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One Hundred Eighth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the seventh day of January, two thousand and three

An Act

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.

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

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

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

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in division A of 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 for this Act is as follows:

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

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Medicare prescription drug benefit.
Sec. 102. Medicare Advantage conforming amendments.
Sec. 103. Medicaid amendments.
Sec. 104. Medigap amendments.
Sec. 105. Additional provisions relating to medicare prescription drug discount card and transitional assistance program.
Sec. 106. State Pharmaceutical Assistance Transition Commission.
Sec. 107. Studies and reports.
Sec. 108. Grants to physicians to implement electronic prescription drug programs.
Sec. 109. Expanding the work of medicare Quality Improvement Organizations to include parts C and D.
Sec. 110. Conflict of interest study.
Sec. 111. Study on employment-based retiree health coverage.

TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

Sec. 201. Implementation of Medicare Advantage program.

Subtitle B—Immediate Improvements

Sec. 211. Immediate improvements.

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

Sec. 221. Establishment of MA regional plans.
Sec. 222. Competition program beginning in 2006.
Sec. 223. Effective date.

Subtitle D—Additional Reforms

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

Subtitle E—Comparative Cost Adjustment (CCA) Program

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

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

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

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

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

Subtitle B—Provisions Relating to Part B Only

Sec. 411. Two-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under the prospective payment system for hospital outpatient department services.
Sec. 412. Establishment of floor on work geographic adjustment.
Sec. 413. Medicare incentive payment program improvements for physician scarcity.

Sec. 414. Payment for rural and urban ambulance services.
Sec. 415. Providing appropriate coverage of rural air ambulance services.
Sec. 416. Treatment of certain clinical diagnostic laboratory tests furnished to hospital outpatients in certain rural areas.
Sec. 417. Extension of telemedicine demonstration project.
Sec. 418. Report on demonstration project permitting skilled nursing facilities to be originating telehealth sites; authority to implement.

Subtitle C—Provisions Relating to Parts A and B

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

Subtitle D—Other Provisions

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

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

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

Subtitle B—Other Provisions

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

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to Physicians' Services

Sec. 601. Revision of updates for physicians' services.
Sec. 602. Treatment of physicians' services furnished in Alaska.
Sec. 603. Inclusion of podiatrists, dentists, and optometrists under private contracting authority.
Sec. 604. GAO study on access to physicians' services.
Sec. 605. Collaborative demonstration-based review of physician practice expense geographic adjustment data.
Sec. 606. MedPAC report on payment for physicians' services.

Subtitle B—Preventive Services

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

Subtitle C—Other Provisions

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

Sec. 630. Five-year authorization of reimbursement for all medicare part B services furnished by certain Indian hospitals and clinics.

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

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

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

Sec. 701. Update in home health services.
Sec. 702. Demonstration project to clarify the definition of homebound.
Sec. 703. Demonstration project for medical adult day care services.
Sec. 704. Temporary suspension of OASIS requirement for collection of data on non-medicare and non-medicaid patients.
Sec. 705. MedPAC study on medicare margins of home health agencies.
Sec. 706. Coverage of religious nonmedical health care institution services furnished in the home.

Subtitle B—Graduate Medical Education

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

Subtitle C—Chronic Care Improvement

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

Subtitle D—Other Provisions

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

TITLE VIII—COST CONTAINMENT

Subtitle A—Cost Containment

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

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

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

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

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

Subtitle A—Regulatory Reform

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

Subtitle B—Contracting Reform

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

Subtitle C—Education and Outreach

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

Subtitle D—Appeals and Recovery

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

Subtitle E—Miscellaneous Provisions

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

TITLE X—MEDICAID AND MISCELLANEOUS PROVISIONS

Subtitle A—Medicaid Provisions

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

Subtitle B—Miscellaneous Provisions

Sec. 1011. Federal reimbursement of emergency health services furnished to undocumented aliens.
Sec. 1012. Commission on Systemic Interoperability.
Sec. 1013. Research on outcomes of health care items and services.
Sec. 1014. Health care that works for all Americans: Citizens Health Care Working Group.

Sec. 1015. Funding start-up administrative costs for medicare reform.
Sec. 1016. Health care infrastructure improvement program.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

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

Subtitle B—Federal Trade Commission Review

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

Subtitle C—Importation of Prescription Drugs

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

TITLE XII—TAX INCENTIVES FOR HEALTH AND RETIREMENT SECURITY

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

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. MEDICARE PRESCRIPTION DRUG BENEFIT.

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

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

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

"PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

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

"ELIGIBILITY, ENROLLMENT, AND INFORMATION

"SEC. 1860D–1. (a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—

"(1) IN GENERAL.—Subject to the succeeding provisions of this part, each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1860D–2(a)) as follows:

"(A) FEE-FOR-SERVICE ENROLLEES MAY RECEIVE COVERAGE THROUGH A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1860D–41(a)(14)).

"(B) MEDICARE ADVANTAGE ENROLLEES.—

"(i) ENROLLEES IN A PLAN PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE RECEIVE COVERAGE THROUGH THE PLAN.—A part D eligible individual who is enrolled in an MA–PD plan obtains such coverage through such plan.

"(ii) LIMITATION ON ENROLLMENT OF MA PLAN ENROLLEES IN PRESCRIPTION DRUG PLANS.—Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.

"(iii) PRIVATE FEE-FOR-SERVICE ENROLLEES IN MA PLANS NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE PERMITTED TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1859(b)(2)) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

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

"(2) COVERAGE FIRST EFFECTIVE JANUARY 1, 2006.—Coverage under prescription drug plans and MA–PD plans shall first be effective on January 1, 2006.

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

"(A) PART D ELIGIBLE INDIVIDUAL.—The term 'part D eligible individual' means an individual who is entitled to benefits under part A or enrolled under part B.

"(B) MA PLAN.—The term 'MA plan' has the meaning given such term in section 1859(b)(1).

"(C) MA–PD PLAN.—The term 'MA–PD plan' means an MA plan that provides qualified prescription drug coverage.

"(b) ENROLLMENT PROCESS FOR PRESCRIPTION DRUG PLANS.—

"(1) ESTABLISHMENT OF PROCESS.—

"(A) IN GENERAL.—The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.

"(B) APPLICATION OF MA RULES.—In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan under the following provisions of section 1851:

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

"(ii) EXERCISE OF CHOICE.—Section 1851(c) (other than paragraph (3)(A) of such section), relating to exercise of choice.

"(iii) COVERAGE ELECTION PERIODS.—Subject to paragraphs (2) and (3) of this subsection, section 1851(e) (other than subparagraphs (B) and (C) of paragraph (2) and the second sentence of paragraph (4)

of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.

"(iv) COVERAGE PERIODS.—Section 1851(f), relating to effectiveness of elections and changes of elections.

"(v) GUARANTEED ISSUE AND RENEWAL.—Section 1851(g) (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section), relating to guaranteed issue and renewal.

"(vi) MARKETING MATERIAL AND APPLICATION FORMS.—Section 1851(h), relating to approval of marketing material and application forms.

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

"(C) SPECIAL RULE.—The process established under subparagraph (A) shall include, in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1860D–14(a)(1)(A)). If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

"(2) INITIAL ENROLLMENT PERIOD.—

"(A) PROGRAM INITIATION.—In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section 1851(e)(3)(B)(iii), as applied under paragraph (1)(B)(iii).

"(B) CONTINUING PERIODS.—In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section 1851(e)(1), as applied under paragraph (1)(B)(iii) of this section, as if 'entitled to benefits under part A or enrolled under part B' were substituted for 'entitled to benefits under part A and enrolled under part B', but in no case shall such period end before the period described in subparagraph (A).

"(3) ADDITIONAL SPECIAL ENROLLMENT PERIODS.—The Secretary shall establish special enrollment periods, including the following:

"(A) INVOLUNTARY LOSS OF CREDITABLE PRESCRIPTION DRUG COVERAGE.—

"(i) IN GENERAL.—In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1860D–13(b)(4)).

"(ii) NOTICE.—In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

"(iii) FAILURE TO PAY PREMIUM.—For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

"(iv) REDUCTION IN COVERAGE.—For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1860D–13(b)(5) (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

"(B) ERRORS IN ENROLLMENT.—In the case described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B.

"(C) EXCEPTIONAL CIRCUMSTANCES.—In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

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

"(E) DISCONTINUANCE OF MA–PD ELECTION DURING FIRST YEAR OF ELIGIBILITY.—In the case of a part D eligible individual who discontinues enrollment in an MA–PD plan under the second sentence of section 1851(e)(4) at the time of the election of coverage under such sentence under the original medicare fee-for-service program.

"(4) INFORMATION TO FACILITATE ENROLLMENT.—

"(A) IN GENERAL.—Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans.

"(B) LIMITATION.—

"(i) PROVISION OF INFORMATION.—The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

"(ii) USE OF INFORMATION.—Such information provided by the Secretary to a PDP sponsor or an MA organization may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA–PD plans.

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

"(6) REFERENCE TO PENALTIES FOR LATE ENROLLMENT.—Section 1860D–13(b) imposes a late enrollment penalty for part D eligible individuals who—

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

"(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

"(c) PROVIDING INFORMATION TO BENEFICIARIES.—

"(1) ACTIVITIES.—The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part. Such activities shall ensure that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A).

"(2) REQUIREMENTS.—The activities described in paragraph (1) shall—

"(A) be similar to the activities performed by the Secretary under section 1851(d), including dissemination (including through the toll-free telephone number 1–800–MEDICARE) of comparative information for prescription drug plans and MA–PD plans; and

"(B) be coordinated with the activities performed by the Secretary under such section and under section 1804.

"(3) COMPARATIVE INFORMATION.—

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

"(i) BENEFITS.—The benefits provided under the plan.

"(ii) MONTHLY BENEFICIARY PREMIUM.—The monthly beneficiary premium under the plan.

"(iii) QUALITY AND PERFORMANCE.—The quality and performance under the plan.

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

"(v) CONSUMER SATISFACTION SURVEYS.—The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1860D–4(d).

"(B) EXCEPTION FOR UNAVAILABILITY OF INFORMATION.—The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan—

"(i) for the first plan year in which it is offered; and

"(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

"(4) INFORMATION ON LATE ENROLLMENT PENALTY.—The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1860D–13(b).

"PRESCRIPTION DRUG BENEFITS

"SEC. 1860D–2. (a) REQUIREMENTS.—

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

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

"(B) ALTERNATIVE PRESCRIPTION DRUG COVERAGE WITH AT LEAST ACTUARIALLY EQUIVALENT BENEFITS AND ACCESS TO NEGOTIATED PRICES.—Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

"(2) PERMITTING SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

"(i) CERTAIN REDUCTIONS IN COST-SHARING.—

"(I) IN GENERAL.—A reduction in the annual deductible, a reduction in the coinsurance percentage, or an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

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

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

"(B) REQUIREMENT.—A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

"(3) BASIC PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term 'basic prescription drug coverage' means either of the following:

"(A) Coverage that meets the requirements of paragraph (1)(A).

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

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

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

"(b) STANDARD PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term 'standard prescription drug coverage' means coverage of covered part D drugs that meets the following requirements:

"(1) DEDUCTIBLE.—

"(A) IN GENERAL.—The coverage has an annual deductible—

"(i) for 2006, that is equal to $250; or

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

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

"(2) BENEFIT STRUCTURE.—

"(A) 25 PERCENT COINSURANCE.—The coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

"(i) equal to 25 percent; or

"(ii) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of 25 percent of such costs.

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

"(3) INITIAL COVERAGE LIMIT.—

"(A) IN GENERAL.—Except as provided in paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

"(i) for 2006, that is equal to $2,250; or

"(ii) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

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

"(4) PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—

"(A) IN GENERAL.—

"(i) IN GENERAL.—The coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to the greater of—

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

"(II) coinsurance that is equal to 5 percent.

"(ii) ADJUSTMENT OF AMOUNT.—For a year after 2006, the dollar amounts specified in clause (i)(I) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6)

for the year involved. Any amount established under this clause that is not a multiple of a 5 cents shall be rounded to the nearest multiple of 5 cents.

"(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

"(i) IN GENERAL.—For purposes of this part, the 'annual out-of-pocket threshold' specified in this subparagraph—

"(I) for 2006, is equal to $3,600; or

"(II) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

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

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

"(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary; and

"(ii) such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1860D–14, or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs.

"(D) INFORMATION REGARDING THIRD-PARTY REIMBURSEMENT.—

"(i) PROCEDURES FOR EXCHANGING INFORMATION.—In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

"(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

"(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

"(ii) AUTHORITY TO REQUEST INFORMATION FROM ENROLLEES.—A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-

party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1851(g)(3)(B) (and as applied under this part under section 1860D–1(b)(1)(B)(v)) for a period specified by the Secretary.

"(5) CONSTRUCTION.—Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering an MA–PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

"(6) ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

"(c) ALTERNATIVE PRESCRIPTION DRUG COVERAGE REQUIREMENTS.—A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1860D–11(c)) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

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

"(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

"(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1860D–15 with respect to such coverage.

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

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

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

"(2) MAXIMUM REQUIRED DEDUCTIBLE.—The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) for the year.

"(3) SAME PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—The coverage provides the coverage required under subsection (b)(4).

"(d) ACCESS TO NEGOTIATED PRICES.—

"(1) ACCESS.—

"(A) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit (described in subsection (b)(3)).

"(B) NEGOTIATED PRICES.—For purposes of this part, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

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

"(2) DISCLOSURE.—A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1927(b)(3)(D) apply to information disclosed to the Secretary under this paragraph.

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

"(e) COVERED PART D DRUG DEFINED.—

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

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

"(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies

associated with the injection of insulin (as defined in regulations of the Secretary),

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

"(2) EXCLUSIONS.—

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

"(B) MEDICARE COVERED DRUGS.—A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual.

"(3) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

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

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

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1860D–4.

"ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG COVERAGE

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

"(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

"(2) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

"(3) QUALIFYING PLAN DEFINED.—For purposes of this section, the term 'qualifying plan' means—

"(A) a prescription drug plan; or

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

"(i) basic prescription drug coverage; or

"(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application

of a credit against such premium of a rebate under section 1854(b)(1)(C).

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

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

"(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1860D–11(g).

"BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

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

"(1) GENERAL INFORMATION.—

"(A) APPLICATION OF MA INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and including the information described in subparagraph (B).

"(B) DRUG SPECIFIC INFORMATION.—The information described in this subparagraph is information concerning the following:

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

"(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

"(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

"(iv) The medication therapy management program required under subsection (c).

"(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

"(3) PROVISION OF SPECIFIC INFORMATION.—

"(A) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

"(B) AVAILABILITY OF INFORMATION ON CHANGES IN FORMULARY THROUGH THE INTERNET.—A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

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

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

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

"(i) the initial coverage limit for the current year; and

"(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1860D–2(b)(4)(C) to the extent practicable, as specified by the Secretary.

"(b) ACCESS TO COVERED PART D DRUGS.—

"(1) ASSURING PHARMACY ACCESS.—

"(A) PARTICIPATION OF ANY WILLING PHARMACY.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

"(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 to a plan.

"(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—

"(i) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

"(ii) APPLICATION OF TRICARE STANDARDS.—The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

"(iii) ADEQUATE EMERGENCY ACCESS.—Such rules shall include adequate emergency access for enrollees.

"(iv) CONVENIENT ACCESS IN LONG-TERM CARE FACILITIES.—Such rules may include standards with respect to access for enrollees who are residing in

long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act).

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

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

"(2) USE OF STANDARDIZED TECHNOLOGY.—

"(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d).

"(B) STANDARDS.—

"(i) IN GENERAL.—The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of title XI and may be based on standards developed by an appropriate standard setting organization.

"(ii) CONSULTATION.—In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

"(iii) IMPLEMENTATION.—The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

"(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

"(A) DEVELOPMENT AND REVISION BY A PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

"(i) IN GENERAL.—The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

"(ii) INCLUSION OF INDEPENDENT EXPERTS.—Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

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

"(II) has expertise in the care of elderly or disabled persons.

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

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

"(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

"(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

"(i) IN GENERAL.—The formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

"(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

"(iii) LIMITATION ON CHANGES IN THERAPEUTIC CLASSIFICATION.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

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

"(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY OR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

"(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

The requirements of this paragraph may be met by a PDP sponsor directly or through arrangements with another entity.

"(c) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

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

"(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i)).

"(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

"(C) A medication therapy management program described in paragraph (2).

"(D) A program to control fraud, abuse, and waste. Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

"(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

"(A) DESCRIPTION.—

"(i) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

"(ii) TARGETED BENEFICIARIES DESCRIBED.—Targeted beneficiaries described in this clause are part D eligible individuals who—

"(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

"(II) are taking multiple covered part D drugs; and

"(III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

"(B) ELEMENTS.—Such program may include elements that promote—

"(i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

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

"(iii) detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

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

"(D) COORDINATION WITH CARE MANAGEMENT PLANS.—The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807.

"(E) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) apply to information disclosed under this subparagraph.

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

"(e) ELECTRONIC PRESCRIPTION PROGRAM.—

"(1) APPLICATION OF STANDARDS.—As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

"(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

"(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

"(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

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

"(B) APPLICATION TO MEDICAL HISTORY INFORMATION.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to

carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

"(C) LIMITATIONS.—Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(D) TIMING.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

"(3) STANDARDS.—

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

"(B) OBJECTIVES.—Such standards shall be consistent with the objectives of improving—

"(i) patient safety;

"(ii) the quality of care provided to patients; and

"(iii) efficiencies, including cost savings, in the delivery of care.

"(C) DESIGN CRITERIA.—Such standards shall—

"(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

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

"(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

"(D) PERMITTING USE OF APPROPRIATE MESSAGING.—Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

"(E) PERMITTING PATIENT DESIGNATION OF DISPENSING PHARMACY.—

"(i) IN GENERAL.—Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

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

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

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

"(4) DEVELOPMENT, PROMULGATION, AND MODIFICATION OF STANDARDS.—

"(A) INITIAL STANDARDS.—Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

"(B) ROLE OF NCVHS.—The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

"(i) Standard setting organizations (as defined in section 1171(8))

"(ii) Practicing physicians.

"(iii) Hospitals.

"(iv) Pharmacies.

"(v) Practicing pharmacists.

"(vi) Pharmacy benefit managers.

"(vii) State boards of pharmacy.

"(viii) State boards of medicine.

"(ix) Experts on electronic prescribing.

"(x) Other appropriate Federal agencies.

"(C) PILOT PROJECT TO TEST INITIAL STANDARDS.—

"(i) IN GENERAL.—During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

"(ii) EXCEPTION.—Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

"(iii) VOLUNTARY PARTICIPATION OF PHYSICIANS AND PHARMACIES.—In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

"(iv) EVALUATION AND REPORT.—

"(I) EVALUATION.—The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

"(II) REPORT TO CONGRESS.—Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

"(D) FINAL STANDARDS.—Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

"(5) RELATION TO STATE LAWS.—The standards promulgated under this subsection shall supersede any State law or regulation that—

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

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

"(6) ESTABLISHMENT OF SAFE HARBOR.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

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

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

"(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

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

"(g) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—

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

"(2) REQUEST FOR A DETERMINATION FOR THE TREATMENT OF TIERED FORMULARY DRUG.—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the

plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

"(h) APPEALS.—

"(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

"(2) LIMITATION IN CASES ON NONFORMULARY DETERMINATIONS.—A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

"(3) TREATMENT OF NONFORMULARY DETERMINATIONS.—If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D–2(b)(4)(C)(i).

"(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—The provisions of section 1852(h) shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

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

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

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

"(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

"(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

"(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses

a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

"(2) TIMING OF NOTICE.—

"(A) IN GENERAL.—Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

"(B) WAIVER.—The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

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

"PDP REGIONS; SUBMISSION OF BIDS; PLAN APPROVAL

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

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

"(2) ESTABLISHMENT OF PDP REGIONS.—

"(A) IN GENERAL.—The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1858(a)(2).

"(B) RELATION TO MA REGIONS.—To the extent practicable, PDP regions shall be the same as MA regions under section 1858(a)(2). The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

"(C) AUTHORITY FOR TERRITORIES.—The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

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

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

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

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

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

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

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

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

"(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

"(iii) assumptions regarding the reinsurance subsidy payments provided under section 1860D–15(b) subtracted from the actuarial value to produce such bid; and

"(iv) administrative expenses assumed in the bid.

"(D) SERVICE AREA.—The service area for the plan.

"(E) LEVEL OF RISK ASSUMED.—

"(i) IN GENERAL.—Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA–PD plan.

"(ii) RISK LEVELS DESCRIBED.—A modification of risk level under this clause may consist of one or more of the following:

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

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

"(III) DECREASE IN SIZE OF RISK CORRIDORS.—A decrease in the threshold risk percentages specified in section 1860D–15(e)(3)(C).

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

"(3) PAPERWORK REDUCTION FOR OFFERING OF PRESCRIPTION DRUG PLANS NATIONALLY OR IN MULTI-REGION AREAS.—The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

"(c) ACTUARIAL VALUATION.—

"(1) PROCESSES.—For purposes of this part, the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—

"(A) an actuarial valuation of standard prescription drug coverage under section 1860D–2(b);

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

"(C) an actuarial valuation of the reinsurance subsidy payments under section 1860D–15(b);

"(D) the use of generally accepted actuarial principles and methodologies; and

"(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

"(2) ACCOUNTING FOR DRUG UTILIZATION.—Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

"(3) RESPONSIBILITIES.—

"(A) PLAN RESPONSIBILITIES.—PDP sponsors and MA organizations are responsible for the preparation and submission of actuarial valuations required under this part for prescription drug plans and MA–PD plans they offer.

"(B) USE OF OUTSIDE ACTUARIES.—Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

"(d) REVIEW OF INFORMATION AND NEGOTIATION.—

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

"(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—Subject to subsection (i), in exercising the authority under paragraph (1), the Secretary—

"(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

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

"(e) APPROVAL OF PROPOSED PLANS.—

"(1) IN GENERAL.—After review and negotiation under subsection (d), the Secretary shall approve or disapprove the prescription drug plan.

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

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

"(B) ACTUARIAL DETERMINATIONS.—The Secretary determines that the plan and PDP sponsor meet the requirements under this part relating to actuarial determinations, including such requirements under section 1860D–2(c).

"(C) APPLICATION OF FEHBP STANDARD.—

"(i) IN GENERAL.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section 1860D–15(b).

"(ii) SUPPLEMENTAL COVERAGE.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to supplemental prescription drug coverage pursuant to section 1860D–2(a)(2) is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for such coverage under the plan.

"(D) PLAN DESIGN.—

"(i) IN GENERAL.—The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

"(ii) USE OF CATEGORIES AND CLASSES IN FORMULARIES.—The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

"(f) APPLICATION OF LIMITED RISK PLANS.—

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

"(2) RULES.—The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

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

"(B) MAXIMIZING ASSUMPTION OF RISK.—The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

"(C) NO FULL UNDERWRITING FOR LIMITED RISK PLANS.—In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

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

"(4) RISK-PLANS DEFINED.—For purposes of this subsection:

"(A) LIMITED RISK PLAN.—The term 'limited risk plan' means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) in its bid submitted for the plan under such subsection. Such term does not include a fallback prescription drug plan.

"(B) FULL RISK PLAN.—The term 'full risk plan' means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

"(g) GUARANTEEING ACCESS TO COVERAGE.—

"(1) SOLICITATION OF BIDS.—

"(A) IN GENERAL.—Separate from the bidding process under subsection (b), the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5).

"(B) ACCEPTANCE OF BIDS.—

"(i) IN GENERAL.—Except as provided in this subparagraph, the provisions of subsection (e) shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts under this subsection with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

"(ii) LIMITATION OF 1 PLAN FOR ALL FALLBACK SERVICE AREAS IN A PDP REGION.—With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

"(iii) 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 a contract under this subsection. The provisions of subsection (d) of section 1874A shall apply to a contract under this section in the same manner as they apply to a contract under such section.

"(iv) TIMING.—The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

"(V) NO NATIONAL FALLBACK PLAN.—The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

"(2) ELIGIBLE FALLBACK ENTITY.—For purposes of this section, the term 'eligible fallback entity' means, with respect

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

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

"(B) does not submit a bid under section 1860D–11(b) for any prescription drug plan for any PDP region for the first year of such contract period.

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

"(3) FALLBACK SERVICE AREA.—For purposes of this subsection, the term 'fallback service area' means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1860D–3(a) will not be met for part D eligible individuals residing in the area for the year.

"(4) FALLBACK PRESCRIPTION DRUG PLAN.—For purposes of this part, the term 'fallback prescription drug plan' means a prescription drug plan that—

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

"(B) meets such other requirements as the Secretary may specify.

"(5) PAYMENTS UNDER THE CONTRACT.—

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

"(i) payment for the actual costs (taking into account negotiated price concessions described in section 1860D–2(d)(1)(B)) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

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

"(B) PERFORMANCE MEASURES.—The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

"(i) COSTS.—The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

"(ii) QUALITY PROGRAMS.—The entity provides such enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.

"(iii) CUSTOMER SERVICE.—The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

"(iv) BENEFIT ADMINISTRATION AND CLAIMS ADJUDICATION.—The entity provides efficient and effective benefit administration and claims adjudication.

"(6) MONTHLY BENEFICIARY PREMIUM.—Except as provided in section 1860D–13(b) (relating to late enrollment penalty) and subject to section 1860D–14 (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent of an amount equal to the Secretary's estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

"(7) GENERAL CONTRACT TERMS AND CONDITIONS.—

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

"(B) PERIOD OF CONTRACT.—

"(i) IN GENERAL.—Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

"(ii) LIMITATION.—A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

"(C) ENTITY NOT PERMITTED TO MARKET OR BRAND FALLBACK PRESCRIPTION DRUG PLANS.—An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

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

"(i) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary—

"(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

"(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

"(j) COORDINATION OF BENEFITS.—A PDP sponsor offering a prescription drug plan shall permit State Pharmaceutical Assistance Programs and Rx plans under sections 1860D–23 and 1860D–24 to coordinate benefits with the plan and, in connection with such coordination with such a Program, not to impose fees that are unrelated to the cost of coordination.

"REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS

"SEC. 1860D–12. (a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

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

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

"(A) IN GENERAL.—Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b).

"(B) REINSURANCE PERMITTED.—The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

"(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

"(b) CONTRACT REQUIREMENTS.—

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

"(2) LIMITATION ON ENTITIES OFFERING FALLBACK PRESCRIPTION DRUG PLANS.—The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

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

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

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

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

"(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):

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

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

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

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

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

"(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D.

"(E) INTERMEDIATE SANCTIONS.—Section 1857(g) (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part.

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

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

"(1) AUTHORIZING WAIVER.—

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

"(B) APPLICATION OF REGIONAL PLAN WAIVER RULE.—In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

"(2) GROUNDS FOR APPROVAL.—

"(A) IN GENERAL.—The grounds for approval under this paragraph are—

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

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

"(B) SPECIAL RULES.—In applying subparagraph (A)(i)—

"(i) the ground of approval described in section 1855(a)(2)(B) is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

"(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

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

"(4) REFERENCES TO CERTAIN PROVISIONS.—In applying provisions of section 1855(a)(2) under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

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

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

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

"(1) ESTABLISHMENT AND PUBLICATION.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

"(2) COMPLIANCE WITH STANDARDS.—A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

"(e) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

"(f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

"(1) IN GENERAL.—Subject to paragraph (2), the Secretary may periodically review the standards established under this

section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

"(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

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

"PREMIUMS; LATE ENROLLMENT PENALTY

"SEC. 1860D–13. (a) MONTHLY BENEFICIARY PREMIUM.—

"(1) COMPUTATION.—

"(A) IN GENERAL.—The monthly beneficiary premium for a prescription drug plan is the base beneficiary premium computed under paragraph (2) as adjusted under this paragraph.

"(B) ADJUSTMENT TO REFLECT DIFFERENCE BETWEEN BID AND NATIONAL AVERAGE BID.—

"(i) ABOVE AVERAGE BID.—If for a month the amount of the standardized bid amount (as defined in paragraph (5)) exceeds the amount of the adjusted national average monthly bid amount (as defined in clause (iii)), the base beneficiary premium for the month shall be increased by the amount of such excess.

"(ii) BELOW AVERAGE BID.—If for a month the amount of the adjusted national average monthly bid amount for the month exceeds the standardized bid amount, the base beneficiary premium for the month shall be decreased by the amount of such excess.

"(iii) ADJUSTED NATIONAL AVERAGE MONTHLY BID AMOUNT DEFINED.—For purposes of this subparagraph, the term 'adjusted national average monthly bid amount' means the national average monthly bid amount computed under paragraph (4), as adjusted under section 1860D–15(c)(2).

"(C) INCREASE FOR SUPPLEMENTAL PRESCRIPTION DRUG BENEFITS.—The base beneficiary premium shall be increased by the portion of the PDP approved bid that is attributable to supplemental prescription drug benefits.

"(D) INCREASE FOR LATE ENROLLMENT PENALTY.—The base beneficiary premium shall be increased by the amount of any late enrollment penalty under subsection (b).

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

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

"(2) BASE BENEFICIARY PREMIUM.—The base beneficiary premium under this paragraph for a prescription drug plan for a month is equal to the product—

"(A) the beneficiary premium percentage (as specified in paragraph (3)); and

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

"(3) BENEFICIARY PREMIUM PERCENTAGE.—For purposes of this subsection, the beneficiary premium percentage for any year is the percentage equal to a fraction—

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

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

"(i) the total reinsurance payments which the Secretary estimates are payable under section 1860D–15(b) with respect to the coverage year; divided by

"(ii) the sum of—

"(I) the amount estimated under clause (i) for the year; and

"(II) the total payments which the Secretary estimates will be paid to prescription drug plans and MA–PD plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by the Secretary and enrollees.

"(4) COMPUTATION OF NATIONAL AVERAGE MONTHLY BID AMOUNT.—

"(A) IN GENERAL.—For each year (beginning with 2006) the Secretary shall compute a national average monthly bid amount equal to the average of the standardized bid amounts (as defined in paragraph (5)) for each prescription drug plan and for each MA–PD plan described in section 1851(a)(2)(A)(i). Such average does not take into account the bids submitted for MSA plans, MA private fee-for-service plan, and specialized MA plans for special needs individuals, PACE programs under section 1894 (pursuant to section 1860D–21(f)), and under reasonable cost reimbursement contracts under section 1876(h) (pursuant to section 1860D–21(e)).

"(B) WEIGHTED AVERAGE.—

"(i) IN GENERAL.—The monthly national average monthly bid amount computed under subparagraph (A) for a year shall be a weighted average, with the weight for each plan being equal to the average number of part D eligible individuals enrolled in such plan in the reference month (as defined in section 1858(f)(4)).

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

"(5) STANDARDIZED BID AMOUNT DEFINED.—For purposes of this subsection, the term 'standardized bid amount' means the following:

"(A) PRESCRIPTION DRUG PLANS.—

"(i) BASIC COVERAGE.—In the case of a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid (as defined in paragraph (6)).

"(ii) SUPPLEMENTAL COVERAGE.—In the case of a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage.

"(B) MA–PD PLANS.—In the case of an MA–PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

"(6) PDP APPROVED BID DEFINED.—For purposes of this part, the term 'PDP approved bid' means, with respect to a prescription drug plan, the bid amount approved for the plan under this part.

"(b) LATE ENROLLMENT PENALTY.—

"(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, in the case of a part D eligible individual described in paragraph (2) with respect to a continuous period of eligibility, there shall be an increase in the monthly beneficiary premium established under subsection (a) in an amount determined under paragraph (3).

"(2) INDIVIDUALS SUBJECT TO PENALTY.—A part D eligible individual described in this paragraph is, with respect to a continuous period of eligibility, an individual for whom there is a continuous period of 63 days or longer (all of which in such continuous period of eligibility) beginning on the day after the last date of the individual's initial enrollment period under section 1860D–1(b)(2) and ending on the date of enrollment under a prescription drug plan or MA–PD plan during all of which the individual was not covered under any creditable prescription drug coverage.

"(3) AMOUNT OF PENALTY.—

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

"(i) an amount that the Secretary determines is actuarially sound for each uncovered month (as defined in subparagraph (B)) in the same continuous period of eligibility; or

"(ii) 1 percent of the base beneficiary premium (computed under subsection (a)(2)) for each such uncovered month in such period.

"(B) UNCOVERED MONTH DEFINED.—For purposes of this subsection, the term 'uncovered month' means, with respect to a part D eligible individual, any month beginning after the end of the initial enrollment period under section 1860D–1(b)(2) unless the individual can demonstrate that the individual had creditable prescription drug coverage (as defined in paragraph (4)) for any portion of such month.

"(4) CREDITABLE PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this part, the term 'creditable prescription drug coverage' means any of the following coverage, but only if the coverage meets the requirement of paragraph (5):

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

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

"(C) GROUP HEALTH PLAN.—Coverage under a group health plan, including a health benefits plan under chapter 89 of title 5, United States Code (commonly known as the Federal employees health benefits program), and a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)).

"(D) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage under a State pharmaceutical assistance program described in section 1860D–23(b)(1).

"(E) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage for veterans, and survivors and dependents of veterans, under chapter 17 of title 38, United States Code.

"(F) PRESCRIPTION DRUG COVERAGE UNDER MEDIGAP POLICIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1)).

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

"(H) OTHER COVERAGE.—Such other coverage as the Secretary determines appropriate.

"(5) ACTUARIAL EQUIVALENCE REQUIREMENT.—Coverage meets the requirement of this paragraph only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage (as determined under section 1860D–11(c)).

"(6) PROCEDURES TO DOCUMENT CREDITABLE PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—The Secretary shall establish procedures (including the form, manner, and time) for the documentation of creditable prescription drug coverage, including procedures to assist in determining whether coverage meets the requirement of paragraph (5).

"(B) DISCLOSURE BY ENTITIES OFFERING CREDITABLE PRESCRIPTION DRUG COVERAGE.—

"(i) IN GENERAL.—Each entity that offers prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) shall provide for disclosure, in a form, manner, and time consistent with standards established by the Secretary, to the Secretary and part D eligible individuals of whether the coverage meets the requirement of paragraph (5) or whether such coverage is changed so it no longer meets such requirement.

"(ii) DISCLOSURE OF NON-CREDITABLE COVERAGE.—In the case of such coverage that does not meet such requirement, the disclosure to part D eligible individuals under this subparagraph shall include information regarding the fact that because such coverage does not meet such requirement there are limitations on

the periods in a year in which the individuals may enroll under a prescription drug plan or an MA–PD plan and that any such enrollment is subject to a late enrollment penalty under this subsection.

"(C) WAIVER OF REQUIREMENT.—In the case of a part D eligible individual who was enrolled in prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) which is not creditable prescription drug coverage because it does not meet the requirement of paragraph (5), the individual may apply to the Secretary to have such coverage treated as creditable prescription drug coverage if the individual establishes that the individual was not adequately informed that such coverage did not meet such requirement.

"(7) CONTINUOUS PERIOD OF ELIGIBILITY.—

"(A) IN GENERAL.—Subject to subparagraph (B), for purposes of this subsection, the term 'continuous period of eligibility' means, with respect to a part D eligible individual, the period that begins with the first day on which the individual is eligible to enroll in a prescription drug plan under this part and ends with the individual's death.

"(B) SEPARATE PERIOD.—Any period during all of which a part D eligible individual is entitled to hospital insurance benefits under part A and—

"(i) which terminated in or before the month preceding the month in which the individual attained age 65; or

"(ii) for which the basis for eligibility for such entitlement changed between section 226(b) and section 226(a), between 226(b) and section 226A, or between section 226A and section 226(a),

shall be a separate continuous period of eligibility with respect to the individual (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this paragraph).

"(c) COLLECTION OF MONTHLY BENEFICIARY PREMIUMS.—

"(1) IN GENERAL.—Subject to paragraphs (2) and (3), the provisions of section 1854(d) shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under part C, except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.

"(2) CREDITING OF LATE ENROLLMENT PENALTY.—

"(A) PORTION ATTRIBUTABLE TO INCREASED ACTUARIAL COSTS.—With respect to late enrollment penalties imposed under subsection (b), the Secretary shall specify the portion of such a penalty that the Secretary estimates is attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under section 1860D–15(c)(1) or through reinsurance payments under section 1860D–15(b)) as a result of such late enrollment.

"(B) COLLECTION THROUGH WITHHOLDING.—In the case of a late enrollment penalty that is collected from a part D eligible individual in the manner described in section 1854(d)(2)(A), the Secretary shall provide that only the

portion of such penalty estimated under subparagraph (A) shall be paid to the PDP sponsor or MA organization offering the part D plan in which the individual is enrolled.

"(C) COLLECTION BY PLAN.—In the case of a late enrollment penalty that is collected from a part D eligible individual in a manner other than the manner described in section 1854(d)(2)(A), the Secretary shall establish procedures for reducing payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of such penalty less the portion of such penalty estimated under subparagraph (A).

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

"PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

"SEC. 1860D–14. (a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME UP TO 150 PERCENT OF POVERTY LINE.—

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

"(A) FULL PREMIUM SUBSIDY.—An income-related premium subsidy equal to—

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

"(ii) 80 percent of any late enrollment penalties imposed under section 1860D–13(b) for the first 60 months in which such penalties are imposed for that individual, and 100 percent of any such penalties for any subsequent month.

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

"(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

"(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—

"(i) INSTITUTIONALIZED INDIVIDUALS.—In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or

couple (as defined in section 1902(q)(1)(B)), the elimination of any beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)).

"(ii) LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—In the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount that does not exceed $1 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)) and $3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).

"(iii) OTHER INDIVIDUALS.—In the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount that does not exceed the copayment amount specified under section 1860D–2(b)(4)(A)(i)(I) for the drug and year involved.

"(E) ELIMINATION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—The elimination of any cost-sharing imposed under section 1860D–2(b)(4)(A).

"(2) OTHER INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF POVERTY LINE.—In the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

"(A) SLIDING SCALE PREMIUM SUBSIDY.—An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

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

"(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

"(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—The substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of coinsurance

of '15 percent' instead of coinsurance of '25 percent' in section 1860D–2(b)(2).

"(E) REDUCTION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—Subject to subsection (c), the substitution for the cost-sharing imposed under section 1860D–2(b)(4)(A) of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified under section 1860D–2(b)(4)(A)(i)(I) for the drug and year involved.

"(3) DETERMINATION OF ELIGIBILITY.—

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

"(i) is enrolled in a prescription drug plan or MA–PD plan;

"(ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and

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

"(B) DETERMINATIONS.—

"(i) IN GENERAL.—The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under title XIX for the State under section 1935(a) or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

"(ii) EFFECTIVE PERIOD.—Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for a determination that the individual is a subsidy eligible individual and shall remain in effect for a period specified by the Secretary, but not to exceed 1 year.

"(iii) REDETERMINATIONS AND APPEALS THROUGH MEDICAID.—Redeterminations and appeals, with respect to eligibility determinations under clause (i) made under a State plan under title XIX, shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such title.

"(iv) REDETERMINATIONS AND APPEALS THROUGH COMMISSIONER.—With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security—

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

"(II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1631(c)(1)(A).

"(v) TREATMENT OF MEDICAID BENEFICIARIES.—Subject to subparagraph (F), the Secretary—

"(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)) or who are recipients of supplemental security income benefits under title XVI shall be treated as subsidy eligible individuals described in paragraph (1); and

"(II) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under title XIX to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1902(a)(10)(E) are treated as being determined to be subsidy eligible individuals described in paragraph (1).

Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

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

"(i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1905(p)(1)(B), without regard to the application of section 1902(r)(2); and

"(ii) the term 'poverty line' has the meaning given such term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by such section.

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

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

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

"(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

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

"(E) ALTERNATIVE RESOURCE STANDARD.—

"(i) IN GENERAL.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the

supplemental security income program) do not exceed—

"(I) for 2006, $10,000 (or $20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

"(II) for a subsequent year the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

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

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

"(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual's assets or resources under this subparagraph; and

"(II) provide such form to States.

"(iii) DOCUMENTATION AND SAFEGUARDS.—Under such process—

"(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

"(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

"(III) matters attested to in the application shall be subject to appropriate methods of verification.

"(iv) METHODOLOGY FLEXIBILITY.—The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1905(p) so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

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

"(4) INDEXING DOLLAR AMOUNTS.—

"(A) COPAYMENT FOR LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—The dollar amounts applied under paragraph (1)(D)(ii)—

"(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or

"(ii) for a subsequent year shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

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

"(B) REDUCED DEDUCTIBLE.—The dollar amount applied under paragraph (2)(B)—

"(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage increase described in section 1860D–2(b)(6) for 2007; or

"(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1860D–2(b)(6) for the year involved.

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

"(b) PREMIUM SUBSIDY AMOUNT.—

"(1) IN GENERAL.—The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA–PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

"(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DEFINED.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'low-income benchmark premium amount' means, with respect to a PDP region in which—

"(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

"(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA–PD plans described in section 1851(a)(2)(A)(i) offered in such region.

"(B) PREMIUM AMOUNTS DESCRIBED.—The premium amounts described in this subparagraph are, in the case of—

"(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

"(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

"(iii) an MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1852(a)(6)(B)(ii)).

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1860D–13(b).

"(3) ACCESS TO 0 PREMIUM PLAN.—In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

"(c) ADMINISTRATION OF SUBSIDY PROGRAM.—

"(1) IN GENERAL.—The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA–PD plan—

"(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

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

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

"(D) the Secretary ensures the confidentiality of individually identifiable information.

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

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

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

"SUBSIDIES FOR PART D ELIGIBLE INDIVIDUALS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

"SEC. 1860D–15. (a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage

for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA–PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA–PD plan of the following subsidies in accordance with this section:

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

"(A) the amount of the plan's standardized bid amount (as defined in section 1860D–13(a)(5)), adjusted under subsection (c)(1), reduced by

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

"(2) SUBSIDY THROUGH REINSURANCE.—The reinsurance payment amount (as defined in subsection (b)).

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

"(b) REINSURANCE PAYMENT AMOUNT.—

"(1) IN GENERAL.—The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

"(2) ALLOWABLE REINSURANCE COSTS.—For purposes of this section, the term 'allowable reinsurance costs' means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

"(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered prescription drug costs' means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

"(4) COVERAGE YEAR DEFINED.—For purposes of this section, the term 'coverage year' means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

"(c) ADJUSTMENTS RELATING TO BIDS.—

"(1) HEALTH STATUS RISK ADJUSTMENT.—

"(A) ESTABLISHMENT OF RISK ADJUSTORS.—The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA–PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

"(B) CONSIDERATIONS.—In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1853(a)(3) to adjust payments to MA organizations for benefits under the original medicare fee-for-service program option.

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

"(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and

"(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary.

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

"(2) GEOGRAPHIC ADJUSTMENT.—

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

"(B) DE MINIMIS RULE.—If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

"(C) BUDGET NEUTRAL ADJUSTMENT.—Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments

made under this part that would have been made if the Secretary had not applied such adjustment.

"(d) PAYMENT METHODS.—

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

"(2) REQUIREMENT FOR PROVISION OF INFORMATION.—

"(A) REQUIREMENT.—Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

"(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

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

"(4) APPLICATION OF ENROLLEE ADJUSTMENT.—The provisions of section 1853(a)(2) shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a).

"(e) PORTION OF TOTAL PAYMENTS TO A SPONSOR OR ORGANIZATION SUBJECT TO RISK (APPLICATION OF RISK CORRIDORS).—

"(1) COMPUTATION OF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'adjusted allowable risk corridor costs' means, for a plan for a coverage year (as defined in subsection (b)(4))—

"(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by

"(ii) the sum of (I) the total reinsurance payments made under subsection (b) to the sponsor of the plan for the year, and (II) the total subsidy payments made under section 1860D–14 to the sponsor of the plan for the year.

"(B) ALLOWABLE RISK CORRIDOR COSTS.—For purposes of this subsection, the term 'allowable risk corridor costs' means, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic

prescription drug coverage taking into account the adjustment under section 1860D–11(c)(2). In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1860D–14(a) of the maximum amount of copayments permitted under such paragraphs.

"(2) ADJUSTMENT OF PAYMENT.—

"(A) NO ADJUSTMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS WITHIN RISK CORRIDOR.—If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)), but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) for the plan for the year, then no payment adjustment shall be made under this subsection.

"(B) INCREASE IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS ABOVE UPPER LIMIT OF RISK CORRIDOR.—

"(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

"(ii) COSTS ABOVE SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

"(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

"(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

"(iii) CONDITIONS FOR APPLICATION OF HIGHER PERCENTAGE FOR 2006 AND 2007.—The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that—

"(I) at least 60 percent of prescription drug plans and MA–PD plans to which this subsection applies have adjusted allowable risk corridor costs

for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

"(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA–PD plan.

"(C) REDUCTION IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS BELOW LOWER LIMIT OF RISK CORRIDOR.—

"(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD LOWER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

"(ii) COSTS BELOW SECOND THRESHOLD LOWER LIMIT.—If the adjusted allowable risk corridor costs for the plan for the year are less the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of—

"(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

"(II) 80 percent of the difference between the second threshold upper limit of the risk corridor and such adjusted allowable risk corridor costs.

"(3) ESTABLISHMENT OF RISK CORRIDORS.—

"(A) IN GENERAL.—For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA–PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

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

"(I) the target amount described in subparagraph (B) for the plan; minus

"(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

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

"(I) the target amount described in subparagraph (B) for the plan; minus

"(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

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

"(I) such target amount; and

"(II) the amount described in clause (i)(II).

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

"(I) such target amount; and

"(II) the amount described in clause (ii)(II).

"(B) TARGET AMOUNT DESCRIBED.—The target amount described in this paragraph is, with respect to a prescription drug plan or an MA–PD plan in a year, the total amount of payments paid to the PDP sponsor or MA–PD organization for the plan for the year, taking into account amounts paid by the Secretary and enrollees, based upon the standardized bid amount (as defined in section 1860D–13(a)(5) and as risk adjusted under subsection (c)(1)), reduced by the total amount of administrative expenses for the year assumed in such standardized bid.

"(C) FIRST AND SECOND THRESHOLD RISK PERCENTAGE DEFINED.—

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

"(I) for 2006 and 2007, and 2.5 percent;

"(II) for 2008 through 2011, 5 percent; and

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

"(ii) SECOND THRESHOLD RISK PERCENTAGE.—Subject to clause (iii), for purposes of this section, the second threshold risk percentage is—

"(I) for 2006 and 2007, 5 percent;

"(II) for 2008 through 2011, 10 percent; and

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

"(iii) REDUCTION OF RISK PERCENTAGE TO ENSURE 2 PLANS IN AN AREA.—Pursuant to section 1860D–11(b)(2)(E)(ii), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (2).

"(4) PLANS AT RISK FOR ENTIRE AMOUNT OF SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—A PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

"(5) NO EFFECT ON MONTHLY PREMIUM.—No adjustment in payments made by reason of this subsection shall affect

the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

"(f) DISCLOSURE OF INFORMATION.—

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

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

"(B) the Secretary shall have the right in accordance with section 1857(d)(2)(B) (as applied under section 1860D–12(b)(3)(C)) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

"(2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

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

"MEDICARE PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

"SEC. 1860D–16. (a) ESTABLISHMENT AND OPERATION OF ACCOUNT.—

"(1) ESTABLISHMENT.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Medicare Prescription Drug Account' (in this section referred to as the 'Account').

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

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

"(b) PAYMENTS FROM ACCOUNT.—

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

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

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

"(C) payments to sponsors of qualified retiree prescription drug plans under section 1860D–22(a); and

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

"(2) TRANSFERS TO MEDICAID ACCOUNT FOR INCREASED ADMINISTRATIVE COSTS.—The Managing Trustee shall transfer from time to time from the Account to the Grants to States for Medicaid account amounts the Secretary certifies are attributable to increases in payment resulting from the application of section 1935(b).

"(3) PAYMENTS OF PREMIUMS WITHHELD.—The Managing Trustee shall make payment to the PDP sponsor or MA organization involved of the premiums (and the portion of late enrollment penalties) that are collected in the manner described in section 1854(d)(2)(A) and that are payable under a prescription drug plan or MA–PD plan offered by such sponsor or organization.

"(4) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

"(c) DEPOSITS INTO ACCOUNT.—

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

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

"(3) APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Account, an amount equivalent to the amount of payments made from the Account under subsection (b) plus such amounts as the Managing Trustee certifies is necessary to maintain an appropriate contingency margin, reduced by the amounts deposited under paragraph (1) or subsection (a)(2).

"(4) INITIAL FUNDING AND RESERVE.—In order to assure prompt payment of benefits provided under this part and the administrative expenses thereunder during the early months of the program established by this part and to provide an initial contingency reserve, there are authorized to be appropriated to the Account, out of any moneys in the Treasury not otherwise appropriated, such amount as the Secretary certifies are required, but not to exceed 10 percent of the estimated total expenditures from such Account in 2006.

"(5) TRANSFER OF ANY REMAINING BALANCE FROM TRANSITIONAL ASSISTANCE ACCOUNT.—Any balance in the Transitional Assistance Account that is transferred under section 1860D–31(k)(5) shall be deposited into the Account.

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

"APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND RELATED MANAGED CARE PROGRAMS

"SEC. 1860D–21. (a) SPECIAL RULES RELATING TO OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

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

"(A) may not offer an MA plan described in section 1851(a)(2)(A) in an area unless either that plan (or another MA plan offered by the organization in that same service area) includes required prescription drug coverage (as defined in paragraph (2)); and

"(B) may not offer prescription drug coverage (other than that required under parts A and B) to an enrollee—

"(i) under an MSA plan; or

"(ii) under another MA plan unless such drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of this section with respect to such coverage are met.

"(2) QUALIFYING COVERAGE.—For purposes of paragraph (1)(A), the term 'required coverage' means with respect to an MA–PD plan—

"(A) basic prescription drug coverage; or

"(B) qualified prescription drug coverage that provides supplemental prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied under the plan (due to the application of a credit against such premium of a rebate under section 1854(b)(1)(C)).

"(b) APPLICATION OF DEFAULT ENROLLMENT RULES.—

"(1) SEAMLESS CONTINUATION.—In applying section 1851(c)(3)(A)(ii), an individual who is enrolled in a health benefits plan shall not be considered to have been deemed to make an election into an MA–PD plan unless such health benefits plan provides any prescription drug coverage.

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

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

"(B) for periods after January 1, 2006, such MA plan is an MA–PD plan.

"(3) DISCONTINUANCE OF MA–PD ELECTION DURING FIRST YEAR OF ELIGIBILITY.—In applying the second sentence of section 1851(e)(4) in the case of an individual who is electing to discontinue enrollment in an MA–PD plan, the individual shall be permitted to enroll in a prescription drug plan under part D at the time of the election of coverage under the original medicare fee-for-service program.

"(4) RULES REGARDING ENROLLEES IN MA PLANS NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE.—In the case

of an individual who is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, if the organization offering such coverage discontinues the offering with respect to the individual of all MA plans that do not provide such coverage—

"(i) the individual is deemed to have elected the original medicare fee-for-service program option, unless the individual affirmatively elects to enroll in an MA–PD plan; and

"(ii) in the case of such a deemed election, the disenrollment shall be treated as an involuntary termination of the MA plan described in subparagraph (B)(ii) of section 1882(s)(3) for purposes of applying such section.

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

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

"(1) IN GENERAL.—Except as otherwise provided, the provisions of this part shall apply under part C with respect to prescription drug coverage provided under MA–PD plans in lieu of the other provisions of part C that would apply to such coverage under such plans.

"(2) WAIVER.—The Secretary shall waive the provisions referred to in paragraph (1) to the extent the Secretary determines that such provisions duplicate, or are in conflict with, provisions otherwise applicable to the organization or plan under part C or as may be necessary in order to improve coordination of this part with the benefits under this part.

"(3) TREATMENT OF MA OWNED AND OPERATED PHARMACIES.—The Secretary may waive the requirement of section 1860D–4(b)(1)(C) in the case of an MA–PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization, if the Secretary determines that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.

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

"(1) REQUIREMENTS REGARDING NEGOTIATED PRICES.—Subsections (a)(1) and (d)(1) of section 1860D–2 and section 1860D–4(b)(2)(A) shall not be construed to require the plan to provide negotiated prices (described in subsection (d)(1)(B) of such section), but shall apply to the extent the plan does so.

"(2) MODIFICATION OF PHARMACY ACCESS STANDARD AND DISCLOSURE REQUIREMENT.—If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost-sharing, and without regard to whether they are participating pharmacies in a network or have entered into contracts or agreements with pharmacies to provide drugs to

enrollees covered by the plan, subsections (b)(1)(C) and (k) of section 1860D–4 shall not apply to the plan.

"(3) DRUG UTILIZATION MANAGEMENT PROGRAM AND MEDICATION THERAPY MANAGEMENT PROGRAM NOT REQUIRED.—The requirements of subparagraphs (A) and (C) of section 1860D–4(c)(1) shall not apply to the plan.

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

"(A) bases such amount on the Secretary's estimate of the amount of such payments that would be payable if the plan were an MA–PD plan described in section 1851(a)(2)(A)(i) and the previous provisions of this subsection did not apply; and

"(B) takes into account the average reinsurance payments made under section 1860D–15(b) for populations of similar risk under MA–PD plans described in such section.

"(5) EXEMPTION FROM RISK CORRIDOR PROVISIONS.—The provisions of section 1860D–15(e) shall not apply.

"(6) EXEMPTION FROM NEGOTIATIONS.—Subsections (d) and (e)(2)(C) of section 1860D–11 shall not apply and the provisions of section 1854(a)(5)(B) prohibiting the review, approval, or disapproval of amounts described in such section shall apply to the proposed bid and terms and conditions described in section 1860D–11(d).

"(7) TREATMENT OF INCURRED COSTS WITHOUT REGARD TO FORMULARY.—The exclusion of costs incurred for covered part D drugs which are not included (or treated as being included) in a plan's formulary under section 1860D–2(b)(4)(B)(i) shall not apply insofar as the plan does not utilize a formulary.

"(e) APPLICATION TO REASONABLE COST REIMBURSEMENT CONTRACTORS.—

"(1) IN GENERAL.—Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of an organization that is providing benefits under a reasonable cost reimbursement contract under section 1876(h) and that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such a contract, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in the same manner as such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1851(a)(2)(A)(i) and coverage under such a contract that so provides qualified prescription drug coverage shall be deemed to be an MA–PD local plan.

"(2) LIMITATION ON ENROLLMENT.—In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the reasonable cost reimbursement contract involved.

"(3) BIDS NOT INCLUDED IN DETERMINING NATIONAL AVERAGE MONTHLY BID AMOUNT.—The bid of an organization offering prescription drug coverage under this subsection shall not be taken into account in computing the national average monthly bid amount and low-income benchmark premium amount under this part.

"(f) APPLICATION TO PACE.—

"(1) IN GENERAL.—Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of a PACE program under section 1894 that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such program, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in a manner that is similar to the manner in which such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1851(a)(2)(A)(ii) and a PACE program that so provides such coverage may be deemed to be an MA–PD local plan.

"(2) LIMITATION ON ENROLLMENT.—In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the PACE program involved.

"(3) BIDS NOT INCLUDED IN DETERMINING STANDARDIZED BID AMOUNT.—The bid of an organization offering prescription drug coverage under this subsection is not be taken into account in computing any average benchmark bid amount and low-income benchmark premium amount under this part.

"SPECIAL RULES FOR EMPLOYER-SPONSORED PROGRAMS

"SEC. 1860D–22. (a) SUBSIDY PAYMENT.—

"(1) IN GENERAL.—The Secretary shall provide in accordance with this subsection for payment to the sponsor of a qualified retiree prescription drug plan (as defined in paragraph (2)) of a special subsidy payment equal to the amount specified in paragraph (3) for each qualified covered retiree under the plan (as defined in paragraph (4)). This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

"(2) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN DEFINED.—For purposes of this subsection, the term 'qualified retiree prescription drug plan' means employment-based retiree health coverage (as defined in subsection (c)(1)) if, with respect to a part D eligible individual who is a participant or beneficiary under such coverage, the following requirements are met:

"(A) ATTESTATION OF ACTUARIAL EQUIVALENCE TO STANDARD COVERAGE.—The sponsor of the plan provides the Secretary, annually or at such other time as the Secretary may require, with an attestation that the actuarial value of prescription drug coverage under the plan (as determined using the processes and methods described in section 1860D–11(c)) is at least equal to the actuarial value of standard prescription drug coverage.

"(B) AUDITS.—The sponsor of the plan, or an administrator of the plan designated by the sponsor, shall maintain (and 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 drug coverage and the accuracy of payments made under this section. The provisions of section 1860D–2(d)(3) shall apply to such information under this section (including such actuarial value and attestation) in a manner similar to the manner in which they apply to financial records of PDP sponsors and MA organizations.

"(C) PROVISION OF DISCLOSURE REGARDING PRESCRIPTION DRUG COVERAGE.—The sponsor of the plan shall provide for disclosure of information regarding prescription drug coverage in accordance with section 1860D–13(b)(6)(B).

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

"(A) IN GENERAL.—For purposes of this subsection, the special subsidy payment amount under this paragraph for a qualifying covered retiree for a coverage year enrolled with the sponsor of a qualified retiree prescription drug plan is, for the portion of the retiree's gross covered retiree plan-related prescription drug costs (as defined in subparagraph (C)(ii)) for such year that exceeds the cost threshold amount specified in subparagraph (B) and does not exceed the cost limit under such subparagraph, an amount equal to 28 percent of the allowable retiree costs (as defined in subparagraph (C)(i)) attributable to such gross covered prescription drug costs.

"(B) COST THRESHOLD AND COST LIMIT APPLICABLE.—

"(i) IN GENERAL.—Subject to clause (ii)—

"(I) the cost threshold under this subparagraph is equal to $250 for plan years that end in 2006; and

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

"(ii) INDEXING.—The cost threshold and cost limit amounts specified in subclauses (I) and (II) of clause (i) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible and the annual out-of-pocket threshold, respectively, are annually adjusted under paragraphs (1) and (4)(B) of section 1860D–2(b).

"(C) DEFINITIONS.—For purposes of this paragraph:

"(i) ALLOWABLE RETIREE COSTS.—The term 'allowable retiree costs' means, with respect to gross covered prescription drug costs under a qualified retiree prescription drug plan by a plan sponsor, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or by or on behalf of a qualifying covered retiree under the plan.

"(ii) GROSS COVERED RETIREE PLAN-RELATED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered retiree plan-related prescription drug costs' means, with respect to a qualifying covered retiree enrolled in a qualified retiree prescription drug plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year. Such costs shall be determined whether they are paid by the retiree or under the plan.

"(iii) COVERAGE YEAR.—The term 'coverage year' has the meaning given such term in section 1860D–15(b)(4).

"(4) QUALIFYING COVERED RETIREE DEFINED.—For purposes of this subsection, the term 'qualifying covered retiree' means a part D eligible individual who is not enrolled in a prescription

drug plan or an MA–PD plan but is covered under a qualified retiree prescription drug plan.

"(5) PAYMENT METHODS, INCLUDING PROVISION OF NECESSARY INFORMATION.—The provisions of section 1860D–15(d) (including paragraph (2), relating to requirement for provision of information) shall apply to payments under this subsection in a manner similar to the manner in which they apply to payment under section 1860D–15(b).

"(6) CONSTRUCTION.—Nothing in this subsection shall be construed as—

"(A) precluding a part D eligible individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in an MA–PD plan;

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

"(C) preventing such employment-based retiree health coverage from providing coverage—

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

"(ii) that is supplemental to the benefits provided under a prescription drug plan or an MA–PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan but who are enrolled in such a prescription drug plan or MA–PD plan; or

"(D) preventing employers to provide for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic prescription drug coverage, so long as the actuarial equivalence requirement of paragraph (2)(A) is met.

"(b) APPLICATION OF MA WAIVER AUTHORITY.—The provisions of section 1857(i) shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled under such coverage.

"(c) DEFINITIONS.—For purposes of this section:

"(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs (whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation) for part D eligible individuals (or for such individuals and their spouses and dependents) under a group health plan based on their status as retired participants in such plan.

"(2) SPONSOR.—The term 'sponsor' means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974, in relation to a group health plan, except that, in the case of a plan maintained jointly by one employer and an employee organization and with respect

to which the employer is the primary source of financing, such term means such employer.

"(3) GROUP HEALTH PLAN.—The term 'group health plan' includes such a plan as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 and also includes the following:

"(A) FEDERAL AND STATE GOVERNMENTAL PLANS.—Such a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing, including a health benefits plan offered under chapter 89 of title 5, United States Code.

"(B) COLLECTIVELY BARGAINED PLANS.—Such a plan established or maintained under or pursuant to one or more collective bargaining agreements.

"(C) CHURCH PLANS.—Such a plan established and maintained for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax under section 501 of the Internal Revenue Code of 1986.

"STATE PHARMACEUTICAL ASSISTANCE PROGRAMS

"SEC. 1860D–23. (a) REQUIREMENTS FOR BENEFIT COORDINATION.—

"(1) IN GENERAL.—Before July 1, 2005, the Secretary shall establish consistent with this section requirements for prescription drug plans to ensure the effective coordination between a part D plan (as defined in paragraph (5)) and a State Pharmaceutical Assistance Program (as defined in subsection (b)) with respect to—

"(A) payment of premiums and coverage; and

"(B) payment for supplemental prescription drug benefits,

for part D eligible individuals enrolled under both types of plans.

"(2) COORDINATION ELEMENTS.—The requirements under paragraph (1) shall include requirements relating to coordination of each of the following:

"(A) Enrollment file sharing.

"(B) The processing of claims, including electronic processing.

"(C) Claims payment.

"(D) Claims reconciliation reports.

"(E) Application of the protection against high out-of-pocket expenditures under section 1860D–2(b)(4).

"(F) Other administrative processes specified by the Secretary.

Such requirements shall be consistent with applicable law to safeguard the privacy of any individually identifiable beneficiary information.

"(3) USE OF LUMP SUM PER CAPITA METHOD.—Such requirements shall include a method for the application by a part D plan of specified funding amounts from a State Pharmaceutical Assistance Program for enrolled individuals for supplemental prescription drug benefits.

"(4) CONSULTATION.—In establishing requirements under this subsection, the Secretary shall consult with State Pharmaceutical Assistance Programs, MA organizations, States, pharmaceutical benefit managers, employers, representatives of part D eligible individuals, the data processing experts, pharmacists, pharmaceutical manufacturers, and other experts.

"(5) PART D PLAN DEFINED.—For purposes of this section and section 1860D–24, the term 'part D plan' means a prescription drug plan and an MA–PD plan.

"(b) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—For purposes of this part, the term 'State Pharmaceutical Assistance Program' means a State program—

"(1) which provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of part D eligible individuals;

"(2) which, in determining eligibility and the amount of assistance to part D eligible individuals under the Program, provides assistance to such individuals in all part D plans and does not discriminate based upon the part D plan in which the individual is enrolled; and

"(3) which satisfies the requirements of subsections (a) and (c).

"(c) RELATION TO OTHER PROVISIONS.—

"(1) MEDICARE AS PRIMARY PAYOR.—The requirements of this section shall not change or affect the primary payor status of a part D plan.

"(2) USE OF A SINGLE CARD.—A card that is issued under section 1860D–4(b)(2)(A) for use under a part D plan may also be used in connection with coverage of benefits provided under a State Pharmaceutical Assistance Program and, in such case, may contain an emblem or symbol indicating such connection.

"(3) OTHER PROVISIONS.—The provisions of section 1860D–24(c) shall apply to the requirements under this section.

"(4) SPECIAL TREATMENT UNDER OUT-OF-POCKET RULE.—In applying section 1860D–2(b)(4)(C)(ii), expenses incurred under a State Pharmaceutical Assistance Program may be counted toward the annual out-of-pocket threshold.

"(5) CONSTRUCTION.—Nothing in this section shall be construed as requiring a State Pharmaceutical Assistance Program to coordinate or provide financial assistance with respect to any part D plan.

"(d) FACILITATION OF TRANSITION AND COORDINATION WITH STATE PHARMACEUTICAL ASSISTANCE PROGRAMS.—

"(1) TRANSITIONAL GRANT PROGRAM.—The Secretary shall provide payments to State Pharmaceutical Assistance Programs with an application approved under this subsection.

"(2) USE OF FUNDS.—Payments under this section may be used by a Program for any of the following:

"(A) Educating part D eligible individuals enrolled in the Program about the prescription drug coverage available through part D plans under this part.

"(B) Providing technical assistance, phone support, and counseling for such enrollees to facilitate selection and enrollment in such plans.

"(C) Other activities designed to promote the effective coordination of enrollment, coverage, and payment between such Program and such plans.

"(3) ALLOCATION OF FUNDS.—Of the amount appropriated to carry out this subsection for a fiscal year, the Secretary shall allocate payments among Programs that have applications approved under paragraph (4) for such fiscal year in proportion to the number of enrollees enrolled in each such Program as of October 1, 2003.

"(4) APPLICATION.—No payments may be made under this subsection except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary.

"(5) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated for each of fiscal years 2005 and 2006, $62,500,000 to carry out this subsection.

"COORDINATION REQUIREMENTS FOR PLANS PROVIDING PRESCRIPTION DRUG COVERAGE

"SEC. 1860D–24. (a) APPLICATION OF BENEFIT COORDINATION REQUIREMENTS TO ADDITIONAL PLANS.—

"(1) IN GENERAL.—The Secretary shall apply the coordination requirements established under section 1860D–23(a) to Rx plans described in subsection (b) in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

"(2) APPLICATION TO TREATMENT OF CERTAIN OUT-OF-POCKET EXPENDITURES.—To the extent specified by the Secretary, the requirements referred to in paragraph (1) shall apply to procedures established under section 1860D–2(b)(4)(D).

"(3) USER FEES.—

"(A) IN GENERAL.—The Secretary may impose user fees for the transmittal of information necessary for benefit coordination under section 1860D–2(b)(4)(D) in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B), except that the Secretary may retain a portion of such fees to defray the Secretary's costs in carrying out procedures under section 1860D–2(b)(4)(D).

"(B) APPLICATION.—A user fee may not be imposed under subparagraph (A) with respect to a State Pharmaceutical Assistance Program.

"(b) RX PLAN.—An Rx plan described in this subsection is any of the following:

"(1) MEDICAID PROGRAMS.—A State plan under title XIX, including such a plan operating under a waiver under section 1115, if it meets the requirements of section 1860D–23(b)(2).

"(2) GROUP HEALTH PLANS.—An employer group health plan.

"(3) FEHBP.—The Federal employees health benefits plan under chapter 89 of title 5, United States Code.

"(4) MILITARY COVERAGE (INCLUDING TRICARE).—Coverage under chapter 55 of title 10, United States Code.

"(5) OTHER PRESCRIPTION DRUG COVERAGE.—Such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription

drug coverage on behalf of part D eligible individuals as the Secretary may specify.

"(c) RELATION TO OTHER PROVISIONS.—

"(1) USE OF COST MANAGEMENT TOOLS.—The requirements of this section shall not impair or prevent a PDP sponsor or MA organization from applying cost management tools (including differential payments) under all methods of operation.

"(2) NO AFFECT ON TREATMENT OF CERTAIN OUT-OF-POCKET EXPENDITURES.—The requirements of this section shall not affect the application of the procedures established under section 1860D–2(b)(4)(D).

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

"MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM

"SEC. 1860D–31. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—The Secretary shall establish a program under this section—

"(A) to endorse prescription drug discount card programs that meet the requirements of this section in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States; and

"(B) to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs.

"(2) PERIOD OF OPERATION.—

"(A) IMPLEMENTATION DEADLINE.—The Secretary shall implement the program under this section so that discount cards and transitional assistance are first available by not later than 6 months after the date of the enactment of this section.

