AMENDMENT TO H.R. 1

OFFERED BY MR. RANGEL OF NEW YORK AND MR. DINGELL OF MICHIGAN

(Amendment is to Medicare Prescription Drug and Modernization Act of 2003)

Strike all after the enacting clause and insert the following:

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 MEDICINE BENEFIT

SEC. 101. VOLUNTARY MEDICARE OUTPATIENT PRESCRIPTION MEDICINE PROGRAM.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.) is amended—

(1) by redesignating section 1859 and part D as section 1858 and part E, respectively; and

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

"PART D—VOLUNTARY PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND DISABLED

"MEDICARE OUTPATIENT PRESCRIPTION MEDICINE BENEFIT

"SEC. 1859. Subject to the succeeding provisions of this part, the voluntary prescription medicine benefit program under this part provides the following:

"(1) PREMIUM.—The monthly premium is $25.

"(2) DEDUCTIBLE.—The annual deductible is $100.

"(3) COINSURANCE.—The coinsurance is 20 percent.

"(4) OUT-OF-POCKET LIMIT.—The annual limit on out-of-pocket spending on covered medicines is $2,000.

"NEGOTIATING FAIR PRICES WITH PHARMACEUTICAL MANUFACTURERS

"SEC. 1859A. (a) AUTHORITY TO NEGOTIATE PRICES WITH MANUFACTURERS.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and containing costs under this part, negotiate contracts with manufacturers of covered outpatient prescription medicines that provide for the maximum prices that may be charged to individuals enrolled under this part by participating pharmacies for dispensing such medicines to such individuals.

"(b) PROMOTION OF BREAKTHROUGH MEDICINES.—In conducting negotiations with manufacturers under this part, the Secretary shall take into account the goal of promoting the development of breakthrough medicines (as defined in section 1859H(b)).

"CONTRACT AUTHORITY

"SEC. 1859B. (a) CONTRACT AUTHORITY.—

"(1) IN GENERAL.—The Secretary is responsible for the administration of this part and shall enter into contracts with appropriate pharmacy contractors on a national or regional basis to administer the benefits under this part.

"(2) PROCEDURES.—The Secretary shall establish procedures under which the Secretary—

"(A) accepts bids submitted by entities to serve as pharmacy contractors under this part in a region or on a national basis;

"(B) awards contracts to such contractors to administer benefits under this part to eligible beneficiaries in the region or on a national basis; and

"(C) provides for the termination (and nonrenewal) of a contract in the case of a contractor's failure to meet the requirements of the contract and this part.

"(3) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into contracts under this part.

"(4) TERMS AND CONDITIONS.—Such contracts shall have such terms and conditions as the Secretary shall specify and shall be for such terms (of at least 2 years, but not to exceed 5 years) as the Secretary shall specify consistent with this part.

"(5) USE OF PHARMACY CONTRACTORS IN PRICE NEGOTIATIONS.—Such contracts shall require the contractor involved to negotiate contracts with manufacturers that provide for maximum prices for covered outpatient prescription medicines that are lower than the maximum prices negotiated under section 1859A(a), if applicable. The price reductions shall be passed on to eligible beneficiaries and the Secretary shall hold the contractor accountable for meeting performance requirements with respect to price reductions and limiting price increases.

"(6) AREA FOR CONTRACTS.—

"(A) REGIONAL BASIS.—

"(i) IN GENERAL.—Except as provided in clause (ii) and subject to subparagraph (B), the contract entered into between the Secretary and a pharmacy contractor shall require the contractor to administer the benefits under this part in a region determined by the Secretary under subparagraph (B) or on a national basis.

"(ii) PARTIAL REGIONAL BASIS.—

"(I) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit the benefits to be administered in a partial region determined appropriate by the Secretary.

"(II) REQUIREMENTS.—If the Secretary permits administration pursuant to subclause (I), the Secretary shall ensure that the partial region in which administration is effected is no smaller than a State and is at least the size of the commercial service area of the contractor for that area.

"(B) DETERMINATION.—

"(i) IN GENERAL.—In determining regions for contracts under this part, the Secretary shall—

"(I) take into account the number of individuals enrolled under this part in an area in order to encourage participation by pharmacy contractors; and

"(II) ensure that there are at least 10 different regions in the United States.

"(ii) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of administrative areas under this paragraph shall not be subject to administrative or judicial review.

"(7) SUBMISSION OF BIDS.—

"(A) SUBMISSION.—

"(i) IN GENERAL.—Subject to subparagraph (B), each entity desiring to serve as a pharmacy

contractor under this part in an area shall submit a bid with respect to such area to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

''(ii) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an entity to submit a single bid for multiple areas if the bid is applicable to all such areas.

''(B) REQUIRED INFORMATION.—The bids described in subparagraph (A) shall include—

''(i) a proposal for the estimated prices of covered outpatient prescription medicines and the projected annual increases in such prices, including the additional reduction in price negotiated below the Secretary's maximum price and differentials between preferred and nonpreferred prices, if applicable;

''(ii) a statement regarding the amount that the entity will charge the Secretary for administering the benefits under the contract;

''(iii) a statement regarding whether the entity will reduce the applicable coinsurance percentage pursuant to section 1859E(a)(1)(A)(ii) and if so, the amount of such reduction and how such reduction is tied to the performance requirements described in subsection (c)(4)(A)(ii);

''(iv) a detailed description of the performance requirements for which the administrative fee of the entity will be subject to risk pursuant to subsection (c)(4)(A)(ii);

''(v) a detailed description of access to pharmacy services provided by the entity, including information regarding whether the pharmacy contractor will use a preferred pharmacy network, and, if so, how the pharmacy contractor will ensure access to pharmacies that choose to be outside of that

network, and whether there will be increased cost-sharing for beneficiaries if they obtain medicines at such pharmacies;

"(vi) a detailed description of the procedures and standards the entity will use for—

"(I) selecting preferred prescription medicines; and

"(II) determining when and how often the list of preferred prescription medicines should be modified;

"(vii) a detailed description of any ownership or shared financial interests with pharmaceutical manufacturers, pharmacies, and other entities involved in the administration or delivery of benefits under this part as proposed in the bid;

"(viii) a detailed description of the entity's estimated marketing and advertising expenditures related to enrolling and retaining eligible beneficiaries; and

"(ix) such other information that the Secretary determines is necessary in order to carry out this part, including information relating to the bidding process under this part.

The procedures under clause (vi) shall include the use of a pharmaceutical and therapeutics committee the members of which include practicing pharmacists.

"(8) AWARDING OF CONTRACTS.—

"(A) NUMBER OF CONTRACTS.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and of containing costs under this part, award in a competitive manner at least 2 contracts to administer benefits under this part in each area specified under paragraph (6), unless only 1 pharmacy contractor submitting a bid meets the minimum standards specified under this part and by the Secretary.

"(B) DETERMINATION.—In determining which of the pharmacy contractors that submitted bids that meet the minimum standards specified under this part and by the Secretary to award a contract, the Secretary shall consider the comparative merits of each bid, as determined on the basis of relevant factors, with respect to—

"(i) how well the contractor meets such minimum standards;

"(ii) the amount that the contractor will charge the Secretary for administering the benefits under the contract;

"(iii) the performance standards established under subsection (c)(2) and performance requirements for which the administrative fee of the entity will be subject to risk pursuant to subsection (c)(4)(A)(ii);

"(iv) the proposed negotiated prices of covered outpatient medicines and annual increases in such prices;

"(v) factors relating to benefits, quality and performance, beneficiary cost-sharing, and consumer satisfaction;

"(vi) past performance and prior experience of the contractor in administering a prescription medicine benefit program;

"(vii) effectiveness of the contractor in containing costs through pricing incentives and utilization management; and

"(viii) such other factors as the Secretary deems necessary to evaluate the merits of each bid.

"(C) EXCEPTION TO CONFLICT OF INTEREST RULES.—In awarding contracts with pharmacy contractors under this part, the Secretary may waive conflict of interest laws generally applicable to Federal acquisitions (subject to such safeguards as the Secretary may

find necessary to impose) in circumstances where the Secretary finds that such waiver—

"(i) is not inconsistent with the—

"(I) purposes of the programs under this part; or

"(II) best interests of beneficiaries enrolled under this part; and

"(ii) permits a sufficient level of competition for such contracts, promotes efficiency of benefits administration, or otherwise serves the objectives of the program under this part.

"(D) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of the Secretary to award or not award a contract to a pharmacy contractor under this part shall not be subject to administrative or judicial review.

"(9) ACCESS TO BENEFITS IN CERTAIN AREAS.—

"(A) AREAS NOT COVERED BY CONTRACTS.—The Secretary shall develop procedures for the provision of covered outpatient prescription medicines under this part to each eligible beneficiary enrolled under this part that resides in an area that is not covered by any contract under this part.

"(B) BENEFICIARIES RESIDING IN DIFFERENT LOCATIONS.—The Secretary shall develop procedures to ensure that each eligible beneficiary enrolled under this part that resides in different areas in a year is provided the benefits under this part throughout the entire year.

"(b) QUALITY, FINANCIAL, AND OTHER STANDARDS AND PROGRAMS.—In consultation with appropriate pharmacy contractors, pharmacists, and health care professionals with expertise in prescribing, dispensing, and the appropriate use of prescription medicines, the Secretary shall establish standards and programs for the administration of this part to ensure appropriate prescribing, dispensing, and utilization of outpatient medicines under this part, to avoid adverse medicine reactions, and to continually reduce errors in the delivery of medically ap-

propriate covered benefits. The Secretary shall not award a contract to a pharmacy contractor under this part unless the Secretary finds that the contractor agrees to comply with such standards and programs and other terms and conditions as the Secretary shall specify. The standards and programs under this subsection shall be applied to any administrative agreements described in subsection (a) the Secretary enters into. Such standards and programs shall include the following:

''(1) ACCESS.—

''(A) IN GENERAL.—The pharmacy contractor shall ensure that covered outpatient prescription medicines are accessible and convenient to eligible beneficiaries enrolled under this part for whom benefits are administered by the pharmacy contractor, including by offering the services 24 hours a day and 7 days a week for emergencies.

''(B) ON-LINE REVIEW.—The pharmacy contractor shall provide for on-line prospective review available 24 hours a day and 7 days a week in order to evaluate each prescription for medicine therapy problems due to duplication, interaction, or incorrect dosage or duration of therapy.

''(C) GUARANTEED ACCESS TO MEDICINES IN RURAL AND HARD-TO-SERVE AREAS.—The Secretary shall ensure that all beneficiaries have guaranteed access to the full range of pharmaceuticals under this part, and shall give special attention to access, pharmacist counseling, and delivery in rural and hard-to-serve areas, including through the use of incentives such as bonus payments to retail pharmacists in rural areas and extra payments to the pharmacy contractor for the cost of rapid delivery of pharmaceuticals and any other actions necessary.

''(D) PREFERRED PHARMACY NETWORKS.—

''(i) IN GENERAL.—If a pharmacy contractor uses a preferred pharmacy network to deliver benefits under this part, such network shall meet min-

imum access standards established by the Secretary.

"(ii) STANDARDS.—In establishing standards under clause (i), the Secretary shall take into account reasonable distances to pharmacy services in both urban and rural areas.

"(E) ADHERENCE TO NEGOTIATED PRICES.—The pharmacy contractor shall have in place procedures to assure compliance of pharmacies with the requirements of subsection (d)(3)(C) (relating to adherence to negotiated prices).

"(F) CONTINUITY OF CARE.—

"(i) IN GENERAL.—The pharmacy contractor shall ensure that, in the case of an eligible beneficiary who loses coverage under this part with such entity under circumstances that would permit a special election period (as established by the Secretary under section 1859C(b)(3)), the contractor will continue to provide coverage under this part to such beneficiary until the beneficiary enrolls and receives such coverage with another pharmacy contractor under this part or, if eligible, with a Medicare+Choice organization.

"(ii) LIMITED PERIOD.—In no event shall a pharmacy contractor be required to provide the extended coverage required under clause (i) beyond the date which is 30 days after the coverage with such contractor would have terminated but for this subparagraph.

"(2) ENROLLEE GUIDELINES.—The pharmacy contractor shall, consistent with State law, apply guidelines for counseling enrollees regarding—

"(A) the proper use of covered outpatient prescription medicine: and

"(B) interactions and contra-indications.

''(3) EDUCATION.—The pharmacy contractor shall apply methods to identify and educate providers, pharmacists, and enrollees regarding—

''(A) instances or patterns concerning the unnecessary or inappropriate prescribing or dispensing of covered outpatient prescription medicines;

''(B) instances or patterns of substandard care;

''(C) potential adverse reactions to covered outpatient prescription medicines;

''(D) inappropriate use of antibiotics;

''(E) appropriate use of generic products; and

''(F) the importance of using covered outpatient prescription medicines in accordance with the instruction of prescribing providers.

''(4) COORDINATION.—The pharmacy contractor shall coordinate with State prescription medicine programs, other pharmacy contractors, pharmacies, and other relevant entities as necessary to ensure appropriate coordination of benefits with respect to enrolled individuals when such individual is traveling outside the home service area, and under such other circumstances as the Secretary may specify.

''(5) COST DATA.—

''(A) The pharmacy contractor shall make data on prescription medicine negotiated prices (including data on discounts) available to the Secretary.

