subsection (a)(2) shall—

(1) include recommendations regarding appropriate performance measures for use in assessing and paying for quality; and

(2) identify options for updating performance measures.

Subtitle C—Application of FEHBP-Style Competitive Reforms

SEC. 241. APPLICATION OF FEHBP-STYLE COMPETITIVE REFORM BEGINNING IN 2010.

(a) IDENTIFICATION OF COMPETITIVE EFFS REGIONS; COMPUTATION OF COMPETITIVE EFFS NON-DRUG BENCHMARKS UNDER EFFS PROGRAM.—

(1) IN GENERAL.—Section 1860E–3, as added by section 201(a), is amended by adding at the end the following new subsection:

''(e) APPLICATION OF COMPETITION.—

''(1) DETERMINATION OF COMPETITIVE EFFS REGIONS.—

''(A) IN GENERAL.—For purposes of this part, the term 'competitive EFFS region' means, for a year beginning with 2010, an EFFS region that the Administrator finds—

''(i) there will be offered in the region during the annual, coordinated election period under section 1851(e)(3)(B) (as ap-

plied under section 1860E–1(c)) before the beginning of the year at least 2 EFFS plans (in addition to the fee-for-service program under parts A and B), each offered by a different EFFS organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of March of the previous year; and

''(ii) during March of the previous year at least the percentage specified in subparagraph (C) of the number of EFFS eligible individuals who reside in the region were enrolled in an EFFS plan.

''(B) PERCENTAGE SPECIFIED.—

''(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of—

''(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States

who are enrolled in EFFS plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) EXCEPTION.—In the case of an EFFS region that was a competitive EFFS region for the previous year, the Medicare Benefits Administrator may continue to treat the region as meeting the requirement of subparagraph (A)(ii) if the region would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

"(2) COMPETITIVE EFFS NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'competitive EFFS non-drug monthly benchmark amount' means, with respect to an EFFS region for a month in a year and subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the region and year. The Administrator shall compute such benchmark

amount for each competitive EFFS region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such a region.

''(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for an EFFS region and a year are the following:

''(A) EFFS COMPONENT.—The product of the following:

''(i) WEIGHTED AVERAGE OF PLAN BIDS IN REGION.—The weighted average of the EFFS plan bids for the region and year (as determined under paragraph (4)(A)).

''(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage determined under paragraph (5) for the region and the year.

''(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

''(i) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service region-specific non-drug amount (as

defined in paragraph (6)) for the region and year.

"(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage (determined under paragraph (5)) for the region and the year.

"(4) DETERMINATION OF WEIGHTED AVERAGE EFFS PLAN BIDS FOR A REGION.—

"(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of EFFS plan bids for an EFFS region and a year is the sum of the following products for EFFS plans described in subparagraph (C) in the region and year:

"(i) UNADJUSTED EFFS STATUTORY NON-DRUG MONTHLY BID AMOUNT.—The unadjusted EFFS statutory non-drug monthly bid amount (as defined in subsection (a)(3)(A)(ii)(I)) for the region and year.

"(ii) PLAN'S SHARE OF EFFS ENROLLMENT IN REGION.—The number of individuals described in subparagraph (B), divided by the total number of such individ-

uals for all EFFS plans described in subparagraph (C) for that region and year.

''(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each EFFS plan described in subparagraph (C) for an EFFS region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part during March of the previous year.

''(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an EFFS region and year, the EFFS plans described in this subparagraph are plans that are offered in the region and year and were offered in the region in March of the previous year.

''(5) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year and an EFFS region, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of the EFFS eligible individuals who are residents of the region during March of the previous year, of such individuals who were not enrolled in an EFFS plan or in a Medicare Advantage plan (or, if greater, such proportion determined for individuals nationally).

"(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(2)(A), subject to subparagraph (C), the term 'fee-for-service region-specific non-drug amount' means, for a competitive EFFS region and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such region for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in an EFFS plan under part E or a Medicare Advantage plan under part C for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) USE OF FULL RISK ADJUSTMENT TO STANDARDIZE FEE-FOR-SERVICE COSTS TO TYPICAL BENEFICIARY.—In determining the adjusted average per capita cost for a region and year under subparagraph (A), such costs shall be adjusted to fully take into account the demographic and health status risk factors established under subsection (c)(3) so that such per

capita costs reflect the average costs for a typical beneficiary residing in the region.

''(C) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the region involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

''(7) APPLICATION OF COMPETITION.—In the case of an EFFS region that is a competitive EFFS region for a year, for purposes of applying subsections (b) and (c)(1) and section 1860E–4(a), any reference to an EFFS region-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive EFFS non-drug monthly benchmark amount under paragraph (2) for the region and year.

"(8) PHASE-IN OF BENCHMARK FOR EACH REGION.—

"(A) USE OF BLENDED BENCHMARK.—In the case of a region that has not been a competitive EFFS region for each of the previous 4 years, the competitive EFFS non-drug monthly benchmark amount shall be equal to the sum of the following:

"(i) NEW COMPETITIVE COMPONENT.—The product of—

"(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and

"(II) the competitive EFFS non-drug monthly benchmark amount for the region and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that region and year; and

"(II) the EFFS region-specific non-drug benchmark amount for the region and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for an EFFS region for a year shall be determined as follows:

"(i) FIRST YEAR (AND REGION NOT COMPETITIVE REGION IN PREVIOUS YEAR).—If the area was not a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to ⅕.

"(ii) COMPETITIVE REGION IN PREVIOUS YEAR.—If the region was a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to the weighted average phase-in proportion determined under this subparagraph for the region for the previous year plus ⅕, but in no case more than 1.".

(2) CONFORMING AMENDMENTS.—

(A) Such section 1860E–3 is further amended—

(i) in subsection (b), by adding at the end the following new paragraph:

''(4) APPLICATION IN COMPETITIVE REGIONS.—For special rules applying this subsection in competitive EFFS regions, see subsection (e)(7).'';

(ii) in subsection (c)(1), by inserting ''and subsection (e)(7)'' after ''(as made applicable under subsection (d))''; and

(iii) in subsection (d) , by striking ''and (e)'' and inserting ''(e), and (k) ''.

(B) Section 1860E–4(a)(1), as inserted by section 201(a)(2), is amended by inserting '', except as provided in section 1860E–3(e)(7)'' after ''paragraph (2)''.

(b) IDENTIFICATION OF COMPETITIVE MEDICARE ADVANTAGE AREAS; APPLICATION OF COMPETITIVE MEDICARE ADVANTAGE NON-DRUG BENCHMARKS UNDER MEDICARE ADVANTAGE PROGRAM.—

(1) IN GENERAL.—Section 1853, as amended by section 221(b)(3), is amended by adding at the end the following new subsection:

''(k) APPLICATION OF COMPETITION.—

''(1) DETERMINATION OF COMPETITIVE MEDICARE ADVANTAGE AREAS.—

''(A) IN GENERAL.—For purposes of this part, the terms 'competitive Medicare Advantage area' and 'CMA area' mean, for a year beginning with 2010, an area (which is a metropolitan statistical area or other area with a substantial number of Medicare Advantage enrollees) that the Administrator finds—

''(i) there will be offered during the annual, coordinated election period under section 1851(e)(3)(B) under this part before the beginning of the year at least 2 Medicare Advantage plans (in addition to the fee-for-service program under parts A and B), each offered by a different Medicare Advantage organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of March of the previous year with respect to the area; and

''(ii) during March of the previous year at least the percentage specified in subparagraph (B) of the number of Medi-

care Advantage eligible individuals who reside in the area were enrolled in a Medicare Advantage plan.

"(B) PERCENTAGE SPECIFIED.—

"(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of—

"(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States who are enrolled in EFFS plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) EXCEPTION.—In the case of an area that was a competitive area for the previous year, the Medicare Benefits Administrator may continue to treat the area as meeting the requirement of subpara-

graph (A)(ii) if the area would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

''(2) COMPETITIVE MEDICARE ADVANTAGE NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'competitive Medicare Advantage non-drug monthly benchmark amount' means, with respect to a competitive Medicare Advantage area for a month in a year subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the area and year. The Administrator shall compute such benchmark amount for each competitive Medicare Advantage area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such an area.

''(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for a competitive Medicare Advantage area and a year are the following:

''(A) MEDICARE ADVANTAGE COMPONENT.—The product of the following:

''(i) WEIGHTED AVERAGE OF MEDICARE ADVANTAGE PLAN BIDS IN AREA.—

The weighted average of the plan bids for the area and year (as determined under paragraph (4)(A)).

''(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage, determined under paragraph (5) for the area and year.

''(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

''(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service area-specific non-drug amount (as defined in paragraph (6)) for the area and year.

''(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage, determined under paragraph (5) for the area and year.

''(4) DETERMINATION OF WEIGHTED AVERAGE MEDICARE ADVANTAGE BIDS FOR AN AREA.—

''(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of plan bids for an area and a year is the sum of the following products for Medicare Advantage plans described in subparagraph (C) in the area and year:

"(i) MONTHLY MEDICARE ADVANTAGE STATUTORY NON-DRUG BID AMOUNT.—The unadjusted Medicare Advantage statutory non-drug monthly bid amount.

"(ii) PLAN'S SHARE OF MEDICARE ADVANTAGE ENROLLMENT IN AREA.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all Medicare Advantage plans described in subparagraph (C) for that area and year.

"(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each Medicare Advantage plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part during March of the previous year.

"(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an area and year, the Medicare Advantage plans described in this subparagraph are plans described in the first sentence of section 1851(a)(2)(A) that are offered in the area and year and were offered in the area in March of the previous year.

''(5) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year and a competitive Medicare Advantage area, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of Medicare Advantage eligible individuals residing in the area who during March of the previous year were not enrolled in a Medicare Advantage plan or in an EFFS plan (or, if greater, such proportion determined for individuals nationally).

''(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—

''(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(1)(A), subject to subparagraph (C), the term 'fee-for-service area-specific non-drug amount' means, for a competitive Medicare Advantage area and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in a Medicare Advantage plan under part C or an EFFS plan under part E for the year, but adjusted to exclude

costs attributable to payments under section 1886(h).

"(B) USE OF FULL RISK ADJUSTMENT TO STANDARDIZE FEE-FOR-SERVICE COSTS TO TYPICAL BENEFICIARY.—In determining the adjusted average per capita cost for an area and year under subparagraph (A), such costs shall be adjusted to fully take into account the demographic and health status risk factors established under subsection (a)(1)(A)(iv) so that such per capita costs reflect the average costs for a typical beneficiary residing in the area.

"(C) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

''(7) APPLICATION OF COMPETITION.—In the case of an area that is a competitive Medicare Advantage area for a year, for purposes of applying subsection (a)(1)(A)(ii) and sections 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any reference to a Medicare Advantage area-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive Medicare Advantage non-drug monthly benchmark amount under paragraph (2) for the area and year.

''(8) PHASE-IN OF BENCHMARK FOR EACH AREA.—

''(A) USE OF BLENDED BENCHMARK.—In the case of an area that has not been a competitive Medicare Advantage area for each of the previous 4 years, the competitive Medicare Advantage non-drug monthly benchmark amount shall be equal to the sum of the following:

''(i) NEW COMPETITIVE COMPONENT.—The product of—

''(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and

"(II) the competitive Medicare Advantage non-drug monthly benchmark amount for the area and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that area and year; and

"(II) the Medicare Advantage area-wide non-drug benchmark amount for the area and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for a Medicare Advantage payment area for a year shall be determined as follows:

"(i) FIRST YEAR (AND AREA NOT COMPETITIVE AREA IN PREVIOUS YEAR).—If the area was not a Medicare Advantage competitive area in the previous year, the weighted average phase-in proportion for the area for the year is equal to ⅕.

''(ii) COMPETITIVE AREA IN PREVIOUS YEAR.—If the area was a competitive Medicare Advantage area in the previous year, the weighted average phase-in proportion for the area for the year is equal to the weighted average phase-in proportion determined under this subparagraph for the area for the previous year plus ⅕, but in no case more than 1.

''(C) MEDICARE ADVANTAGE AREA-WIDE NON-DRUG BENCHMARK AMOUNT.—For purposes of subparagraph (A)(ii)(II), the term 'Medicare Advantage area-wide non-drug benchmark amount' means, for an area and year, the weighted average of the amounts described in section 1853(j) for Medicare Advantage payment area or areas included in the area (based on the number of traditional fee-for-service enrollees in such payment area or areas) and year.''.

(2) APPLICATION.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) in subsection (b)(1)(C)(i), as added by section 221(b)(1)(A), by striking ''(i) REQUIREMENT.—The'' and inserting ''(i) REQUIREMENT

FOR NON-COMPETITIVE AREAS.—In the case of a Medicare Advantage payment area that is not a competitive Medicare Advantage area designated under section 1853(k)(1), the'';

(B) in subsection (b)(1)(C), as so added, by inserting after clause (i) the following new clause:

''(ii) REQUIREMENT FOR COMPETITIVE MEDICARE ADVANTAGE AREAS.—In the case of a Medicare Advantage payment area that is designated as a competitive Medicare Advantage area under section 1853(k)(1), if there are average per capita monthly savings described in paragraph (6) for a Medicare Advantage plan and year, the Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of such savings.''; and

(C) by adding at the end of subsection (b), as amended by sections 221(b)(1)(B) and 221(b)(2), the following new paragraph:

''(6) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR COMPETITIVE MEDICARE ADVANTAGE AREAS.—For purposes of paragraph (1)(C)(ii), the average per capita monthly savings

referred to in such paragraph for a Medicare Advantage plan and year shall be computed in the same manner as the average per capita monthly savings is computed under paragraph (3) except that the reference to the Medicare Advantage area-specific non-drug monthly benchmark amount in paragraph (3)(B)(i) (or to the benchmark amount as adjusted under paragraph (3)(C)(i)) is deemed to be a reference to the competitive Medicare Advantage non-drug monthly benchmark amount (or such amount as adjusted in the manner described in paragraph (3)(B)(i)).''.

(3) ADDITIONAL CONFORMING AMENDMENTS.—

(A) PAYMENT OF PLANS.—Section 1853(a)(1)(A)(ii), as amended by section 221(c)(1), is amended—

(i) in subclauses (I) and (II), by inserting ''(or, insofar as such payment area is a competitive Medicare Advantage area, described in section 1854(b)(6))'' after ''section 1854(b)(3)(C)''; and

(ii) in subclause (II), by inserting ''(or, insofar as such payment area is a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug

monthly benchmark amount)'' after ''Medicare Advantage area-specific non-drug monthly benchmark amount''; and

(B) DISCLOSURE OF INFORMATION.—Section 1853(b)(1)(B), as amended by section 221(e)(1), is amended to read as follows:

''(B) COMPETITION INFORMATION.—For years beginning with 2006, the following:

''(i) BENCHMARKS.—The Medicare Advantage area-specific non-drug benchmark under section 1853(j) and, if applicable, the competitive Medicare Advantage non-drug benchmark under section 1853(k)(2), for the year and competitive Medicare Advantage area involved and the national fee-for-service market share percentage for the area and year.

''(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment).

''(iii) CERTAIN BENCHMARKS AND AMOUNTS.—In the case of a competitive Medicare Advantage area, the Medicare Advantage area-wide non-drug benchmark amount (as defined in subsection (k)(8)(C)) and the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the area.

''(iv) INDIVIDUALS.—The number of individuals counted under subsection (k)(4)(B) and enrolled in each Medicare Advantage plan in the area.''.

(C) DEFINITION OF MONTHLY BASIC PREMIUM.—Section 1854(b)(2)(A)(ii), as amended by section 221(d)(2), is amended by inserting ''(or, in the case of a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug monthly benchmark amount or, in applying this paragraph under part E in the case of a competitive EFFS region, the competitive EFFS non-drug monthly benchmark amount)'' after ''benchmark amount''.

(c) PREMIUM ADJUSTMENT.—

(1) IN GENERAL.—Section 1839 (42 U.S.C. 1395r) is amended by adding at the end the following new subsection:

''(h)(1)(A) In the case of an individual who resides in a competitive Medicare Advantage area under section 1853(k)(1) (regardless of whether such area is in a competitive EFFS region under section 1860E–3(e)) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the competitive Medicare Advantage area in which the individual resides for a month—

''(i) does not exceed the competitive Medicare Advantage non-drug benchmark (as determined under paragraph (2) of section 1853(k), without regard to paragraph (8) thereof) for such area, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjustment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark exceeds such fee-for-service area-specific non-drug amount; or

''(ii) exceeds such competitive Medicare Advantage non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, subject to subparagraph (B), that—

''(I) the sum of the amount of the adjusted premium and the competitive Medicare Advantage non-drug benchmark for the area, is equal to

''(II) the sum of the unadjusted premium plus amount of the fee-for-service area-specific non-drug amount for the area.

''(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (C) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

''(C) The adjustment factor under this subparagraph for an area for a year is equal to—

''(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such area was a competitive Medicare Advantage area; divided by

''(ii) 5.

''(2)(A) In the case of an individual who resides in an area that is within a competitive EFFS region under section 1860E–3(e) but is not within a competitive Medicare Advantage area under section 1853(k)(1) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service region-specific non-drug amount (as defined in section 1860E–3(e)(6)) for a region for a month—

''(i) does not exceed the competitive EFFS non-drug monthly benchmark amount (as determined under paragraph (2) of section 1860E–3(e), without regard to paragraph (8) thereof) for such region, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjustment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark amount exceeds such fee-for-service region-specific non-drug benchmark amount; or

''(ii) exceeds such competitive EFFS non-drug monthly benchmark amount, the amount of the premium for the individual for the month shall be ad-

justed to ensure, subject to subparagraph (B), that—

''(I) the sum of the amount of the adjusted premium and the competitive EFFS non-drug monthly benchmark amount for the region, is equal to

''(II) the sum of the unadjusted premium plus the amount of the EFFS region-specific non-drug monthly bidfor the region.

''(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (C) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

''(C) The adjustment factor under this subparagraph for an EFFS region for a year is equal to—

''(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such region was a competitive EFFS region; divided by

''(ii) 5.

''(3) Nothing in this subsection shall be construed as preventing a reduction under paragraph (1)(A) or paragraph (2)(A) in the premium otherwise applicable under this part to zero or from requiring the provision of a re-

bate to the extent such premium would otherwise be required to be less than zero.

''(4) The adjustment in the premium under this subsection shall be effected in such manner as the Medicare Benefits Administrator determines appropriate.

''(5) In order to carry out this subsection (insofar as it is effected through the manner of collection of premiums under 1840(a)), the Medicare Benefits Administrator shall transmit to the Commissioner of Social Security—

''(A) at the beginning of each year, the name, social security account number, and the amount of the adjustment (if any) under this subsection for each individual enrolled under this part for each month during the year; and

''(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.''.

(2) NO CHANGE IN MEDICARE'S DEFINED BENEFIT PACKAGE.—Nothing in this part (or the amendments made by this part) shall be construed as changing the entitlement to defined benefits under parts A and B of title XVIII of the Social Security Act.

(3) CONFORMING AMENDMENT.—Section 1844(c) (42 U.S.C. 1395w(c)) is amended by insert-

ing ''and without regard to any premium adjustment effected under section 1839(h)'' before the period at the end.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

(1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(A) in subparagraph (A)(ii), by striking ''promptly (as determined in accordance with regulations)'';

(B) in subparagraph (B)—

(i) by redesignating clauses (i) through (iii) as clauses (ii) through (iv), respectively; and

(ii) by inserting before clause (ii), as so redesignated, the following new clause:

''(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall be effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98-369).

(b) CLARIFYING AMENDMENTS TO CONDITIONAL PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is further amended—

(1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence at the end: ''An entity that engages in a business, trade, or profession shall be deemed to have a self-

insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.'';

(2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)(B)—

(A) by striking the first sentence and inserting the following: ''A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.''; and

(B) in the final sentence, by striking ''on the date such notice or other information is received'' and inserting ''on the date notice of, or

information related to, a primary plan's responsibility for such payment or other information is received''; and

(3) in subparagraph (B)(iii), , as redesignated by subsection (a)(2)(B), by striking the first sentence and inserting the following: ''In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.''.

(c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking ''such'' before ''paragraphs''.

SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:

''COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

''SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

''(1) IMPLEMENTATION OF PROGRAMS.—

''(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

''(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in—

''(i) among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

"(I) at least ⅓ of such areas in 2005; and

"(II) at least ⅔ of such areas in 2006; and

"(ii) among items and services in a manner such that the programs apply to the highest cost and highest volume items and services first.

"(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

"(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), including items used in infusion and drugs and supplies used in conjunction with durable medical

equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

"(B) OTHER EQUIPMENT AND SUPPLIES.—Items, equipment, and supplies (as described in section 1842(s)(2)(D) other than enteral nutrients).

"(C) OFF-THE-SHELF ORTHOTICS.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(h) which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the patient.

"(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

"(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

"(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

''(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT.—In the case of a covered item for which payment is made on a rental basis under section 1834(a), the Secretary shall establish a process by which rental agreements for the covered items entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).

''(5) PHYSICIAN AUTHORIZATION.—The Secretary may establish a process under which a physician may prescribe a particular brand or mode of delivery of an item or service if the item or service involved is clinically more appropriate than other similar items or services.

''(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a).

''(b) PROGRAM REQUIREMENTS.—

''(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

''(2) CONDITIONS FOR AWARDING CONTRACT.—

''(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

''(i) The entity meets quality and financial standards specified by the Secretary or developed by the Program Advisory and Oversight Committee established under subsection (c).

''(ii) The total amounts to be paid under the contract (including costs associated with the administration of the contract) are expected to be less than the total amounts that would otherwise be paid.

''(iii) Beneficiary access to a choice of multiple suppliers in the area is maintained.

''(iv) Beneficiary liability is limited to 20 percent of the applicable contract award price, except in such cases where a supplier has furnished an upgraded item and has executed an advanced beneficiary notice.

''(B) DEVELOPMENT OF QUALITY STANDARDS FOR DME PRODUCTS.—

''(i) IN GENERAL.—The quality standards specified under subparagraph (A)(i) shall not be less than the quality standards that would otherwise apply if this section did not apply and shall include consumer services standards. Not later than July 1, 2004, the Secretary shall establish new quality standards for products subject to competitive acquisition under this section. Such standards shall be applied prospectively and shall be published on the website of the Department of Health and Human Services.

''(ii) CONSULTATION WITH PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—The Secretary shall consult with the Program Advisory and Oversight Committee (established under subsection (c)) to review (and advise the Secretary concerning) the quality standards referred to in clause (i).

''(iii) CONSTRUCTION.—Nothing in this subparagraph shall be construed as delaying the effective date of the implementation of the competitive acquisition program under this section.

''(3) CONTENTS OF CONTRACT.—

''(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

''(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts under this section not less often than once every 3 years.

''(4) LIMIT ON NUMBER OF CONTRACTORS.—

''(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet

projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of beneficiaries for such items or services in the geographic area covered under the contract on a timely basis.

''(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

''(5) PAYMENT.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on the bids submitted and accepted under this section for such items and services.

''(6) PARTICIPATING CONTRACTORS.—Payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

''(A) the contractor has submitted a bid for such items and services under this section; and

''(B) the Secretary has awarded a contract to the contractor for such items and services under this section.

In this section, the term 'bid' means a request for a proposal for an item or service that includes the cost of the item or service, and where appropriate, any services that are attendant to the provision of the item or service.

''(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary shall consider the similarity of the clinical efficiency and value of specific codes and products, including products that may provide a therapeutic advantage to beneficiaries, before delineating the categories and products that will be subject to bidding.

''(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH AND COMPLAINT SERVICES.—The Secretary may enter into a contract with an appropriate entity to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such beneficiaries and monitoring quality of services with respect to the program.

''(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

''(1) ESTABLISHMENT.—There is established a Program Advisory and Oversight Committee (hereinafter in this section referred to as the 'Committee').

''(2) MEMBERSHIP; TERMS.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

''(3) DUTIES.—

''(A) TECHNICAL ASSISTANCE.—The Committee shall provide advice and technical assistance to the Secretary with respect to the following functions:

''(i) The implementation of the program under this section.