"(B) EXPEDITING IMPLEMENTATION.—The Secretary shall promulgate regulations to carry out the program under this section which may be effective and final immediately on an interim basis as of the date of publication of the interim final regulation. If the Secretary provides for an interim final regulation, the Secretary shall provide for a period of public comments on such regulation after the date of publication. The Secretary may change or revise such regulation after completion of the period of public comment.

"(C) TERMINATION AND TRANSITION.—

"(i) IN GENERAL.—Subject to clause (ii)—

"(I) the program under this section shall not apply to covered discount card drugs dispensed after December 31, 2005; and

"(II) transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

"(ii) TRANSITION.—In the case of an individual who is enrolled in an endorsed discount card program as

of December 31, 2005, during the individual's transition period (if any) under clause (iii), in accordance with transition rules specified by the Secretary—

"(I) such endorsed program may continue to apply to covered discount card drugs dispensed to the individual under the program during such transition period;

"(II) no annual enrollment fee shall be applicable during the transition period;

"(III) during such period the individual may not change the endorsed program plan in which the individual is enrolled; and

"(IV) the balance of any transitional assistance remaining on January 1, 2006, shall remain available for drugs dispensed during the individual's transition period.

"(iii) TRANSITION PERIOD.—The transition period under this clause for an individual is the period beginning on January 1, 2006, and ending in the case of an individual who—

"(I) is enrolled in a prescription drug plan or an MA–PD plan before the last date of the initial enrollment period under section 1860D–1(b)(2)(A), on the effective date of the individual's coverage under such part; or

"(II) is not so enrolled, on the last day of such initial period.

"(3) VOLUNTARY NATURE OF PROGRAM.—Nothing in this section shall be construed as requiring a discount card eligible individual to enroll in an endorsed discount card program under this section.

"(4) GLOSSARY AND DEFINITIONS OF TERMS.—For purposes of this section:

"(A) COVERED DISCOUNT CARD DRUG.—The term 'covered discount card drug' has the meaning given the term 'covered part D drug' in section 1860D–2(e).

"(B) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—The term 'discount card eligible individual' is defined in subsection (b)(1)(A).

"(C) ENDORSED DISCOUNT CARD PROGRAM; ENDORSED PROGRAM.—The terms 'endorsed discount card program' and 'endorsed program' mean a prescription drug discount card program that is endorsed (and for which the sponsor has a contract with the Secretary) under this section.

"(D) NEGOTIATED PRICE.—Negotiated prices are described in subsection (e)(1)(A)(ii).

"(E) PRESCRIPTION DRUG CARD SPONSOR; SPONSOR.—The terms 'prescription drug card sponsor' and 'sponsor' are defined in subsection (h)(1)(A).

"(F) STATE.—The term 'State' has the meaning given such term for purposes of title XIX.

"(G) TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—The term 'transitional assistance eligible individual' is defined in subsection (b)(2).

"(b) ELIGIBILITY FOR DISCOUNT CARD AND FOR TRANSITIONAL ASSISTANCE.—For purposes of this section:

"(1) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—The term 'discount card eligible individual' means an individual who—

"(i) is entitled to benefits, or enrolled, under part A or enrolled under part B; and

"(ii) subject to paragraph (4), is not an individual described in subparagraph (B).

"(B) INDIVIDUAL DESCRIBED.—An individual described in this subparagraph is an individual described in subparagraph (A)(i) who is enrolled under title XIX (or under a waiver under section 1115 of the requirements of such title) and is entitled to any medical assistance for outpatient prescribed drugs described in section 1905(a)(12).

"(2) TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—Subject to subparagraph (B), the term 'transitional assistance eligible individual' means a discount card eligible individual who resides in one of the 50 States or the District of Columbia and whose income (as determined under subsection (f)(1)(B)) is not more than 135 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

"(B) EXCLUSION OF INDIVIDUALS WITH CERTAIN PRESCRIPTION DRUG COVERAGE.—Such term does not include an individual who has coverage of, or assistance for, covered discount card drugs under any of the following:

"(i) A group health plan or health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), other than coverage under a plan under part C and other than coverage consisting only of excepted benefits (as defined in such section).

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

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

"(3) SPECIAL TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—The term 'special transitional assistance eligible individual' means a transitional assistance eligible individual whose income (as determined under subsection (f)(1)(B)) is not more than 100 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

"(4) TREATMENT OF MEDICAID MEDICALLY NEEDY.—For purposes of this section, the Secretary shall provide for appropriate rules for the treatment of medically needy individuals described in section 1902(a)(10)(C) as discount card eligible individuals and as transitional assistance eligible individuals.

"(c) ENROLLMENT AND ENROLLMENT FEES.—

"(1) ENROLLMENT PROCESS.—The Secretary shall establish a process through which a discount card eligible individual

is enrolled and disenrolled in an endorsed discount card program under this section consistent with the following:

"(A) CONTINUOUS OPEN ENROLLMENT.—Subject to the succeeding provisions of this paragraph and subsection (h)(9), a discount card eligible individual who is not enrolled in an endorsed discount card program and is residing in a State may enroll in any such endorsed program—

"(i) that serves residents of the State; and

"(ii) at any time beginning on the initial enrollment date, specified by the Secretary, and before January 1, 2006.

"(B) USE OF STANDARD ENROLLMENT FORM.—An enrollment in an endorsed program shall only be effected through completion of a standard enrollment form specified by the Secretary. Each sponsor of an endorsed program shall transmit to the Secretary (in a form and manner specified by the Secretary) information on individuals who complete such enrollment forms and, to the extent provided under subsection (f), information regarding certification as a transitional assistance eligible individual.

"(C) ENROLLMENT ONLY IN ONE PROGRAM.—

"(i) IN GENERAL.—Subject to clauses (ii) and (iii), a discount card eligible individual may be enrolled in only one endorsed discount card program under this section.

"(ii) CHANGE IN ENDORSED PROGRAM PERMITTED FOR 2005.—The Secretary shall establish a process, similar to (and coordinated with) the process for annual, coordinated elections under section 1851(e)(3) during 2004, under which an individual enrolled in an endorsed discount card program may change the endorsed program in which the individual is enrolled for 2005.

"(iii) ADDITIONAL EXCEPTIONS.—The Secretary shall permit an individual to change the endorsed discount card program in which the individual is enrolled in the case of an individual who changes residence to be outside the service area of such program and in such other exceptional cases as the Secretary may provide (taking into account the circumstances for special election periods under section 1851(e)(4)). Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a nursing facility) or enrollment in or disenrollment from a plan under part C through which the individual was enrolled in an endorsed program to be an exceptional circumstance.

"(D) DISENROLLMENT.—

"(i) VOLUNTARY.—An individual may voluntarily disenroll from an endorsed discount card program at any time. In the case of such a voluntary disenrollment, the individual may not enroll in another endorsed program, except under such exceptional circumstances as the Secretary may recognize under subparagraph (C)(iii) or during the annual coordinated enrollment period provided under subparagraph (C)(ii).

"(ii) INVOLUNTARY.—An individual who is enrolled in an endorsed discount card program and not a transitional assistance eligible individual may be disenrolled by the sponsor of the program if the individual fails to pay any annual enrollment fee required under the program.

"(E) APPLICATION TO CERTAIN ENROLLEES.—In the case of a discount card eligible individual who is enrolled in a plan described in section 1851(a)(2)(A) or under a reasonable cost reimbursement contract under section 1876(h) that is offered by an organization that also is a prescription discount card sponsor that offers an endorsed discount card program under which the individual may be enrolled and that has made an election to apply the special rules under subsection (h)(9)(B) for such an endorsed program, the individual may only enroll in such an endorsed discount card program offered by that sponsor.

"(2) ENROLLMENT FEES.—

"(A) IN GENERAL.—Subject to the succeeding provisions of this paragraph, a prescription drug card sponsor may charge an annual enrollment fee for each discount card eligible individual enrolled in an endorsed discount card program offered by such sponsor. The annual enrollment fee for either 2004 or 2005 shall not be prorated for portions of a year. There shall be no annual enrollment fee for a year after 2005.

"(B) AMOUNT.—No annual enrollment fee charged under subparagraph (A) may exceed $30.

"(C) UNIFORM ENROLLMENT FEE.—A prescription drug card sponsor shall ensure that the annual enrollment fee (if any) for an endorsed discount card program is the same for all discount card eligible individuals enrolled in the program and residing in the State.

"(D) COLLECTION.—The annual enrollment fee (if any) charged for enrollment in an endorsed program shall be collected by the sponsor of the program.

"(E) PAYMENT OF FEE FOR TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUALS.—Under subsection (g)(1)(A), the annual enrollment fee (if any) otherwise charged under this paragraph with respect to a transitional assistance eligible individual shall be paid by the Secretary on behalf of such individual.

"(F) OPTIONAL PAYMENT OF FEE BY STATE.—

"(i) IN GENERAL.—The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State to the sponsor.

"(ii) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State for enrollment fees described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI.

"(G) RULES IN CASE OF CHANGES IN PROGRAM ENROLLMENT DURING A YEAR.—The Secretary shall provide special rules in the case of payment of an annual enrollment fee for a discount card eligible individual who changes the endorsed program in which the individual is enrolled during a year.

"(3) ISSUANCE OF DISCOUNT CARD.—Each prescription drug card sponsor of an endorsed discount card program shall issue, in a standard format specified by the Secretary, to each discount card eligible individual enrolled in such program a card that establishes proof of enrollment and that can be used in a coordinated manner to identify the sponsor, program, and individual for purposes of the program under this section.

"(4) PERIOD OF ACCESS.—In the case of a discount card eligible individual who enrolls in an endorsed program, access to negotiated prices and transitional assistance, if any, under such endorsed program shall take effect on such date as the Secretary shall specify.

"(d) PROVISION OF INFORMATION ON ENROLLMENT AND PROGRAM FEATURES.—

"(1) SECRETARIAL RESPONSIBILITIES.—

"(A) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to discount card eligible individuals (and prospective eligible individuals) regarding—

"(i) enrollment in endorsed discount card programs; and

"(ii) the features of the program under this section, including the availability of transitional assistance.

"(B) PROMOTION OF INFORMED CHOICE.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which—

"(i) compares the annual enrollment fee and other features of such programs, which may include comparative prices for covered discount card drugs; and

"(ii) includes educational materials on the variability of discounts on prices of covered discount card drugs under an endorsed program.

The dissemination of information under clause (i) shall, to the extent practicable, be coordinated with the dissemination of educational information on other medicare options.

"(C) SPECIAL RULE FOR INITIAL ENROLLMENT DATE UNDER THE PROGRAM.—To the extent practicable, the Secretary shall ensure, through the activities described in subparagraphs (A) and (B), that discount card eligible individuals are provided with such information at least 30 days prior to the initial enrollment date specified under subsection (c)(1)(A)(ii).

"(D) USE OF MEDICARE TOLL-FREE NUMBER.—The Secretary shall provide through the toll-free telephone number 1–800–MEDICARE for the receipt and response to inquiries and complaints concerning the program under this section and endorsed programs.

"(2) PRESCRIPTION DRUG CARD SPONSOR RESPONSIBILITIES.—

"(A) IN GENERAL.—Each prescription drug card sponsor that offers an endorsed discount card program shall make available to discount card eligible individuals (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs by such individuals, including information on enrollment fees and negotiated prices for covered discount card drugs charged to such individuals.

"(B) RESPONSE TO ENROLLEE QUESTIONS.—Each sponsor offering an endorsed discount card program shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to discount card eligible individuals enrolled in the program. The sponsor shall inform transitional assistance eligible individuals enrolled in the program of the availability of such toll-free telephone number to provide information on the amount of available transitional assistance.

"(C) INFORMATION ON BALANCE OF TRANSITIONAL ASSISTANCE AVAILABLE AT POINT-OF-SALE.—Each sponsor offering an endorsed discount card program shall have a mechanism so that information on the amount of transitional assistance remaining under subsection (g)(1)(B) is available (electronically or by telephone) at the point-of-sale of covered discount card drugs.

"(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

"(A) IN GENERAL.—A prescription drug card sponsor offering an endorsed discount card program shall provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

"(B) TIMING OF NOTICE.—

"(i) IN GENERAL.—Subject to clause (ii), the information under subparagraph (A) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

"(ii) WAIVER.—The Secretary may waive clause (i) in such circumstances as the Secretary may specify.

"(e) DISCOUNT CARD FEATURES.—

"(1) SAVINGS TO ENROLLEES THROUGH NEGOTIATED PRICES.—

"(A) ACCESS TO NEGOTIATED PRICES.—

"(i) IN GENERAL.—Each prescription drug card sponsor that offers an endorsed discount card program shall provide each discount card eligible individual enrolled in the program with access to negotiated prices.

"(ii) NEGOTIATED PRICES.—For purposes of this section, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered discount card drugs, and include any dispensing fees for such drugs.

"(B) ENSURING PHARMACY ACCESS.—Each prescription drug card sponsor offering an endorsed discount card program shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than solely by mail order) drugs directly to enrollees to ensure convenient access to covered discount card drugs at negotiated prices (consistent with rules established by the Secretary). The Secretary shall establish convenient access rules under this clause that are no less favorable to enrollees than the standards for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

"(C) PROHIBITION ON CHARGES FOR REQUIRED SERVICES.—

"(i) IN GENERAL.—Subject to clause (ii), a prescription drug card sponsor (and any pharmacy contracting with such sponsor for the provision of covered discount card drugs to individuals enrolled in such sponsor's endorsed discount card program) may not charge an enrollee any amount for any items and services required to be provided by the sponsor under this section.

"(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to prevent—

"(I) the sponsor from charging the annual enrollment fee (except in the case of a transitional assistance eligible individual); and

"(II) the pharmacy dispensing the covered discount card drug, from imposing a charge (consistent with the negotiated price) for the covered discount card drug dispensed, reduced by the amount of any transitional assistance made available.

"(D) INAPPLICABILITY OF MEDICAID BEST PRICE RULES.—The prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(2) REDUCTION OF MEDICATION ERRORS AND ADVERSE DRUG INTERACTIONS.—Each endorsed discount card program shall implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

"(f) ELIGIBILITY PROCEDURES FOR ENDORSED PROGRAMS AND TRANSITIONAL ASSISTANCE.—

"(1) DETERMINATIONS.—

"(A) PROCEDURES.—The determination of whether an individual is a discount card eligible individual or a transitional assistance eligible individual or a special transitional assistance eligible individual (as defined in subsection (b)) shall be determined under procedures specified by the Secretary consistent with this subsection.

"(B) INCOME AND FAMILY SIZE DETERMINATIONS.—For purposes of this section, the Secretary shall define the terms 'income' and 'family size' and shall specify the methods and period for which they are determined. If under such methods income or family size is determined based on the income or family size for prior periods of time, the Secretary shall permit (whether through a process of reconsideration or otherwise) an individual whose income or family size has changed to elect to have eligibility for transitional assistance determined based on income or family size for a more recent period.

"(2) USE OF SELF-CERTIFICATION FOR TRANSITIONAL ASSISTANCE.—

"(A) IN GENERAL.—Under the procedures specified under paragraph (1)(A) an individual who wishes to be treated as a transitional assistance eligible individual or a special transitional assistance eligible individual under this section (or another qualified person on such individual's behalf) shall certify on the enrollment form under subsection (c)(1)(B) (or similar form specified by the Secretary), through a simplified means specified by the Secretary and under penalty of perjury or similar sanction for false statements, as to the amount of the individual's income, family size, and individual's prescription drug coverage (if any) insofar as they relate to eligibility to be a transitional assistance eligible individual or a special transitional assistance eligible individual. Such certification shall be deemed as consent to verification of respective eligibility under paragraph (3). A certification under this paragraph may be provided before, on, or after the time of enrollment under an endorsed program.

"(B) TREATMENT OF SELF-CERTIFICATION.—The Secretary shall treat a certification under subparagraph (A) that is verified under paragraph (3) as a determination that the individual involved is a transitional assistance eligible individual or special transitional assistance eligible individual (as the case may be) for the entire period of the enrollment of the individual in any endorsed program.

"(3) VERIFICATION.—

"(A) IN GENERAL.—The Secretary shall establish methods (which may include the use of sampling and the use of information described in subparagraph (B)) to verify eligibility for individuals who seek to enroll in an endorsed program and for individuals who provide a certification under paragraph (2).

"(B) INFORMATION DESCRIBED.—The information described in this subparagraph is as follows:

"(i) MEDICAID-RELATED INFORMATION.—Information on eligibility under title XIX and provided to the Secretary under arrangements between the Secretary

and States in order to verify the eligibility of individuals who seek to enroll in an endorsed program and of individuals who provide certification under paragraph (2).

"(ii) SOCIAL SECURITY INFORMATION.—Financial information made available to the Secretary under arrangements between the Secretary and the Commissioner of Social Security in order to verify the eligibility of individuals who provide such certification.

"(iii) INFORMATION FROM SECRETARY OF THE TREASURY.—Financial information made available to the Secretary under section 6103(l)(19) of the Internal Revenue Code of 1986 in order to verify the eligibility of individuals who provide such certification.

"(C) VERIFICATION IN CASES OF MEDICAID ENROLLEES.—

"(i) IN GENERAL.—Nothing in this section shall be construed as preventing the Secretary from finding that a discount card eligible individual meets the income requirements under subsection (b)(2)(A) if the individual is within a category of discount card eligible individuals who are enrolled under title XIX (such as qualified medicare beneficiaries (QMBs), specified low-income medicare beneficiaries (SLMBs), and certain qualified individuals (QI–1s)).

"(ii) AVAILABILITY OF INFORMATION FOR VERIFICATION PURPOSES.—As a condition of provision of Federal financial participation to a State that is one of the 50 States or the District of Columbia under title XIX, for purposes of carrying out this section, the State shall provide the information it submits to the Secretary relating to such title in a manner specified by the Secretary that permits the Secretary to identify individuals who are described in subsection (b)(1)(B) or are transitional assistance eligible individuals or special transitional assistance eligible individuals.

"(4) RECONSIDERATION.—

"(A) IN GENERAL.—The Secretary shall establish a process under which a discount card eligible individual, who is determined through the certification and verification methods under paragraphs (2) and (3) not to be a transitional assistance eligible individual or a special transitional assistance eligible individual, may request a reconsideration of the determination.

"(B) CONTRACT AUTHORITY.—The Secretary may enter into a contract to perform the reconsiderations requested under subparagraph (A).

"(C) COMMUNICATION OF RESULTS.—Under the process under subparagraph (A) the results of such reconsideration shall be communicated to the individual and the prescription drug card sponsor involved.

"(g) TRANSITIONAL ASSISTANCE.—

"(1) PROVISION OF TRANSITIONAL ASSISTANCE.—An individual who is a transitional assistance eligible individual (as determined under this section) and who is enrolled with an endorsed program is entitled—

"(A) to have payment made of any annual enrollment fee charged under subsection (c)(2) for enrollment under the program; and

"(B) to have payment made, up to the amount specified in paragraph (2), under such endorsed program of 90 percent (or 95 percent in the case of a special transitional assistance eligible individual) of the costs incurred for covered discount card drugs obtained through the program taking into account the negotiated price (if any) for the drug under the program.

"(2) LIMITATION ON DOLLAR AMOUNT.—

"(A) IN GENERAL.—Subject to subparagraph (B), the amount specified in this paragraph for a transitional assistance eligible individual—

"(i) for costs incurred during 2004, is $600; or

"(ii) for costs incurred during 2005, is—

"(I) $600, plus

"(II) except as provided in subparagraph (E), the amount by which the amount available under this paragraph for 2004 for that individual exceeds the amount of payment made under paragraph (1)(B) for that individual for costs incurred during 2004.

"(B) PRORATION.—

"(i) IN GENERAL.—In the case of an individual not described in clause (ii) with respect to a year, the Secretary may prorate the amount specified in subparagraph (A) for the balance of the year involved in a manner specified by the Secretary.

"(ii) INDIVIDUAL DESCRIBED.—An individual described in this clause is a transitional assistance eligible individual who—

"(I) with respect to 2004, enrolls in an endorsed program, and provides a certification under subsection (f)(2), before the initial implementation date of the program under this section; and

"(II) with respect to 2005, is enrolled in an endorsed program, and has provided such a certification, before February 1, 2005.

"(C) ACCOUNTING FOR AVAILABLE BALANCES IN CASES OF CHANGES IN PROGRAM ENROLLMENT.—In the case of a transitional assistance eligible individual who changes the endorsed discount card program in which the individual is enrolled under this section, the Secretary shall provide a process under which the Secretary provides to the sponsor of the endorsed program in which the individual enrolls information concerning the balance of amounts available on behalf of the individual under this paragraph.

"(D) LIMITATION ON USE OF FUNDS.—Pursuant to subsection (a)(2)(C), no assistance shall be provided under paragraph (1)(B) with respect to covered discount card drugs dispensed after December 31, 2005.

"(E) NO ROLLOVER PERMITTED IN CASE OF VOLUNTARY DISENROLLMENT.—Except in such exceptional cases as the Secretary may provide, in the case of a transitional assistance eligible individual who voluntarily disenrolls from

an endorsed plan, the provisions of subclause (II) of subparagraph (A)(ii) shall not apply.

"(3) PAYMENT.—The Secretary shall provide a method for the reimbursement of prescription drug card sponsors for assistance provided under this subsection.

"(4) COVERAGE OF COINSURANCE.—

"(A) WAIVER PERMITTED BY PHARMACY.—Nothing in this section shall be construed as precluding a pharmacy from reducing or waiving the application of coinsurance imposed under paragraph (1)(B) in accordance with section 1128B(b)(3)(G).

"(B) OPTIONAL PAYMENT OF COINSURANCE BY STATE.—

"(i) IN GENERAL.—The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the coinsurance under paragraph (1)(B) for some or all enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the coinsurance shall be paid directly by the State to the pharmacy involved.

"(ii) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State for coinsurance described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI.

"(iii) NOT TREATED AS MEDICARE COST-SHARING.—Coinsurance described in paragraph (1)(B) shall not be treated as coinsurance under this title for purposes of section 1905(p)(3)(B).

"(C) TREATMENT OF COINSURANCE.—The amount of any coinsurance imposed under paragraph (1)(B), whether paid or waived under this paragraph, shall not be taken into account in applying the limitation in dollar amount under paragraph (2).

"(5) ENSURING ACCESS TO TRANSITIONAL ASSISTANCE FOR QUALIFIED RESIDENTS OF LONG-TERM CARE FACILITIES AND AMERICAN INDIANS.—

"(A) RESIDENTS OF LONG-TERM CARE FACILITIES.—The Secretary shall establish procedures and may waive requirements of this section as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long-term care facilities.

"(B) AMERICAN INDIANS.—The Secretary shall establish procedures and may waive requirements of this section to ensure that, for purposes of providing transitional assistance, pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act) have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

"(6) NO IMPACT ON BENEFITS UNDER OTHER PROGRAMS.—The availability of negotiated prices or transitional assistance under this section shall not be treated as benefits or otherwise taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

"(7) DISREGARD FOR PURPOSES OF PART C.—Nonuniformity of benefits resulting from the implementation of this section (including the provision or nonprovision of transitional assistance and the payment or waiver of any enrollment fee under this section) shall not be taken into account in applying section 1854(f).

"(h) QUALIFICATION OF PRESCRIPTION DRUG CARD SPONSORS AND ENDORSEMENT OF DISCOUNT CARD PROGRAMS; BENEFICIARY PROTECTIONS.—

"(1) PRESCRIPTION DRUG CARD SPONSOR AND QUALIFICATIONS.—

"(A) PRESCRIPTION DRUG CARD SPONSOR AND SPONSOR DEFINED.—For purposes of this section, the terms 'prescription drug card sponsor' and 'sponsor' mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include—

"(i) a pharmaceutical benefit management company;

"(ii) a wholesale or retail pharmacy delivery system;

"(iii) an insurer (including an insurer that offers medicare supplemental policies under section 1882);

"(iv) an organization offering a plan under part C; or

"(v) any combination of the entities described in clauses (i) through (iv).

"(B) ADMINISTRATIVE QUALIFICATIONS.—Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar program and that meets such business stability and integrity requirements as the Secretary may specify.

"(C) ACCOUNTING FOR TRANSITIONAL ASSISTANCE.—The sponsor of an endorsed discount card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) on behalf of transitional assistance eligible individuals.

"(2) APPLICATIONS FOR PROGRAM ENDORSEMENT.—

"(A) SUBMISSION.—Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

"(B) APPROVAL; COMPLIANCE WITH APPLICABLE REQUIREMENTS.—The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card

program. The Secretary may not endorse such a program unless—

"(i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and

"(ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

"(C) TERMINATION OF ENDORSEMENT AND CONTRACTS.—An endorsement of an endorsed program and a contract under subparagraph (B) shall be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(ii)), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

"(D) ENSURING CHOICE OF PROGRAMS.—

"(i) IN GENERAL.—The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

"(ii) LIMITATION ON NUMBER.—The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

"(3) SERVICE AREA ENCOMPASSING ENTIRE STATES.—Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

"(4) SAVINGS TO MEDICARE BENEFICIARIES.—Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1).

"(5) GRIEVANCE MECHANISM.—Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1852(f).

"(6) CONFIDENTIALITY OF ENROLLEE RECORDS.—

"(A) IN GENERAL.—For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of title XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(B) WAIVER AUTHORITY.—In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to in subparagraph (A), for

such appropriate, limited period of time, as the Secretary specifies.

"(7) LIMITATION ON PROVISION AND MARKETING OF PRODUCTS AND SERVICES.—The sponsor of an endorsed discount card program—

"(A) may provide under the program—

"(i) a product or service only if the product or service is directly related to a covered discount card drug; or

"(ii) a discount price for nonprescription drugs; and

"(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to—

"(i) a covered discount card drug; or

"(ii) a drug described in subparagraph (A)(ii) and the marketing consists of information on the discounted price made available for the drug involved.

"(8) ADDITIONAL PROTECTIONS.—Each endorsed discount card program shall meet such additional requirements as the Secretary identifies to protect and promote the interest of discount card eligible individuals, including requirements that ensure that discount card eligible individuals enrolled in endorsed discount card programs are not charged more than the lower of the price based on negotiated prices or the usual and customary price.

"(9) SPECIAL RULES FOR CERTAIN ORGANIZATIONS.—

"(A) IN GENERAL.—In the case of an organization that is offering a plan under part C or enrollment under a reasonable cost reimbursement contract under section 1876(h) that is seeking to be a prescription drug card sponsor under this section, the organization may elect to apply the special rules under subparagraph (B) with respect to enrollees in any plan described in section 1851(a)(2)(A) that it offers or under such contract and an endorsed discount card program it offers, but only if it limits enrollment under such program to individuals enrolled in such plan or under such contract.

"(B) SPECIAL RULES.—The special rules under this subparagraph are as follows:

"(i) LIMITATION ON ENROLLMENT.—The sponsor limits enrollment under this section under the endorsed discount card program to discount card eligible individuals who are enrolled in the part C plan involved or under the reasonable cost reimbursement contract involved and is not required nor permitted to enroll other individuals under such program.

"(ii) PHARMACY ACCESS.—Pharmacy access requirements under subsection (e)(1)(B) are deemed to be met if the access is made available through a pharmacy network (and not only through mail order) and the network used by the sponsor is approved by the Secretary.

"(iii) SPONSOR REQUIREMENTS.—The Secretary may waive the application of such requirements for a sponsor as the Secretary determines to be duplicative

or to conflict with a requirement of the organization under part C or section 1876 (as the case may be) or to be necessary in order to improve coordination of this section with the benefits under such part or section.

"(i) DISCLOSURE AND OVERSIGHT.—

"(1) DISCLOSURE.—Each prescription drug card sponsor offering an endorsed discount card program shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program performance, use of prescription drugs by discount card eligible individuals enrolled in the program, the extent to which negotiated price concessions described in subsection (e)(1)(A)(ii) made available to the entity by a manufacturer are passed through to enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. The provisions of section 1927(b)(3)(D) shall apply to drug pricing data reported under the previous sentence (other than data in aggregate form).

"(2) OVERSIGHT; AUDIT AND INSPECTION AUTHORITY.—The Secretary shall provide appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section. The Secretary shall have the right to audit and inspect any books and records of a prescription discount card sponsor (and of any affiliated organization referred to in subsection (h)(1)(B)) that pertain to the endorsed discount card program under this section, including amounts payable to the sponsor under this section.

"(3) SANCTIONS FOR ABUSIVE PRACTICES.—The Secretary may implement intermediate sanctions or may revoke the endorsement of a program offered by a sponsor under this section if the Secretary determines that the sponsor or the program no longer meets the applicable requirements of this section or that the sponsor has engaged in false or misleading marketing practices. The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for conduct that a party knows or should know is a violation of this section. The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(j) TREATMENT OF TERRITORIES.—

"(1) IN GENERAL.—The Secretary may waive any provision of this section (including subsection (h)(2)(D)) in the case of a resident of a State (other than the 50 States and the District of Columbia) insofar as the Secretary determines it is necessary to secure access to negotiated prices for discount card eligible individuals (or, at the option of the Secretary, individuals described in subsection (b)(1)(A)(i)).

"(2) TRANSITIONAL ASSISTANCE.—

"(A) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia, if the State establishes a plan described in subparagraph (B) (for providing transitional assistance with respect to the provision of prescription drugs to some or all individuals residing in the State who are described in subparagraph (B)(i)), the Secretary shall pay to the State for the entire period

of the operation of this section an amount equal to the amount allotted to the State under subparagraph (C).

"(B) PLAN.—The plan described in this subparagraph is a plan that—

"(i) provides transitional assistance with respect to the provision of covered discount card drugs to some or all individuals who are entitled to benefits under part A or enrolled under part B, who reside in the State, and who have income below 135 percent of the poverty line; and

"(ii) assures that amounts received by the State under this paragraph are used only for such assistance.

"(C) ALLOTMENT LIMIT.—The amount described in this subparagraph for a State is equal to $35,000,000 multiplied by the ratio (as estimated by the Secretary) of—

"(i) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary as of July 1, 2003), to

"(ii) the sum of such numbers for all States to which this paragraph applies.

"(D) CONTINUED AVAILABILITY OF FUNDS.—Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1935(e).

"(k) FUNDING.—

"(1) ESTABLISHMENT OF TRANSITIONAL ASSISTANCE ACCOUNT.—

"(A) IN GENERAL.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Transitional Assistance Account' (in this subsection referred to as the 'Account').

"(B) FUNDS.—The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, the Account as provided in this subsection.

"(C) SEPARATE FROM REST OF TRUST FUND.—Funds provided under this subsection to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

"(2) PAYMENTS FROM ACCOUNT.—

"(A) IN GENERAL.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2).

"(B) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

"(3) APPROPRIATIONS TO COVER BENEFITS.—There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

"(4) FOR ADMINISTRATIVE EXPENSES.—There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary's responsibilities under this section.

"(5) TRANSFER OF ANY REMAINING BALANCE TO MEDICARE PRESCRIPTION DRUG ACCOUNT.—Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Prescription Drug Account under section 1860D–16.

"(6) CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A)) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g)).

"Subpart 5—Definitions and Miscellaneous Provisions

"DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C

"SEC. 1860D–41. (a) DEFINITIONS.—For purposes of this part:

"(1) BASIC PRESCRIPTION DRUG COVERAGE.—The term 'basic prescription drug coverage' is defined in section 1860D–2(a)(3).

"(2) COVERED PART D DRUG.—The term 'covered part D drug' is defined in section 1860D–2(e).

"(3) CREDITABLE PRESCRIPTION DRUG COVERAGE.—The term 'creditable prescription drug coverage' has the meaning given such term in section 1860D–13(b)(4).

"(4) PART D ELIGIBLE INDIVIDUAL.—The term 'part D eligible individual' has the meaning given such term in section 1860D–1(a)(4)(A).

"(5) FALLBACK PRESCRIPTION DRUG PLAN.—The term 'fallback prescription drug plan' has the meaning given such term in section 1860D–11(g)(4).

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

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

"(8) MA PLAN.—The term 'MA plan' has the meaning given such term in section 1860D–1(a)(4)(B).

"(9) MA–PD PLAN.—The term 'MA–PD plan' has the meaning given such term in section 1860D–1(a)(4)(C).

"(10) MEDICARE PRESCRIPTION DRUG ACCOUNT.—The term 'Medicare Prescription Drug Account' means the Account created under section 1860D–16(a).

"(11) PDP APPROVED BID.—The term 'PDP approved bid' has the meaning given such term in section 1860D–13(a)(6).

"(12) PDP REGION.—The term 'PDP region' means such a region as provided under section 1860D–11(a)(2).

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

"(14) PRESCRIPTION DRUG PLAN.—The term 'prescription drug plan' means prescription drug coverage that is offered—

"(A) under a policy, contract, or plan that has been approved under section 1860D–11(e); and

"(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1860D–12(b).

"(15) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' is defined in section 1860D–2(a)(1).

"(16) STANDARD PRESCRIPTION DRUG COVERAGE.—The term 'standard prescription drug coverage' is defined in section 1860D–2(b).

"(17) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—The term 'State Pharmaceutical Assistance Program' has the meaning given such term in section 1860D–23(b).

"(18) SUBSIDY ELIGIBLE INDIVIDUAL.—The term 'subsidy eligible individual' has the meaning given such term in section 1860D–14(a)(3)(A).

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

"(1) any reference to an MA plan included a reference to a prescription drug plan;

"(2) any reference to an MA organization or a provider-sponsored organization included a reference to a PDP sponsor;

"(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D–12(b);

"(4) any reference to part C included a reference to this part; and

"(5) any reference to an election period under section 1851 were a reference to an enrollment period under section 1860D–1.

"MISCELLANEOUS PROVISIONS

"SEC. 1860D–42. (a) ACCESS TO COVERAGE IN TERRITORIES.—The Secretary may waive such requirements of this part, including section 1860D–3(a)(1), insofar as the Secretary determines it is necessary to secure access to qualified prescription drug coverage for part D eligible individuals residing in a State (other than the 50 States and the District of Columbia).

"(b) APPLICATION OF DEMONSTRATION AUTHORITY.—The provisions of section 402 of the Social Security Amendments of 1967 (Public Law 90–248) shall apply with respect to this part and

part C in the same manner it applies with respect to parts A and B, except that any reference with respect to a Trust Fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part shall be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.".

(b) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this title and title II.

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

(d) REPORT ON PROGRESS IN IMPLEMENTATION OF PRESCRIPTION DRUG BENEFIT.—Not later than March 1, 2005, the Secretary shall submit a report to Congress on the progress that has been made in implementing the prescription drug benefit under this title. The Secretary shall include in the report specific steps that have been taken, and that need to be taken, to ensure a timely start of the program on January 1, 2006. The report shall include recommendations regarding an appropriate transition from the program under section 1860D–31 of the Social Security Act to prescription drug benefits under subpart 1 of part D of title XVIII of such Act.

(e) ADDITIONAL CONFORMING CHANGES.—

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

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

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

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

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

"(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D–14(a)(3)), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section).".

(3) MEDICARE PRESCRIPTION DRUG ACCOUNT.—

(A) Section 201(g) (42 U.S.C. 401(g)) is amended—

(i) in paragraph (1)(B)(i)(V), by inserting "(and, of such portion, the portion of such costs which should

have been borne by the Medicare Prescription Drug Account in such Trust Fund)" after "Trust Fund"; and

(ii) in paragraph (1)(B)(ii)(III), by inserting "(and, of such portion, the portion of such costs which should have been borne by the Medicare Prescription Drug Account in such Trust Fund)" after "Trust Fund".

(B) Section 201(i)(1) (42 U.S.C. 401(i)(1)) is amended by inserting "(and for the Medicare Prescription Drug Account and the Transitional Assistance Account in such Trust Fund)" after "Federal Supplementary Medical Insurance Trust Fund".

(C) Section 1841 (42 U.S.C. 1395t) is amended—

(i) in the last sentence of subsection (a)—

(I) by striking "and" before "such amounts"; and

(II) by inserting before the period the following: ", and such amounts as may be deposited in, or appropriated to, the Medicare Prescription Drug Account established by section 1860D–16";

(ii) in subsection (g), by adding at the end the following: "The payments provided for under part D, other than under section 1860D–31(k)(2), shall be made from the Medicare Prescription Drug Account in the Trust Fund.";

(iii) in subsection (h), by inserting "or pursuant to section 1860D–13(c)(1) or 1854(d)(2)(A) (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)" after "1840(d)"; and

(iv) in subsection (i), by inserting after "and section 1842(g)" the following: "and pursuant to sections 1860D–13(c)(1) and 1854(d)(2)(A) (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)".

(D) Section 1853(f) (42 U.S.C. 1395w–23(f)) is amended—

(i) in the heading by striking "TRUST FUND" and inserting "TRUST FUNDS"; and

(ii) by inserting after the first sentence the following: "Payments to MA organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.".

(4) APPLICATION OF CONFIDENTIALITY FOR DRUG PRICING DATA.—Section 1927(b)(3)(D) (42 U.S.C. 1396r–8(b)(3)(D)) is amended by adding after and below clause (iii) the following:

"The previous sentence shall also apply to information disclosed under section 1860D–2(d)(2) or 1860D–4(c)(2)(E).".

(5) CLARIFICATION OF TREATMENT OF PART A ENROLLEES.—Section 1818(a) (42 U.S.C. 1395i–2(a)) is amended by adding at the end the following: "Except as otherwise provided, any reference to an individual entitled to benefits under this part includes an individual entitled to benefits under this part pursuant to an enrollment under this section or section 1818A.".

(6) DISCLOSURE.—Section 6103(l)(7)(D)(ii) of the Internal Revenue Code of 1986 is amended by inserting "or subsidies

provided under section 1860D–14 of such Act" after "Social Security Act".

(7) EXTENSION OF STUDY AUTHORITY.—Section 1875(b) (42 U.S.C. 1395ll(b)) is amended by striking "the insurance programs under parts A and B" and inserting "this title".

(8) CONFORMING AMENDMENTS RELATING TO FACILITATION OF ELECTRONIC PRESCRIBING.—

(A) Section 1128B(b)(3)(C) (42 U.S.C. 1320a–7b(b)(3)(C)) is amended by inserting "or in regulations under section 1860D–3(e)(6)" after "1987".

(B) Section 1877(b) (42 U.S.C. 1395nn(b)) is amended by adding at the end the following new paragraph:

"(5) ELECTRONIC PRESCRIBING.—An exception established by regulation under section 1860D–3(e)(6).".

(9) OTHER CHANGES.—Section 1927(g)(1)(B)(i) (42 U.S.C. 1396r–8(g)(1)(B)(i)) is amended—

(A) by adding "and" at the end of subclause (II); and

(B) by striking subclause (IV).

SEC. 102. MEDICARE ADVANTAGE CONFORMING AMENDMENTS.

(a) CONFORMING AMENDMENTS TO ENROLLMENT PROCESS.—

(1) EXTENDING OPEN ENROLLMENT PERIODS.—Section 1851(e) (42 U.S.C. 1395w–21(e)) is amended—

(A) in paragraph (2), by striking "2004" and "2005" and inserting "2005" and "2006" each place it appears; and

(B) in paragraph (4), by striking "2005" and inserting "2006" each place it appears.

(2) ESTABLISHMENT OF SPECIAL ANNUAL, COORDINATED ELECTION PERIOD FOR 6 MONTHS BEGINNING NOVEMBER 15, 2005.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)) is amended to read as follows:

"(B) ANNUAL, COORDINATED ELECTION PERIOD.—For purposes of this section, the term 'annual, coordinated election period' means—

"(i) with respect to a year before 2002, the month of November before such year;

"(ii) with respect to 2002, 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year;

"(iii) with respect to 2006, the period beginning on November 15, 2005, and ending on May 15, 2006; and

"(iv) with respect to 2007 and succeeding years, the period beginning on November 15 and ending on December 31 of the year before such year.".

(3) SPECIAL INFORMATION CAMPAIGN.—Section 1851(e)(3) (42 U.S.C. 1395w–21(e)(3)) is amended—

(A) in subparagraph (C), by inserting "and during the period described in subparagraph (B)(iii)" after "(beginning with 1999)"; and

(B) in subparagraph (D)—

(i) in the heading by striking "CAMPAIGN IN 1998" and inserting "CAMPAIGNS"; and

(ii) by adding at the end the following: "During the period described in subparagraph (B)(iii), the Secretary shall provide for an educational and publicity

campaign to inform MA eligible individuals about the availability of MA plans (including MA–PD plans) offered in different areas and the election process provided under this section.".

(4) COORDINATING INITIAL ENROLLMENT PERIODS.—Section 1851(e)(1) (42 U.S.C. 1395w–21(e)(1)) is amended by adding at the end the following new sentence: "If any portion of an individual's initial enrollment period under part B occurs after the end of the annual, coordinated election period described in paragraph (3)(B)(iii), the initial enrollment period under this part shall further extend through the end of the individual's initial enrollment period under part B.".

(5) COORDINATION OF EFFECTIVENESS OF ELECTIONS DURING ANNUAL COORDINATED ELECTION PERIOD FOR 2006.—Section 1851(f)(3) (42 U.S.C. 1395w–21(f)(3)) is amended by inserting ", other than the period described in clause (iii) of such subsection" after "subsection (e)(3)(B)".

(6) LIMITATION ON ONE-CHANGE RULE TO SAME TYPE OF PLAN.—Section 1851(e)(2) (42 U.S.C. 1395w–21(e)(2)) is amended—

(A) in subparagraph (B)(i), by inserting ", subparagraph (C)(iii)," after "clause (ii)";

(B) in subparagraph (C)(i), by striking "clause (ii)" and inserting "clauses (ii) and (iii)"; and

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

"(iii) LIMITATION ON EXERCISE OF RIGHT WITH RESPECT TO PRESCRIPTION DRUG COVERAGE.—Effective for plan years beginning on or after January 1, 2006, in applying clause (i) (and clause (i) of subparagraph (B)) in the case of an individual who—

"(I) is enrolled in an MA plan that does provide qualified prescription drug coverage, the individual may exercise the right under such clause only with respect to coverage under the original fee-for-service plan or coverage under another MA plan that does not provide such coverage and may not exercise such right to obtain coverage under an MA–PD plan or under a prescription drug plan under part D; or

"(II) is enrolled in an MA–PD plan, the individual may exercise the right under such clause only with respect to coverage under another MA–PD plan (and not an MA plan that does not provide qualified prescription drug coverage) or under the original fee-for-service plan and coverage under a prescription drug plan under part D.".

(b) PROMOTION OF E-PRESCRIBING BY MA PLANS.—Section 1852(j) (42 U.S.C. 1395w–22(j)) is amended by adding at the end the following new paragraph:

"(7) PROMOTION OF E-PRESCRIBING BY MA PLANS.—

"(A) IN GENERAL.—An MA–PD plan may provide for a separate payment or otherwise provide for a differential payment for a participating physician that prescribes covered part D drugs in accordance with an electronic prescription drug program that meets standards established under section 1860D–4(e).

"(B) CONSIDERATIONS.—Such payment may take into consideration the costs of the physician in implementing such a program and may also be increased for those participating physicians who significantly increase—

"(i) formulary compliance;

"(ii) lower cost, therapeutically equivalent alternatives;

"(iii) reductions in adverse drug interactions; and

"(iv) efficiencies in filing prescriptions through reduced administrative costs.

"(C) STRUCTURE.—Additional or increased payments under this subsection may be structured in the same manner as medication therapy management fees are structured under section 1860D–4(c)(2)(E).".

(c) OTHER CONFORMING AMENDMENTS.—

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

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

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

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

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

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply on and after January 1, 2006.

SEC. 103. MEDICAID AMENDMENTS.

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

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

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

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

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

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

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

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

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

"SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

"SEC. 1935. (a) REQUIREMENTS RELATING TO MEDICARE PRESCRIPTION DRUG LOW-INCOME SUBSIDIES AND MEDICARE TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a), a State shall do the following:

"(1) INFORMATION FOR TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE VERIFICATION.—The State shall provide the Secretary with information to carry out section 1860D–31(f)(3)(B)(i).

"(2) ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—The State shall—

"(A) make determinations of eligibility for premium and cost-sharing subsidies under and in accordance with section 1860D–14;

"(B) inform the Secretary of such determinations in cases in which such eligibility is established; and

"(C) otherwise provide the Secretary with such information as may be required to carry out part D, other than subpart 4, of title XVIII (including section 1860D–14).

"(3) SCREENING FOR ELIGIBILITY, AND ENROLLMENT OF, BENEFICIARIES FOR MEDICARE COST-SHARING.—As part of making an eligibility determination required under paragraph (2) for an individual, the State shall make a determination of the individual's eligibility for medical assistance for any medicare cost-sharing described in section 1905(p)(3) and, if the individual is eligible for any such medicare cost-sharing, offer enrollment to the individual under the State plan (or under a waiver of such plan).

"(b) REGULAR FEDERAL SUBSIDY OF ADMINISTRATIVE COSTS.—The amounts expended by a State in carrying out subsection (a) are expenditures reimbursable under the appropriate paragraph of section 1903(a).".

(b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RESPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES FOR DUALLY ELIGIBLE INDIVIDUALS.—Section 1935, as inserted by subsection (a)(2), is amended by adding at the end the following new subsection:

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

"(1) PHASED-DOWN STATE CONTRIBUTION.—

"(A) IN GENERAL.—Each of the 50 States and the District of Columbia for each month beginning with January 2006 shall provide for payment under this subsection to the Secretary of the product of—

"(i) the amount computed under paragraph (2)(A) for the State and month;

"(ii) the total number of full-benefit dual eligible individuals (as defined in paragraph (6)) for such State and month; and

"(iii) the factor for the month specified in paragraph (5).

"(B) FORM AND MANNER OF PAYMENT.—Payment under subparagraph (A) shall be made in a manner specified by the Secretary that is similar to the manner in which State payments are made under an agreement entered into under section 1843, except that all such payments shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

"(C) COMPLIANCE.—If a State fails to pay to the Secretary an amount required under subparagraph (A), interest shall accrue on such amount at the rate provided under section 1903(d)(5). The amount so owed and applicable interest shall be immediately offset against amounts otherwise payable to the State under section

1903(a), in accordance with the Federal Claims Collection Act of 1996 and applicable regulations.

"(D) DATA MATCH.—The Secretary shall perform such periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals for purposes of computing the amount under subparagraph (A).

"(2) AMOUNT.—

"(A) IN GENERAL.—The amount computed under this paragraph for a State described in paragraph (1) and for a month in a year is equal to—

"(i) 1/12 of the product of—

"(I) the base year State medicaid per capita expenditures for covered part D drugs for full-benefit dual eligible individuals (as computed under paragraph (3)); and

"(II) a proportion equal to 100 percent minus the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State for the fiscal year in which the month occurs; and

"(ii) increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor specified in paragraph (4) for that year.

"(B) NOTICE.—The Secretary shall notify each State described in paragraph (1) not later than October 15 before the beginning of each year (beginning with 2006) of the amount computed under subparagraph (A) for the State for that year.

"(3) BASE YEAR STATE MEDICAID PER CAPITA EXPENDITURES FOR COVERED PART D DRUGS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

"(A) IN GENERAL.—For purposes of paragraph (2)(A), the 'base year State medicaid per capita expenditures for covered part D drugs for full-benefit dual eligible individuals' for a State is equal to the weighted average (as weighted under subparagraph (C)) of—

"(i) the gross per capita medicaid expenditures for prescription drugs for 2003, determined under subparagraph (B); and

"(ii) the estimated actuarial value of prescription drug benefits provided under a capitated managed care plan per full-benefit dual eligible individual for 2003, as determined using such data as the Secretary determines appropriate.

"(B) GROSS PER CAPITA MEDICAID EXPENDITURES FOR PRESCRIPTION DRUGS.—

"(i) IN GENERAL.—The gross per capita medicaid expenditures for prescription drugs for 2003 under this subparagraph is equal to the expenditures, including dispensing fees, for the State under this title during 2003 for covered outpatient drugs, determined per full-benefit-dual-eligible-individual for such individuals not receiving medical assistance for such drugs through a medicaid managed care plan.

"(ii) DETERMINATION.—In determining the amount under clause (i), the Secretary shall—

"(I) use data from the Medicaid Statistical Information System (MSIS) and other available data;

"(II) exclude expenditures attributable to covered outpatient prescription drugs that are not covered part D drugs (as defined in section 1860D–2(e)); and

"(III) reduce such expenditures by the product of such portion and the adjustment factor (described in clause (iii)).

"(iii) ADJUSTMENT FACTOR.—The adjustment factor described in this clause for a State is equal to the ratio for the State for 2003 of—

"(I) aggregate payments under agreements under section 1927; to

"(II) the gross expenditures under this title for covered outpatient drugs referred to in clause (i).

Such factor shall be determined based on information reported by the State in the medicaid financial management reports (form CMS–64) for the 4 quarters of calendar year 2003 and such other data as the Secretary may require.

"(C) WEIGHTED AVERAGE.—The weighted average under subparagraph (A) shall be determined taking into account—

"(i) with respect to subparagraph (A)(i), the average number of full-benefit dual eligible individuals in 2003 who are not described in clause (ii); and

"(ii) with respect to subparagraph (A)(ii), the average number of full-benefit dual eligible individuals in such year who received in 2003 medical assistance for covered outpatient drugs through a medicaid managed care plan.

"(4) APPLICABLE GROWTH FACTOR.—The applicable growth factor under this paragraph for—

"(A) each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Health Expenditure projections for the years involved); and

"(B) a succeeding year, is the annual percentage increase specified in section 1860D–2(b)(6) for the year.

"(5) FACTOR.—The factor under this paragraph for a month—

"(A) in 2006 is 90 percent;

"(B) in 2007 is 88⅓ percent;

"(C) in 2008 is 86⅔ percent;

"(D) in 2009 is 85 percent;

"(E) in 2010 is 83⅓ percent;

"(F) in 2011 is 81⅔ percent;

"(G) in 2012 is 80 percent;

"(H) in 2013 is 78⅓ percent;

"(I) in 2014 is 76⅔ percent; or

"(J) after December 2014, is 75 percent.

"(6) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL DEFINED.—

"(A) IN GENERAL.—For purposes of this section, the term 'full-benefit dual eligible individual' means for a State for a month an individual who—

"(i) has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA–PD plan under part C of such title; and

"(ii) is determined eligible by the State for medical assistance for full benefits under this title for such month under section 1902(a)(10)(A) or 1902(a)(10)(C), by reason of section 1902(f), or under any other category of eligibility for medical assistance for full benefits under this title, as determined by the Secretary.

"(B) TREATMENT OF MEDICALLY NEEDY AND OTHER INDIVIDUALS REQUIRED TO SPEND DOWN.—In applying subparagraph (A) in the case of an individual determined to be eligible by the State for medical assistance under section 1902(a)(10)(C) or by reason of section 1902(f), the individual shall be treated as meeting the requirement of subparagraph (A)(ii) for any month if such medical assistance is provided for in any part of the month.".

(c) MEDICAID COORDINATION WITH MEDICARE PRESCRIPTION DRUG BENEFITS.—Section 1935, as so inserted and amended, is further amended by adding at the end the following new subsection:

"(d) COORDINATION OF PRESCRIPTION DRUG BENEFITS.—

"(1) MEDICARE AS PRIMARY PAYOR.—In the case of a part D eligible individual (as defined in section 1860D–1(a)(3)(A)) who is described in subsection (c)(6)(A)(ii), notwithstanding any other provision of this title, medical assistance is not available under this title for such drugs (or for any cost-sharing respecting such drugs), and the rules under this title relating to the provision of medical assistance for such drugs shall not apply. The provision of benefits with respect to such drugs shall not be considered as the provision of care or services under the plan under this title. No payment may be made under section 1903(a) for prescribed drugs for which medical assistance is not available pursuant to this paragraph.

"(2) COVERAGE OF CERTAIN EXCLUDABLE DRUGS.—In the case of medical assistance under this title with respect to a covered outpatient drug (other than a covered part D drug) furnished to an individual who is enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title, the State may elect to provide such medical assistance in the manner otherwise provided in the case of individuals who are not full-benefit dual eligible individuals or through an arrangement with such plan.".

(d) TREATMENT OF TERRITORIES.—

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

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

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

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

"(e) TREATMENT OF TERRITORIES.—

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

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

"(B) if the State establishes and submits to the Secretary a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to part D eligible individuals), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount for the fiscal period specified in paragraph (3).

"(2) PLAN.—The Secretary shall determine that a plan is described in this paragraph if the plan—

"(A) provides medical assistance with respect to the provision of covered part D drugs (as defined in section 1860D–2(e)) to low-income part D eligible individuals;

"(B) provides assurances that additional amounts received by the State that are attributable to the operation of this subsection shall be used only for such assistance and related administrative expenses and that no more than 10 percent of the amount specified in paragraph (3)(A) for the State for any fiscal period shall be used for such administrative expenses; and

"(C) meets such other criteria as the Secretary may establish.

"(3) INCREASED AMOUNT.—

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

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

"(ii) the ratio (as estimated by the Secretary) of—

"(I) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary based on the most recent available data before the beginning of the year); to

"(II) the sum of such numbers for all States that submit a plan described in paragraph (2).

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

"(i) the last 3 quarters of fiscal year 2006, is equal to $28,125,000;

"(ii) fiscal year 2007, is equal to $37,500,000; or

"(iii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860D–2(b)(6) for the year involved.

"(4) REPORT.—The Secretary shall submit to Congress a report on the application of this subsection 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 1935(e)(1)(B)" after "Subject to subsection (g)".

(e) AMENDMENT TO BEST PRICE.—

(1) IN GENERAL.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(A) by striking "and" at the end of subclause (III);

(B) by striking the period at the end of subclause (IV) and inserting a semicolon; and

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

"(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D–31; and

"(VI) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA–PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.".

(2) IN GENERAL.—Section 1927(c)(1)(C)(i)(VI) of the Social Security Act, as added by paragraph (1), shall apply to prices charged for drugs dispensed on or after January 1, 2006.

(f) EXTENSION OF MEDICARE COST-SHARING FOR PART B PREMIUM FOR QUALIFYING INDIVIDUALS THROUGH SEPTEMBER 2004.—

(1) IN GENERAL.—Section 1902(a)(10)(E)(iv) (42 U.S.C. 1396a(a)(10)(E)(iv)), as amended by section 401(a) of Public Law 108–89, is amended by striking "ending with March 2004" and inserting "ending with September 2004".

(2) TOTAL AMOUNT AVAILABLE FOR ALLOCATION.—Section 1933(g) (42 U.S.C. 1396u–3(g)), as added by section 401(c) of Public Law 108–89, is amended—

(A) in the matter preceding paragraph (1), by striking "March 31, 2004" and inserting "September 30, 2004"; and

(B) in paragraph (2), by striking "$100,000,000" and inserting "$300,000,000".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to calendar quarters beginning on or after April 1, 2004.

(g) OUTREACH BY THE COMMISSIONER OF SOCIAL SECURITY.—Section 1144 (42 U.S.C. 1320b–14) is amended—

(1) in the section heading, by inserting "AND SUBSIDIES FOR LOW-INCOME INDIVIDUALS UNDER TITLE XVIII" after "COST-SHARING";

(2) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by inserting "for the transitional assistance under section 1860D–31(f), or for premium and cost-sharing subsidies under section 1860D–14" before the semicolon; and

(ii) in subparagraph (B), by inserting ", program, and subsidies" after "medical assistance"; and

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by inserting ", the transitional assistance under section 1860D–31(f), or premium and cost-sharing subsidies under section 1860D–14" after "assistance"; and

(ii) in subparagraph (A), by striking "such eligibility" and inserting "eligibility for medicare cost-sharing under the medicaid program"; and

(3) in subsection (b)—

(A) in paragraph (1)(A), by inserting ", for transitional assistance under section 1860D–31(f), or for premium and cost-sharing subsidies for low-income individuals under section 1860D–14" after "1933"; and

(B) in paragraph (2), by inserting ", program, and subsidies" after "medical assistance".

SEC. 104. MEDIGAP AMENDMENTS.

(a) RULES RELATING TO MEDIGAP POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE.—

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

"(v) RULES RELATING TO MEDIGAP POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE.—

"(1) PROHIBITION ON SALE, ISSUANCE, AND RENEWAL OF NEW POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—Notwithstanding any other provision of law, on or after January 1, 2006, a medigap Rx policy (as defined in paragraph (6)(A)) may not be sold, issued, or renewed under this section—

"(i) to an individual who is a part D enrollee (as defined in paragraph (6)(B)); or

"(ii) except as provided in subparagraph (B), to an individual who is not a part D enrollee.

"(B) CONTINUATION PERMITTED FOR NON-PART D ENROLLEES.—Subparagraph (A)(ii) shall not apply to the renewal of a medigap Rx policy that was issued before January 1, 2006.

"(C) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the offering on and after January 1, 2006, of 'H', 'I', and 'J' policies described in paragraph (2)(D)(i) if the benefit packages are modified in accordance with paragraph (2)(C).

"(2) ELIMINATION OF DUPLICATIVE COVERAGE UPON PART D ENROLLMENT.—

"(A) IN GENERAL.—In the case of an individual who is covered under a medigap Rx policy and enrolls under a part D plan—

"(i) before the end of the initial part D enrollment period, the individual may—

"(I) enroll in a medicare supplemental policy without prescription drug coverage under paragraph (3); or

"(II) continue the policy in effect subject to the modification described in subparagraph (C)(i); or

"(ii) after the end of such period, the individual may continue the policy in effect subject to such modification.

"(B) NOTICE REQUIRED TO BE PROVIDED TO CURRENT POLICYHOLDERS WITH MEDIGAP RX POLICY.—No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer provides written notice (in accordance with standards of the Secretary established in consultation with the National Association of Insurance Commissioners) during the 60-

day period immediately preceding the initial part D enrollment period, to each individual who is a policyholder or certificate holder of a medigap Rx policy (at the most recent available address of that individual) of the following:

"(i) If the individual enrolls in a plan under part D during the initial enrollment period under section 1860D–1(b)(2)(A), the individual has the option of—

"(I) continuing enrollment in the individual's current plan, but the plan's coverage of prescription drugs will be modified under subparagraph (C)(i); or

"(II) enrolling in another medicare supplemental policy pursuant to paragraph (3).

"(ii) If the individual does not enroll in a plan under part D during such period, the individual may continue enrollment in the individual's current plan without change, but—

"(I) the individual will not be guaranteed the option of enrollment in another medicare supplemental policy pursuant to paragraph (3); and

"(II) if the current plan does not provide creditable prescription drug coverage (as defined in section 1860D–13(b)(4)), notice of such fact and that there are limitations on the periods in a year in which the individual may enroll under a part D plan and any such enrollment is subject to a late enrollment penalty.

"(iii) Such other information as the Secretary may specify (in consultation with the National Association of Insurance Commissioners), including the potential impact of such election on premiums for medicare supplemental policies.

"(C) MODIFICATION.—

"(i) IN GENERAL.—The policy modification described in this subparagraph is the elimination of prescription coverage for expenses of prescription drugs incurred after the effective date of the individual's coverage under a part D plan and the appropriate adjustment of premiums to reflect such elimination of coverage.

"(ii) CONTINUATION OF RENEWABILITY AND APPLICATION OF MODIFICATION.—No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer—

"(I) continues renewability of medigap Rx policies that it has issued, subject to subclause (II); and

"(II) applies the policy modification described in clause (i) in the cases described in clauses (i)(II) and (ii) of subparagraph (A).

"(D) REFERENCES TO RX POLICIES.—

"(i) H, I, AND J POLICIES.—Any reference to a benefit package classified as 'H', 'I', or 'J' (including the benefit package classified as 'J' with a high deductible feature, as described in subsection (p)(11)) under the standards established under subsection (p)(2) shall be construed as including a reference to such a package as modified under subparagraph (C) and such packages

as modified shall not be counted as a separate benefit package under such subsection.

"(ii) APPLICATION IN WAIVERED STATES.—Except for the modification provided under subparagraph (C), the waivers previously in effect under subsection (p)(2) shall continue in effect.

"(3) AVAILABILITY OF SUBSTITUTE POLICIES WITH GUARANTEED ISSUE.—

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

"(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as 'A', 'B', 'C', or 'F' (including the benefit package classified as 'F' with a high deductible feature, as described in subsection (p)(11)), under the standards established under subsection (p)(2), or a benefit package described in subparagraph (A) or (B) of subsection (w)(2) and that is offered and is available for issuance to new enrollees by such issuer;

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

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

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the effective date of the individual's coverage under a part D plan.

"(B) INDIVIDUAL COVERED.—An individual described in this subparagraph with respect to the issuer of a medicare supplemental policy is an individual who—

"(i) enrolls in a part D plan during the initial part D enrollment period;

"(ii) at the time of such enrollment was enrolled in a medigap Rx policy issued by such issuer; and

"(iii) terminates enrollment in such policy and submits evidence of such termination along with the application for the policy under subparagraph (A).

"(C) SPECIAL RULE FOR WAIVERED STATES.—For purposes of applying this paragraph in the case of a State that provides for offering of benefit packages other than under the classification referred to in subparagraph (A)(i), the references to benefit packages in such subparagraph are deemed references to comparable benefit packages offered in such State.

"(4) ENFORCEMENT.—

"(A) PENALTIES FOR DUPLICATION.—The penalties described in subsection (d)(3)(A)(ii) shall apply with respect to a violation of paragraph (1)(A).

"(B) GUARANTEED ISSUE.—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of paragraph (3) in the same manner as they apply to the requirements of such subsection.

"(5) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met with

respect to a part D enrollee through the continuation of the policy subject to modification under paragraph (2)(C) or the offering of a substitute policy under paragraph (3). The previous sentence shall not be construed to affect the guaranteed renewability of such a modified or substitute policy.

"(6) DEFINITIONS.—For purposes of this subsection:

"(A) MEDIGAP RX POLICY.—The term 'medigap Rx policy' means a medicare supplemental policy—

"(i) which has a benefit package classified as 'H', 'I', or 'J' (including the benefit package classified as 'J' with a high deductible feature, as described in subsection (p)(11)) under the standards established under subsection (p)(2), without regard to this subsection; and

"(ii) to which such standards do not apply (or to which such standards have been waived under subsection (p)(6)) but which provides benefits for prescription drugs.

Such term does not include a policy with a benefit package as classified under clause (i) which has been modified under paragraph (2)(C)(i).

"(B) PART D ENROLLEE.—The term 'part D enrollee' means an individual who is enrolled in a part D plan.

"(C) PART D PLAN.—The term 'part D plan' means a prescription drug plan or an MA–PD plan (as defined for purposes of part D).

"(D) INITIAL PART D ENROLLMENT PERIOD.—The term 'initial part D enrollment period' means the initial enrollment period described in section 1860D–1(b)(2)(A).".

(2) CONFORMING CURRENT GUARANTEED ISSUE PROVISIONS.—

(A) EXTENDING GUARANTEED ISSUE POLICY FOR INDIVIDUALS ENROLLED IN MEDIGAP RX POLICIES WHO TRY MEDICARE ADVANTAGE.—Subsection (s)(3)(C)(ii) of such section is amended—

(i) by striking "(ii) Only" and inserting "(ii)(I) Subject to subclause (II), only"; and

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

"(II) If the medicare supplemental policy referred to in subparagraph (B)(v) was a medigap Rx policy (as defined in subsection (v)(6)(A)), a medicare supplemental policy described in this subparagraph is such policy in which the individual was most recently enrolled as modified under subsection (v)(2)(C)(i) or, at the election of the individual, a policy referred to in subsection (v)(3)(A)(i).".

(B) CONFORMING AMENDMENT.—Section 1882(s)(3)(C)(iii) is amended by inserting "and subject to subsection (v)(1)" after "subparagraph (B)(vi)".

(b) DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP POLICIES.—

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

"(w) DEVELOPMENT OF NEW STANDARDS FOR MEDICARE SUPPLEMENTAL POLICIES.—

"(1) IN GENERAL.—The Secretary shall request the National Association of Insurance Commissioners to review and revise the standards for benefit packages under subsection (p)(1), taking into account the changes in benefits resulting from

enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and to otherwise update standards to reflect other changes in law included in such Act. Such revision shall incorporate the inclusion of the 2 benefit packages described in paragraph (2). Such revisions shall be made consistent with the rules applicable under subsection (p)(1)(E) with the reference to the '1991 NAIC Model Regulation' deemed a reference to the NAIC Model Regulation as published in the Federal Register on December 4, 1998, and as subsequently updated by the National Association of Insurance Commissioners to reflect previous changes in law (and subsection (v)) and the reference to 'date of enactment of this subsection' deemed a reference to the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. To the extent practicable, such revision shall provide for the implementation of revised standards for benefit packages as of January 1, 2006.

"(2) NEW BENEFIT PACKAGES.—The benefit packages described in this paragraph are the following (notwithstanding any other provision of this section relating to a core benefit package):

"(A) FIRST NEW BENEFIT PACKAGE.—A benefit package consisting of the following:

"(i) Subject to clause (ii), coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B, except there shall be no coverage of the part B deductible and coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

"(ii) Coverage for all hospital inpatient coinsurance and 365 extra lifetime days of coverage of inpatient hospital services (as in the current core benefit package).

"(iii) A limitation on annual out-of-pocket expenditures under parts A and B to $4,000 in 2006 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

"(B) SECOND NEW BENEFIT PACKAGE.—A benefit package consisting of the benefit package described in subparagraph (A), except as follows:

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

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

(2) CONFORMING AMENDMENTS.—Section 1882 (42 U.S.C. 1395ss) is amended—

(A) in subsection (g)(1), by inserting "a prescription drug plan under part D or" after "but does not include"; and

(B) in subsection (o)(1), by striking "subsection (p)" and inserting "subsections (p), (v), and (w)".

(c) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—Nothing in this Act shall be construed to require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) to participate as a PDP sponsor under part D of title XVIII of

such Act, as added by section 101, as a condition for issuing such policy.

(2) PROHIBITION ON STATE REQUIREMENT.—A State may not require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) to participate as a PDP sponsor under such part D as a condition for issuing such policy.

SEC. 105. ADDITIONAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM.

(a) EXCLUSION OF COSTS FROM DETERMINATION OF PART B MONTHLY PREMIUM.—Section 1839(g) (42 U.S.C. 1395r(g)) is amended—

(1) by striking "attributable to the application of section" and inserting "attributable to—

"(1) the application of section";

(2) by striking the period and inserting "; and"; and

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

"(2) the medicare prescription drug discount card and transitional assistance program under section 1860D–31.".

(b) APPLICATION OF CONFIDENTIALITY FOR DRUG PRICING DATA.—The last sentence of section 1927(b)(3)(D) (42 U.S.C. 1396r–8(b)(3)(D)), as added by section 101(e)(4), is amended by inserting "and drug pricing data reported under the first sentence of section 1860D–31(i)(1)" after "section 1860D–4(c)(2)(E)".

(c) RULES FOR IMPLEMENTATION.—The following rules shall apply to the medicare prescription drug discount card and transitional assistance program under section 1860D–31 of the Social Security Act, as added by section 101(a):

(1) In promulgating regulations pursuant to subsection (a)(2)(B) of such section 1860D–31—

(A) section 1871(a)(3) of the Social Security Act (42 U.S.C. 1395hh(a)(3)), as added by section 902(a)(1), shall not apply;

(B) chapter 35 of title 44, United States Code, shall not apply; and

(C) sections 553(d) and 801(a)(3)(A) of title 5, United States Code, shall not apply.

(2) Section 1857(c)(5) of the Social Security Act (42 U.S.C. 1395w–27(c)(5)) shall apply with respect to section 1860D–31 of such Act, as added by section 101(a), in the same manner as it applies to part C of title XVIII of such Act.

(3) The administration of such program shall be made without regard to chapter 35 of title 44, United States Code.