''(B) The Secretary shall require, either directly or through a pharmacy contractor, that participating pharmacists, physicians, and manufacturers—

''(i) maintain their prescription medicine cost data (including data on discounts) in a form and manner specified by the Secretary;

''(ii) make such prescription medicine cost data available for review and audit by the Secretary; and

''(iii) certify that the prescription medicine cost data are current, accurate, and complete, and reflect all discounts obtained by the pharmacist or

physician in the purchasing of covered outpatient prescription medicines.

Discounts referred to in subparagraphs (A) and (B) shall include all volume discounts, manufacturer rebates, prompt payment discounts, free goods, in-kind services, or any other thing of financial value provided explicitly or implicitly in exchange for the purchase of a covered outpatient prescription medicine.

''(6) REPORTING.—The pharmacy contractor shall provide the Secretary with periodic reports on—

''(A) the contractor's costs of administering this part;

''(B) utilization of benefits under this part;

''(C) marketing and advertising expenditures related to enrolling and retaining individuals under this part; and

''(D) grievances and appeals.

''(7) RECORDS AND AUDITS.—The pharmacy contractor shall maintain adequate records related to the administration of benefits under this part and afford the Secretary access to such records for auditing purposes.

''(8) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The pharmacy contractor shall comply with requirements of section 1851(h) (relating to marketing material and application forms) with respect to this part in the same manner as such requirements apply under part C, except that the provisions of paragraph (4)(A) of such section shall not apply with respect to discounts or rebates provided in accordance with this part.

''(c) INCENTIVES FOR COST AND UTILIZATION MANAGEMENT AND QUALITY IMPROVEMENT.—

''(1) IN GENERAL.—The Secretary shall include in a contract awarded under subsection (b) with a pharmacy contractor such incentives for cost and utilization management and quality improvement as the Secretary may deem appropriate. The contract may provide financial or other

incentives to encourage greater savings to the program under this part.

''(2) PERFORMANCE STANDARDS.—The Secretary shall provide for performance standards (which may include monetary bonuses if the standards are met and penalties if the standards are not met), including standards relating to the time taken to answer member and pharmacy inquiries (written or by telephone), the accuracy of responses, claims processing accuracy, online system availability, appeal procedure turnaround time, system availability, the accuracy and timeliness of reports, and level of beneficiary satisfaction.

''(3) OTHER INCENTIVES.—Such incentives under this subsection may also include—

''(A) financial incentives under which savings derived from the substitution of generic and other preferred multi-source medicines in lieu of nongeneric and nonpreferred medicines are made available to pharmacy contractors, pharmacies, beneficiaries, and the Federal Medicare Prescription Medicine Trust Fund; and

''(B) any other incentive that the Secretary deems appropriate and likely to be effective in managing costs or utilization or improving quality that does not reduce the access of beneficiaries to medically necessary covered outpatient medicines.

''(4) REQUIREMENTS FOR PROCEDURES.—

''(A) IN GENERAL.—The Secretary shall establish procedures for making payments to each pharmacy contractor with a contract under this part for the administration of the benefits under this part. The procedures shall provide for the following:

''(i) ADMINISTRATIVE PAYMENT.—Payment of administrative fees for such administration.

''(ii) RISK REQUIREMENT.—An adjustment of a percentage (determined under subparagraph (B)) of the administrative fee payments made to a pharmacy contractor to ensure that the contractor, in

administering the benefits under this part, pursues performance requirements established by the Secretary, including the following:

"(I) QUALITY SERVICE.—The contractor provides eligible beneficiaries for whom it administers benefits with quality services, as measured by such factors as sustained pharmacy network access, timeliness and accuracy of service delivery in claims processing and card production, pharmacy and member service support access, and timely action with regard to appeals and current beneficiary service surveys.

"(II) QUALITY CLINICAL CARE.—The contractor provides such beneficiaries with quality clinical care, as measured by such factors as providing notification to such beneficiaries and to providers in order to prevent adverse drug reactions and reduce medication errors and specific clinical suggestions to improve health and patient and prescriber education as appropriate.

"(III) CONTROL OF MEDICARE COSTS.—The contractor contains costs under this part to the Federal Medicare Prescription Medicine Trust Fund and enrollees, as measured by generic substitution rates, price discounts, and other factors determined appropriate by the Secretary that do not reduce the access of beneficiaries to medically necessary covered outpatient prescription medicines.

"(B) PERCENTAGE OF PAYMENT TIED TO RISK.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary shall determine the percentage of the administrative payments to a pharmacy contractor that will be tied to the performance requirements described in subparagraph (A)(ii).

"(ii) LIMITATION ON RISK TO ENSURE PROGRAM STABILITY.—In order to provide for program stability, the Secretary may not establish a percentage to be adjusted under this paragraph at a level that jeopardizes the ability of a pharmacy contractor to administer the benefits under this part or administer such benefits in a quality manner.

"(C) RISK ADJUSTMENT OF PAYMENTS BASED ON ENROLLEES IN PLAN.—To the extent that a pharmacy contractor is at risk under this paragraph, the procedures established under this paragraph may include a methodology for risk adjusting the payments made to such contractor based on the differences in actuarial risk of different enrollees being served if the Secretary determines such adjustments to be necessary and appropriate.

"(d) AUTHORITY RELATING TO PHARMACY PARTICIPATION.—

"(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, a pharmacy contractor may establish consistent with this part conditions for the participation of pharmacies, including conditions relating to quality (including reduction of medical errors) and technology.

"(2) AGREEMENTS WITH PHARMACIES.—Each pharmacy contractor shall enter into a participation agreement with any pharmacy that meets the requirements of this subsection and section 1859E to furnish covered outpatient prescription medicines to individuals enrolled under this part.

"(3) TERMS OF AGREEMENT.—An agreement under this subsection shall include the following terms and conditions:

"(A) APPLICABLE REQUIREMENTS.—The pharmacy shall meet (and throughout the contract period continue to meet) all applicable Federal requirements and State and local licensing requirements.

"(B) ACCESS AND QUALITY STANDARDS.—The pharmacy shall comply with such standards as the Secretary (and such a pharmacy contractor) shall establish concerning the quality of, and enrolled individuals' access to, pharmacy services under this part. Such standards shall require the pharmacy—

"(i) not to refuse to dispense covered outpatient prescription medicines to any individual enrolled under this part;

"(ii) to keep patient records (including records on expenses) for all covered outpatient prescription medicines dispensed to such enrolled individuals;

"(iii) to submit information (in a manner specified by the Secretary to be necessary to administer this part) on all purchases of such medicines dispensed to such enrolled individuals; and

"(iv) to comply with periodic audits to assure compliance with the requirements of this part and the accuracy of information submitted.

"(C) ADHERENCE TO NEGOTIATED PRICES.—(i) The total charge for each medicine dispensed by the pharmacy to an enrolled individual under this part, without regard to whether the individual is financially responsible for any or all of such charge, shall not exceed the price negotiated under section 1859A(a) or, if lower, negotiated under subsection (a)(5) (or, if less, the retail price for the medicine involved) with respect to such medicine plus a reasonable dispensing fee determined contractually with the pharmacy contractor.

"(ii) The pharmacy does not charge (or collect from) an enrolled individual an amount that exceeds the individual's obligation (as determined in accordance with the provisions of this part) of the applicable price described in clause (i).

"(D) ADDITIONAL REQUIREMENTS.—The pharmacy shall meet such additional contract requirements

as the applicable pharmacy contractor specifies under this section.

''(4) APPLICABILITY OF FRAUD AND ABUSE PROVISIONS.—The provisions of section 1128 through 1128C (relating to fraud and abuse) apply to pharmacies participating in the program under this part.

''ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

''SEC. 1859C. (a) ELIGIBILITY.—Each individual who is entitled to hospital insurance benefits under part A or is eligible to be enrolled in the medical insurance program under part B is eligible to enroll in accordance with this section for outpatient prescription medicine benefits under this part.

''(b) VOLUNTARY ENROLLMENT.—

''(1) IN GENERAL.—An individual may enroll under this part only in such manner and form as may be prescribed by regulations, and only during an enrollment period prescribed in or under this subsection.

''(2) INITIAL ENROLLMENT PERIOD.—

''(A) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who satisfies subsection (a) as of November 1, 2005, the initial general enrollment period shall begin on August 1, 2005, and shall end on March 1, 2006.

''(B) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who first satisfies subsection (a) on or after November 1, 2005, the individual's initial enrollment period shall begin on the first day of the third month before the month in which such individual first satisfies such paragraph and shall end seven months later. The Secretary shall apply rules similar to the rule described in the second sentence of section 1837(d).

''(3) SPECIAL ENROLLMENT PERIODS (WITHOUT PREMIUM PENALTY).—

''(A) EMPLOYER COVERAGE AT TIME OF INITIAL GENERAL ENROLLMENT PERIOD.—In the case of an individual who—

"(i) at the time the individual first satisfies subsection (a) is enrolled in a group health plan (including continuation coverage) that provides outpatient prescription medicine coverage by reason of the individual's (or the individual's spouse's) current (or, in the case of continuation coverage, former) employment status, and

"(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual's initial enrollment period,

there shall be a special enrollment period of 6 months beginning with the first month that includes the date of the individual's (or individual's spouse's) retirement from or termination of current employment status with the employer that sponsors the plan, or, in the case of continuation coverage, that includes the date of termination of such coverage, or that includes the date the plan substantially terminates outpatient prescription medicine coverage.

"(B) DROPPING OF RETIREE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who—

"(i) at the time the individual first satisfies subsection (a) is enrolled in a group health plan that provides outpatient prescription medicine coverage other than by reason of the individual's (or the individual's spouse's) current employment; and

"(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual's initial enrollment period,

there shall be a special enrollment period of 6 months beginning with the first month that includes the date that the plan substantially terminates outpatient prescription medicine coverage and ending 6 months later.

"(C) LOSS OF MEDICARE+CHOICE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who is enrolled under part C in a Medicare+Choice plan that provides prescription medicine benefits, if

such enrollment is terminated because of the termination or reduction in service area of the plan, there shall be a special enrollment period of 6 months beginning with the first month that includes the date that such plan is terminated or such reduction occurs and ending 6 months later.

"(D) LOSS OF MEDICAID PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who—

"(i) satisfies subsection (a);

"(ii) loses eligibility for benefits (that include benefits for prescription medicine) under a State plan after having been enrolled (or determined to be eligible) for such benefits under such plan; and

"(iii) is not otherwise enrolled under this subsection at the time of such loss of eligibility,

there shall be a special enrollment period specified by the Secretary of not less than 6 months beginning with the first month that includes the date that the individual loses such eligibility.

"(4) LATE ENROLLMENT WITH PREMIUM PENALTY.—The Secretary shall permit an individual who satisfies subsection (a) to enroll other than during the initial enrollment period under paragraph (2) or a special enrollment period under paragraph (3). But, in the case of such an enrollment, the amount of the monthly premium of the individual is subject to an increase under section 1859C(e)(1).

"(5) INFORMATION.—

"(A) IN GENERAL.—The Secretary shall broadly distribute information to individuals who satisfy subsection (a) on the benefits provided under this part. The Secretary shall periodically make available information on the cost differentials to enrollees for the use of generic medicines and other medicines.

"(B) TOLL-FREE HOTLINE.—The Secretary shall maintain a toll-free telephone hotline (which may be a hotline already used by the Secretary under this title) for purposes of providing assistance to beneficiaries in

the program under this part, including responding to questions concerning coverage, enrollment, benefits, grievances and appeals procedures, and other aspects of such program.

"(6) ENROLLEE DEFINED.—For purposes of this part, the term 'enrollee' means an individual enrolled for benefits under this part.

"(c) COVERAGE PERIOD.—

"(1) IN GENERAL.—The period during which an individual is entitled to benefits under this part (in this subsection referred to as the individual's 'coverage period') shall begin on such a date as the Secretary shall establish consistent with the type of coverage rules described in subsections (a) and (e) of section 1838, except that in no case shall a coverage period begin before January 1, 2006. No payments may be made under this part with respect to the expenses of an individual unless such expenses were incurred by such individual during a period which, with respect to the individual, is a coverage period.

"(2) TERMINATION.—The Secretary shall provide for the application of provisions under this subsection similar to the provisions in section 1838(b).

"(d) PROVISION OF BENEFITS TO MEDICARE+CHOICE ENROLLEES.—In the case of an individual who is enrolled under this part and is enrolled in a Medicare+Choice plan under part C, the individual shall be provided the benefits under this part through such plan and not through payment under this part.

"(e) LATE ENROLLMENT PENALTIES; PAYMENT OF PREMIUMS.—

"(1) LATE ENROLLMENT PENALTY.—

"(A) IN GENERAL.—In the case of a late enrollment described in subsection (b)(4), subject to the succeeding provisions of this paragraph, the Secretary shall establish procedures for increasing the amount of the monthly premium under this part applicable to

such enrollee by an amount that the Secretary determines is actuarially sound for each such period.

"(B) PERIODS TAKEN INTO ACCOUNT.—For purposes of calculating any 12-month period under subparagraph (A), there shall be taken into account months of lapsed coverage in a manner comparable to that applicable under the second sentence of section 1839(b).