''(ii) The establishment of requirements for collection of data.

''(iii) The development of proposals for efficient interaction among manufacturers and distributors of the items and services and providers and beneficiaries.

''(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions

to assist the Secretary in carrying out this section as the Secretary may specify.

''(4) INAPPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

''(d) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in beneficiary cost-sharing, access to and quality of items and services, and beneficiary satisfaction.

''(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

''(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

''(A) for which payment is otherwise made under section 1833(h) or 1834(d)(1) (relating to colorectal cancer screening tests); and

''(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

''(2) TERMS AND CONDITIONS.—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

''(3) REPORT.—The Secretary shall submit to Congress—

''(A) an initial report on the project not later than December 31, 2005; and

''(B) such progress and final reports on the project after such date as the Secretary determines appropriate.''.

(b) CONFORMING AMENDMENTS.—

(1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

(A) in paragraph (1)(B), by striking ''The payment basis'' and inserting ''Subject to subparagraph (E)(i), the payment basis'';

(B) in paragraph (1)(C), by striking ''This subsection'' and inserting ''Subject to subparagraph (E)(ii), this subsection'';

(C) by adding at the end of paragraph (1) the following new subparagraph:

''(E) APPLICATION OF COMPETITIVE ACQUISITION; ELIMINATION OF INHERENT REA-

SONABLENESS AUTHORITY.—In the case of covered items and services that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

''(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied.''; and

(D) in paragraph (10)(B), by inserting ''in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(E)'' after ''under this subsection''.

(2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—

(A) in paragraph (1)(B), by striking ''and (E)'' and inserting '', (E) , and (H)(i)'';

(B) in paragraph (1)(D), by striking ''This subsection'' and inserting ''Subject to subparagraph (H)(ii), this subsection'';

(C) by adding at the end of paragraph (1) the following new subparagraph:

''(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(B) of section 1847(a) that are included in a competitive acquisition program in a competitive acquisition area under such section—

''(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to

adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.''.

(c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Secretary shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

(d) GAO STUDY ON SAFE AND EFFECTIVE HOME INFUSION AND INHALATION THERAPY; STANDARDS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study of the standards, professional services, and related functions necessary for the provision of safe and effective home infusion therapy and home inhalation therapy.

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(3) USE OF FINDINGS IN DEVELOPING STANDARDS.—In promulgating regulations to carry out section 1847 of the Social Security Act, as amended by subsection (a), the Secretary shall ensure that quality standards developed under subsection (b)(2)(B) of such section reflect the findings of the Comptroller General set forth in the report under paragraph (2).

SEC. 303. COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

(1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w–4(c)(2)) is amended—

(A) in subparagraph (B)—

(i) in clause (ii)(II), by striking ''The adjustments'' and inserting ''Subject to clause (iv), the adjustments''; and

(ii) by adding at the end of subparagraph (B), the following new clause:

''(iv) EXCEPTION TO BUDGET NEUTRALITY.—The additional expenditures attributable to clauses (ii) and (iii) of subparagraph (H) shall not be taken into ac-

count in applying clause (ii)(II) for 2005.''; and

(B) by adding at the end the following new subparagraph:

''(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR 2005.—

''(i) IN GENERAL.—As part of the annual process of establishing the physician fee schedule under subsection (b) for 2005, the Secretary shall increase the practice expense relative value units for 2005 consistent with clauses (ii) and (iii).

''(ii) USE OF SUPPLEMENTAL SURVEY DATA.—For 2005 for any specialty that submitted survey data that included expenses for the administration of drugs and biologicals for which payment is made under section 1842(o) (or section 1847A), the Secretary shall use such supplemental survey data in carrying out this subparagraph insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced

Budget Refinement Act of 1999 and insofar as such data are submitted to the Secretary by December 31, 2004.

''(iii) PROVISIONS FOR APPROPRIATE REPORTING AND BILLING FOR PHYSICIANS' SERVICES ASSOCIATED WITH THE ADMINISTRATION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—

''(I) EVALUATION OF CODES.—The Secretary shall promptly evaluate existing codes for physicians' services associated with the administration of covered outpatient drugs and biologicals (as defined in section 1847A(a)(2)(A)) to ensure accurate reporting and billing for such services.

''(II) USE OF EXISTING PROCESSES.—In carrying out subclause (I), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

"(III) IMPLEMENTATION.—In carrying out subclause (I), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1847A or section 1847B, and shall take such steps within the Secretary's authority to expedite such considerations under subclause (II).

"(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED.—Nothing in this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2005.

"(v) CONSULTATION.—Before publishing the notice of proposed rulemaking to carry out this subparagraph, the Secretary shall consult with the Comptroller General of the United States and with groups representing the physician specialties involved.

"(vi) TREATMENT AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE

GROWTH RATE DETERMINATION.—The enactment of subparagraph (B)(iv) and this subparagraph shall be treated as a change in law for purposes of applying subsection (f)(2)(D).''.

(2) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW.—Section 1848(i)(1) (42 U.S.C. 1395w–4(i)(1)) is amended—

(A) by striking ''and'' at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(F) adjustments in practice expense relative value units for 2005 under subsection (c)(2)(H).''.

(3) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NON-PHYSICIAN WORK POOL.—The Secretary shall make adjustments to the non-physician work pool methodology (as such term is used in the regulations promulgated by the Secretary in the Federal Register as of December 31, 2002) for determination of practice expense relative value units under the physician fee schedule described in section

1848(c)(2)(C)(ii) of the Social Security Act so that the practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of other services not determined under such non-physician work pool methodology, as the result of amendments made by paragraph (1).

(b) PAYMENT BASED ON COMPETITION.—Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w–3), as amended by section 302, the following new sections:

''COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS

''SEC. 1847A. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

''(1) IMPLEMENTATION OF PROGRAM.—

''(A) IN GENERAL.—The Secretary shall establish and implement a competitive acquisition program under which—

''(i) competitive acquisition areas are established throughout the United States for contract award purposes for acquisition of and payment for categories of covered outpatient drugs and biologicals (as defined in paragraph (2)) under this part;

"(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program or under section 1847B; and

"(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

"(B) IMPLEMENTATION.—The Secretary shall implement the program so that the program applies to—

"(i) the oncology category beginning in 2005; and

"(ii) the non-oncology category beginning in 2006.

This section shall not apply in the case of a physician who elects section 1847B to apply.

"(C) WAIVER OF CERTAIN PROVISIONS.—In order to promote competition, efficient service, and product quality, in carrying out the program the Secretary may waive such provi-

sions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

''(D) EXCLUSION AUTHORITY.—The Secretary may exclude covered outpatient drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the drugs or biologicals (or class) are not appropriate for competitive bidding due to low volume of utilization by beneficiaries under this part or a unique mode or method of delivery or similar reasons.

''(2) COVERED OUTPATIENT DRUGS AND BIOLOGICALS, CATEGORIES, PROGRAM DEFINED.—For purposes of this section—

''(A) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED.—The term 'covered outpatient drugs and biologicals' means drugs and biologicals to which section 1842(o) applies and which are not covered under section 1847 (relating to competitive acquisition for items of

durable medical equipment). Such term does not include the following:

"(i) Blood clotting factors.

"(ii) Drugs and biologicals furnished to individuals in connection with the treatment of end stage renal disease.

"(iii) Radiopharmaceuticals.

"(iv) Vaccines.

"(B) 2 CATEGORIES.—Each of the following shall be a separate category of covered outpatient drugs and biologicals, as identified by the Secretary:

"(i) ONCOLOGY CATEGORY.—A category (in this section referred to as the 'oncology category') consisting of those covered outpatient drugs and biologicals that, as determined by the Secretary, are typically primarily billed by oncologists or are otherwise used to treat cancer.

"(ii) NON-ONCOLOGY CATEGORIES.—Such numbers of categories (in this section referred to as the 'non-oncology categories') consisting of covered outpatient drugs and biologicals not described in clause (i), and appropriate subcategories of

such drugs and biologicals as the Secretary may specify.

''(C) PROGRAM.—The term 'program' means the competitive acquisition program under this section.

''(D) COMPETITIVE ACQUISITION AREA; AREA.—The terms 'competitive acquisition area' and 'area' mean an appropriate geographic region established by the Secretary under the program.

''(E) CONTRACTOR.—The term 'contractor' means an entity that has entered into a contract with the Secretary under this section.

''(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY.—With respect to covered outpatient drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has not elected section 1847B to apply—

''(A) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

''(B) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsi-

bility of such contractor and shall not be collected unless the drug or biological is administered to the beneficiary involved; and

''(C) the payment under this section (and related coinsurance amounts) for such drugs and biologicals—

''(i) shall be made only to such contractor;

''(ii) shall be conditioned upon the administration of such drugs and biologicals; and

''(iii) shall be based on the average of the bid prices for such drugs and biologicals in the area, as computed under subsection (d).

The Secretary shall provide a process for recoupment in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

''(4) CONTRACT REQUIRED.—

''(A) IN GENERAL.—Payment may not be made under this part for covered outpatient drugs and biologicals prescribed by a physician who has not elected section 1847B to apply

within a category and a competitive acquisition area with respect to which the program applies unless—

''(i) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

''(ii) the physician has elected such contractor under paragraph (5) for such category and area.

''(B) PHYSICIAN CHOICE.—Subparagraph (A) shall not apply for a category of drugs for an area if the physician prescribing the covered outpatient drug in such category and area has elected to apply section 1847B instead of this section.

''(5) CONTRACTOR SELECTION PROCESS.—

''(A) IN GENERAL.—The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of covered outpatient drugs and biologicals for an area, by physicians prescribing such drugs and biologicals in the area of the contractor under

this section that will supply the drugs and biologicals within that category and area. Such selection shall also include the election described in section 1847B(a).

"(B) INFORMATION ON CONTRACTORS.—The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Department's Internet website or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

"(C) SELECTING PHYSICIAN DEFINED.—For purposes of this section, the term 'selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has not elected section 1847B to apply and has selected to apply under this section such contractor for such category and area.

"(b) PROGRAM REQUIREMENTS.—

"(1) CONTRACT FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—The Secretary shall conduct a competition among entities for the acquisition of a covered outpatient drug or biological within

each HCPCS code within each category for each competitive acquisition area.

''(2) CONDITIONS FOR AWARDING CONTRACT.—

''(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of covered outpatient drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

''(i) CAPACITY TO SUPPLY COVERED OUTPATIENT DRUG OR BIOLOGICAL WITHIN CATEGORY.—

''(I) IN GENERAL.—The entity has sufficient arrangements to acquire and to deliver covered outpatient drugs and biologicals within such category in the area specified in the contract at the bid price specified in the contract for all physicians that may elect such entity.

''(II) SHIPMENT METHODOLOGY.—The entity has arrangements

in effect for the shipment at least 5 days each week of covered outpatient drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

''(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS.—The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

''(I) the establishment of procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries regarding the shipment of covered outpatient drugs and biologicals; and

''(II) a grievance process for the resolution of disputes.

''(B) ADDITIONAL CONSIDERATIONS.—The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

"(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

"(ii) the exclusion of the entity under section 1128 from participation under this title.

"(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN.—For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1868(b), as added by section 923 of the Medicare Prescription Drug and Modernization Act of 2003.

"(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA.—In order to provide a choice of at least 2 contractors in each competitive acquisition area for a category of drugs and biologicals, the Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

"(A) The bid prices for covered outpatient drugs and biologicals within the category and area.

''(B) Bid price for distribution of such drugs and biologicals.

''(C) Ability to ensure product integrity.

''(D) Customer service.

''(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

''(F) Such other factors as the Secretary may specify.

''(4) TERMS OF CONTRACTS.—

''(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

''(B) PERIOD OF CONTRACTS.—A contract under this section shall be for a term of 2 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

''(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM.—The Secretary—

''(i) shall require that for all drug and biological products distributed by a contractor under this section be acquired directly from the manufacturer or from a

distributor that has acquired the products directly from the manufacturer; and

''(ii) may require, in the case of such products that are particularly susceptible to counterfeit or diversion, that the contractor comply with such additional product integrity safeguards as may be determined to be necessary.

''(D) IMPLEMENTATION OF ANTI-COUNTERFEITING, QUALITY, SAFETY, AND RECORD KEEPING REQUIREMENTS.—The Secretary shall require each contractor to implement (through its officers, agents, representatives, and employees) requirements relating to the storage and handling of covered outpatient drugs and biologicals and for the establishment and maintenance of distribution records for such drugs and biologicals. A contract under this section may include requirements relating to the following:

''(i) Secure facilities.

''(ii) Safe and appropriate storage of drugs and biologicals.

''(iii) Examination of drugs and biologicals received and dispensed.

''(iv) Disposition of damaged and outdated drugs and biologicals.

''(v) Record keeping and written policies and procedures.

''(vi) Compliance personnel.

''(E) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES.—Under the contract—

''(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

''(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

''(F) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS.—Under the contract the contractor shall only supply covered outpatient drugs and biologicals directly to the selecting physicians and not directly to beneficiaries, except under circumstances and set-

tings where a beneficiary currently receives a drug or biological in the beneficiary's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not—

"(i) require a physician to submit a prescription for each individual treatment; or

"(ii) change a physician's flexibility in terms of writing a prescription for drugs for a single treatment or a course of treatment.

"(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS.—The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous

sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

''(A) The drugs or biologicals are required immediately.

''(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

''(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

''(D) The drugs or biologicals were administered in an emergency situation.

''(6) CONSTRUCTION.—Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

''(c) BIDDING PROCESS.—

''(1) IN GENERAL.—In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the prices bid to acquire and supply the covered outpatient drugs and biologicals for that category and area and the other factors referred to in subsection (b)(3).

''(2) PRICES BID.—The prices bid by an entity under paragraph (1) shall be the prices in effect and available for the supply of contracted drugs and biologicals in the area through the entity for the contract period.

''(3) REJECTION OF CONTRACT OFFER.—The Secretary shall reject the contract offer of an entity with respect to a category of drugs and biologicals for an area if the Secretary estimates that the prices bid, in the aggregate on average, would exceed 100 percent of the average sales price (as determined under section 1847B).

''(4) BIDDING ON A NATIONAL OR REGIONAL BASIS.—Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

''(5) UNIFORMITY OF BIDS WITHIN AREA.—The amount of the bid submitted under a contract offer for any covered outpatient drug or biological for an area shall be the same for that drug or biological for all portions of that area.

''(6) CONFIDENTIALITY OF BIDS.—The provisions of subparagraph (D) of section 1927(b)(3)

shall apply to a bid submitted in a contract offer for a covered outpatient drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

"(A) in that subparagraph to a 'manufacturer or wholesaler' is deemed a reference to a 'bidder' under this section;

"(B) in that section to 'prices charged for drugs' is deemed a reference to a 'bid' submitted under this section; and

"(C) in clause (i) of that section to 'this section', is deemed a reference to 'part B of title XVIII'.

"(7) INCLUSION OF COSTS.—The bid price submitted in a contract offer for a covered outpatient drug or biological shall—

"(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

"(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

''(8) PRICE ADJUSTMENTS DURING CONTRACT PERIOD; DISCLOSURE OF COSTS.—Each contract awarded shall provide for—

''(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

''(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

''(d) COMPUTATION OF AVERAGE BID PRICES FOR A CATEGORY AND AREA.—

''(1) IN GENERAL.—For each year or other contract period for each covered outpatient drug or biological and area with respect to which a competition is conducted under the program, the Secretary shall compute an area average of the bid prices submitted, in contract offers accepted for the category and area, for that year or other contract period.

''(2) SPECIAL RULES.—The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1847B to the use of a price for specific covered

outpatient drugs and biologicals in the following cases:

"(A) NEW DRUGS AND BIOLOGICALS.—A covered outpatient drug or biological for which an average bid price has not been previously determined.

"(B) OTHER CASES.—Such other exceptional cases as the Secretary may specify in regulations, such as oral drugs under section 1861(s)(2)(Q) and immmunosuppressives under section 1861(s)(2)(J).

"(e) COINSURANCE.—

"(1) IN GENERAL.—Coinsurance under this part with respect to a covered outpatient drug or biological for which payment is payable under this section shall be based on 20 percent of the payment basis under this section.

"(2) COLLECTION.—Such coinsurance shall be collected by the contractor that supplies the drug or biological involved and, subject to subsection (a)(3)(B), in the same manner as coinsurance is collected for durable medical equipment under this part.

"(f) SPECIAL PAYMENT RULES.—

''(1) IN GENERAL.—The Secretary may not provide for an adjustment to reimbursement for covered outpatient drugs and biologicals unless adjustments to the practice expense payment adjustment are made on the basis of supplemental surveys under section 1848(c)(2)(H)(ii) of the Social Security Act, as added by subsection (a)(1)(B).

(2) USE IN EXCLUSION CASES.—If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for reimbursement to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847B.

''(3) COORDINATION RULES.—The provisions of section 1842(h)(3) shall apply to a contractor with respect to covered outpatients drugs and biologicals supplied by that contractor in the same manner as they apply to a participating supplier. In order to administer this section, the Secretary may condition payment under this part to a person for the administration of a drug or biological supplied under this section upon person's provision of information on such administration.

''(4) APPLICATION OF REQUIREMENT FOR ASSIGNMENT.—For provision requiring assignment of claims for covered outpatient drugs and biologicals, see section 1842(o)(3).

''(5) PROTECTION FOR BENEFICIARY IN CASE OF MEDICAL NECESSITY DENIAL.—For protection of beneficiaries against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

''(6) PHYSICIAN ROLE IN APPEALS PROCESS.—The Secretary shall establish a procedure under which a physician who prescribes a drug or biological for which payment is made under this section has appeal rights that are similar to those provided to a physician who prescribes durable medical equipment or a laboratory test.

''(g) ADVISORY COMMITTEE.—The Secretary shall establish an advisory committee that includes representatives of parties affected by the program under this section, including physicians, specialty pharmacies, distributors, manufacturers, and beneficiaries. The committee shall advise the Secretary on issues relating to the effective implementation of this section.

''(h) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual report in each of 2005, 2006, and

2007, on the program. Each such report shall include information on savings, reductions in cost-sharing, access to covered outpatient drugs and biologicals, the range of choices of contractors available to providers, and beneficiary and provider satisfaction.

''OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

''SEC. 1847B. (a) IN GENERAL.—

''(1) ELECTION.—In connection with the annual election made by a physician under section 1847A(a)(5), the physician may elect to apply this section to the payment for covered outpatient drugs and biologicals instead of the payment methodology under section 1847A.

''(2) IMPLEMENTATION.—This section shall be implemented with respect to categories of covered outpatient drugs and biologicals described in section 1847A(a)(2)(B).

''(3) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED.—For purposes of this section, the term 'covered outpatient drugs and biologicals' has the meaning given such term in section 1847A(a)(2)(A).

''(b) COMPUTATION OF PAYMENT AMOUNT.—

''(1) IN GENERAL.—If this section applies with respect to a covered outpatient drug or biological,

the amount payable for the drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

"(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 100 percent (or in the case of covered outpatient drugs and biologicals furnished during 2005 and 2006, 112 percent) of the amount determined under paragraph (3); or

"(B) in the case of a single source drug (as defined in subsection (c)(6)(D)), 100 percent (or in the case of covered outpatient drugs and biologicals furnished during 2005 and 2006, 112 percent) of the amount determined under paragraph (4).

"(2) SPECIFICATION OF UNIT.—

"(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a covered outpatient drug shall specify the unit associated with each National Drug Code as part of the submission of data under section 1927(b)(3)(A)(iii).

"(B) UNIT DEFINED.—In this section, the term 'unit' means, with respect to a covered outpatient drug, the lowest identifiable quantity

(such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.

''(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) computed as follows:

''(A) Compute the sum of the products (for each national drug code assigned to such drug products) of—

''(i) the manufacturer's average sales price (as defined in subsection (c)); and

''(ii) the total number of units specified under paragraph (2) sold, as reported under section 1927(b)(3)(A)(iii).

''(B) Divide the sum computed under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all national drug codes assigned to such drug products.

''(4) SINGLE SOURCE DRUG.—The amount specified in this paragraph for a single source drug is the lesser of the following:

''(A) MANUFACTURER'S AVERAGE SALES PRICE.—The manufacturer's average sales price for a national drug code, as computed using the methodology applied under paragraph (3).

''(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) reported for the single source drug.

''(5) BASIS FOR DETERMINATION.—The payment amount shall be determined under this subsection based on information reported under subsection (e) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

''(c) MANUFACTURER'S AVERAGE SALES PRICE.—

''(1) IN GENERAL.—For purposes of this subsection, subject to paragraphs (2) and (3), the manufacturer's 'average sales price' means, of a covered outpatient drug for a NDC code for a calendar quarter for a manufacturer for a unit—

''(A) the manufacturer's total sales (as defined by the Secretary in regulations for pur-

poses of section 1927(c)(1)) in the United States for such drug in the calendar quarter; divided by

"(B) the total number of such units of such drug sold by the manufacturer in such quarter.

"(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

"(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of 'best price' under section 1927(c)(1)(C)(i).

"(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies by regulation as sales to an entity that are nominal in price or do not reflect a market price paid by an entity to which payment is made under this section.

"(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall be determined taking into account volume discounts, prompt pay discounts, cash discounts, the free goods that are

contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug is reduced as a consequence of such rebate.

''(4) AUTHORITY TO DISREGARD AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES.—In the case of a covered outpatient drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug is not sufficiently available from the manufacturer to compute an average sales price for the drug, the Secretary may determine the amount payable under this section for the drug without considering the manufacturer's average sales price of that manufacturer for that drug.

''(5) FREQUENCY OF DETERMINATIONS.—

''(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a covered outpatient drug of a manu-

facturer, shall be determined by such manufacturer under this subsection on a quarterly basis. In making such determination insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology established by the Secretary based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks.

''(B) UPDATES IN RATES.—The payment rates under subsection (b)(1) and (b)(2)(A) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price determined for the most recent calendar quarter.

''(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may use a carrier, fiscal intermediary, or other contractor to determine the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program memorandum or otherwise, any of the provisions of this section.

''(6) DEFINITIONS AND OTHER RULES.—In this section:

''(A) MANUFACTURER.—The term 'manufacturer' means, with respect to a covered outpatient drug, the manufacturer (as defined in section 1927(k)(5)) whose national drug code appears on such drug.

''(B) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' means, with respect to a covered outpatient drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

''(C) MULTIPLE SOURCE DRUG.—The term 'multiple source drug' means, for a calendar quarter, a covered outpatient drug for which there are 2 or more drug products which—

''(i) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Ap-

proved Drug Products with Therapeutic Equivalence Evaluations'),

"(ii) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

"(iii) are sold or marketed in the United States during the quarter.

"(D) SINGLE SOURCE DRUG.—The term 'single source drug' means a covered outpatient drug which is not a multiple source drug and which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application, or which is a biological.

"(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as

therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

"(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

"(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

"(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, 'other than a vaccine' is deemed deleted from section 1927(k)(2)(B).

"(d) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a public health emergency under section 319 of

the Public Health Service Act in which there is a documented inability to access covered outpatient drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

''(e) REPORTS.—

''(1) QUARTERLY REPORT ON AVERAGE SALES PRICE.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the covered outpatient drug or biological, see section 1927(b)(3).

''(2) ANNUAL REPORT TO CONGRESS.—The Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate an annual report on the operation of this section. Such report shall include information on the following:

''(A) Trends in average sales price under subsection (b).

''(B) Administrative costs associated with compliance with this section.

''(C) Total value of payments made under this section.

''(D) Comparison of the average manufacturer price as applied under section 1927 for a covered outpatient drug or biological with the manufacturer's average sales price for the drug or biological under this section.

''(f) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of manufacturer's average sales price under subsection (c).''.

(c) CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS.—Nothing in the amendments made by this section shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.

(d) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

(A) in paragraph (1), by inserting ", subject to section 1847A and 1847B," before "the amount payable for the drug or biological"; and

(B) by adding at the end of paragraph (2) the following: "This paragraph shall not apply in the case of payment under section 1847A or 1847B.".