(4)(A) There shall be no judicial review of a determination not to endorse, or enter into a contract, with a prescription drug card sponsor under section 1860D–31 of the Social Security Act.

(B) In the case of any order issued to enjoin any provision of section 1860D–31 of the Social Security Act (or of any provision of this section), such order shall not affect any other provision of such section (or of this section) and all such provisions shall be treated as severable.

(d) CONFORMING AMENDMENTS TO FEDERAL SMI TRUST FUND FOR TRANSITIONAL ASSISTANCE ACCOUNT.—Section 1841 (42 U.S.C. 1395t), as amended by section 101(e)(3)(C), is amended—

(1) in the last sentence of subsection (a), by inserting after "section 1860D–16" the following: "or the Transitional Assistance Account established by section 1860D–31(k)(1)"; and

(2) in subsection (g), by adding at the end the following: "The payments provided for under section 1860D–31(k)(2) shall be made from the Transitional Assistance Account in the Trust Fund.".

(e) DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF PROVIDING TRANSITIONAL ASSISTANCE UNDER MEDICARE DISCOUNT CARD PROGRAM.—

(1) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for purposes other than tax administration) is amended by adding at the end the following new paragraph:

"(19) DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF PROVIDING TRANSITIONAL ASSISTANCE UNDER MEDICARE DISCOUNT CARD PROGRAM.—

"(A) IN GENERAL.—The Secretary, upon written request from the Secretary of Health and Human Services pursuant to carrying out section 1860D–31 of the Social Security Act, shall disclose to officers, employees, and contractors of the Department of Health and Human Services with respect to a taxpayer for the applicable year—

"(i)(I) whether the adjusted gross income, as modified in accordance with specifications of the Secretary of Health and Human Services for purposes of carrying out such section, of such taxpayer and, if applicable, such taxpayer's spouse, for the applicable year, exceeds the amounts specified by the Secretary of Health and Human Services in order to apply the 100 and 135 percent of the poverty lines under such section, (II) whether the return was a joint return, and (III) the applicable year, or

"(ii) if applicable, the fact that there is no return filed for such taxpayer for the applicable year.

"(B) DEFINITION OF APPLICABLE YEAR.—For the purposes of this subsection, the term 'applicable year' means the most recent taxable year for which information is available in the Internal Revenue Service's taxpayer data information systems, or, if there is no return filed for such taxpayer for such year, the prior taxable year.

"(C) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under this paragraph may be used only for the purposes of determining eligibility for and administering transitional assistance under section 1860D–31 of the Social Security Act.".

(2) CONFIDENTIALITY.—Paragraph (3) of section 6103(a) of such Code is amended by striking "or (16)" and inserting "(16), or (19)".

(3) PROCEDURES AND RECORDKEEPING RELATED TO DISCLOSURES.—Subsection (p)(4) of section 6103 of such Code is amended by striking "(l)(16) or (17)" each place it appears and inserting "(l)(16), (17), or (19)".

(4) UNAUTHORIZED DISCLOSURE OR INSPECTION.—Paragraph (2) of section 7213(a) of such Code is amended by striking "or (16)" and inserting "(16), or (19)".

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 voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act, as added by section 101.

(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 financial assistance to 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 section 1860D–14 of the Social Security Act.

(2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

(4) Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, 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 under this Act.

(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

SEC. 107. STUDIES AND REPORTS.

(a) STUDY REGARDING REGIONAL VARIATIONS IN PRESCRIPTION DRUG SPENDING.—

(1) IN GENERAL.—The Secretary shall conduct a study that examines variations in per capita spending for covered part D drugs under part D of title XVIII of the Social Security Act among PDP regions and, with respect to such spending, the amount of such variation that is attributable to—

(A) price variations (described in section 1860D–15(c)(2) of such Act); and

(B) differences in per capita utilization that is not taken into account in the health status risk adjustment provided under section 1860D–15(c)(1) of such Act.

(2) REPORT AND RECOMMENDATIONS.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include—

(A) information regarding the extent of geographic variation described in paragraph (1)(B);

(B) an analysis of the impact on direct subsidies under section 1860D–15(a)(1) of the Social Security Act in different PDP regions if such subsidies were adjusted to take into account the variation described in subparagraph (A); and

(C) recommendations regarding the appropriateness of applying an additional geographic adjustment factor under section 1860D–15(c)(2) that reflects some or all of the variation described in subparagraph (A).

(b) REVIEW AND REPORT ON CURRENT STANDARDS OF PRACTICE FOR PHARMACY SERVICES PROVIDED TO PATIENTS IN NURSING FACILITIES.—

(1) REVIEW.—

(A) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall conduct a thorough review of the current standards of practice for pharmacy services provided to patients in nursing facilities.

(B) SPECIFIC MATTERS REVIEWED.—In conducting the review under subparagraph (A), the Secretary shall—

(i) assess the current standards of practice, clinical services, and other service requirements generally used for pharmacy services in long-term care settings; and

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

(2) REPORT.—

(A) IN GENERAL.—Not later than the date that is 18 months after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study conducted under paragraph (1)(A).

(B) CONTENTS.—The report submitted under subparagraph (A) shall contain—

(i) a description of the plans of the Secretary to implement the provisions of this Act in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of nursing facility patients; and

(ii) recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to medicare beneficiaries residing in nursing facilities in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

(c) IOM STUDY ON DRUG SAFETY AND QUALITY.—

(1) IN GENERAL.—The Secretary shall enter into a contract with the Institutes of Medicine of the National Academies of Science (such Institutes referred to in this subsection as the "IOM") to carry out a comprehensive study (in this subsection referred to as the "study") of drug safety and quality issues in order to provide a blueprint for system-wide change.

(2) OBJECTIVES.—

(A) The study shall develop a full understanding of drug safety and quality issues through an evidence-based review of literature, case studies, and analysis. This review will consider the nature and causes of medication errors, their impact on patients, the differences in causation, impact, and prevention across multiple dimensions of health care delivery-including patient populations, care settings, clinicians, and institutional cultures.

(B) The study shall attempt to develop credible estimates of the incidence, severity, costs of medication errors that can be useful in prioritizing resources for national quality improvement efforts and influencing national health care policy.

(C) The study shall evaluate alternative approaches to reducing medication errors in terms of their efficacy, cost-effectiveness, appropriateness in different settings and circumstances, feasibility, institutional barriers to implementation, associated risks, and the quality of evidence supporting the approach.

(D) The study shall provide guidance to consumers, providers, payers, and other key stakeholders on high-priority strategies to achieve both short-term and long-term drug safety goals, to elucidate the goals and expected results of such initiatives and support the business case for them, and to identify critical success factors and key levers for achieving success.

(E) The study shall assess the opportunities and key impediments to broad nationwide implementation of medication error reductions, and to provide guidance to policymakers and government agencies (including the Food and Drug Administration, the Centers for Medicare & Medicaid

Services, and the National Institutes of Health) in promoting a national agenda for medication error reduction.

(F) The study shall develop an applied research agenda to evaluate the health and cost impacts of alternative interventions, and to assess collaborative public and private strategies for implementing the research agenda through AHRQ and other government agencies.

(3) CONDUCT OF STUDY.—

(A) EXPERT COMMITTEE.—In conducting the study, the IOM shall convene a committee of leading experts and key stakeholders in pharmaceutical management and drug safety, including clinicians, health services researchers, pharmacists, system administrators, payer representatives, and others.

(B) COMPLETION.—The study shall be completed within an 18-month period.

(4) REPORT.—A report on the study shall be submitted to Congress upon the completion of the study.

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

(d) STUDY OF MULTI-YEAR CONTRACTS.—

(1) IN GENERAL.—The Secretary shall provide for a study on the feasibility and advisability of providing for contracting with PDP sponsors and MA organizations under parts C and D of title XVIII on a multi-year basis.

(2) REPORT.—Not later than January 1, 2007, the Secretary shall submit to Congress a report on the study under paragraph (1). The report shall include such recommendations as the Secretary deems appropriate.

(e) GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to which drug utilization and access to covered part D drugs under part D of title XVIII of the Social Security Act by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals but for the application of section 1860D–14(a)(3)(A)(iii) of such Act.

(2) REPORT.—Not later than September 30, 2007, the Comptroller General shall submit a report to Congress on the study conducted under paragraph (1) that includes such recommendations for legislation as the Comptroller General determines are appropriate.

(f) STUDY ON MAKING PRESCRIPTION PHARMACEUTICAL INFORMATION ACCESSIBLE FOR BLIND AND VISUALLY-IMPAIRED INDIVIDUALS.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary shall undertake a study of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually-impaired individuals.

(B) STUDY TO INCLUDE EXISTING AND EMERGING TECHNOLOGIES.—The study under subparagraph (A) shall include a review of existing and emerging technologies, including assistive technology, that makes essential

information on the content and prescribed use of pharmaceutical medicines available in a usable format for blind and visually-impaired individuals.

(2) REPORT.—

(A) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study required under paragraph (1).

(B) CONTENTS OF REPORT.—The report required under paragraph (1) shall include recommendations for the implementation of usable formats for making prescription pharmaceutical information available to blind and visually-impaired individuals and an estimate of the costs associated with the implementation of each format.

SEC. 108. GRANTS TO PHYSICIANS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS.

(a) IN GENERAL.—The Secretary is authorized to make grants to physicians for the purpose of assisting such physicians to implement electronic prescription drug programs that comply with the standards promulgated or modified under section 1860D–4(e) of the Social Security Act, as inserted by section 101(a).

(b) AWARDING OF GRANTS.—

(1) APPLICATION.—No grant may be made under this section except pursuant to a grant application that is submitted and approved in a time, manner, and form specified by the Secretary.

(2) CONSIDERATIONS AND PREFERENCES.—In awarding grants under this section, the Secretary shall—

(A) give special consideration to physicians who serve a disproportionate number of medicare patients; and

(B) give preference to physicians who serve a rural or underserved area.

(3) LIMITATION ON GRANTS.—Only 1 grant may be awarded under this section with respect to any physician or group practice of physicians.

(c) TERMS AND CONDITIONS.—

(1) IN GENERAL.—Grants under this section shall be made under such terms and conditions as the Secretary specifies consistent with this section.

(2) USE OF GRANT FUNDS.—Funds provided under grants under this section may be used for any of the following:

(A) For purchasing, leasing, and installing computer software and hardware, including handheld computer technologies.

(B) Making upgrades and other improvements to existing computer software and hardware to enable e-prescribing.

(C) Providing education and training to eligible physician staff on the use of technology to implement the electronic transmission of prescription and patient information.

(3) PROVISION OF INFORMATION.—As a condition for the awarding of a grant under this section, an applicant shall provide to the Secretary such information as the Secretary may require in order to—

(A) evaluate the project for which the grant is made; and

(B) ensure that funding provided under the grant is expended only for the purposes for which it is made.

(4) AUDIT.—The Secretary shall conduct appropriate audits of grants under this section.

(5) MATCHING REQUIREMENT.—The applicant for a grant under this section shall agree, with respect to the costs to be incurred by the applicant in implementing an electronic prescription drug program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs. Non-Federal contributions under the previous sentence may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $50,000,000 for fiscal year 2007 and such sums as may be necessary for each of fiscal years 2008 and 2009.

SEC. 109. EXPANDING THE WORK OF MEDICARE QUALITY IMPROVEMENT ORGANIZATIONS TO INCLUDE PARTS C AND D.

(a) APPLICATION TO MEDICARE MANAGED CARE AND PRESCRIPTION DRUG COVERAGE.—Section 1154(a)(1) (42 U.S.C. 1320c–3(a)(1)) is amended by inserting ", to Medicare Advantage organizations pursuant to contracts under part C, and to prescription drug sponsors pursuant to contracts under part D" after "under section 1876".

(b) PRESCRIPTION DRUG THERAPY QUALITY IMPROVEMENT.—Section 1154(a) (42 U.S.C. 1320c–3(a)) is amended by adding at the end the following new paragraph:

"(17) The organization shall execute its responsibilities under subparagraphs (A) and (B) of paragraph (1) by offering to providers, practitioners, Medicare Advantage organizations offering Medicare Advantage plans under part C, and prescription drug sponsors offering prescription drug plans under part D quality improvement assistance pertaining to prescription drug therapy. For purposes of this part and title XVIII, the functions described in this paragraph shall be treated as a review function.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply on and after January 1, 2004.

(d) IOM STUDY OF QIOS.—

(1) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct an evaluation of the program under part B of title XI of the Social Security Act. The study shall include a review of the following:

(A) An overview of the program under such part.

(B) The duties of organizations with contracts with the Secretary under such part.

(C) The extent to which quality improvement organizations improve the quality of care for medicare beneficiaries.

(D) The extent to which other entities could perform such quality improvement functions as well as, or better than, quality improvement organizations.

(E) The effectiveness of reviews and other actions conducted by such organizations in carrying out those duties.

(F) The source and amount of funding for such organizations.

(G) The conduct of oversight of such organizations.

(2) REPORT TO CONGRESS.—Not later than June 1, 2006, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(3) INCREASED COMPETITION.—If the Secretary finds based on the study conducted under paragraph (1) that other entities could improve quality in the medicare program as well as, or better than, the current quality improvement organizations, then the Secretary shall provide for such increased competition through the addition of new types of entities which may perform quality improvement functions.

SEC. 110. CONFLICT OF INTEREST STUDY.

(a) STUDY.—The Federal Trade Commission shall conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers. Such study shall include the following:

(1) An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers compared to mail-order pharmacies not owned by pharmaceutical benefit managers, and community pharmacies.

(2) Whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

(b) 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 subsection (a). Such report shall include recommendations regarding any need for legislation to ensure the fiscal integrity of the voluntary prescription drug benefit program under part D of title XVIII, as added by section 101, that may be appropriated as the result of such study.

(c) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information under subsection (a).

SEC. 111. STUDY ON EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.

(a) STUDY.—The Comptroller General of the United States shall conduct an initial and final study under this subsection to examine trends in employment-based retiree health coverage (as defined in 1860D–22(c)(1) of the Social Security Act, as added by section 101), including coverage under the Federal Employees Health Benefits Program (FEHBP), and the options and incentives available under this Act which may have an effect on the voluntary provision of such coverage.

(b) CONTENT OF INITIAL STUDY.—The initial study under this section shall consider the following:

(1) Trends in employment-based retiree health coverage prior to the date of the enactment of this Act.

(2) The opinions of sponsors of employment-based retiree health coverage concerning which of the options available under this Act they are most likely to utilize for the provision of

health coverage to their medicare-eligible retirees, including an assessment of the administrative burdens associated with the available options.

(3) The likelihood of sponsors of employment-based retiree health coverage to maintain or adjust their levels of retiree health benefits beyond coordination with medicare, including for prescription drug coverage, provided to medicare-eligible retirees after the date of the enactment of this Act.

(4) The factors that sponsors of employment-based retiree health coverage expect to consider in making decisions about any changes they may make in the health coverage provided to medicare-eligible retirees.

(5) Whether the prescription drug plan options available, or the health plan options available under the Medicare Advantage program, are likely to cause employers and other entities that did not provide health coverage to retirees prior to the date of the enactment of this Act to provide supplemental coverage or contributions toward premium expenses for medicare-eligible retirees who may enroll in such options in the future.

(c) CONTENTS OF FINAL STUDY.—The final study under this section shall consider the following:

(1) Changes in the trends in employment-based retiree health coverage since the completion of the initial study by the Comptroller General.

(2) Factors contributing to any changes in coverage levels.

(3) The number and characteristics of sponsors of employment-based retiree health coverage who receive the special subsidy payments under section 1860D–22 of the Social Security Act, as added by section 101, for the provision of prescription drug coverage to their medicare-eligible retirees that is the same or greater actuarial value as the prescription drug coverage available to other medicare beneficiaries without employment-based retiree health coverage.

(4) The extent to which sponsors of employment-based retiree health coverage provide supplemental health coverage or contribute to the premiums for medicare-eligible retirees who enroll in a prescription drug plan or an MA–PD plan.

(5) Other coverage options, including tax-preferred retirement or health savings accounts, consumer-directed health plans, or other vehicles that sponsors of employment-based retiree health coverage believe would assist retirees with their future health care needs and their willingness to sponsor such alternative plan designs.

(6) The extent to which employers or other entities that did not provide employment-based retiree health coverage prior to the date of the enactment of this Act provided some form of coverage or financial assistance for retiree health care needs after the date of the enactment of this Act.

(7) Recommendations by employers, benefits experts, academics, and others on ways that the voluntary provision of employment-based retiree health coverage may be improved and expanded.

(d) REPORTS.—The Comptroller General shall submit a report to Congress on—

(1) the initial study under subsection (b) not later than 1 year after the date of the enactment of this Act; and

(2) the final study under subsection (c) not later than January 1, 2007.

(e) CONSULTATION.—The Comptroller General shall consult with sponsors of employment-based retiree health coverage, benefits experts, human resources professionals, employee benefits consultants, and academics with experience in health benefits and survey research in the development and design of the initial and final studies under this section.

TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

SEC. 201. IMPLEMENTATION OF MEDICARE ADVANTAGE PROGRAM.

(a) IN GENERAL.—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title XVIII of the Social Security Act (as amended by this Act).

(b) REFERENCES.—Subject to subsection (c), any reference to the program under part C of title XVIII of the Social Security Act shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to "Medicare+Choice" is deemed a reference to "Medicare Advantage" and "MA".

(c) TRANSITION.—In order to provide for an orderly transition and avoid beneficiary and provider confusion, the Secretary shall provide for an appropriate transition in the use of the terms "Medicare+Choice" and "Medicare Advantage" (or "MA") in reference to the program under part C of title XVIII of the Social Security Act. Such transition shall be fully completed for all materials for plan years beginning not later than January 1, 2006. Before the completion of such transition, any reference to "Medicare Advantage" or "MA" shall be deemed to include a reference to "Medicare+Choice".

Subtitle B—Immediate Improvements

SEC. 211. IMMEDIATE 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) 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

"(i) IN GENERAL.—For each year specified in clause (ii), the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment, for the MA payment area for individuals who are not enrolled in an MA plan under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(ii) PERIODIC REBASING.—The provisions of clause (i) shall apply for 2004 and for subsequent years as the Secretary shall specify (but not less than once every 3 years).

"(iii) 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 Defense or the Department of Veterans Affairs.".

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking "or (C)" and inserting "(C), or (D)".

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

(1) in paragraph (1)(A), by inserting "(for a year other than 2004)" after "multiplied"; and

(2) in paragraph (5), by inserting "(other than 2004)" after "for each year".

(c) INCREASING MINIMUM PERCENTAGE INCREASE TO NATIONAL GROWTH RATE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended—

(A) in subparagraph (A), by striking "The sum" and inserting "For a year before 2005, the sum";

(B) in subparagraph (B)(iv), by striking "and each succeeding year" and inserting ", 2003, and 2004";

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

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

"(v) For 2004 and each succeeding year, the greater of—

"(I) 102 percent of the annual MA capitation rate under this paragraph for the area for the previous year; or

"(II) the annual MA capitation rate under this paragraph for the area for the previous year increased by the national per capita MA 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 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 MA 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 AND LONG-TERM CARE HOSPITALS.—

(1) IN GENERAL.—Section 1853(g) (42 U.S.C. 1395w–23(g)) is amended—

(A) in the matter preceding paragraph (1), by inserting ", a rehabilitation hospital described in section 1886(d)(1)(B)(ii) or a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B), or a long-term care hospital (described in section 1886(d)(1)(B)(iv))" after "1886(d)(1)(B))"; and

(B) in paragraph (2)(B), by inserting "or other payment provision under this title for inpatient services for the type of facility, hospital, or unit involved, described in the matter preceding paragraph (1), 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 of MA local plans under the Medicare Advantage program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1).

(g) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than July 1, 2006, the Secretary shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced

Budget Refinement Act of 1999 and BIPA) on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

(h) MEDPAC STUDY AND REPORT ON CLARIFICATION OF AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE BENEFICIARY COST-SHARING.—

(1) STUDY.—The Medicare Payment Advisory Commission, in consultation with beneficiaries, consumer groups, employers, and organizations offering plans under part C of title XVIII of the Social Security Act, shall conduct a study to determine the extent to which the cost-sharing structures under such plans affect access to covered services or select enrollees based on the health status of eligible individuals described in section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w–21(a)(3)).

(2) REPORT.—Not later than December 31, 2004, the Commission shall submit a report to Congress on the study conducted under paragraph (1) together with recommendations for such legislation and administrative actions as the Commission considers appropriate.

(i) IMPLEMENTATION OF PROVISIONS.—

(1) ANNOUNCEMENT OF REVISED MEDICARE ADVANTAGE PAYMENT RATES.—Within 6 weeks after the date of the enactment of this Act, the Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties) MA capitation rates under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for 2004, revised in accordance with the provisions of this section.

(2) TRANSITION TO REVISED PAYMENT RATES.—The provisions of section 604 of BIPA (114 Stat. 2763A–555) (other than subsection (a)) shall apply to the provisions of subsections (a) through (d) of this section for 2004 in the same manner as the provisions of such section 604 applied to the provisions of BIPA for 2001.

(3) SPECIAL RULE FOR PAYMENT RATES IN 2004.—

(A) JANUARY AND FEBRUARY.—Notwithstanding the amendments made by subsections (a) through (d), for purposes of making payments under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for January and February 2004, the annual capitation rate for a payment area shall be calculated and the excess amount under section 1854(f)(1)(B) of such Act (42 U.S.C. 1395w–24(f)(1)(B)) shall be determined as if such amendments had not been enacted.

(B) MARCH THROUGH DECEMBER.—Notwithstanding the amendments made by subsections (a) through (d), for purposes of making payments under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for March through December 2004, the annual capitation rate for a payment area shall be calculated and the excess amount under section 1854(f)(1)(B) of such Act (42 U.S.C. 1395w–24(f)(1)(B)) shall be determined, in such manner as the Secretary estimates will ensure that the total of such payments with respect to 2004 is the same as the amounts that would have been if subparagraph (A) had not been enacted.

(C) CONSTRUCTION.—Subparagraphs (A) and (B) shall not be taken into account in computing such capitation rate for 2005 and subsequent years.

(4) PLANS REQUIRED TO PROVIDE NOTICE OF CHANGES IN PLAN BENEFITS.—In the case of an organization offering a plan under part C of title XVIII of the Social Security Act that revises its submission of the information described in section 1854(a)(1) of such Act (42 U.S.C. 1395w–23(a)(1)) for a plan pursuant to the application of paragraph (2), if such revision results in changes in beneficiary premiums, beneficiary cost-sharing, or benefits under the plan, then by not later than 3 weeks after the date the Secretary approves such submission, the organization offering the plan shall provide each beneficiary enrolled in the plan with written notice of such changes.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869 or section 1878 of the Social Security Act (42 U.S.C. 1395ff and 1395oo), or otherwise of any determination made by the Secretary under this subsection or the application of the payment rates determined pursuant to this subsection.

(j) ADDITIONAL AMENDMENTS.—Section 1852(d)(4) (42 U.S.C. 1395w–22(d)(4)) is amended—

(1) in subparagraph (B), by inserting "(other than deemed contracts or agreements under subsection (j)(6))" after "the plan has contracts or agreements"; and

(2) in the last sentence, by inserting before the period at the end the following: ", except that, if a plan entirely meets such requirement with respect to a category of health care professional or provider on the basis of subparagraph (B), it may provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) to provide covered services under the terms of the plan".

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

SEC. 221. ESTABLISHMENT OF MA REGIONAL PLANS.

(a) OFFERING OF MA REGIONAL PLANS.—

(1) IN GENERAL.—Section 1851(a)(2)(A) is amended—

(A) by striking "COORDINATED CARE PLANS.—Coordinated" and inserting the following: "COORDINATED CARE PLANS (INCLUDING REGIONAL PLANS).—

"(i) IN GENERAL.—Coordinated";

(B) by inserting "regional or local" before "preferred provider organization plans"; and

(C) by inserting " (including MA regional plans)" after "preferred provider organization plans".

(2) MORATORIUM ON NEW LOCAL PREFERRED PROVIDER ORGANIZATION PLANS.—The Secretary shall not permit the offering of a local preferred provider organization plan under part C of title XVIII of the Social Security Act during 2006 or 2007 in a service area unless such plan was offered under such part (including under a demonstration project under such part) in such area as of December 31, 2005.

(b) DEFINITION OF MA REGIONAL PLAN; MA LOCAL PLAN.—

(1) IN GENERAL.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraphs:

"(4) MA REGIONAL PLAN.—The term 'MA regional plan' means an MA plan described in section 1851(a)(2)(A)(i)—

"(A) that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

"(B) that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

"(C) the service area of which is one or more entire MA regions.

"(5) MA LOCAL PLAN.—The term 'MA local plan' means an MA plan that is not an MA regional plan.".

(2) CONSTRUCTION.—Nothing in part C of title XVIII of the Social Security Act shall be construed as preventing an MSA plan or MA private fee-for-service plan from having a service area that covers one or more MA regions or the entire nation.

(c) RULES FOR MA REGIONAL PLANS.—Part C of title XVIII (42 U.S.C. 1395w–21 et seq.) is amended by inserting after section 1857 the following new section:

"SPECIAL RULES FOR MA REGIONAL PLANS

"SEC. 1858. (a) REGIONAL SERVICE AREA; ESTABLISHMENT OF MA REGIONS.—

"(1) COVERAGE OF ENTIRE MA REGION.—The service area for an MA regional plan shall consist of an entire MA region established under paragraph (2) and the provisions of section 1854(h) shall not apply to such a plan.

"(2) ESTABLISHMENT OF MA REGIONS.—

"(A) MA REGION.—For purposes of this title, the term 'MA region' means such a region within the 50 States and the District of Columbia as established by the Secretary under this paragraph.

"(B) ESTABLISHMENT.—

"(i) INITIAL ESTABLISHMENT.—Not later than January 1, 2005, the Secretary shall first establish and publish MA regions.

"(ii) PERIODIC REVIEW AND REVISION OF SERVICE AREAS.—The Secretary may periodically review MA regions under this paragraph and, based on such review, may revise such regions if the Secretary determines such revision to be appropriate.

"(C) REQUIREMENTS FOR MA REGIONS.—The Secretary shall establish, and may revise, MA regions under this paragraph in a manner consistent with the following:

"(i) NUMBER OF REGIONS.—There shall be no fewer than 10 regions, and no more than 50 regions.

"(ii) MAXIMIZING AVAILABILITY OF PLANS.—The regions shall maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, especially those residing in rural areas.

"(D) MARKET SURVEY AND ANALYSIS.—Before establishing MA regions, the Secretary shall conduct a market survey and analysis, including an examination of current

insurance markets, to determine how the regions should be established.

"(3) NATIONAL PLAN.—Nothing in this subsection shall be construed as preventing an MA regional plan from being offered in more than one MA region (including all regions).

"(b) APPLICATION OF SINGLE DEDUCTIBLE AND CATASTROPHIC LIMIT ON OUT-OF-POCKET EXPENSES.—An MA regional plan shall include the following:

"(1) SINGLE DEDUCTIBLE.—Any deductible for benefits under the original medicare fee-for-service program option shall be a single deductible (instead of a separate inpatient hospital deductible and a part B deductible) and may be applied differentially for in-network services and may be waived for preventive or other items and services.

"(2) CATASTROPHIC LIMIT.—

"(A) IN-NETWORK.—A catastrophic limit on out-of-pocket expenditures for in-network benefits under the original medicare fee-for-service program option.

"(B) TOTAL.—A catastrophic limit on out-of-pocket expenditures for all benefits under the original medicare fee-for-service program option.

"(c) PORTION OF TOTAL PAYMENTS TO AN ORGANIZATION SUBJECT TO RISK FOR 2006 AND 2007.—

"(1) APPLICATION OF RISK CORRIDORS.—

"(A) IN GENERAL.—This subsection shall only apply to MA regional plans offered during 2006 or 2007.

"(B) NOTIFICATION OF ALLOWABLE COSTS UNDER THE PLAN.—In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization shall notify the Secretary, before such date in the succeeding year as the Secretary specifies, of—

"(i) its total amount of costs that the organization incurred in providing benefits covered under the original medicare fee-for-service program option for all enrollees under the plan in the region in the year and the portion of such costs that is attributable to administrative expenses described in subparagraph (C); and

"(ii) its total amount of costs that the organization incurred in providing rebatable integrated benefits (as defined in subparagraph (D)) and with respect to such benefits the portion of such costs that is attributable to administrative expenses described in subparagraph (C) and not described in clause (i) of this subparagraph.

"(C) ALLOWABLE COSTS DEFINED.—For purposes of this subsection, the term 'allowable costs' means, with respect to an MA regional plan for a year, the total amount of costs described in subparagraph (B) for the plan and year, reduced by the portion of such costs attributable to administrative expenses incurred in providing the benefits described in such subparagraph.

"(D) REBATABLE INTEGRATED BENEFITS.—For purposes of this subsection, the term 'rebatable integrated benefits' means such non-drug supplemental benefits under subclause (I) of section 1854(b)(1)(C)(ii) pursuant to a rebate under such section that the Secretary determines are

integrated with the benefits described in subparagraph (B)(i).

"(2) ADJUSTMENT OF PAYMENT.—

"(A) NO ADJUSTMENT IF ALLOWABLE COSTS WITHIN 3 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there shall be no payment adjustment under this subsection for the plan and year.

"(B) INCREASE IN PAYMENT IF ALLOWABLE COSTS ABOVE 103 PERCENT OF TARGET AMOUNT.—

"(i) COSTS BETWEEN 103 AND 108 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount equal to 50 percent of the difference between such allowable costs and 103 percent of such target amount.

"(ii) COSTS ABOVE 108 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount equal to the sum of—

"(I) 2.5 percent of such target amount; and

"(II) 80 percent of the difference between such allowable costs and 108 percent of such target amount.

"(C) REDUCTION IN PAYMENT IF ALLOWABLE COSTS BELOW 97 PERCENT OF TARGET AMOUNT.—

"(i) COSTS BETWEEN 92 AND 97 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, the Secretary shall reduce the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and such allowable costs.

"(ii) COSTS BELOW 92 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, the Secretary shall reduce the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount (or otherwise recover from the plan an amount) equal to the sum of—

"(I) 2.5 percent of such target amount; and

"(II) 80 percent of the difference between 92 percent of such target amount and such allowable costs.

"(D) TARGET AMOUNT DESCRIBED.—For purposes of this paragraph, the term 'target amount' means, with respect to an MA regional plan offered by an organization in a year, an amount equal to—

"(i) the sum of—

"(I) the total monthly payments made to the organization for enrollees in the plan for the year that are attributable to benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B));

"(II) the total of the MA monthly basic beneficiary premium collectable for such enrollees for the year; and

"(III) the total amount of the rebates under section 1854(b)(1)(C)(ii) that are attributable to rebatable integrated benefits; reduced by

"(ii) the amount of administrative expenses assumed in the bid insofar as the bid is attributable to benefits described in clause (i)(I) or (i)(III).

"(3) DISCLOSURE OF INFORMATION.—

"(A) IN GENERAL.—Each contract under this part shall provide—

"(i) that an MA organization offering an MA regional plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this subsection; and

"(ii) that, pursuant to section 1857(d)(2)(B), the Secretary has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to the Secretary under paragraph (1)(B).

"(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this subsection may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subsection.

"(d) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS.—

"(1) IN GENERAL.—In the case of an MA organization that is offering an MA regional plan in an MA region and—

"(A) meets the requirements of section 1855(a)(1) with respect to at least one such State in such region; and

"(B) with respect to each other State in such region in which it does not meet requirements, it demonstrates to the satisfaction of the Secretary that it has filed the necessary application to meet such requirements,

the Secretary may waive such requirement with respect to each State described in subparagraph (B) for such period of time as the Secretary determines appropriate for the timely processing of such an application by the State (and, if such application is denied, through the end of such plan year as the Secretary determines appropriate to provide for a transition).

"(2) SELECTION OF APPROPRIATE STATE.—In applying paragraph (1) in the case of an MA organization that meets the requirements of section 1855(a)(1) with respect to more than one State in a region, the organization shall select, in a manner

specified by the Secretary among such States, one State the rules of which shall apply in the case of the States described in paragraph (1)(B).

"(e) STABILIZATION FUND.—

"(1) ESTABLISHMENT.—The Secretary shall establish under this subsection an MA Regional Plan Stabilization Fund (in this subsection referred to as the 'Fund') which shall be available for two purposes:

"(A) PLAN ENTRY.—To provide incentives to have MA regional plans offered in each MA region under paragraph (3).

"(B) PLAN RETENTION.—To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (4).

"(2) FUNDING.—

"(A) INITIAL FUNDING.—

"(i) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund during the period beginning on January 1, 2007, and ending on December 31, 2013, a total of $10,000,000,000.

"(ii) PAYMENT FROM TRUST FUNDS.—Such amount shall be available to the Fund, as expenditures are made from the Fund, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f).

"(B) ADDITIONAL FUNDING FROM SAVINGS.—

"(i) IN GENERAL.—There shall also be made available to the Fund, 50 percent of savings described in clause (ii).

"(ii) SAVINGS.—The savings described in this clause are 25 percent of the average per capita savings described in section 1854(b)(4)(C) for which monthly rebates are provided under section 1854(b)(1)(C) in the fiscal year involved that are attributable to MA regional plans.

"(iii) AVAILABILITY.—Funds made available under this subparagraph shall be transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) on a monthly basis.

"(C) OBLIGATIONS.—Amounts in the Fund shall be available in advance of appropriations to MA regional plans in qualifying MA regions only in accordance with paragraph (5).

"(D) ORDERING.—Expenditures from the Fund shall first be made from amounts made available under subparagraph (A).

"(3) PLAN ENTRY FUNDING.—

"(A) IN GENERAL.—Funding is available under this paragraph for a year only as follows:

"(i) NATIONAL PLAN.—For a national bonus payment described in subparagraph (B) for the offering by a single MA organization of an MA regional plan in each MA region in the year, but only if there was

not such a plan offered in each such region in the previous year. Funding under this clause is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

"(ii) REGIONAL PLANS.—Subject to clause (iii), for an increased amount under subparagraph (C) for an MA regional plan offered in an MA region which did not have any MA regional plan offered in the prior year.

"(iii) LIMITATION ON REGIONAL PLAN FUNDING IN CASE OF NATIONAL PLAN.—In no case shall there be any payment adjustment under subparagraph (C) for a year for which a national payment adjustment is made under subparagraph (B).

"(B) NATIONAL BONUS PAYMENT.—The national bonus payment under this subparagraph shall—

"(i) be available to an MA organization only if the organization offers MA regional plans in every MA region;

"(ii) be available with respect to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

"(iii) subject to amounts available under paragraph (5) for a year, be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

"(C) REGIONAL PAYMENT ADJUSTMENT.—

"(i) IN GENERAL.—The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, based on the bid submitted for such plan (or plans) and shall be available to all MA regional plans offered in such region and year. Such amount may be based on the mean, mode, or median, or other measure of such bids and may vary from region to region. The Secretary may not limit the number of plans or bids in a region.

"(ii) MULTI-YEAR FUNDING.—

"(I) IN GENERAL.—Subject to amounts available under paragraph (5), funding under this subparagraph shall be available for a period determined by the Secretary.

"(II) REPORT.—If the Secretary determines that funding will be provided for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

"(iii) APPLICATION TO ALL PLANS IN A REGION.—Funding under this subparagraph with respect to an MA region shall be made available with respect to all MA regional plans offered in the region.

"(iv) LIMITATION ON AVAILABILITY OF PLAN RETENTION FUNDING IN NEXT YEAR.—If an increased amount is made available under this subparagraph with respect to an MA region for a period determined by the Secretary under clause (ii)(I), in no case shall funding be available under paragraph (4) with respect to MA regional plans offered in the region in the year following such period.

"(D) APPLICATION.—Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

"(4) PLAN RETENTION FUNDING.—

"(A) IN GENERAL.—Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in subparagraph (B) but only if the region meets the requirements of subparagraphs (C) and (E).

"(B) PAYMENT INCREASE.—The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, that does not exceed the greater of—

"(i) 3 percent of the benchmark amount applicable in the region; or

"(ii) such amount as (when added to the benchmark amount applicable to the region) will result in the ratio of—

"(I) such additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i) for the region and year, to the adjusted average per capita cost for the region and year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment; being equal to

"(II) the weighted average of such benchmark amounts for all the regions and such year, to the average per capita cost for the United States and such year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment.

"(C) REGIONAL REQUIREMENTS.—The requirements of this subparagraph for an MA region for a year are as follows:

"(i) NOTIFICATION OF PLAN EXIT.—The Secretary has received notice (in such form and manner as the Secretary specifies) before a year that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

"(ii) REGIONAL PLANS AVAILABLE FROM FEWER THAN 2 MA ORGANIZATIONS IN THE REGION.—The Secretary determines that if the plans referred to in clause (i) are not offered in the year, fewer than 2 MA organizations will be offering MA regional plans in the region in the year involved.

"(iii) PERCENTAGE ENROLLMENT IN MA REGIONAL PLANS BELOW NATIONAL AVERAGE.—For the previous year, the Secretary determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of such individuals in the United States enrolled in such plans.

"(D) APPLICATION.—Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

"(E) 2-CONSECUTIVE-YEAR LIMITATION.—

"(i) IN GENERAL.—In no case shall any funding be available under this paragraph in an MA region in a period of consecutive years that exceeds 2 years.

"(ii) REPORT.—If the Secretary determines that funding will be provided under this paragraph for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

"(5) FUNDING LIMITATION.—

"(A) IN GENERAL.—The total amount expended from the Fund as a result of the application of this subsection through the end of a calendar year may not exceed the amount available to the Fund as of the first day of such year. For purposes of this subsection, amounts that are expended under this title insofar as such amounts would not have been expended but for the application of this subsection shall be counted as amounts expended as a result of such application.

"(B) APPLICATION OF LIMITATION.—The Secretary may obligate funds from the Fund for a year only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund at the beginning of the year sufficient amounts to cover all such obligations incurred during the year consistent with subparagraph (A). The Secretary shall take such steps, in connection with computing additional payment amounts under paragraphs (3) and (4) and including limitations on enrollment in MA regional plans receiving such payments, as will ensure that sufficient funds are available to make such payments for the entire year. Funds shall only be made available from the Fund pursuant to an apportionment made in accordance with applicable procedures.

"(6) SECRETARY REPORTS.—Not later than April 1 of each year (beginning in 2008), the Secretary shall submit a report to Congress and the Comptroller General of the United States that includes—

"(A) a detailed description of—

"(i) the total amount expended as a result of the application of this subsection in the previous year compared to the total amount that would have been expended under this title in the year if this subsection had not been enacted;

"(ii) the projections of the total amount that will be expended as a result of the application of this subsection in the year in which the report is submitted compared to the total amount that would have been expended under this title in the year if this subsection had not been enacted;

"(iii) amounts remaining within the funding limitation specified in paragraph (5); and

"(iv) the steps that the Secretary will take under paragraph (5)(B) to ensure that the application of this subsection will not cause expenditures to exceed the amount available in the Fund; and

"(B) a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that the description provided under subparagraph (A) is reasonable, accurate, and based on generally accepted actuarial principles and methodologies.

"(7) BIENNIAL GAO REPORTS.—Not later than January 1 of 2009, 2011, 2013, and 2015, the Comptroller General of the United States shall submit to the Secretary and Congress a report on the application of additional payments under this subsection. Each report shall include—

"(A) an evaluation of—

"(i) the quality of care provided to individuals enrolled in MA regional plans for which additional payments were made under this subsection;

"(ii) the satisfaction of such individuals with benefits under such a plan;

"(iii) the costs to the medicare program for payments made to such plans; and

"(iv) any improvements in the delivery of health care services under such a plan;

"(B) a comparative analysis of the performance of MA regional plans receiving payments under this subsection with MA regional plans not receiving such payments; and

"(C) recommendations for such legislation or administrative action as the Comptroller General determines to be appropriate.

"(f) COMPUTATION OF APPLICABLE MA REGION-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNTS.—

"(1) COMPUTATION FOR REGIONS.—For purposes of section 1853(j)(2) and this section, subject to subsection (e), the term 'MA region-specific non-drug monthly benchmark amount' means, with respect to an MA region for a month in a year, the sum of the 2 components described in paragraph (2) for the region and year. The Secretary shall compute such benchmark amount for each MA region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2006).

"(2) 2 COMPONENTS.—For purposes of paragraph (1), the 2 components described in this paragraph for an MA region and a year are the following:

"(A) STATUTORY COMPONENT.—The product of the following:

"(i) STATUTORY REGION-SPECIFIC NON-DRUG AMOUNT.—The statutory region-specific non-drug amount (as defined in paragraph (3)) for the region and year.

"(ii) STATUTORY NATIONAL MARKET SHARE.—The statutory national market share percentage, determined under paragraph (4) for the year.

"(B) PLAN-BID COMPONENT.—The product of the following:

"(i) WEIGHTED AVERAGE OF MA PLAN BIDS IN REGION.—The weighted average of the plan bids for the region and year (as determined under paragraph (5)(A)).

"(ii) NON-STATUTORY MARKET SHARE.—1 minus the statutory national market share percentage, determined under paragraph (4) for the year.

"(3) STATUTORY REGION-SPECIFIC NON-DRUG AMOUNT.—For purposes of paragraph (2)(A)(i), the term 'statutory region-specific non-drug amount' means, for an MA region and year, an amount equal the sum (for each MA local area within the region) of the product of—

"(A) MA area-specific non-drug monthly benchmark amount under section 1853(j)(1)(A) for that area and year; and

"(B) the number of MA eligible individuals residing in the local area, divided by the total number of MA eligible individuals residing in the region.

"(4) COMPUTATION OF STATUTORY MARKET SHARE PERCENTAGE.—

"(A) IN GENERAL.—The Secretary shall determine for each year a statutory national market share percentage that is equal to the proportion of MA eligible individuals nationally who were not enrolled in an MA plan during the reference month.

"(B) REFERENCE MONTH DEFINED.—For purposes of this part, the term 'reference month' means, with respect to a year, the most recent month during the previous year for which the Secretary determines that data are available to compute the percentage specified in subparagraph (A) and other relevant percentages under this part.

"(5) DETERMINATION OF WEIGHTED AVERAGE MA BIDS FOR A REGION.—

"(A) IN GENERAL.—For purposes of paragraph (2)(B)(i), the weighted average of plan bids for an MA region and a year is the sum, for MA regional plans described in subparagraph (D) in the region and year, of the products (for each such plan) of the following:

"(i) MONTHLY MA STATUTORY NON-DRUG BID AMOUNT.—The unadjusted MA statutory non-drug monthly bid amount for the plan.

"(ii) PLAN'S SHARE OF MA ENROLLMENT IN REGION.—The factor described in subparagraph (B) for the plan.

"(B) PLAN'S SHARE OF MA ENROLLMENT IN REGION.—

"(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, the factor described in this subparagraph for a plan is equal to the number of individuals described in subparagraph (C) for such plan, divided by the total number of such individuals for all MA regional plans described in subparagraph (D) for that region and year.

"(ii) SINGLE PLAN RULE.—In the case of an MA region in which only a single MA regional plan is being offered, the factor described in this subparagraph shall be equal to 1.

"(iii) EQUAL DIVISION AMONG MULTIPLE PLANS IN YEAR IN WHICH PLANS ARE FIRST AVAILABLE.—In the case of an MA region in the first year in which any MA regional plan is offered, if more than one MA regional plan is offered in such year, the factor described in this subparagraph for a plan shall (as specified by the Secretary) be equal to—

"(I) 1 divided by the number of such plans offered in such year; or

"(II) a factor for such plan that is based upon the organization's estimate of projected enrollment, as reviewed and adjusted by the Secretary to ensure reasonableness and as is certified by the Chief Actuary of the Centers for Medicare & Medicaid Services.

"(C) COUNTING OF INDIVIDUALS.—For purposes of subparagraph (B)(i), the Secretary shall count for each MA regional plan described in subparagraph (D) for an MA region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part during the reference month.

"(D) PLANS COVERED.—For an MA region and year, an MA regional plan described in this subparagraph is an MA regional plan that is offered in the region and year and was offered in the region in the reference month.

"(g) ELECTION OF UNIFORM COVERAGE DETERMINATION.—Instead of applying section 1852(a)(2)(C) with respect to an MA regional plan, the organization offering the plan may elect to have a local coverage determination for the entire MA region be the local coverage determination applied for any part of such region (as selected by the organization).

"(h) ASSURING NETWORK ADEQUACY.—

"(1) IN GENERAL.—For purposes of enabling MA organizations that offer MA regional plans to meet applicable provider access requirements under section 1852 with respect to such plans, the Secretary may provide for payment under this section to an essential hospital that provides inpatient hospital services to enrollees in such a plan where the MA organization offering the plan certifies to the Secretary that the organization was unable to reach an agreement between the hospital and the organization regarding provision of such services under the plan. Such payment shall be available only if—

"(A) the organization provides assurances satisfactory to the Secretary that the organization will make payment to the hospital for inpatient hospital services of an amount that is not less than the amount that would be payable

to the hospital under section 1886 with respect to such services; and

"(B) with respect to specific inpatient hospital services provided to an enrollee, the hospital demonstrates to the satisfaction of the Secretary that the hospital's costs of such services exceed the payment amount described in subparagraph (A).

"(2) PAYMENT AMOUNTS.—The payment amount under this subsection for inpatient hospital services provided by a subsection (d) hospital to an enrollee in an MA regional plan shall be, subject to the limitation of funds under paragraph (3), the amount (if any) by which—

"(A) the amount of payment that would have been paid for such services under this title if the enrollees were covered under the original medicare fee-for-service program option and the hospital were a critical access hospital; exceeds

"(B) the amount of payment made for such services under paragraph (1)(A).

"(3) AVAILABLE AMOUNTS.—There shall be available for payments under this subsection—

"(A) in 2006, $25,000,000; and

"(B) in each succeeding year the amount specified in this paragraph for the preceding year increased by the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii)) for the fiscal year ending in such succeeding year.

Payments under this subsection shall be made from the Federal Hospital Insurance Trust Fund.

"(4) ESSENTIAL HOSPITAL.—In this subsection, the term 'essential hospital' means, with respect to an MA regional plan offered by an MA organization, a subsection (d) hospital (as defined in section 1886(d)) that the Secretary determines, based upon an application filed by the organization with the Secretary, is necessary to meet the requirements referred to in paragraph (1) for such plan.".

(d) CONFORMING AMENDMENTS.—

(1) RELATING TO MA REGIONS.—Section 1853(d) (42 U.S.C. 1395w–23(d)) is amended—

(A) by amending the heading to read as follows: "MA PAYMENT AREA; MA LOCAL AREA; MA REGION DEFINED";

(B) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(C) by amending paragraph (1) to read as follows:

"(1) MA PAYMENT AREA.—In this part, except as provided in this subsection, the term 'MA payment area' means—

"(A) with respect to an MA local plan, an MA local area (as defined in paragraph (2)); and

"(B) with respect to an MA regional plan, an MA region (as established under section 1858(a)(2)).";

(D) by inserting after paragraph (1) the following new paragraph:

"(2) MA LOCAL AREA.—The term 'MA local area' means a county or equivalent area specified by the Secretary."; and

(E) in paragraph (4), as so redesignated—

(i) in subparagraph (A), by inserting "for MA local plans" after "paragraph (1)";

(ii) in subparagraph (A)(iii), by striking "paragraph (1)" and inserting "paragraph (1)(A)"; and

(iii) in subparagraph (B)—

(I) by inserting "with respect to MA local plans" after "established under this section";

(II) by inserting "for such plans" after "payments under this section"; and

(III) by inserting "for such plans" after "made under this section".

(2) MA LOCAL AREA DEFINED.—Section 1859(c) (42 U.S.C. 1395w–29(c)) is amended by adding at the end the following:

"(5) MA LOCAL AREA.—The term 'MA local area' is defined in section 1853(d)(2).".

(3) APPLICATION OF SPECIAL BENEFIT RULES TO PPOS AND REGIONAL PLANS.—Section 1852(a) (42 U.S.C. 1395w–22(a)) is amended—

(A) in paragraph (1), by inserting "and except as provided in paragraph (6) for MA regional plans" after "MSA plans"; and

(B) by adding at the end the following new paragraph:

"(6) SPECIAL BENEFIT RULES FOR REGIONAL PLANS.—In the case of an MA plan that is an MA regional plan, benefits under the plan shall include the benefits described in paragraphs (1) and (2) of section 1858(b).".

(4) APPLICATION OF CAPITATION RATES TO LOCAL AREAS.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended by inserting "that is an MA local area" after "for a Medicare+Choice payment area".

(5) NETWORK ADEQUACY HOSPITAL PAYMENTS.—Section 1851(i)(2) (42 U.S.C. 1395w–21(i)(2)) is amended by inserting "1858(h)," after "1857(f)(2),".

SEC. 222. COMPETITION PROGRAM BEGINNING IN 2006.

(a) SUBMISSION OF BIDDING AND REBATE INFORMATION BEGINNING IN 2006.—

(1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) by amending paragraph (1) of subsection (a) to read as follows:

"(1) IN GENERAL.—

"(A) INITIAL SUBMISSION.—Not later than the second Monday in September of 2002, 2003, and 2004 (or the first Monday in June of each subsequent year), each MA organization shall submit to the Secretary, in a form and manner specified by the Secretary and for each MA plan for the service area (or segment of such an area if permitted under subsection (h)) in which it intends to be offered in the following year the following:

"(i) The information described in paragraph (2), (3), (4), or (6)(A) for the type of plan and year involved.

"(ii) The plan type for each plan.

"(iii) The enrollment capacity (if any) in relation to the plan and area.

"(B) BENEFICIARY REBATE INFORMATION.—In the case of a plan required to provide a monthly rebate under subsection (b)(1)(C) for a year, the MA organization offering the plan shall submit to the Secretary, in such form and

manner and at such time as the Secretary specifies, information on—

"(i) the manner in which such rebate will be provided under clause (ii) of such subsection; and

"(ii) the MA monthly prescription drug beneficiary premium (if any) and the MA monthly supplemental beneficiary premium (if any).

"(C) PAPERWORK REDUCTION FOR OFFERING OF MA REGIONAL PLANS NATIONALLY OR IN MULTI-REGION AREAS.—The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of MA regional plans in more than one region (including all regions) through the filing of consolidated information."; and

(B) by adding at the end of subsection (a) the following:

"(6) SUBMISSION OF BID AMOUNTS BY MA ORGANIZATIONS BEGINNING IN 2006.—

"(A) INFORMATION TO BE SUBMITTED.—For an MA plan (other than an MSA plan) for a plan year beginning on or after January 1, 2006, the information described in this subparagraph is as follows:

"(i) The monthly aggregate bid amount for the provision of all items and services under the plan, which amount shall be based on average revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act) in the payment area for an enrollee with a national average risk profile for the factors described in section 1853(a)(1)(C) (as specified by the Secretary).

"(ii) The proportions of such bid amount that are attributable to—

"(I) the provision of benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B));

"(II) the provision of basic prescription drug coverage; and

"(III) the provision of supplemental health care benefits.

"(iii) The actuarial basis for determining the amount under clause (i) and the proportions described in clause (ii) and such additional information as the Secretary may require to verify such actuarial bases and the projected number of enrollees in each MA local area.

"(iv) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such deductibles, coinsurance, and copayments, described in subsection (e)(4)(A).

"(v) With respect to qualified prescription drug coverage, the information required under section 1860D–4, as incorporated under section 1860D–11(b)(2), with respect to such coverage.

In the case of a specialized MA plan for special needs individuals, the information described in this subparagraph is such information as the Secretary shall specify.

"(B) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—

"(i) AUTHORITY.—Subject to clauses (iii) and (iv), the Secretary has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportions described in subparagraph (A)(ii)), including supplemental benefits provided under subsection (b)(1)(C)(ii)(I) and in exercising such authority the Secretary shall have authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code.

"(ii) APPLICATION OF FEHBP STANDARD.—Subject to clause (iv), the Secretary may only accept such a bid amount or proportion if the Secretary determines that such amount and proportions are supported by the actuarial bases provided under subparagraph (A) and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act) of benefits provided under that plan.

"(iii) NONINTERFERENCE.—In order to promote competition under this part and part D and in carrying out such parts, the Secretary may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this title or require a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority under this part.

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

(2) DEFINITION OF BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—Section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)) is amended—

(A) by striking "IN GENERAL.—Except" and inserting "REQUIREMENT.—

"(A) IN GENERAL.—Except"; and

(B) by striking "title XI" and all that follows and inserting the following: "title XI, benefits under the original medicare fee-for-service program option (and, for plan years before 2006, additional benefits required under section 1854(f)(1)(A)).

"(B) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—

"(i) IN GENERAL.—For purposes of this part, the term 'benefits under the original medicare fee-for-service program option' means those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts

A and B or an actuarially equivalent level of cost-sharing as determined in this part.

"(ii) SPECIAL RULE FOR REGIONAL PLANS.—In the case of an MA regional plan in determining an actuarially equivalent level of cost-sharing with respect to benefits under the original medicare fee-for-service program option, there shall only be taken into account, with respect to the application of section 1858(b)(2), such expenses only with respect to subparagraph (A) of such section.".

(3) CONFORMING AMENDMENT RELATING TO SUPPLEMENTAL HEALTH BENEFITS.—Section 1852(a)(3) (42 U.S.C. 1395w–22(a)(3)) is amended by adding at the end the following: "Such benefits may include reductions in cost-sharing below the actuarial value specified in section 1854(e)(4)(B).".

(b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

(1) BENEFICIARY REBATES.—Section 1854(b)(1) (42 U.S.C. 1395w–24(b)(1)) is amended—

(A) in subparagraph (A), by striking "The monthly amount" and inserting "Subject to the rebate under subparagraph (C), the monthly amount (if any)"; and

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

"(C) BENEFICIARY REBATE RULE.—

"(i) REQUIREMENT.—The MA plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3)(C) or (4)(C), as applicable to the plan and year involved.

"(ii) FORM OF REBATE.—A rebate required under this subparagraph shall be provided through the application of the amount of the rebate toward one or more of the following:

"(I) PROVISION OF SUPPLEMENTAL HEALTH CARE BENEFITS AND PAYMENT FOR PREMIUM FOR SUPPLEMENTAL BENEFITS.—The provision of supplemental health care benefits described in section 1852(a)(3) in a manner specified under the plan, which may include the reduction of cost-sharing otherwise applicable as well as additional health care benefits which are not benefits under the original medicare fee-for-service program option, or crediting toward an MA monthly supplemental beneficiary premium (if any).

"(II) PAYMENT FOR PREMIUM FOR PRESCRIPTION DRUG COVERAGE.—Crediting toward the MA monthly prescription drug beneficiary premium.

"(III) PAYMENT TOWARD PART B PREMIUM.—Crediting toward the premium imposed under part B (determined without regard to the application of subsections (b), (h), and (i) of section 1839).

"(iii) DISCLOSURE RELATING TO REBATES.—The plan shall disclose to the Secretary information on the form and amount of the rebate provided under this subparagraph or the actuarial value in the case of supplemental health care benefits.

"(iv) APPLICATION OF PART B PREMIUM REDUCTION.—Insofar as an MA organization elects to provide a rebate under this subparagraph under a plan as a credit toward the part B premium under clause (ii)(III), the Secretary shall apply such credit to reduce the premium under section 1839 of each enrollee in such plan as provided in section 1840(i).".

(2) REVISION OF PREMIUM TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) is amended—

(A) in the heading, by inserting "AND BID" after "PREMIUM";

(B) by redesignating subparagraph (C) as subparagraph (D);

(C) by striking subparagraphs (A) and (B) and inserting the following:

"(A) MA MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'MA monthly basic beneficiary premium' means, with respect to an MA plan—

"(i) described in section 1853(a)(1)(B)(i) (relating to plans providing rebates), zero; or

"(ii) described in section 1853(a)(1)(B)(ii), the amount (if any) by which the unadjusted MA statutory non-drug monthly bid amount (as defined in subparagraph (E)) exceeds the applicable unadjusted MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)).

"(B) MA MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'MA monthly prescription drug beneficiary premium' means, with respect to an MA plan, the base beneficiary premium (as determined under section 1860D–13(a)(2) and as adjusted under section 1860D–13(a)(1)(B)), less the amount of rebate credited toward such amount under section 1854(b)(1)(C)(ii)(II).

"(C) MA MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'MA monthly supplemental beneficiary premium' means, with respect to an MA plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under clause (ii)(III) of such subsection to the provision of supplemental health care benefits, less the amount of rebate credited toward such portion under section 1854(b)(1)(C)(ii)(I).."; and

(D) by adding at the end the following:

"(E) UNADJUSTED MA STATUTORY NON-DRUG MONTHLY BID AMOUNT.—The term 'unadjusted MA statutory non-drug monthly bid amount' means the portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under clause (ii)(I) of such subsection to the provision of benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B)).".

(3) COMPUTATION OF SAVINGS.—Section 1854(b) (42 U.S.C. 1395w–24(b)) is further amended by adding at the end the following new paragraphs:

"(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR LOCAL PLANS.—For purposes of paragraph (1)(C)(i),

the average per capita monthly savings referred to in such paragraph for an MA local plan and year is computed as follows:

"(A) DETERMINATION OF STATEWIDE AVERAGE RISK ADJUSTMENT FOR LOCAL PLANS.—

"(i) IN GENERAL.—Subject to clause (iii), the Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006) for each State, the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) to payment for enrollees in that State for MA local plans.

"(ii) TREATMENT OF STATES FOR FIRST YEAR IN WHICH LOCAL PLAN OFFERED.—In the case of a State in which no MA local plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable States or applied on a national basis.

"(iii) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than States or on a plan-specific basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID FOR LOCAL PLANS.—For each MA plan offered in a local area in a State, the Secretary shall—

"(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(1)) for the area by the average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph for an MA local plan is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(4) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR REGIONAL PLANS.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA regional plan and year is computed as follows:

"(A) DETERMINATION OF REGIONWIDE AVERAGE RISK ADJUSTMENT FOR REGIONAL PLANS.—

"(i) IN GENERAL.—The Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006) for each MA region the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) to payment for enrollees in that region for MA regional plans.

"(ii) TREATMENT OF REGIONS FOR FIRST YEAR IN WHICH REGIONAL PLAN OFFERED.—In the case of an MA region in which no MA regional plan was offered

in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable regions or applied on a national basis.

"(iii) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN REGIONS.—The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than MA regions or on a plan-specific basis.

"(B) DETERMINATION OF RISK-ADJUSTED BENCHMARK AND RISK-ADJUSTED BID FOR REGIONAL PLANS.—For each MA regional plan offered in a region, the Secretary shall—

"(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(2)) for the region by the average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph for an MA regional plan is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).".

(c) COLLECTION OF PREMIUMS.—Section 1854(d) (42 U.S.C. 1395w–24(d)) is amended—

(1) by striking "PREMIUMS.—Each" and inserting "PREMIUMS.—

"(1) IN GENERAL.—Each"; and

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

"(2) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, an MA organization shall permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through—

"(A) withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839;

"(B) an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account); or

"(C) such other means as the Secretary may specify, including payment by an employer or under employment-based retiree health coverage (as defined in section 1860D–22(c)(1)) on behalf of an employee or former employee (or dependent).

All premium payments that are withheld under subparagraph (A) shall be credited to the appropriate Trust Fund (or Account thereof), as specified by the Secretary, under this title and shall be paid to the MA organization involved. No charge may be imposed under an MA plan with respect to the election

of the payment option described in subparagraph (A). The Secretary shall consult with the Commissioner of Social Security and the Secretary of the Treasury regarding methods for allocating premiums withheld under subparagraph (A) among the appropriate Trust Funds and Account.

"(3) INFORMATION NECESSARY FOR COLLECTION.—In order to carry out paragraph (2)(A) with respect to an enrollee who has elected such paragraph to apply, the Secretary shall transmit to the Commissioner of Social Security—

"(A) by the beginning of each year, the name, social security account number, consolidated monthly beneficiary premium described in paragraph (4) owed by such enrollee for each month during the year, and other information determined appropriate by the Secretary, in consultation with the Commissioner of Social Security; and

"(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

"(4) CONSOLIDATED MONTHLY BENEFICIARY PREMIUM.—In the case of an enrollee in an MA plan, the Secretary shall provide a mechanism for the consolidation of—

"(A) the MA monthly basic beneficiary premium (if any);

"(B) the MA monthly supplemental beneficiary premium (if any); and

"(C) the MA monthly prescription drug beneficiary premium (if any).".

(d) COMPUTATION OF MA AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w–23) is amended by adding at the end the following new subsection:

"(j) COMPUTATION OF BENCHMARK AMOUNTS.—For purposes of this part, the term 'MA area-specific non-drug monthly benchmark amount' means for a month in a year—

"(1) with respect to—

"(A) a service area that is entirely within an MA local area, an amount equal to 1/12 of the annual MA capitation rate under section 1853(c)(1) for the area for the year, adjusted as appropriate for the purpose of risk adjustment; or

"(B) a service area that includes more than one MA local area, an amount equal to the average of the amounts described in subparagraph (A) for each such local MA area, weighted by the projected number of enrollees in the plan residing in the respective local MA areas (as used by the plan for purposes of the bid and disclosed to the Secretary under section 1854(a)(6)(A)(iii)), adjusted as appropriate for the purpose of risk adjustment; or

"(2) with respect to an MA region for a month in a year, the MA region-specific non-drug monthly benchmark amount, as defined in section 1858(f) for the region for the year.".

(e) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1) (42 U.S.C. 1395w–23(a)(1)) (42 U.S.C. 1395w–23) is amended—

(A) by redesignating subparagraph (B) as subparagraph (H); and

(B) in subparagraph (A), by striking "in an amount" and all that follows and inserting the following: "in an amount determined as follows:

"(i) PAYMENT BEFORE 2006.—For years before 2006, the payment amount shall be equal to 1/12 of the annual MA capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, adjusted under subparagraph (C) and reduced by the amount of any reduction elected under section 1854(f)(1)(E).

"(ii) PAYMENT FOR ORIGINAL FEE-FOR-SERVICE BENEFITS BEGINNING WITH 2006.—For years beginning with 2006, the amount specified in subparagraph (B).

"(B) PAYMENT AMOUNT FOR ORIGINAL FEE-FOR-SERVICE BENEFITS BEGINNING WITH 2006.—

"(i) PAYMENT OF BID FOR PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case may be, the amount specified in this subparagraph is equal to the unadjusted MA statutory non-drug monthly bid amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G), plus the amount (if any) of any rebate under subparagraph (E).

"(ii) PAYMENT OF BENCHMARK FOR PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case may be, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G).

"(iii) PAYMENT OF BENCHMARK FOR MSA PLANS.—Notwithstanding clauses (i) and (ii), in the case of an MSA plan, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C).

"(C) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

"(D) SEPARATE PAYMENT FOR FEDERAL DRUG SUBSIDIES.—In the case of an enrollee in an MA–PD plan, the MA organization offering such plan also receives—

"(i) subsidies under section 1860D–15 (other than under subsection (g)); and

"(ii) reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–14(c)(1)(C).

"(E) PAYMENT OF REBATE FOR PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case may be, the amount specified in this subparagraph is the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year (as reduced by the amount of any credit provided under section 1854(b)(1)(C)(iv)).

"(F) ADJUSTMENT FOR INTRA-AREA VARIATIONS.—

"(i) INTRA-REGIONAL VARIATIONS.—In the case of payment with respect to an MA regional plan for an MA region, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such region.

"(ii) INTRA-SERVICE AREA VARIATIONS.—In the case of payment with respect to an MA local plan for a service area that covers more than one MA local area, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such service area.

"(G) ADJUSTMENT RELATING TO RISK ADJUSTMENT.—The Secretary shall adjust payments with respect to MA plans as necessary to ensure that—

"(i) the sum of—

"(I) the monthly payment made under subparagraph (A)(ii); and

"(II) the MA monthly basic beneficiary premium under section 1854(b)(2)(A); equals

"(ii) the unadjusted MA statutory non-drug monthly bid amount, adjusted in the manner described in subparagraph (C) and, for an MA regional plan, subparagraph (F).".

(f) CONFORMING CHANGES TO ANNUAL ANNOUNCEMENT PROCESS.—Section 1853(b) (42 U.S.C. 1395w–23(b)(1)) is amended—

(1) by amending paragraph (1) to read as follows:

"(1) ANNUAL ANNOUNCEMENTS.—

"(A) FOR 2005.—The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the second Monday in May of 2004, with respect to each MA payment area, the following:

"(i) MA CAPITATION RATES.—The annual MA capitation rate for each MA payment area for 2005.

"(ii) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in 2005.

"(B) FOR 2006 AND SUBSEQUENT YEARS.—For a year after 2005—

"(i) INITIAL ANNOUNCEMENT.—The Secretary shall determine, and shall announce (in a manner intended

to provide notice to interested parties), not later than the first Monday in April before the calendar year concerned, with respect to each MA payment area, the following:

"(I) MA CAPITATION RATES; MA LOCAL AREA BENCHMARK.—The annual MA capitation rate for each MA payment area for the year.

"(II) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in such year.

"(ii) REGIONAL BENCHMARK ANNOUNCEMENT.—The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each MA region and each MA regional plan for which a bid was submitted under section 1854, the MA region-specific non-drug monthly benchmark amount for that region for the year involved."; and

(2) in paragraph (3), by striking "in the announcement" and all that follows and inserting "in such announcement.".

(g) OTHER AMENDMENTS RELATING TO PREMIUMS AND BID AMOUNTS.—

(1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) by amending the section heading to read as follows:

"PREMIUMS AND BID AMOUNTS";

(B) in the heading of subsection (a), by inserting ", BID AMOUNTS," after "PREMIUMS";

(C) in subsection (a)(2)—

(i) by inserting "BEFORE 2006" after "FOR COORDINATED CARE PLANS"; and

(ii) by inserting "for a year before 2006" after "section 1851(a)(2)(A)";

(D) in subsection (a)(3), by striking "described" and inserting "for any year";

(E) in subsection (a)(4)—

(i) by inserting "BEFORE 2006" after "FOR PRIVATE FEE-FOR-SERVICE PLANS"; and

(ii) by inserting "for a year before 2006" after "section 1852(a)(1)(A)";

(F) in subsection (a)(5)(A), by inserting "paragraphs (2) and (4) of" after "filed under";

(G) in subsection (a)(5)(B), by inserting after "paragraph (3) or" the following: ", in the case of an MA private fee-for-service plan,"; and

(H) in subsection (b)(1)(A) by striking "and" and inserting a comma and by inserting before the period at the end the following: ", and, if the plan provides qualified prescription drug coverage, the MA monthly prescription drug beneficiary premium".

(2) UNIFORMITY.—Section 1854(c) (42 U.S.C. 1395w–24(c)) is amended to read as follows:

"(c) UNIFORM PREMIUM AND BID AMOUNTS.—Except as permitted under section 1857(i), the MA monthly bid amount submitted

under subsection (a)(6), the amounts of the MA monthly basic, prescription drug, and supplemental beneficiary premiums, and the MA monthly MSA premium charged under subsection (b) of an MA organization under this part may not vary among individuals enrolled in the plan.".

(3) PREMIUMS.—Section 1854(d)(1) (42 U.S.C. 1395w–24(d)(1)), as amended by subsection (c)(1), is amended by inserting ", prescription drug," after "basic".

(4) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) (42 U.S.C. 1395w–24(e)) is amended—

(A) in paragraph (1), by striking ".—In" and inserting "BEFORE 2006.—For periods before 2006, in";

(B) in paragraph (2), by striking ".—If" and insert "BEFORE 2006.—For periods before 2006, if";

(C) in paragraph (3), by striking "or (2)" and inserting ", (2), or (4)"; and

(D) in paragraph (4)—

(i) by inserting "AND FOR BASIC BENEFITS BEGINNING IN 2006" after "PLANS";

(ii) in the matter before subparagraph (A), by inserting "and for periods beginning with 2006, with respect to an MA plan described in section 1851(a)(2)(A)" after "MSA plan)";

(iii) in subparagraph (A), by striking "required benefits described in section 1852(a)(1)" and inserting "benefits under the original medicare fee-for-service program option"; and

(iv) in subparagraph (B), by inserting "with respect to such benefits" after "would be applicable".