"(C) PERIODS NOT TAKEN INTO ACCOUNT.—

"(i) IN GENERAL.—For purposes of calculating any 12-month period under subparagraph (A), subject to clause (ii), there shall not be taken into account months for which the enrollee can demonstrate that the enrollee was covered under a group health plan that provides coverage of the cost of prescription medicines whose actuarial value (as defined by the Secretary) to the enrollee equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription medicine benefit program under this part.

"(ii) APPLICATION.—This subparagraph shall only apply with respect to a coverage period the enrollment for which occurs before the end of the 60-day period that begins on the first day of the month which includes the date on which the plan terminates or reduces its service area (in a manner that results in termination of enrollment), ceases to provide, or reduces the value of the prescription medicine coverage under such plan to below the value of the coverage provided under the program under this part.

"(2) INCORPORATION OF PREMIUM PAYMENT AND GOVERNMENT CONTRIBUTIONS PROVISIONS.—The provisions of sections 1840 and 1844(a)(1) shall apply to enrollees under this part in the same manner as they apply to individuals 65 years of age or older enrolled under part B.

For purposes of this subsection, any reference in a section referred to in a previous subsection to the Federal Supplementary Medical Insurance Trust Fund is deemed a reference to the Federal Medicare Prescription Medicine Trust Fund.

''(f) ELECTION OF PHARMACY CONTRACTOR TO ADMINISTER BENEFITS.—The Secretary shall establish a process whereby each individual enrolled under this part and residing in a region may elect the pharmacy contractor that will administer the benefits under this part with respect to the individual. Such process shall permit the individual to make an initial election and to change such an election on at least an annual basis and under such other circumstances as the Secretary shall specify.

''PROVISION OF, AND ENTITLEMENT TO, BENEFITS

''SEC. 1859D. (a) BENEFITS.—Subject to the succeeding provisions of this section, the benefits provided to an enrollee by the program under this part shall consist of the following:

''(1) COVERED OUTPATIENT PRESCRIPTION MEDICINE BENEFITS.—Entitlement to have payment made on the individual's behalf for covered outpatient prescription medicines.

''(2) LIMITATION ON COST-SHARING FOR PART B OUTPATIENT PRESCRIPTION MEDICINES.—

''(A) IN GENERAL.—Once an enrollee has incurred aggregate countable cost-sharing (as defined in subparagraph (B)) equal to the stop-loss limit specified in subsection (c)(4) for expenses in a year, entitlement to the elimination of cost-sharing otherwise applicable under part B for additional expenses incurred in the year for outpatient prescription medicines or biologicals for which payment is made under part B.

''(B) COUNTABLE COST-SHARING DEFINED.—For purposes of this part, the term 'countable cost-sharing' means—

"(i) out-of-pocket expenses for outpatient prescription medicines with respect to which benefits are payable under part B, and

"(ii) cost-sharing under subsections (c)(3)(B) and (c)(3)(C)(i).

"(b) COVERED OUTPATIENT PRESCRIPTION MEDICINE DEFINED.—

"(1) IN GENERAL.—Except as provided in paragraph (2), for purposes of this part the term 'covered outpatient prescription medicine' means any of the following products:

"(A) A medicine which may be dispensed only upon prescription, and—

"(i) which is approved for safety and effectiveness as a prescription medicine under section 505 of the Federal Food, Drug, and Cosmetic Act;

"(ii)(I) which was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and (II) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal

Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such medicine under such section because the Secretary has determined that the medicine is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

''(B) A biological product which—

''(i) may only be dispensed upon prescription;

''(ii) is licensed under section 351 of the Public Health Service Act; and

''(iii) is produced at an establishment licensed under such section to produce such product.

''(C) Insulin approved under appropriate Federal law, and needles, syringes, and disposable pumps for the administration of such insulin.

''(D) A prescribed medicine or biological product that would meet the requirements of subparagraph (A) or (B) but that is available over-the-counter in addition to being available upon prescription, but only if the particular dosage form or strength prescribed and required for the individual is not available over-the-counter.

''(E) Smoking cessation agents (as specified by the Secretary).

''(2) EXCLUSION.—The term 'covered outpatient prescription medicine' does not include—

''(A) medicines or classes of medicines, 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), as the Secretary may specify and does not include such other medicines, classes, and uses as the Secretary may specify consistent with the goals of providing quality care and containing costs under this part;

"(B) except as provided in paragraphs (1)(D) and (1)(E), any product which may be distributed to individuals without a prescription;

"(C) any product when furnished as part of, or as incident to, a diagnostic service or any other item or service for which payment may be made under this title; or

"(D) any product that is covered under part B of this title.

"(c) PAYMENT OF BENEFITS.—

"(1) COVERED OUTPATIENT PRESCRIPTION MEDICINES.—There shall be paid from the Federal Medicare Prescription Medicine Trust Fund, in the case of each enrollee who incurs expenses for medicines with respect to which benefits are payable under this part under subsection (a)(1), amounts equal to the sum of—

"(A) the price for which the medicine is made available under this part (consistent with sections 1859A and 1859B), reduced by any applicable cost-sharing under paragraphs (2) and (3); and

"(B) a reasonable dispensing fee.

The price under subparagraph (A) shall in no case exceed the retail price for the medicine involved.

"(2) DEDUCTIBLE.—The amount of payment under paragraph (1) for expenses incurred in a year, beginning with 2006, shall be reduced by an annual deductible equal to the amount specified in section 1859(2) (subject to adjustment under paragraph (8)). Only expenses for countable cost-sharing (as defined in subsection (a)(2)(B)) shall be taken into account in applying this paragraph.

"(3) COINSURANCE.—

"(A) IN GENERAL.—The amount of payment under paragraph (1) for expenses incurred in a year shall be further reduced (subject to the stop-loss limit under paragraph (4)) by coinsurance as provided under this paragraph.

"(B) PREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a preferred medicine (including a medicine treated as a preferred medicine under paragraph (5)), is equal to 20 percent of the price applicable under paragraph (1)(A) (or such lower percentage as may be provided for under section 1859E(a)(1)(A)(ii)). In this part, the term 'preferred medicine' means, with respect to medicines classified within a therapeutic class, those medicines which have been designated as a preferred medicine by the Secretary or the pharmacy contractor involved with respect to that class and (in the case of a nongeneric medicine) with respect to which a contract has been negotiated under this part.

"(C) NONPREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a nonpreferred medicine that is not treated as a preferred medicine under paragraph (5) is equal to the sum of—

"(i) 20 percent of the price for lowest price preferred medicine that is within the same therapeutic class; and

"(ii) the amount by which—

"(I) the price at which the nonpreferred medicine is made available to the enrollee; exceeds

"(II) the price of such lowest price preferred medicine.

"(4) NO COINSURANCE ONCE OUT-OF-POCKET EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an enrollee has incurred aggregate countable cost-sharing under paragraph (3) (including cost-sharing under part B attributable to outpatient prescription drugs or biologicals) equal to the amount specified in section 1859(4) (subject to adjustment under paragraph (8)) for expenses in a year—

"(A) there shall be no coinsurance under paragraph (3) for additional expenses incurred in the year involved; and

"(B) there shall be no coinsurance under part B for additional expenses incurred in the year involved for outpatient prescription drugs and biologicals.

"(5) APPEALS RIGHTS RELATING TO COVERAGE OF NONPREFERRED MEDICINES.—

"(A) PROCEDURES REGARDING THE DETERMINATION OF MEDICINES THAT ARE MEDICALLY NECESSARY.—Each pharmacy contractor shall have in place procedures on a case-by-case basis to treat a nonpreferred medicine as a preferred medicine under this part if the preferred medicine is determined to be not as effective for the enrollee or to have significant adverse effect on the enrollee. Such procedures shall require that such determinations are based on professional medical judgment, the medical condition of the enrollee, and other medical evidence.

"(B) PROCEDURES REGARDING DENIALS OF CARE.—Such contractor shall have in place procedures to ensure—

"(i) a timely internal review for resolution of denials of coverage (in whole or in part and including those regarding the coverage of nonpreferred medicines) in accordance with the medical exigencies of the case and a timely resolution of complaints, by enrollees in the plan, or by providers, pharmacists, and other individuals acting on behalf of each such enrollee (with the enrollee's consent) in accordance with requirements (as established by the Secretary) that are comparable to such requirements for Medicare+Choice organizations under part C;

"(ii) that the entity complies in a timely manner with requirements established by the Secretary that (I) provide for an external review by an independent entity selected by the Secretary of denials of coverage described in clause (i) not resolved in the favor of the beneficiary (or other complainant)

under the process described in such clause and (II) are comparable to the external review requirements established for Medicare+Choice organizations under part C; and

"(iii) that enrollees are provided with information regarding the appeals procedures under this part at the time of enrollment with a pharmacy contractor under this part and upon request thereafter.

"(6) TRANSFER OF FUNDS TO COVER COSTS OF PART B PRESCRIPTION MEDICINE CATASTROPHIC BENEFIT.—With respect to benefits described in subsection (a)(2), there shall transferred from the Federal Medicare Prescription Medicine Trust Fund to the Federal Supplementary Medical Insurance Trust Fund amounts equivalent to the elimination of cost-sharing described in such subsection.

"(7) PERMITTING APPLICATION UNDER PART B OF NEGOTIATED PRICES.—For purposes of making payment under part B for medicines that would be covered outpatient prescription medicines but for the exclusion under subparagraph (B) or (C) of subsection (b)(2), the Secretary may elect to apply the payment basis used for payment of covered outpatient prescription medicines under this part instead of the payment basis otherwise used under such part, if it results in a lower cost to the program.

"(8) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—With respect to expenses incurred in a year after 2006—

"(i) the deductible under paragraph (2) is equal to the deductible determined under such paragraph (or this subparagraph) for the previous year increased by the percentage increase in per capita program expenditures (as estimated in advance for the year involved under subparagraph (B)); and

"(ii) the stop-loss limit under paragraph (3) is equal to the stop-loss limit determined under such

paragraph (or this subparagraph) for the previous year increased by such percentage increase.

The Secretary shall adjust such percentage increase in subsequent years to take into account misestimations made of the per capita program expenditures under clauses (i) and (ii) in previous years. Any increase under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(B) ESTIMATION OF INCREASE IN PER CAPITA PROGRAM EXPENDITURES.—The Secretary shall before the beginning of each year (beginning with 2007) estimate the percentage increase in average per capita aggregate expenditures from the Federal Medicare Prescription Medicine Trust Fund for the year involved compared to the previous year.

''(C) RECONCILIATION.—The Secretary shall also compute (beginning with 2008) the actual percentage increase in such aggregate expenditures in order to provide for reconciliation of deductibles, stop-loss limits, and premiums under the second sentence of subparagraph (A) and under section 1859D(d)(2).

''(d) AMOUNT OF PREMIUMS.—

''(1) MONTHLY PREMIUM RATE IN 2006.—The monthly premium rate in 2006 for prescription medicine benefits under this part is the amount specified in section 1859(1).

''(2) INFLATION ADJUSTMENT FOR SUBSEQUENT YEARS.—The monthly premium rate for a year after 2006 for prescription medicine benefits under this part is equal to the monthly premium rate for the previous year under this subsection increased by the percentage increase in per capita program expenditures (as estimated in advance for the year involved under subsection (c)(8)(B)). The Secretary shall adjust such percentage in subsequent years to take into account misestimations made of the per capita program expenditures under the previous sentence in previous years. Any increase under this paragraph that is not

a multiple of $1 shall be rounded to the nearest multiple of $1.

"ADMINISTRATION; QUALITY ASSURANCE

"SEC. 1859E. (a) RULES RELATING TO PROVISION OF BENEFITS.—

"(1) PROVISION OF BENEFITS.—

"(A) IN GENERAL.—In providing benefits under this part, the Secretary (directly or through the contracts with pharmacy contractors) shall employ mechanisms to provide benefits appropriately and efficiently, and those mechanisms may include—

"(i) the use of—

"(I) price negotiations (consistent with subsection (b));

"(II) reduced coinsurance (below 20 percent) to encourage the utilization of appropriate preferred medicines; and

"(III) methods to reduce medication errors and encourage appropriate use of medications; and

"(ii) permitting pharmacy contractors, as approved by the Secretary, to make exceptions to section 1859D(c)(3)(C) (relating to cost-sharing for non-preferred medicines) to secure best prices for enrollees so long as the payment amount under section 1859D(c)(1) does not equal zero.

"(B) CONSTRUCTION.—Nothing in this subsection shall be construed to prevent the Secretary (directly or through the contracts with pharmacy contractors) from using incentives to encourage enrollees to select generic or other cost-effective medicines, so long as—

"(i) such incentives are designed not to result in any increase in the aggregate expenditures under the Federal Medicare Prescription Medicine Trust Fund; and

"(ii) a beneficiary's coinsurance shall be no greater than 20 percent in the case of a preferred

medicine (including a nonpreferred medicine treated as a preferred medicine under section 1859D(c)(5)).

''(2) CONSTRUCTION.—Nothing in this part shall preclude the Secretary or a pharmacy contractor from—

''(A) educating prescribing providers, pharmacists, and enrollees about medical and cost benefits of preferred medicines;

''(B) requesting prescribing providers to consider a preferred medicine prior to dispensing of a nonpreferred medicine, as long as such request does not unduly delay the provision of the medicine;

''(C) using mechanisms to encourage enrollees under this part to select cost-effective medicines or less costly means of receiving or administering medicines, including the use of therapeutic interchange programs, disease management programs, and notification to the beneficiary that a more affordable generic medicine equivalent was not selected by the prescribing provider and a statement of the lost cost savings to the beneficiary;

''(D) using price negotiations to achieve reduced prices on covered outpatient prescription medicines, including new medicines, medicines for which there are few therapeutic alternatives, and medicines of particular clinical importance to individuals enrolled under this part; and

''(E) utilizing information on medicine prices of OECD countries and of other payors in the United States in the negotiation of prices under this part.