(2) NO CHANGE IN COVERAGE BASIS.—Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting "(or would have been so included but for the application of section 1847A or 1847B)" after "included in the physicians' bills".

(3) PAYMENT.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(or, if applicable, under section 1847A or 1847B)" after "1842(o)".

(4) CONSOLIDATED REPORTING OF PRICING INFORMATION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (a)(1), by inserting "or under part B of title XVIII" after "section 1903(a)";

(B) in subsection (b)(3)(A)—

(i) in clause (i), by striking "and" at the end;

(ii) in clause (ii), by striking the period and inserting ''; and''; and

(iii) by adding at the end the following new clause:

''(iii) for calendar quarters beginning on or after April 1, 2004, in conjunction with reporting required under clause (i) and by national drug code (NDC)—

''(I) the manufacturer's average sales price (as defined in section 1847B(c)) and the total number of units specified under section 1847B(b)(2)(A);

''(II) if required to make payment under section 1847B, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

''(III) information on those sales that were made at a nominal price or otherwise described in section 1847B(c)(2)(B), which information is subject to audit by the Inspector General of the Department of Health and Human Services;

for a covered outpatient drug or biological for which payment is made under section 1847B.'';

(C) in subsection (b)(3)(B)—

(i) in the heading, by inserting ''AND MANUFACTURER'S AVERAGE SALES PRICE'' after ''PRICE''; and

(ii) by inserting ''and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment'' after ''manufacturer prices''; and

(D) in subsection (b)(3)(D)(i), by inserting ''and section 1847B'' after ''this section''.

(e) GAO STUDY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to assess the impact of the amendments made by this section on the delivery of services, including their impact on—

(A) beneficiary access to drugs and biologicals for which payment is made under part B of title XVIII of the Social Security Act; and

(B) the site of delivery of such services.

(2) REPORT.—Not later than 2 years after the year in which the amendment made by subsection

(a)(1) first takes effect, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(f) MEDPAC RECOMMENDATIONS ON BLOOD CLOTTING FACTORS.—The Medicare Payment Advisory Commission shall submit to Congress, in its annual report in 2004, specific recommendations regarding a payment amount (or amounts) for blood clotting factors and its administration under the medicare program.

(g) ESTABLISHMENT OF PHARMACEUTICAL MANAGEMENT FEE WHERE DRUGS PROVIDED THROUGH A CONTRACTOR.—Section 1848(a) (42 U.S.C. 1395w–4(a)) is amended by adding at the end the following new paragraph:

''(5) RECOGNITION OF PHARMACEUTICAL MANAGEMENT FEE IN CERTAIN CASES.—In establishing the fee schedule under this section, the Secretary shall provide for a separate payment with respect to physicians' services consisting of the unique administrative and management costs associated with covered drugs and biologicals which are furnished to physicians through a contractor under section 1847A (compared with such costs if such drugs and biologicals were acquired directly by such physicians).''.

(h) STUDY ON CODES FOR NON-ONCOLOGY CODES.—

(1) STUDY.—The Secretary shall conduct a study to determine the appropriateness of establishing and implementing separate codes for non-oncology infusions that are based on the level of complexity of the administration and resource consumption.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study. To the extent the Secretary determines it to be appropriate, the Secretary may implement appropriate changes in the payment methodology for such codes.

SEC. 304. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under this section (in this section referred to as the ''project'') to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments under the medicare program for services for which payment is made under part A or part B of title XVIII of the Social Security Act. Under the project—

(1) payment may be made to such a contractor on a contingent basis;

(2) a percentage of the amount recovered may be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of such use with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

(b) SCOPE AND DURATION.—

(1) SCOPE.—The project shall cover at least 2 States that are among the States with—

(A) the highest per capita utilization rates of medicare services, and

(B) at least 3 contractors.

(2) DURATION.—The project shall last for not longer than 3 years.

(c) WAIVER.—The Secretary of Health and Human Services shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge of and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health

plans, or under the medicaid program under title XIX of the Social Security Act.

(e) CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.—A recovery of an overpayment to a provider by a recovery audit contractor shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) REPORT.—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the medicare program and recommendations on the cost-effectiveness of extending or expanding the project.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

SEC. 401. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) DOUBLING THE CAP.—

(1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the following new clause:

''(xiv)(I) In the case of discharges in a fiscal year beginning on or after October 1, 2003, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

''(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 10 percent for a hospital that is not classified as a rural referral center under subparagraph (C).''.

(2) CONFORMING AMENDMENTS.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting ''subject to clause (xiv) and'' before ''for discharges occurring'';

(B) in clause (viii), by striking ''The formula'' and inserting ''Subject to clause (xiv), the formula''; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking ''For purposes'' and inserting ''Subject to clause (xiv), for purposes''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to discharges occurring on or after October 1, 2003.

SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS.

(a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C. 1395ww(d)(3)(A)) is amended—

(1) in clause (iv), by inserting ''and ending on or before September 30, 2003,'' after ''October 1, 1995,''; and

(2) by redesignating clauses (v) and (vi) as clauses (vii) and (viii), respectively, and inserting after clause (iv) the following new clauses:

''(v) For discharges occurring in the fiscal year beginning on October 1, 2003, the average standardized amount for hospitals located in areas other than a large urban area shall be equal to the average standardized amount for hospitals located in a large urban area.''.

(b) CONFORMING AMENDMENTS.—

(1) COMPUTING DRG-SPECIFIC RATES.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

(A) in the heading, by striking ''IN DIFFERENT AREAS'';

(B) in the matter preceding clause (i), by striking '', each of'';

(C) in clause (i)—

(i) in the matter preceding subclause (I), by inserting ''for fiscal years before fiscal year 2004,'' before ''for hospitals''; and

(ii) in subclause (II), by striking ''and'' after the semicolon at the end;

(D) in clause (ii)—

(i) in the matter preceding subclause (I), by inserting ''for fiscal years before fiscal year 2004,'' before ''for hospitals''; and

(ii) in subclause (II), by striking the period at the end and inserting ''; and''; and

(E) by adding at the end the following new clause:

''(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

"(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

"(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.".

(2) TECHNICAL CONFORMING SUNSET.—Section 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting ", for fiscal years before fiscal year 1997," before "a regional adjusted DRG prospective payment rate"; and

(B) in subparagraph (D), in the matter preceding clause (i), by inserting ", for fiscal years before fiscal year 1997," before "a regional DRG prospective payment rate for each region,".

SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOSPITAL CLASSIFICATION.

(a) CLASSIFICATION.—Section 1861(mm) (42 U.S.C. 1395x(mm)) is amended—

(1) in the heading by adding "ESSENTIAL RURAL HOSPITALS" at the end; and

(2) by adding at the end the following new paragraphs:

''(4)(A) The term 'essential rural hospital' means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is located in a rural area (as defined for purposes of section 1886(d)), has more than 25 licensed acute care inpatient beds, has applied to the Secretary for classification as such a hospital, and with respect to which the Secretary has determined that the closure of the hospital would significantly diminish the ability of medicare beneficiaries to obtain essential health care services.

''(B) The determination under subparagraph (A) shall be based on the following criteria:

''(i) HIGH PROPORTION OF MEDICARE BENEFICIARIES RECEIVING CARE FROM HOSPITAL.—(I) A high percentage of such beneficiaries residing in the area of the hospital who are hospitalized (during the most recent year for which complete data are available) receive basic inpatient medical care at the hospital.

''(II) For a hospital with more than 200 licensed beds, a high percentage of such beneficiaries residing in such area who are hospitalized (during

such recent year) receive specialized surgical inpatient care at the hospital.

''(III) Almost all physicians described in section 1861(r)(1) in such area have privileges at the hospital and provide their inpatient services primarily at the hospital.

''(IV) The hospital inpatient score for quality of care is not less than the median hospital score for qualify of care for hospitals in the State, as established under standards of the utilization and quality control peer review organization under part B of title XI or other quality standards recognized by the Secretary.

''(ii) SIGNIFICANT ADVERSE IMPACT IN ABSENCE OF HOSPITAL.—If the hospital were to close—

''(I) there would be a significant amount of time needed for residents to reach emergency treatment, resulting in a potential significant harm to beneficiaries with critical illnesses or injuries;

''(II) there would be an inability in the community to stablize emergency cases for transfers to another acute care setting, result-

ing in a potential for significant harm to medicare beneficiaries; and

''(III) any other nearby hospital lacks the physical and clinical capacity to take over the hospital's typical admissions.

''(C) In making such determination, the Secretary may also consider the following:

''(i) Free-standing ambulatory surgery centers, office-based oncology care, and imaging center services are insufficient in the hospital's area to handle the outpatient care of the hospital.

''(ii) Beneficiaries in nearby areas would be adversely affected if the hospital were to close as the hospital provides specialized knowledge and services to a network of smaller hospitals and critical access hospitals.

''(iii) Medicare beneficiaries would have difficulty in accessing care if the hospital were to close as the hospital provides significant subsidies to support ambulatory care in local clinics, including mental health clinics and to support post acute care.

''(iv) The hospital has a committment to provide graduate medical education in a rural area.

A hospital classified as an essential rural hospital may not change such classification and a hospital so classified shall

not be treated as a sole community hospital, medicare dependent hospital, or rural referral center for purposes of section 1886.''.

(b) PAYMENT BASED ON 102 PERCENT OF ALLOWED COSTS.—

(1) INPATIENT HOSPITAL SERVICES.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following:

''(11) In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting period, the payment under this subsection for inpatient hospital services for discharges occurring during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this paragraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under part A or as waiving any requirement for billing for such services.''.

(2) HOSPITAL OUTPATIENT SERVICES.—Section 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by adding at the end the following new subparagraph:

''(B) SPECIAL RULE FOR ESSENTIAL RURAL HOSPITALS.—In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting pe-

riod, the payment under this subsection for covered OPD services during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this subparagraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under this part or as waiving any requirement for billing for such services.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to cost reporting periods beginning on or after October 1, 2004.

SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED IN HOSPITAL MARKET BASKET.

(a) MORE FREQUENT UPDATES IN WEIGHTS.—After revising the weights used in the hospital market basket under section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most current data available, the Secretary shall establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every 5 years.

(b) REPORT.—Not later than October 1, 2004, the Secretary shall submit a report to Congress on the frequency established under subsection (a), including an ex-

planation of the reasons for, and options considered, in determining such frequency.

SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) INCREASE IN PAYMENT AMOUNTS.—

(1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and 1883(a)(3) (42 U.S.C. 1395f(l); 1395m(g)(1); 42 U.S.C. 1395tt(a)(3)) are each amended by inserting ''equal to 102 percent of'' before ''the reasonable costs''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for services furnished during cost reporting periods beginning on or after October 1, 2003.

(b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—

(1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C. 1395m(g)(5)) is amended—

(A) in the heading—

(i) by inserting ''CERTAIN'' before ''EMERGENCY''; and

(ii) by striking ''PHYSICIANS'' and inserting ''PROVIDERS'';

(B) by striking ''emergency room physicians who are on-call (as defined by the Sec-

retary)'' and inserting ''physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services''; and

(C) by striking ''physicians' services'' and inserting ''services covered under this title''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to costs incurred for services provided on or after January 1, 2004.

(c) MODIFICATION OF THE ISOLATION TEST FOR COST-BASED CAH AMBULANCE SERVICES.—

(1) IN GENERAL.—Section 1834(l)(8) (42 U.S.C. 1395m(l)), as added by section 205(a) of BIPA (114 Stat. 2763A–482), is amended by adding at the end the following: ''The limitation described in the matter following subparagraph (B) in the previous sentence shall not apply if the ambulance services are furnished by such a provider or supplier of ambulance services who is a first responder to emergencies in accordance with local protocols (as determined by the Secretary).''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to ambulances services

furnished on or after the first cost reporting period that begins after the date of the enactment of this Act.

(d) REINSTATEMENT OF PERIODIC INTERIM PAYMENT (PIP).—

(1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is amended—

(A) in the matter before subparagraph (A), by inserting ", in the cases described in subparagraphs (A) through (D)" after "1986"; and

(B) by striking "and" at the end of subparagraph (C);

(C) by adding "and" at the end of subparagraph (D); and

(D) by inserting after subparagraph (D) the following new subparagraph:

"(E) inpatient critical access hospital services;".

(2) DEVELOPMENT OF ALTERNATIVE METHODS OF PERIODIC INTERIM PAYMENTS.—With respect to periodic interim payments to critical access hospitals for inpatient critical access hospital services under section 1815(e)(2)(E) of the Social Security Act, as added by paragraph (1), the Secretary shall develop

alternative methods for such payments that are based on expenditures of the hospital.

(3) REINSTATEMENT OF PIP.—The amendments made by paragraph (1) shall apply to payments made on or after January 1, 2004.

(e) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN PAYMENT ADJUSTMENT.—

(1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C. 1395m(g)(2)) is amended by adding after and below subparagraph (B) the following:

''The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians who have not assigned such billing rights.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall be effective as if included in the enactment of section 403(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (113 Stat. 1501A–371).

(f) FLEXIBILITY IN BED LIMITATION FOR HOSPITALS.—Section 1820 (42 U.S.C. 1395i–4) is amended—

(1) in subsection (c)(2)(B)(iii), by inserting ''subject to paragraph (3)'' after ''(iii) provides'';

(2) by adding at the end of subsection (c) the following new paragraph:

''(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—

''(A) IN GENERAL.—Subject to subparagraph (C), in the case of a hospital that demonstrates that it meets the standards established under subparagraph (B) and has not made the election described in subsection (f)(2)(A), the bed limitations otherwise applicable under paragraph (2)(B)(iii) and subsection (f) shall be increased by 5 beds.

''(B) STANDARDS.—The Secretary shall specify standards for determining whether a critical access hospital has sufficiently strong seasonal variations in patient admissions to justify the increase in bed limitation provided under subparagraph (A).''; and

(3) in subsection (f)—

(A) by inserting ''(1)'' after ''(f)''; and

(B) by adding at the end the following new paragraph:

''(2)(A) A hospital may elect to treat the reference in paragraph (1) to '15 beds' as a reference to '25 beds', but only if no more than 10 beds in the hospital are at any time used for non-acute care services. A hospital that makes such an election is not eligible for the increase provided under subsection (c)(3)(A).

''(B) The limitations in numbers of beds under the first sentence of paragraph (1) are subject to adjustment under subsection (c)(3).''.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to designations made before, on, or after January 1, 2004.

(g) ADDITIONAL 5-YEAR PERIOD OF FUNDING FOR GRANT PROGRAM.—

(1) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by adding at the end the following new paragraph:

''(4) FUNDING.—

''(A) IN GENERAL.—Subject to subparagraph (B), payment for grants made under this subsection during fiscal years 2004 through 2008 shall be made from the Federal Hospital Insurance Trust Fund.

''(B) ANNUAL AGGREGATE LIMITATION.—In no case may the amount of payment pro-

vided for under subparagraph (A) for a fiscal year exceed $25,000,000.''.

(2) CONFORMING AMENDMENT.—Section 1820 (42 U.S.C. 1395i–4) is amended by striking subsection (j).

SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C. 1395ww(h)(4)) is amended—

(1) in subparagraph (F)(i), by inserting ''subject to subparagraph (I),'' after ''October 1, 1997,'';

(2) in subparagraph (H)(i), by inserting ''subject to subparagraph (I),'' after ''subparagraphs (F) and (G),''; and

(3) by adding at the end the following new subparagraph:

''(I) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

''(i) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

''(I) IN GENERAL.—If a hospital's resident level (as defined in clause (iii)(I)) is less than the otherwise applicable resident limit (as defined in clause (iii)(II)) for each of

the reference periods (as defined in subclause (II)), effective for cost reporting periods beginning on or after January 1, 2004, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in subclause (III) (or subclause (IV) if applicable).

''(II) REFERENCE PERIODS DEFINED.—In this clause, the term 'reference periods' means, for a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not, submitted) on or before September 30, 2002.

''(III) REFERENCE RESIDENT LEVEL.—Subject to subclause (IV), the reference resident level specified in this subclause for a hospital is the highest resident level for the hospital during any of the reference periods.

''(IV) ADJUSTMENT PROCESS.—Upon the timely request of a hospital,

the Secretary shall adjust (subject to audit) the reference resident level for a hospital to be the resident level for the hospital for the cost reporting period that includes July 1, 2003.

''(V) AFFILIATION.—With respect to hospitals which are members of the same affiliated group (as defined by the Secretary under subparagraph (H)(ii)), the provisions of this section shall be applied with respect to such an affiliated group by deeming the affiliated group to be a single hospital.

''(ii) REDISTRIBUTION.—

''(I) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in such limits attributable to clause (i) (without taking into account any adjustment under subclause (IV) of such clause).

''(II) EFFECTIVE DATE.—No increase under subclause (I) shall be permitted or taken into account for a hospital for any portion of a cost reporting period that occurs before July 1, 2004, or before the date of the hospital's application for an increase under this clause. No such increase shall be permitted for a hospital unless the hospital has applied to the Secretary for such increase by December 31, 2005.

''(III) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall take into account the need for such an increase by specialty and location involved, consistent with subclause (IV).

''(IV) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase

in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall first distribute the increase to programs of hospitals located in rural areas or in urban areas that are not large urban areas (as defined for purposes of subsection (d)) on a first-come-first-served basis (as determined by the Secretary) based on a demonstration that the hospital will fill the positions made available under this clause and not to exceed an increase of 25 full-time equivalent positions with respect to any hospital.

''(V) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this clause, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average

per resident amount computed under subparagraph (E) for that hospital.

''(VI) CONSTRUCTION.—Nothing in this clause shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6) or as affecting the ability of a hospital to establish new medical residency training programs under subparagraph (H).

''(iii) RESIDENT LEVEL AND LIMIT DEFINED.—In this subparagraph:

''(I) RESIDENT LEVEL.—The term 'resident level' means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under this paragraph), in the fields of allopathic and osteopathic medicine for the hospital.

''(II) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit

otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.''.

(b) CONFORMING AMENDMENT TO IME.—Section 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended by adding at the end the following: ''The provisions of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentece of this clause in the same manner as it applies with respect to subparagraph (F) of such subsection.''.

(c) REPORT ON EXTENSION OF APPLICATIONS UNDER REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND SOLE COMMUNITY HOSPITALS UNDER PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.

(a) HOLD HARMLESS PROVISIONS.—

(1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended—

(A) in the heading, by striking ''SMALL'' and inserting ''CERTAIN'';

(B) by inserting ''or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area'' after ''100 beds''; and

(C) by striking ''2004'' and inserting ''2006''.

(2) EFFECTIVE DATE.—The amendment made by subsection (a)(2) shall apply with respect to payment for OPD services furnished on and after January 1, 2004.

(b) STUDY; ADJUSTMENT.—

(1) STUDY.—The Secretary shall conduct a study to determine if, under the prospective payment system for hospital outpatient department services under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), costs incurred by rural providers of services by ambulatory payment classification groups (APCs) exceed those costs incurred by urban providers of services.

(2) ADJUSTMENT.—Insofar as the Secretary determines under paragraph (1) that costs incurred by rural providers exceed those costs incurred by

urban providers of services, the Secretary shall provide for an appropriate adjustment under such section 1833(t) to reflect those higher costs by January 1, 2005.

SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended—

(1) in clause (i)(II), by striking ''clauses (ii) and (iii)'' and inserting ''clauses (ii), (iii), and (iv)''; and

(2) by adding at the end the following new clause:

''(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Services described in this clause are—

''(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

''(II) Federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were not furnished by an individual affiliated with a rural health clinic or a Federally qualified health center.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished on or after January 1, 2004.

SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTITIONERS AS ATTENDING PHYSICIANS TO SERVE HOSPICE PATIENTS.

(a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C. 1395x(dd)(3)(B)) is amended by inserting ''or nurse practitioner (as defined in subsection (aa)(5))'' after ''the physician (as defined in subsection (r)(1))''.

(b) CLARIFICATION OF HOSPICE ROLE OF NURSE PRACTITIONERS.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C. 1395f(a)(7)(A)(i)(I)) is amended by inserting ''(which for purposes of this subparagraph does not include a nurse practitioner)'' after ''attending physician (as defined in section 1861(dd)(3)(B))''.

SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.

Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–486), as paragraph (9); and

(2) by adding at the end the following new paragraph:

''(10) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW MEDICARE POPULATION DENSITY AREAS.—

''(A) IN GENERAL.—In the case of ground ambulance services furnished on or after January 1, 2004, for which the transportation originates in a qualified rural area (as defined in subparagraph (B)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for the base rate in the lowest quartile as compared to the average cost for the base rate for such services that is in the highest quartile of all rural county populations.

"(B) QUALIFIED RURAL AREA DEFINED.—For purposes of subparagraph (A), the term 'qualified rural area' is a rural area (as defined in section 1886(d)(2)(D)) with a population density of medicare beneficiaries residing in the area that is in the lowest quartile of all rural county populations.".

SEC. 411. TWO-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during 2004 and 2005, the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

SEC. 412. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7(b)(3)), as amended by section 101(b)(2), is amended—

(1) in subparagraph (F), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(H) any remuneration between a public or nonprofit private health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations or loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.''.

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits a patient's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) INTERIM FINAL EFFECT.—No later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1)(B). Such rule shall be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period of not more than 60 days) for public comment, as is consistent with this subsection.

SEC. 413. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for

physicians' services in different geographic areas. Such study shall include—

(1) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(2) an evaluation of the measures used for such adjustment, including the frequency of revisions; and

(3) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

SEC. 414. TREATMENT OF MISSING COST REPORTING PERIODS FOR SOLE COMMUNITY HOSPITALS.

(a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C. 1395ww(b)(3)(I)) is amended by adding at the end the following new clause:

''(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to cost reporting periods beginning on or after January 1, 2004.

SEC. 415. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.

Section 4207 of Balanced Budget Act of 1997 (Public Law 105–33) is amended—

(1) in subsection (a)(4), by striking ''4-year'' and inserting ''8-year''; and

(2) in subsection (d)(3), by striking ''$30,000,000'' and inserting ''$60,000,000''.

SEC. 416. ADJUSTMENT TO THE MEDICARE INPATIENT HOSPITAL PPS WAGE INDEX TO REVISE THE LABOR-RELATED SHARE OF SUCH INDEX.

(a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(1) by striking ''WAGE LEVELS.—The Secretary'' and inserting ''WAGE LEVELS.—

''(i) IN GENERAL.—Except as provided in clause (ii), the Secretary''; and

(2) by adding at the end the following new clause:

''(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2004.—

''(I) IN GENERAL.—Except as provided in subclause (II), for discharges occurring on or after October 1, 2003, the Secretary shall substitute the '62 percent' for the proportion described in the first sentence of clause (i).

''(II) HOLD HARMLESS FOR CERTAIN HOSPITALS.—If the application of subclause (I) would result in lower payments to a hospital than would otherwise be made, then this subparagraph shall be applied as if this clause had not been enacted.''.

(b) WAIVING BUDGET NEUTRALITY.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended by subsection (a), is amended by adding at the end of clause (i) the following new sentence: ''The Secretary shall apply the previous sentence for any period as if the amendments made by section 402(a) of the Medicare Prescription Drug and Modernization Act of 2003 had not been enacted.''.

SEC. 417. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS FOR PHYSICIAN SCARCITY.

(a) ADDITIONAL BONUS PAYMENT FOR CERTAIN PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—Section 1833 (42 U.S.C. 1395*l*) is amended by adding at the end the following new subsection:

''(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

''(1) IN GENERAL.—In the case of physicians' services furnished in a year—

''(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

''(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

"(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall periodically determine, for each county or equivalent area in the United States, the following:

"(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

"(i) primary care physicians; or

"(ii) physicians who are not primary care physicians.

"(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the coun-

ty and are entitled to benefits under part A or enrolled under this part, or both.

''(C) DETERMINATION OF RATIOS.—

''(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the 'primary care ratio') of the number of primary care physicians (determined under subparagraph (A)(i)), to number of medicare beneficiaries determined under subparagraph (B).

''(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(ii)), to number of medicare beneficiaries determined under subparagraph (B).

''(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

''(4) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

''(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios

that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph; and

''(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph.