(5) MODIFICATION OF ACR PROCESS.—Section 1854(f) (42 U.S.C. 1395w–24(f)) is amended—

(A) in the heading, by inserting "BEFORE 2006" after "ADDITIONAL BENEFITS"; and

(B) in paragraph (1)(A), by striking "Each" and inserting "For years before 2006, each".

(h) PLAN INCENTIVES.—Section 1852(j)(4) (42 U.S.C. 1395w–22(j)(4)) is amended—

(1) by inserting "the organization provides assurances satisfactory to the Secretary that" after "unless";

(2) in clause (ii)—

(A) by striking "the organization—" and all that follows through "(I) provides" and inserting "the organization provides";

(B) by striking ", and" and inserting a period; and

(C) by striking subclause (II); and

(3) by striking clause (iii).

(i) CONTINUATION OF TREATMENT OF ENROLLEES WITH END-STAGE RENAL DISEASE.—Section 1853(a)(1)(H), as redesignated under subsection (d)(1)(A), is amended—

(1) by amending the second sentence to read as follows: "Such rates of payment shall be actuarially equivalent to rates that would have been paid with respect to other enrollees in the MA payment area (or such other area as specified by the Secretary) under the provisions of this section as in effect before the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003."; and

(2) by adding at the end the following new sentence: "The Secretary may apply the competitive bidding methodology provided for in this section, with appropriate adjustments to account for the risk adjustment methodology applied to end stage renal disease payments.".

(j) FACILITATION OF EMPLOYER SPONSORSHIP OF MA PLANS.—Section 1857(i) (42 U.S.C. 1395w–27(i)) is amended—

(1) by designating the matter following the heading as a paragraph (1) with the heading "CONTRACTS WITH MA ORGANIZATIONS.—" and appropriate indentation; and

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

"(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.".

(k) EXPANSION OF MEDICARE BENEFICIARY EDUCATION AND INFORMATION CAMPAIGN.—Section 1857(e)(2) (42 U.S.C. 1395w–27(e)(2)) is amended—

(1) in subparagraph (A) by inserting "and a PDP sponsor under part D" after "organization";

(2) in subparagraph (B)—

(A) by inserting "and each PDP sponsor with a contract under part D" after "contract under this part";

(B) by inserting "or sponsor's" after "organization's"; and

(C) by inserting ", section 1860D–1(c)," after "information)";

(3) in subparagraph (C)—

(A) by inserting "and ending with fiscal year 2005" after "beginning with fiscal year 2001";

(B) by inserting "and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000," after "$100,000,000,"; and

(C) by inserting "and section 1860D–12(b)(3)(D)" after "under this paragraph";

(4) in subparagraph (D)—

(A) in clause (i) by inserting "and section 1860D–1(c)" after "section 1851";

(B) in clause (ii)(III), by striking "and" at the end of subclause (III);

(C) in clause (ii)(IV), by striking "each succeeding fiscal year." and inserting "each succeeding fiscal year before fiscal year 2006; and"; and

(D) in clause (ii), by adding at the end the following new subclause:

"(V) the applicable portion (as defined in subparagraph (F)) of $200,000,000 in fiscal year 2006 and each succeeding fiscal year."; and

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

"(F) APPLICABLE PORTION DEFINED.—In this paragraph, the term 'applicable portion' means, for a fiscal year—

"(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

"(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D.".

(l) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: "The Secretary shall not approve a plan of an organization if the Secretary determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.".

(2) RELATING TO REBATES.—

(A) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking "80 percent of any reduction elected under section 1854(f)(1)(E)" and inserting "any credit provided under section 1854(b)(1)(C)(ii)(III)".

(B) The first sentence of section 1840(i) (42 U.S.C. 1395s(i)) is amended by inserting "and to reflect any credit provided under section 1854(b)(1)(C)(iv)" after "section 1854(f)(1)(E)".

(C) Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting "or any credits provided under section 1854(b)(1)(C)(iv)" after "section 1854(f)(1)(E)".

(3) OTHER CONFORMING AND TECHNICAL AMENDMENTS.—

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

(i) in subparagraph (B), by striking "a plan" and inserting "an MA local plan";

(ii) in subparagraph (B), by striking "basic benefits described in section 1852(a)(1)(A)" and inserting "benefits under the original medicare fee-for-service program option"; and

(iii) in subparagraph (C), by striking "in a Medicare+Choice plan" and inserting "in an MA local plan".

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

(i) in paragraph (3), by adding at the end the following new subparagraph:

"(F) CATASTROPHIC COVERAGE AND SINGLE DEDUCTIBLE.—In the case of an MA regional plan, a description of the catastrophic coverage and single deductible applicable under the plan.";

(ii) in paragraph (4)(A)(ii), by inserting ", including information on the single deductible (if applicable) under section 1858(b)(1)" after "cost sharing";

(iii) in paragraph (4)(B)(i), by striking "Medicare+Choice monthly basic" and all that follows

and inserting "monthly amount of the premium charged to an individual."; and

(iv) by amending subparagraph (E) of subsection (d)(4) to read as follows:

"(E) SUPPLEMENTAL BENEFITS.—Supplemental health care benefits, including any reductions in cost-sharing under section 1852(a)(3) and the terms and conditions (including premiums) for such benefits.".

(C) Section 1857(d)(1) (42 U.S.C. 1395w–27(d)(1)) is amended by striking ", costs, and computation of the adjusted community rate" and inserting "and costs, including allowable costs under section 1858(c)".

(D) Section 1851(a)(3)(B)(ii) (42 U.S.C. 1395w–21(a)(3)(B)(ii)) is amended by striking "section 1851(e)(4)(A)" and inserting "subsection (e)(4)(A)".

(E) Section 1851(f)(1) (42 U.S.C. 1395w–21(f)(1)) is amended by striking "subsection (e)(1)(A)" and inserting "subsection (e)(1)".

SEC. 223. EFFECTIVE DATE.

(a) EFFECTIVE DATE.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1, 2006.

(b) ISSUANCE OF REGULATIONS.—The Secretary shall revise the regulations previously promulgated to carry out part C of title XVIII of the Social Security Act to carry out the provisions of this Act.

Subtitle D—Additional Reforms

SEC. 231. SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)), as amended by section 221(a), is amended by adding at the end the following new clause:

"(ii) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—Specialized MA plans for special needs individuals (as defined in section 1859(b)(6)) may be any type of coordinated care plan.".

(b) SPECIALIZED MA PLAN FOR SPECIAL NEEDS INDIVIDUALS DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)), as amended by section 221(b), is amended by adding at the end the following new paragraph:

"(6) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—

"(A) IN GENERAL.—The term 'specialized MA plan for special needs individuals' means an MA plan that exclusively serves special needs individuals (as defined in subparagraph (B)).

"(B) SPECIAL NEEDS INDIVIDUAL.—The term 'special needs individual' means an MA eligible individual who—

"(i) is institutionalized (as defined by the Secretary);

"(ii) is entitled to medical assistance under a State plan under title XIX; or

"(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such

a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.

The Secretary may waive application of section 1851(a)(3)(B) in the case of an individual described in clause (i), (ii), or (iii) of this subparagraph and may apply rules similar to the rules of section 1894(c)(4) for continued eligibility of special needs individuals.".

(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 MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2009, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.".

(d) AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MA PLANS.—In promulgating regulations to carry out section 1851(a)(2)(A)(ii) of the Social Security Act (as added by subsection (a)) and section 1859(b)(6) of such Act (as added by subsection (b)), the Secretary may provide (notwithstanding section 1859(b)(6)(A) of such Act) for the offering of specialized MA plans for special needs individuals by MA plans that disproportionately serve special needs individuals.

(e) REPORT TO CONGRESS.—Not later than December 31, 2007, the Secretary shall submit to Congress a report that assesses the impact of specialized MA plans for special needs individuals on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(f) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS INDIVIDUALS; TRANSITION.—No later than 1 year after the date of the enactment of this Act, the Secretary shall issue final regulations to establish requirements for special needs individuals under section 1859(b)(6)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.

(a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–26(b)(3)) is amended to read as follows:

"(3) RELATION TO STATE LAWS.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.".

(b) CONFORMING AMENDMENT.—Section 1854(g) (42 U.S.C. 1395w–24(g)) is amended by inserting "or premiums paid to such organizations under this part" after "section 1853".

(c) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of the enactment of this Act.

SEC. 233. MEDICARE MSAS.

(a) EXEMPTION FROM REPORTING REQUIREMENT.—

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w–22(e)(1)) is amended by inserting "(other than MSA plans)" after "plans".

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: ", if required under such section";

(B) in subsection (e)(2)(A), by striking ", a non-network MSA plan,"; and

(C) in subsection (e)(2)(B), by striking ", NON-NETWORK MSA PLANS," and ", a non-network MSA plan,".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply on and after the date of the enactment of this Act but shall not apply to contract years beginning on or after January 1, 2006.

(b) MAKING PROGRAM PERMANENT AND ELIMINATING CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is amended—

(1) in the heading, by striking "ON A DEMONSTRATION BASIS";

(2) by striking the first sentence of subparagraph (A); and

(3) by striking the second sentence of subparagraph (C).

(c) APPLYING LIMITATIONS ON BALANCE BILLING.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amended by inserting "or with an organization offering an MSA plan" after "section 1851(a)(2)(A)".

(d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A) (42 U.S.C. 1395w–21(e)(5)(A)) is amended—

(1) by adding "or" at the end of clause (i);

(2) by striking ", or" at the end of clause (ii) and inserting a semicolon; and

(3) by striking clause (iii).

SEC. 234. 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), a reasonable cost reimbursement contract under this subsection may be extended or renewed 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—

"(I) 2 or more MA regional plans described in clause (iii); or

"(II) 2 or more MA local plans described in clause (iii).

"(iii) A plan described in this clause for a year for a service area is a plan described in section 1851(a)(2)(A)(i) if the service area for the year meets the following minimum enrollment requirements:

"(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population

of more than 250,000 and counties contiguous to such Metropolitan Statistical Area, 5,000 individuals.

"(II) With respect to any other portion of such area, 1,500 individuals.".

SEC. 235. TWO-YEAR 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 amended by section 6135 of the Omnibus Budget Reconciliation Act of 1989, section 13557 of the Omnibus Budget Reconciliation Act of 1993, section 4017 of BBA, section 534 of BBRA (113 Stat. 1501A–390), and section 633 of BIPA, is amended by striking "December 31, 2004" and inserting "December 31, 2006".

SEC. 236. PAYMENT BY PACE PROVIDERS FOR MEDICARE AND MEDICAID SERVICES FURNISHED BY NONCONTRACT PROVIDERS.

(a) MEDICARE SERVICES.—

(1) MEDICARE SERVICES FURNISHED BY PROVIDERS OF SERVICES.—Section 1866(a)(1)(O) (42 U.S.C. 1395cc(a)(1)(O)) is amended—

(A) by striking "part C or" and inserting "part C, with a PACE provider under section 1894 or 1934, or";

(B) by striking "(i)";

(C) by striking "and (ii)";

(D) by inserting "(or, in the case of a PACE provider, contract or other agreement)" after "have a contract"; and

(E) by striking "members of the organization" and inserting "members of the organization or PACE program eligible individuals enrolled with the PACE provider,".

(2) MEDICARE SERVICES FURNISHED BY PHYSICIANS AND OTHER ENTITIES.—Section 1894(b) (42 U.S.C. 1395eee(b)) is amended by adding at the end the following new paragraphs:

"(3) TREATMENT OF MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

"(A) APPLICATION OF MEDICARE ADVANTAGE REQUIREMENT WITH RESPECT TO MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—Section 1852(k)(1) (relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under this title) shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as such section applies to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to in such section.

"(B) REFERENCE TO RELATED PROVISION FOR NONCONTRACT PROVIDERS OF SERVICES.—For the provision relating to limitations on balance billing against PACE providers for services covered under this title furnished by noncontract providers of services, see section 1866(a)(1)(O).

"(4) REFERENCE TO RELATED PROVISION FOR SERVICES COVERED UNDER TITLE XIX BUT NOT UNDER THIS TITLE.—For provisions relating to limitations on payments to providers participating under the State plan under title XIX that do not have a contract or other agreement with a PACE provider establishing payment amounts for services covered under such plan (but not under this title) when such services are furnished to enrollees of that PACE provider, see section 1902(a)(66).".

(b) MEDICAID SERVICES.—

(1) REQUIREMENT UNDER STATE PLAN.—Section 1902(a) (42 U.S.C. 1396a(a)), as amended by section 103(a), is amended—

(A) in paragraph (65), by striking "and" at the end;

(B) in paragraph (66), by striking the period at the end and inserting "; and"; and

(C) by inserting after paragraph (66) the following new paragraph:

"(67) provide, with respect to services covered under the State plan (but not under title XVIII) that are furnished to a PACE program eligible individual enrolled with a PACE provider by a provider participating under the State plan that does not have a contract or other agreement with the PACE provider that establishes payment amounts for such services, that such participating provider may not require the PACE provider to pay the participating provider an amount greater than the amount that would otherwise be payable for the service to the participating provider under the State plan for the State where the PACE provider is located (in accordance with regulations issued by the Secretary).".

(2) APPLICATION UNDER MEDICAID.—Section 1934(b) (42 U.S.C. 1396u–4(b)) is amended by adding at the end the following new paragraphs:

"(3) TREATMENT OF MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

"(A) APPLICATION OF MEDICARE ADVANTAGE REQUIREMENT WITH RESPECT TO MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—Section 1852(k)(1) (relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under title XVIII) shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as such section applies to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to in such section.

"(B) REFERENCE TO RELATED PROVISION FOR NONCONTRACT PROVIDERS OF SERVICES.—For the provision relating to limitations on balance billing against PACE providers for services covered under title XVIII furnished by noncontract providers of services, see section 1866(a)(1)(O).

"(4) REFERENCE TO RELATED PROVISION FOR SERVICES COVERED UNDER THIS TITLE BUT NOT UNDER TITLE XVIII.—For provisions relating to limitations on payments to providers participating under the State plan under this title that do not have

a contract or other agreement with a PACE provider establishing payment amounts for services covered under such plan (but not under title XVIII) when such services are furnished to enrollees of that PACE provider, see section 1902(a)(67).".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004.

SEC. 237. REIMBURSEMENT FOR FEDERALLY QUALIFIED HEALTH CENTERS PROVIDING SERVICES UNDER MA PLANS.

(a) REIMBURSEMENT.—Section 1833(a)(3) (42 U.S.C. 1395l(a)(3)) is amended to read as follows:

"(3) in the case of services described in section 1832(a)(2)(D)—

"(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

"(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which—

"(i) the amount of payment that would have otherwise been provided under subparagraph (A) (calculated as if '100 percent' were substituted for '80 percent' in such subparagraph) for such services if the individual had not been so enrolled; exceeds

"(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B);".

(b) CONTINUATION OF MONTHLY PAYMENTS.—

(1) IN GENERAL.—Section 1853(a) (42 U.S.C. 1395w–23(a)) is amended by adding at the end the following new paragraph:

"(4) PAYMENT RULE FOR FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—If an individual who is enrolled with an MA plan under this part receives a service from a federally qualified health center that has a written agreement with the MA organization that offers such plan for providing such a service (including any agreement required under section 1857(e)(3))—

"(A) the Secretary shall pay the amount determined under section 1833(a)(3)(B) directly to the federally qualified health center not less frequently than quarterly; and

"(B) the Secretary shall not reduce the amount of the monthly payments under this subsection as a result of the application of subparagraph (A).".

(2) CONFORMING AMENDMENTS.—

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

(i) in paragraph (1), by inserting "1853(a)(4)," after "Subject to sections 1852(a)(5),"; and

(ii) in paragraph (2), by inserting "1853(a)(4)," after "Subject to sections".

(B) Section 1853(c)(5) is amended by striking "subsections (a)(3)(C)(iii) and (i)" and inserting "subsections (a)(3)(C)(iii), (a)(4), and (i)".

(c) ADDITIONAL CONTRACT REQUIREMENTS.—Section 1857(e) (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

"(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS.—

"(A) PAYMENT LEVELS AND AMOUNTS.—A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

"(B) COST-SHARING.—Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).".

(d) SAFE HARBOR.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)), as amended by section 101(f)(2), is amended—

(1) in subparagraph (F), by striking "and" after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting "; and"; and

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

"(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4).".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services provided on or after January 1, 2006, and contract years beginning on or after such date.

SEC. 238. INSTITUTE OF MEDICINE EVALUATION AND REPORT ON HEALTH CARE PERFORMANCE MEASURES.

(a) EVALUATION.—

(1) IN GENERAL.—Not later than the date that is 2 months after the date of the enactment of this Act, the Secretary shall enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences (in this section

referred to as the "Institute") shall conduct an evaluation of leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) SPECIFIC MATTERS EVALUATED.—In conducting the evaluation under paragraph (1), the Institute shall—

(A) catalogue, review, and evaluate the validity of leading health care performance measures;

(B) catalogue and evaluate the success and utility of alternative performance incentive programs in public or private sector settings; and

(C) identify and prioritize options to implement policies that align performance with payment under the medicare program that indicate—

(i) the performance measurement set to be used and how that measurement set will be updated;

(ii) the payment policy that will reward performance; and

(iii) the key implementation issues (such as data and information technology requirements) that must be addressed.

(3) SCOPE OF HEALTH CARE PERFORMANCE MEASURES.—The health care performance measures described in paragraph (2)(A) shall encompass a variety of perspectives, including physicians, hospitals, other health care providers, health plans, purchasers, and patients.

(4) CONSULTATION WITH MEDPAC.—In evaluating the matters described in paragraph (2)(C), the Institute shall consult with the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(b) REPORT.—Not later than the date that is 18 months after the date of enactment of this Act, the Institute shall submit to the Secretary and appropriate committees of jurisdiction of the Senate and House of Representatives a report on the evaluation conducted under subsection (a)(1) describing the findings of such evaluation and recommendations for an overall strategy and approach for aligning payment with performance, including options for updating performance measures, in the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act, the Medicare Advantage program under part C of such title, and any other programs under such title XVIII.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for purposes of conducting the evaluation and preparing the report required by this section.

Subtitle E—Comparative Cost Adjustment (CCA) Program

SEC. 241. COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM.

(a) IN GENERAL.—Part C of title XVIII is amended by adding at the end the following new section:

"COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM

"SEC. 1860C–1. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—The Secretary shall establish a program under this section (in this section referred to as the 'CCA program') for the application of comparative cost adjustment in CCA areas selected under this section.

"(2) DURATION.—The CCA program shall begin January 1, 2010, and shall extend over a period of 6 years, and end on December 31, 2015.

"(3) REPORT.—Upon the completion of the CCA program, the Secretary shall submit a report to Congress. Such report shall include the following, with respect to both this part and the original medicare fee-for-service program:

"(A) An evaluation of the financial impact of the CCA program.

"(B) An evaluation of changes in access to physicians and other health care providers.

"(C) Beneficiary satisfaction.

"(D) Recommendations regarding any extension or expansion of the CCA program.

"(b) REQUIREMENTS FOR SELECTION OF CCA AREAS.—

"(1) CCA AREA DEFINED.—

"(A) IN GENERAL.—For purposes of this section, the term 'CCA area' means an MSA that meets the requirements of paragraph (2) and is selected by the Secretary under subsection (c).

"(B) MSA DEFINED.—For purposes of this section, the term 'MSA' means a Metropolitan Statistical Area (or such similar area as the Secretary recognizes).

"(2) REQUIREMENTS FOR CCA AREAS.—The requirements of this paragraph for an MSA to be a CCA area are as follows:

"(A) MA ENROLLMENT REQUIREMENT.—For the reference month (as defined under section 1858(f)(4)(B)) with respect to 2010, at least 25 percent of the total number of MA eligible individuals who reside in the MSA were enrolled in an MA local plan described in section 1851(a)(2)(A)(i).

"(B) 2 PLAN REQUIREMENT.—There will be offered in the MSA during the annual, coordinated election period under section 1851(e)(3)(B) before the beginning of 2010 at least 2 MA local plans described in section 1851(a)(2)(A)(i) (in addition to the fee-for-service program under parts A and B), each offered by a different MA organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of the reference month.

"(c) SELECTION OF CCA AREAS.—

"(1) GENERAL SELECTION CRITERIA.—The Secretary shall select CCA areas from among those MSAs qualifying under subsection (b) in a manner that—

"(A) seeks to maximize the opportunity to test the application of comparative cost adjustment under this title;

"(B) does not seek to maximize the number of MA eligible individuals who reside in such areas; and

"(C) provides for geographic diversity consistent with the criteria specified in paragraph (2).

"(2) SELECTION CRITERIA.—With respect to the selection of MSAs that qualify to be CCA areas under subsection (b), the following rules apply, to the maximum extent feasible:

"(A) MAXIMUM NUMBER.—The number of such MSAs selected may not exceed the lesser of (i) 6, or (ii) 25 percent of the number of MSAs that meet the requirement of subsection (b)(2)(A).

"(B) ONE OF 4 LARGEST AREAS BY POPULATION.—At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the largest total population of MA eligible individuals.

"(C) ONE OF 4 AREAS WITH LOWEST POPULATION DENSITY.—At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the lowest population density (as measured by residents per square mile or similar measure of density).

"(D) MULTISTATE AREA.—At least one such qualifying MSA shall be selected that includes a multi-State area. Such an MSA may be an MSA described in subparagraph (B) or (C).

"(E) LIMITATION WITHIN SAME GEOGRAPHIC REGION.—No more than 2 such MSAs shall be selected that are, in whole or in part, within the same geographic region (as specified by the Secretary) of the United States.

"(F) PRIORITY TO AREAS NOT WITHIN CERTAIN DEMONSTRATION PROJECTS.—Priority shall be provided for those qualifying MSAs that do not have a demonstration project in effect as of the date of the enactment of this section for medicare preferred provider organization plans under this part.

"(d) APPLICATION OF COMPARATIVE COST ADJUSTMENT.—

"(1) IN GENERAL.—In the case of a CCA area for a year—

"(A) for purposes of applying this part with respect to payment for MA local plans, any reference to an MA area-specific non-drug monthly benchmark amount shall be treated as a reference to such benchmark computed as if the CCA area-specific non-drug monthly benchmark amount (as defined in subsection (e)(1)) were substituted for the amount described in section 1853(j)(1)(A) for the CCA area and year involved, as phased in under paragraph (3); and

"(B) with respect to months in the year for individuals residing in the CCA area who are not enrolled in an MA plan, the amount of the monthly premium under section 1839 is subject to adjustment under subsection (f).

"(2) EXCLUSION OF MA LOCAL AREAS WITH FEWER THAN 2 ORGANIZATIONS OFFERING MA PLANS.—

"(A) IN GENERAL.—In no case shall an MA local area that is within an MSA be included as part of a CCA area unless for 2010 (and, except as provided in subparagraph (B), for a subsequent year) there is offered in each part of such MA local area at least 2 MA local plans described in section 1851(a)(2)(A)(i) each of which is offered by a different MA organization.

"(B) CONTINUATION.—If an MA local area meets the requirement of subparagraph (A) and is included in a CCA area for 2010, such local area shall continue to be included in such CCA area for a subsequent year notwithstanding that it no longer meets such requirement so long as there is at least one MA local plan described in section 1851(a)(2)(A)(i) that is offered in such local area.

"(3) PHASE-IN OF CCA BENCHMARK.—

"(A) IN GENERAL.—In applying this section for a year before 2013, paragraph (1)(A) shall be applied as if the phase-in fraction under subparagraph (B) of the CCA non-drug monthly benchmark amount for the year were substituted for such fraction of the MA area-specific non-drug monthly benchmark amount.

"(B) PHASE-IN FRACTION.—The phase-in fraction under this subparagraph is—

"(i) for 2010 ¼; and

"(ii) for a subsequent year is the phase-in fraction under this subparagraph for the previous year increased by ¼, but in no case more than 1.

"(e) COMPUTATION OF CCA BENCHMARK AMOUNT.—

"(1) CCA NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this section, the term 'CCA non-drug monthly benchmark amount' means, with respect to a CCA area for a month in a year, the sum of the 2 components described in paragraph (2) for the area and year. The Secretary shall compute such benchmark amount for each such CCA area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which the CCA area is so selected.

"(2) 2 COMPONENTS.—For purposes of paragraph (1), the 2 components described in this paragraph for a CCA area and a year are the following:

"(A) MA LOCAL COMPONENT.—The product of the following:

"(i) WEIGHTED AVERAGE OF MEDICARE ADVANTAGE PLAN BIDS IN AREA.—The weighted average of the plan bids for the area and year (as determined under paragraph (3)(A)).

"(ii) NON-FFS MARKET SHARE.—One minus the fee-for-service market share percentage, determined under paragraph (4) for the area and year.

"(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

"(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service area-specific non-drug amount (as defined in paragraph (5)) for the area and year.

"(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage, determined under paragraph (4) for the area and year.

"(3) DETERMINATION OF WEIGHTED AVERAGE MA BIDS FOR A CCA AREA.—

"(A) IN GENERAL.—For purposes of paragraph (2)(A)(i), the weighted average of plan bids for a CCA area and a year is, subject to subparagraph (D), the sum of the

following products for MA local plans described in subparagraph (C) in the area and year:

"(i) MONTHLY MEDICARE ADVANTAGE STATUTORY NON-DRUG BID AMOUNT.—The accepted unadjusted MA statutory non-drug monthly bid amount.

"(ii) PLAN'S SHARE OF MEDICARE ADVANTAGE ENROLLMENT IN AREA.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all MA plans described in subparagraph (C) for that area and year.

"(B) COUNTING OF INDIVIDUALS.—The Secretary shall count, for each MA local plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part during the reference month for that year.

"(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an area and year, the MA local plans described in this subparagraph are MA local plans described in section 1851(a)(2)(A)(i) that are offered in the area and year and were offered in the CCA area in the reference month.

"(D) COMPUTATION OF WEIGHTED AVERAGE OF PLAN BIDS.—In calculating the weighted average of plan bids for a CCA area under subparagraph (A)—

"(i) in the case of an MA local plan that has a service area only part of which is within such CCA area, the MA organization offering such plan shall submit a separate bid for such plan for the portion within such CCA area; and

"(ii) the Secretary shall adjust such separate bid (or, in the case of an MA local plan that has a service area entirely within such CCA area, the plan bid) as may be necessary to take into account differences between the service area of such plan within the CCA area and the entire CCA area and the distribution of plan enrollees of all MA local plans offered within the CCA area.

"(4) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Secretary shall determine, for a year and a CCA area, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') equal to—

"(A) the total number of MA eligible individuals residing in such area who during the reference month for the year were not enrolled in any MA plan; divided by

"(B) the sum of such number and the total number of MA eligible individuals residing in such area who during such reference month were enrolled in an MA local plan described in section 1851(a)(2)(A)(i),

or, if greater, such proportion determined for individuals nationally.

"(5) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (2)(B)(i) and subsection (f)(2)(A), subject to subparagraph (C), the term 'fee-for-service area-specific non-drug amount' means, for a CCA area and a year, the adjusted average per capita cost for such area and year involved, determined under section 1876(a)(4) and adjusted as appropriate for

the purpose of risk adjustment for benefits under the original medicare fee-for-service program option for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in an MA plan for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) USE OF FULL RISK ADJUSTMENT TO STANDARDIZE FEE-FOR-SERVICE COSTS TO TYPICAL BENEFICIARY.—In determining the adjusted average per capita cost for an area and year under subparagraph (A), such costs shall be adjusted to fully take into account the demographic and health status risk factors established under section 1853(a)(1)(A)(iv) so that such per capita costs reflect the average costs for a typical beneficiary residing in the CCA area.

"(C) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the 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.

"(f) PREMIUM ADJUSTMENT.—

"(1) APPLICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), in the case of an individual who is enrolled under part B, who resides in a CCA area, and who is not enrolled in an MA plan under this part, the monthly premium otherwise applied under part B (determined without regard to subsections (b), (f), and (i) of section 1839 or any adjustment under this subsection) shall be adjusted in accordance with paragraph (2), but only in the case of premiums for months during the period in which the CCA program under this section for such area is in effect.

"(B) NO PREMIUM ADJUSTMENT FOR SUBSIDY ELIGIBLE BENEFICIARIES.—No premium adjustment shall be made under this subsection for a premium for a month if the individual is determined to be a subsidy eligible individual (as defined in section 1860D–14(a)(3)(A)) for the month.

"(2) AMOUNT OF ADJUSTMENT.—

"(A) IN GENERAL.—Under this paragraph, subject to the exemption under paragraph (1)(B) and the limitation under subparagraph (B), if the fee-for-service area-specific non-drug amount (as defined in section (e)(5)) for a CCA area in which an individual resides for a month—

"(i) does not exceed the CCA non-drug monthly benchmark amount (as determined under subsection (e)(1)) for such area and month, the amount of the premium for the individual for the month shall be reduced, by an amount equal to 75 percent of the amount by which such CCA benchmark exceeds such fee-for-service area-specific non-drug amount; or

"(ii) exceeds such CCA non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, that—

"(I) the sum of the amount of the adjusted premium and the CCA non-drug benchmark for the area; is equal to

"(II) the sum of the unadjusted premium plus the amount of such fee-for-service area-specific non-drug amount for the area.

"(B) LIMITATION.—In no case shall the actual amount of an adjustment under subparagraph (A) for an area and month in a year result in an adjustment that exceeds the maximum adjustment permitted under subparagraph (C) for the area and year, or, if less, the maximum annual adjustment permitted under subparagraph (D) for the area and year.

"(C) PHASE-IN OF ADJUSTMENT.—The amount of an adjustment under subparagraph (A) for a CCA area and year may not exceed the product of the phase-in fraction for the year under subsection (d)(3)(B) multiplied by the amount of the adjustment otherwise computed under subparagraph (A) for the area and year, determined without regard to this subparagraph and subparagraph (D).

"(D) 5-PERCENT LIMITATION ON ADJUSTMENT.—The amount of the adjustment under this subsection for months in a year shall not exceed 5 percent of the amount of the monthly premium amount determined for months in the year under section 1839 without regard to subsections (b), (f), and (i) of such section and this subsection.".

(b) CONFORMING AMENDMENTS.—

(1) MA LOCAL PLANS.—

(A) Section 1853(j)(1)(A) (42 U.S.C. 1395w–23(j)(1)(A)), as added by section 222(d), is amended by inserting "subject to section 1860C–1(d)(2)(A)," after "within an MA local area,".

(B) Section 1853(b)(1)(B), as amended by section 222(f)(1), is amended by adding at the end the following new clause:

"(iii) BENCHMARK ANNOUNCEMENT FOR CCA LOCAL AREAS.—The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each CCA area (as defined in section 1860C–1(b)(1)(A)), the CCA non-drug monthly benchmark amount under section 1860C–1(e)(1) for that area for the year involved.".

(2) PREMIUM ADJUSTMENT.—

(A) Section 1839 (42 U.S.C. 1395r) is amended by adding at the end the following new subsection:

"(h) POTENTIAL APPLICATION OF COMPARATIVE COST ADJUSTMENT IN CCA AREAS.—

"(1) IN GENERAL.—Certain individuals who are residing in a CCA area under section 1860C–1 who are not enrolled in an MA plan under part C may be subject to a premium adjustment under subsection (f) of such section for months in which the CCA program under such section is in effect in such area.

"(2) NO EFFECT ON LATE ENROLLMENT PENALTY OR INCOME-RELATED ADJUSTMENT IN SUBSIDIES.—Nothing in this subsection or section 1860C–1(f) shall be construed as affecting the amount of any premium adjustment under subsection (b) or (i). Subsection (f) shall be applied without regard to any premium adjustment referred to in paragraph (1).

"(3) IMPLEMENTATION.—In order to carry out a premium adjustment under this subsection and section 1860C–1(f) (insofar as it is effected through the manner of collection of premiums under section 1840(a)), the Secretary shall transmit to the Commissioner of Social Security—

"(A) at the beginning of each year, the name, social security account number, and the amount of the premium adjustment (if any) for each individual enrolled under this part for each month during the year; and

"(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.".

(B) Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting "and without regard to any premium adjustment effected under sections 1839(h) and 1860C–1(f)" before the period at the end.

(c) NO CHANGE IN MEDICARE'S DEFINED BENEFIT PACKAGE.—Nothing in this part (or the amendments made by this part) shall be construed as changing the entitlement to defined benefits under parts A and B of title XVIII of the Social Security Act.

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.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(1) in subparagraph (A)(ii), by striking "promptly (as determined in accordance with regulations)"; and

(2) in subparagraph (B)—

(A) by redesignating clauses (i) through (v) as clauses (ii) through (vi), respectively; and

(B) 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.".

(b) CLARIFYING AMENDMENTS TO CONDITIONAL PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)), as amended by subsection (a), is 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)(A)—

(A) by striking the first sentence and inserting the following: "A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."; and

(B) in the final sentence, by striking "on the date such notice or other information is received" and inserting "on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received"; and

(3) in subparagraph (B)(iii), as redesignated by subsection (a)(2)(A), 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".

(d) EFFECTIVE DATES.—The amendments made by this section shall be effective—

(1) in the case of subsection (a), as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98–369); and

(2) in the case of subsections (b) and (c), as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1980 (Public Law 96–499; 94 Stat. 2647).

SEC. 302. PAYMENT FOR DURABLE MEDICAL EQUIPMENT; COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) QUALITY ENHANCEMENT AND FRAUD REDUCTION.—

(1) ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT SUPPLIERS.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

(A) by transferring paragraph (17), as added by section 4551(c)(1) of the Balanced Budget Act of 1997 (111 Stat. 458), to the end of such section and redesignating such paragraph as paragraph (19); and

(B) by adding at the end the following new paragraph:

"(20) IDENTIFICATION OF QUALITY STANDARDS.—

"(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

"(i) furnish any such item or service for which payment is made under this part; and

"(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

"(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS.—Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(b), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

"(C) QUALITY STANDARDS.—The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

"(D) ITEMS AND SERVICES DESCRIBED.—The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

"(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

"(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

"(iii) Items and services described in section 1842(s)(2).

"(E) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.".

(2) ESTABLISHMENT OF CLINICAL CONDITIONS OF COVERAGE STANDARDS FOR ITEMS OF DURABLE MEDICAL EQUIPMENT.—Section 1834(a)(1) (42 U.S.C. 1395m(a)(1)) is amended by adding at the end the following new subparagraph:

"(E) CLINICAL CONDITIONS FOR COVERAGE.—

"(i) IN GENERAL.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

"(ii) REQUIREMENTS.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

"(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

"(iv) STANDARDS FOR POWER WHEELCHAIRS.—Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

"(v) LIMITATION ON PAYMENT FOR COVERED ITEMS.—Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.".

(b) COMPETITIVE ACQUISITION.—

(1) 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—

"(i) shall be phased in among competitive acquisition areas in a manner so that the competition under the programs occurs in—

"(I) 10 of the largest metropolitan statistical areas in 2007;

"(II) 80 of the largest metropolitan statistical areas in 2009; and

"(III) additional areas after 2009; and

"(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

"(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 would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation 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 and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

"(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

"(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 AND OXYGEN.—In the case of a covered item for which payment is made on a rental basis under section 1834(a) and in the case of payment for oxygen under section 1834(a)(5), the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers 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.—

"(A) IN GENERAL.—With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

"(B) NO EFFECT ON PAYMENT AMOUNT.—A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

"(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), section 1834(h), or section 1842(s), as appropriate.

"(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 applicable quality standards specified by the Secretary under section 1834(a)(20).

"(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

"(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

"(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

"(B) TIMELY IMPLEMENTATION OF PROGRAM.—Any delay in the implementation of quality standards under section 1834(a)(20) or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

"(3) CONTENTS OF CONTRACT.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

"(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts under this section not less often than once every 3 years.

"(4) LIMIT ON NUMBER OF CONTRACTORS.—

"(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals 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.—

"(A) IN GENERAL.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

"(B) REDUCED BENEFICIARY COST-SHARING.—

"(i) APPLICATION OF COINSURANCE.—Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

"(ii) APPLICATION OF DEDUCTIBLE.—Before applying clause (i), the individual shall be required to meet the deductible described in section 1833(b).

"(C) PAYMENT ON ASSIGNMENT-RELATED BASIS.—Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

"(D) CONSTRUCTION.—Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

"(6) PARTICIPATING CONTRACTORS.—

"(A) IN GENERAL.—Except as provided in subsection (a)(4), 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—

"(i) the contractor has submitted a bid for such items and services under this section; and

"(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

"(B) BID DEFINED.—In this section, the term 'bid' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

"(C) RULES FOR MERGERS AND ACQUISITIONS.—In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

"(D) PROTECTION OF SMALL SUPPLIERS.—In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

"(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

"(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH, AND COMPLAINT SERVICES.—The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

"(9) AUTHORITY TO CONTRACT FOR IMPLEMENTATION.—The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

"(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(A) the establishment of payment amounts under paragraph (5);

"(B) the awarding of contracts under this section;

"(C) the designation of competitive acquisition areas under subsection (a)(1)(A);

"(D) the phased-in implementation under subsection (a)(1)(B);

"(E) the selection of items and services for competitive acquisition under subsection (a)(2); or

"(F) the bidding structure and number of contractors selected under this section.

"(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

"(1) ESTABLISHMENT.—The Secretary shall establish 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) ADVICE.—The Committee shall provide advice to the Secretary with respect to the following functions:

"(i) The implementation of the program under this section.

"(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

"(iii) The establishment of requirements for collection of data for the efficient management of the program.

"(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals.

"(v) The establishment of quality standards under section 1834(a)(20).

"(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.

"(5) TERMINATION.—The Committee shall terminate on December 31, 2009.

"(d) REPORT.—Not later than July 1, 2009, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

"(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 would otherwise be made under section 1833(h) (other than for pap smear laboratory tests under paragraph (7) of such section) or section 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.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2), excluding subsection (b)(5)(B) and other conditions as the Secretary determines to be appropriate.

"(B) APPLICATION OF CLIA QUALITY STANDARDS.—The quality standards established by the Secretary under section 353 of the Public Health Service Act for clinical diagnostic laboratory tests shall apply to such tests under the demonstration project under this section in lieu of quality standards described in subsection (b)(2)(A)(i).

"(3) REPORT.—The Secretary shall submit to Congress—

"(A) an initial report on the project not later than December 31, 2005; and

"(B) such progress and final reports on the project after such date as the Secretary determines appropriate.".

(2) CONFORMING AMENDMENTS.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking "and (U)" and inserting "(U)";

(B) by inserting before the semicolon at the end the following: ", and (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts

paid shall be the amounts described in section 1847(b)(5)"; and

(C) in clause (D)—

(i) by striking "or (ii)" and inserting "(ii)"; and

(ii) by adding at the end the following: "or (iii) on the basis of a rate established under a demonstration project under section 1847(e), the amount paid shall be equal to 100 percent of such rate,".

(3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION ON SUPPLIERS.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act, as amended by paragraph (1), on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment.

(B) REPORT.—Not later than January 1, 2009, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A) and shall include in the report such recommendations as the Comptroller General determines appropriate.

(c) TRANSITIONAL FREEZE.—

(1) DME.—

(A) IN GENERAL.—Section 1834(a)(14) (42 U.S.C. 1395m(a)(14)) is amended—

(i) in subparagraph (E), by striking "and" at the end;

(ii) in subparagraph (F)—

(I) by striking "a subsequent year" and inserting "2003"; and

(II) by striking "the previous year." and inserting "2002;"; and

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

"(G) for 2004 through 2006—

"(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

"(ii) in the case of covered items not described in clause (i), 0 percentage points;

"(H) for 2007—

"(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

"(ii) in the case of covered items not described in clause (i), 0 percentage points; and

"(I) for 2008—

"(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

"(ii) in the case of covered items not described in clause (i), 0 percentage points; and

"(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.".

(B) GAO REPORT ON CLASS III MEDICAL DEVICES.—Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary, a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) furnished to medicare beneficiaries during 2007 and 2008.

(2) PAYMENT RULE FOR SPECIFIED ITEMS.—Section 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

"(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

"(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

"(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

"(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled 'Median FEHP Price' in the table entitled 'SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS' included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

"(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

"(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.".

(3) PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—Section 1834(h)(4)(A) (42 U.S.C. 1395m(h)(4)(A)) is amended—

(A) in clause (vii), by striking "and" at the end;

(B) in clause (viii), by striking "a subsequent year" and inserting "2003"; and

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

"(ix) for 2004, 2005, and 2006, 0 percent; and

"(x) for a subsequent year, 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;".

(d) CONFORMING AMENDMENTS.—

(1) DURABLE MEDICAL EQUIPMENT; LIMITATION 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 (F)(i), the payment basis";

(B) in paragraph (1)(C), by striking "This subsection" and inserting "Subject to subparagraph (F)(ii), this subsection";

(C) by adding at the end of paragraph (1) the following new subparagraph:

"(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2009, 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)(F)" after "under this subsection".

(2) OFF-THE-SHELF ORTHOTICS; LIMITATION 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"; and

(C) by adding at the end of paragraph (1) the following new subparagraph:

"(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, 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.".

(3) OTHER ITEMS AND SERVICES; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1842(s) (42 U.S.C. 1395u(s)) is amended—

(A) in the first sentence of paragraph (1), by striking "The Secretary" and inserting "Subject to paragraph (3), the Secretary"; and

(B) by adding at the end the following new paragraph:

"(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

"(A) 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

"(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) 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.".

(e) REPORT ON ACTIVITIES OF SUPPLIERS.—The Inspector General of the Department of Health and Human Services 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. Not later than July 1, 2009, the Inspector General shall submit to Congress a report on such study.

SEC. 303. PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

(1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w–4(c)(2)) is amended—

(A) in subparagraph (B)—

(i) in clause (ii)(II), by striking "The adjustments" and inserting "Subject to clause (iv), the adjustments"; and

(ii) by adding at the end of subparagraph (B), the following new clause:

"(iv) EXEMPTION FROM BUDGET NEUTRALITY.—The additional expenditures attributable to—

"(I) subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004;

"(II) subparagraph (I) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year for a specialty described in subparagraph (I)(ii)(II); and

"(III) subparagraph (J) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year."; and

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

"(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING IN 2004.—

"(i) USE OF SURVEY DATA.—In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 if the survey—

"(I) covers practice expenses for oncology drug administration services; and

"(II) meets criteria established by the Secretary for acceptance of such surveys.

"(ii) PRICING OF CLINICAL ONCOLOGY NURSES IN PRACTICE EXPENSE METHODOLOGY.—If the survey described in clause (i) includes data on wages, salaries, and compensation of clinical oncology nurses, the Secretary shall utilize such data in the methodology for determining practice expense relative value units under subsection (c).

"(iii) WORK RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES.—In establishing the relative value units under this paragraph for drug administration services described in clause (iv) furnished on or after January 1, 2004, the Secretary shall establish work relative value units equal to the work

relative value units for a level 1 office medical visit for an established patient.

"(iv) DRUG ADMINISTRATION SERVICES DESCRIBED.—The drug administration services described in this clause are physicians' services—

"(I) which are classified as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy); chemotherapy administration services; and therapeutic, prophylactic, or diagnostic injections;

"(II) for which there are no work relative value units assigned under this subsection as of such date; and

"(III) for which national relative value units have been assigned under this subsection as of such date.

"(I) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING WITH 2005.—

"(i) IN GENERAL.—In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2005 or 2006, the Secretary shall adjust the practice expense relative value units for such year consistent with clause (ii).

"(ii) USE OF SUPPLEMENTAL SURVEY DATA.—

"(I) IN GENERAL.—Subject to subclause (II), if a specialty submits to the Secretary by not later than March 1, 2004, for 2005, or March 1, 2005, for 2006, data that includes expenses for the administration of drugs and biologicals for which the payment amount is determined pursuant to section 1842(o), the Secretary shall use such supplemental survey data in carrying out this subparagraph for the years involved insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

"(II) LIMITATION ON SPECIALTY.—Subclause (I) shall apply to a specialty only insofar as not less than 40 percent of payments for the specialty under this title in 2002 are attributable to the administration of drugs and biologicals, as determined by the Secretary.

"(III) APPLICATION.—This clause shall not apply with respect to a survey to which subparagraph (H)(i) applies.

"(J) PROVISIONS FOR APPROPRIATE REPORTING AND BILLING FOR PHYSICIANS' SERVICES ASSOCIATED WITH THE ADMINISTRATION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—

"(i) EVALUATION OF CODES.—The Secretary shall promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting

and billing for such services, taking into account levels of complexity of the administration and resource consumption.

"(ii) USE OF EXISTING PROCESSES.—In carrying out clause (i), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

"(iii) IMPLEMENTATION.—In carrying out clause (i), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1847A or section 1847B, and shall take such steps within the Secretary's authority to expedite such considerations under clause (ii).

"(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED.—Nothing in subparagraph (H) or (I) or this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively.".

(2) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL.—The Secretary shall make adjustments to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the Federal Register on December 31, 2002 (67 Fed. Reg. 251)), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of services not determined under such methodology, as a result of the amendments made by paragraph (1).

(3) PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECHNIQUE.—

(A) REVIEW OF POLICY.—The Secretary shall review the policy, as in effect on October 1, 2003, with respect to payment under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for the administration of more than 1 drug or biological to an individual on a single day through the push technique.

(B) MODIFICATION OF POLICY.—After conducting the review under subparagraph (A), the Secretary shall modify such payment policy as the Secretary determines to be appropriate.

(C) EXEMPTION FROM BUDGET NEUTRALITY UNDER PHYSICIAN FEE SCHEDULE.—If the Secretary modifies such payment policy pursuant to subparagraph (B), any increased expenditures under title XVIII of the Social Security Act resulting from such modification shall be treated as additional expenditures attributable to subparagraph (H) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)), as added by paragraph (1)(B), for purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).

(4) TRANSITIONAL ADJUSTMENT.—

(A) IN GENERAL.—In order to provide for a transition during 2004 and 2005 to the payment system established under the amendments made by this section, in the case of physicians' services consisting of drug administration services described in subparagraph (H)(iv) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)), as added by paragraph (1)(B), furnished on or after January 1, 2004, and before January 1, 2006, in addition to the amount determined under the fee schedule under section 1848(b) of such Act (42 U.S.C. 1395w–4(b)) there also shall be paid to the physician from the Federal Supplementary Medical Insurance Trust Fund an amount equal to the applicable percentage specified in subparagraph (B) of such fee schedule amount for the services so determined.

(B) APPLICABLE PERCENTAGE.—The applicable percentage specified in this subparagraph for services furnished—

(i) during 2004, is 32 percent; and

(ii) during 2005, is 3 percent.

(5) MEDPAC REVIEW AND REPORTS; SECRETARIAL RESPONSE.—

(A) REVIEW.—The Medicare Payment Advisory Commission shall review the payment changes made under this section insofar as they affect payment under part B of title XVIII of the Social Security Act—

(i) for items and services furnished by oncologists; and

(ii) for drug administration services furnished by other specialists.

(B) OTHER MATTERS STUDIED.—In conducting the review under subparagraph (A), the Commission shall also review such changes as they affect—

(i) the quality of care furnished to individuals enrolled under part B and the satisfaction of such individuals with that care;

(ii) the adequacy of reimbursement as applied in, and the availability in, different geographic areas and to different physician practice sizes; and

(iii) the impact on physician practices.

(C) REPORTS.—The Commission shall submit to the Secretary and Congress—

(i) not later than January 1, 2006, a report on the review conducted under subparagraph (A)(i); and

(ii) not later than January 1, 2007, a report on the review conducted under subparagraph (A)(ii).

Each such report may include such recommendations regarding further adjustments in such payments as the Commission deems appropriate.

(D) SECRETARIAL RESPONSE.—As part of the rulemaking with respect to payment for physicians services under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for 2007, the Secretary may make appropriate adjustments to payment for items and services described in subparagraph (A)(i), taking into account the report submitted under such subparagraph (C)(i).

(b) APPLICATION OF MARKET-BASED PAYMENT SYSTEMS.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

(1) in paragraph (1), by striking "equal to 95 percent of the average wholesale price." and inserting "equal to the following:

"(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

"(i) A drug or biological furnished before January 1, 2004.

"(ii) Blood clotting factors furnished during 2004.

"(iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.

"(iv) A vaccine described in subparagraph (A) or (B) of section 1861(s)(10) furnished on or after January 1, 2004.

"(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

"(B) In the case of a drug or biological furnished during 2004 that is not described in—

"(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

"(ii) subparagraph (D)(i), or

"(iii) subparagraph (F),

the amount determined under paragraph (4).

"(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005, the amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13), as the case may be for the drug or biological.

"(D)(i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

"(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1847 on or after January 1, 2007, the amount provided under section 1847.

"(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished—

"(i) in 2004, the amount of payment provided under paragraph (4); and

"(ii) in 2005 and subsequent years, the amount of payment provided under section 1847A.

"(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

"(G) The provisions of subparagraphs (A) through (F) of this paragraph shall not apply to an inhalation drug or biological furnished through durable medical equipment covered under section 1861(n)."; and

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

"(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

"(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled 'Average of GAO and OIG data (percent)' in the table entitled 'Table 3.—Medicare Part B Drugs in the Most Recent GAO and OIG Studies' published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

"(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

"(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

"(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.".

(c) APPLICATION OF AVERAGE SALES PRICE METHODS BEGINNING IN 2005.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w–3), as amended by section 302(b), the following new section:

"USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

"SEC. 1847A. (a) APPLICATION.—

"(1) IN GENERAL.—Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1842(o)(1)(C) and that are furnished on or after January 1, 2005.

"(2) ELECTION.—This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B for that section to apply instead of this section for the payment for drugs and biologicals.

"(b) PAYMENT AMOUNT.—

"(1) IN GENERAL.—Subject to subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

"(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3); or

"(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4).

"(2) SPECIFICATION OF UNIT.—

"(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1927(b)(3)(A)(iii).

"(B) UNIT DEFINED.—In this section, the term 'unit' means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet,

milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

"(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) determined by—

"(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

"(i) the manufacturer's average sales price (as defined in subsection (c)); and

"(ii) the total number of units specified under paragraph (2) sold; and

"(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

"(4) SINGLE SOURCE DRUG OR BIOLOGICAL.—The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

"(A) AVERAGE SALES PRICE.—The average sales price as determined using the methodology applied under paragraph (3) for all National Drug Codes assigned to such drug or biological product.

"(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for all National Drug Codes assigned to such drug or biological product.

"(5) BASIS FOR PAYMENT AMOUNT.—The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

"(c) MANUFACTURER'S AVERAGE SALES PRICE.—

"(1) IN GENERAL.—For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's 'average sales price' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

"(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

"(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

"(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

"(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of 'best price' under section 1927(c)(1)(C)(i).

"(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1927(c)(1)(C)(ii)(III), except as the Secretary may otherwise provide).

"(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

"(4) PAYMENT METHODOLOGY IN CASES WHERE AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS UNAVAILABLE.—In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—

"(A) the wholesale acquisition cost; or

"(B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

"(5) FREQUENCY OF DETERMINATIONS.—

"(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

"(B) UPDATES IN PAYMENT AMOUNTS.—The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

"(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

"(6) DEFINITIONS AND OTHER RULES.—In this section:

"(A) MANUFACTURER.—The term 'manufacturer' means, with respect to a drug or biological, the manufacturer (as defined in section 1927(k)(5)).

"(B) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

"(C) MULTIPLE SOURCE DRUG.—

"(i) IN GENERAL.—The term 'multiple source drug' means, for a calendar quarter, a drug for which there are 2 or more drug products which—

"(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

"(III) are sold or marketed in the United States during the quarter.

"(ii) EXCEPTION.—With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

"(D) SINGLE SOURCE DRUG OR BIOLOGICAL.—The term 'single source drug or biological' means—

"(i) a biological; or

"(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

"(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

"(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

"(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if

they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

"(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, 'other than a vaccine' is deemed deleted from section 1927(k)(2)(B).

"(d) MONITORING OF MARKET PRICES.—

"(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

"(2) COMPARISON OF PRICES.—Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

"(A) the widely available market price for such drugs and biologicals (if any); and

"(B) the average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.

"(3) LIMITATION ON AVERAGE SALES PRICE.—

"(A) IN GENERAL.—The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

"(B) APPLICABLE THRESHOLD PERCENTAGE DEFINED.—In this paragraph, the term 'applicable threshold percentage' means—

"(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

"(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

"(C) AUTHORITY TO ADJUST AVERAGE SALES PRICE.—If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

"(i) the widely available market price for the drug or biological (if any); or

"(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.

"(4) CIVIL MONEY PENALTY.—

"(A) IN GENERAL.—If the Secretary determines that a manufacturer has made a misrepresentation in the

reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

"(B) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (B) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

"(5) WIDELY AVAILABLE MARKET PRICE.—

"(A) IN GENERAL.—In this subsection, the term 'widely available market price' means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

"(B) CONSIDERATIONS.—In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

"(i) Manufacturers.

"(ii) Wholesalers.

"(iii) Distributors.

"(iv) Physician supply houses.

"(v) Specialty pharmacies.

"(vi) Group purchasing arrangements.

"(vii) Surveys of physicians.

"(viii) Surveys of suppliers.

"(ix) Information on such market prices from insurers.

"(x) Information on such market prices from private health plans.

"(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

"(f) QUARTERLY REPORT ON AVERAGE SALES PRICE.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1927(b)(3).

"(g) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

"(2) the identification of units (and package size) under subsection (b)(2);

"(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

"(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

"(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).".

(2) REPORT ON SALES TO PHARMACY BENEFIT MANAGERS.—

(A) STUDY.—The Secretary shall conduct a study on sales of drugs and biologicals to large volume purchasers, such as pharmacy benefit managers and health maintenance organizations, for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent physicians.

(B) 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 on whether such sales to large volume purchasers should be excluded from the computation of a manufacturer's average sales price under section 1847A of the Social Security Act, as added by paragraph (1).

(3) INSPECTOR GENERAL REPORT ON ADEQUACY OF REIMBURSEMENT RATE UNDER AVERAGE SALES PRICE METHODOLOGY.—

(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the ability of physician practices in the specialties of hematology, hematology/oncology, and medical oncology of different sizes, especially particularly large practices, to obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the average sales price for the drugs and biologicals. In conducting the study, the Inspector General shall conduct an audit of a representative sample of such practices to determine the adequacy of reimbursement under section 1847A of the Social Security Act, as added by paragraph (1).

(B) REPORT.—Not later October 1, 2005, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A), and shall include recommendations on the adequacy of reimbursement for such drugs and biologicals under such section 1847A.

(d) PAYMENT BASED ON COMPETITION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1847A, as added by subsection (c), the following new section:

"COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS

"SEC. 1847B. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

"(1) IMPLEMENTATION OF PROGRAM.—

"(A) IN GENERAL.—The Secretary shall establish and implement a competitive acquisition program under which—

"(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

"(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1847A; and

"(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

This section shall not apply in the case of a physician who elects section 1847A to apply.

"(B) IMPLEMENTATION.—For purposes of implementing the program, the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

"(C) WAIVER OF CERTAIN PROVISIONS.—In order to promote competition, in carrying out the program 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.

"(D) EXCLUSION AUTHORITY.—The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals—

"(i) is not likely to result in significant savings; or

"(ii) is likely to have an adverse impact on access to such drugs or biologicals.

"(2) COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS AND PROGRAM DEFINED.—For purposes of this section—

"(A) COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS DEFINED.—The term 'competitively biddable drugs and biologicals' means a drug or biological described in section 1842(o)(1)(C) and furnished on or after January 1, 2006.

"(B) PROGRAM.—The term 'program' means the competitive acquisition program under this section.

"(C) COMPETITIVE ACQUISITION AREA; AREA.—The terms 'competitive acquisition area' and 'area' mean an appropriate geographic region established by the Secretary under the program.

"(D) CONTRACTOR.—The term 'contractor' means an entity that has entered into a contract with the Secretary under this section.

"(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY.—

"(A) IN GENERAL.—With respect to competitively biddable drugs and biologicals which are supplied under the

program in an area and which are prescribed by a physician who has elected this section to apply—

"(i) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

"(ii) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved; and

"(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals—

"(I) shall be made only to such contractor; and

"(II) shall be conditioned upon the administration of such drugs and biologicals.

"(B) PROCESS FOR ADJUSTMENTS.—The Secretary shall provide a process for adjustments to payments in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

"(C) INFORMATION FOR PURPOSES OF COST-SHARING.—The Secretary shall provide a process by which physicians submit information to contractors for purposes of the collection of any applicable deductible or coinsurance amounts under subparagraph (A)(ii).

"(4) CONTRACT REQUIRED.—Payment may not be made under this part for competitively biddable drugs and biologicals prescribed by a physician who has elected this section to apply within a category and a competitive acquisition area with respect to which the program applies unless—

"(A) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

"(B) the physician has elected such contractor under paragraph (5) for such category and area.

"(5) CONTRACTOR SELECTION PROCESS.—

"(A) ANNUAL SELECTION.—

"(i) IN GENERAL.—The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of competitively biddable drugs and biologicals for an area by selecting physicians.

"(ii) TIMING OF SELECTION.—The selection of a contractor under clause (i) shall be made at the time of the election described in section 1847A(a) for this section to apply and shall be coordinated with agreements entered into under section 1842(h).

"(B) INFORMATION ON CONTRACTORS.—The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

"(C) SELECTING PHYSICIAN DEFINED.—For purposes of this section, the term 'selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area.

"(b) PROGRAM REQUIREMENTS.—

"(1) CONTRACT FOR COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS.—The Secretary shall conduct a competition among entities for the acquisition of competitively biddable drugs and biologicals. Notwithstanding any other provision of this title, in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.

"(2) CONDITIONS FOR AWARDING CONTRACT.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of competitively biddable drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

"(i) CAPACITY TO SUPPLY COMPETITIVELY BIDDABLE DRUG OR BIOLOGICAL WITHIN CATEGORY.—

"(I) IN GENERAL.—The entity has sufficient arrangements to acquire and to deliver competitively biddable drugs and biologicals within such category in the area specified in the contract.

"(II) SHIPMENT METHODOLOGY.—The entity has arrangements in effect for the shipment at least 5 days each week of competitively biddable drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

"(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS.—The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

"(I) the establishment of procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

"(II) a grievance and appeals process for the resolution of disputes.

"(B) ADDITIONAL CONSIDERATIONS.—The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

"(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

"(ii) the exclusion of the entity under section 1128 from participation under this title.

"(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN.—For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1868(b), as added by section 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

"(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA.—The Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

"(A) The bid prices for competitively biddable drugs and biologicals within the category and area.

"(B) Bid price for distribution of such drugs and biologicals.

"(C) Ability to ensure product integrity.

"(D) Customer service.

"(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

"(F) Such other factors as the Secretary may specify.

"(4) TERMS OF CONTRACTS.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

"(B) PERIOD OF CONTRACTS.—A contract under this section shall be for a term of 3 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

"(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM.—A contractor (as defined in subsection (a)(2)(D)) shall—

"(i) acquire all drug and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

"(ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.

Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs or biologicals.

"(D) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES.—Under the contract—

"(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

"(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

"(E) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS.—Under the contract the contractor shall only supply competitively biddable drugs and biologicals directly to the selecting physicians and not directly to individuals,

except under circumstances and settings where an individual currently receives a drug or biological in the individual's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not—

"(i) require a physician to submit a prescription for each individual treatment; or

"(ii) change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.

"(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS.—The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

"(A) The drugs or biologicals are required immediately.

"(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

"(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

"(D) The drugs or biologicals were administered in an emergency situation.

"(6) CONSTRUCTION.—Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

"(c) BIDDING PROCESS.—

"(1) IN GENERAL.—In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the bid price and the other factors referred to in subsection (b)(3).

"(2) BID DEFINED.—In this section, the term 'bid' means an offer to furnish a competitively biddable drug or biological for a particular price and time period.

"(3) BIDDING ON A NATIONAL OR REGIONAL BASIS.—Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

"(4) UNIFORMITY OF BIDS WITHIN AREA.—The amount of the bid submitted under a contract offer for any competitively biddable drug or biological for an area shall be the same for that drug or biological for all portions of that area.

"(5) CONFIDENTIALITY OF BIDS.—The provisions of subparagraph (D) of section 1927(b)(3) shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

"(A) in that subparagraph to a 'manufacturer or wholesaler' is deemed a reference to a 'bidder' under this section;

"(B) in that section to 'prices charged for drugs' is deemed a reference to a 'bid' submitted under this section; and

"(C) in clause (i) of that section to 'this section', is deemed a reference to 'part B of title XVIII'.

"(6) INCLUSION OF COSTS.—The bid price submitted in a contract offer for a competitively biddable drug or biological shall—

"(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

"(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

"(7) PRICE ADJUSTMENTS DURING CONTRACT PERIOD; DISCLOSURE OF COSTS.—Each contract awarded shall provide for—

"(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

"(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

"(d) COMPUTATION OF PAYMENT AMOUNTS.—

"(1) IN GENERAL.—Payment under this section for competitively biddable drugs or biologicals shall be based on bids submitted and accepted under this section for such drugs or biologicals in an area. Based on such bids the Secretary shall determine a single payment amount for each competitively biddable drug or biological in the area.

"(2) SPECIAL RULES.—The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1847A to the use of a price for specific competitively biddable drugs and biologicals in the following cases:

"(A) NEW DRUGS AND BIOLOGICALS.—A competitively biddable drug or biological for which a payment and billing code has not been established.

"(B) OTHER CASES.—Such other exceptional cases as the Secretary may specify in regulations.

"(e) COST-SHARING.—

"(1) APPLICATION OF COINSURANCE.—Payment under this section for competitively biddable drugs and biologicals shall be in an amount equal to 80 percent of the payment basis described in subsection (d)(1).

"(2) DEDUCTIBLE.—Before applying paragraph (1), the individual shall be required to meet the deductible described in section 1833(b).

"(3) COLLECTION.—Such coinsurance and deductible shall be collected by the contractor that supplies the drug or biological involved. Subject to subsection (a)(3)(B), such coinsurance and deductible may be collected in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part.

"(f) SPECIAL PAYMENT RULES.—

"(1) USE IN EXCLUSION CASES.—If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for payment to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847A.

"(2) APPLICATION OF REQUIREMENT FOR ASSIGNMENT.—For provision requiring assignment of claims for competitively biddable drugs and biologicals, see section 1842(o)(3).

"(3) PROTECTION FOR BENEFICIARY IN CASE OF MEDICAL NECESSITY DENIAL.—For protection of individuals against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

"(g) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

"(1) the establishment of payment amounts under subsection (d)(1);

"(2) the awarding of contracts under this section;

"(3) the establishment of competitive acquisition areas under subsection (a)(2)(C);

"(4) the phased-in implementation under subsection (a)(1)(B);

"(5) the selection of categories of competitively biddable drugs and biologicals for competitive acquisition under such subsection or the selection of a drug in the case of multiple source drugs; or

"(6) the bidding structure and number of contractors selected under this section.".

(2) REPORT.—Not later than July 1, 2008, the Secretary shall submit to Congress a report on the program conducted under section 1847B of the Social Security Act, as added by paragraph (1). Such report shall include information on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors available to physicians, the satisfaction of physicians and of individuals enrolled under this part, and information comparing prices for drugs and biologicals under such section and section 1847A of such Act, as added by subsection (c).

(e) ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINISTRATION OF DRUGS AND BIOLOGICALS.—

(1) ITEMS AND SERVICES RELATING TO FURNISHING OF BLOOD CLOTTING FACTORS.—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (b)(2), is amended by adding at the end the following new paragraph:

"(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled 'Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost', provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

"(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

"(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

"(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

"(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.".

(2) PHARMACY SUPPLYING FEE FOR CERTAIN DRUGS AND BIOLOGICALS.—Section 1842(o) (42 U.S.C. 1395u(o)), as previously amended, is amended by adding at the end the following new paragraph:

"(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1861(s)(2) and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).".

(f) LINKAGE OF REVISED DRUG PAYMENTS AND INCREASES FOR DRUG ADMINISTRATION.—The Secretary shall not implement the revisions in payment amounts for drugs and biologicals administered by physicians as a result of the amendments made by subsection (b) with respect to 2004 unless the Secretary concurrently makes adjustments to the practice expense payment adjustment under the amendments made by subsection (a).

(g) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW.—

(1) DRUGS.—Section 1842(o) (42 U.S.C. 1395u(o)), as previously amended, is amended by adding at the end the following new paragraph:

"(7) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).".

(2) PHYSICIAN FEE SCHEDULE.—Section 1848(i)(1)(B) (42 U.S.C. 1395w–4(i)(1)(B)) is amended by striking "subsection (c)(2)(F)" and inserting "subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I)".

(3) MULTIPLE CHEMOTHERAPY AGENTS, OTHER SERVICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL, AND TRANSITIONAL ADJUSTMENT.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (2) through (4) of subsection (a).

(h) CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS.—Nothing in the amendments made by this section shall be construed as changing the payment methodology under

part B of title XVIII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.

(i) CONFORMING AMENDMENTS.—

(1) APPLICATION OF ASP AND COMPETITIVE BIDDING.—Section 1842(o)(2) (42 U.S.C. 1395u(o)(2)) is amended by adding at the end the following: "This paragraph shall not apply in the case of payment under paragraph (1)(C).".

(2) NO CHANGE IN COVERAGE BASIS.—Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting "(or would have been so included but for the application of section 1847B)" after "included in the physicians' bills".

(3) PAYMENT.—(A) Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(or, if applicable, under section 1847, 1847A, or 1847B)" after "1842(o)".

(B) Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is amended—

(i) by striking "and" at the end of subparagraph (H);

(ii) by striking the semicolon at the end of subparagraph (I) and inserting ", and"; and

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

"(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive area under section 1847B, that is not furnished by an entity under a contract under such section;".

(4) CONSOLIDATED REPORTING OF PRICING INFORMATION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (a)(1), by inserting "or under part B of title XVIII" after "section 1903(a)";

(B) in subsection (b)(3)(A)—

(i) in clause (i), by striking "and" at the end and inserting a semicolon;

(ii) in clause (ii), by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

"(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

"(II) if required to make payment under section 1847A, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

"(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii).

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services.";

(C) in subsection (b)(3)(B)—

(i) in the heading, by inserting "AND MANUFACTURER'S AVERAGE SALES PRICE" after "PRICE"; and

(ii) by inserting "and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment" after "manufacturer prices"; and

(D) in subsection (b)(3)(D)—

(i) in the matter preceding clause (i), by inserting "(other than the wholesale acquisition cost for purposes of carrying out section 1847A)" after "subsection (a)(6)(A)(ii)"; and

(ii) in clause (i), by inserting ", to carry out section 1847A (including the determination and implementation of the payment amount), or to carry out section 1847B" after "this section".

(5) IMPLEMENTATION.—The provisions of chapter 8 of title 5, United States Code, shall not apply with respect to regulations implementing the amendments made by subsections (a), (b), and (e)(3), to regulations implementing section 304, and to regulations implementing the amendment made by section 305(a), insofar as such regulations apply in 2004.

(6) REPEAL OF STUDY.—Section 4556 of the Balanced Budget Act of 1997 (42 U.S.C. 1395u note) is amended by striking subsection (c).

(j) APPLICATION TO CERTAIN PHYSICIAN SPECIALTIES.—Insofar as the amendments made by this section apply to payments for drugs or biologicals and drug administration services furnished by physicians, such amendments shall only apply to physicians in the specialties of hematology, hematology/oncology, and medical oncology under title XVIII of the Social Security Act.