''(b) PRICE NEGOTIATIONS PROCESS.—

''(1) REQUIREMENTS WITH RESPECT TO PREFERRED MEDICINES.—Negotiations of contracts with manufacturers with respect to covered outpatient prescription medicines under this part shall be conducted in a manner so that—

''(A) there is at least a contract for a medicine within each therapeutic class (as defined by the Sec-

retary in consultation with such Medicare Prescription Medicine Advisory Committee);

"(B) if there is more than 1 medicine available in a therapeutic class, there are contracts for at least 2 medicines within such class unless determined clinically inappropriate in accordance with standards established by the Secretary; and

"(C) if there are more than 2 medicines available in a therapeutic class, there is a contract for at least 2 medicines within such class and a contract for generic medicine substitute if available unless determined clinically inappropriate in accordance with standards established by the Secretary.

"(2) ESTABLISHMENT OF THERAPEUTIC CLASSES.—The Secretary, in consultation with the Medicare Prescription Medicine Advisory Committee (established under section 1859H), shall establish for purposes of this part therapeutic classes and assign to such classes covered outpatient prescription medicines.

"(3) DISCLOSURE CONCERNING PREFERRED MEDICINES.—The Secretary shall provide, through pharmacy contractors or otherwise, for—

"(A) disclosure to current and prospective enrollees and to participating providers and pharmacies in each service area a list of the preferred medicines and differences in applicable cost-sharing between such medicines and nonpreferred medicines; and

"(B) advance disclosure to current enrollees and to participating providers and pharmacies in each service area of changes to any such list of preferred medicines and differences in applicable cost-sharing.

"(4) NO REVIEW.—The Secretary's establishment of therapeutic classes and the assignment of medicines to such classes and the Secretary's determination of what is a breakthrough medicine are not subject to administrative or judicial review.

''(c) CONFIDENTIALITY.—The Secretary shall ensure that the confidentiality of individually identifiable health information relating to the provision of benefits under this part is protected, consistent with the standards for the privacy of such information promulgated by the Secretary under the Health Insurance Portability and Accountability Act of 1996, or any subsequent comprehensive and more protective set of confidentiality standards enacted into law or promulgated by the Secretary. Nothing in this subsection shall be construed as preventing the coordination of data with a State prescription medicine program so long as such program has in place confidentiality standards that are equal to or exceed the standards used by the Secretary.

''(d) FRAUD AND ABUSE SAFEGUARDS.—The Secretary, through the Office of the Inspector General, is authorized and directed to issue regulations establishing appropriate safeguards to prevent fraud and abuse under this part. Such safeguards, at a minimum, should include compliance programs, certification data, audits, and recordkeeping practices. In developing such regulations, the Secretary shall consult with the Attorney General and other law enforcement and regulatory agencies.

''FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST FUND

''SEC. 1859F. (a) ESTABLISHMENT.—There is hereby created on the books of the Treasury of the United States a trust fund to be known as the 'Federal Medicare Prescription Medicine 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.

''(b) APPLICATION OF SMI TRUST FUND PROVISIONS.—The provisions of subsections (b) through (i) of section 1841 shall apply to this part and the Trust Fund in the same manner as they apply to part B and the Federal Supplementary Medical Insurance Trust Fund, respectively.

''COMPENSATION FOR EMPLOYERS COVERING RETIREE MEDICINE COSTS

''SEC. 1859G. (a) IN GENERAL.—In the case of an individual who is eligible to be enrolled under this part and is a participant or beneficiary under a group health plan that provides outpatient prescription medicine coverage to retirees the actuarial value of which is not less than the actuarial value of the coverage provided under this part, the Secretary shall make payments to such plan subject to the provisions of this section. Such payments shall be treated as payments under this part for purposes of sections 1859F and 1859C(e)(2). In applying the previous sentence with respect to section 1859C(e)(2), the amount of the Government contribution referred to in section 1844(a)(1)(A) is deemed to be equal to the aggregate amount of the payments made under this section.

''(b) REQUIREMENTS.—To receive payment under this section, a group health plan shall comply with the following requirements:

''(1) COMPLIANCE WITH REQUIREMENTS.—The group health plan shall comply with the requirements of this Act and other reasonable, necessary, and related requirements that are needed to administer this section, as determined by the Secretary.

''(2) ANNUAL ASSURANCES AND NOTICE BEFORE TERMINATION.—The sponsor of the plan shall—

''(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered under the group health plan meets the requirements of this section and will continue to meet such requirements for the duration of the sponsor's participation in the program under this section; and

''(B) guarantee that it will give notice to the Secretary and covered enrollees—

''(i) at least 120 days before terminating its plan, and

''(ii) immediately upon determining that the actuarial value of the prescription medicine benefit

under the plan falls below the actuarial value required under subsection (a).

"(3) BENEFICIARY INFORMATION.—The sponsor of the plan shall report to the Secretary, for each calendar quarter for which it seeks a payment under this section, the names and social security numbers of all enrollees described in subsection (a) covered under such plan during such quarter and the dates (if less than the full quarter) during which each such individual was covered.

"(4) AUDITS.—The sponsor or plan seeking payment under this section shall agree to maintain, and to afford the Secretary access to, such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription medicine coverage, the accuracy of payments made, and such other matters as may be appropriate.

"(c) PAYMENT.—

"(1) IN GENERAL.—The sponsor of a group health plan that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall be entitled to have payment made on a quarterly basis of the amount specified in paragraph (2) for each individual described in subsection (a) who during the quarter is covered under the plan and was not enrolled in the insurance program under this part.

"(2) AMOUNT OF PAYMENT.—

"(A) IN GENERAL.—The amount of the payment for a quarter shall approximate, for each such covered individual, ⅔ of the sum of the monthly Government contribution amounts (computed under subparagraph (B)) for each of the 3 months in the quarter.

"(B) COMPUTATION OF MONTHLY GOVERNMENT CONTRIBUTION AMOUNT.—For purposes of subparagraph (A), the monthly Government contribution amount for a month in a year is equal to the amount by which—

"(i) 1/12 of the average per capita aggregate expenditures, as estimated under section 1859D(c)(8) for the year involved; exceeds

"(ii) the monthly premium rate under section 1859D(d) for the month involved.

"MEDICARE PRESCRIPTION MEDICINE ADVISORY COMMITTEE

"SEC. 1859H. (a) ESTABLISHMENT OF COMMITTEE.—There is established a Medicare Prescription Medicine Advisory Committee (in this section referred to as the 'Committee').

"(b) FUNCTIONS OF COMMITTEE.—The Committee shall advise the Secretary on policies related to—

"(1) the development of guidelines for the implementation and administration of the outpatient prescription medicine benefit program under this part; and

"(2) the development of—

"(A) standards required of pharmacy contractors under section 1859D(c)(5) for determining if a medicine is as effective for an enrollee or has a significant adverse effect on an enrollee under this part;

"(B) standards for—

"(i) defining therapeutic classes;

"(ii) adding new therapeutic classes;

"(iii) assigning to such classes covered outpatient prescription medicines; and

"(iv) identifying breakthrough medicines;

"(C) procedures to evaluate the bids submitted by pharmacy contractors under this part;

"(D) procedures for negotiations, and standards for entering into contracts, with manufacturers, including identifying medicines or classes of medicines where Secretarial negotiation is most likely to yield savings under this part significantly above those that which could be achieved by a pharmacy contractor; and

"(E) procedures to ensure that pharmacy contractors with a contract under this part are in compliance with the requirements under this part.

For purposes of this part, a medicine is a 'breakthrough medicine' if the Secretary, in consultation with the Committee, determines it is a new product that will make a significant and major improvement by reducing physical or mental illness, reducing mortality, or reducing disability, and that no other product is available to beneficiaries that achieves similar results for the same condition. The Committee may consider cost-effectiveness in establishing standards for defining therapeutic classes and assigning drugs to such classes under subparagraph (B).

''(c) STRUCTURE AND MEMBERSHIP OF THE COMMITTEE.—

''(1) STRUCTURE.—The Committee shall be composed of 19 members who shall be appointed by the Secretary.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The members of the Committee shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education, experience, and attainments, exceptionally qualified to perform the duties of members of the Committee.

''(B) SPECIFIC MEMBERS.—Of the members appointed under paragraph (1)—

''(i) 5 shall be chosen to represent practicing physicians, 2 of whom shall be gerontologists;

''(ii) 2 shall be chosen to represent practicing nurse practitioners;

''(iii) 4 shall be chosen to represent practicing pharmacists;

''(iv) 1 shall be chosen to represent the Centers for Medicare & Medicaid Services;

''(v) 4 shall be chosen to represent actuaries, pharmacoeconomists, researchers, and other appropriate experts;

''(vi) 1 shall be chosen to represent emerging medicine technologies;

"(vii) 1 shall be chosen to represent the Food and Drug Administration; and

"(viii) 1 shall be chosen to represent individuals enrolled under this part.

"(d) TERMS OF APPOINTMENT.—Each member of the Committee shall serve for a term determined appropriate by the Secretary. The terms of service of the members initially appointed shall begin on January 1, 2005.

"(e) CHAIRPERSON.—The Secretary shall designate a member of the Committee as Chairperson. The term as Chairperson shall be for a 1-year period.

"(f) COMMITTEE PERSONNEL MATTERS.—

"(1) MEMBERS.—

"(A) COMPENSATION.—Each member of the Committee who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee. All members of the Committee who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

"(B) TRAVEL EXPENSES.—The members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Committee.

"(2) STAFF.—The Committee may appoint such personnel as the Committee considers appropriate.

"(g) OPERATION OF THE COMMITTEE.—

''(1) MEETINGS.—The Committee shall meet at the call of the Chairperson (after consultation with the other members of the Committee) not less often than quarterly to consider a specific agenda of issues, as determined by the Chairperson after such consultation.

''(2) QUORUM.—Ten members of the Committee shall constitute a quorum for purposes of conducting business.

''(h) FEDERAL ADVISORY COMMITTEE ACT.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Committee.

''(i) TRANSFER OF PERSONNEL, RESOURCES, AND ASSETS.—For purposes of carrying out its duties, the Secretary and the Committee may provide for the transfer to the Committee of such civil service personnel in the employ of the Department of Health and Human Services (including the Centers for Medicare & Medicaid Services), and such resources and assets of the Department used in carrying out this title, as the Committee requires.

''(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out the purposes of this section.''.

(b) APPLICATION OF GENERAL EXCLUSIONS FROM COVERAGE.—

(1) APPLICATION TO PART D.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended in the matter preceding paragraph (1) by striking ''part A or part B'' and inserting ''part A, B, or D''.

(2) PRESCRIPTION MEDICINES NOT EXCLUDED FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is amended—

(A) in subparagraph (H), by striking ''and'' at the end;

(B) in subparagraph (I), by striking the semicolon at the end and inserting '', and''; and

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

"(J) in the case of prescription medicines covered under part D, which are not prescribed in accordance with such part;".

(c) CONFORMING AMENDMENTS.—(1) Part C of title XVIII is amended—

(A) in section 1851(a)(2)(B) (42 U.S.C. 1395w–21(a)(2)(B)), by striking "1859(b)(3)" and inserting "1858(b)(3)";

(B) in section 1851(a)(2)(C) (42 U.S.C. 1395w–21(a)(2)(C)), by striking "1859(b)(2)" and inserting "1858(b)(2)";

(C) in section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)), by striking "1859(b)(3)" and inserting "1858(b)(3)";

(D) in section 1852(a)(3)(B)(ii) (42 U.S.C. 1395w–22(a)(3)(B)(ii)), by striking "1859(b)(2)(B)" and inserting "1858(b)(2)(B)";

(E) in section 1853(a)(1)(A) (42 U.S.C. 1395w–23(a)(1)(A)), by striking "1859(e)(4)" and inserting "1858(e)(4)"; and

(F) in section 1853(a)(3)(D) (42 U.S.C. 1395w–23(a)(3)(D)), by striking "1859(e)(4)" and inserting "1858(e)(4)".

(2) Section 1171(a)(5)(D) (42 U.S.C. 1320d(a)(5)(D)) is amended by striking "or (C)" and inserting "(C), or (D)".

SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRESCRIPTION MEDICINE COVERAGE UNDER THE MEDICARE+CHOICE PROGRAM.

(a) REQUIRING AVAILABILITY OF AN ACTUARIALLY EQUIVALENT PRESCRIPTION MEDICINE BENEFIT.—Section 1851 (42 U.S.C. 1395w–21) is amended by adding at the end the following new subsection:

"(j) AVAILABILITY OF PRESCRIPTION MEDICINE BENEFITS.—

"(1) IN GENERAL.—Notwithstanding any other provision of this part, each Medicare+Choice organization that makes available a Medicare+Choice plan described in sec-

tion 1851(a)(2)(A) shall make available such a plan that offers coverage of covered outpatient prescription medicines that is at least actuarially equivalent to the benefits provided under part D. Information respecting such benefits shall be made available in the same manner as information on other benefits provided under this part is made available. Nothing in this paragraph shall be construed as requiring the offering of such coverage separate from coverage that includes benefits under parts A and B.