There is no administrative or judicial review respecting the identification of a county or area or the assignment of a specialty of any physician under this paragraph.

''(5) RURAL CENSUS TRACKS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed.

Reg. 6725) as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

''(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term 'physician' means a physician described in section 1861(r)(1) and the term 'primary care physician' means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

''(7) PUBLICATION OF LIST OF COUNTIES.—In carrying out this subsection for a year, the Secretary shall include, as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county under this subsection for the year involved.''.

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT PROGRAM.—

(1) IN GENERAL.—Section 1833(m) (42 U.S.C. 1395*l*(m)) is amended—

(A) by inserting ''(1)'' after ''(m)''; and

(B) by adding at the end the following new paragraphs:

''(2) The Secretary shall establish procedures under which the Secretary, and not the physician furnishing the service, is responsible for determining when a payment is required to be made under paragraph (1).

''(3) In carrying out paragraph (1) for a year, the Secretary shall include, as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a health professional shortage area under paragraph (1) for the year involved.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to physicians' services furnished or after January 1, 2004.

SEC. 418. RURAL HOSPICE DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project for the delivery of hospice care to medicare beneficiaries in rural areas. Under the project medicare beneficiaries who are unable to receive hospice care in the home for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided

by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

(b) SCOPE OF PROJECT.—The Secretary shall conduct the project under this section with respect to no more than 3 hospice programs over a period of not longer than 5 years each.

(c) COMPLIANCE WITH CONDITIONS.—Under the demonstration project—

(1) the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the home or to meet the requirements of section 1861(dd)(2)(A)(iii) of the Social Security Act; and

(2) payments for hospice care shall be made at the rates otherwise applicable to such care under title XVIII of such Act.

The Secretary may require the program to comply with such additional quality assurance standards for its provision of services in its facility as the Secretary deems appropriate.

(d) REPORT.—Upon completion of the project, the Secretary shall submit a report to Congress on the project and shall include in the report recommendations regarding extension of such project to hospice programs serving rural areas.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended—

(1) by striking ''and'' at the end of subclause (XVIII);

(2) by striking subclause (XIX); and

(3) by inserting after subclause (XVIII) the following new subclauses:

''(XIX) for each of fiscal years 2004 through 2006, the market basket percentage increase minus 0.4 percentage points for hospitals in all areas; and

''(XX) for fiscal year 2007 and each subsequent fiscal year, the market basket percentage increase for hospitals in all areas.''.

SEC. 502. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

''(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.''.

(b) ELIGIBILITY STANDARD FOR TECHNOLOGY OUTLIERS.—

(1) MINIMUM PERIOD FOR RECOGNITION OF NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

(A) by inserting ''(I)'' after ''(vi)''; and

(B) by adding at the end the following new subclause:

''(II) Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-year period that begins on the effective date of implementation of a code under ICD–9–CM (or a successor coding methodology) that enables the identification of specific discharges in which the service or technology has been used.''.

(2) ADJUSTMENT OF THRESHOLD.—Section 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended by inserting ''(applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved)'' after ''is inadequate''.

(3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is further amended by adding at the end the following subclause:

''(III) The Secretary shall by regulation provide for further clarification of the criteria applied to determine whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries. Under such criteria, in determining whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries, the Secretary shall deem a service or technology as meeting such requirement if the service or technology is a drug or biological that is designated under section 506 of the

Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of title 21, Code of Federal Regulations, or designated for priority review when the marketing application for such drug or biological was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority review has been provided under section 515(d)(5) of such Act. Nothing in this subclause shall be construed as effecting the authority of the Secretary to determine whether items and services are medically necessary and appropriate under section 1862(a)(1).''.

(4) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by paragraph (1), is amended—

(A) in clause (i), by adding at the end the following: ''Such mechanism shall be modified to meet the requirements of clause (viii).''; and

(B) by adding at the end the following new clause:

''(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described in the second sentence of clause (vi)(III) represents an advance in medical tech-

nology that substantially improves the diagnosis or treatment of beneficiaries as follows:

''(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

''(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

''(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, medicare beneficiaries, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.''.

(c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further amended by adding at the end the following new clause:

''(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the

Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).''.

(d) IMPROVEMENT IN PAYMENT FOR NEW TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after ''the estimated average cost of such service or technology'' the following: ''(based on the marginal rate applied to costs under subparagraph (A))''.

(e) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL INPATIENT TECHNOLOGY.—

(1) IN GENERAL.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking ''subject to paragraph (4)(C)(iii),''.

(2) NOT BUDGET NEUTRAL.—There shall be no reduction or other adjustment in payments under section 1886 of the Social Security Act because an

additional payment is provided under subsection (d)(5)(K)(ii)(III) of such section.

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2005.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2004 THAT ARE DENIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2005 under the amendments made by this section; and

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS IN PUERTO RICO.

Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking ''for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)'' and inserting ''the applicable Puerto Rico percentage (specified in subparagraph (E))''; and

(B) in clause (ii), by striking ''for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)'' and inserting ''the applicable Federal percentage (specified in subparagraph (E))''; and

(2) by adding at the end the following new subparagraph:

''(E) For purposes of subparagraph (A), for discharges occurring—

''(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

''(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico percent-

age is 50 percent and the applicable Federal percentage is 50 percent;

''(iii) during fiscal year 2004, the applicable Puerto Rico percentage is 41 percent and the applicable Federal percentage is 59 percent;

''(iv) during fiscal year 2005, the applicable Puerto Rico percentage is 33 percent and the applicable Federal percentage is 67 percent; and

''(v) on or after October 1, 2005, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.''.

SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICATION REFORM .

(a) IN GENERAL.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following:

''(11)(A) In order to recognize commuting patterns among Metropolitan Statistical Areas and between such Areas and rural areas, the Secretary shall establish a process, upon application of a subsection (d) hospital that establishes that it is a qualifying hospital described in subparagraph (B), for an increase of the wage index applied under paragraph (3)(E) for the hospital in the amount computed under subparagraph (D).

''(B) A qualifying hospital described in this subparagraph is a subsection (d) hospital—

''(i) the average wages of which exceed the average wages for the area in which the hospital is located; and

''(ii) which has at least 10 percent of its employees who reside in one or more higher wage index areas.

''(C) For purposes of this paragraph, the term 'higher wage index area' means, with respect to a hospital, an area with a wage index that exceeds that of the area in which the hospital is located.

''(D) The increase in the wage index under subparagraph (A) for a hospital shall be equal to the percentage of the employees of the hospital that resides in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

''(i) the difference between (I) the wage index for such area, and (II) the wage index of the area in which the hospital is located (before the application of this paragraph); and

''(ii) the number of employees of the hospital that reside in such higher wage index area divided by the total number of such employees that reside in all high wage index areas.

''(E) The process under this paragraph shall be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10) with respect to data submitted by hospitals to the Board on the location of residence of hospital employees and wages under the applicable schedule established for geographic reclassification.

''(F) A reclassification under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

''(G) A hospital that is reclassified under this paragraph for a period is not eligible for reclassification under paragraphs (8) or (10) during that period.

''(H) Any increase in a wage index under this paragraph for a hospital shall not be taken into account for purposes of—

''(i) computing the wage index for the area in which the hospital is located or any other area; or

''(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall first apply to the wage index for discharges occurring on or after October 1, 2004.

SEC. 505. MEDPAC REPORT ON SPECIALTY HOSPITALS.

(a) MEDPAC STUDY.—The Medicare Payment Advisory Commission shall conduct a study of specialty hospitals compared with other similar general acute care hospitals under the medicare program. Such study shall examine—

(1) whether there are excessive self-referrals;

(2) quality of care furnished;

(3) the impact of specialty hospitals on such general acute care hospitals; and

(4) differences in the scope of services, medicaid utilization, and uncompensated care furnished.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a), and shall include any recommendations for legislation or administrative change as the Secretary determines appropriate.

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 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, 2003.

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:

''(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician who is either the medical director or an employee of a hospice program and that consist of—

''(A) an evaluation of the individual's need for pain and symptom management;

''(B) counseling the individual with respect to end-of-life issues and care options; and

''(C) advising the individual regarding advanced care planning.''.

(b) PAYMENT.—Section 1814(i) (42 U.S.C. l395f(i)) is amended by adding at the end the following new paragraph:

''(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount equivalent to the amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.''.

(c) CONFORMING AMENDMENT.—Section 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended by inserting before the comma at the end the following: ''and services described in section 1812(a)(5)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to services provided by a hospice program on or after January 1, 2004.

SEC. 513. CORRECTION OF TRUST FUND HOLDINGS.

(a) IN GENERAL.—Within 120 days after the effective date of this section, the Secretary of the Treasury shall take the actions described in subsection (b) with respect to the Federal Hospital Insurance Trust Fund (in this section referred to as the ''Trust Fund'') with the goal being that, after the actions are taken, the holdings of the Trust Fund will replicate, to the extent practicable in the judgment of the Secretary of the Treasury, in consultation

with the Secretary, the obligations that would have been held by the trust fund if the clerical error had not occurred.

(b) OBLIGATIONS ISSUED AND REDEEMED.—The Secretary of the Treasury shall—

(1) issue to the Trust Fund obligations under chapter 31 of title 31, United States Code, that bear issue dates, interest rates, and maturity dates as the obligations that—

(A) would have been issued to the Trust Fund if the clerical error had not occurred; or

(B) were issued to the Trust Fund and were redeemed by reason of the clerical error; and

(2) redeem from the Trust Fund obligations that would have been redeemed from the Trust Fund if the clerical error had not occurred.

(c) APPROPRIATION TO TRUST FUND.—Within 120 days after the effective date of this section, there is hereby appropriated to the Trust Fund, out of any money in the Treasury not otherwise appropriated, an amount determined by the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, to be equal to the interest income lost by the trust fund through the date of credit by reason of the clerical error.

(d) CLERICAL ERROR DEFINED.—For purposes of this section, the term ''clerical error'' means the failure to have transferred the correct amount from the general fund to the Trust Fund, which failure occurred on April 15, 2001.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

SEC. 601. REVISION OF UPDATES FOR PHYSICIANS' SERVICES.

(a) UPDATE FOR 2004 AND 2005.—

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraph:

''(5) UPDATE FOR 2004 AND 2005.—The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.''.

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting ''and paragraph (5)'' after ''subparagraph (D)''.

(3) NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The amendments made by this sub-

section shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).

(b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING GROSS DOMESTIC PRODUCT.—

(1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C. 1395w–4(f)(2)(C)) is amended—

(A) by striking ''projected'' and inserting ''annual average''; and

(B) by striking ''from the previous applicable period to the applicable period involved'' and inserting ''during the 10-year period ending with the applicable period involved''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to computations of the sustainable growth rate for years beginning with 2003.

SEC. 602. STUDIES ON ACCESS TO PHYSICIANS' SERVICES.

(a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSICIANS' SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians' services under the medicare program. The study shall include—

(A) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(B) an examination of changes in the use by beneficiaries of physicians' services over time;

(C) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include a determination whether—

(A) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(B) access by medicare beneficiaries to physicians' services may have improved, remained constant, or deteriorated over time.

(b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply.

(2) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(c) GAO STUDY OF MEDICARE PAYMENT FOR INHALATION THERAPY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the medicare program.

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES.

(a) PRACTICE EXPENSE COMPONENT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit

to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

(1) The effect of such refinements on payment for physicians' services.

(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

(5) The effect of such refinements on physician participation under the medicare program.

(b) VOLUME OF PHYSICIAN SERVICES.—The Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the volume of physicians' services under part B of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

(1) An analysis of recent and historic growth in the components that the Secretary includes under the sustainable growth rate (under section 1848(f) of the Social Security Act).

(2) An examination of the relative growth of volume in physician services between medicare beneficiaries and other populations.

(3) An analysis of the degree to which new technology, including coverage determinations of the Centers for Medicare & Medicaid Services, has affected the volume of physicians' services.

(4) An examination of the impact on volume of demographic changes.

(5) An examination of shifts in the site of service of services that influence the number and intensity of services furnished in physicians' offices and the extent to which changes in reimbursement rates to other providers have affected these changes.

(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.

SEC. 604. INCLUSION OF PODIATRISTS AND DENTISTS UNDER PRIVATE CONTRACTING AUTHORITY.

Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is amended by striking ''section 1861(r)(1)'' and inserting ''paragraphs (1), (2), and (3) of section 1861(r)''.

SEC. 605. ESTABLISHMENT OF FLOOR ON WORK GEOGRAPHIC ADJUSTMENT.

(a) MINIMUM INDEX.—Section 1848(e)(1) (42 U.S.C. 1395w–4(e)(1)) is amended by adding at the end the following new subparagraph:

''(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDEX.—

''(i) IN GENERAL.—Subject to clause (ii), after calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2006, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.

''(ii) SECRETARIAL DISCRETION.—Clause (i) shall have no force or effect in law if the Secretary determines, taking into account the report of the Comptroller General under section 605(b)(2) of the

Medicare Prescription Drug and Modernization Act of 2003, that there is no sound economic rationale for the implementation of that clause.''.

(b) GAO REPORT.—

(1) EVALUATION.—As part of the study on geographic differences in payments for physicians' services conducted under section 413, the Comptroller General of the United States shall evaluate the following:

(A) Whether there is a sound economic basis for the implementation of the adjustment of the work geographic index under section 1848(e)(1) of the Social Security Act under subsection (a) in those areas in which the adjustment applies.

(B) The effect of such adjustment on physician location and retention in areas affected by such adjustment, taking into account—

(i) differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas; and

(ii) the mobility of physicians, including specialists, over the last decade.

(C) The appropriateness of establishing a floor of 1.0 for the work geographic index.

(2) REPORT.—By not later than September 1, 2004, the Comptroller General shall submit to Congress and to the Secretary a report on the evaluation conducted under paragraph (1).

Subtitle B—Preventive Services

SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (U), by striking ''and'' at the end;

(2) in subparagraph (V), by inserting ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(W) an initial preventive physical examination (as defined in subsection (ww));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Initial Preventive Physical Examination

''(ww) The term 'initial preventive physical examination' means physicians' services consisting of a physical

examination with the goal of health promotion and disease detection and includes items and services (excluding clinical laboratory tests), as determined by the Secretary, consistent with the recommendations of the United States Preventive Services Task Force.''.

(c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

(1) DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(A) by striking ''and'' before ''(6)'', and

(B) by inserting before the period at the end the following: '', and (7) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww))''.

(2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) in clause (N), by inserting ''(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))'' after ''80 percent''; and

(B) in clause (O), by inserting ''(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))'' after ''80 percent''.

(d) PAYMENT AS PHYSICIANS' SERVICES.—Section 1848(j)(3) (42 U.S.C. 1395w–4(j)(3)) is amended by inserting ''(2)(W),'' after ''(2)(S),''.

(e) OTHER CONFORMING AMENDMENTS.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (1)—

(A) by striking ''and'' at the end of subparagraph (H);

(B) by striking the semicolon at the end of subparagraph (I) and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(J) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual's first coverage period begins under part B;''; and

(2) in paragraph (7), by striking ''or (H)'' and inserting ''(H), or (J)''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004, but only for individuals whose coverage period begins on or after such date.

SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD LIPID SCREENING.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 611(a), is amended—

(1) in subparagraph (V), by striking ''and'' at the end;

(2) in subparagraph (W), by inserting ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(X) cholesterol and other blood lipid screening tests (as defined in subsection (XX));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by section 611(b), is amended by adding at the end the following new subsection:

''Cholesterol and Other Blood Lipid Screening Test

''(xx)(1) The term 'cholesterol and other blood lipid screening test' means diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels.

''(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cholesterol and other blood lipid screening tests, except that such frequency may not be more often than once every 2 years.''.

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section 611(e), is amended—

(1) by striking ''and'' at the end of subparagraph (I);

(2) by striking the semicolon at the end of subparagraph (J) and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(K) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(xx)(1)), which is performed more frequently than is covered under section 1861(xx)(2).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL CANCER SCREENING TESTS.

(a) IN GENERAL.—The first sentence of section 1833(b) (42 U.S.C. 1395*l*(b)), as amended by section 611(c)(1), is amended—

(1) by striking ''and'' before ''(7)''; and

(2) by inserting before the period at the end the following: '', and (8) such deductible shall not apply

with respect to colorectal cancer screening tests (as described in section 1861(pp)(1))''.

(b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii) and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are each amended—

(1) by striking ''DEDUCTIBLE AND'' in the heading; and

(2) in subclause (I), by striking ''deductible or'' each place it appears.

(c) EFFECTIVE DATE.—The amendment made by this section shall apply to items and services furnished on or after Janaury 1, 2004.

SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: ''and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

Subtitle C—Other Services

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.—

(1) MODIFICATION OF AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) by redesignating paragraph (13) as paragraph (14); and

(B) by inserting after paragraph (12) the following new paragraph:

''(13) DRUG APC PAYMENT RATES.—

''(A) IN GENERAL.—With respect to payment for covered OPD services that includes a specified covered outpatient drug (defined in subparagraph (B)), the amount provided for payment for such drug under the payment system under this subsection for services furnished in—

''(i) 2004, 2005, or 2006, shall in no case—

''(I) exceed 95 percent of the average wholesale price for the drug; or

''(II) be less than the transition percentage (under subparagraph (C))

of the average wholesale price for the drug; or

''(ii) a subsequent year, shall be equal to the average price for the drug for that area and year established under the competitive acquisition program under section 1847A as calculated and applied by the Secretary for purposes of this paragraph.

''(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

''(i) IN GENERAL.—In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in 1927(k)(2), that is—

''(I) a radiopharmaceutical; or

''(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

''(ii) EXCEPTION.—Such term does not include—

"(I) a drug for which payment is first made on or after January 1, 2003, under paragraph (6); or

"(II) a drug for a which a temporary HCPCS code has not been assigned.

"(C) TRANSITION TOWARDS HISTORICAL AVERAGE ACQUISITION COST.—The transition percentage under this subparagraph for drugs furnished in a year is determined in accordance with the following table:

For the year—	The transition percentage for—		
	Single source drugs are—	Innovator multiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	46%

"(D) PAYMENT FOR NEW DRUGS UNTIL TEMPORARY HCPCS CODE ASSIGNED.—With respect to payment for covered OPD services that includes a covered outpatient drug (as defined in 1927(k)) for a which a temporary HCPCS code has not been assigned, the amount provided for payment for such drug under the payment system under this subsection shall be equal to 95 percent of the average wholesale price for the drug.

''(E) CLASSES OF DRUGS.—For purposes of this paragraph, each of the following shall be treated as a separate class of drugs:

''(i) SOLE SOURCE DRUGS.—A sole source drug which for purposes of this paragraph means a drug or biological that is not a multiple source drug (as defined in subclauses (I) and (II) of section 1927(k)(7)(A)(i)) and is not a drug approved under an abbreviated new drug application under section 355(j) of the Federal Food, Drug, and Cosmetic Act.

''(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—Innovator multiple source drugs (as defined in section 1927(k)(7)(A)(ii)).

''(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—Noninnovator multiple source drugs (as defined in section 1927(k)(7)(A)(iii)).

''(F) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION FACTORS.—Additional expenditures resulting from this paragraph and paragraph (14)(C) in a year shall not be taken into account in establishing the conversion factor for that year.''.

(2) REDUCTION IN THRESHOLD FOR SEPARATE APCS FOR DRUGS.—Section 1833(t)(14), as redesignated by paragraph (1)(A), is amended by adding at the end the following new subparagraph:

''(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs to $50 per administration.''.

(3) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by adding at the end the following new subparagraph:

''(E) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory procedure codes established separately for drugs.''.

(4) PAYMENT FOR PASS THROUGH DRUGS.—Clause (i) of section 1833(t)(6)(D) (42 U.S.C. 1395l(t)(6)(D)) is amended by inserting after ''under section 1842(o)'' the following: ''(or if the drug is covered under a competitive acquisition contract under section 1847A for an area, an amount

determined by the Secretary equal to the average price for the drug for that area and year established under such section as calculated and applied by the Secretary for purposes of this paragraph)''.

(5) EFFECTIVE DATE.—The amendments made by this subsection shall apply to services furnished on or after January 1, 2004.

(b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

(1) IN GENERAL.—Section 1833(t)(14), as so redesignated and amended by subsection (a)(2), is amended by adding at the end the following new subparagraph:

''(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy furnished on or after January 1, 2004, and before January 1, 2007, the payment basis for the device under this subsection shall be equal to the hospital's charges for each device furnished, adjusted to cost.''.

(2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2) is amended—

(A) in subparagraph (F), by striking ''and'' at the end;

(B) in subparagraph (G), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new subparagraph:

''(H) with respect to devices of brachytherapy, the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.''.

(3) GAO REPORT.—The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(t)(13)(B) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.

(c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—

(1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

"(F) LIMITATION ON APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—The Secretary may not apply a 'functional equivalence' payment standard (including such standard promulgated on November 1, 2002) or any other similar standard in order to deem a particular product to be functionally equivalent (or a similar standard) unless the Commissioner of Food and Drugs establishes a functional equivalence standard and certifies, under such standards, that the two products are functionally equivalent. If the Commissioner makes such a certification with respect to two or more products, the Secretary may, after complying with applicable rulemaking requirements, implement such standard with respect to such products under this subsection.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biologi-

cal on or after the date of the enactment of this Act, unless such application was being made to such drug or biological prior to June 13, 2003.

(d) HOSPITAL ACQUISITION COST STUDY.—

(1) IN GENERAL.—The Secretary shall conduct a study on the costs incurred by hospitals in acquiring covered outpatient drugs for which payment is made under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

(2) DRUGS COVERED.—The study in paragraph (1) shall not include those drugs for which the acquisition costs is less than $50 per administration.

(3) REPRESENTATIVE SAMPLE OF HOSPITALS.—In conducting the study under paragraph (1), the Secretary shall collect data from a statistically valid sample of hospitals with an urban/rural stratification.

(4) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations with respect to the following:

(A) Whether the study should be repeated, and if so, how frequently.

(B) Whether the study produced useful data on hospital acquisition cost.

(C) Whether data produced in the study is appropriate for use in making adjustments to payments for drugs and biologicals under section 1847A of the Social Security Act.

(D) Whether separate estimates can be made of overhead costs, including handing and administering costs for drugs.

SEC. 622. PAYMENT FOR AMBULANCE SERVICES.

(a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by section 410(a), is amended—

(1) in paragraph (2)(E), by inserting ''consistent with paragraph (11)'' after ''in an efficient and fair manner''; and

(2) by adding at the end the following new paragraph:

''(11) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of

the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

"(A) For 2004, the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

"(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

"(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

"(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

"(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the 9 Census divisions using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.''.

(b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—Section 1834(l), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

''(12) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after January 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to such miles.''.

(c) GAO REPORT ON COSTS AND ACCESS.—Not later than December 31, 2005, the Comptroller General of the United States shall submit to Congress an initial report

on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule (under section 1834(l) of the Social Security Act, as amended by this section). Not later than December 31, 2007, the Comptroller General shall submit to Congress a final report on such access and supply.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to ambulance services furnished on or after January 1, 2004.

SEC. 623. RENAL DIALYSIS SERVICES.

(a) DEMONSTRATION OF ALTERNATIVE DELIVERY MODELS.—

(1) USE OF ADVISORY BOARD.—In carrying out the demonstration project relating to improving care for people with end-stage renal disease through alternative delivery models (as published in the Federal Register of June 4, 2003), the Secretary shall establish an advisory board comprised of representatives described in paragraph (2) to provide advice and recommendations with respect to the establishment and operation of such demonstration project.

(2) REPRESENTATIVES.—Representatives referred to in paragraph (1) include representatives of the following:

(A) Patient organizations.

(B) Clinicians.

(C) The medicare payment advisory commission, established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(D) The National Kidney Foundation.

(E) The National Institute of Diabetes and Digestive and Kidney Diseases of National Institutes of Health.

(F) End-stage renal disease networks.

(G) Medicare contractors to monitor quality of care.

(I) providers of services and renal dialysis facilities furnishing end-stage renal disease services.

(J) Economists.