SEC. 304. EXTENSION OF APPLICATION OF PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS TO OTHER PHYSICIAN SPECIALTIES.

Notwithstanding section 303(j), the amendments made by section 303 shall also apply to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology.

SEC. 305. PAYMENT FOR INHALATION DRUGS.

(a) IN GENERAL.—Section 1842(o)(1)(G) (42 U.S.C. 1395u(o)(1)(G)), as added by section 303(b), is amended to read as follows:

"(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1861(n) that are furnished—

"(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and

"(ii) in 2005 and subsequent years, the amount provided under section 1847A for the drug or biological.".

(b) 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 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 paragraph (1).

SEC. 306. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.

(a) IN GENERAL.—The Secretary 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 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) such percentage as the Secretary may specify of the amount recovered shall 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 shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge of and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health plans, or under the medicaid program under title XIX of the Social Security Act.

(e) CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.—A recovery of an overpayment to a provider by a recovery audit contractor shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) REPORT.—The Secretary 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.information' means information about a conviction for a relevant crime or a finding of patient or resident abuse.

SEC. 307. PILOT PROGRAM FOR NATIONAL AND STATE BACKGROUND CHECKS ON DIRECT PATIENT ACCESS EMPLOYEES OF LONG-TERM CARE FACILITIES OR PROVIDERS.

(a) AUTHORITY TO CONDUCT PROGRAM.—The Secretary, in consultation with the Attorney General, shall establish a pilot program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees.

(b) REQUIREMENTS.—

(1) IN GENERAL.—Under the pilot program, a long-term care facility or provider in a participating State, prior to employing a direct patient access employee that is first hired on or after the commencement date of the pilot program in the State, shall conduct a background check on the employee in accordance with such procedures as the participating State shall establish.

(2) PROCEDURES.—

(A) IN GENERAL.—The procedures established by a participating State under paragraph (1) should be designed to—

(i) give a prospective direct access patient employee notice that the long-term care facility or provider is required to perform background checks with respect to new employees;

(ii) require, as a condition of employment, that the employee—

(I) provide a written statement disclosing any disqualifying information;

(II) provide a statement signed by the employee authorizing the facility to request national and State criminal history background checks;

(III) provide the facility with a rolled set of the employee's fingerprints; and

(IV) provide any other identification information the participating State may require;

(iii) require the facility or provider to check any available registries that would be likely to contain disqualifying information about a prospective employee of a long-term care facility or provider; and

(iv) permit the facility or provider to obtain State and national criminal history background checks on the prospective employee through a 10-fingerprint

check that utilizes State criminal records and the Integrated Automated Fingerprint Identification System of the Federal Bureau of Investigation.

(B) ELIMINATION OF UNNECESSARY CHECKS.—The procedures established by a participating State under paragraph (1) shall permit a long-term care facility or provider to terminate the background check at any stage at which the facility or provider obtains disqualifying information regarding a prospective direct patient access employee.

(3) PROHIBITION ON HIRING OF ABUSIVE WORKERS.—

(A) IN GENERAL.—A long-term care facility or provider may not knowingly employ any direct patient access employee who has any disqualifying information.

(B) PROVISIONAL EMPLOYMENT.—

(i) IN GENERAL.—Under the pilot program, a participating State may permit a long-term care facility or provider to provide for a provisional period of employment for a direct patient access employee pending completion of a background check, subject to such supervision during the employee's provisional period of employment as the participating State determines appropriate.

(ii) SPECIAL CONSIDERATION FOR CERTAIN FACILITIES AND PROVIDERS.—In determining what constitutes appropriate supervision of a provisional employee, a participating State shall take into account cost or other burdens that would be imposed on small rural long-term care facilities or providers, as well as the nature of care delivered by such facilities or providers that are home health agencies or providers of hospice care.

(4) USE OF INFORMATION; IMMUNITY FROM LIABILITY.—

(A) USE OF INFORMATION.—A participating State shall ensure that a long-term care facility or provider that obtains information about a direct patient access employee pursuant to a background check uses such information only for the purpose of determining the suitability of the employee for employment.

(B) IMMUNITY FROM LIABILITY.—A participating State shall ensure that a long-term care facility or provider that, in denying employment for an individual selected for hire as a direct patient access employee (including during any period of provisional employment), reasonably relies upon information obtained through a background check of the individual, shall not be liable in any action brought by the individual based on the employment determination resulting from the information.

(5) AGREEMENTS WITH EMPLOYMENT AGENCIES.—A participating State may establish procedures for facilitating the conduct of background checks on prospective direct patient access employees that are hired by a long-term care facility or provider through an employment agency (including a temporary employment agency).

(6) PENALTIES.—A participating State may impose such penalties as the State determines appropriate to enforce the requirements of the pilot program conducted in that State.

(c) PARTICIPATING STATES.—

(1) IN GENERAL.—The Secretary shall enter into agreements with not more than 10 States to conduct the pilot program under this section in such States.

(2) REQUIREMENTS FOR STATES.—An agreement entered into under paragraph (1) shall require that a participating State—

(A) be responsible for monitoring compliance with the requirements of the pilot program;

(B) have procedures by which a provisional employee or an employee may appeal or dispute the accuracy of the information obtained in a background check performed under the pilot program; and

(C) agree to—

(i) review the results of any State or national criminal history background checks conducted regarding a prospective direct patient access employee to determine whether the employee has any conviction for a relevant crime;

(ii) immediately report to the entity that requested the criminal history background checks the results of such review; and

(iii) in the case of an employee with a conviction for a relevant crime that is subject to reporting under section 1128E of the Social Security Act (42 U.S.C. 1320a–7e), report the existence of such conviction to the database established under that section.

(3) APPLICATION AND SELECTION CRITERIA.—

(A) APPLICATION.—A State seeking to participate in the pilot program established under this section, shall submit an application to the Secretary containing such information and at such time as the Secretary may specify.

(B) SELECTION CRITERIA.—

(i) IN GENERAL.—In selecting States to participate in the pilot program, the Secretary shall establish criteria to ensure—

(I) geographic diversity;

(II) the inclusion of a variety of long-term care facilities or providers;

(III) the evaluation of a variety of payment mechanisms for covering the costs of conducting the background checks required under the pilot program; and

(IV) the evaluation of a variety of penalties (monetary and otherwise) used by participating States to enforce the requirements of the pilot program in such States.

(ii) ADDITIONAL CRITERIA.—The Secretary shall, to the greatest extent practicable, select States to participate in the pilot program in accordance with the following:

(I) At least one participating State should permit long-term care facilities or providers to provide for a provisional period of employment pending completion of a background check and at least one such State should not permit such a period of employment.

(II) At least one participating State should establish procedures under which employment

agencies (including temporary employment agencies) may contact the State directly to conduct background checks on prospective direct patient access employees.

(III) At least one participating State should include patient abuse prevention training (including behavior training and interventions) for managers and employees of long-term care facilities and providers as part of the pilot program conducted in that State.

(iii) INCLUSION OF STATES WITH EXISTING PROGRAMS.—Nothing in this section shall be construed as prohibiting any State which, as of the date of the enactment of this Act, has procedures for conducting background checks on behalf of any entity described in subsection (g)(5) from being selected to participate in the pilot program conducted under this section.

(d) PAYMENTS.—Of the amounts made available under subsection (f) to conduct the pilot program under this section, the Secretary shall—

(1) make payments to participating States for the costs of conducting the pilot program in such States; and

(2) reserve up to 4 percent of such amounts to conduct the evaluation required under subsection (e).

(e) EVALUATION.—The Secretary, in consultation with the Attorney General, shall conduct by grant, contract, or interagency agreement an evaluation of the pilot program conducted under this section. Such evaluation shall—

(1) review the various procedures implemented by participating States for long-term care facilities or providers to conduct background checks of direct patient access employees and identify the most efficient, effective, and economical procedures for conducting such background checks;

(2) assess the costs of conducting such background checks (including start-up and administrative costs);

(3) consider the benefits and problems associated with requiring employees or facilities or providers to pay the costs of conducting such background checks;

(4) consider whether the costs of conducting such background checks should be allocated between the medicare and medicaid programs and if so, identify an equitable methodology for doing so;

(5) determine the extent to which conducting such background checks leads to any unintended consequences, including a reduction in the available workforce for such facilities or providers;

(6) review forms used by participating States in order to develop, in consultation with the Attorney General, a model form for such background checks;

(7) determine the effectiveness of background checks conducted by employment agencies; and

(8) recommend appropriate procedures and payment mechanisms for implementing a national criminal background check program for such facilities and providers.

(f) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary to carry out

the pilot program under this section for the period of fiscal years 2004 through 2007, $25,000,000.

(g) DEFINITIONS.—In this section:

(1) CONVICTION FOR A RELEVANT CRIME.—The term "conviction for a relevant crime" means any Federal or State criminal conviction for—

(A) any offense described in section 1128(a) of the Social Security Act (42 U.S.C. 1320a–7); and

(B) such other types of offenses as a participating State may specify for purposes of conducting the pilot program in such State.

(2) DISQUALIFYING INFORMATION.—The term "disqualifying information" means a conviction for a relevant crime or a finding of patient or resident abuse.

(3) FINDING OF PATIENT OR RESIDENT ABUSE.—The term "finding of patient or resident abuse" means any substantiated finding by a State agency under section 1819(g)(1)(C) or 1919(g)(1)(C) of the Social Security Act (42 U.S.C. 1395i–3(g)(1)(C), 1396r(g)(1)(C)) or a Federal agency that a direct patient access employee has committed—

(A) an act of patient or resident abuse or neglect or a misappropriation of patient or resident property; or

(B) such other types of acts as a participating State may specify for purposes of conducting the pilot program in such State.

(4) DIRECT PATIENT ACCESS EMPLOYEE.—The term "direct patient access employee" means any individual (other than a volunteer) that has access to a patient or resident of a long-term care facility or provider through employment or through a contract with such facility or provider, as determined by a participating State for purposes of conducting the pilot program in such State.

(5) LONG-TERM CARE FACILITY OR PROVIDER.—

(A) IN GENERAL.—The term "long-term care facility or provider" means the following facilities or providers which receive payment for services under title XVIII or XIX of the Social Security Act:

(i) A skilled nursing facility (as defined in section 1819(a) of the Social Security Act) (42 U.S.C. 1395i–3(a)).

(ii) A nursing facility (as defined in section 1919(a) in such Act) (42 U.S.C. 1396r(a)).

(iii) A home health agency.

(iv) A provider of hospice care (as defined in section 1861(dd)(1) of such Act) (42 U.S.C. 1395x(dd)(1)).

(v) A long-term care hospital (as described in section 1886(d)(1)(B)(iv) of such Act) (42 U.S.C. 1395ww(d)(1)(B)(iv)).

(vi) A provider of personal care services.

(vii) A residential care provider that arranges for, or directly provides, long-term care services.

(viii) An intermediate care facility for the mentally retarded (as defined in section 1905(d) of such Act) 42 U.S.C. 1396d(d)).

(B) ADDITIONAL FACILITIES OR PROVIDERS.—During the first year in which a pilot program under this section is conducted in a participating State, the State may expand

the list of facilities or providers under subparagraph (A) (on a phased-in basis or otherwise) to include such other facilities or providers of long-term care services under such titles as the participating State determines appropriate.

(C) EXCEPTIONS.—Such term does not include—

(i) any facility or entity that provides, or is a provider of, services described in subparagraph (A) that are exclusively provided to an individual pursuant to a self-directed arrangement that meets such requirements as the participating State may establish in accordance with guidance from the Secretary; or

(ii) any such arrangement that is obtained by a patient or resident functioning as an employer.

(6) PARTICIPATING STATE.—The term "participating State" means a State with an agreement under subsection (c)(1).

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

SEC. 401. EQUALIZING URBAN AND RURAL STANDARDIZED PAYMENT AMOUNTS UNDER THE MEDICARE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM.

(a) IN GENERAL.—Section 1886(d)(3)(A)(iv) (42 U.S.C. 1395ww(d)(3)(A)(iv)) is amended—

(1) by striking "(iv) For discharges" and inserting "(iv)(I) Subject to subclause (II), for discharges"; and

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

"(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B)(i) for the fiscal year involved.".

(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,".

(3) ADDITIONAL TECHNICAL AMENDMENT.—Section 1886(d)(3)(A)(iii) (42 U.S.C. 1395ww(d)(3)(A)(iii)) is amended by striking "in an other urban area" and inserting "in an urban area".

(c) EQUALIZING URBAN AND RURAL STANDARDIZED PAYMENT AMOUNTS UNDER THE MEDICARE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM FOR HOSPITALS IN PUERTO RICO.—

(1) IN GENERAL.—Section 1886(d)(9)(A) (42 U.S.C. 1395ww(d)(9)(A)), as amended by section 504, is amended—

(A) in clause (i), by striking "and" after the comma at the end; and

(B) by striking clause (ii) and inserting the following new clause:

"(ii) the applicable Federal percentage (specified in subparagraph (E)) of—

"(I) for discharges beginning in a fiscal year beginning on or after October 1, 1997, and before October 1, 2003, the discharge-weighted average of—

"(aa) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area,

"(bb) such rate for hospitals located in other urban areas, and

"(cc) such rate for hospitals located in a rural area,

for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels; and

"(II) for discharges in a fiscal year beginning on or after October 1, 2003, the national DRG prospective payment rate determined under paragraph (3)(D)(iii) for hospitals located in any area for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels.

As used in this section, the term 'subsection (d) Puerto Rico hospital' means a hospital that is located in Puerto Rico and that would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the 50 States.".

(2) APPLICATION OF PUERTO RICO STANDARDIZED AMOUNT BASED ON LARGE URBAN AREAS.—Section 1886(d)(9)(C) (42 U.S.C. 1395ww(d)(9)(C)) is amended—

(A) in clause (i)—

(i) by striking "(i) The Secretary" and inserting "(i)(I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary"; and

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

"(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved.";

(B) in clause (ii), by inserting "(or for fiscal year 2004 and thereafter, the average standardized amount)" after "each of the average standardized amounts"; and

(C) in clause (iii)(I), by striking "for hospitals located in an urban or rural area, respectively".

(d) IMPLEMENTATION.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c)(1) of this section shall have no effect on the authority of the Secretary, under subsection (b)(2) of section 402 of Public Law 108–89, to delay implementation of the extension of provisions equalizing urban and rural standardized inpatient hospital payments under subsection (a) of such section 402.

(2) APPLICATION OF PUERTO RICO STANDARDIZED AMOUNT BASED ON LARGE URBAN AREAS.—The authority of the Secretary referred to in paragraph (1) shall apply with respect to the amendments made by subsection (c)(2) of this section in the same manner as that authority applies with respect to the extension of provisions equalizing urban and rural standardized inpatient hospital payments under subsection (a) of such section 402, except that any reference in subsection (b)(2)(A) of such section 402 is deemed to be a reference to April 1, 2004.

SEC. 402. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) DOUBLING THE CAP.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the following new clause:

"(xiv)(I) In the case of discharges occurring on or after April 1, 2004, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

"(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C).".

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

(1) in paragraph (5)(F)—

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting "subject to clause (xiv) and" before "for discharges occurring";

(B) in clause (viii), by striking "The formula" and inserting "Subject to clause (xiv), the formula"; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking "For purposes" and inserting "Subject to clause (xiv), for purposes"; and

(2) in paragraph (2)(C)(iv)—

(A) by striking "or" before "the enactment of section 303"; and

(B) by inserting before the period at the end the following: ", or the enactment of section 402(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003".

SEC. 403. ADJUSTMENT TO THE MEDICARE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM WAGE INDEX TO REVISE THE LABOR-RELATED SHARE OF SUCH INDEX.

(a) ADJUSTMENT.—

(1) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(A) by striking "WAGE LEVELS.—The Secretary" and inserting "WAGE LEVELS.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary"; and

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

"(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2005.—For discharges occurring on or after October 1, 2004, the Secretary shall substitute '62 percent' for the proportion described in the first sentence of clause (i), unless the application of this clause would result in lower payments to a hospital than would otherwise be made.".

(2) 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 403(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.".

(b) APPLICATION TO PUERTO RICO HOSPITALS.—Section 1886(d)(9)(C)(iv) (42 U.S.C. 1395ww(d)(9)(C)(iv)) is amended—

(1) by inserting "(I)" after "(iv)";

(2) by striking "paragraph (3)(E)" and inserting "paragraph (3)(E)(i)"; and

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

"(II) For discharges occurring on or after October 1, 2004, the Secretary shall substitute '62 percent' for the proportion described in the first sentence of clause (i), unless the application of this subclause would result in lower payments to a hospital than would otherwise be made.".

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) INCORPORATION OF EXPLANATION IN RULEMAKING.—The Secretary shall include in the publication of the final rule for payment for inpatient hospital services under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) for fiscal year 2006, an explanation of the reasons for, and options considered, in determining frequency established under subsection (a).

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), and 1395tt(a)(3)) are each amended by inserting "equal to 101 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 January 1, 2004.

(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 amendments made by paragraph (1) shall apply with respect to costs incurred for services furnished on or after January 1, 2005.

(c) AUTHORIZATION 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";

(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 TIMING 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 the timing of such payments.

(3) AUTHORIZATION OF PIP.—The amendments made by paragraph (1) shall apply to payments made on or after July 1, 2004.

(d) CONDITION FOR APPLICATION OF SPECIAL PROFESSIONAL SERVICE 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 or other practitioner 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 and practitioners who have not assigned such billing rights.".

(2) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the amendment made by paragraph (1) shall apply to cost reporting periods beginning on or after July 1, 2004.

(B) RULE OF APPLICATION.—In the case of a critical access hospital that made an election under section 1834(g)(2) of the Social Security Act (42 U.S.C. 1395m(g)(2)) before November 1, 2003, the amendment made by paragraph (1) shall apply to cost reporting periods beginning on or after July 1, 2001.

(e) REVISION OF BED LIMITATION FOR HOSPITALS.—

(1) IN GENERAL.—Section 1820(c)(2)(B)(iii) (42 U.S.C. 1395i–4(c)(2)(B)(iii)) is amended by striking "15 (or, in the case of a facility under an agreement described in subsection (f), 25)" and inserting "25".

(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 apply to designations made before, on, or after January 1, 2004, but any election made pursuant to regulations promulgated to carry out such amendments shall only apply prospectively.

(f) PROVISIONS RELATING TO FLEX GRANTS.—

(1) ADDITIONAL 4-YEAR PERIOD OF FUNDING.—Section 1820(j) (42 U.S.C. 1395i–4(j)) is amended by inserting before the period at the end the following: ", and for making grants to all States under paragraphs (1) and (2) of subsection (g), $35,000,000 in each of fiscal years 2005 through 2008".

(2) ADDITIONAL REQUIREMENTS AND ADMINISTRATION.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by adding at the end the following new paragraphs:

"(4) ADDITIONAL REQUIREMENTS WITH RESPECT TO FLEX GRANTS.—With respect to grants awarded under paragraph (1)

or (2) from funds appropriated for fiscal year 2005 and subsequent fiscal years—

"(A) CONSULTATION WITH THE STATE HOSPITAL ASSOCIATION AND RURAL HOSPITALS ON THE MOST APPROPRIATE WAYS TO USE GRANTS.—A State shall consult with the hospital association of such State and rural hospitals located in such State on the most appropriate ways to use the funds under such grant.

"(B) LIMITATION ON USE OF GRANT FUNDS FOR ADMINISTRATIVE EXPENSES.—A State may not expend more than the lesser of—

"(i) 15 percent of the amount of the grant for administrative expenses; or

"(ii) the State's federally negotiated indirect rate for administering the grant.

"(5) USE OF FUNDS FOR FEDERAL ADMINISTRATIVE EXPENSES.—Of the total amount appropriated for grants under paragraphs (1) and (2) for a fiscal year (beginning with fiscal year 2005), up to 5 percent of such amount shall be available to the Health Resources and Services Administration for purposes of administering such grants.".

(g) AUTHORITY TO ESTABLISH PSYCHIATRIC AND REHABILITATION DISTINCT PART UNITS.—

(1) IN GENERAL.—Section 1820(c)(2) (42 U.S.C. 1395i–4(c)(2)) is amended by adding at the end the following:

"(E) AUTHORITY TO ESTABLISH PSYCHIATRIC AND REHABILITATION DISTINCT PART UNITS.—

"(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, a critical access hospital may establish—

"(I) a psychiatric unit of the hospital that is a distinct part of the hospital; and

"(II) a rehabilitation unit of the hospital that is a distinct part of the hospital,

if the distinct part meets the requirements (including conditions of participation) that would otherwise apply to the distinct part if the distinct part were established by a subsection (d) hospital in accordance with the matter following clause (v) of section 1886(d)(1)(B), including any regulations adopted by the Secretary under such section.

"(ii) LIMITATION ON NUMBER OF BEDS.—The total number of beds that may be established under clause (i) for a distinct part unit may not exceed 10.

"(iii) EXCLUSION OF BEDS FROM BED COUNT.—In determining the number of beds of a critical access hospital for purposes of applying the bed limitations referred to in subparagraph (B)(iii) and subsection (f), the Secretary shall not take into account any bed established under clause (i).

"(iv) EFFECT OF FAILURE TO MEET REQUIREMENTS.—If a psychiatric or rehabilitation unit established under clause (i) does not meet the requirements described in such clause with respect to a cost reporting period, no payment may be made under this title to the hospital for services furnished in such unit during such period. Payment to the hospital for services furnished

in the unit may resume only after the hospital has demonstrated to the Secretary that the unit meets such requirements.".

(2) PAYMENT ON A PROSPECTIVE PAYMENT BASIS.—Section 1814(l) (42 U.S.C. 1395f(l)) is amended—

(A) by striking "(l) The amount" and inserting "(l)(1) Except as provided in paragraph (2), the amount"; and

(B) by adding at the end the following new paragraph:

"(2) In the case of a distinct part psychiatric or rehabilitation unit of a critical access hospital described in section 1820(c)(2)(E), the amount of payment for inpatient critical access hospital services of such unit shall be equal to the amount of the payment that would otherwise be made if such services were inpatient hospital services of a distinct part psychiatric or rehabilitation unit, respectively, described in the matter following clause (v) of section 1886(d)(1)(B).".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to cost reporting periods beginning on or after October 1, 2004.

(h) WAIVER AUTHORITY.—

(1) IN GENERAL.—Section 1820(c)(2)(B)(i)(II) (42 U.S.C. 1395i–4(c)(2)(B)(i)(II)) is amended by inserting "before January 1, 2006," after "is certified".

(2) GRANDFATHERING WAIVER AUTHORITY FOR CERTAIN FACILITIES.—Section 1820(h) (42 U.S.C. 1395i–4(h)) is amended—

(A) in the heading preceding paragraph (1), by striking "OF CERTAIN FACILITIES" and inserting "PROVISIONS"; and

(B) by adding at the end the following new paragraph:

"(3) STATE AUTHORITY TO WAIVE 35-MILE RULE.—In the case of a facility that was designated as a critical access hospital before January 1, 2006, and was certified by the State as being a necessary provider of health care services to residents in the area under subsection (c)(2)(B)(i)(II), as in effect before such date, the authority under such subsection with respect to any redesignation of such facility shall continue to apply notwithstanding the amendment made by section 405(h)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.".

SEC. 406. MEDICARE INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.

(a) IN GENERAL.—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) IN GENERAL.—In addition to any payments calculated under this section for a subsection (d) hospital, for discharges occurring during a fiscal year (beginning with fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in subparagraph (C)(i)) for discharges occurring during that fiscal year that is equal to the applicable percentage increase (determined under subparagraph (B) for the hospital involved) in the amount paid to such hospital under this section for such discharges (determined without regard to this paragraph).

"(B) APPLICABLE PERCENTAGE INCREASE.—The Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) as follows:

"(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

"(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

"(iii) In no case shall the applicable percentage increase exceed 25 percent.

"(C) DEFINITIONS.—

"(i) LOW-VOLUME HOSPITAL.—For purposes of this paragraph, the term 'low-volume hospital' means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and has less than 800 discharges during the fiscal year.

"(ii) DISCHARGE.—For purposes of subparagraph (B) and clause (i), the term 'discharge' means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A.".

(b) JUDICIAL REVIEW.—Section 1886(d)(7)(A) (42 U.S.C. 1395ww(d)(7)(A)) is amended by inserting after "to subsection (e)(1)" the following: "or the determination of the applicable percentage increase under paragraph (12)(A)(ii)".

SEC. 407. 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. 408. RECOGNITION OF ATTENDING NURSE PRACTITIONERS AS ATTENDING PHYSICIANS TO SERVE HOSPICE PATIENTS.

(a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C. 1395x(dd)(3)(B)) is amended by inserting "or nurse practitioner (as defined in subsection (aa)(5))" after "the physician (as defined in subsection (r)(1))".

(b) CLARIFICATION OF HOSPICE ROLE OF NURSE PRACTITIONERS.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C. 1395f(a)(7)(A)(i)(I))

is amended by inserting "(which for purposes of this subparagraph does not include a nurse practitioner)" after "attending physician (as defined in section 1861(dd)(3)(B))".

SEC. 409. RURAL HOSPICE DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project for the delivery of hospice care to medicare beneficiaries in rural areas. Under the project medicare beneficiaries who are unable to receive hospice care in the facility for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

(b) SCOPE OF PROJECT.—The Secretary shall conduct the project under this section with respect to no more than 3 hospice programs over a period of not longer than 5 years each.

(c) COMPLIANCE WITH CONDITIONS.—Under the demonstration project—

(1) the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the home or to meet the requirements of section 1861(dd)(2)(A)(iii) of the Social Security Act; and

(2) payments for hospice care shall be made at the rates otherwise applicable to such care under title XVIII of such Act.

The Secretary may require the program to comply with such additional quality assurance standards for its provision of services in its facility as the Secretary deems appropriate.

(d) REPORT.—Upon completion of the project, the Secretary shall submit a report to Congress on the project and shall include in the report recommendations regarding extension of such project to hospice programs serving rural areas.

SEC. 410. 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 furnished by an individual not 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, 2005.

SEC. 410A. RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT OF RURAL COMMUNITY HOSPITAL (RCH) DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals (as defined in subsection (f)(1)) to furnish covered inpatient hospital services (as defined in subsection (f)(2)) to medicare beneficiaries.

(2) DEMONSTRATION AREAS.—The program shall be conducted in rural areas selected by the Secretary in States with low population densities, as determined by the Secretary.

(3) APPLICATION.—Each rural community hospital that is located in a demonstration area selected under paragraph (2) that desires to participate in the demonstration program under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(4) SELECTION OF HOSPITALS.—The Secretary shall select from among rural community hospitals submitting applications under paragraph (3) not more than 15 of such hospitals to participate in the demonstration program under this section.

(5) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period.

(6) IMPLEMENTATION.—The Secretary shall implement the demonstration program not later than January 1, 2005, but may not implement the program before October 1, 2004.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment under the demonstration program for covered inpatient hospital services furnished in a rural community hospital, other than such services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part, is—

(A) for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration program, the reasonable costs of providing such services; and

(B) for discharges occurring in a subsequent cost reporting period under the demonstration program, the lesser of—

(i) the reasonable costs of providing such services in the cost reporting period involved; or

(ii) the target amount (as defined in paragraph (2), applicable to the cost reporting period involved.

(2) TARGET AMOUNT.—For purposes of paragraph (1)(B)(ii), the term "target amount" means, with respect to a rural community hospital for a particular 12-month cost reporting period—

(A) in the case of the second such reporting period for which this subsection is in effect, the reasonable costs of providing such covered inpatient hospital services as determined under paragraph (1)(A), and

(B) in the case of a later reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B))) in the market basket percentage increase

(as defined in clause (iii) of such section) for that particular cost reporting period.

(c) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) of such funds as are necessary for the costs of carrying out the demonstration program under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

(d) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(e) REPORT.—Not later than 6 months after the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(f) DEFINITIONS.—In this section:

(1) RURAL COMMUNITY HOSPITAL DEFINED.—

(A) IN GENERAL.—The term "rural community hospital" means a hospital (as defined in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e))) that—

(i) is located in a rural area (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))) or treated as being so located pursuant to section 1886(d)(8)(E) of such Act (42 U.S.C. 1395ww(d)(8)(E));

(ii) subject to paragraph (2), has fewer than 51 acute care inpatient beds, as reported in its most recent cost report;

(iii) makes available 24-hour emergency care services; and

(iv) is not eligible for designation, or has not been designated, as a critical access hospital under section 1820.

(B) TREATMENT OF PSYCHIATRIC AND REHABILITATION UNITS.—For purposes of paragraph (1)(B), beds in a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital shall not be counted.

(2) COVERED INPATIENT HOSPITAL SERVICES.—The term "covered inpatient hospital services" means inpatient hospital services, and includes extended care services furnished under an agreement under section 1883 of the Social Security Act (42 U.S.C. 1395tt).

Subtitle B—Provisions Relating to Part B Only

SEC. 411. TWO-YEAR EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND SOLE COMMUNITY HOSPITALS UNDER THE 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 paragraph (1)(B) shall apply with respect to cost reporting periods beginning on and after January 1, 2004.

(b) STUDY; AUTHORIZATION OF ADJUSTMENT.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(1) by redesignating paragraph (13) as paragraph (16); and

(2) by inserting after paragraph (12) the following new paragraph:

"(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

"(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

"(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.".

SEC. 412. ESTABLISHMENT OF FLOOR ON WORK GEOGRAPHIC ADJUSTMENT.

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), and (E)"; and

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

"(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDEX.—After calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2007, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.".

SEC. 413. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS FOR PHYSICIAN SCARCITY.

(a) ADDITIONAL INCENTIVE PAYMENT FOR CERTAIN PHYSICIAN SCARCITY AREAS.—Section 1833 (42 U.S.C. 1395l) 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 on or after January 1, 2005, and before January 1, 2008—

"(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 establish 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 (in this subsection referred to as 'individuals').

"(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 the number of individuals 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 the number of individuals 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.—

"(A) IN GENERAL.—The Secretary shall identify—

"(i) 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 individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

"(ii) 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 individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

"(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

"(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

"(D) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

"(i) the identification of a county or area;

"(ii) the assignment of a specialty of any physician under this paragraph;

"(iii) the assignment of a physician to a county under paragraph (2); or

"(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

"(5) RURAL CENSUS TRACTS.—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; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on

the Internet website of the Centers for Medicare & Medicaid Services.".

(b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT PROGRAM.—

(1) IN GENERAL.—Section 1833(m) (42 U.S.C. 1395l(m)) is amended—

(A) by inserting "(1)" after "(m)";

(B) in paragraph (1), as designated by subparagraph (A)—

(i) by inserting "in a year" after "In the case of physicians' services furnished"; and

(ii) by inserting "as identified by the Secretary prior to the beginning of such year" after "as a health professional shortage area"; and

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

"(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

"(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

"(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

"(A) the identification of a county or area;

"(B) the assignment of a specialty of any physician under this paragraph;

"(C) the assignment of a physician to a county under this subsection; or

"(D) the assignment of a postal ZIP Code to a county or other area under this subsection.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to physicians' services furnished on or after January 1, 2005.

(c) GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.—

(1) 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—

(A) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(B) an evaluation of the measures used for such adjustment, including the frequency of revisions;

(C) 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; and

(D) an evaluation of the effect of the adjustment to the physician work geographic index under section 1848(e)(1)(E) of the Social Security Act, as added by section 412, on physician location and retention in areas affected by such adjustment, taking into account—

(i) differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas; and

(ii) the mobility of physicians, including specialists, over the last decade.

(2) 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 paragraph (1). 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. PAYMENT FOR RURAL AND URBAN 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)) is amended—

(1) in paragraph (2)(E), by inserting "consistent with paragraph (11)" after "in an efficient and fair manner"; and

(2) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–486), as paragraph (9); and

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

"(10) 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 ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

"(A) For 2004 (for services furnished on or after July 1, 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 nine census divisions (referred to in section 1886(d)(2)) 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 amended by adding at the end the following new paragraph:

"(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after July 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 miles in excess of 50 miles in such trip.".

(c) IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.—

(1) IN GENERAL.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by subsections (a) and (b), is amended by adding at the end the following new paragraph:

"(12) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

"(A) IN GENERAL.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

"(B) IDENTIFICATION OF QUALIFIED RURAL AREAS.—

"(i) DETERMINATION OF POPULATION DENSITY IN AREA.—Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

"(ii) RANKING OF AREAS.—The Secretary shall rank each such area based on such population density.

"(iii) IDENTIFICATION OF QUALIFIED RURAL AREAS.—The Secretary shall identify those areas (in subparagraph (A) referred to as 'qualified rural areas') with the lowest population densities that represent, if each such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

"(iv) RURAL AREA.—For purposes of this paragraph, the term 'rural area' has the meaning given such term in section 1886(d)(2)(D). If 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 a rural area for purposes of this paragraph.

"(v) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of an area under this subparagraph.".

(2) USE OF DATA.—In order to promptly implement section 1834(l)(12) of the Social Security Act, as added by paragraph (1), the Secretary may use data furnished by the Comptroller General of the United States.

(d) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by subsections (a), (b), and (c), is amended by adding at the end the following new paragraph:

"(13) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

"(A) IN GENERAL.—After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, for which the transportation originates in—

"(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent; and

"(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent.

"(B) APPLICATION OF INCREASED PAYMENTS AFTER 2006.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the period specified in such subparagraph.".

(e) IMPLEMENTATION.—The Secretary may implement the amendments made by this section, and revise the conversion factor applicable under section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)) for purposes of implementing such amendments, on an interim final basis, or by program instruction.

(f) 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 Act). Not later than December 31, 2007, the Comptroller General shall submit to Congress a final report on such access and supply.

(g) TECHNICAL AMENDMENTS.—(1) Section 221(c) of BIPA (114 Stat. 2763A–487) is amended by striking "subsection (b)(2)" and inserting "subsection (b)(3)".

(2) Section 1861(v)(1) (42 U.S.C. 1395x(v)(1)) is amended by moving subparagraph (U) 4 ems to the left.

SEC. 415. PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.

(a) COVERAGE.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by subsections (a), (b), (c), and (d) of section 414, is amended by adding at the end the following new paragraph:

"(14) PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.—

"(A) IN GENERAL.—The regulations described in section 1861(s)(7) shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

"(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

"(ii) complies with equipment and crew requirements established by the Secretary.

"(B) SATISFACTION OF REQUIREMENT OF MEDICALLY NECESSARY.—The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

"(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who reasonably determines or certifies that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

"(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

"(C) RURAL AIR AMBULANCE SERVICE DEFINED.—For purposes of this paragraph, the term 'rural air ambulance service' means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1886(d)(2)(D)) or in 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)).

"(D) LIMITATION.—

"(i) IN GENERAL.—Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance

service, or an entity under common ownership with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

"(ii) EXCEPTION.—Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1887) which are reimbursed under part A and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.".

(b) CONFORMING AMENDMENT.—Section 1861(s)(7) (42 U.S.C. 1395x(s)(7)) is amended by inserting ", subject to section 1834(l)(14)," after "but".

(c) EFFECTIVE DATE.—The amendments made by this subsection shall apply to services furnished on or after January 1, 2005.

SEC. 416. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED TO HOSPITAL OUTPATIENTS IN CERTAIN RURAL AREAS.

(a) IN GENERAL.—Notwithstanding subsections (a), (b), and (h) of section 1833 of the Social Security Act (42 U.S.C. 1395l) 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 during a cost reporting period described in subsection (b) by a hospital with fewer than 50 beds that is located in a qualified rural area (identified under paragraph (12)(B)(iii) of section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)), as added by section 414(c)) as part of outpatient services of the hospital, the amount of payment for such test shall be 100 percent of the reasonable costs of the hospital in furnishing such test.

(b) APPLICATION.—A cost reporting period described in this subsection is a cost reporting period beginning during the 2-year period beginning on July 1, 2004.

(c) PROVISION AS PART OF OUTPATIENT HOSPITAL SERVICES.—For purposes of subsection (a), in determining whether clinical diagnostic laboratory services are furnished as part of outpatient services of a hospital, the Secretary shall apply the same rules that are used to determine whether clinical diagnostic laboratory services are furnished as an outpatient critical access hospital service under section 1834(g)(4) of the Social Security Act (42 U.S.C. 1395m(g)(4)).

SEC. 417. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.

Section 4207 of the 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. 418. REPORT ON DEMONSTRATION PROJECT PERMITTING SKILLED NURSING FACILITIES TO BE ORIGINATING TELEHEALTH SITES; AUTHORITY TO IMPLEMENT.

(a) EVALUATION.—The Secretary, acting through the Administrator of the Health Resources and Services Administration in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a)) are treated as originating sites for telehealth services.

(b) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the evaluation conducted under subsection (a). Such report shall include recommendations on mechanisms to ensure that permitting a skilled nursing facility to serve as an originating site for the use of telehealth services or any other service delivered via a telecommunications system does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, as is otherwise required by the Secretary.

(c) AUTHORITY TO EXPAND ORIGINATING TELEHEALTH SITES TO INCLUDE SKILLED NURSING FACILITIES.—Insofar as the Secretary concludes in the report required under subsection (b) that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), and that the Secretary can establish the mechanisms to ensure such permission does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, the Secretary may deem a skilled nursing facility to be an originating site under paragraph (4)(C)(ii) of such section beginning on January 1, 2006.

Subtitle C—Provisions Relating to Parts A and B

SEC. 421. ONE-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—With respect to episodes and visits ending on or after April 1, 2004, and before April 1, 2005, 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))), the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

(c) NO EFFECT ON SUBSEQUENT PERIODS.—The payment increase provided under subsection (a) for a period under such subsection—

(1) shall not apply to episodes and visits ending after such period; and

(2) shall not be taken into account in calculating the payment amounts applicable for episodes and visits occurring after such period.

SEC. 422. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) IN GENERAL.—Section 1886(h) (42 U.S.C. 1395ww(h)(4)) is amended—

(1) in paragraph (4)(F)(i), by inserting "subject to paragraph (7)," after "October 1, 1997,";

(2) in paragraph (4)(H)(i), by inserting "and subject to paragraph (7)" after "subparagraphs (F) and (G)"; and

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

"(7) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

"(A) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

"(i) PROGRAMS SUBJECT TO REDUCTION.—

"(I) IN GENERAL.—Except as provided in subclause (II), if a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2005, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such otherwise applicable resident limit and such reference resident level.

"(II) EXCEPTION FOR SMALL RURAL HOSPITALS.—This subparagraph shall not apply to a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds.

"(ii) REFERENCE RESIDENT LEVEL.—

"(I) IN GENERAL.—Except as otherwise provided in subclauses (II) and (III), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

"(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAMS.—If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program that is not reflected on the most recent settled cost report, after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes July 1, 2003, as determined by the Secretary.

"(III) EXPANSIONS UNDER NEWLY APPROVED PROGRAMS.—Upon the timely request of a hospital, the Secretary shall adjust the reference resident level specified under subclause (I) or (II) to include

the number of medical residents that were approved in an application for a medical residency training program that was approved by an appropriate accrediting organization (as determined by the Secretary) before January 1, 2002, but which was not in operation during the cost reporting period used under subclause (I) or (II), as the case may be, as determined by the Secretary.

"(iii) AFFILIATION.—The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.

"(B) REDISTRIBUTION.—

"(i) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005. The aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

"(ii) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005, made available under this subparagraph, as determined by the Secretary.

"(iii) 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 clause (i), the Secretary shall distribute the increase to programs of hospitals located in the following priority order:

"(I) First, to hospitals located in rural areas (as defined in subsection (d)(2)(D)(ii)).

"(II) Second, to hospitals located in urban areas that are not large urban areas (as defined for purposes of subsection (d)).

"(III) Third, to other hospitals in a State if the residency training program involved is in a specialty for which there are not other residency training programs in the State.

Increases of residency limits within the same priority category under this clause shall be determined by the Secretary.

"(iv) LIMITATION.—In no case shall more than 25 full-time equivalent additional residency positions be made available under this subparagraph 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 subparagraph, 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 paragraph (4)(E) for that hospital.

"(vi) CONSTRUCTION.—Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90–248, or as affecting the ability of a hospital to establish new medical residency training programs under paragraph (4)(H).

"(C) RESIDENT LEVEL AND LIMIT DEFINED.—In this paragraph:

"(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 paragraph (4)), 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) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph.

"(D) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this paragraph.".

(b) CONFORMING PROVISIONS.—(1) Section 1886(d)(5)(B) (42 U.S.C. 1395ww(d)(5)(B)) is amended—

(A) in the second sentence of clause (ii), by striking "For discharges" and inserting "Subject to clause (ix), for discharges";

(B) in clause (v), by adding at the end the following: "The provisions of subsection (h)(7) shall apply with respect to the first sentence of this clause in the same manner as it applies with respect to subsection (h)(4)(F)(i)."; and

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

"(ix) For discharges occurring on or after July 1, 2005, insofar as an additional payment amount under this subparagraph is attributable to resident positions redistributed to a hospital under subsection (h)(7)(B), in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in a manner as if 'c' were equal to 0.66 with respect to such resident positions.".

(2) Chapter 35 of title 44, United States Code, shall not apply with respect to applications under section 1886(h)(7) of the Social Security Act, as added by subsection (a)(3).

(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)).

Subtitle D—Other Provisions

SEC. 431. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7(b)(3)), as amended by section 101(e)(2), is amended—

(1) in subparagraph (F), by striking "and" after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting "; and"; and

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

"(H) any remuneration between a 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, 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 shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits an individual'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) DEADLINE.—Not later than 1 year after the date of the enactment of this Act the Secretary shall publish final regulations establishing the standards described in paragraph (1).

SEC. 432. OFFICE OF RURAL HEALTH POLICY IMPROVEMENTS.

Section 711(b) (42 U.S.C. 912(b)) is amended—

(1) in paragraph (3), by striking "and" after the comma at the end;

(2) in paragraph (4), by striking the period at the end and inserting ", and"; and

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

"(5) administer grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.".

SEC. 433. MEDPAC STUDY ON RURAL HOSPITAL PAYMENT ADJUSTMENTS.

(a) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study of the impact of sections 401 through 406, 411, 416, and 505. The Commission shall analyze the effect on total payments, growth in costs, capital spending, and such other payment effects under those sections.

(b) REPORTS.—

(1) INTERIM REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress an interim report on the matters studied under subsection (a) with respect only to changes to the critical access hospital provisions under section 405.

(2) FINAL REPORT.—Not later than 3 years after the date of the enactment of this Act, the Commission shall submit to Congress a final report on all matters studied under subsection (a).

SEC. 434. FRONTIER EXTENDED STAY CLINIC DEMONSTRATION PROJECT.

(a) AUTHORITY TO CONDUCT DEMONSTRATION PROJECT.—The Secretary shall waive such provisions of the medicare program established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as are necessary to conduct a demonstration project under which frontier extended stay clinics described in subsection (b) in isolated rural areas are treated as providers of items and services under the medicare program.

(b) CLINICS DESCRIBED.—A frontier extended stay clinic is described in this subsection if the clinic—

(1) is located in a community where the closest short-term acute care hospital or critical access hospital is at least 75 miles away from the community or is inaccessible by public road; and

(2) is designed to address the needs of—

(A) seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers; or

(B) patients who need monitoring and observation for a limited period of time.

(c) SPECIFICATION OF CODES.—The Secretary shall determine the appropriate life-safety codes for such clinics that treat patients for needs referred to in subsection (b)(2).

(d) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), there are authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, such sums as are necessary to conduct the demonstration project under this section.

(2) BUDGET NEUTRAL IMPLEMENTATION.—In conducting the demonstration project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration project under this section was not implemented.

(e) THREE-YEAR PERIOD.—The Secretary shall conduct the demonstration under this section for a 3-year period.

(f) REPORT.—Not later than the date that is 1 year after the date on which the demonstration project concludes, the Secretary shall submit to Congress a report on the demonstration project, together with such recommendations for legislation or administrative action as the Secretary determines appropriate.

(g) DEFINITIONS.—In this section, the terms "hospital" and "critical access hospital" have the meanings given such terms in subsections (e) and (mm), respectively, of section 1861 of the Social Security Act (42 U.S.C. 1395x).

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

(a) IN GENERAL.—Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended—

(1) by striking "and" at the end of subclause (XVIII);

(2) by striking subclause (XIX); and

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

"(XIX) for each of fiscal years 2004 through 2007, subject to clause (vii), the market basket percentage increase for hospitals in all areas; and

"(XX) for fiscal year 2008 and each subsequent fiscal year, the market basket percentage increase for hospitals in all areas.".

(b) SUBMISSION OF HOSPITAL QUALITY DATA.—Section 1886(b)(3)(B) (42 U.S.C. 1395ww(b)(3)(B)) is amended by adding at the end the following new clause:

"(vii)(I) For purposes of clause (i)(XIX) for each of fiscal years 2005 through 2007, in a case of a subsection (d) hospital that does not submit data to the Secretary in accordance with subclause (II) with respect to such a fiscal year, the applicable percentage increase under such clause for such fiscal year shall be reduced by 0.4 percentage points. Such reduction shall apply only with respect to the fiscal year involved, and the Secretary shall not take into account such reduction in computing the applicable

percentage increase under clause (i)(XIX) for a subsequent fiscal year.

"(II) Each subsection (d) hospital shall submit to the Secretary quality data (for a set of 10 indicators established by the Secretary as of November 1, 2003) that relate to the quality of care furnished by the hospital in inpatient settings in a form and manner, and at a time, specified by the Secretary for purposes of this clause, but with respect to fiscal year 2005, the Secretary shall provide for a 30-day grace period for the submission of data by a hospital.".

(c) GAO STUDY AND REPORT ON APPROPRIATENESS OF PAYMENTS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES.—

(1) STUDY.—The Comptroller General of the United States, using the most current data available, shall conduct a study to determine—

(A) the appropriate level and distribution of payments in relation to costs under the prospective payment system under section 1886 of the Social Security Act (42 U.S.C. 1395ww) for inpatient hospital services furnished by subsection (d) hospitals (as defined in subsection (d)(1)(B) of such section); and

(B) whether there is a need to adjust such payments under such system to reflect legitimate differences in costs across different geographic areas, kinds of hospitals, and types of cases.

(2) REPORT.—Not later than 24 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 study conducted under paragraph (1) together with such recommendations for legislative and administrative action as the Comptroller General determines appropriate.

SEC. 502. REVISION OF THE INDIRECT MEDICAL EDUCATION (IME) ADJUSTMENT PERCENTAGE.

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

(1) in subclause (VI), by striking "and" after the semicolon at the end;

(2) in subclause (VII)—

(A) by inserting "and before April 1, 2004," after "on or after October 1, 2002,"; and

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

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

"(VIII) on or after April 1, 2004, and before October 1, 2004, 'c' is equal to 1.47;

"(IX) during fiscal year 2005, 'c' is equal to 1.42;

"(X) during fiscal year 2006, 'c' is equal to 1.37;

"(XI) during fiscal year 2007, 'c' is equal to 1.32; and

"(XII) on or after October 1, 2007, 'c' is equal to 1.35.".

(b) CONFORMING AMENDMENT RELATING TO DETERMINATION OF STANDARDIZED AMOUNT.—Section 1886(d)(2)(C)(i) (42 U.S.C. 1395ww(d)(2)(C)(i)) is amended—

(1) by striking "1999 or" and inserting "1999,"; and

(2) by inserting ", or the Medicare Prescription Drug, Improvement, and Modernization Act of 2003" after "2000".

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

SEC. 503. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM.

(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) ADJUSTMENT OF THRESHOLD.—Section 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended by inserting "(applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved)" after "is inadequate".

(2) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by subsection (a), 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 represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under part A 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, such individuals, 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)), as amended by subsections (a) and (b), is amended by adding at the end the following new clause:

"(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated

with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).".

(d) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL INPATIENT TECHNOLOGY.—

(1) IN GENERAL.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking "subject to paragraph (4)(C)(iii),".

(2) NOT BUDGET NEUTRAL.—There shall be no reduction or other adjustment in payments under section 1886 of the Social Security Act because an additional payment is provided under subsection (d)(5)(K)(ii)(III) of such section.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2005.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2004 THAT ARE DENIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2005 under the amendments made by this section; and

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 504. 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 April 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

"(iii) on or after April 1, 2004, and before October 1, 2004, the applicable Puerto Rico percentage is 37.5 percent and the applicable Federal percentage is 62.5 percent; and

"(iv) on or after October 1, 2004, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.".

SEC. 505. WAGE INDEX ADJUSTMENT RECLASSIFICATION REFORM.

(a) IN GENERAL.—Section 1886(d) (42 U.S.C. 1395ww(d)), as amended by section 406, is amended by adding at the end the following new paragraph:

"(13)(A) In order to recognize commuting patterns among geographic areas, the Secretary shall establish a process through application or otherwise for an increase of the wage index applied under paragraph (3)(E) for subsection (d) hospitals located in a qualifying county described in subparagraph (B) in the amount computed under subparagraph (D) based on out-migration of hospital employees who reside in that county to any higher wage index area.

"(B) The Secretary shall establish criteria for a qualifying county under this subparagraph based on the out-migration referred to in subparagraph (A) and differences in the area wage indices. Under such criteria the Secretary shall, utilizing such data as the Secretary determines to be appropriate, establish—

"(i) a threshold percentage, established by the Secretary, of the weighted average of the area wage index or indices for the higher wage index areas involved;

"(ii) a threshold (of not less than 10 percent) for minimum out-migration to a higher wage index area or areas; and

"(iii) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area in which the qualifying county is located.

"(C) For purposes of this paragraph, the term 'higher wage index area' means, with respect to a county, an area with a wage index that exceeds that of the county.

"(D) The increase in the wage index under subparagraph (A) for a qualifying county shall be equal to the percentage of the hospital employees residing in the qualifying county who are employed 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 higher wage index area, and

"(II) the wage index of the qualifying county; and

"(ii) the number of hospital employees residing in the qualifying county who are employed in such higher wage index area divided by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area.

"(E) The process under this paragraph may be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10). As the Secretary determines to be appropriate to carry out such process, the Secretary may require

hospitals (including subsection (d) hospitals and other hospitals) and critical access hospitals, as required under section 1866(a)(1)(T), to submit data regarding the location of residence, or the Secretary may use data from other sources.

"(F) A wage index increase 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 waive the application of such wage index increase.

"(G) A hospital in a county that has a wage index increase under this paragraph for a period and that has not waived the application of such an increase under subparagraph (F) is not eligible for reclassification under paragraph (8) or (10) during that period.

"(H) Any increase in a wage index under this paragraph for a county shall not be taken into account for purposes of—

"(i) computing the wage index for portions of the wage index area (not including the county) in which the county is located; or

"(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).

"(I) The thresholds described in subparagraph (B), data on hospital employees used under this paragraph, and any determination of the Secretary under the process described in subparagraph (E) shall be final and shall not be subject to judicial review.".

(b) CONFORMING AMENDMENTS.—Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)) is amended—

(1) in subparagraph (R), by striking "and" at the end;

(2) in subparagraph (S), by striking the period at the end and inserting ", and"; and

(3) by inserting after subparagraph (S) the following new subparagraph:

"(T) in the case of hospitals and critical access hospitals, to furnish to the Secretary such data as the Secretary determines appropriate pursuant to subparagraph (E) of section 1886(d)(12) to carry out such section.".

(c) EFFECTIVE DATE.—The amendments made by this section shall first apply to the wage index for discharges occurring on or after October 1, 2004. In initially implementing such amendments, the Secretary may modify the deadlines otherwise applicable under clauses (ii) and (iii)(I) of section 1886(d)(10)(C) of the Social Security Act (42 U.S.C. 1395ww(d)(10)(C)), for submission of, and actions on, applications relating to changes in hospital geographic reclassification.

SEC. 506. LIMITATION ON CHARGES FOR INPATIENT HOSPITAL CONTRACT HEALTH SERVICES PROVIDED TO INDIANS BY MEDICARE PARTICIPATING HOSPITALS.

(a) IN GENERAL.—Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)), as amended by section 505(b), is amended—

(1) in subparagraph (S), by striking "and" at the end;

(2) in subparagraph (T), by striking the period and inserting ", and"; and

(3) by inserting after subparagraph (T) the following new subparagraph:

"(U) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care both—

"(i) under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act), with respect to items and services that are covered under such program and furnished to an individual eligible for such items and services under such program; and

"(ii) under any program funded by the Indian Health Service and operated by an urban Indian organization with respect to the purchase of items and services for an eligible urban Indian (as those terms are defined in such section 4),

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply as of a date specified by the Secretary of Health and Human Services (but in no case later than 1 year after the date of enactment of this Act) to medicare participation agreements in effect (or entered into) on or after such date.

(c) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out the amendments made by subsection (a).

SEC. 507. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO MEDICARE LIMITS ON PHYSICIAN REFERRALS.

(a) LIMITS ON PHYSICIAN REFERRALS.—

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

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

(i) by striking ", and" at the end of subparagraph (A) and inserting a semicolon; and

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

"(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the hospital is not a specialty hospital (as defined in subsection (h)(7)); and".

(B) 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 subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is primarily or exclusively engaged in the care and treatment of one of the following categories:

"(i) Patients with a cardiac condition.

"(ii) Patients with an orthopedic condition.

"(iii) Patients receiving a surgical procedure.

"(iv) Any other specialized category of services 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 November 18, 2003; or

"(II) under development as of such date;

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

"(iii) for which the type of categories described in subparagraph (A) at any time on or after such date is no different than the type of such categories as of such date;

"(iv) for which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

"(v) that meets such other requirements as the Secretary may specify.".

(2) OWNERSHIP AND INVESTMENT INTERESTS IN A RURAL PROVIDER.—Section 1877(d)(2) (42 U.S.C. 1395nn(d)(2)) is amended to read as follows:

"(2) RURAL PROVIDERS.—In the case of designated health services furnished in a rural area (as defined in section 1886(d)(2)(D)) by an entity, if—

"(A) substantially all of the designated health services furnished by the entity are furnished to individuals residing in such a rural area; and

"(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the entity is not a specialty hospital (as defined in subsection (h)(7)).".

(b) 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)(1)(B), in determining whether a hospital is under development as of November 18, 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.

(c) STUDIES.—

(1) MEDPAC STUDY.—The Medicare Payment Advisory Commission, in consultation with the Comptroller General of the United States, shall conduct a study to determine—

(A) any differences in the costs of health care services furnished to patients by physician-owned specialty hospitals and the costs of such services furnished by local

full-service community hospitals within specific diagnosis-related groups;

(B) the extent to which specialty hospitals, relative to local full-service community hospitals, treat patients in certain diagnosis-related groups within a category, such as cardiology, and an analysis of the selection;

(C) the financial impact of physician-owned specialty hospitals on local full-service community hospitals;

(D) how the current diagnosis-related group system should be updated to better reflect the cost of delivering care in a hospital setting; and

(E) the proportions of payments received, by type of payer, between the specialty hospitals and local full-service community hospitals.

(2) HHS STUDY.—The Secretary shall conduct a study of a representative sample of specialty hospitals—

(A) to determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest;

(B) to determine the referral patterns of physician owners, including the percentage of patients they referred to physician-owned specialty hospitals and the percentage of patients they referred to local full-service community hospitals for the same condition;

(C) to compare the quality of care furnished in physician-owned specialty hospitals and in local full-service community hospitals for similar conditions and patient satisfaction with such care; and

(D) to assess the differences in uncompensated care, as defined by the Secretary, between the specialty hospital and local full-service community hospitals, and the relative value of any tax exemption available to such hospitals.

(3) REPORTS.—Not later than 15 months after the date of the enactment of this Act, the Commission and the Secretary, respectively, shall each submit to Congress a report on the studies conducted under paragraphs (1) and (2), respectively, and shall include any recommendations for legislation or administrative changes.

SEC. 508. ONE-TIME APPEALS PROCESS FOR HOSPITAL WAGE INDEX CLASSIFICATION.

(a) ESTABLISHMENT OF PROCESS.—

(1) IN GENERAL.—The Secretary shall establish not later than January 1, 2004, by instruction or otherwise a process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State (or, at the discretion of the Secretary, within a contiguous State) to which to be reclassified.

(2) PROCESS REQUIREMENTS.—The process established under paragraph (1) shall be consistent with the following:

(A) Such an appeal may be filed as soon as possible after the date of the enactment of this Act but shall be filed by not later than February 15, 2004.

(B) Such an appeal shall be heard by the Medicare Geographic Reclassification Review Board.

(C) There shall be no further administrative or judicial review of a decision of such Board.

(3) RECLASSIFICATION UPON SUCCESSFUL APPEAL.—If the Medicare Geographic Reclassification Review Board determines that the hospital is a qualifying hospital (as defined in subsection (c)), the hospital shall be reclassified to the area selected under paragraph (1). Such reclassification shall apply with respect to discharges occurring during the 3-year period beginning with April 1, 2004.

(4) INAPPLICABILITY OF CERTAIN PROVISIONS.—Except as the Secretary may provide, the provisions of paragraphs (8) and (10) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) shall not apply to an appeal under this section.

(b) APPLICATION OF RECLASSIFICATION.—In the case of an appeal decided in favor of a qualifying hospital under subsection (a), the wage index reclassification shall not affect the wage index computation for any area or for any other hospital and shall not be effected in a budget neutral manner. The provisions of this section shall not affect payment for discharges occurring after the end of the 3-year-period referred to in subsection (a).

(c) QUALIFYING HOSPITAL DEFINED.—For purposes of this section, the term "qualifying hospital" means a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) that—

(1) does not qualify for a change in wage index classification under paragraph (8) or (10) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) on the basis of requirements relating to distance or commuting; and

(2) meets such other criteria, such as quality, as the Secretary may specify by instruction or otherwise.

The Secretary may modify the wage comparison guidelines promulgated under section 1886(d)(10)(D) of such Act (42 U.S.C. 1395ww(d)(10)(D)) in carrying out this section.

(d) WAGE INDEX CLASSIFICATION.—For purposes of this section, the term "wage index classification" means the geographic area in which it is classified for purposes of determining for a fiscal year the factor used to adjust the DRG prospective payment rate under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E) of such section.

(e) LIMITATION ON EXPENDITURES.—The aggregate amount of additional expenditures resulting from the application of this section shall not exceed $900,000,000.

(f) TRANSITIONAL EXTENSION.—Any reclassification of a county or other area made by Act of Congress for purposes of making payments under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) that expired on September 30, 2003, shall be deemed to be in effect during the period beginning on January 1, 2004, and ending on September 30, 2004.

Subtitle B—Other Provisions

SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

"(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

"(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable (determined without regard to any increase under section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, or under section 314(a) of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000), shall be increased by 128 percent to reflect increased costs associated with such residents.

"(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.".

(b) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2004.

SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(1) by striking "and" at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting "; and"; and

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

"(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 (as defined in section 1861(r)(1)) who is either the medical director or an employee of a hospice program and that—

"(A) consist of—

"(i) an evaluation of the individual's need for pain and symptom management, including the individual's need for hospice care; and

"(ii) counseling the individual with respect to hospice care and other care options; and

"(B) may include advising the individual regarding advanced care planning.".

(b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(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 established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decisionmaking of low complexity 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, 2005.

SEC. 513. STUDY ON PORTABLE DIAGNOSTIC ULTRASOUND SERVICES FOR BENEFICIARIES IN SKILLED NURSING FACILITIES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of portable diagnostic ultrasound services furnished to medicare beneficiaries in skilled nursing facilities. Such study shall consider the following:

(1) TYPES OF EQUIPMENT; TRAINING.—The types of portable diagnostic ultrasound services furnished to such beneficiaries, the types of portable ultrasound equipment used to furnish such services, and the technical skills, or training, or both, required for technicians to furnish such services.

(2) CLINICAL APPROPRIATENESS.—The clinical appropriateness of transporting portable diagnostic ultrasound diagnostic and technicians to patients in skilled nursing facilities as opposed to transporting such patients to a hospital or other facility that furnishes diagnostic ultrasound services.

(3) FINANCIAL IMPACT.—The financial impact if Medicare were make a separate payment for portable ultrasound diagnostic services, including the impact of separate payments—

(A) for transportation and technician services for residents during a resident in a part A stay, that would otherwise be paid for under the prospective payment system for covered skilled nursing facility services (under section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e)); and

(B) for such services for residents in a skilled nursing facility after a part A stay.

(4) CREDENTIALING REQUIREMENTS.—Whether the Secretary should establish credentialing or other requirements for technicians that furnish diagnostic ultrasound services to medicare beneficiaries.

(b) REPORT.—Not later than 2 years 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), and shall include any recommendations for legislation or administrative change as the Comptroller General determines appropriate.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to 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 amendments made by paragraph (1) shall apply to computations of the sustainable growth rate for years beginning with 2003.

SEC. 602. TREATMENT OF PHYSICIANS' SERVICES FURNISHED IN ALASKA.

Section 1848(e)(1) (42 U.S.C. 1395w–4(e)(1)), as amended by section 421, is amended—

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

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

"(G) FLOOR FOR PRACTICE EXPENSE, MALPRACTICE, AND WORK GEOGRAPHIC INDICES FOR SERVICES FURNISHED IN ALASKA.—For purposes of payment for services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, after calculating the practice expense, malpractice, and work geographic indices in clauses (i), (ii), and (iii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.67 if such index would otherwise be less than 1.67.".

SEC. 603. INCLUSION OF PODIATRISTS, DENTISTS, AND OPTOMETRISTS UNDER PRIVATE CONTRACTING AUTHORITY.

Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is amended by striking "section 1861(r)(1)" and inserting "paragraphs (1), (2), (3), and (4) of section 1861(r)".

SEC. 604. GAO STUDY ON ACCESS TO PHYSICIANS' SERVICES.

(a) 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—

(1) 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;

(2) an examination of changes in the use by beneficiaries of physicians' services over time; and

(3) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(b) 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 subsection (a). The report shall include a determination whether—

(1) 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

(2) access by medicare beneficiaries to physicians' services may have improved, remained constant, or deteriorated over time.

SEC. 605. COLLABORATIVE DEMONSTRATION-BASED REVIEW OF PHYSICIAN PRACTICE EXPENSE GEOGRAPHIC ADJUSTMENT DATA.

(a) IN GENERAL.—Not later than January 1, 2005, the Secretary shall, in collaboration with State and other appropriate organizations representing physicians, and other appropriate persons, review and consider alternative data sources than those currently used in establishing the geographic index for the practice expense component under the medicare physician fee schedule under section 1848(e)(1)(A)(i) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(A)(i)).

(b) SITES.—The Secretary shall select two physician payment localities in which to carry out subsection (a). One locality shall include rural areas and at least one locality shall be a statewide locality that includes both urban and rural areas.

(c) REPORT AND RECOMMENDATIONS.—

(1) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the review and consideration conducted under subsection (a). Such report shall include information on the alternative developed data sources considered by the Secretary under subsection (a), including the accuracy and validity of the data as measures of the elements of the geographic index for practice expenses under the medicare physician fee schedule as well as the feasibility of using such alternative data nationwide in lieu of current proxy data used in such index, and the estimated impacts of using such alternative data.

(2) RECOMMENDATIONS.—The report submitted under paragraph (1) shall contain recommendations on which data sources reviewed and considered under subsection (a) are appropriate for use in calculating the geographic index for practice expenses under the medicare physician fee schedule.

SEC. 606. 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 PHYSICIANS' SERVICES.—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 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 (42 U.S.C. 1395w–4(f))).

(2) An examination of the relative growth of volume in physicians' 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 or 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 effected 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)(iii), 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)(1) The term 'initial preventive physical examination' means physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure, and an electrocardiogram) with the goal of health promotion and disease

detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2), but does not include clinical laboratory tests.

"(2) The screening and other preventive services described in this paragraph include the following:

"(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).

"(B) Screening mammography as defined in subsection (jj).

"(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).

"(D) Prostate cancer screening tests as defined in subsection (oo).

"(E) Colorectal cancer screening tests as defined in subsection (pp).

"(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).

"(G) Bone mass measurement as defined in subsection (rr).

"(H) Screening for glaucoma as defined in subsection (uu).

"(I) Medical nutrition therapy services as defined in subsection (vv).

"(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).

"(K) Diabetes screening tests as defined in subsection (yy).".

(c) 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),".

(d) OTHER CONFORMING AMENDMENTS.—(1) Section 1862(a) (42 U.S.C. 1395y(a)), as amended by section 303(i)(3)(B), is amended—

(A) in paragraph (1)—

(i) by striking "and" at the end of subparagraph (I);

(ii) by striking the semicolon at the end of subparagraph (J) and inserting ", and"; and

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

"(K) 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

(B) in paragraph (7), by striking "or (H)" and inserting "(H), or (K)".

(2) Clauses (i) and (ii) of section 1861(s)(2)(K) (42 U.S.C. 1395x(s)(2)(K)) are each amended by inserting "and services described in subsection (ww)(1)" after "services which would be physicians' services".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2005, but only for individuals whose coverage period under part B begins on or after such date.

SEC. 612. COVERAGE OF CARDIOVASCULAR SCREENING BLOOD TESTS.

(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)(iii), 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) cardiovascular screening blood tests (as defined in subsection (xx)(1));".

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Cardiovascular Screening Blood Test

"(xx)(1) The term 'cardiovascular screening blood test' means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

"(A) Cholesterol levels and other lipid or triglyceride levels.

"(B) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by noninvasive testing.

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force.

"(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency for each type of cardiovascular screening blood 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(d), 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 cardiovascular screening blood tests (as defined in section 1861(xx)(1)), which are 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. COVERAGE OF DIABETES SCREENING TESTS.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 612(a), 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 (as defined in subsection (yy));".

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by section 612(b), is amended by adding at the end the following new subsection:

"Diabetes Screening Tests

"(yy)(1) The term 'diabetes screening tests' means 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 of the following risk factors for diabetes:

"(A) Hypertension.

"(B) Dyslipidemia.

"(C) Obesity, defined as a body mass index greater than or equal to 30 kg/m^2.

"(D) Previous identification of an elevated impaired fasting glucose.

"(E) Previous identification of impaired glucose tolerance.

"(F) A risk factor consisting of at least 2 of the following characteristics:

"(i) Overweight, defined as a body mass index greater than 25, but less than 30, kg/m^2.

"(ii) A family history of diabetes.

"(iii) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

"(iv) 65 years of age or older.

"(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 section 612(c), is amended—

(1) by striking "and" at the end of subparagraph (K);

(2) by striking the semicolon at the end of subparagraph (L) and inserting ", and"; and

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

"(M) in the case of a diabetes screening test (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 January 1, 2005.

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 diagnostic mammography".

(b) CONFORMING AMENDMENT.—Section 1833(a)(2)(E)(i) (42 U.S.C. 1395l(a)(2)(E)(i)) is amended by inserting "and, for services furnished on or after January 1, 2005, diagnostic mammography" after "screening mammography".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply—

(1) in the case of screening mammography, to services furnished on or after the date of the enactment of this Act; and

(2) in the case of diagnostic mammography, to services furnished on or after January 1, 2005.

Subtitle C—Other Provisions

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.—

(1) SPECIAL RULES FOR CERTAIN DRUGS AND BIOLOGICALS.—Section 1833(t) (42 U.S.C. 1395l(t)), as amended by section 411(b), is amended by inserting after paragraph (13) the following new paragraphs:

"(14) DRUG APC PAYMENT RATES.—

"(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

"(i) in 2004, in the case of—

"(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

"(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

"(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

"(ii) in 2005, in the case of—

"(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

"(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

"(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

"(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

"(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

"(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary 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 section 1927(k)(2)) for which a separate ambulatory

payment classification group (APC) has been established and 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 or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

"(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

"(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

"(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

"(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

"(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

"(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

"(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

"(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

"(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

"(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs

for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

"(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

"(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

"(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

"(I) a description and analysis of the data available with regard to such expenses;

"(II) a recommendation as to whether such a payment adjustment should be made; and

"(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

"(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

"(F) CLASSES OF DRUGS.—For purposes of this paragraph:

"(i) SOLE SOURCE DRUGS.—The term 'sole source drug' means—

"(I) a biological product (as defined under section 1861(t)(1)); or

"(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

"(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term 'innovator multiple source drug' has the meaning given such term in section 1927(k)(7)(A)(ii).