''(2) TREATMENT OF PRESCRIPTION MEDICINE ENROLLEES.—In the case of a Medicare+Choice eligible individual who is enrolled under part D, the benefits described in paragraph (1) shall be treated in the same manner as benefits described in part B for purposes of coverage and payment and any reference in this part to the Federal Supplementary Medical Insurance Trust Fund shall be deemed, with respect to such benefits, to be a reference to the Federal Medicare Prescription Medicine Trust Fund.''.

(b) APPLICATION OF QUALITY STANDARDS.—Section 1852(e)(2)(A) (42 U.S.C. 1395w–22(e)(2)(A)) is amended—

(1) by striking ''and'' at the end of clause (xi);

(2) by striking the period at the end of clause (xii) and inserting '', and''; and

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

''(xiii) comply with the standards, and apply the programs, under section 1859B(b) for covered outpatient prescription medicines under the plan.''.

(c) PAYMENT SEPARATE FROM PAYMENT FOR PART A AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w–23) is amended—

(1) in subsection (a)(1)(A), by striking ''and (i)'' and inserting ''(i), and (j)''; and

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

''(j) PAYMENT FOR PRESCRIPTION MEDICINE COVERAGE OPTION.—

''(1) IN GENERAL.—In the case of a Medicare+Choice plan that provides prescription medicine benefits described

in section 1851(j)(1), the amount of payment otherwise made to the Medicare+Choice organization offering the plan shall be increased by the amount described in paragraph (2). Such payments shall be made in the same manner and time as the amount otherwise paid, but such amount shall be payable from the Federal Medicare Prescription Medicine Trust Fund.

''(2) AMOUNT.—The amount described in this paragraph is the monthly Government contribution amount computed under section 1859G(c)(2)(B), but subject to adjustment under paragraph (3). Such amount shall be uniform geographically and shall not vary based on the Medicare+Choice payment area involved.

''(3) RISK ADJUSTMENT.—The Secretary shall establish a methodology for the adjustment of the payment amount under this subsection in a manner that takes into account the relative risks for use of outpatient prescription medicines by Medicare+Choice enrollees. Such methodology shall be designed in a manner so that the total payments under this title (including part D) are not changed as a result of the application of such methodology.''.

(d) SEPARATE APPLICATION OF ADJUSTED COMMUNITY RATE (ACR).—Section 1854 (42 U.S.C. 1395w–24) is amended by adding at the end the following:

''(i) APPLICATION TO PRESCRIPTION MEDICINE COVERAGE.—The Secretary shall apply the previous provisions of this section (including the computation of the adjusted community rate) separately with respect to prescription medicine benefits described in section 1851(j)(1).''.

(f) CONFORMING AMENDMENTS.—

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

(A) in subsection (a)(1)(A), by striking ''parts A and B'' and inserting ''parts A, B, and D''; and

(B) in subsection (i) by inserting ''(and, if applicable, part D)'' after ''parts A and B''.

(2) Section 1852(a)(1)(A) (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting ''(and under part D

to individuals also enrolled under such part)'' after ''parts A and B''.

(3) Section 1852(d)(1) (42 U.S.C. 1395w–22(d)(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:

''(F) the plan for part D benefits guarantees coverage of any specifically named prescription medicine for an enrollee to the extent that it would be required to be covered under part D.

In carrying out subparagraph (F), a Medicare+Choice organization has the same authority to enter into contracts with respect to coverage of preferred medicines as the Secretary has under part D, but subject to an independent contractor appeal or other appeal process that would be applicable to determinations by such a pharmacy contractor consistent with section 1859D(e)(5).''.

(e) LIMITATION ON COST-SHARING.—Section 1854(e) (42 U.S.C. 1395w–24(e)) is amended by adding at the end the following new paragraph:

''(5) LIMITATION ON COST-SHARING.—In no event may a Medicare+Choice organization include a requirement that an enrollee pay cost-sharing in excess of the cost-sharing otherwise permitted under part D.''.

SEC. 103. MEDIGAP REVISIONS.

(a) REQUIRED COVERAGE OF COVERED OUTPATIENT PRESCRIPTION MEDICINES.—Section 1882(p)(2)(B) (42 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before ''and'' at the end the following: ''including a requirement that an appropriate number of policies provide coverage of medicines which complements but does not duplicate the medicine benefits that beneficiaries are otherwise eligible for benefits under part D of this title (with the Secretary and the National Association of Insurance Commissioners determining the appropriate level

of medicine benefits that each benefit package must provide and ensuring that policies providing such coverage are affordable for beneficiaries;''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on January 1, 2006.

(c) TRANSITION PROVISIONS.—

(1) IN GENERAL.—If the Secretary of Health and Human Services identifies a State as requiring a change to its statutes or regulations to conform its regulatory program to the amendments made by this section, the State regulatory program shall not be considered to be out of compliance with the requirements of section 1882 of the Social Security Act due solely to failure to make such change until the date specified in paragraph (4).

(2) NAIC STANDARDS.—If, within 9 months after the date of enactment of this Act, the National Association of Insurance Commissioners (in this subsection referred to as the ''NAIC'') modifies its NAIC Model Regulation relating to section 1882 of the Social Security Act (referred to in such section as the 1991 NAIC Model Regulation, as subsequently modified) to conform to the amendments made by this section, such revised regulation incorporating the modifications shall be considered to be the applicable NAIC model regulation (including the revised NAIC model regulation and the 1991 NAIC Model Regulation) for the purposes of such section.

(3) SECRETARY STANDARDS.—If the NAIC does not make the modifications described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall make the modifications described in such paragraph and such revised regulation incorporating the modifications shall be considered to be the appropriate regulation for the purposes of such section.

(4) DATE SPECIFIED.—

(A) IN GENERAL.—Subject to subparagraph (B), the date specified in this paragraph for a State is the earlier of—

(i) the date the State changes its statutes or regulations to conform its regulatory program to the changes made by this section; or

(ii) 1 year after the date the NAIC or the Secretary first makes the modifications under paragraph (2) or (3), respectively.

(B) ADDITIONAL LEGISLATIVE ACTION REQUIRED.—In the case of a State which the Secretary identifies as—

(i) requiring State legislation (other than legislation appropriating funds) to conform its regulatory program to the changes made in this section; but

(ii) having a legislature which is not scheduled to meet in 2004 in a legislative session in which such legislation may be considered;

the date specified in this paragraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 2004. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME BENEFICIARIES.

(a) QMB COVERAGE OF PREMIUMS AND COST-SHARING.—Section 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is amended—

(1) in subparagraph (A)—

(A) by striking ''and'' at the end of clause (i),

(B) by adding ''and'' at the end of clause (ii), and

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

''(iii) premiums under section 1859D(d).'';

(2) in subparagraph (B), by inserting ''and section 1859D(c)(3)(B) and 1859D(c)(3)(C)(i)'' after ''1813''; and

(3) in subparagraph (C), by striking ''and section 1833(b)'' and inserting '', section 1833(b), and section 1859D(e)(2)''.

(b) EXPANDED SLMB ELIGIBILITY.—Section 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is amended—

(1) by striking ''and'' at the end of clause (iii);

(2) by adding ''and'' at the end of clause (iv); and

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

''(v)(I) for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) and medicare cost-sharing described in section 1905(p)(3)(B) and section 1905(p)(3)(C) but only insofar as it relates to benefits provided under part D of title XVIII, subject to section 1905(p)(4), for individuals (other than qualified medicare beneficiaries) who are enrolled under part D of title XVIII and are described in section 1905(p)(1)(B) or would be so described but for the fact that their income exceeds 100 percent, but is less than 150 percent, of the official poverty line (referred to in such section) for a family of the size involved;

''(II) subject to section 1905(p)(4), for individuals (other than qualified medicare beneficiaries and individuals described in subclause (I)) who are enrolled under part D of title XVIII and would be described in section 1905(p)(1)(B) but for the fact that their income exceeds 150 percent, but is less than 175 percent, of the official poverty line (referred to in such section) for a family of the size involved, for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) and medicare cost-sharing described in section 1905(p)(3)(B) and section 1905(p)(3)(C) but only insofar as it relates to benefits provided under part D of title XVIII, and the assistance for medicare cost-sharing described in section 1905(p)(3)(A)(iii) is reduced (on a sliding scale based on income) from 100 percent to 0 percent as the in-

come increases from 150 percent to 175 percent of such poverty line;''.

(c) FEDERAL FINANCING.—The third sentence of section 1905(b) (42 U.S.C. 1396d(b)) is amended by inserting before the period at the end the following: ''and with respect to amounts expended that are attributable to section 1902(a)(10)(E)(v) (other than for individuals described in section 1905(p)(1)(B))''.

(d) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—Section 1905(p) (42 U.S.C. 1396d(p)) is amended—

(A) by redesignating paragraphs (5) and (6) as paragraphs (6) and (7), respectively; and

(B) by inserting after paragraph (4) the following new paragraph:

''(5)(A) In the case of a State, other than the 50 States and the District of Columbia—

''(i) the provisions of paragraph (3) insofar as they relate to section 1859D and the provisions of section 1902(a)(10)(E)(v) shall not apply to residents of such State; and

''(ii) if the State establishes a plan described in subparagraph (B) (for providing medical assistance with respect to the provision of prescription medicines 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 subparagraph (C).

''(B) The plan described in this subparagraph is a plan that—

''(i) provides medical assistance with respect to the provision of covered outpatient medicines (as defined in section 1859D(b)) to low-income medicare beneficiaries; and

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

''(C)(i) The amount specified in this subparagraph for a State for a year is equal to the product of—

''(I) the aggregate amount specified in clause (ii); 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.

''(ii) The aggregate amount specified in this clause for—

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

''(II) a subsequent year, is equal to the aggregate amount specified in this clause for the previous year increased by annual percentage increase specified in section 1859D(c)(8)(B) for the year involved.

''(D) The Secretary shall submit to Congress a report on the application of this paragraph and may include in the report such recommendations as the Secretary deems appropriate.''.

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting ''and section 1905(p)(5)(A)(ii)'' after ''Subject to subsection (g)''.

(e) APPLICATION OF COST-SHARING.—Section 1902(n)(2) (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the following: ''The previous sentence shall not apply to medicare cost-sharing relating to benefits under part D of title XVIII.''.

(f) EFFECTIVE DATE.—The amendments made by this section apply to medical assistance for premiums and cost-sharing incurred on or after January 1, 2006, with regard to whether regulations to implement such amendments are promulgated by such date.

SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXPANSION OF MEMBERSHIP.—

(1) IN GENERAL.—Section 1805(c) (42 U.S.C. 1395b–6(c)) is amended—

(A) in paragraph (1), by striking ''17'' and inserting ''19''; and

(B) in paragraph (2)(B), by inserting ''experts in the area of pharmacology and prescription medicine benefit programs,'' after ''other health professionals,''.

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

(A) IN GENERAL.—For purposes of staggering the initial terms of members of the Medicare Payment Advisory Commission under section 1805(c)(3) of the Social Security Act (42 U.S.C. 1395b–6(c)(3)), the initial terms of the 2 additional members of the Commission provided for by the amendment under paragraph (1)(A) are as follows:

(i) One member shall be appointed for 1 year.

(ii) One member shall be appointed for 2 years.

(B) COMMENCEMENT OF TERMS.—Such terms shall begin on January 1, 2004.

(b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42 U.S.C. 1395b–6(b)(2)) is amended by adding at the end the following new subparagraph:

''(D) PRESCRIPTION MEDICINE BENEFIT PROGRAM.—Specifically, the Commission shall review, with respect to the prescription medicine benefit program under part D, the following:

''(i) The methodologies used for the management of costs and utilization of prescription medicines.

''(ii) The prices negotiated and paid, including trends in such prices and applicable discounts and comparisons with prices under section 1859E(a)(2)(E).

''(iii) The relationship of pharmacy acquisition costs to the prices so negotiated and paid.

''(iv) The methodologies used to ensure access to covered outpatient prescription medicines and to ensure quality in the appropriate dispensing and utilization of such medicines.

''(v) The impact of the program on promoting the development of breakthrough medicines.''.

SEC. 106. 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+Choice 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).

TITLE II—MEDICARE+CHOICE

SEC. 201. MEDICARE+CHOICE 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+Choice 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+Choice 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) REVISION OF BLEND.—

(1) REVISION OF NATIONAL AVERAGE USED IN CALCULATION OF BLEND.—Section 1853(c)(4)(B)(i)(II) (42 U.S.C. 1395w–23(c)(4)(B)(i)(II)) is amended by inserting ''who (with respect to determinations for 2004) are enrolled in a Medicare+Choice plan'' after ''the average number of medicare beneficiaries''.