(K) Researchers.

(b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDIATRIC FACILITIES.—

(1) IN GENERAL.—Section 422(a)(2) of BIPA is amended—

(A) in subparagraph (A), by striking ''and (C)'' and inserting '', (C), and (D)'';

(B) in subparagraph (B), by striking ''In the case'' and inserting ''Subject to subparagraph (D), in the case''; and

(C) by adding at the end the following new subparagraph:

''(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.''.

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amended by subsection (b), is further amended by striking ''Until'' and inserting ''Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and until''.

(c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED IN 2004.—Notwithstanding

any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2004, the composite payment rate otherwise established under section 1881(b)(7) of such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by 1.6 percent.

SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) 1-YEAR MORATORIUM ON THERAPY CAPS.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking ''and 2002'' and inserting ''2002, and 2004''.

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than December 31, 2003, the Secretary shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (relating to utilization patterns for outpatient therapy).

(c) IDENTIFICATION OF CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY CAP.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of

Sciences to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps under section 1833(g)(4) of the Social Security Act (42 U.S.C. 1395l(g)(4)).

(2) REPORTS TO CONGRESS.—

(A) PRELIMINARY REPORT.—Not later than July 1, 2004, the Secretary shall submit to Congress a preliminary report on the conditions and diseases identified under paragraph (1).

(B) FINAL REPORT.—Not later than September 1, 2004, the Secretary shall submit to Congress a final report on such conditions and diseases.

(C) RECOMMENDATIONS.—Not later than October 1, 2004, the Secretary shall submit to Congress a recommendation of criteria, with respect to such conditions and disease, under which a waiver of the therapy caps would apply.

(d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL THERAPIST SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access to physical therapist services in States authorizing such services without a physician referral and in States

that require such a physician referral. The study shall—

(A) examine the use of and referral patterns for physical therapist services for patients age 50 and older in States that authorize such services without a physician referral and in States that require such a physician referral;

(B) examine the use of and referral patterns for physical therapist services for patients who are medicare beneficiaries;

(C) examine the potential effect of prohibiting a physician from referring patients to physical therapy services owned by the physician and provided in the physician's office;

(D) examine the delivery of physical therapists' services within the facilities of Department of Defense; and

(E) analyze the potential impact on medicare beneficiaries and on expenditures under the medicare program of eliminating the need for a physician referral and physician certification for physical therapist services under the medicare program.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted

under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS.

Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended in the last sentence by inserting ''and each of fiscal years 2004 through 2008'' after ''In each of the fiscal years 1998 through 2002''.

SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS UNDER THE FEE SCHEDULE FOR ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o)) is amended—

(1) in paragraph (1), by striking ''no more than the limits established under paragraph (2)'' and inserting ''no more than the amount of payment applicable under paragraph (2)''; and

(2) in paragraph (2), to read as follows:

''(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

''(B) The Secretary or a carrier may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

''(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.''.

(b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by inserting ''(and includes shoes described in section 1861(s)(12))'' after ''in section 1861(s)(9)''.

(2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amended by striking subparagraph (C).

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished on or after January 1, 2004.

SEC. 627. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILITARY RETIREES; SPECIAL ENROLLMENT PERIOD.

(a) WAIVER OF PENALTY.—

(1) IN GENERAL.—Section 1839(b) (42 U.S.C. 1395r(b)) is amended by adding at the end the following new sentence: ''No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to premiums for months beginning with January 2004. The Secretary of Health and Human Services shall establish a method for providing rebates of premium penalties

paid for months on or after January 2004 for which a penalty does not apply under such amendment but for which a penalty was previously collected.

(b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

(1) IN GENERAL.—In the case of any individual who, as of the date of the enactment of this Act, is 65 years of age or older, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act, and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the first day of the month following the month in which the individual enrolls.

SEC. 628. PART B DEDUCTIBLE.

Section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(1) by striking ''1991 and'' and inserting ''1991,''; and

(2) by striking ''and subsequent years'' and inserting ''and each subsequent year through 2003, and for a subsequent year after 2003 the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1)''.

SEC. 629. EXTENSION OF COVERAGE OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) FOR THE TREATMENT OF PRIMARY IMMUNE DEFICIENCY DISEASES IN THE HOME.

(a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as amended by sections 611(a) and 612(a) is amended—

(1) in subsection (s)(2)—

(A) by striking ''and'' at the end of subparagraph (W);

(B) by adding ''and'' at the end of subparagraph (X); and

(C) by adding at the end the following new subparagraph:

''(Y) intravenous immune globulin for the treatment of primary immune deficiency dis-

eases in the home (as defined in subsection (yy));''; and

(2) by adding at the end the following new subsection:

''Intravenous Immune Globulin

''(yy) The term 'intravenous immune globulin' means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.''.

(b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting ''(including intravenous immune globulin (as defined in section 1861(yy)))'' after ''with respect to drugs and biologicals''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished administered on or after January 1, 2004.

SEC. 630. MEDICARE COVERAGE OF DIABETES LABORATORY DIAGNOSTIC TESTS.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by sections 611 and 612, is amended—

(1) in subparagraph (W), by striking ''and'' at the end;

(2) in subparagraph (X), by adding ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(Y) diabetes screening tests and services (as defined in subsection (yy));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by sections 611 and 612, is further amended by adding at the end the following new subsection:

''Diabetes Screening Tests and Services

''(yy)(1) The term 'diabetes screening tests' means diagnostic testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including—

''(A) a fasting plasma glucose test; and

''(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

''(2) For purposes of paragraph (1), the term 'individual at risk for diabetes' means an individual who has any, a combination of, or all of the following risk factors for diabetes:

''(A) A family history of diabetes.

''(B) Overweight defined as a body mass index greater than or equal to 25 kg/m2.

''(C) Habitual physical inactivity.

''(D) Belonging to a high-risk ethnic or racial group.

''(E) Previous identification of an elevated impaired fasting glucose.

''(F) Identification of impaired glucose tolerance.

''(G) Hypertension.

''(H) Dyslipidemia.

''(I) History of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

''(J) Polycystic ovary syndrome.

''(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.''.

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by sections 611 and 612, is amended—

(1) by striking ''and'' at the end of subparagraph (J);

(2) by striking the semicolon at the end of subparagraph (K) and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(L) in the case of a diabetes screening tests or service (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after the date that is 90 days after the date of enactment of this Act.

SEC. 631. DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN PRESCRIPTION DRUGS AND BIOLOGICS.

(a) DEMONSTRATION PROJECT.—The Secretary shall conduct a demonstration project under part B of title XVIII of the Social Security Act under which payment is made for drugs or biologics that are prescribed as replacements for drugs and biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q) of such Act (42 U.S.C. 1395x(s)(2)(A), 1395x(s)(2)(Q))), or both, for which payment is made under such part.

(b) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in 3 States selected by the Secretary.

(c) DURATION.—The Secretary shall conduct the demonstration project for the 2-year period beginning on the date that is 90 days after the date of the enactment of this Act, but in no case may the project extend beyond December 31, 2005.

(d) LIMITATION.—Under the demonstration project over the duration of the project, the Secretary may not provide—

(1) coverage for more than 10,000 patients; and

(2) more than $100,000,000 in funding.

(e) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient access to care and patient outcomes under the project, as well as an analysis of the cost effectiveness of the project, including an evaluation of the costs savings (if any) to the medicare program attributable to reduced physicians' services and hospital outpatient departments services for administration of the biological.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 701. UPDATE IN HOME HEALTH SERVICES.

(a) CHANGE TO CALENDER YEAR UPDATE.—

(1) IN GENERAL.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

(A) in paragraph (3)(B)(i)—

(i) by striking ''each fiscal year (beginning with fiscal year 2002)'' and inserting ''fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004)''; and

(ii) by inserting ''or year'' after ''the fiscal year'';

(B) in paragraph (3)(B)(ii)(II), by striking ''any subsequent fiscal year'' and inserting ''2004 and any subsequent year'';

(C) in paragraph (3)(B)(iii), by inserting ''or year'' after ''fiscal year'' each place it appears;

(D) in paragraph (3)(B)(iv)—

(i) by inserting ''or year'' after ''fiscal year'' each place it appears; and

(ii) by inserting ''or years'' after ''fiscal years''; and

(E) in paragraph (5), by inserting ''or year'' after ''fiscal year''.

(2) TRANSITION RULE.—The standard prospective payment amount (or amounts) under section 1895(b)(3) of the Social Security Act for the calendar quarter beginning on October 1, 2003, shall be such amount (or amounts) for the previous calendar quarter.

(b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B), is amended—

(1) by striking ''or'' at the end of subclause (I);

(2) by redesignating subclause (II) as subclause (III);

(3) in subclause (III), as so redesignated, by striking ''2004'' and inserting ''2007''; and

(4) by inserting after subclause (I) the following new subclause:

''(II) each of 2004, 2005, and 2006 the home health market basket percentage increase minus 0.4 percentage points; or''.

SEC. 702. ESTABLISHMENT OF REDUCED COPAYMENT FOR A HOME HEALTH SERVICE EPISODE OF CARE FOR CERTAIN BENEFICIARIES.

(a) PART A.—

(1) IN GENERAL.—Section 1813(a) (42 U.S.C. 1395e(a)) is amended by adding at the end the following new paragraph:

''(5)(A)(i) Subject to clause (ii), the amount payable for home health services furnished to the individual under this title for each episode of care beginning in a year (beginning with 2004) shall be reduced by a copayment equal to the copayment amount specified in subparagraph (B)(ii) for such year.

''(ii) The copayment under clause (i) shall not apply—

''(I) in the case of an individual who has been determined to be entitled to medical assistance under section 1902(a)(10)(A) or 1902(a)(10)(C) or to be a qualified medicare beneficiary (as defined in section 1905(p)(1)), a specified low-income medicare beneficiary described in section 1902(a)(10)(E)(iii), or a qualifying individual described in section 1902(a)(10)(E)(iv)(I); and

''(II) in the case of an episode of care which consists of 4 or fewer visits.

''(B)(i) The Secretary shall estimate, before the beginning of each year (beginning with 2004), the national average payment under this title per episode for home health services projected for the year involved.

''(ii) For each year the copayment amount under this clause is equal to 1.5 percent of the national average payment estimated for the year involved under clause (i). Any amount determined under the preceding sentence which is not a multiple of $5 shall be rounded to the nearest multiple of $5.

''(iii) There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the estimation of average payment under clause (i).''.

(2) TIMELY IMPLEMENTATION.—Unless the Secretary of Health and Human Services otherwise provides on a timely basis, the copayment amount specified under section 1813(a)(5)(B)(ii) of the Social Security Act (as added by paragraph (1)) for 2004 shall be deemed to be $40.

(b) CONFORMING PROVISIONS.—

(1) Section 1833(a)(2)(A) (42 U.S.C. 1395l(a)(2)(A)) is amended by inserting ''less the copayment amount applicable under section 1813(a)(5)'' after ''1895''.

(2) Section 1866(a)(2)(A)(i) (42 U.S.C. 1395cc(a)(2)(A)(i)) is amended—

(A) by striking ''or coinsurance'' and inserting '', coinsurance, or copayment''; and

(B) by striking ''or (a)(4)'' and inserting ''(a)(4), or (a)(5)''.

SEC. 703. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

SEC. 704. DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND.

(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of the enactment of this Act, the Sec-

retary shall conduct a two-year demonstration project under part B of title XVIII of the Social Security Act under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be homebound for purposes of receiving home health services under the medicare program.

(b) MEDICARE BENEFICIARY DESCRIBED.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if—

(1) the beneficiary has been certified by one physician as an individual who has a permanent and severe condition that will not improve;

(2) the beneficiary requires the individual to receive assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the individual's life;

(3) the beneficiary requires skilled nursing services on a permanent basis and the skilled nursing is more than medication management;

(4) either (A) an attendant is needed during the day to monitor and treat the beneficiary's medical condition, or (B) the beneficiary needs daily

skilled nursing on a permanent basis and the skilled nursing is more than medication management; and

(5) the beneficiary requires technological assistance or the assistance of another person to leave the home.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

(d) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000.

(e) DATA.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program.

(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e) and shall include—

(1) an examination of whether the provision of home health services to medicare beneficiaries under the project—

(A) adversely effects the provision of home health services under the medicare program; or

(B) directly causes an unreasonable increase of expenditures under the medicare program for the provision of such services that is directly attributable to such clarification;

(2) the specific data evidencing the amount of any increase in expenditures that is a directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the medicare program; and

(3) specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to the medicare program.

(g) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent

and for such period as the Secretary determines is necessary to conduct demonstration projects.

(h) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the medicare program.

(i) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

(j) DEFINITIONS.—In this section:

(1) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual who is enrolled under part B of title XVIII of the Social Security Act.

(2) HOME HEALTH SERVICES.—The term ''home health services'' has the meaning given such term in section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ''activities of daily living'' means eating, toileting, transferring, bathing, and dressing.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

Subtitle B—Direct Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)—

(A) by inserting ''AND 2004 THROUGH 2013'' after ''AND 2002''; and

(B) by inserting ''or during the period beginning with fiscal year 2004 and ending with fiscal year 2013'' after ''during fiscal year 2001 or fiscal year 2002''; and

(2) in subclause (II)—

(A) by striking ''fiscal year 2004, or fiscal year 2005,'' and

(B) by striking ''For a'' and inserting ''For the''.

Subtitle C—Chronic Care Improvement

SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT UNDER TRADITIONAL FEE-FOR-SERVICE.

Title XVIII, as amended by section 105(a), is amended by inserting after section 1807 the following new section:

''CHRONIC CARE IMPROVEMENT

''SEC. 1808. (a) IN GENERAL.—

''(1) IN GENERAL.—The Secretary shall establish a process for providing chronic care improvement programs in each CCIA region for medicare beneficiaries who are not enrolled under part C or E and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke, prostate and colon cancer, hypertension, or other disease as identified by the Secretary as appropriate for chronic care improvement. Such a process shall begin to be implemented no later than 1 year after the date of the enactment of this section.

''(2) TERMINOLOGY.—For purposes of this section:

''(A) CCIA REGION.—The term 'CCIA region' means a chronic care improvement admin-

istrative region delineated under subsection (b)(2).

"(B) CHRONIC CARE IMPROVEMENT PROGRAM.—The terms 'chronic care improvement program' and 'program' means such a program provided by a contractor under this section.

"(C) CONTRACTOR.—The term 'contractor' means an entity with a contract to provide a chronic care improvement program in a CCIA region under this section.

"(D) INDIVIDUAL PLAN.—The term 'individual plan' means a chronic care improvement plan established under subsection (c)(5) for an individual.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as expanding the amount, duration, or scope of benefits under this title.

"(b) COMPETITIVE BIDDING PROCESS.—

"(1) IN GENERAL.—Under this section the Secretary shall award contracts to qualified entities for chronic care improvement programs for each CCIA region under this section through a competitive bidding process.

"(2) PROCESS.—Under such process—

''(A) the Secretary shall delineate the United States into multiple chronic care improvement administrative regions; and

''(B) the Secretary shall select at least 2 winning bidders in each CCIA region on the basis of the ability of each bidder to carry out a chronic care improvement program in accordance with this section, in order to achieve improved health and financial outcomes.

''(3) ELIGIBLE CONTRACTOR.—A contractor may be a disease improvement organization, health insurer, provider organization, a group of physicians, or any other legal entity that the Secretary determines appropriate.

''(c) CHRONIC CARE IMPROVEMENT PROGRAMS.—

''(1) IN GENERAL.—Each contract under this section shall provide for the operation of a chronic care improvement program by a contractor in a CCIA region consistent with this subsection.

''(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PARTICIPANTS.—Each contractor shall have a method for identifying medicare beneficiaries in the region to whom it will offer services under its program. The contractor shall identify such beneficiaries through claims or other data and other

means permitted consistent with applicable disclosure provisions.

''(3) INITIAL CONTACT BY SECRETARY.—The Secretary shall communicate with each beneficiary identified under paragraph (2) as a prospective participant in one or more programs concerning participation in a program. Such communication may be made by the Secretary (or on behalf of the Secretary) and shall include information on the following:

''(A) A description of the advantages to the beneficiary in participating in a program.

''(B) Notification that the contractor offering a program may contact the beneficiary directly concerning such participation.

''(C) Notification that participation in a program is voluntary.

''(D) A description of the method for the beneficiary to select the single program in which the beneficiary wishes to participate and for declining to participate and a method for obtaining additional information concerning such participation.

''(4) PARTICIPATION.—A medicare beneficiary may participate in only one program under this sec-

tion and may terminate participation at any time in a manner specified by the Secretary.

''(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT PLANS.—

''(A) IN GENERAL.—For each beneficiary participating in a program of a contractor under this section, the contractor shall develop with the beneficiary an individualized, goal-oriented chronic care improvement plan.

''(B) ELEMENTS OF INDIVIDUAL PLAN.—Each individual plan developed under subparagraph (A) shall include a single point of contact to coordinate care and the following, as appropriate:

''(i) Self-improvement education for the beneficiary (such as education for disease management through medical nutrition therapy) and support education for health care providers, primary caregivers, and family members.

''(ii) Coordination of health care services, such as application of a prescription drug regimen and home health services.

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

"(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

"(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

"(C) CONTRACTOR RESPONSIBILITIES.—In establishing and carrying out individual plans under a program, a contractor shall, directly or through subcontractors—

"(i) guide participants in managing their health, including all their comorbidities, and in performing activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

''(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

''(6) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for programs and contractors under this section.

''(7) ACCREDITATION.—The Secretary may provide that programs that are accredited by qualified organizations may be deemed to meet such requirements under this section as the Secretary may specify.

''(c) CONTRACT TERMS.—

''(1) IN GENERAL.—A contract under this section shall contain such terms and conditions as the Secretary may specify consistent with this section. The Secretary may not enter into a contract with an entity under this section unless the entity meets such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the population to be served.

''(2) USE OF SUBCONTRACTORS PERMITTED.—A contractor may carry out a program directly or through contracts with subcontractors.

''(3) BUDGET NEUTRAL PAYMENT CONDITION.—In entering into a contract with an entity under this subsection, the Secretary shall establish payment rates that assure that there will be no net aggregate increase in payments under this title over any period of 3 years or longer, as agreed to by the Secretary. Under this section, the Secretary shall assure that medicare program outlays plus administrative expenses (that would not have been paid under this title without implementation of this section), including contractor fees, shall not exceed the expenditures that would have been incurred under this title for a comparable population in the absence of the program under this section for the 3-year contract period.

''(4) AT RISK RELATIONSHIP.—For purposes of section 1128B(b)(3)(F), a contract under this section shall be treated as a risk-sharing arrangement referred to in such section.

''(5) PERFORMANCE STANDARDS.—Payment to contractors under this section shall be subject to the contractor's meeting of clinical and financial performance standards set by the Secretary.

''(6) CONTRACTOR OUTCOMES REPORT.—Each contractor offering a program shall monitor and re-

port to the Secretary, in a manner specified by the Secretary, the quality of care and efficacy of such program in terms of—

"(A) process measures, such as reductions in errors of treatment and rehospitalization rates;

"(B) beneficiary and provider satisfaction;

"(C) health outcomes; and

"(D) financial outcomes.

"(7) PHASED IN IMPLEMENTATION.—Nothing in this section shall be construed as preventing the Secretary from phasing in the implementation of programs.

"(d) BIANNUAL OUTCOMES REPORTS.—The Secretary shall submit to the Congress biannual reports on the implementation of this section. Each such report shall include information on—

"(1) the scope of implementation (in terms of both regions and chronic conditions);

"(2) program design; and

"(3) improvements in health outcomes and financial efficiencies that result from such implementation.

"(e) CLINICAL TRIALS.—The Secretary shall conduct randomized clinical trials, that compare program partici-

pants with medicare beneficiaries who are offered, but decline, to participate, in order to assess the potential of programs to—

''(1) reduce costs under this title; and

''(2) improve health outcomes under this title.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary, in appropriate part from the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for contracts with chronic care improvement programs under this section.

''(g) LIMITATION ON FUNDING.—In no case shall the funding under this section exceed $100,000,000 over a period of 3 years.''.

SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE PROGRAMS.

(a) UNDER MEDICARE ADVANTAGE PROGRAM.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(1) by amending subsection (e) to read as follows:

''(e) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS FOR BENEFICIARIES WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—

''(1) IN GENERAL.—Each Medicare Advantage organization with respect to each Medicare Advantage plan it offers shall have in effect, for enrollees with multiple or sufficiently severe chronic conditions, a chronic care improvement program that is designed to manage the needs of such enrollees and that meets the requirements of this subsection.

''(2) ENROLLEE WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—For purposes of this subsection, the term 'enrollee with multiple or sufficiently severe chronic conditions' means, with respect to an enrollee in a Medicare Advantage plan of a Medicare Advantage organization, an enrollee in the plan who has one or more chronic conditions, such as congestive heart failure, diabetes, COPD, stroke, prostate and colon cancer, hypertension, or other disease as identified by the organization as appropriate for chronic care improvement.

''(3) GENERAL REQUIREMENTS.—

''(A) IN GENERAL.—Each chronic care improvement program under this subsection shall be conducted consistent with this subsection.

''(B) IDENTIFICATION OF ENROLLEES.—Each such program shall have a method for monitoring and identifying enrollees with mul-

tiple or sufficiently severe chronic conditions that meet the organization's criteria for participation under the program.

"(C) DEVELOPMENT OF PLANS.—For an enrollee identified under subparagraph (B) for participation in a program, the program shall develop, with the enrollee's consent, an individualized, goal-oriented chronic care improvement plan for chronic care improvement.

"(D) ELEMENTS OF PLANS.—Each chronic care improvement plan developed under subparagraph (C) shall include a single point of contact to coordinate care and the following, as appropriate:

"(i) Self-improvement education for the enrollee (such as education for disease management through medical nutrition therapy) and support education for health care providers, primary caregivers, and family members.

"(ii) Coordination of health care services, such as application of a prescription drug regimen and home health services.

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

"(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

"(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

"(E) ORGANIZATION RESPONSIBILITIES.—In establishing and carrying out chronic care improvement plans for participants under this paragraph, a Medicare Advantage organization shall, directly or through subcontractors—

"(i) guide participants in managing their health, including all their comorbidities, and in performing the activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guidelines or

other criteria as determined by the Secretary; and

''(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

''(3) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for chronic care improvement programs under this section.

''(4) ACCREDITATION.—The Secretary may provide that chronic care improvement programs that are accredited by qualified organizations may be deemed to meet such requirements under this subsection as the Secretary may specify.

''(5) OUTCOMES REPORT.—Each Medicare Advantage organization with respect to its chronic care improvement program under this subsection shall monitor and report to the Secretary information on the quality of care and efficacy of such program as the Secretary may require.''; and

(2) by amending subparagraph (I) of subsection (c)(1) to read as follows:

''(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A description of the organization's

chronic care improvement program under subsection (e).''.

(b) APPLICATION UNDER ENHANCED FEE-FOR-SERVICE PROGRAM.—Section 1860E–2(c)(3), as inserted by section 201(a), is amended by inserting '', including subsection (e) (relating to implementation of chronic care improvement programs)'' after ''The provisions of section 1852''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply for contract years beginning on or after 1 year after the date of the enactment of this Act.

SEC. 723. INSTITUTE OF MEDICINE REPORT.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall contract with the Institute of Medicine of the National Academy of Sciences to conduct a study of the barriers to effective integrated care improvement for medicare beneficiaries with multiple or severe chronic conditions across settings and over time and to submit a report under subsection (b).

(2) SPECIFIC ITEMS.—The study shall examine the statutory and regulatory barriers to coordinating care across settings for medicare beneficiaries in

transition from one setting to another (such as between hospital, nursing facility, home health, hospice, and home). The study shall specifically identify the following:

(A) Clinical, financial, or administrative requirements in the medicare program that present barriers to effective, seamless transitions across care settings.

(B) Policies that impede the establishment of administrative and clinical information systems to track health status, utilization, cost, and quality data across settings.

(C) State-level requirements that may present barriers to better care for medicare beneficiaries.