"(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term 'noninnovator multiple source drug' has the meaning given such term in section 1927(k)(7)(A)(iii).

"(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term 'reference average wholesale price' means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

"(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing

the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

"(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.".

(2) REDUCTION IN THRESHOLD FOR SEPARATE APCS FOR DRUGS.—Section 1833(t)(16), as redesignated section 411(b), is amended by adding at the end the following new subparagraph:

"(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.".

(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 AND BIOLOGICAL APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.".

(4) PAYMENT FOR PASS THROUGH DRUGS.—Section 1833(t)(6)(D)(i) (42 U.S.C. 1395l(t)(6)(D)(i)) is amended by inserting after "under section 1842(o)" the following: "(or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph)".

(5) CONFORMING AMENDMENT TO BUDGET NEUTRALITY REQUIREMENT.—Section 1833(t)(9)(B) (42 U.S.C. 1395l(t)(9)(B)) is amended by adding at the end the following: "In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).".

(6) EFFECTIVE DATE.—The amendments made by this subsection shall apply to items and services furnished on or after January 1, 2004.

(b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

(1) IN GENERAL.—Section 1833(t)(16), as redesignated by section 411(b) and as 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 consisting of a seed or seeds (or radioactive source) 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. Charges for such devices shall not be included in determining any outlier payment under this subsection.".

(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 consisting of a seed or seeds (or radioactive source), 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)(16)(C) 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.

SEC. 622. LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.

Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

"(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

"(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

"(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

"(I) such application was being made to such drug or biological prior to such date of enactment; and

"(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

"(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be

identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.".

SEC. 623. PAYMENT FOR RENAL DIALYSIS SERVICES.

(a) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED.—The last sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended—

(1) by striking "and" before "for such services" the second place it appears;

(2) by inserting "and before January 1, 2005," after "January 1, 2001,"; and

(3) by inserting before the period at the end the following: ", and for such services furnished on or after January 1, 2005, by 1.6 percent above such composite rate payment amounts for such services furnished on December 31, 2004".

(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)) is amended by striking "The Secretary" and inserting "Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary".

(c) INSPECTOR GENERAL STUDIES ON ESRD DRUGS.—

(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct two studies with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the medicare program which are separately billed by end stage renal disease facilities.

(2) STUDIES ON ESRD DRUGS.—

(A) EXISTING DRUGS.—The first study under paragraph (1) shall be conducted with respect to such drugs and biologicals for which a billing code exists prior to January 1, 2004.

(B) NEW DRUGS.—The second study under paragraph (1) shall be conducted with respect to such drugs and biologicals for which a billing code does not exist prior to January 1, 2004.

(3) MATTERS STUDIED.—Under each study conducted under paragraph (1), the Inspector General shall—

(A) determine the difference between the amount of payment made to end stage renal disease facilities under

title XVIII of the Social Security Act for such drugs and biologicals and the acquisition costs of such facilities for such drugs and biologicals and which are separately billed by end stage renal disease facilities, and

(B) estimate the rates of growth of expenditures for such drugs and biologicals billed by such facilities.

(4) REPORTS.—

(A) EXISTING ESRD DRUGS.—Not later than April 1, 2004, the Inspector General shall report to the Secretary on the study described in paragraph (2)(A).

(B) NEW ESRD DRUGS.—Not later than April 1, 2006, the Inspector General shall report to the Secretary on the study described in paragraph (2)(B).

(d) BASIC CASE-MIX ADJUSTED COMPOSITE RATE FOR RENAL DIALYSIS FACILITY SERVICES.—(1) Section 1881(b) (42 U.S.C. 1395rr(b)) is amended by adding at the end the following new paragraphs:

"(12)(A) In lieu of payment under paragraph (7) beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted prospective payment system for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to such individuals at home. The case-mix under such system shall be for a limited number of patient characteristics.

"(B) The system described in subparagraph (A) shall include—

"(i) the services comprising the composite rate established under paragraph (7); and

"(ii) the difference between payment amounts under this title for separately billed drugs and biologicals (including erythropoietin) and acquisition costs of such drugs and biologicals, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—

"(I) beginning with 2005, for such drugs and biologicals for which a billing code exists prior to January 1, 2004; and

"(II) beginning with 2007, for such drugs and biologicals for which a billing code does not exist prior to January 1, 2004,

adjusted to 2005, or 2007, respectively, as determined to be appropriate by the Secretary.

"(C)(i) In applying subparagraph (B)(ii) for 2005, such payment amounts under this title shall be determined using the methodology specified in paragraph (13)(A)(i).

"(ii) For 2006, the Secretary shall provide for an adjustment to the payments under clause (i) to reflect the difference between the payment amounts using the methodology under paragraph (13)(A)(i) and the payment amount determined using the methodology applied by the Secretary under paragraph (13)(A)(iii) of such paragraph, as estimated by the Secretary.

"(D) The Secretary shall adjust the payment rates under such system by a geographic index as the Secretary determines to be appropriate. If the Secretary applies a geographic index under this paragraph that differs from the index applied under paragraph (7) the Secretary shall phase-in the application of the index under this paragraph over a multiyear period.

"(E)(i) Such system shall be designed to result in the same aggregate amount of expenditures for such services, as estimated by the Secretary, as would have been made for 2005 if this paragraph did not apply.

"(ii) The adjustment made under subparagraph (B)(ii)(II) shall be done in a manner to result in the same aggregate amount of expenditures after such adjustment as would otherwise have been made for such services for 2006 or 2007, respectively, as estimated by the Secretary, if this paragraph did not apply.

"(F) Beginning with 2006, the Secretary shall annually increase the basic case-mix adjusted payment amounts established under this paragraph, by an amount determined by—

"(i) applying the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable to the component of the basic case-mix adjusted system described in subparagraph (B)(ii); and

"(ii) converting the amount determined in clause (i) to an increase applicable to the basic case-mix adjusted payment amounts established under subparagraph (B).

Nothing in this paragraph shall be construed as providing for an update to the composite rate component of the basic case-mix adjusted system under subparagraph (B).

"(G) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the case-mix system, relative weights, payment amounts, the geographic adjustment factor, or the update for the system established under this paragraph, or the determination of the difference between medicare payment amounts and acquisition costs for separately billed drugs and biologicals (including erythropoietin) under this paragraph and paragraph (13).

"(13)(A) The payment amounts under this title for separately billed drugs and biologicals furnished in a year, beginning with 2004, are as follows:

"(i) For such drugs and biologicals (other than erythropoietin) furnished in 2004, the amount determined under section 1842(o)(1)(A)(v) for the drug or biological.

"(ii) For such drugs and biologicals (including erythropoietin) furnished in 2005, the acquisition cost of the drug or biological, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Insofar as the Inspector General has not determined the acquisition cost with respect to a drug or biological, the Secretary shall determine the payment amount for such drug or biological.

"(iii) For such drugs and biologicals (including erythropoietin) furnished in 2006 and subsequent years, such acquisition cost or the amount determined under section 1847A for the drug or biological, as the Secretary may specify.

"(B)(i) Drugs and biologicals (including erythropoietin) which were separately billed under this subsection on the day before the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 shall continue to be separately billed on and after such date.

"(ii) Nothing in this paragraph, section 1842(o), section 1847A, or section 1847B shall be construed as requiring or authorizing

the bundling of payment for drugs and biologicals into the basic case-mix adjusted payment system under this paragraph.".

(2) Paragraph (7) of such section is amended in the first sentence by striking "The Secretary" and inserting "Subject to paragraph (12), the Secretary".

(3) Paragraph (11)(B) of such section is amended by inserting "subject to paragraphs (12) and (13)" before "payment for such item".

(e) DEMONSTRATION OF BUNDLED CASE-MIX ADJUSTED PAYMENT SYSTEM FOR ESRD SERVICES.—

(1) IN GENERAL.—The Secretary shall establish a demonstration project of the use of a fully case-mix adjusted payment system for end stage renal disease services under section 1881 of the Social Security Act (42 U.S.C. 1395rr) for patient characteristics identified in the report under subsection (f) that bundles into such payment rates amounts for—

(A) drugs and biologicals (including erythropoietin) furnished to end stage renal disease patients under the medicare program which are separately billed by end stage renal disease facilities (as of the date of the enactment of this Act); and

(B) clinical laboratory tests related to such drugs and biologicals.

(2) FACILITIES INCLUDED IN THE DEMONSTRATION.—In conducting the demonstration under this subsection, the Secretary shall ensure the participation of a sufficient number of providers of dialysis services and renal dialysis facilities, but in no case to exceed 500. In selecting such providers and facilities, the Secretary shall ensure that the following types of providers are included in the demonstration:

(A) Urban providers and facilities.

(B) Rural providers and facilities.

(C) Not-for-profit providers and facilities.

(D) For-profit providers and facilities.

(E) Independent providers and facilities.

(F) Specialty providers and facilities, including pediatric providers and facilities and small providers and facilities.

(3) TEMPORARY ADD-ON PAYMENT FOR DIALYSIS SERVICES FURNISHED UNDER THE DEMONSTRATION.—

(A) IN GENERAL.—During the period of the demonstration project, the Secretary shall increase payment rates that would otherwise apply under section 1881(b) of such Act (42 U.S.C. 1395rr(b)) by 1.6 percent for dialysis services furnished in facilities in the demonstration site.

(B) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as—

(i) as an annual update under section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b));

(ii) as increasing the baseline for payments under such section; or

(iii) requiring the budget neutral implementation of the demonstration project under this subsection.

(4) 3-YEAR PERIOD.—The Secretary shall conduct the demonstration under this subsection for the 3-year period beginning on January 1, 2006.

(5) USE OF ADVISORY BOARD.—

(A) IN GENERAL.—In carrying out the demonstration under this subsection, the Secretary shall establish an advisory board comprised of representatives described in subparagraph (B) to provide advice and recommendations with respect to the establishment and operation of such demonstration.

(B) REPRESENTATIVES.—Representatives referred to in subparagraph (A) include representatives of the following:

(i) Patient organizations.

(ii) Individuals with expertise in end stage renal dialysis services, such as clinicians, economists, and researchers.

(iii) The Medicare Payment Advisory Commission, established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(iv) The National Institutes of Health.

(v) Network organizations under section 1881(c) of the Social Security Act (42 U.S.C. 1395rr(c)).

(vi) Medicare contractors to monitor quality of care.

(vii) Providers of services and renal dialysis facilities furnishing end stage renal disease services.

(C) TERMINATION OF ADVISORY PANEL.—The advisory panel shall terminate on December 31, 2008.

(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, $5,000,000 in fiscal year 2006 to conduct the demonstration under this subsection.

(f) REPORT ON A BUNDLED PROSPECTIVE PAYMENT SYSTEM FOR END STAGE RENAL DISEASE SERVICES.—

(1) REPORT.—

(A) IN GENERAL.—Not later than October 1, 2005, the Secretary shall submit to Congress a report detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. The report shall include a description of the methodology to be used for the establishment of payment rates, including components of the new system described in paragraph (2).

(B) RECOMMENDATIONS.—The Secretary shall include in such report recommendations on elements, features, and methodology for a bundled prospective payment system or other issues related to such system as the Secretary determines to be appropriate.

(2) ELEMENTS AND FEATURES OF A BUNDLED PROSPECTIVE PAYMENT SYSTEM.—The report required under paragraph (1) shall include the following elements and features of a bundled prospective payment system:

(A) BUNDLE OF ITEMS AND SERVICES.—A description of the bundle of items and services to be included under the prospective payment system.

(B) CASE MIX.—A description of the case-mix adjustment to account for the relative resource use of different types of patients.

(C) WAGE INDEX.—A description of an adjustment to account for geographic differences in wages.

(D) RURAL AREAS.—The appropriateness of establishing a specific payment adjustment to account for additional costs incurred by rural facilities.

(E) OTHER ADJUSTMENTS.—Such other adjustments as may be necessary to reflect the variation in costs incurred by facilities in caring for patients with end stage renal disease.

(F) UPDATE FRAMEWORK.—A methodology for appropriate updates under the prospective payment system.

(G) ADDITIONAL RECOMMENDATIONS.—Such other matters as the Secretary determines to be appropriate.

SEC. 624. TWO-YEAR MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) ADDITIONAL MORATORIUM ON THERAPY CAPS.—

(1) 2004 AND 2005.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking "and 2002" and inserting "2002, 2004, and 2005".

(2) REMAINDER OF 2003.—For the period beginning on the date of the enactment of this Act and ending of December 31, 2003, the Secretary shall not apply the provisions of paragraphs (1), (2), and (3) of section 1833(g) to expenses incurred with respect to services described in such paragraphs during such period. Nothing in the preceding sentence shall be construed as affecting the application of such paragraphs by the Secretary before the date of the enactment of this Act.

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than March 31, 2004, the Secretary shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 457) (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 (Appendix F, 113 Stat. 1501A–352), as enacted into law by section 1000(a)(6) of Public Law 106–113 (relating to utilization patterns for outpatient therapy).

(c) GAO REPORT IDENTIFYING CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY CAP.—

(1) STUDY.—The Comptroller General of the United States shall identify conditions or diseases that may justify waiving the application of the therapy caps under section 1833(g) of the Social Security Act (42 U.S.C. 1395l(g)) with respect to such conditions or diseases.

(2) REPORT TO CONGRESS.—Not later than October 1, 2004, the Comptroller General shall submit to Congress a report on the conditions and diseases identified under paragraph (1), and shall include a recommendation of criteria, with respect to such conditions and disease, under which a waiver of the therapy caps would apply.

SEC. 625. 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 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 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 eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the first day of the month following the month in which the individual enrolls.

SEC. 626. PAYMENT FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS.

(a) REDUCTIONS IN PAYMENT UPDATES.—Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended to read as follows:

"(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

"(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

"(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

"(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.".

(b) REPEAL OF SURVEY REQUIREMENT AND IMPLEMENTATION OF NEW SYSTEM.—Section 1833(i)(2) (42 U.S.C. 1395l(i)(2)) is amended—

(1) in subparagraph (A)—

(A) in the matter preceding clause (i), by striking "The" and inserting "For services furnished prior to the implementation of the system described in subparagraph (D), the"; and

(B) in clause (i), by striking "taken not later than January 1, 1995, and every 5 years thereafter,"; and

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

"(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

"(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary.

"(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

"(iv) There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.".

(c) CONFORMING AMENDMENT.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended by adding the following new subparagraph:

"(G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system,".

(d) GAO STUDY OF AMBULATORY SURGICAL CENTER PAYMENTS.—

(1) STUDY.—

(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)). The study shall also examine how accurately ambulatory payment categories reflect procedures furnished in ambulatory surgical centers.

(B) CONSIDERATION OF ASC DATA.—In conducting the study under paragraph (1), the Comptroller General shall

consider data submitted by ambulatory surgical centers regarding the matters described in clauses (i) through (iii) of paragraph (2)(B).

(2) REPORT AND RECOMMENDATIONS.—

(A) REPORT.—Not later than January 1, 2005, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(B) RECOMMENDATIONS.—The report submitted under subparagraph (A) shall include recommendations on the following matters:

(i) The appropriateness of using the groups of covered services and relative weights established under the outpatient prospective payment system as the basis of payment for ambulatory surgical centers.

(ii) If the relative weights under such hospital outpatient prospective payment system are appropriate for such purpose—

(I) whether the payment rates for ambulatory surgical centers should be based on a uniform percentage of the payment rates or weights under such outpatient system; or

(II) whether the payment rates for ambulatory surgical centers should vary, or the weights should be revised, based on specific procedures or types of services (such as ophthalmology and pain management services).

(iii) Whether a geographic adjustment should be used for payment of services furnished in ambulatory surgical centers, and if so, the labor and nonlabor shares of such payment.

SEC. 627. 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)(B), 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 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, 2005.

SEC. 628. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

Section 1833(h)(2)(A)(ii)(IV) (42 U.S.C. 1395l(h)(2)(A)(ii)(IV)) is amended by striking "and 1998 through 2002" and inserting ", 1998 through 2002, and 2004 through 2008".

SEC. 629. INDEXING PART B DEDUCTIBLE TO INFLATION.

The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended by striking "and $100 for 1991 and subsequent years" and inserting the following: ", $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1)".

SEC. 630. FIVE-YEAR AUTHORIZATION OF REIMBURSEMENT FOR ALL MEDICARE PART B SERVICES FURNISHED BY CERTAIN INDIAN HOSPITALS AND CLINICS.

Section 1880(e)(1)(A) (42 U.S.C. 1395qq(e)(1)(A)) is amended by inserting "(and for items and services furnished during the 5-year period beginning on January 1, 2005, all items and services for which payment may be made under part B)" after "for services described in paragraph (2)".

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

SEC. 641. DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN PRESCRIPTION DRUGS AND BIOLOGICALS.

(a) DEMONSTRATION PROJECT.—The Secretary shall conduct a demonstration project under part B of title XVIII of the Social Security Act under which payment is made for drugs or biologicals that are prescribed as replacements for drugs and biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q) of such Act (42 U.S.C. 1395x(s)(2)(A), 1395x(s)(2)(Q)), or both, for which payment is made under such part. Such project shall provide for cost-sharing applicable with respect to such drugs or biologicals in the same manner as cost-sharing applies with respect to part D drugs under standard prescription drug coverage (as defined in section 1860D–2(b) of the Social Security Act, as added by section 101(a)).

(b) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in sites selected by the Secretary.

(c) DURATION.—The Secretary shall conduct the demonstration project for the 2-year period beginning on the date that is 90

days after the date of the enactment of this Act, but in no case may the project extend beyond December 31, 2005.

(d) LIMITATION.—Under the demonstration project over the duration of the project, the Secretary may not provide—

(1) coverage for more than 50,000 patients; and

(2) more than $500,000,000 in funding.

(e) REPORT.—Not later than July 1, 2006, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient access to care and patient outcomes under the project, as well as an analysis of the cost effectiveness of the project, including an evaluation of the costs savings (if any) to the medicare program attributable to reduced physicians' services and hospital outpatient departments services for administration of the biological.

SEC. 642. 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 (X);

(B) by adding "and" at the end of subparagraph (Y); and

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

"(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));"; and

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

"Intravenous Immune Globulin

"(zz) The term 'intravenous immune globulin' means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.".

(b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(including intravenous immune globulin (as defined in section 1861(zz)))" 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. 643. MEDPAC STUDY OF COVERAGE OF SURGICAL FIRST ASSISTING SERVICES OF CERTIFIED REGISTERED NURSE FIRST ASSISTANTS.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the "Commission") shall conduct a study on the feasibility and advisability of providing for payment under part B of title XVIII of the Social Security Act for surgical first assisting services furnished by a certified registered nurse first assistant to medicare beneficiaries.

(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under

subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

(c) DEFINITIONS.—In this section:

(1) SURGICAL FIRST ASSISTING SERVICES.—The term "surgical first assisting services" means services consisting of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care (as determined by the Secretary) furnished by a certified registered nurse first assistant (as defined in paragraph (2)) which the certified registered nurse first assistant is legally authorized to perform by the State in which the services are performed.

(2) CERTIFIED REGISTERED NURSE FIRST ASSISTANT.—The term "certified registered nurse first assistant" means an individual who—

(A) is a registered nurse and is licensed to practice nursing in the State in which the surgical first assisting services are performed;

(B) has completed a minimum of 2,000 hours of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care; and

(C) is certified as a registered nurse first assistant by an organization recognized by the Secretary.

SEC. 644. MEDPAC STUDY OF PAYMENT FOR CARDIO-THORACIC SURGEONS.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the "Commission") shall conduct a study on the practice expense relative values established by the Secretary of Health and Human Services under the medicare physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians in the specialties of thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical staff for patient care in hospitals.

(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

SEC. 645. STUDIES RELATING TO VISION IMPAIRMENTS.

(a) COVERAGE OF OUTPATIENT VISION SERVICES FURNISHED BY VISION REHABILITATION PROFESSIONALS UNDER PART B.—

(1) STUDY.—The Secretary shall conduct a study to determine the feasibility and advisability of providing for payment for vision rehabilitation services furnished by vision rehabilitation professionals.

(2) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with recommendations for such legislation or administrative action as the Secretary determines to be appropriate.

(3) VISION REHABILITATION PROFESSIONAL DEFINED.—In this subsection, the term "vision rehabilitation professional" means an orientation and mobility specialist, a rehabilitation teacher, or a low vision therapist.

(b) REPORT ON APPROPRIATENESS OF A DEMONSTRATION PROJECT TO TEST FEASIBILITY OF USING PPO NETWORKS TO REDUCE COSTS OF ACQUIRING EYEGLASSES FOR MEDICARE BENEFICIARIES AFTER CATARACT SURGERY.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the feasibility of establishing a two-year demonstration project under which the Secretary enters into arrangements with vision care preferred provider organization networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with insertion of an intraocular lens on behalf of Medicare beneficiaries. In such report, the Secretary shall include an estimate of potential cost savings to the Medicare program through the use of such networks, taking into consideration quality of service and beneficiary access to services offered by vision care preferred provider organization networks.

SEC. 646. MEDICARE HEALTH CARE QUALITY DEMONSTRATION PROGRAMS.

Title XVIII (42 U.S.C. 1395 et seq.) is amended by inserting after section 1866B the following new section:

"HEALTH CARE QUALITY DEMONSTRATION PROGRAM

"SEC. 1866C. (a) DEFINITIONS.—In this section:

"(1) BENEFICIARY.—The term 'beneficiary' means an individual who is entitled to benefits under part A and enrolled under part B, including any individual who is enrolled in a Medicare Advantage plan under part C.

"(2) HEALTH CARE GROUP.—

"(A) IN GENERAL.—The term 'health care group' means—

"(i) a group of physicians that is organized at least in part for the purpose of providing physician's services under this title;

"(ii) an integrated health care delivery system that delivers care through coordinated hospitals, clinics, home health agencies, ambulatory surgery centers, skilled nursing facilities, rehabilitation facilities and clinics, and employed, independent, or contracted physicians; or

"(iii) an organization representing regional coalitions of groups or systems described in clause (i) or (ii).

"(B) INCLUSION.—As the Secretary determines appropriate, a health care group may include a hospital or any other individual or entity furnishing items or services for which payment may be made under this title that is affiliated with the health care group under an arrangement structured so that such hospital, individual, or entity participates in a demonstration project under this section.

"(3) PHYSICIAN.—Except as otherwise provided for by the Secretary, the term 'physician' means any individual who furnishes services that may be paid for as physicians' services under this title.

"(b) DEMONSTRATION PROJECTS.—The Secretary shall establish a 5-year demonstration program under which the Secretary shall approve demonstration projects that examine health delivery factors

that encourage the delivery of improved quality in patient care, including—

"(1) the provision of incentives to improve the safety of care provided to beneficiaries;

"(2) the appropriate use of best practice guidelines by providers and services by beneficiaries;

"(3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research;

"(4) encourage shared decision making between providers and patients;

"(5) the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources;

"(6) the appropriate use of culturally and ethnically sensitive health care delivery; and

"(7) the financial effects on the health care marketplace of altering the incentives for care delivery and changing the allocation of resources.

"(c) ADMINISTRATION BY CONTRACT.—

"(1) IN GENERAL.—Except as otherwise provided in this section, the Secretary may administer the demonstration program established under this section in a manner that is similar to the manner in which the demonstration program established under section 1866A is administered in accordance with section 1866B.

"(2) ALTERNATIVE PAYMENT SYSTEMS.—A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include proposals for the use of alternative payment systems for items and services provided to beneficiaries by the group that are designed to—

"(A) encourage the delivery of high quality care while accomplishing the objectives described in subsection (b); and

"(B) streamline documentation and reporting requirements otherwise required under this title.

"(3) BENEFITS.—A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include modifications to the package of benefits available under the original medicare fee-for-service program under parts A and B or the package of benefits available through a Medicare Advantage plan under part C. The criteria employed under the demonstration program under this section to evaluate outcomes and determine best practice guidelines and incentives shall not be used as a basis for the denial of medicare benefits under the demonstration program to patients against their wishes (or if the patient is incompetent, against the wishes of the patient's surrogate) on the basis of the patient's age or expected length of life or of the patient's present or predicted disability, degree of medical dependency, or quality of life.

"(d) ELIGIBILITY CRITERIA.—To be eligible to receive assistance under this section, an entity shall—

"(1) be a health care group;

"(2) meet quality standards established by the Secretary, including—

"(A) the implementation of continuous quality improvement mechanisms that are aimed at integrating community-based support services, primary care, and referral care;

"(B) the implementation of activities to increase the delivery of effective care to beneficiaries;

"(C) encouraging patient participation in preference-based decisions;

"(D) the implementation of activities to encourage the coordination and integration of medical service delivery; and

"(E) the implementation of activities to measure and document the financial impact on the health care marketplace of altering the incentives of health care delivery and changing the allocation of resources; and

"(3) meet such other requirements as the Secretary may establish.

"(e) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII as may be necessary to carry out the purposes of the demonstration program established under this section.

"(f) BUDGET NEUTRALITY.—With respect to the 5-year period of the demonstration program under subsection (b), the aggregate expenditures under this title for such period shall not exceed the aggregate expenditures that would have been expended under this title if the program established under this section had not been implemented.

"(g) NOTICE REQUIREMENTS.—In the case of an individual that receives health care items or services under a demonstration program carried out under this section, the Secretary shall ensure that such individual is notified of any waivers of coverage or payment rules that are applicable to such individual under this title as a result of the participation of the individual in such program.

"(h) PARTICIPATION AND SUPPORT BY FEDERAL AGENCIES.—In carrying out the demonstration program under this section, the Secretary may direct—

"(1) the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;

"(2) the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program; and

"(3) the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Center for Medicare Choices to support linkages of relevant medicare data to registry information from participating health care groups for the beneficiary populations served by the participating groups, for analysis supporting the purposes of the demonstration program, consistent with the applicable provisions of the Health Insurance Portability and Accountability Act of 1996.".

SEC. 647. MEDPAC STUDY ON DIRECT ACCESS TO PHYSICAL THERAPY SERVICES.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the "Commission") shall conduct a study

on the feasibility and advisability of allowing medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as comprehensive rehabilitation facility services.

(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

(c) DIRECT ACCESS DEFINED.—The term "direct access" means, with respect to outpatient physical therapy services and physical therapy services furnished as comprehensive outpatient rehabilitation facility services, coverage of and payment for such services in accordance with the provisions of title XVIII of the Social Security Act, except that sections 1835(a)(2), 1861(p), and 1861(cc) of such Act (42 U.S.C. 1395n(a)(2), 1395x(p), and 1395x(cc), respectively) shall be applied—

(1) without regard to any requirement that—

(A) an individual be under the care of (or referred by) a physician; or

(B) services be provided under the supervision of a physician; and

(2) by allowing a physician or a qualified physical therapist to satisfy any requirement for—

(A) certification and recertification; and

(B) establishment and periodic review of a plan of care.

SEC. 648. DEMONSTRATION PROJECT FOR CONSUMER-DIRECTED CHRONIC OUTPATIENT SERVICES.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Subject to the succeeding provisions of this section, the Secretary shall establish demonstration projects (in this section referred to as "demonstration projects") under which the Secretary shall evaluate methods that improve the quality of care provided to individuals with chronic conditions and that reduce expenditures that would otherwise be made under the medicare program on behalf of such individuals for such chronic conditions, such methods to include permitting those beneficiaries to direct their own health care needs and services.

(2) INDIVIDUALS WITH CHRONIC CONDITIONS DEFINED.—In this section, the term "individuals with chronic conditions" means an individual entitled to benefits under part A of title XVIII of the Social Security Act, and enrolled under part B of such title, but who is not enrolled under part C of such title who is diagnosed as having one or more chronic conditions (as defined by the Secretary), such as diabetes.

(b) DESIGN OF PROJECTS.—

(1) EVALUATION BEFORE IMPLEMENTATION OF PROJECT.—

(A) IN GENERAL.—In establishing the demonstration projects under this section, the Secretary shall evaluate best practices employed by group health plans and practices under State plans for medical assistance under the medicaid program under title XIX of the Social Security Act, as well as best practices in the private sector or other areas, of methods that permit patients to self-direct the

provision of personal care services. The Secretary shall evaluate such practices for a 1-year period and, based on such evaluation, shall design the demonstration project.

(B) REQUIREMENT FOR ESTIMATE OF BUDGET NEUTRAL COSTS.—As part of the evaluation under subparagraph (A), the Secretary shall evaluate the costs of furnishing care under the projects. The Secretary may not implement the demonstration projects under this section unless the Secretary determines that the costs of providing care to individuals with chronic conditions under the project will not exceed the costs, in the aggregate, of furnishing care to such individuals under title XVIII of the Social Security Act, that would otherwise be paid without regard to the demonstration projects for the period of the project.

(2) SCOPE OF SERVICES.—The Secretary shall determine the appropriate scope of personal care services that would apply under the demonstration projects.

(c) VOLUNTARY PARTICIPATION.—Participation of providers of services and suppliers, and of individuals with chronic conditions, in the demonstration projects shall be voluntary.

(d) DEMONSTRATION PROJECTS SITES.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall conduct a demonstration project in at least one area that the Secretary determines has a population of individuals entitled to benefits under part A of title XVIII of the Social Security Act, and enrolled under part B of such title, with a rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

(e) EVALUATION AND REPORT.—

(1) EVALUATIONS.—The Secretary shall conduct evaluations of the clinical and cost effectiveness of the demonstration projects.

(2) REPORTS.—Not later than 2 years after the commencement of the demonstration projects, and biannually thereafter, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(A) An analysis of the patient outcomes and costs of furnishing care to the individuals with chronic conditions participating in the projects as compared to such outcomes and costs to other individuals for the same health conditions.

(B) Evaluation of patient satisfaction under the demonstration projects.

(C) Such recommendations regarding the extension, expansion, or termination of the projects as the Secretary determines appropriate.

(f) 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.

(g) AUTHORIZATION OF APPROPRIATIONS.—(1) Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

(2) There are authorized to be appropriated from such Trust Fund such sums as may be necessary for the Secretary to enter

into contracts with appropriate organizations for the deign, implementation, and evaluation of the demonstration project.

(3) In no case may expenditures under this section exceed the aggregate expenditures that would otherwise have been made for the provision of personal care services.

SEC. 649. MEDICARE CARE MANAGEMENT PERFORMANCE DEMONSTRATION.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures for—

(A) promoting continuity of care;

(B) helping stabilize medical conditions;

(C) preventing or minimizing acute exacerbations of chronic conditions; and

(D) reducing adverse health outcomes, such as adverse drug interactions related to polypharmacy.

(2) SITES.—The Secretary shall designate no more than 4 sites at which to conduct the demonstration program under this section, of which—

(A) two shall be in an urban area;

(B) one shall be in a rural area; and

(C) one shall be in a State with a medical school with a Department of Geriatrics that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 3-year period.

(4) CONSULTATION.—In carrying out the demonstration program under this section, the Secretary shall consult with private sector and non-profit groups that are undertaking similar efforts to improve quality and reduce avoidable hospitalizations for chronically ill patients.

(b) PARTICIPATION.—

(1) IN GENERAL.—A physician who provides care for a minimum number of eligible beneficiaries (as specified by the Secretary) may participate in the demonstration program under this section if such physician agrees, to phase-in over the course of the 3-year demonstration period and with the assistance provided under subsection (d)(2)—

(A) the use of health information technology to manage the clinical care of eligible beneficiaries consistent with paragraph (3); and

(B) the electronic reporting of clinical quality and outcomes measures in accordance with requirements established by the Secretary under the demonstration program.

(2) SPECIAL RULE.—In the case of the sites referred to in subparagraphs (B) and (C) of subsection (a)(2), a physician who provides care for a minimum number of beneficiaries with two or more chronic conditions, including dementia (as specified by the Secretary), may participate in the program under this section if such physician agrees to the requirements in subparagraphs (A) and (B) of paragraph (1).

(3) PRACTICE STANDARDS.—Each physician participating in the demonstration program under this section must demonstrate the ability—

(A) to assess each eligible beneficiary for conditions other than chronic conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing care management requirements;

(B) to serve as the primary contact of eligible beneficiaries in accessing items and services for which payment may be made under the medicare program;

(C) to establish and maintain health care information system for such beneficiaries;

(D) to promote continuity of care across providers and settings;

(E) to use evidence-based guidelines and meet such clinical quality and outcome measures as the Secretary shall require;

(F) to promote self-care through the provision of patient education and support for patients or, where appropriate, family caregivers;

(G) when appropriate, to refer such beneficiaries to community service organizations; and

(H) to meet such other complex care management requirements as the Secretary may specify.

The guidelines and measures required under subparagraph (E) shall be designed to take into account beneficiaries with multiple chronic conditions.

(c) PAYMENT METHODOLOGY.—Under the demonstration program under this section the Secretary shall pay a per beneficiary amount to each participating physician who meets or exceeds specific performance standards established by the Secretary with respect to the clinical quality and outcome measures reported under subsection (b)(1)(B). Such amount may vary based on different levels of performance or improvement.

(d) ADMINISTRATION.—

(1) USE OF QUALITY IMPROVEMENT ORGANIZATIONS.—The Secretary shall contract with quality improvement organizations or such other entities as the Secretary deems appropriate to enroll physicians and evaluate their performance under the demonstration program under this section.

(2) TECHNICAL ASSISTANCE.—The Secretary shall require in such contracts that the contractor be responsible for technical assistance and education as needed to physicians enrolled in the demonstration program under this section for the purpose of aiding their adoption of health information technology, meeting practice standards, and implementing required clinical and outcomes measures.

(e) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying out the demonstration program under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed

the amount which the Secretary estimates would have been paid if the demonstration program under this section was not implemented.

(f) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq. and 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(g) REPORT.—Not later than 12 months after the date of completion of the demonstration program under this section, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(h) DEFINITIONS.—In this section:

(1) ELIGIBLE BENEFICIARY.—The term "eligible beneficiary" means any individual who—

(A) is entitled to benefits under part A and enrolled for benefits under part B of title XVIII of the Social Security Act and is not enrolled in a plan under part C of such title; and

(B) has one or more chronic medical conditions specified by the Secretary (one of which may be cognitive impairment).

(2) HEALTH INFORMATION TECHNOLOGY.—The term "health information technology" means email communication, clinical alerts and reminders, and other information technology that meets such functionality, interoperability, and other standards as prescribed by the Secretary.

SEC. 650. GAO STUDY AND REPORT ON THE PROPAGATION OF CONCIERGE CARE.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on concierge care (as defined in paragraph (2)) to determine the extent to which such care—

(A) is used by medicare beneficiaries (as defined in section 1802(b)(5)(A) of the Social Security Act (42 U.S.C. 1395a(b)(5)(A))); and

(B) has impacted upon the access of medicare beneficiaries (as so defined) to items and services for which reimbursement is provided under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) CONCIERGE CARE.—In this section, the term "concierge care" means an arrangement under which, as a prerequisite for the provision of a health care item or service to an individual, a physician, practitioner (as described in section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C))), or other individual—

(A) charges a membership fee or another incidental fee to an individual desiring to receive the health care item or service from such physician, practitioner, or other individual; or

(B) requires the individual desiring to receive the health care item or service from such physician, practitioner, or other individual to purchase an item or service.

(b) REPORT.—Not later than the date that is 12 months after the date of enactment of this Act, the Comptroller General of

the United States shall submit to Congress a report on the study conducted under subsection (a)(1) together with such recommendations for legislative or administrative action as the Comptroller General determines to be appropriate.

SEC. 651. DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE.

(a) DEFINITIONS.—In this section:

(1) CHIROPRACTIC SERVICES.—The term "chiropractic services" has the meaning given that term by the Secretary for purposes of the demonstration projects, but shall include, at a minimum—

(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and

(B) diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided.

(2) DEMONSTRATION PROJECT.—The term "demonstration project" means a demonstration project established by the Secretary under subsection (b)(1).

(3) ELIGIBLE BENEFICIARY.—The term "eligible beneficiary" means an individual who is enrolled under part B of the medicare program.

(4) MEDICARE PROGRAM.—The term "medicare program" means the health benefits program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(b) DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE.—

(1) ESTABLISHMENT.—The Secretary shall establish demonstration projects in accordance with the provisions of this section for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the medicare program (in addition to the coverage provided for services consisting of treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Social Security Act (42 U.S.C. 1395x(r)(5))).

(2) NO PHYSICIAN APPROVAL REQUIRED.—In establishing the demonstration projects, the Secretary shall ensure that an eligible beneficiary who participates in a demonstration project, including an eligible beneficiary who is enrolled for coverage under a Medicare+Choice plan (or, on and after January 1, 2006, under a Medicare Advantage plan), is not required to receive approval from a physician or other health care provider in order to receive a chiropractic service under a demonstration project.

(3) CONSULTATION.—In establishing the demonstration projects, the Secretary shall consult with chiropractors, organizations representing chiropractors, eligible beneficiaries, and organizations representing eligible beneficiaries.

(4) PARTICIPATION.—Any eligible beneficiary may participate in the demonstration projects on a voluntary basis.

(c) CONDUCT OF DEMONSTRATION PROJECTS.—

(1) DEMONSTRATION SITES.—

(A) SELECTION OF DEMONSTRATION SITES.—The Secretary shall conduct demonstration projects at 4 demonstration sites.

(B) GEOGRAPHIC DIVERSITY.—Of the sites described in subparagraph (A)—

(i) two shall be in rural areas; and

(ii) two shall be in urban areas.

(C) SITES LOCATED IN HPSAS.—At least 1 site described in clause (i) of subparagraph (B) and at least 1 site described in clause (ii) of such subparagraph shall be located in an area that is designated under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) as a health professional shortage area.

(2) IMPLEMENTATION; DURATION.—

(A) IMPLEMENTATION.—The Secretary shall not implement the demonstration projects before October 1, 2004.

(B) DURATION.—The Secretary shall complete the demonstration projects by the date that is 2 years after the date on which the first demonstration project is implemented.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall conduct an evaluation of the demonstration projects—

(A) to determine whether eligible beneficiaries who use chiropractic services use a lesser overall amount of items and services for which payment is made under the medicare program than eligible beneficiaries who do not use such services;

(B) to determine the cost of providing payment for chiropractic services under the medicare program;

(C) to determine the satisfaction of eligible beneficiaries participating in the demonstration projects and the quality of care received by such beneficiaries; and

(D) to evaluate such other matters as the Secretary determines is appropriate.

(2) REPORT.—Not later than the date that is 1 year after the date on which the demonstration projects conclude, the Secretary shall submit to Congress a report on the evaluation conducted under paragraph (1) together with such recommendations for legislation or administrative action as the Secretary determines is appropriate.

(e) WAIVER OF MEDICARE REQUIREMENTS.—The Secretary shall waive compliance with such requirements of the medicare program to the extent and for the period the Secretary finds necessary to conduct the demonstration projects.

(f) FUNDING.—

(1) DEMONSTRATION PROJECTS.—

(A) IN GENERAL.—Subject to subparagraph (B) and paragraph (2), the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying out the demonstration projects under this section.

(B) LIMITATION.—In conducting the demonstration projects under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.

(2) EVALUATION AND REPORT.—There are authorized to be appropriated such sums as are necessary for the purpose of developing and submitting the report to Congress under subsection (d).

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 701. UPDATE IN HOME HEALTH SERVICES.

(a) CHANGE TO CALENDAR YEAR UPDATE.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

(1) in paragraph (3)(B)(i)—

(A) 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

(B) by inserting "or year" after "the fiscal year";

(2) in paragraph (3)(B)(ii)—

(A) in subclause (I), by striking "or" at the end;

(B) by redesignating subclause (II) as subclause (III);

(C) in subclause (III), as so redesignated, by striking "any subsequent fiscal year" and inserting "2004 and any subsequent year"; and

(D) by inserting after subclause (I) the following new subclause:

"(II) for the last calendar quarter of 2003 and the first calendar quarter of 2004, the home health market basket percentage increase; or";

(3) in paragraph (3)(B)(iii), by inserting "or year" after "fiscal year" each place it appears; and

(4) in paragraph (3)(B)(iv)—

(A) by inserting "or year" after "fiscal year" each place it appears; and

(B) by inserting "or years" after "fiscal years"; and

(5) in paragraph (5), by inserting "or year" after "fiscal year".

(b) ADJUSTMENT TO 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)(2), is amended—

(1) by striking "or" at the end of subclause (II);

(2) by redesignating subclause (III) as subclause (IV);

(3) in subclause (IV), as so redesignated, by striking "2004" and inserting "2007"; and

(4) by inserting after subclause (II) the following new subclause:

"(III) the last 3 calendar quarters of 2004, and each of 2005 and 2006 the home health market basket percentage increase minus 0.8 percentage points; or".

SEC. 702. 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 2-year demonstration project under part B of title XVIII of the Social Security Act under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be homebound for purposes of receiving home health services under the medicare program.

(b) MEDICARE BENEFICIARY DESCRIBED.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if—

(1) the beneficiary has been certified by one physician as an individual who has a permanent and severe, disabling condition that is not expected to improve;

(2) the beneficiary is dependent upon assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the beneficiary's life;

(3) the beneficiary requires skilled nursing services for the rest of the beneficiary's life and the skilled nursing is more than medication management;

(4) an attendant is required to visit the beneficiary on a daily basis to monitor and treat the beneficiary's medical condition or to assist the beneficiary with activities of daily living;

(5) the beneficiary requires technological assistance or the assistance of another person to leave the home; and

(6) the beneficiary does not regularly work in a paid position full-time or part-time outside 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). The report shall include the following:

(1) An examination of whether the provision of home health services to medicare beneficiaries under the project has had any of the following effects:

(A) Has adversely affected the provision of home health services under the medicare program.

(B) Has directly caused an 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 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.

(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 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 Medical 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.

SEC. 703. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY-CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary 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.—Subject to paragraph (2), 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) ADJUSTMENT IN CASE OF OVERUTILIZATION OF SUBSTITUTE ADULT DAY-CARE SERVICES TO ENSURE BUDGET NEUTRALITY.—The Secretary shall monitor the expenditures under the demonstration project and under title XVIII of the Social Security Act for home health services. If the Secretary estimates that the total expenditures under the demonstration project and under such title XVIII for home health services for a period determined by the Secretary exceed expenditures that would have been made under such title XVIII for home health services for such period if the demonstration project had not been conducted, the Secretary shall adjust the rate of payment to medical adult day-care facilities under paragraph (1) in order to eliminate such excess.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in not more than 5 sites in 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 than 6 months after the completion 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) is licensed and certified by the State in which it operates or 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. 704. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 467) or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as "non-medicare/medicaid OASIS information").

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the second month beginning after the date as of which the Secretary has published final regulations regarding the collection and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

SEC. 705. 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. 706. COVERAGE OF RELIGIOUS NONMEDICAL HEALTH CARE INSTITUTION SERVICES FURNISHED IN THE HOME.

(a) IN GENERAL.—Section 1821(a) (42 U.S.C. 1395i–5(a)) is amended—

(1) in the matter preceding paragraph (1), by inserting "and for home health services furnished an individual by a religious nonmedical health care institution" after "religious nonmedical health care institution"; and

(2) in paragraph (2)—

(A) by striking "or extended care services" and inserting ", extended care services, or home health services"; and

(B) by inserting ", or receiving services from a home health agency," after "skilled nursing facility".

(b) DEFINITION.—Section 1861 (42 U.S.C. 1395x), as amended by section 642, is amended by adding at the end the following new section:

"Extended Care in Religious Nonmedical Health Care Institutions

"(aaa)(1) The term 'home health agency' also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such an institution to individuals in their homes, and that are comparable to items and services furnished to individuals by a home health agency that is not religious nonmedical health care institution.

"(2)(A) Subject to subparagraphs (B), payment may be made with respect to services provided by such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821.

"(B) Notwithstanding any other provision of this title, payment may not be made under subparagraph (A)—

"(i) in a year insofar as such payments exceed $700,000; and

"(ii) after December 31, 2006.".

Subtitle B—Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)—

(A) by inserting "AND 2004 THROUGH 2013" after "AND 2002"; and

(B) by inserting "or during the period beginning with fiscal year 2004 and ending with fiscal year 2013" after "during fiscal year 2001 or fiscal year 2002"; and

(2) in subclause (II)—

(A) by striking "fiscal year 2004, or fiscal year 2005," and

(B) by striking "For a" and inserting "For the".

SEC. 712. EXCEPTION TO INITIAL RESIDENCY PERIOD FOR GERIATRIC RESIDENCY OR FELLOWSHIP PROGRAMS.

(a) CLARIFICATION OF CONGRESSIONAL INTENT.—Congress intended section 1886(h)(5)(F)(ii) of the Social Security Act (42 U.S.C. 1395ww(h)(5)(F)(ii)), as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99–272), to provide an exception to the initial residency period for geriatric residency or fellowship programs such that, where a particular approved geriatric training program requires a resident to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatric training program are treated as part of the resident's initial residency period, but are not counted against any limitation on the initial residency period.

(b) INTERIM FINAL REGULATORY AUTHORITY AND EFFECTIVE DATE.—The Secretary shall promulgate interim final regulations consistent with the congressional intent expressed in this section after notice and pending opportunity for public comment to be effective for cost reporting periods beginning on or after October 1, 2003.

SEC. 713. TREATMENT OF VOLUNTEER SUPERVISION.

(a) MORATORIUM ON CHANGES IN TREATMENT.—During the 1-year period beginning on January 1, 2004, for purposes of applying subsections (d)(5)(B) and (h) of section 1886 of the Social Security Act (42 U.S.C. 1395ww), the Secretary shall allow all hospitals to count residents in osteopathic and allopathic family practice programs in existence as of January 1, 2002, who are training

at non-hospital sites, without regard to the financial arrangement between the hospital and the teaching physician practicing in the non-hospital site to which the resident has been assigned.

(b) STUDY AND REPORT.—

(1) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study of the appropriateness of alternative payment methodologies under such sections for the costs of training residents in non-hospital settings.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.

Subtitle C—Chronic Care Improvement

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

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

"CHRONIC CARE IMPROVEMENT

"SEC. 1807. (a) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS.—

"(1) IN GENERAL.—The Secretary shall provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs in accordance with this section. Each such program shall be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under this title for targeted beneficiaries with one or more threshold conditions.

"(2) DEFINITIONS.—For purposes of this section:

"(A) CHRONIC CARE IMPROVEMENT PROGRAM.—The term 'chronic care improvement program' means a program described in paragraph (1) that is offered under an agreement under subsection (b) or (c).

"(B) CHRONIC CARE IMPROVEMENT ORGANIZATION.—The term 'chronic care improvement organization' means an entity that has entered into an agreement under subsection (b) or (c) to provide, directly or through contracts with subcontractors, a chronic care improvement program under this section. Such an entity may be a disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities, or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program under this section.

"(C) CARE MANAGEMENT PLAN.—The term 'care management plan' means a plan established under subsection (d) for a participant in a chronic care improvement program.

"(D) THRESHOLD CONDITION.—The term 'threshold condition' means a chronic condition, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or conditions, as selected

by the Secretary as appropriate for the establishment of a chronic care improvement program.

"(E) TARGETED BENEFICIARY.—The term 'targeted beneficiary' means, with respect to a chronic care improvement program, an individual who—

"(i) is entitled to benefits under part A and enrolled under part B, but not enrolled in a plan under part C;

"(ii) has one or more threshold conditions covered under such program; and

"(iii) has been identified under subsection (d)(1) as a potential participant in such program.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as—

"(A) expanding the amount, duration, or scope of benefits under this title;

"(B) providing an entitlement to participate in a chronic care improvement program under this section;

"(C) providing for any hearing or appeal rights under section 1869, 1878, or otherwise, with respect to a chronic care improvement program under this section; or

"(D) providing benefits under a chronic care improvement program for which a claim may be submitted to the Secretary by any provider of services or supplier (as defined in section 1861(d)).

"(b) DEVELOPMENTAL PHASE (PHASE I).—

"(1) IN GENERAL.—In carrying out this section, the Secretary shall enter into agreements consistent with subsection (f) with chronic care improvement organizations for the development, testing, and evaluation of chronic care improvement programs using randomized controlled trials. The first such agreement shall be entered into not later than 12 months after the date of the enactment of this section.

"(2) AGREEMENT PERIOD.—The period of an agreement under this subsection shall be for 3 years.

"(3) MINIMUM PARTICIPATION.—

"(A) IN GENERAL.—The Secretary shall enter into agreements under this subsection in a manner so that chronic care improvement programs offered under this section are offered in geographic areas that, in the aggregate, consist of areas in which at least 10 percent of the aggregate number of medicare beneficiaries reside.

"(B) MEDICARE BENEFICIARY DEFINED.—In this paragraph, the term 'medicare beneficiary' means an individual who is entitled to benefits under part A, enrolled under part B, or both, and who resides in the United States.

"(4) SITE SELECTION.—In selecting geographic areas in which agreements are entered into under this subsection, the Secretary shall ensure that each chronic care improvement program is conducted in a geographic area in which at least 10,000 targeted beneficiaries reside among other individuals entitled to benefits under part A, enrolled under part B, or both to serve as a control population.

"(5) INDEPENDENT EVALUATIONS OF PHASE I PROGRAMS.—The Secretary shall contract for an independent evaluation of the programs conducted under this subsection. Such evaluation shall be done by a contractor with knowledge of chronic

care management programs and demonstrated experience in the evaluation of such programs. Each evaluation shall include an assessment of the following factors of the programs:

"(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.

"(B) Beneficiary and provider satisfaction.

"(C) Health outcomes.

"(D) Financial outcomes, including any cost savings to the program under this title.

"(c) EXPANDED IMPLEMENTATION PHASE (PHASE II).—

"(1) IN GENERAL.—With respect to chronic care improvement programs conducted under subsection (b), if the Secretary finds that the results of the independent evaluation conducted under subsection (b)(6) indicate that the conditions specified in paragraph (2) have been met by a program (or components of such program), the Secretary shall enter into agreements consistent with subsection (f) to expand the implementation of the program (or components) to additional geographic areas not covered under the program as conducted under subsection (b), which may include the implementation of the program on a national basis. Such expansion shall begin not earlier than 2 years after the program is implemented under subsection (b) and not later than 6 months after the date of completion of such program.

"(2) CONDITIONS FOR EXPANSION OF PROGRAMS.—The conditions specified in this paragraph are, with respect to a chronic care improvement program conducted under subsection (b) for a threshold condition, that the program is expected to—

"(A) improve the clinical quality of care;

"(B) improve beneficiary satisfaction; and

"(C) achieve targets for savings to the program under this title specified by the Secretary in the agreement within a range determined to be appropriate by the Secretary, subject to the application of budget neutrality with respect to the program and not taking into account any payments by the organization under the agreement under the program for risk under subsection (f)(3)(B).

"(3) INDEPENDENT EVALUATIONS OF PHASE II PROGRAMS.—The Secretary shall carry out evaluations of programs expanded under this subsection as the Secretary determines appropriate. Such evaluations shall be carried out in the similar manner as is provided under subsection (b)(5).

"(d) IDENTIFICATION AND ENROLLMENT OF PROSPECTIVE PROGRAM PARTICIPANTS.—

"(1) IDENTIFICATION OF PROSPECTIVE PROGRAM PARTICIPANTS.—The Secretary shall establish a method for identifying targeted beneficiaries who may benefit from participation in a chronic care improvement program.

"(2) INITIAL CONTACT BY SECRETARY.—The Secretary shall communicate with each targeted beneficiary concerning participation in a chronic care improvement program. Such communication may be made by 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 organization 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 participate or for declining to participate and the method for obtaining additional information concerning such participation.

"(3) VOLUNTARY PARTICIPATION.—A targeted beneficiary may participate in a chronic care improvement program on a voluntary basis and may terminate participation at any time.

"(e) CHRONIC CARE IMPROVEMENT PROGRAMS.—

"(1) IN GENERAL.—Each chronic care improvement program shall—

"(A) have a process to screen each targeted beneficiary for conditions other than threshold conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing an individualized, goal-oriented care management plan under paragraph (2);

"(B) provide each targeted beneficiary participating in the program with such plan; and

"(C) carry out such plan and other chronic care improvement activities in accordance with paragraph (3).

"(2) ELEMENTS OF CARE MANAGEMENT PLANS.—A care management plan for a targeted beneficiary shall be developed with the beneficiary and shall, to the extent appropriate, include the following:

"(A) A designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers under the plan.

"(B) Self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members.

"(C) Education for physicians and other providers and collaboration to enhance communication of relevant clinical information.

"(D) 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.

"(E) The provision of information about hospice care, pain and palliative care, and end-of-life care.

"(3) CONDUCT OF PROGRAMS.—In carrying out paragraph (1)(C) with respect to a participant, the chronic care improvement organization shall—

"(A) guide the participant in managing the participant's health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant;

"(B) use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

"(C) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

"(4) ADDITIONAL RESPONSIBILITIES.—

"(A) OUTCOMES REPORT.—Each chronic care improvement organization offering a chronic care improvement program shall monitor and report to the Secretary, in a manner specified by the Secretary, on health care quality, cost, and outcomes.

"(B) ADDITIONAL REQUIREMENTS.—Each such organization and program shall comply with such additional requirements as the Secretary may specify.

"(5) ACCREDITATION.—The Secretary may provide that chronic care improvement programs and chronic care improvement organizations that are accredited by qualified organizations (as defined by the Secretary) may be deemed to meet such requirements under this section as the Secretary may specify.

"(f) TERMS OF AGREEMENTS.—

"(1) TERMS AND CONDITIONS.—

"(A) IN GENERAL.—An agreement under this section with a chronic care improvement organization shall contain such terms and conditions as the Secretary may specify consistent with this section.

"(B) CLINICAL, QUALITY IMPROVEMENT, AND FINANCIAL REQUIREMENTS.—The Secretary may not enter into an agreement with such an organization under this section for the operation of a chronic care improvement program unless—

"(i) the program and organization meet the requirements of subsection (e) and such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the targeted beneficiaries to be served; and

"(ii) the organization demonstrates to the satisfaction of the Secretary that the organization is able to assume financial risk for performance under the agreement (as applied under paragraph (3)(B)) with respect to payments made to the organization under such agreement through available reserves, reinsurance, withholds, or such other means as the Secretary determines appropriate.

"(2) MANNER OF PAYMENT.—Subject to paragraph (3)(B), the payment under an agreement under—

"(A) subsection (b) shall be computed on a per-member per-month basis; or

"(B) subsection (c) may be on a per-member per-month basis or such other basis as the Secretary and organization may agree.

"(3) APPLICATION OF PERFORMANCE STANDARDS.—

"(A) SPECIFICATION OF PERFORMANCE STANDARDS.—Each agreement under this section with a chronic care improvement organization shall specify performance standards for each of the factors specified in subsection (c)(2), including clinical quality and spending targets under this title, against which the performance of the chronic care

improvement organization under the agreement is measured.

"(B) ADJUSTMENT OF PAYMENT BASED ON PERFORMANCE.—

"(i) IN GENERAL.—Each such agreement shall provide for adjustments in payment rates to an organization under the agreement insofar as the Secretary determines that the organization failed to meet the performance standards specified in the agreement under subparagraph (A).

"(ii) FINANCIAL RISK FOR PERFORMANCE.—In the case of an agreement under subsection (b) or (c), the agreement shall provide for a full recovery for any amount by which the fees paid to the organization under the agreement exceed the estimated savings to the programs under this title attributable to implementation of such agreement.

"(4) BUDGET NEUTRAL PAYMENT CONDITION.—Under this section, the Secretary shall ensure that the aggregate sum of medicare program benefit expenditures for beneficiaries participating in chronic care improvement programs and funds paid to chronic care improvement organizations under this section, shall not exceed the medicare program benefit expenditures that the Secretary estimates would have been made for such targeted beneficiaries in the absence of such programs.

"(g) FUNDING.—(1) Subject to paragraph (2), there are appropriated to the Secretary, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for agreements with chronic care improvement programs under this section.

"(2) In no case shall the funding under this section exceed $100,000,000 in aggregate increased expenditures under this title (after taking into account any savings attributable to the operation of this section) over the 3-fiscal-year period beginning on October 1, 2003.".

(b) REPORTS.—The Secretary shall submit to Congress reports on the operation of section 1807 of the Social Security Act, as added by subsection (a), as follows:

(1) Not later than 2 years after the date of the implementation of such section, the Secretary shall submit to Congress an interim report on the scope of implementation of the programs under subsection (b) of such section, the design of the programs, and preliminary cost and quality findings with respect to those programs based on the following measures of the programs:

(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.

(B) Beneficiary and provider satisfaction.

(C) Health outcomes.

(D) Financial outcomes.

(2) Not later than 3 years and 6 months after the date of the implementation of such section the Secretary shall submit to Congress an update to the report required under paragraph (1) on the results of such programs.

(3) The Secretary shall submit to Congress 2 additional biennial reports on the chronic care improvement programs

conducted under such section. The first such report shall be submitted not later than 2 years after the report is submitted under paragraph (2). Each such report shall include information on—

(A) the scope of implementation (in terms of both regions and chronic conditions) of the chronic care improvement programs;

(B) the design of the programs; and

(C) the improvements in health outcomes and financial efficiencies that result from such implementation.

SEC. 722. MEDICARE ADVANTAGE QUALITY IMPROVEMENT PROGRAMS.

(a) IN GENERAL.—Section 1852(e) (42 U.S.C. 1395w–22(e)) is amended—

(1) in the heading, by striking "ASSURANCE" and inserting "IMPROVEMENT";

(2) by amending paragraphs (1) through (3) to read as follows:

"(1) IN GENERAL.—Each MA organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by such organization (other than an MA private fee-for-service plan or an MSA plan).

"(2) CHRONIC CARE IMPROVEMENT PROGRAMS.—As part of the quality improvement program under paragraph (1), each MA organization shall have a chronic care improvement program. Each chronic care improvement program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

"(3) DATA.—

"(A) COLLECTION, ANALYSIS, AND REPORTING.—

"(i) IN GENERAL.—Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality.

"(ii) APPLICATION TO MA REGIONAL PLANS.—The Secretary shall establish as appropriate by regulation requirements for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality for MA organizations with respect to MA regional plans. Such requirements may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans.

"(iii) APPLICATION TO PREFERRED PROVIDER ORGANIZATIONS.—Clause (i) shall apply to MA organizations with respect to MA local plans that are preferred provider organization plans only insofar as services are furnished by providers or services, physicians, and other health care practitioners and suppliers that have contracts with such organization to furnish services under such plans.

"(iv) DEFINITION OF PREFERRED PROVIDER ORGANIZATION PLAN.—In this subparagraph, the term 'preferred provider organization plan' means an MA plan that—

"(I) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

"(II) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

"(III) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

"(B) LIMITATIONS.—

"(i) TYPES OF DATA.—The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

"(ii) CHANGES IN TYPES OF DATA.—Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

"(iii) CONSTRUCTION.—Nothing in the subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D).";

(3) in paragraph (4)(B)—

(A) by amending clause (i) to read as follows:

"(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs)."; and

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

"(vii) The requirements described in section 1860D–4(j), to the extent such requirements apply under section 1860D–21(c)."; and

(4) by striking paragraph (5).

(b) CONFORMING AMENDMENT.—Section 1852(c)(1)(I) (42 U.S.C. 1395w–22(c)(1)(I)) is amended to read as follows:

"(I) QUALITY IMPROVEMENT PROGRAM.—A description of the organization's quality improvement program under subsection (e).".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to contract years beginning on and after January 1, 2006.

SEC. 723. CHRONICALLY ILL MEDICARE BENEFICIARY RESEARCH, DATA, DEMONSTRATION STRATEGY.

(a) DEVELOPMENT OF PLAN.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall develop a plan to improve quality of care and reduce the cost of care for chronically ill medicare beneficiaries.

(b) PLAN REQUIREMENTS.—The plan will utilize existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill medicare beneficiaries. The plan shall—

(1) integrate existing data sets including, the Medicare Current Beneficiary Survey (MCBS), Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS), data from Quality Improvement Organizations (QIO), and claims data;

(2) identify any new data needs and a methodology to address new data needs;

(3) plan for the collection of such data in a data warehouse; and

(4) develop a research agenda using such data.

(c) CONSULTATION.—In developing the plan under this section, the Secretary shall consult with experts in the fields of care for the chronically ill (including clinicians).

(d) IMPLEMENTATION.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall implement the plan developed under this section. The Secretary may contract with appropriate entities to implement such plan.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary in fiscal years 2004 and 2005 to carry out this section.

Subtitle D—Other Provisions

SEC. 731. 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), as amended by sections 948 and 950, is amended—

(A) in the third sentence of subsection (a), by inserting "consistent with subsection (l)" after "the Secretary shall ensure"; and

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

"(l) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

"(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

"(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

"(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

"(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

"(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—

"(A) PERIOD FOR PROPOSED DECISION.—Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

"(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

"(C) 60-DAY PERIOD FOR FINAL DECISION.—Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

"(i) make a final decision on the request;

"(ii) include in such final decision summaries of the public comments received and responses to such comments;

"(iii) 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

"(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

"(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

"(5) LOCAL COVERAGE DETERMINATION PROCESS.—

"(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—

"(A) NATIONAL COVERAGE DETERMINATION.—The term 'national coverage determination' means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

"(B) LOCAL COVERAGE DETERMINATION.—The term 'local coverage determination' has the meaning given that in section 1869(f)(2)(B).".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to national coverage determinations as of January 1, 2004, and section 1862(l)(5) of the Social Security Act, as added by such paragraph, shall apply to local coverage determinations made on or after July 1, 2004.

(b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y), as amended by subsection (a), is amended by adding at the end the following new subsection:

"(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

"(1) IN GENERAL.—In the case of an individual entitled to benefits under part A, or enrolled under part B, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

"(2) CATEGORY A CLINICAL TRIAL.—For purposes of paragraph (1), a 'category A clinical trial' means a trial of a medical device if—

"(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

"(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

"(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to routine costs incurred on and after January 1, 2005, and, as of such date, section 411.15(o) of title 42, Code of Federal Regulations, is superseded to the extent inconsistent with section 1862(m) of the Social Security Act, as added by such paragraph.

(3) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed as applying to, or affecting, coverage or payment for a nonexperimental/investigational (category B) device.

(c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not later than July 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. 732. EXTENSION OF TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE.

Section 542(c) of BIPA (114 Stat. 2763A–551) is amended by inserting ", and for services furnished during 2005 and 2006" before the period at the end.

SEC. 733. PAYMENT FOR PANCREATIC ISLET CELL INVESTIGATIONAL TRANSPLANTS FOR MEDICARE BENEFICIARIES IN CLINICAL TRIALS.

(a) CLINICAL TRIAL.—

(1) IN GENERAL.—The Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation which includes medicare beneficiaries.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary to conduct the clinical investigation under paragraph (1).

(b) MEDICARE PAYMENT.—Not earlier than October 1, 2004, the Secretary shall pay for the routine costs as well as transplantation and appropriate related items and services (as described in subsection (c)) in the case of medicare beneficiaries who are participating in a clinical trial described in subsection (a) as if such transplantation were covered under title XVIII of such Act and as would be paid under part A or part B of such title for such beneficiary.

(c) SCOPE OF PAYMENT.—For purposes of subsection (b):

(1) The term "routine costs" means reasonable and necessary routine patient care costs (as defined in the Centers for Medicare & Medicaid Services Coverage Issues Manual, section 30–1), including immunosuppressive drugs and other followup care.

(2) The term "transplantation and appropriate related items and services" means items and services related to the acquisition and delivery of the pancreatic islet cell transplantation, notwithstanding any national noncoverage determination contained in the Centers for Medicare & Medicaid Services Coverage Issues Manual.

(3) The term "medicare beneficiary" means an individual who is entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both.

(d) CONSTRUCTION.—The provisions of this section shall not be construed—

(1) to permit payment for partial pancreatic tissue or islet cell transplantation under title XVIII of the Social Security Act other than payment as described in subsection (b); or

(2) as authorizing or requiring coverage or payment conveying—

(A) benefits under part A of such title to a beneficiary not entitled to such part A; or

(B) benefits under part B of such title to a beneficiary not enrolled in such part B.

SEC. 734. RESTORATION OF MEDICARE TRUST FUNDS.

(a) DEFINITIONS.—In this section:

(1) CLERICAL ERROR.—The term "clerical error" means a failure that occurs on or after April 15, 2001, to have transferred the correct amount from the general fund of the Treasury to a Trust Fund.

(2) TRUST FUND.—The term "Trust Fund" means the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i) and the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t).

(b) CORRECTION OF TRUST FUND HOLDINGS.—

(1) IN GENERAL.—The Secretary of the Treasury shall take the actions described in paragraph (2) with respect to the Trust Fund with the goal being that, after such actions are taken, the holdings of the Trust Fund will replicate, to the extent practicable in the judgment of the Secretary of the Treasury, in consultation with the Secretary, the holdings that would have been held by the Trust Fund if the clerical error involved had not occurred.

(2) OBLIGATIONS ISSUED AND REDEEMED.—The Secretary of the Treasury shall—

(A) issue to the Trust Fund obligations under chapter 31 of title 31, United States Code, that bear issue dates, interest rates, and maturity dates that are the same as those for the obligations that—

(i) would have been issued to the Trust Fund if the clerical error involved had not occurred; or

(ii) were issued to the Trust Fund and were redeemed by reason of the clerical error involved; and

(B) redeem from the Trust Fund obligations that would have been redeemed from the Trust Fund if the clerical error involved had not occurred.

(c) APPROPRIATION.—There is appropriated to the Trust Fund, out of any money in the Treasury not otherwise appropriated, an amount determined by the Secretary of the Treasury, in consultation with the Secretary, to be equal to the interest income lost by the Trust Fund through the date on which the appropriation is being made as a result of the clerical error involved.

(d) CONGRESSIONAL NOTICE.—In the case of a clerical error that occurs after April 15, 2001, the Secretary of the Treasury, before taking action to correct the error under this section, shall notify the appropriate committees of Congress concerning such error and the actions to be taken under this section in response to such error.

(e) DEADLINE.—With respect to the clerical error that occurred on April 15, 2001, not later than 120 days after the date of the enactment of this Act—

(1) the Secretary of the Treasury shall take the actions under subsection (b)(1); and

(2) the appropriation under subsection (c) shall be made.

SEC. 735. 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 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.

(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.

(e) REPRESENTATION OF EXPERTS IN PRESCRIPTION DRUGS.—

(1) IN GENERAL.—Section 1805(c)(2)(B) (42 U.S.C. 1395b–6(c)(2)(B)) is amended by inserting "experts in the area of pharmaco-economics or prescription drug benefit programs," after "other health professionals,".

(2) APPOINTMENT.—The Comptroller General of the United States shall ensure that the membership of the Commission complies with the amendment made by paragraph (1) with respect to appointments made on or after the date of the enactment of this Act.

SEC. 736. TECHNICAL AMENDMENTS.

(a) PART A.—(1) Section 1814(a) (42 U.S.C. 1395f(a)) is amended—

(A) by striking the seventh sentence, as added by section 322(a)(1) of BIPA (114 Stat. 2763A–501); and

(B) in paragraph (7)(A)—

(i) in clause (i), by inserting before the comma at the end the following: "based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness"; and

(ii) in clause (ii), by inserting before the semicolon at the end the following: "based on such clinical judgment".