(2) CHANGE IN BUDGET NEUTRALITY.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

(A) in paragraph (1)(A), by inserting ''(for a year before 2004)'' after ''multiplied''; and

(B) in paragraph (5), by inserting ''(before 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 (B)(iv), by striking ''and each succeeding year'' and inserting '', 2003, and 2004'';

(B) in subparagraph (C)(iv), by striking ''and each succeeding year'' and inserting ''and 2003''; and

(C) 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+Choice capitation rate under this paragraph for the area for the previous year; or

''(II) the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year increased by the national per capita Medicare+Choice 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 paragraph (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 subsection (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+Choice 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+CHOICE 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+Choice plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

(h) LIMITATION ON APPLICATION TO 2004 AND 2005.—Notwithstanding any other provision of law, the amendments made by this section shall only apply to payment rates for 2004

and 2005 and for subsequent years the payment shall be made on the basis of law as in effect before the date of the enactment of this Act.

SEC. 202. MAKING PERMANENT CHANGE IN MEDICARE+CHOICE 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''.

SEC. 203. SPECIALIZED MEDICARE+CHOICE 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+Choice plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.''.

(b) SPECIALIZED MEDICARE+CHOICE 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+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

''(A) IN GENERAL.—The term 'specialized Medicare+Choice plan for special needs beneficiaries' means a Medicare+Choice plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

''(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare+Choice 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+Choice 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+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice 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) 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+Choice 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).

(e) 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 of Health and Human Services shall issue 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. 204. MEDICARE MSAS.

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)''.

SEC. 205. 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+Choice 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 popu-

lation 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. 206. EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.

The last sentence of section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as previously amended, is amended by striking ''December 31, 2004, but only with respect to'' and all that follows and inserting ''December 31, 2009, but only with respect to individuals who reside in the city in which the project is operated and so long as the total number of individuals participating in the project does not exceed the number of such individuals participating as of January 1, 1996.''.

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 in-

serting ''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 2009; and

"(II) at least ⅔ of such areas in 2010; 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, 2007, 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).

"(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, 2008; 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 REASONABLENESS 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.

SEC. 303. REFORM OF PAYMENT FOR DRUGS AND BIOLOGICALS UNDER THE MEDICARE PROGRAM.

(a) PAYMENT REFORM.—

(1) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended to read as follows:

"(o) PAYMENT FOR DRUGS AND BIOLOGICALS.—

"(1) GENERAL RULE.—If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological shall be based on the following:

"(A) MULTI-SOURCE (GENERIC) DRUGS.—In the case of a drug or biological that meets the requirements for a multi-source drug under subclauses (I) and (II) of section 1927(k)(7)(A)(i), 105 percent of the volume-weighted median average acquisition price for any drug or biological covered under the same medicare HCPCS code.

"(B) SINGLE SOURCE (BRAND) DRUGS AND BIOLOGICALS.—In the case of a drug or biological that meets the requirements for a single source drug under section 1927(k)(7)(A)(iv), 105 percent of the average acquisition price for the drug or biological.

"(C) ACCESS EXCEPTION.—The Secretary may modify the rate otherwise applicable in order to assure access to necessary drugs and biologicals in the case of sole community providers in rural and other areas where the providers are not reasonably able to obtain the drugs and biologicals at the payment rates otherwise applicable. Such modification shall not result in a change of more than 15 percent of the rate otherwise applicable.

"(D) DATA-RELATED EXCEPTION.—If the Secretary determines that there is insufficient data available with respect to compute an average acquisition price for a drug or biological for a quarter or that, because of a significant change in price from quarter-to-quarter, the available data on the average acquisition price does not accurately reflect the actual, current acquisition cost for the drug or biological, the Secretary may substitute for the quarters involved an appropriate payment for the drug or biological for such average acquisition price.

"(E) APPLICATION OF NDC CODES.—If the Secretary determines that it is appropriate to provide for payment under this subsection using national drug code (NDC) instead of HCPCS codes, in applying subparagraph (A) the reference to the same HCPCS code shall be deemed a reference to the appropriate national drug codes for those drugs or biologicals that are therapeutically and pharmaceutically equivalent and bioequivalent (as defined for purposes of section 1927(k)(7)(A)).

"(2) DEFINITION OF AVERAGE ACQUISITION PRICE.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'average acquisition price' means, with respect to a drug or biological and with respect to each dosage form and strength of the drug or biological product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package), the average of all final sales prices charged by the manufacturer of the drug or biological product in the United States, excluding sales exempt from inclusion in the calculation of best price under section 1927(c)(1)(C) (other than under clause (ii)(III) of such section) and excluding sales subject to a rebate under section 1927, as reported under paragraph (3).

"(B) NET PRICE.—Such average acquisition price shall be calculated net of all of the following (as estimated by the Secretary):

''(i) Volume discounts.

''(ii) Prompt pay discounts and cash discounts.

''(iii) Charge-backs.

''(iv) Short-dated product discounts (for spoilage and other factors).

''(v) Free goods and services.

''(vi) Rebates.

''(vii) All other price concessions provided by the drug manufacturer.

The Secretary may make subsequent adjustments in such average acquisition price to take into account updated information and differences between the price previously estimated and the actual average acquisition price.

''(C) WEIGHTING.—The average of all final sales prices described in subparagraph (A) shall be determined by dividing—

''(i) the sum of all final prices charged by the manufacturer (net of the adjustments made under subparagraph (B)) for sales in the period involved that are included in subparagraph (A) for the drug or biological, by

''(ii) the total number of units of such sales in the period.

''(D) DISTRIBUTION OF REPORTS.—The Secretary shall promptly distribute applicable payment rates under this subsection to carriers and fiscal intermediaries and other contractors that make payment for drugs and biologicals under this section in order to apply a uniform reimbursement rate under this section.

''(3) PRICE REPORTING REQUIREMENT.—

''(A) IN GENERAL.—As a condition for payment for any drug or biological of a manufacturer under this subsection, the manufacturer of the drug or biological shall—

''(i) report, on a quarterly basis, to the Secretary (or the Secretary's designee) the manufacturer's average acquisition price and the information required under subparagraph (C) for all drugs and biologicals of the manufacturer by national drug code (NDC);

''(ii) maintain such records (in written or electronic form) regarding such sales and prices for all such drugs and biologicals as may be necessary to audit the information so reported or required to be reported; and

''(iii) provide the Secretary with access to such records in order to permit the Secretary to audit information so reported or required to be reported.

''(B) PENALTIES.—The provisions of section 1927(b)(3)(C) shall apply with respect to the reporting of information under subparagraph (A) in the same manner as it applies to the reporting of information under section 1927(b)(3)(A), except that the reference in clause (i) of such section to $10,000 is deemed a reference to $100,000 and any reference to a suspension of an agreement is deemed a reference to a suspension of payment for the drug or biological involved under this part. The Secretary shall promptly refer to the Inspector General of the Department of Health and Human Services and, if appropriate, to appropriate officials in the Department of Justice cases in which the Secretary becomes aware of a false price representation made in the information submitted under this paragraph.

''(C) FORM OF REPORTING.—Information required to be reported under subparagraph (A)(i) shall be reported in a form and manner specified by the Secretary. The information required to be reported shall include the identification of the generic name of the drug or biological and its brand name (if any), the national drug code (NDC) and the HCPCS code assigned

to the drug or biological, the dosage form, strength, volume, and package size involved. The information for a quarter shall be submitted not later than 30 days after the end of the quarter. The information shall be accompanied by a written and signed certification by an officer of the manufacturer attesting to the accuracy of the information reported. Such information shall include updated information on the net price realized (taking into account rebates and other amounts affecting net price), regardless of the period for which such a rebate or other adjustment in net price might have been earned.

''(D) AUDITING.—The Secretary shall audit on a periodic basis information reported or required to be reported under this paragraph. The Secretary may conduct such independent price gathering activities, such as surveys and review of published catalog information or other transactional information, as may be appropriate to verify the accuracy of the information reported.

''(4) DISPENSING FEE.—If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary shall pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. Such a dispensing fee shall be subject to adjustment from year to year based upon changes in the consumer price index over time and may be adjusted as the Secretary determines to be appropriate to reflect differences in the costs of dispensing different drugs and biologicals.

''(5) PAYMENT REQUIRED ON AN ASSIGNMENT-RELATED BASIS.—

''(A) IN GENERAL.—Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

''(B) APPLICATION OF ENFORCEMENT PROVISIONS.—The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C).''.

(2) EFFECTIVE DATE.—Subject to subsection (i)(2), the amendment made by paragraph (1) shall apply to drugs and biologicals furnished on or after January 1, 2004.

(b) MEDICARE PAYMENT FOR DRUG ADMINISTRATION SERVICES.—

(1) IN GENERAL.—The Secretary shall revise the practice expense relative value units for drug administration services for years beginning with the year 2005 in accordance with this subsection. For purposes of this subsection, the term ''drug administration services'' includes chemotherapy administration services, therapeutic and diagnostic infusions and injections, and such other services as the Secretary specifies.

(2) DIRECT COSTS EQUAL TO 100 PERCENT OF CPEP ESTIMATES.—Using the information, including estimates of clinical staff time, developed in the clinical practice expert panel process, including refinements by American Medical Association committees, the Secretary shall estimate the costs of the nursing and other clinical staff, supplies, and procedure-specific equipment (exceeding a cost specified by the Secretary) used in furnishing each type of drug administration service. The Secretary shall utilize without revision the minutes of clinical staff time determined in such process. The Secretary shall convert the information from such process to estimated costs by applying the most current available data on staff salary, supply, and equipment costs, and such costs shall be updated to 2005 based on estimated changes in prices since the date of such data.

(3) TOTAL PRACTICE EXPENSES.—The Secretary shall estimate the total practice expenses of each drug administration service by assuming that the direct costs for the

service determined under paragraph (3) are 33.2 percent of such total practice expenses.

(4) CONVERSION TO RELATIVE VALUE UNITS.—The Secretary shall convert the total practice expenses determined under paragraph (3) to practice expense relative value units for each drug administration service by dividing such expenses by the conversion factor that will be in effect for the physician fee schedule for 2005. The relative value units as so determined shall be used in determining the fee schedule amounts paid for drug administration services under section 1848 of the Social Security Act (42 U.S.C. 1395w–4).

(5) UPDATES.—For years after 2005, the relative values determined under paragraph (4) shall continue in effect except that the Secretary shall revise them as necessary to maintain their accuracy, provided that such revisions are consistent with the methodology set forth in this subsection.

(6) MULTIPLE PUSHES.—In establishing the payment amounts under this subsection, the Secretary shall establish the payment amount for intravenous chemotherapy administration by push technique based on the administration of a single drug. The Secretary shall make the same payment for each additional drug administered by push technique during the same encounter, except to the extent that the Secretary finds that the cost of administering additional drugs is less than the cost of administering the first drug.

(c) PAYMENTS FOR CHEMOTHERAPY SUPPORT SERVICES.—

(1) GENERAL.—Beginning in 2005, the Secretary shall recognize and make payments under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for chemotherapy support services furnished incident to physicians' services. For the purposes of this section, the term ''chemotherapy support services'' are services furnished by the staff of physicians to patients undergoing treatment for cancer that were not included in the computation of clinical

staff costs under subsection b(2). Such services include social worker services, nutrition counseling, psychosocial services, and similar services.

(2) DIRECT COSTS.—The Secretary shall estimate the cost of the salary and benefits of staff furnishing chemotherapy support services as they are provided in oncology practices that furnish these services to cancer patients in a manner that is considered to be high quality care. The estimate shall be based on the weekly cost of such services per patient receiving chemotherapy.

(3) TOTAL COSTS.—The Secretary shall estimate the total practice expenses of chemotherapy support services by assuming that the direct costs for the service determined under paragraph (2) are 33.2 percent of such total practice expenses.

(4) CONVERSION TO RELATIVE VALUE UNITS.—The Secretary shall convert the total practice expenses determined under paragraph (3) to practice expense relative value units for chemotherapy support services by dividing such expenses by the conversion factor that will be in effect for the physician fee schedule for 2005. The relative value units as so determined shall be used in determining the fee schedule amounts paid for chemotherapy support services under such section 1848.

(5) UPDATES.—For years after 2005, the relative values determined under paragraph (4) shall continue in effect except that the Secretary shall revise them as necessary to maintain their accuracy, provided that such revisions are consistent with the methodology set forth in this subsection.

(d) CANCER THERAPY MANAGEMENT SERVICES.—Beginning in 2005, the Secretary shall recognize and establish a payment amount for the service of cancer therapy management to account for the greater pre-service and post-service work associated with visits and consultations conducted by physicians treating cancer patients compared to typical visits and con-

sultations. The payment amount may vary by the level and type of the related visit or consultation.

(e) OTHER SERVICES WITHOUT PHYSICIAN WORK RELATIVE VALUE UNITS.—Beginning in 2005, the Secretary shall develop a revised methodology for determining the payment amounts for services that are paid under the fee schedule established by section 1848 of the Social Security Act (42 U.S.C. 1395w–4) and that do not have physician work relative value units, including radiation oncology services. Such methodology shall result in payment amounts that fully cover the costs of furnishing such services. Until such time as the methodology for such services is revised and implemented, all such services shall be protected from further payment cuts due to factors such as shifts in utilization or removal of any one specialty's services that are paid under the fee schedule established by such section 1848 and that do not have physician work relative value units.

(f) REPORT TO CONGRESS.—Not later than April 1, 2004, the Secretary shall submit to Congress a report on the payment amounts that are projected to be adopted under subsections (b), (c), (d), and (e) of this section.

(g) INSTITUTE OF MEDICINE STUDY.—

(1) GENERAL.—The Secretary shall request the Institute of Medicine to conduct the study described in this subsection.