(3) CONSULTATION.—The study under this subsection shall be conducted in consultation with experts in the field of chronic care, consumers, and family caregivers, working to integrate care delivery and create more seamless transitions across settings and over time.

(b) REPORT.—The report under this subsection shall be submitted to the Secretary and Congress not later than 18 months after the date of the enactment of this Act.

SEC. 724. MEDPAC REPORT.

(a) EVALUATION.—shall conduct an evaluation that includes a description of the status of the implementation of chronic care improvement programs under section 1808 of the Social Security Act, the quality of health care services provided to individuals in such program, the health status of the participants of such program, and the cost savings attributed to implementation of such program.

(b) REPORT.—Not later than 2 years after the date of implementation of such chronic care improvement programs, the Commission shall submit a report on such evaluation.

Subtitle D—Other Provisions

SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

''(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.''.

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–

6(b)(2)(B)(i)) is amended by inserting ''the efficient provision of'' after ''expenditures for''.

(c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at the end the following: ''Members of the Commission shall be treated as employees of the Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95-521).''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on January 1, 2004.

(d) ADDITIONAL REPORTS.—

(1) DATA NEEDS AND SOURCES.—The Medicare Payment Advisory Commission shall conduct a study, and submit a report to Congress by not later than June 1, 2004, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services. The Commission shall examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Congress, by not later than June 1, 2004, a report on the following:

(A) Investments, endowments, and fundraising of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project (in this section referred to as the ''demonstration project'') under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment for an episode of care for home health services, a portion of which consists of substitute medical adult day care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 u.s.c. 1395fff). In no case may a home health agency, or a medical adult day care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day care services furnished under the plan of care.

(2) BUDGET NEUTRALITY FOR DEMONSTRATION PROJECT.—Notwithstanding any other provision of law, the Secretary shall provide for an appropriate reduction in the aggregate amount of additional payments made under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to reflect any increase in amounts expended from the Trust Funds as a result of the demonstration project conducted under this section.

(c) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in not more than 5 States selected by the Secretary that license

or certify providers of services that furnish medical adult day care services.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

(e) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the demonstration project shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 15,000.

(f) PREFERENCE IN SELECTING AGENCIES.—In selecting home health agencies to participate under the demonstration project, the Secretary shall give preference to those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day care services.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary for the purposes of carrying out the demonstration project, other than waiving the requirement that an individual be homebound in order to be eligible for benefits for home health services.

(h) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration project. Not later 30 months after the commencement of the project, the Secretary shall sub-

mit to Congress a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the project as compared to such outcomes and costs to beneficiaries receiving only home health services for the same health conditions.

(2) Such recommendations regarding the extension, expansion, or termination of the project as the Secretary determines appropriate.

(i) DEFINITIONS.—In this section:

(1) HOME HEALTH AGENCY.—The term ''home health agency'' has the meaning given such term in section 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

(2) MEDICAL ADULT DAY CARE FACILITY.—The term ''medical adult day care facility'' means a facility that—

(A) has been licensed or certified by a State to furnish medical adult day care services in the State for a continuous 2-year period;

(B) is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;

(C) meets such standards established by the Secretary to assure quality of care and such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day care services.

(3) MEDICAL ADULT DAY CARE SERVICES.—The term ''medical adult day care services'' means—

(A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day care facility;

(B) a program of supervised activities furnished in a group setting in the facility that—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) is designed to promote physical and mental health of the individuals; and

(C) such other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual entitled

to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.

(a) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the third sentence of subsection (a) by inserting ''consistent with subsection (k)'' after ''the Secretary shall ensure''; and

(B) by adding at the end the following new subsection:

''(k) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

''(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents

under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

''(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

''(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

''(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

''(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—At the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall—

''(A) make a draft of proposed decision on the request available to the public through the

Medicare Internet site of the Department of Health and Human Services or other appropriate means;

"(B) provide a 30-day period for public comment on such draft;

"(C) make a final decision on the request within 60 days of the conclusion of the 30-day period referred to under subparagraph (B);

"(D) include in such final decision summaries of the public comments received and responses thereto;

"(E) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

"(F) in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coding change.

"(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee,

the Secretary shall consult with appropriate outside clinical experts.

''(5) LOCAL COVERAGE DETERMINATION PROCESS.—With respect to local coverage determinations made on or after January 1, 2004—

''(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

''(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

''(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

''(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection, the terms 'national coverage determination'

and 'local coverage determination' have the meaning given such terms in paragraphs (1)(B) and (2)(B), respectively, of section 1869(f).''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to national and local coverage determinations as of January 1, 2004.

(b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS.—

(1) IN GENERAL.—With respect to the coverage of routine costs of care for beneficiaries participating in a qualifying clinical trial, as set forth on the date of the enactment of this Act in National Coverage Determination 30-1 of the Medicare Coverage Issues Manual, the Secretary shall deem clinical trials conducted in accordance with an investigational device exemption approved under section 520(g) of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j(g)) to be automatically qualified for such coverage.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing or requiring the Secretary to modify the regulations set forth on the date of the enactment of this Act at subpart B of part 405 of title 42, Code of Federal Regulations, or subpart A of part 411 of such title,

relating to coverage of, and payment for, a medical device that is the subject of an investigational device exemption by the Food and Drug Administration (except as may be necessary to implement paragraph (1)).

(3) EFFECTIVE DATE.—This subsection shall apply to clinical trials begun before, on, or after the date of the enactment of this Act and to items and services furnished on or after such date.

(c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not later than January 1, 2004, the Secretary shall implement revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act.

SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES.

(a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w–4(i)) is amended by adding at the end the following new paragraph:

''(4) TREATMENT OF CERTAIN INPATIENT PHYSICIAN PATHOLOGY SERVICES.—

''(A) IN GENERAL.—With respect to services furnished on or after January 1, 2004, and before January 1, 2009, if an independent laboratory furnishes the technical component of a

physician pathology service to a fee-for-service medicare beneficiary who is an inpatient or outpatient of a covered hospital, the Secretary shall treat such component as a service for which payment shall be made to the laboratory under this section and not as an inpatient hospital service for which payment is made to the hospital under section 1886(d) or as a hospital outpatient service for which payment is made to the hospital under section 1833(t).

''(B) DEFINITIONS.—In this paragraph:

''(i) COVERED HOSPITAL.—

''(I) IN GENERAL.—The term 'covered hospital' means, with respect to an inpatient or outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service medicare beneficiaries who were hospital inpatients or outpatients, respectively, and submitted claims for payment for such component to a carrier with a

contract under section 1842 and not to the hospital.

''(II) CHANGE IN OWNERSHIP DOES NOT AFFECT DETERMINATION.—A change in ownership with respect to a hospital on or after the date referred to in subclause (I) shall not affect the determination of whether such hospital is a covered hospital for purposes of such subclause.

''(ii) FEE-FOR-SERVICE MEDICARE BENEFICIARY.—The term 'fee-for-service medicare beneficiary' means an individual who is entitled to benefits under part A, or enrolled under this part, or both, but is not enrolled in any of the following:

''(I) A Medicare+Choice plan under part C.

''(II) A plan offered by an eligible organization under section 1876.

''(III) A program of all-inclusive care for the elderly (PACE) under section 1894.

''(IV) A social health maintenance organization (SHMO) dem-

onstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203).''.

(b) CONFORMING AMENDMENT.—Section 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–550), as enacted into law by section 1(a)(6) of Public Law 106–554, is repealed.

(c) EFFECTIVE DATES.—The amendments made by this section shall take effect as if included in the enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463), as enacted into law by section 1(a)(6) of Public Law 106–554.

SEC. 735. CLINICAL INVESTIGATION OF MEDICARE PANCREATIC ISLET CELL TRANSPLANTS.

The Secretary shall authorize payment under title XVIII of the Social Security Act for the routine costs for items and services for medicare beneficiaries received as part of a clinical investigation of pancreatic islet cell transplants conducted by the National Institutes of Health.

SEC. 736. DEMONSTRATION PROJECT FOR CONSUMER-DIRECTED CHRONIC OUTPATIENT SERVICES.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Subject to the succeeding provisions of this section, the Secretary shall establish demonstration projects (in this section referred to as ''demonstration projects'') under which the Secretary shall evaluate methods that improve the quality of care provided to medicare beneficiaries with chronic conditions and that reduce expenditures that would otherwise be made under the medicare program on behalf of such individuals for such chronic conditions, such methods to include permitting those beneficiaries to direct their own health care needs and services.

(2) MEDICARE BENEFICIARIES WITH CHRONIC CONDITIONS DEFINED.—In this section, the term ''medicare beneficiaries with chronic conditions'' means an individual entitled to benefits under part A of title XVIII of the Social Security Act, and enrolled under part B of such title, but who is not enrolled under part C of such title who is diagnosed as having one or more chronic conditions (as defined by the Secretary), such as diabetes.

(b) DESIGN OF PROJECTS.—

(1) IN GENERAL.—In establishing the demonstration projects under this section, the Secretary shall evaluate practices employed by group health

plans and practices under State plans for medical assistance under the medicaid program under title XIX of the Social Security Act that permit patients to self-direct the provision of personal care services.

(2) SCOPE OF SERVICES.—The Secretary shall determine the appropriate scope of personal care services that would apply under the demonstration projects.

(c) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the demonstration projects shall be voluntary.

(d) DEMONSTRATION PROJECTS SITES.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall conduct no fewer than 3 demonstration projects established under this section. Of those demonstration projects, the Secretary shall conduct at least one in each of the following areas:

(1) An urban area.

(2) A rural area.

(3) An area that the Secretary determines has a medicare population with rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

(e) EVALUATION AND REPORT.—

(1) EVALUATIONS.—The Secretary shall conduct evaluations of the clinical and cost effectiveness of the demonstration projects.

(2) REPORTS.—Not later than 2 years after the commencement of the demonstration projects, and biannually thereafter, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(A) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the projects as compared to such outcomes and costs to other beneficiaries for the same health conditions.

(B) Evaluation of patient satisfaction under the demonstration projects.

(C) Such recommendations regarding the extension, expansion, or termination of the projects as the Secretary determines appropriate.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS ADMINISTRATION.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by sections 105 and 721, is amended by inserting after 1808 the following new section:

''MEDICARE BENEFITS ADMINISTRATION

''SEC. 1809. (a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

''(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF ACTUARY.—

''(1) ADMINISTRATOR.—

''(A) IN GENERAL.—The Medicare Benefits Administration shall be headed by an administrator to be known as the 'Medicare Benefits Administrator' (in this section referred to as the 'Administrator') who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

''(B) COMPENSATION.—The Administrator shall be paid at the rate of basic pay payable

for level III of the Executive Schedule under section 5314 of title 5, United States Code.

''(C) TERM OF OFFICE.—The Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of an Administrator's term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

''(D) GENERAL AUTHORITY.—The Administrator shall be responsible for the exercise of all powers and the discharge of all duties of the Administration, and shall have authority and control over all personnel and activities thereof.

''(E) RULEMAKING AUTHORITY.—The Administrator may prescribe such rules and regulations as the Administrator determines necessary or appropriate to carry out the functions of the Administration. The regulations prescribed by the Administrator shall be subject to the rulemaking procedures established under section 553 of title 5, United States Code. The

Administrator shall provide for the issuance of new regulations to carry out parts C, D, and E.

''(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL UNITS.—The Administrator may establish, alter, consolidate, or discontinue such organizational units or components within the Administration as the Administrator considers necessary or appropriate, except as specified in this section.

''(G) AUTHORITY TO DELEGATE.—The Administrator may assign duties, and delegate, or authorize successive redelegations of, authority to act and to render decisions, to such officers and employees of the Administration as the Administrator may find necessary. Within the limitations of such delegations, redelegations, or assignments, all official acts and decisions of such officers and employees shall have the same force and effect as though performed or rendered by the Administrator.

''(2) DEPUTY ADMINISTRATOR.—

''(A) IN GENERAL.—There shall be a Deputy Administrator of the Medicare Benefits Administration who shall be appointed by the

President, by and with the advice and consent of the Senate.

''(B) COMPENSATION.—The Deputy Administrator shall be paid at the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

''(C) TERM OF OFFICE.—The Deputy Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of a Deputy Administrator's term of office, such Deputy Administrator may continue in office until the entry upon office of such a successor. A Deputy Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

''(D) DUTIES.—The Deputy Administrator shall perform such duties and exercise such powers as the Administrator shall from time to time assign or delegate. The Deputy Administrator shall be Acting Administrator of the Administration during the absence or disability of the Administrator and, unless the President

designates another officer of the Government as Acting Administrator, in the event of a vacancy in the office of the Administrator.

''(3) CHIEF ACTUARY.—

''(A) IN GENERAL.—There is established in the Administration the position of Chief Actuary. The Chief Actuary shall be appointed by, and in direct line of authority to, the Administrator of such Administration. The Chief Actuary shall be appointed from among individuals who have demonstrated, by their education and experience, superior expertise in the actuarial sciences. The Chief Actuary may be removed only for cause.

''(B) COMPENSATION.—The Chief Actuary shall be compensated at the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

''(C) DUTIES.—The Chief Actuary shall exercise such duties as are appropriate for the office of the Chief Actuary and in accordance with professional standards of actuarial independence.

''(4) SECRETARIAL COORDINATION OF PROGRAM ADMINISTRATION.—The Secretary shall ensure appropriate coordination between the Administrator and the Administrator of the Centers for Medicare & Medicaid Services in carrying out the programs under this title.

''(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

''(1) DUTIES.—

''(A) GENERAL DUTIES.—The Administrator shall carry out parts C, D, and E, including—

''(i) negotiating, entering into, and enforcing, contracts with plans for the offering of Medicare Advantage plans under part C and EFFS plans under part E, including the offering of qualified prescription drug coverage under such plans; and

''(ii) negotiating, entering into, and enforcing, contracts with PDP sponsors for the offering of prescription drug plans under part D.

''(B) OTHER DUTIES.—The Administrator shall carry out any duty provided for under part C, part D, or part E, including demonstration projects carried out in part or in whole

under such parts, the programs of all-inclusive care for the elderly (PACE program) under section 1894, the social health maintenance organization (SHMO) demonstration projects (referred to in section 4104(c) of the Balanced Budget Act of 1997), medicare cost contractors under section 1876(h), and through a Medicare Advantage project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of a interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved).

''(C) PRESCRIPTION DRUG CARD.—The Administrator shall carry out section 1807 (relating to the medicare prescription drug discount card endorsement program).

''(D) NONINTERFERENCE.—In carrying out its duties with respect to the provision of qualified prescription drug coverage to beneficiaries under this title, the Administrator may not—

''(i) require a particular formulary or institute a price structure for the reimbursement of covered outpatient drugs;

''(ii) interfere in any way with negotiations between PDP sponsors and Medicare Advantage organizations and EFFS organizations and drug manufacturers, wholesalers, or other suppliers of covered outpatient drugs; and

''(iii) otherwise interfere with the competitive nature of providing such coverage through such sponsors and organizations.

''(E) ANNUAL REPORTS.—Not later March 31 of each year, the Administrator shall submit to Congress and the President a report on the administration of parts C, D, and E during the previous fiscal year.

''(2) STAFF.—

''(A) IN GENERAL.—The Administrator, with the approval of the Secretary, may employ, without regard to chapter 31 of title 5, United States Code, other than sections 3102 through 3108, 3110 through 3113, 3136m and 3151, such officers and employees as are necessary to

administer the activities to be carried out through the Medicare Benefits Administration. The Administrator shall employ staff with appropriate and necessary expertise in negotiating contracts in the private sector.

''(B) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

''(i) IN GENERAL.—The staff of the Medicare Benefits Administration shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 (other than section 5101) and chapter 53 (other than section 5301) of such title (relating to classification and schedule pay rates).

''(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

''(C) LIMITATION ON FULL-TIME EQUIVALENT STAFFING FOR CURRENT CMS FUNCTIONS BEING TRANSFERRED.—The Administrator may not employ under this paragraph a number of full-time equivalent employees, to carry out

functions that were previously conducted by the Centers for Medicare & Medicaid Services and that are conducted by the Administrator by reason of this section, that exceeds the number of such full-time equivalent employees authorized to be employed by the Centers for Medicare & Medicaid Services to conduct such functions as of the date of the enactment of this Act.

''(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

''(A) IN GENERAL.—The Secretary, the Administrator, and the Administrator of the Centers for Medicare & Medicaid Services shall establish an appropriate transition of responsibility in order to redelegate the administration of part C from the Secretary and the Administrator of the Centers for Medicare & Medicaid Services to the Administrator as is appropriate to carry out the purposes of this section.

''(B) TRANSFER OF DATA AND INFORMATION.—The Secretary shall ensure that the Administrator of the Centers for Medicare & Medicaid Services transfers to the Administrator of the Medicare Benefits Administration such in-

formation and data in the possession of the Administrator of the Centers for Medicare & Medicaid Services as the Administrator of the Medicare Benefits Administration requires to carry out the duties described in paragraph (1).

''(C) CONSTRUCTION.—Insofar as a responsibility of the Secretary or the Administrator of the Centers for Medicare & Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare & Medicaid Services in this title or title XI with respect to such responsibility is deemed to be a reference to the Administrator.

''(d) OFFICE OF BENEFICIARY ASSISTANCE.—

''(1) ESTABLISHMENT.—The Secretary shall establish within the Medicare Benefits Administration an Office of Beneficiary Assistance to coordinate functions relating to outreach and education of medicare beneficiaries under this title, including the functions described in paragraph (2). The Office shall be separate operating division within the Administration.

''(2) DISSEMINATION OF INFORMATION ON BENEFITS AND APPEALS RIGHTS.—

''(A) DISSEMINATION OF BENEFITS INFORMATION.—The Office of Beneficiary Assistance shall disseminate, directly or through contract, to medicare beneficiaries, by mail, by posting on the Internet site of the Medicare Benefits Administration and through a toll-free telephone number, information with respect to the following:

''(i) Benefits, and limitations on payment (including cost-sharing, stop-loss provisions, and formulary restrictions) under parts C, D, and E.

''(ii) Benefits, and limitations on payment under parts A and B, including information on medicare supplemental policies under section 1882.

Such information shall be presented in a manner so that medicare beneficiaries may compare benefits under parts A, B, D, and medicare supplemental policies with benefits under Medicare Advantage plans under part C and EFFS plans under part E.

''(B) DISSEMINATION OF APPEALS RIGHTS INFORMATION.—The Office of Beneficiary Assistance shall disseminate to medicare bene-

ficiaries in the manner provided under subparagraph (A) a description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program under parts A and B, the Medicare Advantage program under part C, the Voluntary Prescription Drug Benefit Program under part D, and the Enhanced Fee-for-Service program under part E.

''(e) MEDICARE POLICY ADVISORY BOARD.—

''(1) ESTABLISHMENT.—There is established within the Medicare Benefits Administration the Medicare Policy Advisory Board (in this section referred to the 'Board'). The Board shall advise, consult with, and make recommendations to the Administrator of the Medicare Benefits Administration with respect to the administration of parts C, D, and E, including the review of payment policies under such parts.

''(2) REPORTS.—

''(A) IN GENERAL.—With respect to matters of the administration of parts C, D, and E the Board shall submit to Congress and to the Administrator of the Medicare Benefits Administration such reports as the Board determines

appropriate. Each such report may contain such recommendations as the Board determines appropriate for legislative or administrative changes to improve the administration of such parts, including the topics described in subparagraph (B). Each such report shall be published in the Federal Register.

''(B) TOPICS DESCRIBED.—Reports required under subparagraph (A) may include the following topics:

''(i) FOSTERING COMPETITION.—Recommendations or proposals to increase competition under parts C, D, and E for services furnished to medicare beneficiaries.

''(ii) EDUCATION AND ENROLLMENT.—Recommendations for the improvement to efforts to provide medicare beneficiaries information and education on the program under this title, and specifically parts C, D, and E, and the program for enrollment under the title.

''(iii) IMPLEMENTATION OF RISK-ADJUSTMENT.—Evaluation of the implementation under section 1853(a)(3)(C) of the

risk adjustment methodology to payment rates under that section to Medicare Advantage organizations offering Medicare Advantage plans (and the corresponding payment provisions under part E) that accounts for variations in per capita costs based on health status, geography, and other demographic factors.

''(iv) RURAL ACCESS.—Recommendations to improve competition and access to plans under parts C, D, and E in rural areas.

''(C) MAINTAINING INDEPENDENCE OF BOARD.—The Board shall directly submit to Congress reports required under subparagraph (A). No officer or agency of the United States may require the Board to submit to any officer or agency of the United States for approval, comments, or review, prior to the submission to Congress of such reports.

''(3) DUTY OF ADMINISTRATOR OF MEDICARE BENEFITS ADMINISTRATION.—With respect to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report is submitted, the Administrator of the Medicare Bene-

fits Administration shall submit to Congress and the President an analysis of recommendations made by the Board in such report. Each such analysis shall be published in the Federal Register.

''(4) MEMBERSHIP.—

''(A) APPOINTMENT.—Subject to the succeeding provisions of this paragraph, the Board shall consist of seven members to be appointed as follows:

''(i) Three members shall be appointed by the President.

''(ii) Two members shall be appointed by the Speaker of the House of Representatives, with the advice of the chairmen and the ranking minority members of the Committees on Ways and Means and on Energy and Commerce of the House of Representatives.

''(iii) Two members shall be appointed by the President pro tempore of the Senate with the advice of the chairman and the ranking minority member of the Senate Committee on Finance.

''(B) QUALIFICATIONS.—The members shall be chosen on the basis of their integrity,

impartiality, and good judgment, and shall be individuals who are, by reason of their education and experience in health care benefits management, exceptionally qualified to perform the duties of members of the Board.

''(C) PROHIBITION ON INCLUSION OF FEDERAL EMPLOYEES.—No officer or employee of the United States may serve as a member of the Board.

''(5) COMPENSATION.—Members of the Board shall receive, for each day (including travel time) they are engaged in the performance of the functions of the board, compensation at rates not to exceed the daily equivalent to the annual rate in effect for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

''(6) TERMS OF OFFICE.—

''(A) IN GENERAL.—The term of office of members of the Board shall be 3 years.

''(B) TERMS OF INITIAL APPOINTEES.—As designated by the President at the time of appointment, of the members first appointed—

''(i) one shall be appointed for a term of 1 year;

"(ii) three shall be appointed for terms of 2 years; and

"(iii) three shall be appointed for terms of 3 years.

"(C) REAPPOINTMENTS.—Any person appointed as a member of the Board may not serve for more than 8 years.

"(D) VACANCY.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Board shall be filled in the manner in which the original appointment was made.

"(7) CHAIR.—The Chair of the Board shall be elected by the members. The term of office of the Chair shall be 3 years.

"(8) MEETINGS.—The Board shall meet at the call of the Chair, but in no event less than three times during each fiscal year.

"(9) DIRECTOR AND STAFF.—

"(A) APPOINTMENT OF DIRECTOR.—The Board shall have a Director who shall be appointed by the Chair.

"(B) IN GENERAL.—With the approval of the Board, the Director may appoint, without regard to chapter 31 of title 5, United States Code, such additional personnel as the Director considers appropriate.

"(C) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

"(i) IN GENERAL.—The Director and staff of the Board shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 and chapter 53 of such title (relating to classification and schedule pay rates).

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(D) ASSISTANCE FROM THE ADMINISTRATOR OF THE MEDICARE BENEFITS ADMINISTRATION.—The Administrator of the Medicare

Benefits Administration shall make available to the Board such information and other assistance as it may require to carry out its functions.

''(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

''(f) FUNDING.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account), such sums as are necessary to carry out this section.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

(2) DUTIES WITH RESPECT TO ELIGIBILITY DETERMINATIONS AND ENROLLMENT.—The Administrator of the Medicare Benefits Administration shall carry out enrollment under title XVIII of the Social Security Act, make eligibility determinations under

such title, and carry out parts C and E of such title for years beginning or after January 1, 2006.

(3) TRANSITION.—Before the date the Administrator of the Medicare Benefits Administration is appointed and assumes responsibilities under this section and section 1807 of the Social Security Act, the Secretary of Health and Human Services shall provide for the conduct of any responsibilities of such Administrator that are otherwise provided under law.