(2) Section 1814(b) (42 U.S.C. 1395f(b)), in the matter preceding paragraph (1), is amended by inserting a comma after "1813".

(3) Section 1815(e)(1)(B) (42 U.S.C. 1395g(e)(1)(B)), in the matter preceding clause (i), is amended by striking "of hospital" and inserting "of a hospital".

(4) Section 1816(c)(2)(B)(ii) (42 U.S.C. 1395h(c)(2)(B)(ii)) is amended—

(A) by striking "and" at the end of subclause (III); and

(B) by striking the period at the end of subclause (IV) and inserting ", and".

(5) Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is amended—

(A) in clause (i)(I), by striking the comma at the end and inserting a semicolon; and

(B) in clause (ii), by striking "the Medicare and medicaid programs" and inserting "the programs under this title and title XIX".

(6) Section 1817(k)(6)(B) (42 U.S.C. 1395i(k)(6)(B)) is amended by striking "Medicare program under title XVIII" and inserting "program under this title".

(7) Section 1818 (42 U.S.C. 1395i–2) is amended—

(A) in subsection (d)(6)(A) is amended by inserting "of such Code" after "3111(b)"; and

(B) in subsection (g)(2)(B) is amended by striking "subsection (b)." and inserting "subsection (b)".

(8) Section 1819 (42 U.S.C. 1395i–3) is amended—

(A) in subsection (b)(4)(C)(i), by striking "at least at least" and inserting "at least";

(B) in subsection (d)(1)(A), by striking "physical mental" and inserting "physical, mental"; and

(C) in subsection (f)(2)(B)(iii), by moving the last sentence 2 ems to the left.

(9) Section 1886(b)(3)(I)(i)(I) (42 U.S.C. 1395ww(b)(3)(I)(i)(I)) is amended by striking "the the" and inserting "the".

(10) The heading of subsection (mm) of section 1861 (42 U.S.C. 1395x) is amended to read as follows:

"Critical Access Hospital; Critical Access Hospital Services".

(11) Paragraphs (1) and (2) of section 1861(tt) (42 U.S.C. 1395x(tt)) are each amended by striking "rural primary care" and inserting "critical access".

(12) Section 1865(b)(3)(B) (42 U.S.C. 1395bb(b)(3)(B)) is amended by striking "section 1819 and 1861(j)" and inserting "sections 1819 and 1861(j)".

(13) Section 1866(b)(2) (42 U.S.C. 1395cc(b)(2)) is amended by moving subparagraph (D) 2 ems to the left.

(14) Section 1867 (42 U.S.C. 1395dd) is amended—

(A) in the matter following clause (ii) of subsection (d)(1)(B), by striking "is is" and inserting "is";

(B) in subsection (e)(1)(B), by striking "a pregnant women" and inserting "a pregnant woman"; and

(C) in subsection (e)(2), by striking "means hospital" and inserting "means a hospital".

(15) Section 1886(g)(3)(B) (42 U.S.C. 1395ww(g)(3)(B)) is amended by striking "(as defined in subsection (d)(5)(D)(iii)" and inserting "(as defined in subsection (d)(5)(D)(iii))".

(b) PART B.—(1) Section 1833(h)(5)(D) (42 U.S.C. 1395l(h)(5)(D)) is amended by striking "clinic,," and inserting "clinic,".

(2) Section 1833(t)(3)(C)(ii) (42 U.S.C. 1395l(t)(3)(C)(ii)) is amended by striking "clause (iii)" and inserting "clause (iv)".

(3) Section 1861(v)(1)(S)(ii)(III) (42 U.S.C. 1395x(v)(1)(S)(ii)(III)) is amended by striking "(as defined in section 1886(d)(5)(D)(iii)" and inserting "(as defined in section 1886(d)(5)(D)(iii))".

(4) Section 1834(b)(4)(D)(iv) (42 U.S.C. 1395m(b)(4)(D)(iv)) is amended by striking "clauses (vi)" and inserting "clause (vi)".

(5) Section 1834(m)(4)(C)(ii)(III) (42 U.S.C. 1395m(m)(4)(C)(ii)(III)) is amended by striking "1861(aa)(s)" and inserting "1861(aa)(2)".

(6) Section 1838(a)(1) (42 U.S.C. 1395q(a)(1)) is amended by inserting a comma after "1966".

(7) The second sentence of section 1839(a)(4) (42 U.S.C. 1395r(a)(4)) is amended by striking "which will" and inserting "will".

(8) Section 1842(c)(2)(B)(ii) (42 U.S.C. 1395u(c)(2)(B)(ii)) is amended—

(A) by striking "and" at the end of subclause (III); and

(B) by striking the period at the end of subclause (IV) and inserting ", and".

(9) Section 1842(i)(2) (42 U.S.C. 1395u(i)(2)) is amended by striking "services, a physician" and inserting "services, to a physician".

(10) Section 1848(i)(3)(A) (42 U.S.C. 1395w–4(i)(3)(A)) is amended by striking "a comparable services" and inserting "comparable services".

(11) Section 1861(s)(2)(K)(i) (42 U.S.C. 1395x(s)(2)(K)(i)) is amended by striking "; and but" and inserting ", but".

(12) Section 1861(aa)(1)(B) (42 U.S.C. 1395x(aa)(1)(B)) is amended by striking ",," and inserting a comma.

(13) Section 128(b)(2) of BIPA (114 Stat. 2763A–480) is amended by striking "Not later that" and inserting "Not later than" each place it appears.

(c) PARTS A AND B.—(1) Section 1812(a)(3) (42 U.S.C. 1395d(a)(3)) is amended—

(A) by striking "for individuals not" and inserting "in the case of individuals not"; and

(B) by striking "for individuals so" and inserting "in the case of individuals so".

(2)(A) Section 1814(a) (42 U.S.C. 1395f(a)) is amended in the sixth sentence by striking "leave home," and inserting "leave home and".

(B) Section 1835(a) (42 U.S.C. 1395n(a)) is amended in the seventh sentence by striking "leave home," and inserting "leave home and".

(3) Section 1891(d)(1) (42 U.S.C. 1395bbb(d)(1)) is amended by striking "subsection (c)(2)(C)(I)" and inserting "subsection (c)(2)(C)(i)(I)".

(4) Section 1861(v) (42 U.S.C. 1395x(v)) is amended by moving paragraph (8) (including clauses (i) through (v) of such paragraph) 2 ems to the left.

(5) Section 1866B(b)(7)(D) (42 U.S.C. 1395cc–2(b)(7)(D)) is amended by striking "(c)(2)(A)(ii)" and inserting "(c)(2)(B)".

(6) Section 1886(h)(3)(D)(ii)(III) (42 U.S.C. 1395ww(h)(3)(D)(ii)(III)) is amended by striking "and" after the comma at the end.

(7) Section 1893(a) (42 U.S.C. 1395ddd(a)) is amended by striking "Medicare program" and inserting "medicare program".

(8) Section 1896(b)(4) (42 U.S.C. 1395ggg(b)(4)) is amended by striking "701(f)" and inserting "712(f)".

(d) PART C.—(1) Section 1853 (42 U.S.C. 1395w–23), as amended by section 607 of BIPA (114 Stat. 2763A–558), is amended—

(A) in subsection (a)(3)(C)(ii), by striking "clause (iii)" and inserting "clause (iv)";

(B) in subsection (a)(3)(C), by redesignating the clause (iii) added by such section 607 as clause (iv); and

(C) in subsection (c)(5), by striking "(a)(3)(C)(iii)" and inserting "(a)(3)(C)(iv)".

(2) Section 1876 (42 U.S.C. 1395mm) is amended—

(A) in subsection (c)(2)(B), by striking "signifcant" and inserting "significant"; and

(B) in subsection (j)(2), by striking "this setion" and inserting "this section".

(e) MEDIGAP.—Section 1882 (42 U.S.C. 1395ss) is amended—

(1) in subsection (d)(3)(A)(i)(II), by striking "plan a medicare supplemental policy" and inserting "plan, a medicare supplemental policy";

(2) in subsection (d)(3)(B)(iii)(II), by striking "to the best of the issuer or seller's knowledge" and inserting "to the best of the issuer's or seller's knowledge";

(3) in subsection (g)(2)(A), by striking "medicare supplement policies" and inserting "medicare supplemental policies";

(4) in subsection (p)(2)(B), by striking ", and" and inserting "; and"; and

(5) in subsection (s)(3)(A)(iii), by striking "pre-existing" and inserting "preexisting".

TITLE VIII—COST CONTAINMENT

Subtitle A—Cost Containment

SEC. 801. INCLUSION IN ANNUAL REPORT OF MEDICARE TRUSTEES OF INFORMATION ON STATUS OF MEDICARE TRUST FUNDS.

(a) DETERMINATIONS OF EXCESS GENERAL REVENUE MEDICARE FUNDING.—

(1) IN GENERAL.—The Board of Trustees of each medicare trust fund shall include in the annual reports submitted under subsection (b)(2) of sections 1817 and 1841 of the Social Security Act (42 U.S.C. 1395i and 1395t)—

(A) the information described in subsection (b); and

(B) a determination as to whether there is projected to be excess general revenue medicare funding (as defined in subsection (c)) for the fiscal year in which the report is submitted or for any of the succeeding 6 fiscal years.

(2) MEDICARE FUNDING WARNING.—For purposes of section 1105(h) of title 31, United States Code, and this subtitle, an affirmative determination under paragraph (1)(B) in 2 consecutive annual reports shall be treated as a medicare funding warning in the year in which the second such report is made.

(3) 7-FISCAL-YEAR REPORTING PERIOD.—For purposes of this subtitle, the term "7-fiscal-year reporting period" means, with respect to a year in which an annual report described in paragraph (1) is made, the period of 7 consecutive fiscal years beginning with the fiscal year in which the report is submitted.

(b) INFORMATION.—The information described in this subsection for an annual report in a year is as follows:

(1) PROJECTIONS OF GROWTH OF GENERAL REVENUE SPENDING.—A statement of the general revenue medicare funding as a percentage of the total medicare outlays for each of the following:

(A) Each fiscal year within the 7-fiscal-year reporting period.

(B) Previous fiscal years and as of 10, 50, and 75 years after such year.

(2) COMPARISON WITH OTHER GROWTH TRENDS.—A comparison of the trend of such percentages with the annual growth rate in the following:

(A) The gross domestic product.

(B) Private health costs.

(C) National health expenditures.

(D) Other appropriate measures.

(3) PART D SPENDING.—Expenditures, including trends in expenditures, under part D of title XVIII of the Social Security Act, as added by section 101.

(4) COMBINED MEDICARE TRUST FUND ANALYSIS.—A financial analysis of the combined medicare trust funds if general revenue medicare funding were limited to the percentage specified in subsection (c)(1)(B) of total medicare outlays.

(c) DEFINITIONS.—For purposes of this section:

(1) EXCESS GENERAL REVENUE MEDICARE FUNDING.—The term "excess general revenue medicare funding" means, with respect to a fiscal year, that—

(A) general revenue medicare funding (as defined in paragraph (2)), expressed as a percentage of total medicare outlays (as defined in paragraph (4)) for the fiscal year; exceeds

(B) 45 percent.

(2) GENERAL REVENUE MEDICARE FUNDING.—The term "general revenue medicare funding" means for a year—

(A) the total medicare outlays (as defined in paragraph (4)) for the year; minus

(B) the dedicated medicare financing sources (as defined in paragraph (3)) for the year.

(3) DEDICATED MEDICARE FINANCING SOURCES.—The term "dedicated medicare financing sources" means the following:

(A) HOSPITAL INSURANCE TAX.—Amounts appropriated to the Hospital Insurance Trust Fund under the third sentence of section 1817(a) of the Social Security Act (42 U.S.C. 1395i(a)) and amounts transferred to such Trust Fund under section 7(c)(2) of the Railroad Retirement Act of 1974 (45 U.S.C. 231f(c)(2)).

(B) TAXATION OF CERTAIN OASDI BENEFITS.—Amounts appropriated to the Hospital Insurance Trust Fund under section 121(e)(1)(B) of the Social Security Amendments of 1983 (Public Law 98–21), as inserted by section 13215(c) of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

(C) STATE TRANSFERS.—The State share of amounts paid to the Federal Government by a State under section 1843 of the Social Security Act (42 U.S.C. 1395v) or pursuant to section 1935(c) of such Act.

(D) PREMIUMS.—The following premiums:

(i) PART A.—Premiums paid by non-Federal sources under sections 1818 and section 1818A (42 U.S.C. 1395i–2 and 1395i–2a) of such Act.

(ii) PART B.—Premiums paid by non-Federal sources under section 1839 of such Act (42 U.S.C. 1395r), including any adjustments in premiums under such section.

(iii) PART D.—Monthly beneficiary premiums paid under part D of title XVIII of such Act, as added by section 101, and MA monthly prescription drug beneficiary premiums paid under part C of such title insofar as they are attributable to basic prescription drug coverage.

Premiums under clauses (ii) and (iii) shall be determined without regard to any reduction in such premiums attributable to a beneficiary rebate under section 1854(b)(1)(C) of such title, as amended by section 222(b)(1), and premiums under clause (iii) are deemed to include any amounts paid under section 1860D–13(b) of such title, as added by section 101.

(E) GIFTS.—Amounts received by the medicare trust funds under section 201(i) of the Social Security Act (42 U.S.C. 401(i)).

(4) TOTAL MEDICARE OUTLAYS.—The term "total medicare outlays" means total outlays from the medicare trust funds and shall—

(A) include payments made to plans under part C of title XVIII of the Social Security Act that are attributable to any rebates under section 1854(b)(1)(C) of such Act (42 U.S.C. 1395w–24(b)(1)(C)), as amended by section 222(b)(1);

(B) include administrative expenditures made in carrying out title XVIII of such Act and Federal outlays under section 1935(b) of such Act, as added by section 103(a)(2); and

(C) offset outlays by the amount of fraud and abuse collections insofar as they are applied or deposited into a medicare trust fund.

(5) MEDICARE TRUST FUND.—The term "medicare trust fund" means—

(A) the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i); and

(B) the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t), including the Medicare Prescription Drug Account under such Trust Fund.

(d) CONFORMING AMENDMENTS.—

(1) FEDERAL HOSPITAL INSURANCE TRUST FUND.—Section 1817(b)(2) (42 U.S.C. 1395i(b)(2)) is amended by adding at the end the following: "Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.".

(2) FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841(b)(2) (42 U.S.C. 1395t(b)(2)) is amended by adding at the end the following: "Each report provided

under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.".

(e) NOTICE OF MEDICARE FUNDING WARNING.—Whenever any report described in subsection (a) contains a determination that for any fiscal year within the 7-fiscal-year reporting period there will be excess general revenue medicare funding, Congress and the President should address the matter under existing rules and procedures.

SEC. 802. PRESIDENTIAL SUBMISSION OF LEGISLATION.

(a) IN GENERAL.—Section 1105 of title 31, United States Code, is amended by adding at the end the following new subsection:

"(h)(1) If there is a medicare funding warning under section 801(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 made in a year, the President shall submit to Congress, within the 15-day period beginning on the date of the budget submission to Congress under subsection (a) for the succeeding year, proposed legislation to respond to such warning.

"(2) Paragraph (1) does not apply if, during the year in which the warning is made, legislation is enacted which eliminates excess general revenue medicare funding (as defined in section 801(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) for the 7-fiscal-year reporting period, as certified by the Board of Trustees of each medicare trust fund (as defined in section 801(c)(5) of such Act) not later than 30 days after the date of the enactment of such legislation.".

(b) SENSE OF CONGRESS.—It is the sense of Congress that legislation submitted pursuant to section 1105(h) of title 31, United States Code, in a year should be designed to eliminate excess general revenue medicare funding (as defined in section 801(c)) for the 7-fiscal-year period that begins in such year.

SEC. 803. PROCEDURES IN THE HOUSE OF REPRESENTATIVES.

(a) INTRODUCTION AND REFERRAL OF PRESIDENT'S LEGISLATIVE PROPOSAL.—

(1) INTRODUCTION.—In the case of a legislative proposal submitted by the President pursuant to section 1105(h) of title 31, United States Code, within the 15-day period specified in paragraph (1) of such section, the Majority Leader of the House of Representatives (or his designee) and the Minority Leader of the House of Representatives (or his designee) shall introduce such proposal (by request), the title of which is as follows: "A bill to respond to a medicare funding warning." Such bill shall be introduced within 3 legislative days after Congress receives such proposal.

(2) REFERRAL.—Any legislation introduced pursuant to paragraph (1) shall be referred to the appropriate committees of the House of Representatives.

(b) DIRECTION TO THE APPROPRIATE HOUSE COMMITTEES.—

(1) IN GENERAL.—In the House, in any year during which the President is required to submit proposed legislation to Congress under section 1105(h) of title 31, United States Code, the appropriate committees shall report medicare funding legislation by not later than June 30 of such year.

(2) MEDICARE FUNDING LEGISLATION.—For purposes of this section, the term "medicare funding legislation" means—

(A) legislation introduced pursuant to subsection (a)(1), but only if the legislative proposal upon which the legislation is based was submitted within the 15-day period referred to in such subsection; or

(B) any bill the title of which is as follows: "A bill to respond to a medicare funding warning.".

(3) CERTIFICATION.—With respect to any medicare funding legislation or any amendment to such legislation to respond to a medicare funding warning, the chairman of the Committee on the Budget of the House shall certify—

(A) whether or not such legislation eliminates excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in the 7-fiscal-year reporting period; and

(B) with respect to such an amendment, whether the legislation, as amended, would eliminate excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in such 7-fiscal-year reporting period.

(c) FALLBACK PROCEDURE FOR FLOOR CONSIDERATION IF THE HOUSE FAILS TO VOTE ON FINAL PASSAGE BY JULY 30.—

(1) After July 30 of any year during which the President is required to submit proposed legislation to Congress under section 1105(h) of title 31, United States Code, unless the House of Representatives has voted on final passage of any medicare funding legislation for which there is an affirmative certification under subsection (b)(3)(A), then, after the expiration of not less than 30 calendar days (and concurrently 5 legislative days), it is in order to move to discharge any committee to which medicare funding legislation which has such a certification and which has been referred to such committee for 30 calendar days from further consideration of the legislation.

(2) A motion to discharge may be made only by an individual favoring the legislation, may be made only if supported by one-fifth of the total membership of the House (a quorum being present), and is highly privileged in the House. Debate thereon shall be limited to not more than one hour, the time to be divided in the House equally between those favoring and those opposing the motion. An amendment to the motion is not in order, and it is not in order to move to reconsider the vote by which the motion is agreed to or disagreed to.

(3) Only one motion to discharge a particular committee may be adopted under this subsection in any session of a Congress.

(4) Notwithstanding paragraph (1), it shall not be in order to move to discharge a committee from further consideration of medicare funding legislation pursuant to this subsection during a session of a Congress if, during the previous session of the Congress, the House passed medicare funding legislation for which there is an affirmative certification under subsection (b)(3)(A).

(d) FLOOR CONSIDERATION IN THE HOUSE OF DISCHARGED LEGISLATION.—

(1) In the House, not later than 3 legislative days after any committee has been discharged from further consideration

of legislation under subsection (c), the Speaker shall resolve the House into the Committee of the Whole for consideration of the legislation.

(2) The first reading of the legislation shall be dispensed with. All points of order against consideration of the legislation are waived. General debate shall be confined to the legislation and shall not exceed five hours, which shall be divided equally between those favoring and those opposing the legislation. After general debate the legislation shall be considered for amendment under the five-minute rule. During consideration of the legislation, no amendments shall be in order in the House or in the Committee of the Whole except those for which there has been an affirmative certification under subsection (b)(3)(B). All points of order against consideration of any such amendment in the Committee of the Whole are waived. The legislation, together with any amendments which shall be in order, shall be considered as read. During the consideration of the bill for amendment, the Chairman of the Committee of the Whole may accord priority in recognition on the basis of whether the Member offering an amendment has caused it to be printed in the portion of the Congressional Record designated for that purpose in clause 8 of Rule XVIII of the Rules of the House of Representatives. Debate on any amendment shall not exceed one hour, which shall be divided equally between those favoring and those opposing the amendment, and no pro forma amendments shall be offered during the debate. The total time for debate on all amendments shall not exceed 10 hours. At the conclusion of consideration of the legislation for amendment, the Committee shall rise and report the legislation to the House with such amendments as may have been adopted. The previous question shall be considered as ordered on the legislation and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions. If the Committee of the Whole rises and reports that it has come to no resolution on the bill, then on the next legislative day the House shall, immediately after the third daily order of business under clause 1 of Rule XIV of the Rules of the House of Representatives, resolve into the Committee of the Whole for further consideration of the bill.

(3) All appeals from the decisions of the Chair relating to the application of the Rules of the House of Representatives to the procedure relating to any such legislation shall be decided without debate.

(4) Except to the extent specifically provided in the preceding provisions of this subsection, consideration of any such legislation and amendments thereto (or any conference report thereon) shall be governed by the Rules of the House of Representatives applicable to other bills and resolutions, amendments, and conference reports in similar circumstances.

(e) LEGISLATIVE DAY DEFINED.—As used in this section, the term "legislative day" means a day on which the House of Representatives is in session.

(f) RESTRICTION ON WAIVER.—In the House, the provisions of this section may be waived only by a rule or order proposing only to waive such provisions.

(g) RULEMAKING POWER.—The provisions of this section are enacted by the Congress—

(1) as an exercise of the rulemaking power of the House of Representatives and, as such, shall be considered as part of the rules of that House and shall supersede other rules only to the extent that they are inconsistent therewith; and

(2) with full recognition of the constitutional right of that House to change the rules (so far as they relate to the procedures of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

SEC. 804. PROCEDURES IN THE SENATE.

(a) INTRODUCTION AND REFERRAL OF PRESIDENT'S LEGISLATIVE PROPOSAL.—

(1) INTRODUCTION.—In the case of a legislative proposal submitted by the President pursuant to section 1105(h) of title 31, United States Code, within the 15-day period specified in paragraph (1) of such section, the Majority Leader and Minority Leader of the Senate (or their designees) shall introduce such proposal (by request), the title of which is as follows: "A bill to respond to a medicare funding warning." Such bill shall be introduced within 3 days of session after Congress receives such proposal.

(2) REFERRAL.—Any legislation introduced pursuant to paragraph (1) shall be referred to the Committee on Finance.

(b) MEDICARE FUNDING LEGISLATION.—For purposes of this section, the term "medicare funding legislation" means—

(1) legislation introduced pursuant to subsection (a)(1), but only if the legislative proposal upon which the legislation is based was submitted within the 15-day period referred to in such subsection; or

(2) any bill the title of which is as follows: "A bill to respond to a medicare funding warning.".

(c) QUALIFICATION FOR SPECIAL PROCEDURES.—

(1) IN GENERAL.—The special procedures set forth in subsections (d) and (e) shall apply to medicare funding legislation, as described in subsection (b), only if the legislation—

(A) is medicare funding legislation that is passed by the House of Representatives; or

(B) contains matter within the jurisdiction of the Committee on Finance in the Senate.

(2) FAILURE TO QUALIFY FOR SPECIAL PROCEDURES.—If the medicare funding legislation does not satisfy paragraph (1), then the legislation shall be considered under the ordinary procedures of the Standing Rules of the Senate.

(d) DISCHARGE.—

(1) IN GENERAL.—If the Committee on Finance has not reported medicare funding legislation described in subsection (c)(1) by June 30 of a year in which the President is required to submit medicare funding legislation to Congress under section 1105(h) of title 31, United States Code, then any Senator may move to discharge the Committee of any single medicare funding legislation measure. Only one such motion shall be in order in any session of Congress.

(2) DEBATE LIMITS.—Debate in the Senate on any such motion to discharge, and all appeals in connection therewith, shall be limited to not more than 2 hours. The time shall be equally divided between, and controlled by, the maker of

the motion and the Majority Leader, or their designees, except that in the event the Majority Leader is in favor of such motion, the time in opposition thereto shall be controlled by the Minority Leader or the Minority Leader's designee. A point of order under this subsection may be made at any time. It is not in order to move to proceed to another measure or matter while such motion (or the motion to reconsider such motion) is pending.

(3) AMENDMENTS.—No amendment to the motion to discharge shall be in order.

(4) EXCEPTION IF CERTIFIED LEGISLATION ENACTED.—Notwithstanding paragraph (1), it shall not be in order to discharge the Committee from further consideration of medicare funding legislation pursuant to this subsection during a session of a Congress if the chairman of the Committee on the Budget of the Senate certifies that medicare funding legislation has been enacted that eliminates excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in the 7-fiscal-year reporting period.

(e) CONSIDERATION.—After the date on which the Committee on Finance has reported medicare funding legislation described in subsection (c)(1), or has been discharged (under subsection (d)) from further consideration of, such legislation, it is in order (even though a previous motion to the same effect has been disagreed to) for any Member of the Senate to move to proceed to the consideration of such legislation.

(f) RULES OF THE SENATE.—This section is enacted by the Senate—

(1) as an exercise of the rulemaking power of the Senate and as such it is deemed a part of the rules of the Senate, but applicable only with respect to the procedure to be followed in the Senate in the case of a bill described in this paragraph, and it supersedes other rules only to the extent that it is inconsistent with such rules; and

(2) with full recognition of the constitutional right of the Senate to change the rules (so far as relating to the procedure of the Senate) at any time, in the same manner, and to the same extent as in the case of any other rule of the Senate.

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

SEC. 811. INCOME-RELATED REDUCTION IN PART B PREMIUM SUBSIDY.

(a) IN GENERAL.—Section 1839 (42 U.S.C. 1395r), as amended by section 241(c), is amended by adding at the end the following:

"(i) REDUCTION IN PREMIUM SUBSIDY BASED ON INCOME.—

"(1) IN GENERAL.—In the case of an individual whose modified adjusted gross income exceeds the threshold amount under paragraph (2), the monthly amount of the premium subsidy applicable to the premium under this section for a month after December 2006 shall be reduced (and the monthly premium shall be increased) by the monthly adjustment amount specified in paragraph (3).

"(2) THRESHOLD AMOUNT.—For purposes of this subsection, the threshold amount is—

"(A) except as provided in subparagraph (B), $80,000, and

"(B) in the case of a joint return, twice the amount applicable under subparagraph (A) for the calendar year.

"(3) MONTHLY ADJUSTMENT AMOUNT.—

"(A) IN GENERAL.—Subject to subparagraph (B), the monthly adjustment amount specified in this paragraph for an individual for a month in a year is equal to the product of the following:

"(i) SLIDING SCALE PERCENTAGE.—The applicable percentage specified in the table in subparagraph (C) for the individual minus 25 percentage points.

"(ii) UNSUBSIDIZED PART B PREMIUM AMOUNT.—200 percent of the monthly actuarial rate for enrollees age 65 and over (as determined under subsection (a)(1) for the year).

"(B) 5-YEAR PHASE IN.—The monthly adjustment amount specified in this paragraph for an individual for a month in a year before 2011 is equal to the following percentage of the monthly adjustment amount specified in subparagraph (A):

"(i) For 2007, 20 percent.

"(ii) For 2008, 40 percent.

"(iii) For 2009, 60 percent.

"(iv) for 2010, 80 percent.

"(C) APPLICABLE PERCENTAGE.—

"(i) IN GENERAL.—

"If the modified adjusted gross income is:	**The applicable percentage is:**
More than $80,000 but not more than $100,000	35 percent
More than $100,000 but not more than $150,000	50 percent
More than $150,000 but not more than $200,000	65 percent
More than $200,000	80 percent.

"(ii) JOINT RETURNS.—In the case of a joint return, clause (i) shall be applied by substituting dollar amounts which are twice the dollar amounts otherwise applicable under clause (i) for the calendar year.

"(iii) MARRIED INDIVIDUALS FILING SEPARATE RETURNS.—In the case of an individual who—

"(I) is married as of the close of the taxable year (within the meaning of section 7703 of the Internal Revenue Code of 1986) but does not file a joint return for such year, and

"(II) does not live apart from such individual's spouse at all times during the taxable year,

clause (i) shall be applied by reducing each of the dollar amounts otherwise applicable under such clause for the calendar year by the threshold amount for such year applicable to an unmarried individual.

"(4) MODIFIED ADJUSTED GROSS INCOME.—

"(A) IN GENERAL.—For purposes of this subsection, the term 'modified adjusted gross income' means adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986)—

"(i) determined without regard to sections 135, 911, 931, and 933 of such Code; and

"(ii) increased by the amount of interest received or accrued during the taxable year which is exempt from tax under such Code.

In the case of an individual filing a joint return, any reference in this subsection to the modified adjusted gross income of such individual shall be to such return's modified adjusted gross income.

"(B) TAXABLE YEAR TO BE USED IN DETERMINING MODIFIED ADJUSTED GROSS INCOME.—

"(i) IN GENERAL.—In applying this subsection for an individual's premiums in a month in a year, subject to clause (ii) and subparagraph (C), the individual's modified adjusted gross income shall be such income determined for the individual's last taxable year beginning in the second calendar year preceding the year involved.

"(ii) TEMPORARY USE OF OTHER DATA.—If, as of October 15 before a calendar year, the Secretary of the Treasury does not have adequate data for an individual in appropriate electronic form for the taxable year referred to in clause (i), the individual's modified adjusted gross income shall be determined using the data in such form from the previous taxable year. Except as provided in regulations prescribed by the Commissioner of Social Security in consultation with the Secretary, the preceding sentence shall cease to apply when adequate data in appropriate electronic form are available for the individual for the taxable year referred to in clause (i), and proper adjustments shall be made to the extent that the premium adjustments determined under the preceding sentence were inconsistent with those determined using such taxable year.

"(iii) NON-FILERS.—In the case of individuals with respect to whom the Secretary of the Treasury does not have adequate data in appropriate electronic form for either taxable year referred to in clause (i) or clause (ii), the Commissioner of Social Security, in consultation with the Secretary, shall prescribe regulations which provide for the treatment of the premium adjustment with respect to such individual under this subsection, including regulations which provide for—

"(I) the application of the highest applicable percentage under paragraph (3)(C) to such individual if the Commissioner has information which indicates that such individual's modified adjusted gross income might exceed the threshold amount for the taxable year referred to in clause (i), and

"(II) proper adjustments in the case of the application of an applicable percentage under subclause (I) to such individual which is inconsistent with such individual's modified adjusted gross income for such taxable year.

"(C) USE OF MORE RECENT TAXABLE YEAR.—

"(i) IN GENERAL.—The Commissioner of Social Security in consultation with the Secretary of the Treasury shall establish a procedures under which an

individual's modified adjusted gross income shall, at the request of such individual, be determined under this subsection—

"(I) for a more recent taxable year than the taxable year otherwise used under subparagraph (B), or

"(II) by such methodology as the Commissioner, in consultation with such Secretary, determines to be appropriate, which may include a methodology for aggregating or disaggregating information from tax returns in the case of marriage or divorce.

"(ii) STANDARD FOR GRANTING REQUESTS.—A request under clause (i)(I) to use a more recent taxable year may be granted only if—

"(I) the individual furnishes to such Commissioner with respect to such year such documentation, such as a copy of a filed Federal income tax return or an equivalent document, as the Commissioner specifies for purposes of determining the premium adjustment (if any) under this subsection; and

"(II) the individual's modified adjusted gross income for such year is significantly less than such income for the taxable year determined under subparagraph (B) by reason of the death of such individual's spouse, the marriage or divorce of such individual, or other major life changing events specified in regulations prescribed by the Commissioner in consultation with the Secretary.

"(5) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—In the case of any calendar year beginning after 2007, each dollar amount in paragraph (2) or (3) shall be increased by an amount equal to—

"(i) such dollar amount, multiplied by

"(ii) the percentage (if any) by which the average of the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with August of the preceding calendar year exceeds such average for the 12-month period ending with August 2006.

"(B) ROUNDING.—If any dollar amount after being increased under subparagraph (A) is not a multiple of $1,000, such dollar amount shall be rounded to the nearest multiple of $1,000.

"(6) JOINT RETURN DEFINED.—For purposes of this subsection, the term 'joint return' has the meaning given to such term by section 7701(a)(38) of the Internal Revenue Code of 1986.".

(b) CONFORMING AMENDMENTS.—

(1) Section 1839 (42 U.S.C. 1395r) is amended—

(A) in subsection (a)(2), by striking "and (f)" and inserting "(f), and (i)";

(B) in subsection (b), inserting "(without regard to any adjustment under subsection (i))" after "subsection (a)"; and

(C) in subsection (f)—

(i) by striking "and if" and inserting "if"; and

(ii) by inserting "and if the amount of the individual's premium is not adjusted for such January under subsection (i)," after "section 1840(b)(1),".

(2) Section 1844 (42 U.S.C. 1395w) is amended—

(A) in subsection (a)(1)—

(i) in subparagraph (B), by striking "plus" at the end and inserting "minus"; and

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

"(C) the aggregate amount of additional premium payments attributable to the application of section 1839(i); plus"; and

(B) in subsection (c), by inserting before the period at the end the following: "and without regard to any premium adjustment under section 1839(i)".

(c) REPORTING REQUIREMENTS FOR SECRETARY OF THE TREASURY.—

(1) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for purposes other than tax administration), as amended by section 105(e), is amended by adding at the end the following new paragraph:

"(20) DISCLOSURE OF RETURN INFORMATION TO CARRY OUT MEDICARE PART B PREMIUM SUBSIDY ADJUSTMENT.—

"(A) IN GENERAL.—The Secretary shall, upon written request from the Commissioner of Social Security, disclose to officers, employees, and contractors of the Social Security Administration return information of a taxpayer whose premium (according to the records of the Secretary) may be subject to adjustment under section 1839(i) of the Social Security Act. Such return information shall be limited to—

"(i) taxpayer identity information with respect to such taxpayer,

"(ii) the filing status of such taxpayer,

"(iii) the adjusted gross income of such taxpayer,

"(iv) the amounts excluded from such taxpayer's gross income under sections 135 and 911 to the extent such information is available,

"(v) the interest received or accrued during the taxable year which is exempt from the tax imposed by chapter 1 to the extent such information is available,

"(vi) the amounts excluded from such taxpayer's gross income by sections 931 and 933 to the extent such information is available,

"(vii) such other information relating to the liability of the taxpayer as is prescribed by the Secretary by regulation as might indicate in the case of a taxpayer who is an individual described in subsection (i)(4)(B)(iii) of section 1839 of the Social Security Act that the amount of the premium of the taxpayer under such section may be subject to adjustment under subsection (i) of such section and the amount of such adjustment, and

"(viii) the taxable year with respect to which the preceding information relates.

"(B) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under subparagraph

(A) may be used by officers, employees, and contractors of the Social Security Administration only for the purposes of, and to the extent necessary in, establishing the appropriate amount of any premium adjustment under such section 1839(i)."

(2) CONFORMING AMENDMENTS.—

(A) Paragraph (3) of section 6103(a) of such Code, as amended by section 105(e)(1), is amended by striking "or (19)" and inserting "(19), or (20)".

(B) Paragraph (4) of section 6103(p) of such Code, as amended by section 105(e)(3), is amended by striking "(l)(16), (17), or (19)" each place it appears and inserting "(l)(16), (17), (19), or (20)".

(C) Paragraph (2) of section 7213(a) of such Code, as amended by section 105(e)(4), is amended by striking "or (19)" and inserting "(19), or (20)".

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

SEC. 900. ADMINISTRATIVE IMPROVEMENTS WITHIN THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS).

(a) COORDINATED ADMINISTRATION OF MEDICARE PRESCRIPTION DRUG AND MEDICARE ADVANTAGE PROGRAMS.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by section 721, is amended by inserting after 1807 the following new section:

"PROVISIONS RELATING TO ADMINISTRATION

"SEC. 1808. (a) COORDINATED ADMINISTRATION OF MEDICARE PRESCRIPTION DRUG AND MEDICARE ADVANTAGE PROGRAMS.—

"(1) IN GENERAL.—There is within the Centers for Medicare & Medicaid Services a center to carry out the duties described in paragraph (3).

"(2) DIRECTOR.—Such center shall be headed by a director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

"(3) DUTIES.—The duties described in this paragraph are the following:

"(A) The administration of parts C and D.

"(B) The provision of notice and information under section 1804.

"(C) Such other duties as the Secretary may specify.

"(4) DEADLINE.—The Secretary shall ensure that the center is carrying out the duties described in paragraph (3) by not later than January 1, 2008.".

(b) MANAGEMENT STAFF FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—Such section is further amended by adding at the end the following new subsection:

"(b) EMPLOYMENT OF MANAGEMENT STAFF.—

"(1) IN GENERAL.—The Secretary may employ, within the Centers for Medicare & Medicaid Services, such individuals as management staff as the Secretary determines to be appropriate. With respect to the administration of parts C and D,

such individuals shall include individuals with private sector expertise in negotiations with health benefits plans.

"(2) ELIGIBILITY.—To be eligible for employment under paragraph (1) an individual shall be required to have demonstrated, by their education and experience (either in the public or private sector), superior expertise in at least one of the following areas:

"(A) The review, negotiation, and administration of health care contracts.

"(B) The design of health care benefit plans.

"(C) Actuarial sciences.

"(D) Compliance with health plan contracts.

"(E) Consumer education and decision making.

"(F) Any other area specified by the Secretary that requires specialized management or other expertise.

"(3) RATES OF PAYMENT.—

"(A) PERFORMANCE-RELATED PAY.—Subject to subparagraph (B), the Secretary shall establish the rate of pay for an individual employed under paragraph (1). Such rate shall take into account expertise, experience, and performance.

"(B) LIMITATION.—In no case may the rate of compensation determined under subparagraph (A) exceed the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.".

(c) REQUIREMENT FOR DEDICATED ACTUARY FOR PRIVATE HEALTH PLANS.—Section 1117(b) (42 U.S.C. 1317(b)) is amended by adding at the end the following new paragraph:

"(3) In the office of the Chief Actuary there shall be an actuary whose duties relate exclusively to the programs under parts C and D of title XVIII and related provisions of such title.".

(d) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

(1) IN GENERAL.—Section 5314 of title 5, United States Code, is amended by adding at the end the following:

"Administrator of the Centers for Medicare & Medicaid Services.".

(2) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking "Administrator of the Health Care Financing Administration.".

(3) EFFECTIVE DATE.—The amendments made by this subsection take effect on January 1, 2004.

(e) CONFORMING AMENDMENTS RELATING TO HEALTH CARE FINANCING ADMINISTRATION.—

(1) AMENDMENTS TO THE SOCIAL SECURITY ACT.—The Social Security Act is amended—

(A) in section 1117 (42 U.S.C. 1317)—

(i) in the heading to read as follows:

"APPOINTMENT OF THE ADMINISTRATOR AND CHIEF ACTUARY OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES";

(ii) in subsection (a), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services"; and

(iii) in subsection (b)(1)—

(I) by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services"; and

(II) by striking "Administration" and inserting "Centers";

(B) in section 1140(a) (42 U.S.C. 1320b–10(a))—

(i) in paragraph (1), by striking "Health Care Financing Administration" both places it appears in the matter following subparagraph (B) and inserting "Centers for Medicare & Medicaid Services";

(ii) in paragraph (1)(A)—

(I) by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services"; and

(II) by striking "HCFA" and inserting "CMS"; and

(iii) in paragraph (1)(B), by striking "Health Care Financing Administration" both places it appears and inserting "Centers for Medicare & Medicaid Services";

(C) in section 1142(b)(3) (42 U.S.C. 1320b–12(b)(3)), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(D) in section 1817(b) (42 U.S.C. 1395i(b))—

(i) by striking "Health Care Financing Administration", both in the fifth sentence of the matter preceding paragraph (1) and in the second sentence of the matter following paragraph (4), and inserting "Centers for Medicare & Medicaid Services"; and

(ii) by striking "Chief Actuarial Officer" in the second sentence of the matter following paragraph (4) and inserting "Chief Actuary";

(E) in section 1841(b) (42 U.S.C. 1395t(b))—

(i) by striking "Health Care Financing Administration", both in the fifth sentence of the matter preceding paragraph (1) and in the second sentence of the matter following paragraph (4), and inserting "Centers for Medicare & Medicaid Services"; and

(ii) by striking "Chief Actuarial Officer" in the second sentence of the matter following paragraph (4) and inserting "Chief Actuary";

(F) in section 1852(a)(5) (42 U.S.C. 1395w–22(a)(5)), by striking "Health Care Financing Administration" in the matter following subparagraph (B) and inserting "Centers for Medicare & Medicaid Services";

(G) in section 1853 (42 U.S.C. 1395w–23)—

(i) in subsection (b)(4), by striking "Health Care Financing Administration" in the first sentence and inserting "Centers for Medicare & Medicaid Services"; and

(ii) in subsection (c)(7), by striking "Health Care Financing Administration" in the last sentence and inserting "Centers for Medicare & Medicaid Services";

(H) in section 1854(a)(5)(A) (42 U.S.C. 1395w–24(a)(5)(A)), by striking "Health Care Financing Administration"and inserting "Centers for Medicare & Medicaid Services";

(I) in section 1857(d)(4)(A)(ii) (42 U.S.C. 1395w–27(d)(4)(A)(ii)), by striking "Health Care Financing Administration" and inserting "Secretary";

(J) in section 1862(b)(5)(A)(ii) (42 U.S.C. 1395y(b)(5)(A)(ii)), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(K) in section 1927(e)(4) (42 U.S.C. 1396r–8(e)(4)), by striking "HCFA" and inserting "The Secretary";

(L) in section 1927(f)(2) (42 U.S.C. 1396r–8(f)(2)), by striking "HCFA" and inserting "The Secretary"; and

(M) in section 2104(g)(3) (42 U.S.C. 1397dd(g)(3)) by inserting "or CMS Form 64 or CMS Form 21, as the case may be," after "HCFA Form 64 or HCFA Form 21".

(2) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.—The Public Health Service Act is amended—

(A) in section 501(d)(18) (42 U.S.C. 290aa(d)(18)), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(B) in section 507(b)(6) (42 U.S.C. 290bb(b)(6)), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(C) in section 916 (42 U.S.C. 299b–5)—

(i) in subsection (b)(2), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services"; and

(ii) in subsection (c)(2), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(D) in section 921(c)(3)(A) (42 U.S.C. 299c(c)(3)(A)), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(E) in section 1318(a)(2) (42 U.S.C. 300e–17(a)(2)), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(F) in section 2102(a)(7) (42 U.S.C. 300aa–2(a)(7)), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services"; and

(G) in section 2675(a) (42 U.S.C. 300ff–75(a)), by striking "Health Care Financing Administration" in the first sentence and inserting "Centers for Medicare & Medicaid Services".

(3) AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.—Section 6103(l)(12) of the Internal Revenue Code of 1986 is amended—

(A) in subparagraph (B), by striking "Health Care Financing Administration" in the matter preceding clause (i) and inserting "Centers for Medicare & Medicaid Services"; and

(B) in subparagraph (C)—

(i) by striking "HEALTH CARE FINANCING ADMINISTRATION" in the heading and inserting "CENTERS FOR MEDICARE & MEDICAID SERVICES"; and

(ii) by striking "Health Care Financing Administration" in the matter preceding clause (i) and inserting "Centers for Medicare & Medicaid Services".

(4) AMENDMENTS TO TITLE 10, UNITED STATES CODE.—Title 10, United States Code, is amended—

(A) in section 1086(d)(4), by striking "administrator of the Health Care Financing Administration" in the last sentence and inserting "Administrator of the Centers for Medicare & Medicaid Services"; and

(B) in section 1095(k)(2), by striking "Health Care Financing Administration" in the second sentence and inserting "Centers for Medicare & Medicaid Services".

(5) AMENDMENTS TO THE ALZHEIMER'S DISEASE AND RELATED DEMENTIAS SERVICES RESEARCH ACT OF 1992.—The Alzheimer's Disease and Related Dementias Research Act of 1992 (42 U.S.C. 11271 et seq.) is amended—

(A) in the heading of subpart 3 of part D to read as follows:

"Subpart 3—Responsibilities of the Centers for Medicare & Medicaid Services";

(B) in section 937 (42 U.S.C. 11271)—

(i) in subsection (a), by striking "National Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(ii) in subsection (b)(1), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services";

(iii) in subsection (b)(2), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services"; and

(iv) in subsection (c), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services"; and

(C) in section 938 (42 U.S.C. 11272), by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

(6) MISCELLANEOUS AMENDMENTS.—

(A) REHABILITATION ACT OF 1973.—Section 202(b)(8) of the Rehabilitation Act of 1973 (29 U.S.C. 762(b)(8)) is amended by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

(B) INDIAN HEALTH CARE IMPROVEMENT ACT.—Section 405(d)(1) of the Indian Health Care Improvement Act (25 U.S.C. 1645(d)(1)) is amended by striking "Health Care Financing Administration" in the matter preceding subparagraph (A) and inserting "Centers for Medicare & Medicaid Services".

(C) INDIVIDUALS WITH DISABILITIES EDUCATION ACT.—Section 644(b)(5) of the Individuals with Disabilities Education Act (20 U.S.C. 1444(b)(5)) is amended by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

(D) THE HOME HEALTH CARE AND ALZHEIMER'S DISEASE AMENDMENTS OF 1990.—Section 302(a)(9) of the Home Health Care and Alzheimer's Disease Amendments of 1990 (42 U.S.C. 242q–1(a)(9)) is amended by striking "Health

Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

(E) THE CHILDREN'S HEALTH ACT OF 2000.—Section 2503(a) of the Children's Health Act of 2000 (42 U.S.C. 247b–3a(a)) is amended by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

(F) THE NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT OF 1993.—Section 1909 of the National Institutes of Health Revitalization Act of 1993 (42 U.S.C. 299a note) is amended by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

(G) THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990.—Section 4359(d) of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 1395b–3(d)) is amended by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

(H) THE MEDICARE, MEDICAID, AND SCHIP BENEFITS IMPROVEMENT AND PROTECTION ACT OF 2000.—Section 104(d)(4) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (42 U.S.C. 1395m note) is amended by striking "Health Care Financing Administration" and inserting "Health Care".

(7) ADDITIONAL AMENDMENT.—Section 403 of the Act entitled, "An Act to authorize certain appropriations for the territories of the United States, to amend certain Acts relating thereto, and for other purposes", enacted October 15, 1977 (48 U.S.C. 1574–1; 48 U.S.C. 1421q–1), is amended by striking "Health Care Financing Administration" and inserting "Centers for Medicare & Medicaid Services".

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 (commonly 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 division 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 services furnished before the effective date of the change, unless the Secretary determines that—

"(i) such retroactive application is necessary to comply with statutory requirements; or

"(ii) failure to apply the change retroactively would be contrary to the public interest.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(e)(1), as added by subsection (a), is amended by adding at the end the following:

"(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

"(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

"(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

(c) RELIANCE ON GUIDANCE.—

(1) IN GENERAL.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

"(2)(A) If—

"(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in

section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

"(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

"(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this title or the provisions of title XI insofar as they relate to this title (including interest under a repayment plan under section 1893 or otherwise) relating to the provision of such items or service or such claim 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 and shall only apply to a penalty or interest imposed with respect to guidance provided on or after July 24, 2003.

SEC. 904. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 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 903(a)(1), 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 3 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 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 (including the function of developing local coverage determinations, as defined in section 1869(f)(2)(B)), 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, including (subject to paragraph (5)) functions under the Medicare Integrity Program under section 1893, 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 a contract entered into 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 section, the Federal Acquisition Regulation applies to contracts under this section.

"(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 5 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.—

"(i) IN GENERAL.—The Secretary shall develop contract performance requirements to carry out the specific requirements applicable under this title to a function described in subsection (a)(4) and shall develop standards for measuring the extent to which a contractor has met such requirements.

"(ii) CONSULTATION.—In developing such performance requirements and standards for measurement, the Secretary shall consult with providers of services, organizations representative of beneficiaries under this title, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

"(iii) PUBLICATION OF STANDARDS.—The Secretary shall make such performance requirements and measurement standards available to the public.

"(B) CONSIDERATIONS.—The Secretary shall include, as one of the standards developed under subparagraph (A), provider and beneficiary satisfaction levels.

"(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 published 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 the United States) 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.

"(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 OR COMPROMISES.—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 Regulation.".

(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,";

(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, 2011.

(2) GENERAL TRANSITION RULES.—

(A) AUTHORITY TO CONTINUE TO ENTER INTO NEW AGREEMENTS AND CONTRACTS AND WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—Prior to October 1, 2005, the Secretary may, consistent with subparagraph (B), continue to enter into agreements under section 1816 and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u). The Secretary may enter into new agreements under section 1816 prior to

October 1, 2005, without regard to any of the provider nomination provisions of such section.

(B) APPROPRIATE TRANSITION.—The Secretary shall take such steps as are necessary to provide for an appropriate transition from agreements under section 1816 and contracts under 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 TRANSITION CONTRACTS.—Notwithstanding the amendments made by this section, 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 during the period that begins on the date of the enactment of this Act and ends on October 1, 2011, 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) SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this section.

(g) 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 to 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 to 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 the Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

"(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.".

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

"PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

"SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a), is amended by adding at the end the following new subsection:

"(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.".

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a) and subsection (b), is further amended by adding at the end the following new subsection:

"(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

"(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers, and individuals entitled to

benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

"(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services, and suppliers may obtain information 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.

"(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this subsection.".

(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) such sums as may be necessary for fiscal years beginning with fiscal year 2005.

"(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)). Such education and training activities for small providers of services and suppliers may include the provision of technical assistance (such as review of billing systems and internal controls to determine program compliance and to suggest more efficient and effective means of achieving such compliance).

"(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 WEBSITES.—

(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 WEBSITES; 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 website 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—

"(1) of the screens used for identifying claims that will be subject to medical review; or

"(2) 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 921(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) GAO EVALUATION.—Not later than 2 years after 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.

(e) 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.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, from amounts not otherwise appropriated in the Treasury, such sums as may be necessary to carry out this section.

SEC. 923. MEDICARE BENEFICIARY OMBUDSMAN.

(a) IN GENERAL.—Section 1808, as added and amended by section 900, is amended by adding at the end the following new subsection:

"(c) MEDICARE BENEFICIARY OMBUDSMAN.—

"(1) 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.

"(2) DUTIES.—The Medicare Beneficiary Ombudsman shall—

"(A) 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;

"(B) provide assistance with respect to complaints, grievances, and requests referred to in subparagraph (A), including—

"(i) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, MA organization, or the Secretary;

"(ii) assistance to such individuals with any problems arising from disenrollment from an MA plan under part C; and

"(iii) assistance to such individuals in presenting information under section 1839(i)(4)(C) (relating to income-related premium adjustment; and

"(C) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

"(3) 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 MA plans and changes to those plans. Nothing in this paragraph shall preclude further collaboration between the Ombudsman and such programs.".

(b) DEADLINE FOR APPOINTMENT.—By not later than 1 year after the date of the enactment of this Act, the Secretary shall appoint the Medicare Beneficiary Ombudsman under section 1808(c) of the Social Security Act, as added by subsection (a).

(c) FUNDING.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund, established under section 1817 of the Social Security Act (42 U.S.C. 1395i), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) to carry out section 1808(c) of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (a), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

(d) 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 telephone 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 telephone number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding the medicare program at the location of existing local offices of the Social Security Administration.

(b) LOCATIONS.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by individuals referred to in subsection (a).

(2) ASSISTANCE FOR RURAL BENEFICIARIES.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a)) with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking "hospice services" and inserting "hospice care and post-hospital extended care services"; and

(B) by inserting before the period at the end the following: "and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than April 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) CONTENTS.—The plan shall include information on the following:

(A) WORKLOAD.—The number of such administrative law judges and support staff required now and in the

future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes.

(B) COST PROJECTIONS AND FINANCING.—Funding levels required for fiscal year 2005 and subsequent fiscal years to carry out the functions transferred under the plan.

(C) TRANSITION TIMETABLE.—A timetable for the transition.

(D) REGULATIONS.—The establishment of specific regulations to govern the appeals process.

(E) CASE TRACKING.—The development of a unified case tracking system that will facilitate the maintenance and transfer of case specific data across both the fee-for-service and managed care components of the medicare program.

(F) FEASIBILITY OF PRECEDENTIAL AUTHORITY.—The feasibility of developing a process to give decisions of the Departmental Appeals Board in the Department of Health and Human Services addressing broad legal issues binding, precedential authority.

(G) ACCESS TO ADMINISTRATIVE LAW JUDGES.—The feasibility of—

(i) filing appeals with administrative law judges electronically; and

(ii) conducting hearings using tele- or video-conference technologies.

(H) INDEPENDENCE OF ADMINISTRATIVE LAW JUDGES.—The steps that should be taken to ensure the independence of administrative law judges consistent with the requirements of subsection (b)(2).

(I) GEOGRAPHIC DISTRIBUTION.—The steps that should be taken to provide for an appropriate geographic distribution of administrative law judges throughout the United States to carry out subsection (b)(3).

(J) HIRING.—The steps that should be taken to hire administrative law judges (and support staff) to carry out subsection (b)(4).

(K) PERFORMANCE STANDARDS.—The appropriateness of establishing performance standards for administrative law judges with respect to timelines for decisions in cases under title XVIII of the Social Security Act taking into account requirements under subsection (b)(2) for the independence of such judges and consistent with the applicable provisions of title 5, United States Code relating to impartiality.

(L) SHARED RESOURCES.—The steps that should be taken to carry out subsection (b)(6) (relating to the arrangements with the Commissioner of Social Security to share office space, support staff, and other resources, with appropriate reimbursement).

(M) TRAINING.—The training that should be provided to administrative law judges with respect to laws and regulations under title XVIII of the Social Security Act.

(3) ADDITIONAL INFORMATION.—The plan may also include recommendations for further congressional action, including modifications to the requirements and deadlines established

under section 1869 of the Social Security Act (42 U.S.C. 1395ff) (as amended by this Act).

(4) 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 officer of the Department of Health and Human Services.

(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 Acts, the Secretary shall have authority to hire administrative law judges to hear such cases, taking into consideration those judges with expertise 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 (42 U.S.C. 1395ff) (as amended by this Act), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund, established under section 1817 of the Social Security Act (42 U.S.C. 1395i), and the Federal Supplementary

Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) 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)) is amended by striking "of the Social Security Administration".

SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)) is amended—

(A) in paragraph (1)(A), by inserting ", subject to paragraph (2)," before "to judicial review of the Secretary's final decision"; and

(B) 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) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have 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 for a specific matter in dispute 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 entity that the Departmental Appeals Board does not have 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 entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity 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 entity—

"(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have 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 the date of the determination described in such clause; 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 ANY AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) 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 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 title.

"(D) REVIEW ENTITY DEFINED.—For purposes of this subsection, the term 'review entity' means an entity of up to three reviewers who are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.".

(2) CONFORMING AMENDMENT.—Section 1869(b)(1)(F)(ii) (42 U.S.C. 1395ff(b)(1)(F)(ii)) is amended to read as follows:

"(ii) REFERENCE TO EXPEDITED ACCESS TO JUDICIAL REVIEW.—For the provision relating to expedited access to judicial review, see paragraph (2).".

(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) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.—

(1) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)), as amended by subsection (b), is amended by adding at the end the following new subparagraph:

"(C)(i) The Secretary shall develop and implement a process to expedite proceedings under this subsection in which—

"(I) the remedy of termination of participation has been imposed;

"(II) a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) has been imposed, but only if such remedy has been imposed on an immediate basis; or

"(III) a determination has been made as to a finding of substandard quality of care that results in the loss of approval of a skilled nursing facility's nurse aide training program.

"(ii) Under such process under clause (i), priority shall be provided in cases of termination described in clause (i)(I).

"(iii) 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.".

(2) WAIVER OF DISAPPROVAL OF NURSE-AIDE TRAINING PROGRAMS.—Sections 1819(f)(2) and section 1919(f)(2) (42 U.S.C. 1395i–3(f)(2) and 1396r(f)(2)) are each amended—

(A) in subparagraph (B)(iii), by striking "subparagraph (C)" and inserting "subparagraphs (C) and (D)"; and

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

"(D) WAIVER OF DISAPPROVAL OF NURSE-AIDE TRAINING PROGRAMS.—Upon application of a nursing facility, the Secretary may waive the application of subparagraph (B)(iii)(I)(c) if the imposition of the civil monetary penalty was not related to the quality of care provided to residents of the facility. Nothing in this subparagraph shall be construed as eliminating any requirement upon a facility to pay a civil monetary penalty described in the preceding sentence.".

(3) 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, established under section 1817 of the Social Security Act (42 U.S.C. 1395i), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) to the Secretary such additional sums for fiscal year 2004 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.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

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 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)) 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)) is amended by adding at the end the following new paragraphs:

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the determination shall include—

"(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

"(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

"(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

"(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 individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

"(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 individual provided such written 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)) 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)) 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)) is amended 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)) 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) is amended—

(A) by amending subsection (c)(3)(D) to read as follows:

"(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).."; and

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

"(g) QUALIFICATIONS OF REVIEWERS.—

"(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

"(A) each individual conducting a review shall meet the qualifications of paragraph (2);

"(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

"(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a 'reviewing professional'), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

"(2) INDEPENDENCE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

"(i) not be a related party (as defined in paragraph (5));

"(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

"(iii) not otherwise have a conflict of interest with such a party.

"(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

"(I) the individual is not involved in the provision of items or services in the case under review;

"(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, or such individual's 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 contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

"(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

"(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

"(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

"(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

"(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

"(B) The individual (or authorized representative).

"(C) The health care professional that provides the items or services involved in the case.

"(D) The institution at which the items or services (or treatment) involved in the case are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

"(F) Any other party determined under any regulations to have a substantial interest in the case involved.".

(3) REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking "not fewer than 12 qualified independent contractors under this subsection" and inserting "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 under section 1893(f)(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 described in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through

the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

"(B) HARDSHIP.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

"(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

"(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

"(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

"(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

"(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

"(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

"(ii) there is an indication of fraud or abuse committed against the program.

"(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

"(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be 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 contractor' has the meaning given such term in section 1889(g).

"(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—

"(A) there is a sustained or high level of payment error; or

"(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

"(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 methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.".

(b) EFFECTIVE DATES AND DEADLINES.—

(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.

(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act, as added by subsection (a), shall take effect on the date of the enactment of this Act.

(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) of the Social Security Act, as added by subsection (a).

(7) PAYMENT AUDITS.—Section 1893A(f)(7) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as added by subsection (a).

SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) by adding at the end of the heading the following: "; ENROLLMENT PROCESSES"; and

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

"(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) ENROLLMENT PROCESS.—

"(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

"(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

"(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

"(2) HEARING RIGHTS IN CASES OF DENIAL OR 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) DEADLINE.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first develop the process under subsection (a).

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 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 physicians' services (as defined in section 1848(j)(3)), 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 participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under this title and who has consented to the physician making the request under this subsection for those physicians' services.

"(ii) An individual entitled to benefits under this title, but only with respect to a physicians' service for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a).

"(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the physicians' 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 physicians' 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 a physicians' service, as to whether the physicians' 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 physicians' service, supporting documentation relating to the medical necessity for the physicians' 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 physicians' service is so covered;

"(ii) the physicians' service is not so covered; or

"(iii) the contractor lacks sufficient information to make a coverage determination with respect to the physicians' service.

"(B) CONTENTS OF NOTICE FOR CERTAIN DETERMINATIONS.—

"(i) NONCOVERAGE.—If the contractor makes the determination described in subparagraph (A)(ii), the contractor shall include in the notice 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 a description of any applicable rights under subsection (a).

"(ii) INSUFFICIENT INFORMATION.—If the contractor makes the determination described in subparagraph (A)(iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

"(C) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

"(D) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request by a participating physician under paragraph (1)(B)(i), the process shall provide that the individual to whom the physicians' service is proposed to be furnished shall be informed of any determination described in subparagraph (A)(ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the physicians' service and have a claim submitted for the physicians' service.

"(5) 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.

"(6) LIMITATION ON FURTHER REVIEW.—

"(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (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 physicians' 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 physicians' 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 physicians'

service 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 physicians' services, there shall be no prior determination under this subsection with respect to such physicians' services.".

(b) EFFECTIVE DATE; SUNSET; 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) SUNSET.—Such prior determination process shall not apply to requests filed after the end of the 5-year period beginning on the first date on which requests for determinations under such process are accepted.

(3) 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.

(4) 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 ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(h) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 36 months after the date on which section 1869(h) 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—

(i) the number and types of procedures for which a prior determination has been sought;

(ii) determinations made under the process;

(iii) the percentage of beneficiaries prevailing;

(iv) in those cases in which the beneficiaries do not prevail, the reasons why such beneficiaries did not prevail; and

(v) changes in receipt of services resulting from the application of such process;

(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; and

(C) recommendations for improvements or continuation of such process.

(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 enrolled under part 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.

SEC. 939. APPEALS BY PROVIDERS WHEN THERE IS NO OTHER PARTY AVAILABLE.

(a) IN GENERAL.—Section 1870 (42 U.S.C. 1395gg) is amended by adding at the end the following new subsection:

"(h) Notwithstanding subsection (f) or any other provision of law, the Secretary shall permit a provider of services or supplier to appeal any determination of the Secretary under this title relating to services rendered under this title to an individual who subsequently dies if there is no other party available to appeal such determination.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply to items and services furnished on or after such date.

SEC. 940. REVISIONS TO APPEALS TIMEFRAMES AND AMOUNTS.

(a) TIMEFRAMES.—Section 1869 (42 U.S.C. 1395ff) is amended—

(1) in subsection (a)(3)(C)(ii), by striking "30-day period" each place it appears and inserting "60-day period"; and

(2) in subsection (c)(3)(C)(i), by striking "30-day period" and inserting "60-day period".

(b) AMOUNTS.—

(1) IN GENERAL.—Section 1869(b)(1)(E) (42 U.S.C. 1395ff(b)(1)(E)) is amended by adding at the end the following new clause:

"(iii) ADJUSTMENT OF DOLLAR AMOUNTS.—For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased

by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $10 shall be rounded to the nearest multiple of $10.".

(2) CONFORMING AMENDMENTS.—(A) Section 1852(g)(5) (42 U.S.C. 1395w–22(g)(5)) is amended by adding at the end the following: "The provisions of section 1869(b)(1)(E)(iii) shall apply with respect to dollar amounts specified in the first 2 sentences of this paragraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).".

(B) Section 1876(b)(5)(B) (42 U.S.C. 1395mm(b)(5)(B)) is amended by adding at the end the following: "The provisions of section 1869(b)(1)(E)(iii) shall apply with respect to dollar amounts specified in the first 2 sentences of this subparagraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).".

SEC. 940A. MEDIATION PROCESS FOR LOCAL COVERAGE DETERMINATIONS.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff), as amended by section 938(a), is amended by adding at the end the following new subsection:

"(i) MEDIATION PROCESS FOR LOCAL COVERAGE DETERMINATIONS.—

"(1) ESTABLISHMENT OF PROCESS.—The Secretary shall establish a mediation process under this subsection through the use of a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

"(2) RESPONSIBILITY OF MEDIATOR.—Under the process established in paragraph (1), such a mediator shall mediate in disputes between groups representing providers of services, suppliers (as defined in section 1861(d)), and the medical director for a medicare administrative contractor whenever the regional administrator (as defined by the Secretary) involved determines that there was a systematic pattern and a large volume of complaints from such groups regarding decisions of such director or there is a complaint from the co-chair of the advisory committee for that contractor to such regional administrator regarding such dispute.".

(b) INCLUSION IN MAC CONTRACTS.—Section 1874A(b)(3)(A)(i), as added by section 911(a)(1), is amended by adding at the end the following: "Such requirements shall include specific performance duties expected of a medical director of a medicare administrative contractor, including requirements relating to professional relations and the availability of such director to conduct medical determination activities within the jurisdiction of such a contractor.".

Subtitle E—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new or modified documentation guidelines (which for purposes of this section includes clinical examples) for 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 such guidelines;

(4) finds, based on reports submitted under subsection (b)(5) with respect to pilot projects conducted for such or related guidelines, 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 MODIFIED OR NEW EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

(1) IN GENERAL.—With respect to proposed new or modified documentation guidelines referred to in subsection (a), the Secretary shall conduct under this subsection appropriate and representative pilot projects to test the proposed guidelines.

(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary (but in no case to exceed 1 year) 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 with respect to proposed new or modified documentation guidelines—

(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 codes used for billing purposes for such services;

(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) STUDY OF IMPACT.—Each pilot project shall examine the effect of the proposed 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.

(5) REPORT ON PILOT PROJECTS.—Not later than 6 months after the date of completion of pilot projects carried out under this subsection with respect to a proposed guideline described in paragraph (1), the Secretary shall submit to Congress a report on the pilot projects. Each such report shall include a finding by the Secretary of whether the objectives described in subsection (c) will be met in the implementation of such proposed guideline.

(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) is amended—

(1) by adding at the end of the heading the following: "; COUNCIL FOR TECHNOLOGY AND INNOVATION";

(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) 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 website 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 website 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 website 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 timeframe 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 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).

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 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)), as amended by section 512(b), is amended by adding at the end the following new paragraph:

"(5) 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), as amended by section 506, is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (T), by striking "and" at the end;

(B) in subparagraph (U), by striking the period at the end and inserting ", and"; and

(C) by inserting after subparagraph (U) the following new subparagraph:

"(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under 18(b) of such Act), 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)(V) (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)(U) 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)) 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)) 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, after consulting with the Inspector General of the Department of Health and Human Services, 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 at the end, after the subsection transferred and redesignated by section 948(a), the following new subsection:

"(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

"(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

SEC. 951. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA.

Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall arrange to furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage under such section for that hospital for the current cost reporting year. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C. 1395u(b)(6)(A)) is amended by striking "or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service," and inserting "or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such 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 as described in clause (A)" and inserting "except to an employer or entity as described in subparagraph (A)".

(c) EFFECTIVE DATE.—The amendments made by this 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—MEDICAID AND MISCELLANEOUS PROVISIONS

Subtitle A—Medicaid Provisions

SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS.

(a) TEMPORARY INCREASE.—Section 1923(f)(3) (42 U.S.C. 1396r–4(f)(3)) is amended—

(1) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (C)"; and

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

"(C) SPECIAL, TEMPORARY INCREASE IN ALLOTMENTS ON A ONE-TIME, NON-CUMULATIVE BASIS.—The DSH allotment for any State (other than a State with a DSH allotment determined under paragraph (5))—

"(i) for fiscal year 2004 is equal to 116 percent of the DSH allotment for the State for fiscal year 2003 under this paragraph, notwithstanding subparagraph (B); and

"(ii) for each succeeding fiscal year is equal to the DSH allotment for the State for fiscal year 2004 or, in the case of fiscal years beginning with the fiscal year specified in subparagraph (D) for that State, the DSH allotment for the State for the previous fiscal year increased by the percentage change in the consumer price index for all urban consumers (all items; U.S. city average), for the previous fiscal year.

"(D) FISCAL YEAR SPECIFIED.—For purposes of subparagraph (C)(ii), the fiscal year specified in this subparagraph for a State is the first fiscal year for which the Secretary estimates that the DSH allotment for that State will equal (or no longer exceed) the DSH allotment for that State under the law as in effect before the date of the enactment of this subparagraph.".