(2) BASELINE STUDY.—The first phase of the study shall include the following objectives:

(A) An assessment of the extent to which the current medicare payment system, prior to implementation of the amendments made by this section, facilitates appropriate access to care by cancer patients in the various treatment settings.

(B) The identification of the comprehensive range of services furnished to cancer patients in the outpatient setting, including support services such as psychosocial services and counseling, and recommendations

regarding the types of services that ought to be furnished to medicare patients with cancer.

(C) A discussion of the practice standards necessary to assure the safe provision of services to cancer patients.

(D) An analysis of the extent to which the current medicare payment system supports the role of nurses in the provision of oncology services and recommendations for any necessary improvements in the payment system in that respect.

(E) The development of a framework for assessing how the amendments made by this act affect the provision of care to medicare patients with cancer in the various treatment settings.

(3) SECOND PHASE OF STUDY.—After the implementation of the amendments made by this section, the study shall determine whether and how those amendments affected the provision of care to medicare patients with cancer.

(4) CONSULTATION.—The Institute of Medicine shall consult with the National Cancer Policy Board and organizations representing cancer patients and survivors, oncologists, oncology nurses, social workers, cancer centers, and other healthcare professionals who treat cancer patients in planning and carrying out this study.

(5) DUE DATES.—

(A) The study required by paragraph (2) shall be submitted to the Congress and the Secretary of Health and Human Services no later than June 30, 2004.

(B) The study required by paragraph (3) shall be submitted to the Congress and the Secretary of Health and Human Services no later than December 31, 2006.

(i) STUDY OF PAYMENTS FOR BLOOD CLOTTING FACTORS AND OTHER BIOLOGICALS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall provide for a study of the appropriateness of the medicare payment methodology for blood

clotting factors and other biologicals under part B of title XVIII of the Social Security Act. Not later than 9 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on such study and shall include in such report recommendations regarding whether to apply the payment methodology provided under the amendment made by subsection (a)(1) and alternative recommendations for appropriate dispensing fees.

(2) DELAY IN EFFECTIVE DATE.—The amendment made by subsection (a)(1) shall not apply to blood clotting factors furnished before the first day of the first calendar year that begins at least 6 months after the date the report under paragraph (1) has been submitted to the Congress.

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 WITH PRIVATE INSURERS.—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 in recovery audits with private insurers or under the medicaid program under title XIX of such 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 inves-

tigating 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. FAIRNESS IN THE MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT FOR RURAL HOSPITALS.

(a) EQUALIZING DSH PAYMENT AMOUNTS.—

(1) IN GENERAL.—Section 1886(d)(5)(F)(vii) (42 U.S.C. 1395ww(d)(5)(F)(vii)) is amended by inserting ", and, after October 1, 2004, for any other hospital described in clause (iv)," after "clause (iv)(I)" in the matter preceding subclause (I).

(2) CONFORMING AMENDMENTS.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in clause (iv)—

(i) in subclause (II)—

(I) by inserting "and before October 1, 2004," after "April 1, 2001,"; and

(II) by inserting "or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii)" after "clause (xiii)";

(ii) in subclause (III)—

(I) by inserting "and before October 1, 2004," after "April 1, 2001,"; and

(II) by inserting "or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the

applicable formula described in clause (vii)'' after ''clause (xii)'';

(iii) in subclause (IV)—

(I) by inserting ''and before October 1, 2004,'' after ''April 1, 2001,''; and

(II) by inserting ''or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii)'' after ''clause (x) or (xi)'';

(iv) in subclause (V)—

(I) by inserting ''and before October 1, 2004,'' after ''April 1, 2001,''; and

(II) by inserting ''or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii)'' after ''clause (xi)''; and

(v) in subclause (VI)—

(I) by inserting ''and before October 1, 2004,'' after ''April 1, 2001,''; and

(II) by inserting ''or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii)'' after ''clause (x)'';

(B) in clause (viii), by striking ''The formula'' and inserting ''For discharges occurring before October 1, 2004, the formula''; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking ''For purposes'' and inserting ''With respect to discharges occurring before October 1, 2004, for purposes''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to discharges occurring on or after October 1, 2004.

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.

''(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, resulting 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 pro-

vides 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.

''(C) QUALITY CARE.—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.

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 period, 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 explanation 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 Secretary)'' 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) PERMITTING CAHS TO ALLOCATE SWING BEDS AND ACUTE CARE INPATIENT BEDS SUBJECT TO A TOTAL LIMIT OF 25 BEDS.—

(1) IN GENERAL.—Section 1820(e)(2)(B)(iii) (42 U.S.C. 1395i–4(e)(2)(B)(iii)) is amended to read as follows:

''(iii) provides not more than a total of 25 extended care service beds (pursuant to an agreement under subsection (f)) and acute care inpatient beds (meeting such standards as the Secretary may establish) for providing inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient;''.

(2) CONFORMING AMENDMENT.—Section 1820(f) (42 U.S.C. 1395i–4(f)) is amended by striking ''and the number of beds used at any time for acute care inpatient services does not exceed 15 beds''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall with respect to designations made on or after October 1, 2004.

(d) ELIMINATION OF THE ISOLATION TEST FOR COST-BASED CAH AMBULANCE SERVICES.—

(1) ELIMINATION.—

(A) IN GENERAL.—Section 1834(l)(8) (42 U.S.C. 1395m(l)(8)), as added by section 205(a) of BIPA (114 Stat. 2763A–482), is amended by striking the comma at the end of subparagraph (B) and all that follows and inserting a period.

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall apply to services furnished on or after January 1, 2005.

(2) TECHNICAL CORRECTION.—Section 1834(l) (42 U.S.C. 1395m(l)) is amended by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–486), as paragraph (9).

(e) 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.

(f) 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).

(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 provided 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 may adjust 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) PROHIBITION ON NURSE PRACTITIONER CERTIFYING NEED FOR HOSPICE.—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 an increase in the base rate of the fee schedule for mileage for a trip established under this subsection. In establishing such increase, the Secretary shall, based on the relationship of cost and volume, estimate the average increase in cost per trip for such services as compared with the cost per trip for the average ambulance service.

''(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 three quartiles 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 10 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)) is amended—

(1) in subparagraph (E), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (F), by striking the period at the end and inserting ''; and''; and

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

''(G) 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)(G) 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 estab-

lishing 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 county 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. MEDICARE INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.

Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following new paragraph:

''(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.—

''(A) PAYMENT ADJUSTMENT.—

''(i) IN GENERAL.—Notwithstanding any other provision of this section, for each cost reporting period (beginning with the cost reporting period that begins in fiscal year 2004), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in clause (iii)) for discharges occurring during that cost reporting period which is equal to the applicable percentage increase (determined under clause (ii)) in the amount paid to such hospital under this section for such discharges.

''(ii) APPLICABLE PERCENTAGE INCREASE.—The Secretary shall determine a percentage increase applicable under this paragraph that ensures that—

''(I) no percentage increase in payments under this paragraph exceeds 25 percent of the amount of payment that would (but for this paragraph) otherwise be made to a low-volume hospital under this section for each discharge;

''(II) low-volume hospitals that have the lowest number of discharges during a cost reporting period receive the highest percentage

increases in payments due to the application of this paragraph; and

"(III) the percentage increase in payments to any low-volume hospital due to the application of this paragraph is reduced as the number of discharges per cost reporting period increases.

"(iii) LOW-VOLUME HOSPITAL DEFINED.—For purposes of this paragraph, the term 'low-volume hospital' means, for a cost reporting period, a subsection (d) hospital (as defined in paragraph (1)(B)) other than a critical access hospital (as defined in section 1861(mm)(1)) that—

"(I) the Secretary determines had an average of less than 2,000 discharges (determined with respect to all patients and not just individuals receiving benefits under this title) during the 3 most recent cost reporting periods for which data are available that precede the cost reporting period to which this paragraph applies; and

"(II) is located at least 15 miles from a like hospital (or is deemed by the Secretary to be so located by reason of such factors as the Secretary determines appropriate, including the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (after taking into account the location of such alternative source of inpatient care and any weather or travel conditions that may affect such travel time).

"(B) PROHIBITING CERTAIN REDUCTIONS.—Notwithstanding subsection (e), the Secretary shall not reduce the payment amounts under this section to offset the increase in payments resulting from the application of subparagraph (A).".

SEC. 419. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED BY A SOLE COMMUNITY HOSPITAL.

Notwithstanding subsections (a), (b), and (h) of section 1833 of the Social Security Act (42 U.S.C. 1395*l*) and section 1834(d)(1) of such Act (42 U.S.C. 1395m(d)(1)), in the case of a clinical diagnostic laboratory test covered under part B of title XVIII of such Act that is furnished in 2004 or 2005 by a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of such Act (42 U.S.C. 1395ww(d)(5)(D)(iii))) as part of services furnished to patients of the hospital, the following rules shall apply:

(1) PAYMENT BASED ON REASONABLE COSTS.—The amount of payment for such test shall be 100 percent of the reasonable costs of the hospital in furnishing such test.

(2) NO BENEFICIARY COST-SHARING.—Notwithstanding section 432, no coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under such part B shall apply with respect to such test.

SEC. 420. ESTABLISHMENT OF FLOOR ON GEOGRAPHIC ADJUSTMENTS OF PAYMENTS FOR PHYSICIANS' SERVICES.

Section 1848(e)(1) (42 U.S.C. 1395w–4(e)(1)) is amended—

(1) in subparagraph (A), by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraphs (B), (C), (E), and (F)''; and

(2) by adding at the end the following new subparagraphs:

''(E) FLOOR FOR WORK GEOGRAPHIC INDICES.—

''(i) IN GENERAL.—For purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2008, after calculating the work geographic indices in subparagraph (A)(iii), the Secretary shall increase the work geographic index to the work floor index for any locality for which such geographic index is less than the work floor index.

"(ii) WORK FLOOR INDEX.—For purposes of clause (i), the term 'applicable floor index' means—

"(I) 0.980 with respect to services furnished during 2004; and

"(II) 1.000 for services furnished during 2005, 2006, and 2007.

"(F) FLOOR FOR PRACTICE EXPENSE AND MALPRACTICE GEOGRAPHIC INDICES.—For purposes of payment for services furnished on or after January 1, 2005, and before January 1, 2008, after calculating the practice expense and malpractice indices in clauses (i) and (ii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.00 for any locality for which such index is less than 1.00.

SEC. 421. AMBULANCE PAYMENT RATES.

(a) PAYMENT RATES.—Section 1834(l)(3) (42 U.S.C. 1395m(l)(3)) is amended to read as follows:

"(3) PAYMENT RATES.—

"(A) IN GENERAL.—Subject to any adjustment under subparagraph (B) and paragraph (9) and the full payment of a national mileage rate pursuant to subparagraph (2)(E), in establishing such fee schedule, the following rules shall apply:

"(i) PAYMENT RATES IN 2003.—

"(I) GROUND AMBULANCE SERVICES.—In the case of ground ambulance services furnished under this part in 2003, the Secretary shall set the payment rates under the fee schedule for such services at a rate based on the average costs (as determined by the Secretary on the basis of the most recent and reliable information available) incurred by full cost ambulance suppliers in providing nonemergency basic life support ambulance services covered under this title, with adjustments to the rates for other ground ambulance service levels to be determined based on the rule established under

paragraph (1). For the purposes of the preceding sentence, the term 'full cost ambulance supplier' means a supplier for which volunteers or other unpaid staff comprise less than 20 percent of the supplier's total staff and which receives less than 20 percent of space and other capital assets free of charge.

"(II) OTHER AMBULANCE SERVICES.—In the case of ambulance services not described in subclause (I) that are furnished under this part in 2003, the Secretary shall set the payment rates under the fee schedule for such services based on the rule established under paragraph (1).

"(ii) PAYMENT RATES IN SUBSEQUENT YEARS FOR ALL AMBULANCE SERVICES.—In the case of any ambulance service furnished under this part in 2004 or any subsequent year, the Secretary shall set the payment rates under the fee schedule for such service at amounts equal to the payment rate under the fee schedule for that service furnished during the previous year, increased by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.

"(B) ADJUSTMENT IN RURAL RATES.—For years beginning with 2004, the Secretary, after taking into consideration the recommendations contained in the report submitted under section 221(b)(3) the Medicare, Medicaid, and SCHIP Benefits Improvements and Protection Act of 2000, shall adjust the fee schedule payment rates that would otherwise apply under this subsection for ambulance services provided in low density rural areas based on the increased cost (if any) of providing such services in such areas.".

(b) CONFORMING AMENDMENT.—Section 221(c) of BIPA is repealed.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. ADJUSTMENT FOR INDIRECT COSTS OF MEDICAL EDUCATION (IME).

Section 1886(d)(5)(B)(ii) (42 U.S.C. 1395ww(d)(5)(B)(ii)) is amended—

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

(2) in subclause (VII)—

(A) by striking ''on or after October 1, 2002,'' and inserting ''during fiscal year 2003,''; and

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

(3) by inserting after subclause (VII) the following new subclauses:

''(VIII) during each of fiscal years 2004 and 2005, ''c'' is equal to 1.47; and

''(IX) on or after October 1, 2005, ''c'' is equal to 1.35.''.