(c) MISCELLANEOUS ADMINISTRATIVE PROVISIONS.—

(1) ADMINISTRATOR AS MEMBER OF THE BOARD OF TRUSTEES OF THE MEDICARE TRUST FUNDS.—Section 1817(b) and section 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each amended by striking ''and the Secretary of Health and Human Services, all ex officio,'' and inserting ''the Secretary of Health and Human Services, and the Administrator of the Medicare Benefits Administration, all ex officio,''.

(2) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES; LEVEL FOR MEDICARE BENEFITS ADMINISTRATOR.—

(A) IN GENERAL.—Section 5314 of title 5, United States Code, by adding at the end the following:

''Administrator of the Centers for Medicare & Medicaid Services.

''Administrator of the Medicare Benefits Administration.''.

(B) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking ''Administrator of the Health Care Financing Administration.''.

(C) EFFECTIVE DATE.—The amendments made by this paragraph take effect on January 1, 2004.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.

(a) CONSTRUCTION.—Nothing in this title shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729

through 3733 of title 31, United States Code (known as the False Claims Act); or

(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

''Supplier

''(d) The term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.''.

SEC. 902. ISSUANCE OF REGULATIONS.

(a) REGULAR TIMELINE FOR PUBLICATION OF FINAL RULES.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

''(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

''(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

''(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an expla-

nation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

''(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act. The Secretary shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.

(b) LIMITATIONS ON NEW MATTER IN FINAL REGULATIONS.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

''(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a

previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 903. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh), as amended by section 902(a), is amended by adding at the end the following new subsection:

''(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

''(i) such retroactive application is necessary to comply with statutory requirements; or

''(ii) failure to apply the change retroactively would be contrary to the public interest.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(e)(1), as added by subsection (a), is amended by adding at the end the following:

''(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

''(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding

described in the first sentence, and a brief statement of the reasons for such finding.

''(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

(c) RELIANCE ON GUIDANCE.—

(1) IN GENERAL.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

''(2)(A) If—

''(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

''(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

''(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

''(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act but shall not apply to any sanction for which notice was provided on or before the date of the enactment of this Act.

SEC. 904. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the

feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than one year after the date of the enactment of this Act.

(b) REPORT ON LEGAL AND REGULATORY INCONSISTENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by section 2(a), is amended by adding at the end the following new subsection:

''(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

''(2) In preparing a report under paragraph (1), the Secretary shall collect—

''(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

''(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

''(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.''.

Subtitle B—Contracting Reform

SEC. 911. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE ADMINISTRATION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

''CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

''SEC. 1874A. (a) AUTHORITY.—

''(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

''(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

''(A) the entity has demonstrated capability to carry out such function;

''(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

''(C) the entity has sufficient assets to financially support the performance of such function; and

''(D) the entity meets such other requirements as the Secretary may impose.

''(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

"(A) IN GENERAL.—The term 'medicare administrative contractor' means an agency, organization, or other person with a contract under this section.

"(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the 'appropriate' medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

"(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

"(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provi-

sions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

''(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

''(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

''(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.

''(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instruc-

tions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

''(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions relating to provider education, training, and technical assistance.

''(G) ADDITIONAL FUNCTIONS.—Performing such other functions as are necessary to carry out the purposes of this title.

''(5) RELATIONSHIP TO MIP CONTRACTS.—

''(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

''(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

''(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

''(b) CONTRACTING REQUIREMENTS.—

''(1) USE OF COMPETITIVE PROCEDURES.—

''(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

''(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other

provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

''(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

''(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

''(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

''(3) PERFORMANCE REQUIREMENTS.—

''(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection (a)(4).

''(B) CONSULTATION.— In developing such requirements, the Secretary may consult with providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, or both, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

''(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

''(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements;

''(ii) shall be used for evaluating contractor performance under the contract; and

''(iii) shall be consistent with the written statement of work provided under the contract.

''(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

''(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

''(B) to maintain such records and afford such access thereto as the Secretary finds nec-

essary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

''(5) SURETY BOND.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

''(c) TERMS AND CONDITIONS.—

''(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

''(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare adminis-

trative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

''(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

''(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

''(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

''(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—

''(A) IN GENERAL.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

''(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code (commonly known as the 'False Claims Act').

''(4) INDEMNIFICATION BY SECRETARY.—

''(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relat-

ing directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

''(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

''(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

''(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person de-

scribed in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

''(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

''(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

''(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.''.

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph

(1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows: ''PROVISIONS RELATING TO THE ADMINISTRATION OF PART A''.

(2) Subsection (a) is amended to read as follows:

''(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.''.

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking ''agreement under this section'' and inserting ''contract under section

1874A that provides for making payments under this part''.

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking ''An agreement with an agency or organization under this section'' and inserting ''A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part''; and

(B) by striking ''such agency or organization'' and inserting ''such medicare administrative contractor'' each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

''PROVISIONS RELATING TO THE ADMINISTRATION OF PART B''.

(2) Subsection (a) is amended to read as follows:

''(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.''.

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking ''carriers'' and inserting ''medicare administrative contractors''; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking ''Each such contract shall provide that the carrier'' and inserting ''The Secretary'';

(ii) by striking ''will'' the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting ''shall'';

(iii) in subparagraph (B), in the matter before clause (i), by striking ''to the policyholders and subscribers of the carrier'' and inserting ''to the policyholders and subscribers of the medicare administrative contractor'';

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking ''if it makes determinations or payments with respect to physicians' services,'' in the matter preceding clause (i); and

(II) by striking ''carrier'' and inserting ''medicare administrative contractor'' in clause (i);

(vi) by striking subparagraph (I);

(vii) in subparagraph (L), by striking the semicolon and inserting a period;

(viii) in the first sentence, after subparagraph (L), by striking ''and shall contain'' and all that follows through the period; and

(ix) in the seventh sentence, by inserting ''medicare administrative contractor,'' after ''carrier,''; and

(D) by striking paragraph (5);

(E) in paragraph (6)(D)(iv), by striking ''carrier'' and inserting ''medicare administrative contractor''; and

(F) in paragraph (7), by striking ''the carrier'' and inserting ''the Secretary'' each place it appears.

(4) Subsection (c) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking ''contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B),'' and inserting ''contract under section 1874A that provides for making payments under this part'';

(C) in paragraph (3)(A), by striking ''subsection (a)(1)(B)'' and inserting ''section 1874A(a)(3)(B)'';

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking ''carrier'' and inserting ''medicare administrative contractor''; and

(E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking ''carrier or carriers'' and inserting ''medicare administrative contractor or contractors''.

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking ''Each carrier having an agreement with the Secretary under

subsection (a)'' and inserting ''The Secretary''; and

(ii) by striking ''Each such carrier'' and inserting ''The Secretary'';

(B) in paragraph (3)(A)—

(i) by striking ''a carrier having an agreement with the Secretary under subsection (a)'' and inserting ''medicare administrative contractor having a contract under section 1874A that provides for making payments under this part''; and

(ii) by striking ''such carrier'' and inserting ''such contractor'';

(C) in paragraph (3)(B)—

(i) by striking ''a carrier'' and inserting ''a medicare administrative contractor'' each place it appears; and

(ii) by striking ''the carrier'' and inserting ''the contractor'' each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking ''carriers'' and inserting ''medicare administrative contractors'' each place it appears.

(8) Subsection (l) is amended—

(A) in paragraph (1)(A)(iii), by striking ''carrier'' and inserting ''medicare administrative contractor''; and

(B) in paragraph (2), by striking ''carrier'' and inserting ''medicare administrative contractor''.

(9) Subsection (p)(3)(A) is amended by striking ''carrier'' and inserting ''medicare administrative contractor''.

(10) Subsection (q)(1)(A) is amended by striking ''carrier''.

(d) EFFECTIVE DATE; TRANSITION RULE.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2005, and the Secretary is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date

(except as otherwise provided under this Act, other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2010.

(D) WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—During the period beginning on the date of the enactment of this Act and before the date specified under subparagraph (A), the Secretary may enter into new agreements under section 1816 of the Social Security Act (42 U.S.C. 1395h) without regard to any of the provider nomination provisions of such section.

(2) GENERAL TRANSITION RULES.—The Secretary shall take such steps, consistent with paragraph (1)(B) and (1)(C), as are necessary to provide for an appropriate transition from contracts under section 1816 and section 1842 of the Social Security

Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A, as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to a medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) REPORTS ON IMPLEMENTATION.—

(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2004, the Secretary shall submit a

report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY FOR MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1), is amended by adding at the end the following new subsection:

''(e) REQUIREMENTS FOR INFORMATION SECURITY.—

''(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b) of title 44, United States Code (other than the requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

''(2) INDEPENDENT AUDITS.—

"(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

"(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

"(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by

the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40, United States Code.

''(B) DEADLINE FOR INITIAL EVALUATION.—

''(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

''(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor

commences functions referred to in clause (i) under this section.

''(C) REPORTS ON EVALUATIONS.—

''(i) TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

''(ii) TO CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

''(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.''.

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than

subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

''PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

''SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a), is amended by adding at the end the following new subsection:

''(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error

rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.''.

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later

than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a) and subsection (b), is further amended by adding at the end the following new subsection:

''(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

''(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

''(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

''(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services and suppliers may obtain information re-

garding billing, coding, claims, coverage, and other appropriate information under this title.

''(4) MONITORING OF CONTRACTOR RESPONSES.—

''(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

''(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

''(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

''(B) DEVELOPMENT OF STANDARDS.—

''(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

''(ii) EVALUATION.—In conducting evaluations of individual medicare adminis-

trative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

''(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2004.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C.

1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

''(b) ENHANCED EDUCATION AND TRAINING.—

''(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) $25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

''(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

''(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

''(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

''(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term 'small provider of services or supplier' means—

''(A) a provider of services with fewer than 25 full-time-equivalent employees; or

''(B) a supplier with fewer than 10 full-time-equivalent employees.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (d), is further amended by adding at the end the following new subsection:

''(d) INTERNET SITES; FAQS.—The Secretary, and each medicare contractor insofar as it provides services

(including claims processing) for providers of services or suppliers, shall maintain an Internet site which—

''(1) provides answers in an easily accessible format to frequently asked questions, and

''(2) includes other published materials of the contractor,

that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsections (d) and (e), is further amended by adding at the end the following new subsections:

''(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track pro-

viders of services or suppliers for the purpose of conducting any type of audit or prepayment review.

''(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

''(g) DEFINITIONS.—For purposes of this section, the term 'medicare contractor' includes the following:

''(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

''(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the ''demonstration program'') under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding billing and related systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term ''small providers of services or suppliers'' means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 5(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

(d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS IDENTIFIED AS CORRECTED.—The Secretary shall

provide that, absent evidence of fraud and notwithstanding any other provision of law, any errors found in a compliance review for a small provider of services or supplier that participates in the demonstration program shall not be subject to recovery action if the technical assistance personnel under the program determine that—

(1) the problem that is the subject of the compliance review has been corrected to their satisfaction within 30 days of the date of the visit by such personnel to the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

The previous sentence applies only to claims filed as part of the demonstration program and lasts only for the duration of such program and only as long as the small provider of services or supplier is a participant in such program.

(e) GAO EVALUATION.—Not later than 2 years after the date of the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for

small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(f) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the demonstration program—

(1) for fiscal year 2005, $1,000,000, and

(2) for fiscal year 2006, $6,000,000.

SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDICARE BENEFICIARY OMBUDSMAN.

(a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following: ''; MEDICARE PROVIDER OMBUDSMAN'';

(2) by inserting ''PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)'' after ''(a)'';

(3) in paragraph (1), as so redesignated under paragraph (2), by striking ''in this section'' and inserting ''in this subsection'';

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

(5) by adding at the end the following new subsection:

''(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

''(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and

Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

''(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

''(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

''(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.''.

(b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII, as previously amended, is amended by inserting after section 1809 the following new section:

''MEDICARE BENEFICIARY OMBUDSMAN

''SEC. 1810. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

''(b) DUTIES.—The Medicare Beneficiary Ombudsman shall—

''(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

''(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

''(A) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary;

''(B) assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

''(C) assistance to such individuals in presenting information under section 1860D–2(b)(4)(D)(v); and

''(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

''(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs.''.

(c) DEADLINE FOR APPOINTMENT.—The Secretary shall appoint the Medicare Provider Ombudsman and the Medicare Beneficiary Ombudsman, under the amendments made by subsections (a) and (b), respectively, by not later than 1 year after the date of the enactment of this Act.

(d) FUNDING.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the provisions of subsection (b) of section 1868 of the Social Security Act (relating to the Medicare Provider Ombudsman), as added by subsection (a)(5) and section 1807 of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (b), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

(e) USE OF CENTRAL, TOLL-FREE NUMBER (1–800–MEDICARE).—

(1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by adding at the end the following: ''The Secretary shall provide, through the toll-free number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance

with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.''.

(2) MONITORING ACCURACY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the ''demonstration program'') under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding the medicare program at the location of existing local offices of the Social Security Administration.

(b) LOCATIONS.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by individuals referred to in subsection (a).

(2) ASSISTANCE FOR RURAL BENEFICIARIES.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a))

with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking ''hospice services'' and inserting ''hospice care and post-hospital extended care services''; and

(B) by inserting before the period at the end the following: ''and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than October 1, 2004, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from

the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Administration to the Secretary.

(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally

and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another other officer of the Department.

(3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in appropriations Act, the Secretary shall have authority to hire administrative law judges to hear such cases, giving priority to those judges with prior experience in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) FINANCING.—Amounts payable under law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall

become payable to the Secretary for the functions so transferred.

(6) SHARED RESOURCES.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (as amended by section 521 of BIPA, 114 Stat. 2763A–534), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of BIPA (114 Stat. 2763A–543), is amended by striking ''of the Social Security Administration''.

SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Section 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is amended—

(1) in paragraph (1)(A), by inserting '', subject to paragraph (2),'' before ''to judicial review of the Secretary's final decision'';

(2) in paragraph (1)(F)—

(A) by striking clause (ii);

(B) by striking ''PROCEEDING'' and all that follows through ''DETERMINATION'' and inserting ''DETERMINATIONS AND RECONSIDERATIONS''; and

(C) by redesignating subclauses (I) and (II) as clauses (i) and (ii) and by moving the indentation of such subclauses (and the matter that follows) 2 ems to the left; and

(3) by adding at the end the following new paragraph:

''(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

''(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case of an appeal.

''(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate re-

view panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.

''(C) ACCESS TO JUDICIAL REVIEW.—

''(i) IN GENERAL.—If the appropriate review panel—

''(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

"(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

"(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

"(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or

"(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

"(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

"(iv) INTEREST ON AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this Act.

"(D) REVIEW PANELS.—For purposes of this subsection, a 'review panel' is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental

Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.''.

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting ''(A)'' after ''(h)(1)''; and

(2) by adding at the end the following new subparagraph:

''(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

(d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.—

(1) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which the remedy of termination of participation, or a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i–3(h)(2)(B)) which is applied on an immediate basis, has been imposed. Under such process priority shall be provided in cases of termination.

(2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary

such additional sums for fiscal year 2005 and each subsequent fiscal year as may be necessary. The purposes for which such amounts are available include increasing the number of administrative law judges (and their staffs) and the appellate level staff at the Departmental Appeals Board of the Department of Health and Human Services and educating such judges and staffs on long-term care issues.

(e) PROCESS FOR REINSTATEMENT OF APPROVAL OF CERTAIN SNF TRAINING PROGRAMS.—

(1) IN GENERAL.—In the case of a termination of approval of a nurse aide training program described in paragraph (2) of a skilled nursing facility, the Secretary shall develop and implement a process for the reinstatement of approval of such program before the end of the mandatory 2 year disapproval period if the facility and program is certified by the Secretary, in coordination with the applicable State survey and certification agency and after public notice, as being in compliance with applicable requirements and as having remedied any deficiencies in the facility or program that resulted in noncompliance.

(2) TERMINATION OF APPROVAL DESCRIBED.—A termination of approval of a training program de-

scribed in this paragraph is a mandatory 2-year disapproval provided for under section 1819(f)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395i–3(f)(2)(B)(iii)) if the only basis for the mandatory disapproval was the assessment of a civil money penalty of not less than $5,000.

SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by BIPA and as amended by section 932(a), is further amended by adding at the end the following new paragraph:

''(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(b) USE OF PATIENTS' MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended by inserting ''(including the medical records of the individual involved)'' after ''clinical experience''.

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amended by BIPA, is amended by adding at the end the following new paragraphs:

''(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

''(A) the written notice on the determination shall include—

''(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

''(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

"(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section; and

"(B) the person provided such notice may obtain, upon request, the specific provision of the policy, manual, or regulation used in making the determination.

"(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the redetermination shall include—

"(i) the specific reasons for the redetermination;

"(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

"(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

"(iv) notification of the right to appeal the redetermination and instructions

on how to initiate such an appeal under this section;

''(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

''(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.''.

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is amended—

(A) by inserting ''be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)'' after ''in writing, ''; and

(B) by inserting ''and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section'' after ''such decision,''.

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended—

(A) in the heading, by inserting ''; NOTICE'' after ''SECRETARY''; and

(B) by adding at the end the following new paragraph:

''(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

''(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

''(B) the procedures for obtaining additional information concerning the decision; and

''(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.''.

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking ''prepare'' and inserting ''submit'' and by striking ''with respect to'' and all that follows through ''and relevant policies''.

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

(1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C. 1395ff(c)(3)), as amended by BIPA, is amended—

(A) in subparagraph (A), by striking ''sufficient training and expertise in medical science and legal matters'' and inserting ''sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing''; and

(B) by adding at the end the following new subparagraph:

''(K) INDEPENDENCE REQUIREMENTS.—

''(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

''(I) is not a related party (as defined in subsection (g)(5));

''(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

''(III) does not otherwise have a conflict of interest with such a party.

"(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

"(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.".

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is amended—

(A) by amending subsection (c)(3)(D) to read as follows:

"(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).''; and

(B) by adding at the end the following new subsection:

''(g) QUALIFICATIONS OF REVIEWERS.—

''(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

''(A) each individual conducting a review shall meet the qualifications of paragraph (2);

''(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

''(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a 'reviewing professional'), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

''(2) INDEPENDENCE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

"(i) not be a related party (as defined in paragraph (5));

"(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

"(iii) not otherwise have a conflict of interest with such a party.

"(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

"(I) the individual is not involved in the provision of items or services in the case under review;

"(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part

B, or both, (or authorized representative) and neither party objects; and

"(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

"(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

"(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term 'participation agreement' means an agreement relating to the provision of health care services by the individual and does not include the provi-

sion of services as a reviewer under this subsection.

''(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

''(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

''(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

''(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

''(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific

individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

''(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

''(B) The individual (or authorized representative).

''(C) The health care professional that provides the items or services involved in the case.

''(D) The institution at which the items or services (or treatment) involved in the case are provided.

''(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

''(F) Any other party determined under any regulations to have a substantial interest in the case involved.''.

(3) REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking ''not fewer than 12 qualified independent contractors under this subsection'' and inserting

"with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection".

(4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, (114 Stat. 2763A–534).

(5) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 934. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by sections 912(b), 921(b)(1), and 921(c)(1), is further amended by adding at the end the following new subsection:

"(h) CONDUCT OF PREPAYMENT REVIEW.—

"(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

"(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

"(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

"(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

"(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term 'random prepayment review' means a demand for the production of records or documentation absent cause with respect to a claim.

''(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

''(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).

''(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect 1 year after the date of the enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 935. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

"(f) RECOVERY OF OVERPAYMENTS.—

"(1) USE OF REPAYMENT PLANS.—

"(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

"(B) HARDSHIP.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

"(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

"(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

"(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

"(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment

plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

''(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

''(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

''(ii) there is an indication of fraud or abuse committed against the program.

''(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

''(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be con-

strued as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

''(2) LIMITATION ON RECOUPMENT.—

''(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

''(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, in-

terest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

''(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section 1889(g).

''(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

''(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

''(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

''(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or sup-

plier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

''(5) CONSENT SETTLEMENT REFORMS.—

''(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

''(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

''(i) communicate to the provider of services or supplier—

''(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

''(II) the nature of the problems identified in such evaluation; and

"(III) the steps that the provider of services or supplier should take to address the problems; and

"(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

"(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

"(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

"(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

"(I) the opportunity for a statistically valid random sample; or

"(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

''(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term 'consent settlement' means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

''(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

''(7) PAYMENT AUDITS.—

"(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

"(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

"(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

"(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

''(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

''(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

''(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

''(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.''.

(b) EFFECTIVE DATES AND DEADLINES.—

(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.

(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by

subsection (a), shall apply to actions taken after the date of the enactment of this Act.

(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act, as added by subsection (a), shall take effect on the date of the enactment of this Act.

(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) of the Social Security Act, as added by subsection (a).

(7) PAYMENT AUDITS.—Section 1893A(f)(7) of the Social Security Act, as added by subsection (a),

shall apply to audits initiated after the date of the enactment of this Act.

(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as added by subsection (a).

SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) by adding at the end of the heading the following: ''; ENROLLMENT PROCESSES''; and

(2) by adding at the end the following new subsection:

''(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

''(1) ENROLLMENT PROCESS.—

''(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

''(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

''(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

''(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.''.

(b) EFFECTIVE DATES.—

(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section 1866(j)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

(2) CONSULTATION.—Section 1866(j)(1)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

(3) HEARING RIGHTS.—Section 1866(j)(2) of the Social Security Act, as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 937. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS.

(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 301(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under

the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) PERMITTING USE OF CORRECTED AND SUPPLEMENTARY DATA.—

(1) IN GENERAL.—Section 1886(d)(10)(D)(vi) (42 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after subclause (II) at the end the following: ''Notwithstanding subclause (I), a hospital may submit, and the Secretary may accept upon verification, data that corrects or supplements the data described in such subclause without regard to whether the corrected or supplementary data relate to a cost report that has been settled.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to fiscal years beginning with fiscal year 2004.

(3) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS PERMITTED FOR FISCAL YEAR 2004.—

(A) IN GENERAL.—Notwithstanding any other provision of law, a hospital may submit (or resubmit) an application for a change described in section 1886(d)(10)(C)(i)(II) of the

Social Security Act for fiscal year 2004 if the hospital demonstrates on a timely basis to the satisfaction of the Secretary that the use of corrected or supplementary data under the amendment made by paragraph (1) would materially affect the approval of such an application.

(B) APPLICATION OF BUDGET NEUTRALITY.—If one or more hospital's applications are approved as a result of paragraph (1) and subparagraph (A) for fiscal year 2004, the Secretary shall make a proportional adjustment in the standardized amounts determined under section 1886(d)(3) of the Social Security Act (42 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure that approval of such applications does not result in aggregate payments under section 1886(d) of such Act that are greater or less than those that would otherwise be made if paragraph (1) and subparagraph (A) did not apply.

SEC. 938. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA

and section 933(d)(2)(B), is further amended by adding at the end the following new subsection:

"(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

"(1) ESTABLISHMENT OF PROCESS.—

"(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to eligible items and services described in subparagraph (C), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

"(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:

"(i) A physician, but only with respect to eligible items and services for which the physician may be paid directly.

"(ii) An individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives, from the physician who may be paid

directly for the item or service, an advance beneficiary notice under section 1879(a) that payment may not be made (or may no longer be made) for the item or service under this title.

''(C) ELIGIBLE ITEMS AND SERVICES.—For purposes of this subsection and subject to paragraph (2), eligible items and services are items and services which are physicians' services (as defined in paragraph (4)(A) of section 1848(f) for purposes of calculating the sustainable growth rate under such section).

''(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

''(3) REQUEST FOR PRIOR DETERMINATION.—

''(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination,

before the furnishing of an eligible item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

''(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the item or service, supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

''(4) RESPONSE TO REQUEST.—

''(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

''(i) the item or service is so covered;

''(ii) the item or service is not so covered; or

"(iii) the contractor lacks sufficient information to make a coverage determination.

If the contractor makes the determination described in clause (iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

"(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

"(C) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or serv-

ice and have a claim submitted for the item or service.