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 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 technology 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. In such case, the new technology would no longer meet the threshold of exceeding 75 percent of the standard deviation for the diagnosis-related group involved under clause (ii)(I). 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.—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),''.

(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 2003 THAT ARE DENIED.—In the case of an applica-

tion 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 percentage 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 cost reporting period beginning on or after October 1, 2004.

SEC. 505. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO MEDICARE LIMITS ON PHYSICIAN REFERRALS.

(a) OWNERSHIP AND INVESTMENT INTERESTS IN WHOLE HOSPITALS.—

(1) IN GENERAL.—Section 1877(d)(3) (42 U.S.C. 1395nn(d)(3)) is amended—

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

(B) by redesignating subparagraph (B) as subparagraph (C) and inserting after subparagraph (A) the following:

''(B) the hospital is not a specialty hospital (as defined in subsection (h)(7)); and''.

(2) DEFINITION.—Section 1877(h) (42 U.S.C. 1395nn(h)) is amended by adding at the end the following:

''(7) SPECIALTY HOSPITAL.—

''(A) IN GENERAL.—For purposes of this section, except as provided in subparagraph (B), the term 'specialty hospital' means a hospital that is primarily or exclusively engaged in the care and treatment of one of the following:

''(i) patients with a cardiac condition;

''(ii) patients with an orthopedic condition;

''(iii) patients receiving a surgical procedure; or

''(iv) any other specialized category of patients or cases that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital under this section.

''(B) EXCEPTION.—For purposes of this section, the term 'specialty hospital' does not include any hospital—

''(i) determined by the Secretary—

''(I) to be in operation before June 12, 2003; or

''(II) under development as of such date;

''(ii) for which the number of beds and the number of physician investors at any time on or after such date is no greater than the number of such beds or investors as of such date; and

''(iii) that meets such other requirements as the Secretary may specify.''.

(b) EFFECTIVE DATE.—Subject to subsection (c), the amendments made by this section shall apply to referrals made for designated health services on or after January 1, 2004.

(c) APPLICATION OF EXCEPTION FOR HOSPITALS UNDER DEVELOPMENT.—For purposes of section 1877(h)(7)(B)(i)(II) of the Social Security Act, as added by subsection (a)(2), in determining whether a hospital is under development as of June 12, 2003, the Secretary shall consider—

(1) whether architectural plans have been completed, funding has been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received; and

(2) any other evidence the Secretary determines would indicate whether a hospital is under development as of such date.

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.

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 subsection 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.

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) ADJUSTMENT TO TECHNICAL COMPONENT.—For diagnostic mammography performed on or after January 1, 2004, for which payment is made under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4), the Secretary, based on the most recent cost data available, shall provide for an appropriate adjustment in the payment amount for the technical component of the diagnostic mammography.

(c) 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 procedure 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 drug or biological to be identical to or similar to another drug or biological with respect to its mechanism of action or clinical effect to deny pass-through status to new drugs or biologics or to remove such status of an existing eligible drug or biologic under this paragraph unless—

"(i) the Secretary develops by regulation (after providing notice and a period for public comment) criteria for the application of such standard; and

"(ii) such criteria provide for coordination with the Federal Food and Drug Administration and require scientific studies that show the clinical relationship between the drugs or biologicals treated as functionally equivalent.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biological 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 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 not be less than 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 estab-

lished 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 pe-

riod 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. 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 diseases 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 in-

serting ''(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. 629. 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.

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. 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. 703. 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 Secretary 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 the beneficiary—

(1) has been certified by one physician as an individual who has a permanent and severe condition that will not improve;

(2) 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) requires 1 or more home health services to achieve a functional condition that gives the individual the ability to leave home; and

(4) 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—Chronic Care Improvement

SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT UNDER TRADITIONAL FEE-FOR-SERVICE.

Title XVIII is amended by inserting after section 1806 the following new section:

"CHRONIC CARE IMPROVEMENT

"SEC. 1807. (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 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 administrative 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 section 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 co-morbidities, 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 un-

less 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 report 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 participants 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+CHOICE PLANS.

(a) IN GENERAL.—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+Choice organization with respect to each Medicare+Choice 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+Choice plan of a Medicare+Choice 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 multiple 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+Choice organization shall, directly or through subcontractors—

''(i) guide participants in managing their health, including all their co-morbidities, 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+Choice 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) 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 1807 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 C—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 submit 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) CRITERIA AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the criteria the Secretary uses

in making national coverage determinations, including how evidence to demonstrate that a procedure or device is reasonable and necessary is considered.

"(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 12 months after the date of the request.

"(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—At the end of the 6-month period 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 or temporary or permanent

code during the 60-day period referred to in subparagraph (C).

"(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, 2001, and before Janu-

ary 1, 2006, 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) demonstration 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. MEDICARE PANCREATIC ISLET CELL TRANSPLANT DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—In order to test the appropriateness of pancreatic islet cell transplantation, not later than 120 days after the date of the enactment of this Act, the Secretary shall establish a demonstration project which the Secretary, provides for payment under the medicare program under title XVIII of the Social Security Act for pancreatic islet cell transplantation and related items and services in the case of medicare beneficiaries who have type I (juvenile) diabetes and have end stage renal disease.

(b) DURATION OF PROJECT.—The authority of the Secretary to conduct the demonstration project under this section shall terminate on the date that is 5 years after the date of the establishment of the project.

(c) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the outcomes of the demonstration project. Not later than 120 days after the date of the termination of the demonstration project under subsection (b), the

Secretary shall submit to Congress a report on the project, including recommendations for such legislative and administrative action as the Secretary deems appropriate.

(d) PAYMENT METHODOLOGY.—The Secretary shall establish an appropriate payment methodology for the provision of items and services under the demonstration project, which may include a payment methodology that bundles, to the maximum extent feasible, payment for all such items and services.

(e) WAIVER AUTHORITY.—The Secretary may waive compliance with the requirements of title XVIII of the Social Security Act to such extent and for such period as the Secretary determines is necessary to conduct the demonstration project.

TITLE VIII—MEDICAID

SEC. 801. CONTINUATION OF MEDICAID DSH ALLOTMENT ADJUSTMENTS UNDER BIPA 2000.

(a) IN GENERAL.—Section 1923(f) of the Social Security Act (42 U.S.C. 1396r–4(f))—

(1) in paragraph (2)—

(A) in the heading, by striking ''THROUGH 2002'' and inserting ''THROUGH 2000'';

(B) by striking ''ending with fiscal year 2002'' and inserting ''ending with fiscal year 2000''; and

(C) in the table in such paragraph, by striking the columns labeled ''FY 01'' and ''FY02'';

(2) in paragraph (3)(A), by striking ''paragraph (2)'' and inserting ''paragraph (4)''; and

(3) in paragraph (4), as added by section 701(a)(1) of 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)—

(A) by striking ''FOR FISCAL YEARS 2001 AND 2002'' in the heading;

(B) in subparagraph (A), by striking ''Notwithstanding paragraph (2), the'' and inserting ''The'';

(C) in subparagraph (C)—

(i) by striking ''NO APPLICATION'' and inserting ''APPLICATION''; and

(ii) by striking ''without regard to'' and inserting ''taking into account''.

(b) INCREASE IN MEDICAID DSH ALLOTMENT FOR THE DISTRICT OF COLUMBIA.—

(1) IN GENERAL.—Effective for DSH allotments beginning with fiscal year 2003, the item in the table contained in section 1923(f)(2) of the Social Security Act (42 U.S.C. 1396r–4(f)(2)) for the District of Columbia for the DSH allotment for FY 00 (fiscal year 2000) is amended by striking ''32'' and inserting ''49''.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing the application of section 1923(f)(4) of the Social Security Act (as amended by subsection (a)) to the District of Columbia for fiscal year 2003 and subsequent fiscal years.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to DSH allotments for fiscal years beginning with fiscal year 2003.

SEC. 802. INCREASE IN FLOOR FOR TREATMENT AS AN EXTREMELY LOW DSH STATE TO 3 PERCENT IN FISCAL YEAR 2003.

(a) INCREASE IN DSH FLOOR.—Section 1923(f)(5) of the Social Security Act (42 U.S.C. 1396r–4(f)(5)) is amended—

(1) by striking ''fiscal year 1999'' and inserting ''fiscal year 2001'';

(2) by striking ''August 31, 2000'' and inserting ''August 31, 2002'';

(3) by striking ''1 percent'' each place it appears and inserting ''3 percent''; and

(4) by striking ''fiscal year 2001'' and inserting ''fiscal year 2003''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) take effect as if enacted on October 1, 2002, and apply to DSH allotments under title XIX of the Social Security Act for fiscal year 2003 and each fiscal year thereafter.

SEC. 803. 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)''.

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 explanation 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 serv-

ices 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 au-

thority 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 902(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 provisions 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 instructions 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 necessary 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 administrative 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 relating 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 described 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 per-

formance 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 tele-

phone number at which such individuals, providers of services and suppliers may obtain information regarding 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 administrative 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 providers 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 admin-

istration 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 para-

graph (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 review 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.

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, includ-

ing 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), each 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 provision of services as a reviewer under this subsection.

"(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent con-

tractor 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 re-

payment 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 construed 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, interest 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 con-

tractor' 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 supplier 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 method-

ology 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 NONRENEWAL.—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 re-

gard 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 ini-

tial 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 service 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 determination 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 re-

port 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 Technology 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 recommendations (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 preceding sentence, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary before 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 for the reporting of diagnoses, the Secretary may implement ICD-10-PCS only with respect to inpatient services 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 provide 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.

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 notwithstanding 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 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 described in subclause (II) of section 1886(d)(5)(F)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)(vi)) used in computing the disproportionate patient percentage under such section for that hospital. 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.

TITLE X—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 1001. 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; or

"(E) a drug that is inhaled during surgery.

"(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, after consultation with the United States Trade Representative and the Commissioner of Customs, 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 safeguards be in place to ensure 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 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); and

"(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect

the public health or as a means to facilitate the importation of prescription drugs.

''(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 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) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

''(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)(aa) 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.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States 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

''(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 or otherwise complying with this Act; 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 importation into

the United States shall register with the Secretary the name and place of business of 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) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

"(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

"(j) 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 organization (including the United Nations and affiliates) or to a government of a foreign country.

"(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

"(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

"(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

"(B) exercise discretion to permit individuals to make such importations in circumstances in which—

"(i) the importation is clearly for personal use; and

"(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

"(2) WAIVER AUTHORITY.—

"(A) IN GENERAL.—The Secretary may 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.

"(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individ-

uals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

"(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

"(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

"(B) is accompanied by a copy of a valid prescription;

"(C) is imported from Canada, from a seller registered with the Secretary;

"(D) is a prescription drug approved by the Secretary under chapter V;

"(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

"(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

"(l) 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, the United States Trade Representative, and the Commissioner of Patents and Trademarks 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 determine 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).

"(m) 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.

"(n) EFFECTIVENESS OF SECTION.—

"(1) IN GENERAL.—If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

"(2) PROCEDURE.—The Secretary shall not submit a certification under paragraph (1) unless, after a hearing on the record under sections 556 and 557 of title 5, United States Code, the Secretary—

"(A)(i) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

"(ii) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

"(iii) identifies specifically the causes of the increased risk; and

"(iv)(I) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

"(II) if the Secretary determines that any measures described in subclause (I) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

"(B) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

''(C)(i) compares in specific terms the detriment identified under subparagraph (A) with the benefits identified under subparagraph (B); and

''(ii) determines that the benefits do not outweigh the detriment.

''(o) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

''(p) CONDITIONS.—This section shall become effective only if the Secretary certifies to the Congress that 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 covered products 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)''.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

SEC. 1101. SHORT TITLE.

This title may be cited as the ''Greater Access to Affordable Pharmaceuticals Act''.

SEC. 1102. 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), 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

(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''; and

(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 validity and infringement and if the court decides that such patent has been infringed, the

approval shall be made effective as provided in subclause (II).'';

(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.—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 does not bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice given under paragraph (2)(B) was received, the applicant may bring a civil action against the owner or holder (but not against any owner or holder that has brought such a civil action against that applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

''(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 (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), 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 no-

tice 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

(2) in subsection (c)(3)—

(A) in the first sentence, by striking ''under the following'' and inserting ''by applying 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''; and

(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 approval shall be made effective as provided in clause (ii).''; 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.—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 does not bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice given under subsection (b)(3) was received, the applicant may bring a civil action against the owner or holder (but not against any owner or holder that has brought such a civil action against that applicant, unless that civil action was dismissed without

prejudice) for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

"(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) INFRINGEMENT ACTIONS.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

"(5) The filing of an application described in paragraph (2) that includes a 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), and the failure of the owner of the patent to bring an ac-

tion for infringement of a patent that is the subject of the certification before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of that section is received, shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed.''.

(d) 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 information 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. 1103. 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 1102) 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.—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.—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 certification 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. 1104. 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. 1105. REMEDIES FOR INFRINGEMENT.

Section 287 of title 35, United States Code, is amended by adding at the end the following:

''(d) CONSIDERATION.—In making a determination with respect to remedy brought for infringement of a patent that claims a drug or a method or using a drug, the court shall consider whether information on the patent was filed as required under 21 U.S.C. 355 (b) or (c), and, if such information was required to be filed but was not, the court may refuse to award treble damages under section 284.''.

SEC. 1106. 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)''.