''(5) EFFECT OF DETERMINATIONS.—

''(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

''(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

''(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

''(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

''(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the de-

termination is based, and the right to such a redetermination.

''(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

''(6) LIMITATION ON FURTHER REVIEW.—

''(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

''(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

''(i) decides not to seek a prior determination under this subsection with respect to items or services; or

''(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

''(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determination under this subsection with respect to such items or services.''.

(b) EFFECTIVE DATE; TRANSITION.—

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for the acceptance of requests for determinations under such process filed not later

than 18 months after the date of the enactment of this Act.

(2) TRANSITION.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act.

(3) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)), the amendment made by subsection (a) shall not be considered to be a change in law or regulation.

(c) PROVISIONS RELATING TO ADVANCE BENEFICIARY NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

(1) DATA COLLECTION.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on

such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage policies under the medicare program.

(3) GAO REPORT REPORT ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States

shall submit to Congress a report on the use of the prior determination process under such section. Such report shall include—

(A) information concerning the types of procedures for which a prior determination has been sought, determinations made under the process, and changes in receipt of services resulting from the application of such process; and

(B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and beneficiaries.

(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term ''advance beneficiary notice'' means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

Subtitle V—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new documentation guidelines for, or clinical examples of, evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary—

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test modifications to the evaluation and management documentation guidelines;

(4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

(b) PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

(1) IN GENERAL.—The Secretary shall conduct under this subsection appropriate and representative pilot projects to test new evaluation and management documentation guidelines referred to in subsection (a).

(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing

physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current Procedures Terminology (CPT) code book of the American Medical Association;

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

(4) BANNING OF TARGETING OF PILOT PROJECT PARTICIPANTS.—Data collected under this subsection shall not be used as the basis for overpayment demands or post-payment audits. Such limitation applies only to claims filed as part of the pilot project and lasts only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

(5) STUDY OF IMPACT.—Each pilot project shall examine the effect of the new evaluation and management documentation guidelines on—

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

(6) PERIODIC REPORTS.—The Secretary shall submit to Congress periodic reports on the pilot projects under this subsection.

(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

(1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately;

(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

(3) increase accuracy by reviewers; and

(4) educate both physicians and reviewers.

(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—

(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are—

(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act; and

(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study

under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act.

(5) REPORT TO CONGRESS.—(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits

in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term ''rural area'' has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

(2) the term ''teaching settings'' are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1868 (42 U.S.C. 1395ee), as amended by section 921(a), is amended by adding at the end the following new subsection:

''(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

''(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as 'CMS').

''(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Tech-

nology and Innovation (appointed or designated under paragraph (4)).

''(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

''(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.''.

(b) METHODS FOR DETERMINING PAYMENT BASIS FOR NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

''(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as 'new tests').

''(B) Determinations under subparagraph (A) shall be made only after the Secretary—

''(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

''(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

''(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and rec-

ommendations (and data on which the recommendations are based);

''(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

''(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

''(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

''(i) set forth the criteria for making determinations under subparagraph (A); and

''(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

''(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

''(E) For purposes of this paragraph:

''(i) The term 'HCPCS' refers to the Health Care Procedure Coding System.

''(ii) A code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).''.

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter

time frame by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using of quarterly samples or special surveys or any other methods. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

(2) REPORT.—By not later than October 1, 2004, the Comptroller General shall submit a report to Congress on the study under paragraph (1).

(d) PROCESS FOR ADOPTION OF ICD CODES AS DATA STANDARD.—Section 1172(f) (42 U.S.C. 1320d–1(f)) is amended by inserting after the first sentence the following: ''Notwithstanding the first sentence of this subsection, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary, within 1 year after the date of the enactment of this sentence, with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System ('ICD–10–PCS') and the International Classification of Diseases, 10th Revision, Clinical Modification ('ICD–10–CM') as a standard under this

part, then the Secretary may adopt ICD–10–PCS and ICD–10–CM as such a standard.''.

SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) IN GENERAL.—The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(b) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A or enrolled under part B, or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.

SEC. 944. EMTALA IMPROVEMENTS.

(a) PAYMENT FOR EMTALA-MANDATED SCREENING AND STABILIZATION SERVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

''(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to items and services furnished on or after January 1, 2004.

(b) NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

''(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.''.

(c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.—

(1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—

(A) in the first sentence, by inserting ''or in terminating a hospital's participation under this title'' after ''in imposing sanctions under paragraph (1)''; and

(B) by adding at the end the following new sentences: ''Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall pro-

vide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

(d) MODIFICATION OF REQUIRMENT FOR MEDICAL SCREENING EXAMINATIONS FOR PATIENTS NOT REQUESTING EMERGENCY DEPARTMENT SERVICES.—

(1) IN GENERAL.—Section 1867(a) (42 U.S.C. 1395dd(a)) is amended—

(A) by designating all that follows ''(a) MEDICAL SCREENING REQUIREMENT.—'' as paragraph (1) with the heading ''IN GENERAL.—'';

(B) by aligning such paragraph with the paragraph added by paragraph (3); and

(C) by adding at the end the following new paragraph:

''(2) EXCEPTION FOR CERTAIN CASES.—The requirement for an appropriate medical screening examination under paragraph (1) shall not apply in the case of an individual who comes to the emer-

gency department and neither the individual, nor another person on the individual's behalf, requests examination or treatment for an emergency medical condition (such as a request solely for preventive services, such as blood pressure screening or non-emergency laboratory and diagnostic tests).''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

SEC. 945. EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) TECHNICAL ADVISORY GROUP.

(a) ESTABLISHMENT.—The Secretary shall establish a Technical Advisory Group (in this section referred to as the ''Advisory Group'') to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA) and its implementation. In this section, the term ''EMTALA'' refers to the provisions of section 1867 of the Social Security Act (42 U.S.C. 1395dd).

(b) MEMBERSHIP.—The Advisory Group shall be composed of 19 members, including the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services and of which—

(1) 4 shall be representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and at least 2 of which have not been cited for EMTALA violations;

(2) 7 shall be practicing physicians drawn from the fields of emergency medicine, cardiology or cardiothoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology, and psychiatry, with not more than one physician from any particular field;

(3) 2 shall represent patients;

(4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and

(5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

(c) GENERAL RESPONSIBILITIES.—The Advisory Group—

(1) shall review EMTALA regulations;

(2) may provide advice and recommendations to the Secretary with respect to those regulations and their application to hospitals and physicians;

(3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and

(4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.

(d) ADMINISTRATIVE MATTERS.—

(1) CHAIRPERSON.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.

(2) MEETINGS.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.

(e) TERMINATION.—The Advisory Group shall terminate 30 months after the date of its first meeting.

(f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group notwith-

standing any limitation that may apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following:

''(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

''(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such

services directly would be impracticable and prohibitively expensive.''.

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

''(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (R), by striking ''and'' at the end;

(B) in subparagraph (S), by striking the period at the end and inserting '', and''; and

(C) by inserting after subparagraph (S) the following new subparagraph:

''(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).''; and

(2) by adding at the end of subsection (b) the following new paragraph:

''(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

''(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

''(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.''.

(b) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2004.

SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)—

(A) is transferred to section 1862 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the last sentence of subsection (a), by striking ''established under section 1114(f)''; and

(B) in subsection (j), as so transferred and redesignated—

(i) by striking ''under subsection (f)''; and

(ii) by striking ''section 1862(a)(1)'' and inserting ''subsection (a)(1)''.

(b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by section 521 of BIPA, is amended—

(A) in subclause (III), by striking ''policy'' and inserting ''determination''; and

(B) in subclause (IV), by striking ''medical review policies'' and inserting ''coverage determinations''.

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w–22(a)(2)(C)) is amended by striking ''policy'' and ''POLICY'' and inserting ''determination'' each place it appears and ''DETERMINATION'', respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended—

(1) in subparagraph (A)(iv), by striking ''subclause (I), (II), or (III)'' and inserting ''clause (i), (ii), or (iii)'';

(2) in subparagraph (B), by striking ''clause (i)(IV)'' and ''clause (i)(III)'' and inserting ''subparagraph (A)(iv)'' and ''subparagraph (A)(iii)'', respectively; and

(3) in subparagraph (C), by striking ''clause (i)'', ''subclause (IV)'' and ''subparagraph (A)'' and inserting ''subparagraph (A)'', ''clause (iv)'' and ''paragraph (1)(A)'', respectively each place it appears.

(d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section

1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

(e) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 949. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: ''Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.''.

SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by adding after subsection (g) the following new subsection:

''(h)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

''(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

SEC. 951. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA.

Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall arrange to furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C.

1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage under such section for that hospital for the current cost reporting year. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C. 1395u(b)(6)(A)) is amended by striking ''or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service,'' and inserting ''or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity (as defined by the Secretary), to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such other program integrity and other safeguards as the Secretary may determine to be appropriate,''.

(b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is

amended by striking ''except to an employer or facility'' and inserting ''except to an employer, entity, or other person''.

(c) EFFECTIVE DATE.—The amendments made by section shall apply to payments made on or after the date of the enactment of this Act.

SEC. 953. OTHER PROVISIONS.

(a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

(1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the appropriateness of the updates in the conversion factor under subsection (d)(3) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4), including the appropriateness of the sustainable growth rate formula under subsection (f) of such section for 2002 and succeeding years. Such report shall examine the stability and predictability of such updates and rate and alternatives for the use of such rate in the updates.

(2) PHYSICIAN COMPENSATION GENERALLY.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall

submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act, and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w–4).

(b) ANNUAL PUBLICATION OF LIST OF NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act in the previous year and information on how to get more information with respect to such determinations.

(c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO ARE NOT MEDICARE BENEFICIARIES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the implications if there were flexibility in the application of the medicare conditions of participation for home health agencies with respect to groups or types of patients who are not medicare beneficiaries. The report shall include an analysis of

the potential impact of such flexible application on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to such recipients.

(d) OIG REPORT ON NOTICES RELATING TO USE OF HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall submit a report to Congress on—

(1) the extent to which hospitals provide notice to medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days.

SEC. 954. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not

eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as ''non-medicare/medicaid OASIS information'').

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the 2nd month beginning after the date as of which the Secretary has published final regulations regarding the collection and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

TITLE X—MEDICAID

SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS.

Section 1923(f)(3) (42 U.S.C. 1396r–4(f)(3)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (C)''; and

(2) by adding at the end the following new subparagraphs:

''(C) SPECIAL, TEMPORARY INCREASE IN ALLOTMENTS ON A ONE-TIME, NON-CUMULATIVE BASIS.—The DSH allotment for any State—

''(i) for fiscal year 2004 is equal to 120 percent of the DSH allotment for the State for fiscal year 2003 under this paragraph, notwithstanding subparagraph (B); and

''(ii) for each succeeding fiscal year is equal to the DSH allotment for the State for fiscal year 2004 or, in the case of fiscal years beginning with the fiscal year specified in subparagraph (D) for that State, the percentage change in the consumer price index for all urban consumers (all items; U.S. city average), for the previous fiscal year.

''(D) FISCAL YEAR SPECIFIED.—For purposes of subparagraph (C)(ii), the fiscal year specified in this subparagraph for a State is the first fiscal year for which the Secretary estimates that the DSH allotment for that State

will equal (or no longer exceed) the DSH allotment for that State under the law as in effect before the date of the enactment of this subparagraph.''.

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.

(a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is amended by inserting before the semicolon the following: ''(including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act)''.

(b) ANTI-DIVERSION PROTECTION.—Section 1927(c)(1)(C) (42 U.S.C. 1396r–8(c)(1)(C)) is amended by adding at the end the following:

''(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described

in section 340B(a)(5)(C) of the Public Health Service Act.''.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

SEC. 1101. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraph (B) and inserting the following:

''(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

''(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

"(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

"(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

"(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

"(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

"(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

''(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

''(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

''(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.''; and

(B) by adding at the end the following subparagraph:

''(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

''(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.''; and

(2) in paragraph (5)—

(A) in subparagraph (B)—

(i) by striking ''under the following'' and inserting ''by applying the following to each certification made under paragraph (2)(A)(vii)''; and

(ii) in clause (iii)—

(I) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted.''; and

(II) in the second sentence—

(aa) by striking subclause (I) and inserting the following:

''(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(aa) the date on which the court enters judgment reflecting the decision; or

''(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;'';

(bb) by striking subclause (II) and inserting the following:

''(II) if before the expiration of such period the district court decides that the patent has been infringed—

''(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

''(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination

that there is no cause of action for patent infringement or invalidity); or

''(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

''(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;'';

(cc) in subclause (III), by striking ''on the date of such court decision.'' and inserting ''as provided in subclause (I); or'';

(dd) by inserting after subclause (III) the following:

''(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent va-

lidity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).''; and

(ee) in the matter after and below subclause (IV) (as added by item (dd)), by striking ''Until the expiration'' and all that follows;

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(C) by inserting after subparagraph (B) the following:

''(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

''(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

''(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subpara-

graph (B)(iii) unless the forty-five day period referred to in such subparagraph has expired, and unless, if the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (II). Any such action shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

''(II) RIGHT OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I), the document described in this subclause is a document providing a right of confidential access to the application of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the right of confidential access shall contain such restrictions as to persons entitled to access, and on the

use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. Any person provided a right of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided a right of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

''(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

''(I) IN GENERAL.—If an owner of the patent or the holder of the ap-

proved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

"(aa) the drug for which the application was approved; or

"(bb) an approved method of using the drug.

"(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

"(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil

action under subparagraph (i) or a counterclaim under subparagraph (ii).''.

(b) APPLICATIONS GENERALLY.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)—

(A) by striking paragraph (3) and inserting the following:

''(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

''(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

''(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

''(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

''(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

''(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

''(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

''(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

''(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for

the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

''(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.''; and

(B)(i) by redesignating paragraph (4) as paragraph (5); and

(ii) by inserting after paragraph (3) the following paragraph:

''(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

''(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.''; and

(2) in subsection (c)(3)—

(A) in the first sentence, by striking ''under the following'' and inserting ''by apply-

ing the following to each certification made under subsection (b)(2)(A)(iv)'';

(B) in subparagraph (C)—

(i) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted.'';

(ii) in the second sentence—

(I) by striking ''paragraph (3)(B)'' and inserting ''subsection (b)(3)'';

(II) by striking clause (i) and inserting the following:

''(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive

determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(I) the date on which the court enters judgment reflecting the decision; or

''(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;'';

(III) by striking clause (ii) and inserting the following:

''(ii) if before the expiration of such period the district court decides that the patent has been infringed—

''(I) if the judgment of the district court is appealed, the approval shall be made effective on—

''(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

''(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

''(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;'';

(IV) in clause (iii), by striking ''on the date of such court decision.'' and inserting ''as provided in clause (i); or'';

(V) by inserting after clause (iii), the following:

''(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the ap-

proval shall be made effective as provided in clause (ii).''; and

(VI) in the matter after and below clause (iv) (as added by subclause (V)), by striking ''Until the expiration'' and all that follows; and

(iii) in the third sentence, by striking ''paragraph (3)(B)'' and inserting ''subsection (b)(3)'';

(C) by redesignating subparagraph (D) as subparagraph (E); and

(D) by inserting after subparagraph (C) the following:

''(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

''(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

''(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless the forty-five

day period referred to in such subparagraph has expired, and unless, if the notice the applicant provided under subsection (b)(3) relates to noninfringement, the notice was accompanied by a document described in subclause (II). Any such action shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

''(II) RIGHT OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I), the document described in this subclause is a document providing a right of confidential access to the application of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the right of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of

any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. Any person provided a right of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided a right of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

''(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

''(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection

(b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

"(aa) the drug for which the application was approved; or

"(bb) an approved method of using the drug.

"(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

"(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil

action under clause (i) or a counterclaim under clause (ii).''.

(c) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the amendments made by subsections (a), (b), and (c) apply to any proceeding under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is pending on or after the date of enactment of this Act regardless of the date on which the proceeding was commenced or is commenced.

(2) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—The amendments made by subsections (a)(1) and (b)(1) apply with respect to any certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) after the date of enactment of this Act in an application filed under subsection (b)(2) or (j) of that section or in an amendment or supplement to an application filed under subsection (b)(2) or (j) of that section.

(3) EFFECTIVE DATE OF APPROVAL.—The amendments made by subsections (a)(2)(A)(ii)(I) and (b)(2)(B)(i) apply with respect to any patent in-

formation submitted under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) made after the date of enactment of this Act.

SEC. 1102. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 1101) is amended—

(1) in subparagraph (B), by striking clause (iv) and inserting the following:

''(iv) 180-DAY EXCLUSIVITY PERIOD.—

''(I) DEFINITIONS.—In this paragraph:

''(aa) 180-DAY EXCLUSIVITY PERIOD.—The term '180-day exclusivity period' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

''(bb) FIRST APPLICANT.—As used in this subsection, the term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for

approval of a drug, submits a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) for the drug.

''(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term 'substantially complete application' means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

''(dd) TENTATIVE APPROVAL.—

''(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (E) or section 505A, or

there is a 7-year period of exclusivity for the listed drug under section 527.

''(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

''(II) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.''; and

(2) by inserting after subparagraph (C) the following:

''(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

"(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

"(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

"(aa) the earlier of the date that is—

"(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

"(BB) 30 months after the date of submission of the application of the first applicant; or

"(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the

date as of which, as to each of the patents with respect to which the first applicant submitted a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

''(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

''(BB) In an infringement action or a declaratory judgment action described in

subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

''(CC) The patent expires.

''(DD) The patent is withdrawn by the holder of the application approved under subsection (b).

''(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

''(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certifi-

cation qualifying the applicant for the 180-day exclusivity period.

''(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

''(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final

decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

''(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

''(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

''(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

''(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

''(II) no applicant shall be eligible for a 180-day exclusivity period.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act.

(2) COLLUSIVE AGREEMENTS.—If a forfeiture event described in section 505(j)(5)(D)(i)(V) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(iv) of that Act without regard to when

the first certification under section 505(j)(2)(A)(vii)(IV) of that Act for the listed drug was made.

(3) DECISION OF A COURT WHEN THE 180-DAY EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.—With respect to an application filed before, on, or after the date of enactment of this Act for a listed drug for which a certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act and for which neither of the events described in subclause (I) or (II) of section 505(j)(5)(B)(iv) of that Act (as in effect on the day before the date of enactment of this Act) has occurred on or before the date of enactment of this Act, the term ''decision of a court'' as used in clause (iv) of section 505(j)(5)(B) of that Act means a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

SEC. 1103. BIOAVAILABILITY AND BIOEQUIVALENCE.

(a) IN GENERAL.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

(1) by striking subparagraph (A) and inserting the following:

''(A)(i) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

''(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.''; and

(2) by adding at the end the following:

''(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.''.

(b) EFFECT OF AMENDMENT.—The amendment made by subsection (a) does not alter the standards for approval of drugs under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

SEC. 1104. CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(F)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)''; and

(3) in subsections (e) and (l), by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''.

Subtitle B—Federal Trade Commission Review

SEC. 1111. DEFINITIONS.

In this subtitle:

(1) ANDA.—The term ''ANDA'' means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) BRAND NAME DRUG.—The term ''brand name drug'' means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act.

(3) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means the party that holds the approved application referred to in para-

graph (2) for a brand name drug that is a listed drug in an ANDA, or a party that is the owner of a patent for which information is submitted for such drug under subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act.

(4) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(5) GENERIC DRUG.—The term ''generic drug'' means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved.

(6) GENERIC DRUG APPLICANT.—The term ''generic drug applicant'' means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(7) LISTED DRUG.—The term ''listed drug'' means a brand name drug that is listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act.

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certifi-

cation under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

SEC. 1113. FILING DEADLINES.

Any filing required under section 1112 shall be filed with the Commission not later than 10 business days after the date the agreements are executed.

SEC. 1114. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Commission pursuant to this subtitle shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. 1115. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company or generic drug applicant fails to comply with any provision of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion

determines necessary or appropriate, upon application of the Commission.

SEC. 1116. RULEMAKING.

The Commission, by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle—

(1) may define the terms used in this subtitle;

(2) may exempt classes of persons or agreements from the requirements of this subtitle; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 1117. SAVINGS CLAUSE.

Any action taken by the Commission, or any failure of the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

SEC. 1118. EFFECTIVE DATE.

This subtitle shall—

(1) take effect 30 days after the date of enactment of this Act; and

(2) shall apply to agreements described in section 1112 that are entered into 30 days after the date of enactment of this Act.

Subtitle C—Importation of Prescription Drugs

SEC. 1121. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

"SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

"(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(C) an infused drug (including a peritoneal dialysis solution);

"(D) an intravenously injected drug;

"(E) a drug that is inhaled during surgery; or

"(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

"(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

"(5) WHOLESALER.—

"(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

''(b) REGULATIONS.—The Secretary shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with all other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e);

''(3) require that any prescription drug from Canada imported by a domestic pharmacist or wholesaler under this section be contained in packaging which the Secretary has determined to be reasonably certain to be tamper-resistant and not capable of counterfeiting;

''(4) require that all prescription drugs from Canada imported by a domestic pharmacist or a wholesaler under this section contain a statement designed to inform the end-user of such drug that such drug has been imported from a foreign seller other than a manufacturer;

''(5) require that only prescription drugs which have not left the possession of the first Canadian recipient of such prescription drugs after receipt from the manufacturer of such prescription drugs be eligible for importation into the United States under this section;

''(6) require, if determined appropriate by the Secretary, that all prescription drugs imported from Canada under this section by domestic pharmacists and wholesalers enter the United States through ports of entry designated by the Secretary for purposes of this section;

''(7) contain any additional provisions determined by the Secretary to be appropriate to protect the public health; and

''(8) contain any additional provisions determined by the Secretary to be appropriate to facilitate the importation of prescription drugs that do not jeopardize the public health.

"(d) INFORMATION AND RECORDS.—

"(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

"(A) The name and quantity of the active ingredient of the prescription drug.

"(B) A description of the dosage form of the prescription drug.

"(C) The date on which the prescription drug is shipped.

"(D) The quantity of the prescription drug that is shipped.

"(E) The point of origin and destination of the prescription drug.

"(F) The price paid and the price charged by the importer for the prescription drug.

"(G) Documentation from the foreign seller specifying—

"(i) the original source of the prescription drug; and

"(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

"(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

"(I) The name, address, telephone number, and professional license number (if any) of the importer.

"(J)(i) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

"(ii) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

"(iii) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

"(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

"(i) is approved for marketing in the United States and is not adulterated or misbranded; and

"(ii) meets all labeling requirements under this Act.

"(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

"(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

"(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

"(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

"(e) TESTING.—The regulations under subsection (b) shall require—

"(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the

importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing under this section; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for impor-

tation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian or-

ganization (including the United Nations and affiliates) or to a government of a foreign country.

''(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—The Secretary may, for drugs being imported from a licensed Canadian pharmacy, grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate. Such conditions shall include conditions that such drug or device be—

''(1) in the possession of an individual when the individual enters the United States;

''(2) imported by such individual from a licensed pharmacy for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply, which individual will use the drug or device (or for a family member of such individual);

''(3) accompanied by a copy of a valid prescription;

''(4) imported from Canada, from a seller registered with the Secretary;

''(5) a prescription drug approved by the Secretary under chapter V that is not adulterated or misbranded;

''(6) in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(7) imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(k) STUDIES; REPORTS.—

''(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

''(I) importations of prescription drugs made under the regulations under subsection (b); and

''(II) information and documentation submitted under subsection (d).

''(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

''(I) evaluate the compliance of importers with the regulations under subsection (b);

"(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

"(III) consult with the Secretary to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

"(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

"(2) BY THE COMPTROLLER GENERAL.—

"(A) STUDY.—The Comptroller General of the United States shall conduct a study to de-

termine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(l) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(m) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

''(n) CONDITIONS.—This section shall become effective only if the Secretary demonstrates to the Congress that the implementation of this section will—

''(1) pose no additional risk to the public's health and safety; and

''(2) result in a significant reduction in the cost of prescription drugs to the American consumer.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804''; and

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

○