(b) INCREASE IN FLOOR FOR TREATMENT AS A LOW DSH STATE.—Section 1923(f)(5) (42 U.S.C. 1396r–4(f)(5)) is amended—

(1) in the paragraph heading, by striking "EXTREMELY";

(2) by striking "In the case of" and inserting the following:

"(A) FOR FISCAL YEARS 2001 THROUGH 2003 FOR EXTREMELY LOW DSH STATES.—In the case of";

(3) by inserting "before fiscal year 2004" after "In subsequent years"; and

(4) by adding at the end the following:

"(B) FOR FISCAL YEAR 2004 AND SUBSEQUENT FISCAL YEARS.—In the case of a State in which the total expenditures under the State plan (including Federal and State shares) for disproportionate share hospital adjustments under this section for fiscal year 2000, as reported to the Administrator of the Centers for Medicare & Medicaid Services as of August 31, 2003, is greater than 0 but less than 3 percent of the State's total amount of expenditures under the State plan for medical assistance during the fiscal year, the DSH allotment for the State with respect to—

"(i) fiscal year 2004 shall be the DSH allotment for the State for fiscal year 2003 increased by 16 percent;

"(ii) each succeeding fiscal year before fiscal year 2009 shall be the DSH allotment for the State for the previous fiscal year increased by 16 percent; and

"(iii) fiscal year 2009 and any subsequent fiscal year, shall be the DSH allotment for the State for the previous year subject to an increase for inflation as provided in paragraph (3)(A).".

(c) ALLOTMENT ADJUSTMENT.—Section 1923(f) (42 U.S.C. 1396r–4(f)) is amended—

(1) in paragraph (3)(A), by striking "The DSH" and inserting "Except as provided in paragraph (6), the DSH";

(2) by redesignating paragraph (6) as paragraph (7); and

(3) by inserting after paragraph (5) the following:

"(6) ALLOTMENT ADJUSTMENT.—Only with respect to fiscal year 2004 or 2005, if a statewide waiver under section 1115 is revoked or terminated before the end of either such fiscal year and there is no DSH allotment for the State, the Secretary shall—

"(A) permit the State whose waiver was revoked or terminated to submit an amendment to its State plan that would describe the methodology to be used by the State (after the effective date of such revocation or termination) to identify and make payments to disproportionate share hospitals, including children's hospitals and institutions for mental diseases or other mental health facilities (other than State-owned institutions or facilities), on the basis of the proportion of patients served by such hospitals that are low-income patients with special needs; and

"(B) provide for purposes of this subsection for computation of an appropriate DSH allotment for the State for fiscal year 2004 or 2005 (or both) that would not exceed the amount allowed under paragraph (3)(B)(ii) and that does not result in greater expenditures under this title than would have been made if such waiver had not been revoked or terminated.

In determining the amount of an appropriate DSH allotment under subparagraph (B) for a State, the Secretary shall take into account the level of DSH expenditures for the State for the fiscal year preceding the fiscal year in which the waiver commenced.".

(d) INCREASED REPORTING AND OTHER REQUIREMENTS TO ENSURE THE APPROPRIATE USE OF MEDICAID DSH PAYMENT ADJUSTMENTS.—Section 1923 (42 U.S.C. 1396r–4) is amended by adding at the end the following new subsection:

"(j) ANNUAL REPORTS AND OTHER REQUIREMENTS REGARDING PAYMENT ADJUSTMENTS.—With respect to fiscal year 2004 and each fiscal year thereafter, the Secretary shall require a State, as a condition of receiving a payment under section 1903(a)(1) with respect to a payment adjustment made under this section, to do the following:

"(1) REPORT.—The State shall submit an annual report that includes the following:

"(A) An identification of each disproportionate share hospital that received a payment adjustment under this section for the preceding fiscal year and the amount of the payment adjustment made to such hospital for the preceding fiscal year.

"(B) Such other information as the Secretary determines necessary to ensure the appropriateness of the payment adjustments made under this section for the preceding fiscal year.

"(2) INDEPENDENT CERTIFIED AUDIT.—The State shall annually submit to the Secretary an independent certified audit that verifies each of the following:

"(A) The extent to which hospitals in the State have reduced their uncompensated care costs to reflect the total amount of claimed expenditures made under this section.

"(B) Payments under this section to hospitals that comply with the requirements of subsection (g).

"(C) Only the uncompensated care costs of providing inpatient hospital and outpatient hospital services to individuals described in paragraph (1)(A) of such subsection are included in the calculation of the hospital-specific limits under such subsection.

"(D) The State included all payments under this title, including supplemental payments, in the calculation of such hospital-specific limits.

"(E) The State has separately documented and retained a record of all of its costs under this title, claimed expenditures under this title, uninsured costs in determining payment adjustments under this section, and any payments made on behalf of the uninsured from payment adjustments under this section.".

(e) CLARIFICATION REGARDING NON-REGULATION OF TRANSFERS.—

(1) IN GENERAL.—Nothing in section 1903(w) of the Social Security Act (42 U.S.C. 1396b(w)) shall be construed by the Secretary as prohibiting a State's use of funds as the non-Federal share of expenditures under title XIX of such Act where such funds are transferred from or certified by a publicly-owned regional medical center located in another State and described in paragraph (2), so long as the Secretary determines that such use of funds is proper and in the interest of the program under title XIX.

(2) CENTER DESCRIBED.—A center described in this paragraph is a publicly-owned regional medical center that—

(A) provides level 1 trauma and burn care services;

(B) provides level 3 neonatal care services;

(C) is obligated to serve all patients, regardless of State of origin;

(D) is located within a Standard Metropolitan Statistical Area (SMSA) that includes at least 3 States, including the States described in paragraph (1);

(E) serves as a tertiary care provider for patients residing within a 125 mile radius; and

(F) meets the criteria for a disproportionate share hospital under section 1923 of such Act in at least one State other than the one in which the center is located.

(3) EFFECTIVE PERIOD.—This subsection shall apply through December 31, 2005.

SEC. 1002. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS FOR THE MEDICAID DRUG REBATE PROGRAM.

(a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is amended by inserting before the semicolon the following: "(including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act)".

(b) ANTI-DIVERSION PROTECTION.—Section 1927(c)(1)(C) (42 U.S.C. 1396r–8(c)(1)(C)) is amended by adding at the end the following:

"(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.".

SEC. 1003. EXTENSION OF MORATORIUM.

(a) IN GENERAL.—Section 6408(a)(3) of the Omnibus Budget Reconciliation Act of 1989, as amended by section 13642 of the Omnibus Budget Reconciliation Act of 1993 and section 4758 of the Balanced Budget Act of 1997, is amended—

(1) by striking "until December 31, 2002", and

(2) by striking "Kent Community Hospital Complex in Michigan or."

(b) EFFECTIVE DATES.—

(1) PERMANENT EXTENSION.—The amendment made by subsection (a)(1) shall take effect as if included in the amendment made by section 4758 of the Balanced Budget Act of 1997.

(2) MODIFICATION.—The amendment made by subsection (a)(2) shall take effect on the date of enactment of this Act.

Subtitle B—Miscellaneous Provisions

SEC. 1011. FEDERAL REIMBURSEMENT OF EMERGENCY HEALTH SERVICES FURNISHED TO UNDOCUMENTED ALIENS.

(a) TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—

(1) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $250,000,000 for each of fiscal years 2005 through 2008 for the purpose of making allotments under this section for payments to eligible providers in States described in paragraph (1) or (2) of subsection (b).

(2) AVAILABILITY.—Funds appropriated under paragraph (1) shall remain available until expended.

(b) STATE ALLOTMENTS.—

(1) BASED ON PERCENTAGE OF UNDOCUMENTED ALIENS.—

(A) IN GENERAL.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use $167,000,000 of such amount to make allotments for such fiscal year in accordance with subparagraph (B).

(B) FORMULA.—The amount of the allotment for payments to eligible providers in each State for a fiscal year shall be equal to the product of—

(i) the total amount available for allotments under this paragraph for the fiscal year; and

(ii) the percentage of undocumented aliens residing in the State as compared to the total number of such aliens residing in all States, as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the 2000 decennial census.

(2) BASED ON NUMBER OF UNDOCUMENTED ALIEN APPREHENSION STATES.—

(A) IN GENERAL.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use $83,000,000 of such amount to make allotments, in addition to amounts allotted under paragraph (1), for such fiscal year for each of the 6 States with the highest number of undocumented alien apprehensions for such fiscal year.

(B) DETERMINATION OF ALLOTMENTS.—The amount of the allotment for each State described in subparagraph (A) for a fiscal year shall be equal to the product of—

(i) the total amount available for allotments under this paragraph for the fiscal year; and

(ii) the percentage of undocumented alien apprehensions in the State in that fiscal year as compared to the total of such apprehensions for all such States for the preceding fiscal year.

(C) DATA.—For purposes of this paragraph, the highest number of undocumented alien apprehensions for a fiscal year shall be based on the apprehension rates for the 4-consecutive-quarter period ending before the beginning of the fiscal year for which information is available for undocumented aliens in such States, as reported by the Department of Homeland Security.

(c) USE OF FUNDS.—

(1) AUTHORITY TO MAKE PAYMENTS.—From the allotments made for a State under subsection (b) for a fiscal year, the Secretary shall pay the amount (subject to the total amount available from such allotments) determined under paragraph (2) directly to eligible providers located in the State for the provision of eligible services to aliens described in paragraph (5) to the extent that the eligible provider was not otherwise reimbursed (through insurance or otherwise) for such services during that fiscal year.

(2) DETERMINATION OF PAYMENT AMOUNTS.—

(A) IN GENERAL.—Subject to subparagraph (B), the payment amount determined under this paragraph shall be an amount determined by the Secretary that is equal to the lesser of—

(i) the amount that the provider demonstrates was incurred for the provision of such services; or

(ii) amounts determined under a methodology established by the Secretary for purposes of this subsection.

(B) PRO-RATA REDUCTION.—If the amount of funds allotted to a State under subsection (b) for a fiscal year is insufficient to ensure that each eligible provider in that State receives the amount of payment calculated under subparagraph (A), the Secretary shall reduce that amount of payment with respect to each eligible provider to ensure that the entire amount allotted to the State for that fiscal year is paid to such eligible providers.

(3) METHODOLOGY.—In establishing a methodology under paragraph (2)(A)(ii), the Secretary—

(A) may establish different methodologies for types of eligible providers;

(B) may base payments for hospital services on estimated hospital charges, adjusted to estimated cost, through the application of hospital-specific cost-to-charge ratios;

(C) shall provide for the election by a hospital to receive either payments to the hospital for—

(i) hospital and physician services; or

(ii) hospital services and for a portion of the on-call payments made by the hospital to physicians; and

(D) shall make quarterly payments under this section to eligible providers.

If a hospital makes the election under subparagraph (C)(i), the hospital shall pass on payments for services of a physician to the physician and may not charge any administrative or other fee with respect to such payments.

(4) LIMITATION ON USE OF FUNDS.—Payments made to eligible providers in a State from allotments made under subsection (b) for a fiscal year may only be used for costs incurred in providing eligible services to aliens described in paragraph (5).

(5) ALIENS DESCRIBED.—For purposes of paragraphs (1) and (2), aliens described in this paragraph are any of the following:

(A) Undocumented aliens.

(B) Aliens who have been paroled into the United States at a United States port of entry for the purpose of receiving eligible services.

(C) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a biometric machine readable border crossing identification card (also referred to as a "laser visa") issued in accordance with the requirements of regulations prescribed under section 101(a)(6) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(6)).

(d) APPLICATIONS; ADVANCE PAYMENTS.—

(1) DEADLINE FOR ESTABLISHMENT OF APPLICATION PROCESS.—

(A) IN GENERAL.—Not later than September 1, 2004, the Secretary shall establish a process under which eligible providers located in a State may request payments under subsection (c).

(B) INCLUSION OF MEASURES TO COMBAT FRAUD AND ABUSE.—The Secretary shall include in the process established under subparagraph (A) measures to ensure that inappropriate, excessive, or fraudulent payments are not made from the allotments determined under subsection (b), including certification by the eligible provider of the veracity of the payment request.

(2) ADVANCE PAYMENT; RETROSPECTIVE ADJUSTMENT.—The process established under paragraph (1) may provide for making payments under this section for each quarter of a fiscal year on the basis of advance estimates of expenditures submitted by applicants for such payments and such other investigation as the Secretary may find necessary, and for making reductions or increases in the payments as necessary to adjust for any overpayment or underpayment for prior quarters of such fiscal year.

(e) DEFINITIONS.—In this section:

(1) ELIGIBLE PROVIDER.—The term "eligible provider" means a hospital, physician, or provider of ambulance services (including an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization).

(2) ELIGIBLE SERVICES.—The term "eligible services" means health care services required by the application of section 1867 of the Social Security Act (42 U.S.C. 1395dd), and related hospital inpatient and outpatient services and ambulance services (as defined by the Secretary).

(3) HOSPITAL.—The term "hospital" has the meaning given such term in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e)), except that such term shall include a critical access hospital (as defined in section 1861(mm)(1) of such Act (42 U.S.C. 1395x(mm)(1)).

(4) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)).

(5) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

(6) STATE.—The term "State" means the 50 States and the District of Columbia.

SEC. 1012. COMMISSION ON SYSTEMIC INTEROPERABILITY.

(a) ESTABLISHMENT.—The Secretary shall establish a commission to be known as the "Commission on Systemic Interoperability" (in this section referred to as the "Commission").

(b) DUTIES.—

(1) IN GENERAL.—The Commission shall develop a comprehensive strategy for the adoption and implementation of health care information technology standards, that includes a timeline and prioritization for such adoption and implementation.

(2) CONSIDERATIONS.—In developing the comprehensive health care information technology strategy under paragraph (1), the Commission shall consider—

(A) the costs and benefits of the standards, both financial impact and quality improvement;

(B) the current demand on industry resources to implement this Act and other electronic standards, including HIPAA standards; and

(C) the most cost-effective and efficient means for industry to implement the standards.

(3) NONINTERFERENCE.—In carrying out this section, the Commission shall not interfere with any standards development of adoption processes underway in the private or public sector and shall not replicate activities related to such standards or the national health information infrastructure underway within the Department of Health and Human Services.

(4) REPORT.—Not later than October 31, 2005, the Commission shall submit to the Secretary and to Congress a report describing the strategy developed under paragraph (1), including an analysis of the matters considered under paragraph (2).

(c) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 11 members appointed as follows:

(A) The President shall appoint three members, one of whom the President shall designate as Chairperson.

(B) The Majority Leader of the Senate shall appoint two members.

(C) The Minority Leader of the Senate shall appoint two members.

(D) The Speaker of the House of Representatives shall appoint two members.

(E) The Minority Leader of the House of Representatives shall appoint two members.

(2) QUALIFICATIONS.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, health plans and integrated delivery systems, reimbursement of health facilities, practicing physicians, practicing pharmacists, and other providers of health services, health care technology and information systems, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

(d) TERMS.—Each member shall be appointed for the life of the Commission.

(e) COMPENSATION.—

(1) RATES OF PAY.—Members shall each be paid at a rate not to exceed the daily equivalent of the rate of basic pay for level IV of the Executive Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

(2) PROHIBITION OF COMPENSATION OF FEDERAL EMPLOYEES.—Members of the Commission who are full-time officers or employees of the United States or Members of Congress may not receive additional pay, allowances, or benefits by reason of their service on the Commission.

(3) TRAVEL EXPENSES.—Each member shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

(f) QUORUM.—A majority of the members of the Commission shall constitute a quorum but a lesser number may hold hearings.

(g) DIRECTOR AND STAFF OF COMMISSION; EXPERTS AND CONSULTANTS.—

(1) DIRECTOR.—The Commission shall have a Director who shall be appointed by the Chairperson. The Director shall be paid at a rate not to exceed the rate of basic pay for level IV of the Executive Schedule.

(2) STAFF.—With the approval of the Commission, the Director may appoint and fix the pay of such additional personnel as the Director considers appropriate.

(3) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—The Director and staff of the Commission may be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and may be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates, except that an individual so

appointed may not receive pay in excess of level IV of the Executive Schedule.

(4) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the Director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(5) STAFF OF FEDERAL AGENCIES.—Upon request of the Chairperson, the head of any Federal department or agency may detail, on a reimbursable basis, any of the personnel of that department or agency to the Commission to assist it in carrying out its duties under this Act.

(h) POWERS OF COMMISSION.—

(1) HEARINGS AND SESSIONS.—The Commission may, for the purpose of carrying out this Act, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Commission considers appropriate.

(2) POWERS OF MEMBERS AND AGENTS.—Any member or agent of the Commission may, if authorized by the Commission, take any action which the Commission is authorized to take by this section.

(3) OBTAINING OFFICIAL DATA.—The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this Act. Upon request of the Chairperson of the Commission, the head of that department or agency shall furnish that information to the Commission.

(4) GIFTS, BEQUESTS, AND DEVISES.—The Commission may accept, use, and dispose of gifts, bequests, or devises of services or property, both real and personal, for the purpose of aiding or facilitating the work of the Commission. Gifts, bequests, or devises of money and proceeds from sales of other property received as gifts, bequests, or devises shall be deposited in the Treasury and shall be available for disbursement upon order of the Commission. For purposes of Federal income, estate, and gift taxes, property accepted under this subsection shall be considered as a gift, bequest, or devise to the United States.

(5) MAILS.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

(6) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission, on a reimbursable basis, the administrative support services necessary for the Commission to carry out its responsibilities under this Act.

(7) CONTRACT AUTHORITY.—The Commission may enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5)).

(i) TERMINATION.—The Commission shall terminate on 30 days after submitting its report pursuant to subsection (b)(3).

(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 1013. RESEARCH ON OUTCOMES OF HEALTH CARE ITEMS AND SERVICES.

(a) RESEARCH, DEMONSTRATIONS, AND EVALUATIONS.—

(1) IMPROVEMENT OF EFFECTIVENESS AND EFFICIENCY.—

(A) IN GENERAL.—To improve the quality, effectiveness, and efficiency of health care delivered pursuant to the programs established under titles XVIII, XIX, and XXI of the Social Security Act, the Secretary acting through the Director of the Agency for Healthcare Research and Quality (in this section referred to as the "Director"), shall conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to—

(i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and

(ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs.

(B) SPECIFICATION.—To respond to priorities and information requests in subparagraph (A), the Secretary may conduct or support, by grant, contract, or interagency agreement, research, demonstrations, evaluations, technology assessments, or other activities, including the provision of technical assistance, scientific expertise, or methodological assistance.

(2) PRIORITIES.—

(A) IN GENERAL.—The Secretary shall establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section.

(B) INITIAL LIST.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall establish an initial list of priorities for research related to health care items and services (including prescription drugs).

(C) PROCESS.—In carrying out subparagraph (A), the Secretary—

(i) shall ensure that there is broad and ongoing consultation with relevant stakeholders in identifying the highest priorities for research, demonstrations, and evaluations to support and improve the programs established under titles XVIII, XIX, and XXI of the Social Security Act;

(ii) may include health care items and services which impose a high cost on such programs, as well as those which may be underutilized or overutilized and which may significantly improve the prevention, treatment, or cure of diseases and conditions (including chronic conditions) which impose high direct or indirect costs on patients or society; and

(iii) shall ensure that the research and activities undertaken pursuant to this section are responsive to the specified priorities and are conducted in a timely manner.

(3) EVALUATION AND SYNTHESIS OF SCIENTIFIC EVIDENCE.—

(A) IN GENERAL.—The Secretary shall—

(i) evaluate and synthesize available scientific evidence related to health care items and services (including prescription drugs) identified as priorities in accordance with paragraph (2) with respect to the comparative clinical effectiveness, outcomes, appropriateness, and provision of such items and services (including prescription drugs);

(ii) identify issues for which existing scientific evidence is insufficient with respect to such health care items and services (including prescription drugs);

(iii) disseminate to prescription drug plans and MA–PD plans under part D of title XVIII of the Social Security Act, other health plans, and the public the findings made under clauses (i) and (ii); and

(iv) work in voluntary collaboration with public and private sector entities to facilitate the development of new scientific knowledge regarding health care items and services (including prescription drugs).

(B) INITIAL RESEARCH.—The Secretary shall complete the evaluation and synthesis of the initial research required by the priority list developed under paragraph (2)(B) not later than 18 months after the development of such list.

(C) DISSEMINATION.—

(i) IN GENERAL.—To enhance patient safety and the quality of health care, the Secretary shall make available and disseminate in appropriate formats to prescription drugs plans under part D, and MA–PD plans under part C, of title XVIII of the Social Security Act, other health plans, and the public the evaluations and syntheses prepared pursuant to subparagraph (A) and the findings of research conducted pursuant to paragraph (1). In carrying out this clause the Secretary, in order to facilitate the availability of such evaluations and syntheses or findings at every decision point in the health care system, shall—

(I) present such evaluations and syntheses or findings in a form that is easily understood by the individuals receiving health care items and services (including prescription drugs) under such plans and periodically assess that the requirements of this subclause have been met; and

(II) provide such evaluations and syntheses or findings and other relevant information through easily accessible and searchable electronic mechanisms, and in hard copy formats as appropriate.

(ii) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as—

(I) affecting the authority of the Secretary or the Commissioner of Food and Drugs under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act; or

(II) conferring any authority referred to in subclause (I) to the Director.

(D) ACCOUNTABILITY.—In carrying out this paragraph, the Secretary shall implement activities in a manner that—

(i) makes publicly available all scientific evidence relied upon and the methodologies employed, provided such evidence and method are not protected from public disclosure by section 1905 of title 18, United States Code, or other applicable law so that the results of the research, analyses, or syntheses can be evaluated or replicated; and

(ii) ensures that any information needs and unresolved issues identified in subparagraph (A)(ii) are taken into account in priority-setting for future research conducted by the Secretary.

(4) CONFIDENTIALITY.—

(A) IN GENERAL.—In making use of administrative, clinical, and program data and information developed or collected with respect to the programs established under titles XVIII, XIX, and XXI of the Social Security Act, for purposes of carrying out the requirements of this section or the activities authorized under title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), such data and information shall be protected in accordance with the confidentiality requirements of title IX of the Public Health Service Act.

(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require or permit the disclosure of data provided to the Secretary that is otherwise protected from disclosure under the Federal Food, Drug, and Cosmetic Act, section 1905 of title 18, United States Code, or other applicable law.

(5) EVALUATIONS.—The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on outcomes and utilization of health care items and services.

(6) IMPROVING INFORMATION AVAILABLE TO HEALTH CARE PROVIDERS, PATIENTS, AND POLICYMAKERS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall identify options that could be undertaken in voluntary collaboration with private and public entities (as appropriate) for the—

(A) provision of more timely information through the programs established under titles XVIII, XIX, and XXI of the Social Security Act, regarding the outcomes and quality of patient care, including clinical and patient-reported outcomes, especially with respect to interventions and conditions for which clinical trials would not be feasible or raise ethical concerns that are difficult to address;

(B) acceleration of the adoption of innovation and quality improvement under such programs; and

(C) development of management tools for the programs established under titles XIX and XXI of the Social Security Act, and with respect to the programs established under such titles, assess the feasibility of using administrative or claims data, to—

(i) improve oversight by State officials;

(ii) support Federal and State initiatives to improve the quality, safety, and efficiency of services provided under such programs; and

(iii) provide a basis for estimating the fiscal and coverage impact of Federal or State program and policy changes.

(b) RECOMMENDATIONS.—

(1) DISCLAIMER.—In carrying out this section, the Director shall—

(A) not mandate national standards of clinical practice or quality health care standards; and

(B) include in any recommendations resulting from projects funded and published by the Director, a corresponding reference to the prohibition described in subparagraph (A).

(2) REQUIREMENT FOR IMPLEMENTATION.—Research, evaluation, and communication activities performed pursuant to this section shall reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in health care delivery systems, recognizing that patient subpopulations and patient and physician preferences may vary.

(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to provide the Director with authority to mandate a national standard or require a specific approach to quality measurement and reporting.

(c) RESEARCH WITH RESPECT TO DISSEMINATION.—The Secretary, acting through the Director, may conduct or support research with respect to improving methods of disseminating information in accordance with subsection (a)(3)(C).

(d) LIMITATION ON CMS.—The Administrator of the Centers for Medicare & Medicaid Services may not use data obtained in accordance with this section to withhold coverage of a prescription drug.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

SEC. 1014. HEALTH CARE THAT WORKS FOR ALL AMERICANS: CITIZENS HEALTH CARE WORKING GROUP.

(a) FINDINGS.—Congress finds the following:

(1) In order to improve the health care system, the American public must engage in an informed national public debate to make choices about the services they want covered, what health care coverage they want, and how they are willing to pay for coverage.

(2) More than a trillion dollars annually is spent on the health care system, yet—

(A) 41,000,000 Americans are uninsured;

(B) insured individuals do not always have access to essential, effective services to improve and maintain their health; and

(C) employers, who cover over 170,000,000 Americans, find providing coverage increasingly difficult because of rising costs and double digit premium increases.

(3) Despite increases in medical care spending that are greater than the rate of inflation, population growth, and Gross Domestic Product growth, there has not been a commensurate improvement in our health status as a nation.

(4) Health care costs for even just 1 member of a family can be catastrophic, resulting in medical bills potentially harming the economic stability of the entire family.

(5) Common life occurrences can jeopardize the ability of a family to retain private coverage or jeopardize access to public coverage.

(6) Innovations in health care access, coverage, and quality of care, including the use of technology, have often come from States, local communities, and private sector organizations, but more creative policies could tap this potential.

(7) Despite our Nation's wealth, the health care system does not provide coverage to all Americans who want it.

(b) PURPOSES.—The purposes of this section are—

(1) to provide for a nationwide public debate about improving the health care system to provide every American with the ability to obtain quality, affordable health care coverage; and

(2) to provide for a vote by Congress on the recommendations that result from the debate.

(c) ESTABLISHMENT.—The Secretary, acting through the Agency for Healthcare Research and Quality, shall establish an entity to be known as the Citizens' Health Care Working Group (referred to in this section as the "Working Group").

(d) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Working Group shall be composed of 15 members. One member shall be the Secretary. The Comptroller General of the United States shall appoint 14 members.

(2) QUALIFICATIONS.—

(A) IN GENERAL.—The membership of the Working Group shall include—

(i) consumers of health services that represent those individuals who have not had insurance within 2 years of appointment, that have had chronic illnesses, including mental illness, are disabled, and those who receive insurance coverage through medicare and medicaid; and

(ii) individuals with expertise in financing and paying for benefits and access to care, business and labor perspectives, and providers of health care.

The membership shall reflect a broad geographic representation and a balance between urban and rural representatives.

(B) PROHIBITED APPOINTMENTS.—Members of the Working Group shall not include Members of Congress or other elected government officials (Federal, State, or local). Individuals appointed to the Working Group shall not be paid employees or representatives of associations or advocacy organizations involved in the health care system.

(e) PERIOD OF APPOINTMENT.—Members of the Working Group shall be appointed for a life of the Working Group. Any vacancies shall not affect the power and duties of the Working Group but shall be filled in the same manner as the original appointment.

(f) DESIGNATION OF THE CHAIRPERSON.—Not later than 15 days after the date on which all members of the Working Group have

been appointed under subsection (d)(1), the Comptroller General shall designate the chairperson of the Working Group.

(g) SUBCOMMITTEES.—The Working Group may establish subcommittees if doing so increases the efficiency of the Working Group in completing its tasks.

(h) DUTIES.—

(1) HEARINGS.—Not later than 90 days after the date of the designation of the chairperson under subsection (f), the Working Group shall hold hearings to examine—

(A) the capacity of the public and private health care systems to expand coverage options;

(B) the cost of health care and the effectiveness of care provided at all stages of disease;

(C) innovative State strategies used to expand health care coverage and lower health care costs;

(D) local community solutions to accessing health care coverage;

(E) efforts to enroll individuals currently eligible for public or private health care coverage;

(F) the role of evidence-based medical practices that can be documented as restoring, maintaining, or improving a patient's health, and the use of technology in supporting providers in improving quality of care and lowering costs; and

(G) strategies to assist purchasers of health care, including consumers, to become more aware of the impact of costs, and to lower the costs of health care.

(2) ADDITIONAL HEARINGS.—The Working Group may hold additional hearings on subjects other than those listed in paragraph (1) so long as such hearings are determined to be necessary by the Working Group in carrying out the purposes of this section. Such additional hearings do not have to be completed within the time period specified in paragraph (1) but shall not delay the other activities of the Working Group under this section.

(3) THE HEALTH REPORT TO THE AMERICAN PEOPLE.—Not later than 90 days after the hearings described in paragraphs (1) and (2) are completed, the Working Group shall prepare and make available to health care consumers through the Internet and other appropriate public channels, a report to be entitled, "The Health Report to the American People". Such report shall be understandable to the general public and include—

(A) a summary of—

(i) health care and related services that may be used by individuals throughout their life span;

(ii) the cost of health care services and their medical effectiveness in providing better quality of care for different age groups;

(iii) the source of coverage and payment, including reimbursement, for health care services;

(iv) the reasons people are uninsured or underinsured and the cost to taxpayers, purchasers of health services, and communities when Americans are uninsured or underinsured;

(v) the impact on health care outcomes and costs when individuals are treated in all stages of disease;

(vi) health care cost containment strategies; and

(vii) information on health care needs that need to be addressed;

(B) examples of community strategies to provide health care coverage or access;

(C) information on geographic-specific issues relating to health care;

(D) information concerning the cost of care in different settings, including institutional-based care and home and community-based care;

(E) a summary of ways to finance health care coverage; and

(F) the role of technology in providing future health care including ways to support the information needs of patients and providers.

(4) COMMUNITY MEETINGS.—

(A) IN GENERAL.—Not later than 1 year after the date on which all the members of the Working Group have been appointed under subsection (d)(1) and appropriations are first made available to carry out this section, the Working Group shall initiate health care community meetings throughout the United States (in this paragraph referred to as "community meetings"). Such community meetings may be geographically or regionally based and shall be completed within 180 days after the initiation of the first meeting.

(B) NUMBER OF MEETINGS.—The Working Group shall hold a sufficient number of community meetings in order to receive information that reflects—

(i) the geographic differences throughout the United States;

(ii) diverse populations; and

(iii) a balance among urban and rural populations.

(C) MEETING REQUIREMENTS.—

(i) FACILITATOR.—A State health officer may be the facilitator at the community meetings.

(ii) ATTENDANCE.—At least 1 member of the Working Group shall attend and serve as chair of each community meeting. Other members may participate through interactive technology.

(iii) TOPICS.—The community meetings shall, at a minimum, address the following questions:

(I) What health care benefits and services should be provided?

(II) How does the American public want health care delivered?

(III) How should health care coverage be financed?

(IV) What trade-offs are the American public willing to make in either benefits or financing to ensure access to affordable, high quality health care coverage and services?

(iv) INTERACTIVE TECHNOLOGY.—The Working Group may encourage public participation in community meetings through interactive technology and other means as determined appropriate by the Working Group.

(D) INTERIM REQUIREMENTS.—Not later than 180 days after the date of completion of the community meetings, the Working Group shall prepare and make available to the public through the Internet and other appropriate public channels, an interim set of recommendations on health care coverage and ways to improve and strengthen the health care system based on the information and preferences expressed at the community meetings. There shall be a 90-day public comment period on such recommendations.

(i) RECOMMENDATIONS.—Not later than 120 days after the expiration of the public comment period described in subsection (h)(4)(D), the Working Group shall submit to Congress and the President a final set of recommendations.

(j) ADMINISTRATION.—

(1) EXECUTIVE DIRECTOR.—There shall be an Executive Director of the Working Group who shall be appointed by the chairperson of the Working Group in consultation with the members of the Working Group.

(2) COMPENSATION.—While serving on the business of the Working Group (including travel time), a member of the Working Group shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code, and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the chairperson of the Working Group. For purposes of pay and employment benefits, rights, and privileges, all personnel of the Working Group shall be treated as if they were employees of the Senate.

(3) INFORMATION FROM FEDERAL AGENCIES.—The Working Group may secure directly from any Federal department or agency such information as the Working Group considers necessary to carry out this section. Upon request of the Working Group, the head of such department or agency shall furnish such information.

(4) POSTAL SERVICES.—The Working Group may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(k) DETAIL.—Not more than 10 Federal Government employees employed by the Department of Labor and 10 Federal Government employees employed by the Department of Health and Human Services may be detailed to the Working Group under this section without further reimbursement. Any detail of an employee shall be without interruption or loss of civil service status or privilege.

(l) TEMPORARY AND INTERMITTENT SERVICES.—The chairperson of the Working Group may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

(m) ANNUAL REPORT.—Not later than 1 year after the date of enactment of this Act, and annually thereafter during the existence of the Working Group, the Working Group shall report to Congress and make public a detailed description of the expenditures

of the Working Group used to carry out its duties under this section.

(n) SUNSET OF WORKING GROUP.—The Working Group shall terminate on the date that is 2 years after the date on which all the members of the Working Group have been appointed under subsection (d)(1) and appropriations are first made available to carry out this section.

(o) ADMINISTRATION REVIEW AND COMMENTS.—Not later than 45 days after receiving the final recommendations of the Working Group under subsection (i), the President shall submit a report to Congress which shall contain—

(1) additional views and comments on such recommendations; and

(2) recommendations for such legislation and administrative actions as the President considers appropriate.

(p) REQUIRED CONGRESSIONAL ACTION.—Not later than 45 days after receiving the report submitted by the President under subsection (o), each committee of jurisdiction of Congress, the Committee on Finance of the Senate, the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Ways and Means of the House of Representatives, the Committee on Energy and Commerce of the House of Representatives, Committee on Education and the Workforce of the House of Representatives, shall hold at least 1 hearing on such report and on the final recommendations of the Working Group submitted under subsection (i).

(q) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, other than subsection (h)(3), $3,000,000 for each of fiscal years 2005 and 2006.

(2) HEALTH REPORT TO THE AMERICAN PEOPLE.—There are authorized to be appropriated for the preparation and dissemination of the Health Report to the American People described in subsection (h)(3), such sums as may be necessary for the fiscal year in which the report is required to be submitted.

SEC. 1015. FUNDING START-UP ADMINISTRATIVE COSTS FOR MEDICARE REFORM.

(a) IN GENERAL.—There are appropriated to carry out this Act (including the amendments made by this Act), to be transferred from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund—

(1) not to exceed $1,000,000,000 for the Centers for Medicare & Medicaid Services; and

(2) not to exceed $500,000,000 for the Social Security Administration.

(b) AVAILABILITY.—Amounts provided under subsection (a) shall remain available until September 30, 2005.

(c) APPLICATION.—From amounts provided under subsection (a)(2), the Social Security Administration may reimburse the Internal Revenue Service for expenses in carrying out this Act (and the amendments made by this Act).

(d) TRANSFER.—The President may transfer amounts provided under subsection (a) between the Centers for Medicare & Medicaid Services and the Social Security Administration. Notice of such transfers shall be transmitted within 15 days to the authorizing committees of the House of Representatives and of the Senate.

SEC. 1016. HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM.

Title XVIII is amended by adding at the end the following new section:

"HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

"SEC. 1897. (a) ESTABLISHMENT.—The Secretary shall establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of projects described in subsection (d).

"(b) APPLICATION.—No loan may be provided under this section to a qualifying hospital except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary. A loan under this section shall be on such terms and conditions and meet such requirements as the Secretary determines appropriate.

"(c) SELECTION CRITERIA.—

"(1) IN GENERAL.—The Secretary shall establish criteria for selecting among qualifying hospitals that apply for a loan under this section. Such criteria shall consider the extent to which the project for which loan is sought is nationally or regionally significant, in terms of expanding or improving the health care infrastructure of the United States or the region or in terms of the medical benefit that the project will have.

"(2) QUALIFYING HOSPITAL DEFINED.—For purposes of this section, the term 'qualifying hospital' means a hospital that—

"(A) is engaged in research in the causes, prevention, and treatment of cancer; and

"(B) is designated as a cancer center for the National Cancer Institute or is designated by the State as the official cancer institute of the State.

"(d) PROJECTS.—A project described in this subsection is a project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

"(e) STATE AND LOCAL PERMITS.—The provision of a loan under this section with respect to a project shall not—

"(1) relieve any recipient of the loan of any obligation to obtain any required State or local permit or approval with respect to the project;

"(2) limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project; or

"(3) otherwise supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

"(f) FORGIVENESS OF INDEBTEDNESS.—The Secretary may forgive a loan provided to a qualifying hospital under this section under terms and conditions that are analogous to the loan forgiveness provision for student loans under part D of title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a et seq.), except that the Secretary shall condition such forgiveness on the establishment by the hospital of—

"(A) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

"(B) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and

"(C)(i) unique research resources (such as population databases); or

"(ii) an affiliation with an entity that has unique research resources.

"(g) FUNDING.—

"(1) IN GENERAL.—There are appropriated, out of amounts in the Treasury not otherwise appropriated, to carry out this section, $200,000,000, to remain available during the period beginning on July 1, 2004, and ending on September 30, 2008.

"(2) ADMINISTRATIVE COSTS.—From funds made available under paragraph (1), the Secretary may use, for the administration of this section, not more than $2,000,000 for each of fiscal years 2004 through 2008.

"(3) AVAILABILITY.—Amounts appropriated under this section shall be available for obligation on July 1, 2004.

"(h) REPORT TO CONGRESS.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit to Congress a report on the projects for which loans are provided under this section and a recommendation as to whether the Congress should authorize the Secretary to continue loans under this section beyond fiscal year 2008.".

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

SEC. 1101. THIRTY-MONTH STAY-OF-EFFECTIVENESS PERIOD.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraph (B) and inserting the following:

"(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

"(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

"(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

"(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

"(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect

to another such certification contained in the application or in an amendment or supplement to the application.

"(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

"(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

"(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

"(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

"(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

"(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."; and

(B) by adding at the end the following subparagraph:

"(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

"(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

"(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term 'listed drug' for purposes of this subparagraph."; and

(2) in paragraph (5)—

(A) in subparagraph (B)—

(i) by striking "under the following" and inserting "by applying the following to each certification made under paragraph (2)(A)(vii)"; and

(ii) in clause (iii)—

(I) in the first sentence, by striking "unless" and all that follows and inserting "unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted."; and

(II) in the second sentence—

(aa) by striking subclause (I) and inserting the following:

"(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

"(aa) the date on which the court enters judgment reflecting the decision; or

"(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;";

(bb) by striking subclause (II) and inserting the following:

"(II) if before the expiration of such period the district court decides that the patent has been infringed—

"(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

"(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

"(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

"(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;";

(cc) in subclause (III), by striking "on the date of such court decision." and inserting "as provided in subclause (I); or";

(dd) by inserting after subclause (III) the following:

"(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent 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).."; and

(ee) in the matter after and below subclause (IV) (as added by item (dd)), by striking "Until the expiration" and all that follows;

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(C) by inserting after subparagraph (B) the following:

"(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

"(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

"(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is

the subject of the certification referred to in subparagraph (B)(iii) unless—

"(aa) the 45-day period referred to in such subparagraph has expired;

"(bb) neither the owner of such patent nor 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 brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

"(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

"(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer

of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

"(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

"(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (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 clause (i) or a counterclaim under clause (ii).".

(b) APPLICATIONS GENERALLY.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)—

(A) by striking paragraph (3) and inserting the following:

"(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

"(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

"(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

"(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

"(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

"(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

"(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

"(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

"(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

"(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

"(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."; and

(B)(i) by redesignating paragraph (4) as paragraph (5); and

(ii) by inserting after paragraph (3) the following paragraph:

"(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

"(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength."; and

(2) in subsection (c)(3)—

(A) in the first sentence, by striking "under the following" and inserting "by applying the following to each certification made under subsection (b)(2)(A)";

(B) in subparagraph (C)—

(i) in the first sentence, by striking "unless" and all that follows and inserting "unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted.";

(ii) in the second sentence—

(I) by striking "paragraph (3)(B)" and inserting "subsection (b)(3)";

(II) by striking clause (i) and inserting the following:

"(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

"(I) the date on which the court enters judgment reflecting the decision; or

"(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;";

(III) by striking clause (ii) and inserting the following:

"(ii) if before the expiration of such period the district court decides that the patent has been infringed—

"(I) if the judgment of the district court is appealed, the approval shall be made effective on—

"(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

"(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

"(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;";

(IV) in clause (iii), by striking "on the date of such court decision." and inserting "as provided in clause (i); or";

(V) by inserting after clause (iii), the following:

"(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).."; and

(VI) in the matter after and below clause (iv) (as added by subclause (V)), by striking "Until the expiration" and all that follows; and

(iii) in the third sentence, by striking "paragraph (3)(B)" and inserting "subsection (b)(3)";

(C) by redesignating subparagraph (D) as subparagraph (E); and

(D) by inserting after subparagraph (C) the following:

"(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

"(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

"(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code,

by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

"(aa) the 45-day period referred to in such subparagraph has expired;

"(bb) neither the owner of such patent nor 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 brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

"(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

"(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons

entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

"(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

"(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

"(aa) the drug for which the application was approved; or

"(bb) an approved method of using the drug.

"(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

"(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).".

(c) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the amendments made by subsections (a) and (b) 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 the 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) submitted on or after August 18, 2003, in an application filed under subsection (b) or (j) of that section or in an amendment or supplement to an application filed under subsection (b) 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) on or after August 18, 2003.

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

"(5) Where a person has filed 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 neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.".

SEC. 1102. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 1101) is amended—

(1) in subparagraph (B), by striking clause (iv) and inserting the following:

"(iv) 180-DAY EXCLUSIVITY PERIOD.—

"(I) 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.

"(II) DEFINITIONS.—In this paragraph:

"(aa) 180-DAY EXCLUSIVITY PERIOD.—The term '180-day exclusivity period' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

"(bb) FIRST APPLICANT.—As used in this subsection, the term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

"(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term 'substantially complete application' means an application under this subsection that on its face is sufficiently complete to permit

a substantive review and contains all the information required by paragraph (2)(A).

"(dd) TENTATIVE APPROVAL.—

"(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) 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."; 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 and lawfully maintained 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 information submitted under subsection (b) or (c) 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 the 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 the 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 the 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 the 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 the enactment of this Act) has occurred on or before the date of the enactment of this Act, the term "decision of a court" as used in clause (iv) of section 505(j)(5)(B) of that Act means a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

SEC. 1103. BIOAVAILABILITY AND BIOEQUIVALENCE.

(a) IN GENERAL.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

(1) by striking subparagraph (A) and inserting the following:

"(A)(i) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action."; and

(2) by adding at the end the following:

"(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference

between the drug and the listed drug in safety and therapeutic effect.".

(b) EFFECT OF AMENDMENT.—The amendment made by subsection (a) does not alter the standards for approval of drugs under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

SEC. 1104. CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking "(j)(5)(D)(ii)" each place it appears and inserting "(j)(5)(F)(ii)";

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking "(j)(5)(D)" each place it appears and inserting "(j)(5)(F)"; and

(3) in subsections (e) and (l), by striking "505(j)(5)(D)" each place it appears and inserting "505(j)(5)(F)".

Subtitle B—Federal Trade Commission Review

SEC. 1111. DEFINITIONS.

In this subtitle:

(1) ANDA.—The term "ANDA" means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) ASSISTANT ATTORNEY GENERAL.—The term "Assistant Attorney General" means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BRAND NAME DRUG.—The term "brand name drug" means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act.

(4) BRAND NAME DRUG COMPANY.—The term "brand name drug company" means the party that holds the approved application referred to in paragraph (3) for a brand name drug that is a listed drug in an ANDA, or a party that is the owner of a patent for which information is submitted for such drug under subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act.

(5) COMMISSION.—The term "Commission" means the Federal Trade Commission.

(6) GENERIC DRUG.—The term "generic drug" means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved.

(7) GENERIC DRUG APPLICANT.—The term "generic drug applicant" means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(8) LISTED DRUG.—The term "listed drug" means a brand name drug that is listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act.

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties

involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

SEC. 1113. FILING DEADLINES.

Any filing required under section 1112 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. 1114. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this subtitle shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. 1115. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company or generic drug applicant fails to comply with any provision of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission.

SEC. 1116. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle—

(1) may define the terms used in this subtitle;

(2) may exempt classes of persons or agreements from the requirements of this subtitle; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 1117. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

SEC. 1118. EFFECTIVE DATE.

This subtitle shall—

(1) take effect 30 days after the date of the enactment of this Act; and

(2) shall apply to agreements described in section 1112 that are entered into 30 days after the date of the enactment of this Act.

Subtitle C—Importation of Prescription Drugs

SEC. 1121. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

"SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

"(a) DEFINITIONS.—In this section:

"(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

"(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

"(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

"(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(C) an infused drug (including a peritoneal dialysis solution);

"(D) an intravenously injected drug;

"(E) a drug that is inhaled during surgery; or

"(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

"(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

"(5) WHOLESALER.—

"(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

"(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

"(b) REGULATIONS.—The Secretary, 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 is not adulterated or misbranded; and

"(ii) meets all labeling requirements under this Act.

"(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

"(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

"(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

"(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

"(e) TESTING.—The regulations under subsection (b) shall require—

"(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

"(2) if the tests are conducted by the importer—

"(A) that information needed to—

"(i) authenticate the prescription drug being tested; and

"(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

"(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing 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 and the name of the United States agent for the establishment.

"(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific

prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

"(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

"(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

"(j) 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 individuals 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.

"(k) 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.

"(l) EFFECTIVENESS OF SECTION.—

"(1) COMMENCEMENT OF PROGRAM.—This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will—

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

"(2) TERMINATION OF PROGRAM.—

"(A) 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.

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

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

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

"(ii) 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

"(iii)(I) compares in specific terms the detriment identified under clause (i) with the benefits identified under clause (ii); and

"(II) determines that the benefits do not outweigh the detriment.

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

(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)".

SEC. 1122. STUDY AND REPORT ON IMPORTATION OF DRUGS.

The Secretary, in consultation with appropriate government agencies, shall conduct a study on the importation of drugs into the United States pursuant to section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 1121 of this Act). Not later than 12 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of the Congress a report providing the findings of such study.

SEC. 1123. STUDY AND REPORT ON TRADE IN PHARMACEUTICALS.

The President's designees shall conduct a study and report on issues related to trade and pharmaceuticals.

TITLE XII—TAX INCENTIVES FOR HEALTH AND RETIREMENT SECURITY

SEC. 1201. HEALTH SAVINGS ACCOUNTS.

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 of the Internal Revenue Code of 1986 (relating to additional itemized deductions for individuals) is amended by redesignating section 223 as section 224 and by inserting after section 222 the following new section:

"SEC. 223. HEALTH SAVINGS ACCOUNTS.

"(a) DEDUCTION ALLOWED.—In the case of an individual who is an eligible individual for any month during the taxable year, there shall be allowed as a deduction for the taxable year an amount equal to the aggregate amount paid in cash during such taxable year by or on behalf of such individual to a health savings account of such individual.

"(b) LIMITATIONS.—

"(1) IN GENERAL.—The amount allowable as a deduction under subsection (a) to an individual for the taxable year shall not exceed the sum of the monthly limitations for months during such taxable year that the individual is an eligible individual.

"(2) MONTHLY LIMITATION.—The monthly limitation for any month is 1/12 of—

"(A) in the case of an eligible individual who has self-only coverage under a high deductible health plan as of the first day of such month, the lesser of—

"(i) the annual deductible under such coverage, or

"(ii) $2,250, or

"(B) in the case of an eligible individual who has family coverage under a high deductible health plan as of the first day of such month, the lesser of—

"(i) the annual deductible under such coverage, or

"(ii) $4,500.

"(3) ADDITIONAL CONTRIBUTIONS FOR INDIVIDUALS 55 OR OLDER.—

"(A) IN GENERAL.—In the case of an individual who has attained age 55 before the close of the taxable year, the applicable limitation under subparagraphs (A) and (B) of paragraph (2) shall be increased by the additional contribution amount.

"(B) ADDITIONAL CONTRIBUTION AMOUNT.—For purposes of this section, the additional contribution amount is the amount determined in accordance with the following table:

"For taxable years beginning in:	The additional contribution amount is:
2004	$500
2005	$600
2006	$700
2007	$800
2008	$900
2009 and thereafter	$1,000.

"(4) COORDINATION WITH OTHER CONTRIBUTIONS.—The limitation which would (but for this paragraph) apply under this subsection to an individual for any taxable year shall be reduced (but not below zero) by the sum of—

"(A) the aggregate amount paid for such taxable year to Archer MSAs of such individual, and

"(B) the aggregate amount contributed to health savings accounts of such individual which is excludable from the taxpayer's gross income for such taxable year under section 106(d) (and such amount shall not be allowed as a deduction under subsection (a)).

Subparagraph (A) shall not apply with respect to any individual to whom paragraph (5) applies.

"(5) SPECIAL RULE FOR MARRIED INDIVIDUALS.—In the case of individuals who are married to each other, if either spouse has family coverage—

"(A) both spouses shall be treated as having only such family coverage (and if such spouses each have family coverage under different plans, as having the family coverage with the lowest annual deductible), and

"(B) the limitation under paragraph (1) (after the application of subparagraph (A) and without regard to any additional contribution amount under paragraph (3))—

"(i) shall be reduced by the aggregate amount paid to Archer MSAs of such spouses for the taxable year, and

"(ii) after such reduction, shall be divided equally between them unless they agree on a different division.

"(6) DENIAL OF DEDUCTION TO DEPENDENTS.—No deduction shall be allowed under this section to any individual with respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which such individual's taxable year begins.

"(7) MEDICARE ELIGIBLE INDIVIDUALS.—The limitation under this subsection for any month with respect to an individual shall be zero for the first month such individual is entitled to benefits under title XVIII of the Social Security Act and for each month thereafter.

"(c) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

"(1) ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—The term 'eligible individual' means, with respect to any month, any individual if—

"(i) such individual is covered under a high deductible health plan as of the 1st day of such month, and

"(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

"(I) which is not a high deductible health plan, and

"(II) which provides coverage for any benefit which is covered under the high deductible health plan.

"(B) CERTAIN COVERAGE DISREGARDED.—Subparagraph (A)(ii) shall be applied without regard to—

"(i) coverage for any benefit provided by permitted insurance, and

"(ii) coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

"(2) HIGH DEDUCTIBLE HEALTH PLAN.—

"(A) IN GENERAL.—The term 'high deductible health plan' means a health plan—

"(i) which has an annual deductible which is not less than—

"(I) $1,000 for self-only coverage, and

"(II) twice the dollar amount in subclause (I) for family coverage, and

"(ii) the sum of the annual deductible and the other annual out-of-pocket expenses required to be paid under the plan (other than for premiums) for covered benefits does not exceed—

"(I) $5,000 for self-only coverage, and

"(II) twice the dollar amount in subclause (I) for family coverage.

"(B) EXCLUSION OF CERTAIN PLANS.—Such term does not include a health plan if substantially all of its coverage is coverage described in paragraph (1)(B).

"(C) SAFE HARBOR FOR ABSENCE OF PREVENTIVE CARE DEDUCTIBLE.—A plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1871 of the Social Security Act, except as otherwise provided by the Secretary).

"(D) SPECIAL RULES FOR NETWORK PLANS.—In the case of a plan using a network of providers—

"(i) ANNUAL OUT-OF-POCKET LIMITATION.—Such plan shall not fail to be treated as a high deductible health plan by reason of having an out-of-pocket limitation for services provided outside of such network which exceeds the applicable limitation under subparagraph (A)(ii).

"(ii) ANNUAL DEDUCTIBLE.—Such plan's annual deductible for services provided outside of such network shall not be taken into account for purposes of subsection (b)(2).

"(3) PERMITTED INSURANCE.—The term 'permitted insurance' means—

"(A) insurance if substantially all of the coverage provided under such insurance relates to—

"(i) liabilities incurred under workers' compensation laws,

"(ii) tort liabilities,

"(iii) liabilities relating to ownership or use of property, or

"(iv) such other similar liabilities as the Secretary may specify by regulations,

"(B) insurance for a specified disease or illness, and

"(C) insurance paying a fixed amount per day (or other period) of hospitalization.

"(4) FAMILY COVERAGE.—The term 'family coverage' means any coverage other than self-only coverage.

"(5) ARCHER MSA.—The term 'Archer MSA' has the meaning given such term in section 220(d).

"(d) HEALTH SAVINGS ACCOUNT.—For purposes of this section—

"(1) IN GENERAL.—The term 'health savings account' means a trust created or organized in the United States as a health savings account exclusively for the purpose of paying the qualified medical expenses of the account beneficiary, but only if the written governing instrument creating the trust meets the following requirements:

"(A) Except in the case of a rollover contribution described in subsection (f)(5) or section 220(f)(5), no contribution will be accepted—

"(i) unless it is in cash, or

"(ii) to the extent such contribution, when added to previous contributions to the trust for the calendar year, exceeds the sum of—

"(I) the dollar amount in effect under subsection (b)(2)(B)(ii), and

"(II) the dollar amount in effect under subsection (b)(3)(B).

"(B) The trustee is a bank (as defined in section 408(n)), an insurance company (as defined in section 816), or another person who demonstrates to the satisfaction of

the Secretary that the manner in which such person will administer the trust will be consistent with the requirements of this section.

"(C) No part of the trust assets will be invested in life insurance contracts.

"(D) The assets of the trust will not be commingled with other property except in a common trust fund or common investment fund.

"(E) The interest of an individual in the balance in his account is nonforfeitable.

"(2) QUALIFIED MEDICAL EXPENSES.—

"(A) IN GENERAL.—The term 'qualified medical expenses' means, with respect to an account beneficiary, amounts paid by such beneficiary for medical care (as defined in section 213(d) for such individual, the spouse of such individual, and any dependent (as defined in section 152) of such individual, but only to the extent such amounts are not compensated for by insurance or otherwise.

"(B) HEALTH INSURANCE MAY NOT BE PURCHASED FROM ACCOUNT.—Subparagraph (A) shall not apply to any payment for insurance.

"(C) EXCEPTIONS.—Subparagraph (B) shall not apply to any expense for coverage under—

"(i) a health plan during any period of continuation coverage required under any Federal law,

"(ii) a qualified long-term care insurance contract (as defined in section 7702B(b)),

"(iii) a health plan during a period in which the individual is receiving unemployment compensation under any Federal or State law, or

"(iv) in the case of an account beneficiary who has attained the age specified in section 1811 of the Social Security Act, any health insurance other than a medicare supplemental policy (as defined in section 1882 of the Social Security Act).

"(3) ACCOUNT BENEFICIARY.—The term 'account beneficiary' means the individual on whose behalf the health savings account was established.

"(4) CERTAIN RULES TO APPLY.—Rules similar to the following rules shall apply for purposes of this section:

"(A) Section 219(d)(2) (relating to no deduction for rollovers).

"(B) Section 219(f)(3) (relating to time when contributions deemed made).

"(C) Except as provided in section 106(d), section 219(f)(5) (relating to employer payments).

"(D) Section 408(g) (relating to community property laws).

"(E) Section 408(h) (relating to custodial accounts).

"(e) TAX TREATMENT OF ACCOUNTS.—

"(1) IN GENERAL.—A health savings account is exempt from taxation under this subtitle unless such account has ceased to be a health savings account. Notwithstanding the preceding sentence, any such account is subject to the taxes imposed by section 511 (relating to imposition of tax on unrelated business income of charitable, etc. organizations).

"(2) ACCOUNT TERMINATIONS.—Rules similar to the rules of paragraphs (2) and (4) of section 408(e) shall apply to health savings accounts, and any amount treated as distributed under such rules shall be treated as not used to pay qualified medical expenses.

"(f) TAX TREATMENT OF DISTRIBUTIONS.—

"(1) AMOUNTS USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a health savings account which is used exclusively to pay qualified medical expenses of any account beneficiary shall not be includible in gross income.

"(2) INCLUSION OF AMOUNTS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a health savings account which is not used exclusively to pay the qualified medical expenses of the account beneficiary shall be included in the gross income of such beneficiary.

"(3) EXCESS CONTRIBUTIONS RETURNED BEFORE DUE DATE OF RETURN.—

"(A) IN GENERAL.—If any excess contribution is contributed for a taxable year to any health savings account of an individual, paragraph (2) shall not apply to distributions from the health savings accounts of such individual (to the extent such distributions do not exceed the aggregate excess contributions to all such accounts of such individual for such year) if—

"(i) such distribution is received by the individual on or before the last day prescribed by law (including extensions of time) for filing such individual's return for such taxable year, and

"(ii) such distribution is accompanied by the amount of net income attributable to such excess contribution.

Any net income described in clause (ii) shall be included in the gross income of the individual for the taxable year in which it is received.

"(B) EXCESS CONTRIBUTION.—For purposes of subparagraph (A), the term 'excess contribution' means any contribution (other than a rollover contribution described in paragraph (5) or section 220(f)(5)) which is neither excludable from gross income under section 106(d) nor deductible under this section.

"(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—

"(A) IN GENERAL.—The tax imposed by this chapter on the account beneficiary for any taxable year in which there is a payment or distribution from a health savings account of such beneficiary which is includible in gross income under paragraph (2) shall be increased by 10 percent of the amount which is so includible.

"(B) EXCEPTION FOR DISABILITY OR DEATH.—Subparagraph (A) shall not apply if the payment or distribution is made after the account beneficiary becomes disabled within the meaning of section 72(m)(7) or dies.

"(C) EXCEPTION FOR DISTRIBUTIONS AFTER MEDICARE ELIGIBILITY.—Subparagraph (A) shall not apply to any payment or distribution after the date on which the account

beneficiary attains the age specified in section 1811 of the Social Security Act.

"(5) ROLLOVER CONTRIBUTION.—An amount is described in this paragraph as a rollover contribution if it meets the requirements of subparagraphs (A) and (B).

"(A) IN GENERAL.—Paragraph (2) shall not apply to any amount paid or distributed from a health savings account to the account beneficiary to the extent the amount received is paid into a health savings account for the benefit of such beneficiary not later than the 60th day after the day on which the beneficiary receives the payment or distribution.

"(B) LIMITATION.—This paragraph shall not apply to any amount described in subparagraph (A) received by an individual from a health savings account if, at any time during the 1-year period ending on the day of such receipt, such individual received any other amount described in subparagraph (A) from a health savings account which was not includible in the individual's gross income because of the application of this paragraph.

"(6) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—For purposes of determining the amount of the deduction under section 213, any payment or distribution out of a health savings account for qualified medical expenses shall not be treated as an expense paid for medical care.

"(7) TRANSFER OF ACCOUNT INCIDENT TO DIVORCE.—The transfer of an individual's interest in a health savings account to an individual's spouse or former spouse under a divorce or separation instrument described in subparagraph (A) of section 71(b)(2) shall not be considered a taxable transfer made by such individual notwithstanding any other provision of this subtitle, and such interest shall, after such transfer, be treated as a health savings account with respect to which such spouse is the account beneficiary.

"(8) TREATMENT AFTER DEATH OF ACCOUNT BENEFICIARY.—

"(A) TREATMENT IF DESIGNATED BENEFICIARY IS SPOUSE.—If the account beneficiary's surviving spouse acquires such beneficiary's interest in a health savings account by reason of being the designated beneficiary of such account at the death of the account beneficiary, such health savings account shall be treated as if the spouse were the account beneficiary.

"(B) OTHER CASES.—

"(i) IN GENERAL.—If, by reason of the death of the account beneficiary, any person acquires the account beneficiary's interest in a health savings account in a case to which subparagraph (A) does not apply—

"(I) such account shall cease to be a health savings account as of the date of death, and

"(II) an amount equal to the fair market value of the assets in such account on such date shall be includible if such person is not the estate of such beneficiary, in such person's gross income for the taxable year which includes such date, or if such person is the estate of such beneficiary,

in such beneficiary's gross income for the last taxable year of such beneficiary.

"(ii) SPECIAL RULES.—

"(I) REDUCTION OF INCLUSION FOR PREDEATH EXPENSES.—The amount includible in gross income under clause (i) by any person (other than the estate) shall be reduced by the amount of qualified medical expenses which were incurred by the decedent before the date of the decedent's death and paid by such person within 1 year after such date.

"(II) DEDUCTION FOR ESTATE TAXES.—An appropriate deduction shall be allowed under section 691(c) to any person (other than the decedent or the decedent's spouse) with respect to amounts included in gross income under clause (i) by such person.

"(g) COST-OF-LIVING ADJUSTMENT.—

"(1) IN GENERAL.—Each dollar amount in subsections (b)(2) and (c)(2)(A) shall be increased by an amount equal to—

"(A) such dollar amount, multiplied by

"(B) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins determined by substituting for 'calendar year 1992' in subparagraph (B) thereof—

"(i) except as provided in clause (ii), 'calendar year 1997', and

"(ii) in the case of each dollar amount in subsection (c)(2)(A), 'calendar year 2003'.

"(2) ROUNDING.—If any increase under paragraph (1) is not a multiple of $50, such increase shall be rounded to the nearest multiple of $50.

"(h) REPORTS.—The Secretary may require—

"(1) the trustee of a health savings account to make such reports regarding such account to the Secretary and to the account beneficiary with respect to contributions, distributions, the return of excess contributions, and such other matters as the Secretary determines appropriate, and

"(2) any person who provides an individual with a high deductible health plan to make such reports to the Secretary and to the account beneficiary with respect to such plan as the Secretary determines appropriate.

The reports required by this subsection shall be filed at such time and in such manner and furnished to such individuals at such time and in such manner as may be required by the Secretary.".

(b) DEDUCTION ALLOWED WHETHER OR NOT INDIVIDUAL ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of section 62 of such Code is amended by inserting after paragraph (18) the following new paragraph:

"(19) HEALTH SAVINGS ACCOUNTS.—The deduction allowed by section 223.".

(c) ROLLOVERS FROM ARCHER MSAS PERMITTED.—Subparagraph (A) of section 220(f)(5) of such Code (relating to rollover contribution) is amended by inserting "or a health savings account (as defined in section 223(d))" after "paid into an Archer MSA".

(d) EXCLUSIONS FOR EMPLOYER CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—

(1) EXCLUSION FROM INCOME TAX.—Section 106 of such Code (relating to contributions by employer to accident and health plans) is amended by adding at the end the following new subsection:

"(d) CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—

"(1) IN GENERAL.—In the case of an employee who is an eligible individual (as defined in section 223(c)(1)), amounts contributed by such employee's employer to any health savings account (as defined in section 223(d)) of such employee shall be treated as employer-provided coverage for medical expenses under an accident or health plan to the extent such amounts do not exceed the limitation under section 223(b) (determined without regard to this subsection) which is applicable to such employee for such taxable year.

"(2) SPECIAL RULES.—Rules similar to the rules of paragraphs (2), (3), (4), and (5) of subsection (b) shall apply for purposes of this subsection.

"(3) CROSS REFERENCE.—

"For penalty on failure by employer to make comparable contributions to the health savings accounts of comparable employees, see section 4980G.".

(2) EXCLUSION FROM EMPLOYMENT TAXES.—

(A) RAILROAD RETIREMENT TAX.—Subsection (e) of section 3231 of such Code is amended by adding at the end the following new paragraph:

"(11) HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—The term 'compensation' shall not include any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(d).".

(B) UNEMPLOYMENT TAX.—Subsection (b) of section 3306 of such Code is amended by striking "or" at the end of paragraph (16), by striking the period at the end of paragraph (17) and inserting "; or", and by inserting after paragraph (17) the following new paragraph:

"(18) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(d).".

(C) WITHHOLDING TAX.—Subsection (a) of section 3401 of such Code is amended by striking "or" at the end of paragraph (20), by striking the period at the end of paragraph (21) and inserting "; or", and by inserting after paragraph (21) the following new paragraph:

"(22) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(d).".

(3) EMPLOYER CONTRIBUTIONS REQUIRED TO BE SHOWN ON W–2.—Subsection (a) of section 6051 of such Code is amended by striking "and" at the end of paragraph (10), by striking the period at the end of paragraph (11) and inserting ", and", and by inserting after paragraph (11) the following new paragraph:

"(12) the amount contributed to any health savings account (as defined in section 223(d)) of such employee or such employee's spouse.".

(4) PENALTY FOR FAILURE OF EMPLOYER TO MAKE COMPARABLE HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—

(A) IN GENERAL.—Chapter 43 of such Code is amended by adding after section 4980F the following new section:

"SEC. 4980G. FAILURE OF EMPLOYER TO MAKE COMPARABLE HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.

"(a) GENERAL RULE.—In the case of an employer who makes a contribution to the health savings account of any employee during a calendar year, there is hereby imposed a tax on the failure of such employer to meet the requirements of subsection (b) for such calendar year.

"(b) RULES AND REQUIREMENTS.—Rules and requirements similar to the rules and requirements of section 4980E shall apply for purposes of this section.

"(c) REGULATIONS.—The Secretary shall issue regulations to carry out the purposes of this section, including regulations providing special rules for employers who make contributions to Archer MSAs and health savings accounts during the calendar year.".

(B) CLERICAL AMENDMENT.—The table of sections for chapter 43 of such Code is amended by adding after the item relating to section 4980F the following new item:

"Sec. 4980G. Failure of employer to make comparable health savings account contributions.".

(e) TAX ON EXCESS CONTRIBUTIONS.—Section 4973 of such Code (relating to tax on excess contributions to certain tax-favored accounts and annuities) is amended—

(1) by striking "or" at the end of subsection (a)(3), by inserting "or" at the end of subsection (a)(4), and by inserting after subsection (a)(4) the following new paragraph:

"(5) a health savings account (within the meaning of section 223(d)),", and

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

"(g) EXCESS CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—For purposes of this section, in the case of health savings accounts (within the meaning of section 223(d)), the term 'excess contributions' means the sum of—

"(1) the aggregate amount contributed for the taxable year to the accounts (other than a rollover contribution described in section 220(f)(5) or 223(f)(5)) which is neither excludable from gross income under section 106(d) nor allowable as a deduction under section 223 for such year, and

"(2) the amount determined under this subsection for the preceding taxable year, reduced by the sum of—

"(A) the distributions out of the accounts which were included in gross income under section 223(f)(2), and

"(B) the excess (if any) of—

"(i) the maximum amount allowable as a deduction under section 223(b) (determined without regard to section 106(d)) for the taxable year, over

"(ii) the amount contributed to the accounts for the taxable year.

For purposes of this subsection, any contribution which is distributed out of the health savings account in a distribution to which section 223(f)(3) applies shall be treated as an amount not contributed.".

(f) TAX ON PROHIBITED TRANSACTIONS.—

(1) Section 4975 of such Code (relating to tax on prohibited transactions) is amended by adding at the end of subsection (c) the following new paragraph:

"(6) SPECIAL RULE FOR HEALTH SAVINGS ACCOUNTS.—An individual for whose benefit a health savings account (within the meaning of section 223(d)) is established shall be exempt from the tax imposed by this section with respect to any transaction concerning such account (which would otherwise be taxable under this section) if, with respect to such transaction, the account ceases to be a health savings account by reason of the application of section 223(e)(2) to such account.".

(2) Paragraph (1) of section 4975(e) of such Code is amended by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively, and by inserting after subparagraph (D) the following new subparagraph:

"(E) a health savings account described in section 223(d),".

(g) FAILURE TO PROVIDE REPORTS ON HEALTH SAVINGS ACCOUNTS.—Paragraph (2) of section 6693(a) of such Code (relating to reports) is amended by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively, and by inserting after subparagraph (B) the following new subparagraph:

"(C) section 223(h) (relating to health savings accounts),".

(h) EXCEPTION FROM CAPITALIZATION OF POLICY ACQUISITION EXPENSES.—Subparagraph (B) of section 848(e)(1) of such Code (defining specified insurance contract) is amended by striking "and" at the end of clause (iii), by striking the period at the end of clause (iv) and inserting ", and", and by adding at the end the following new clause:

"(v) any contract which is a health savings account (as defined in section 223(d)).".

(i) HEALTH SAVINGS ACCOUNTS MAY BE OFFERED UNDER CAFETERIA PLANS.—Paragraph (2) of section 125(d) (relating to cafeteria plan defined) is amended by adding at the end the following new subparagraph:

"(D) EXCEPTION FOR HEALTH SAVINGS ACCOUNTS.—Subparagraph (A) shall not apply to a plan to the extent of amounts which a covered employee may elect to have the employer pay as contributions to a health savings account established on behalf of the employee.".

(j) CLERICAL AMENDMENT.—The table of sections for part VII of subchapter B of chapter 1 of such Code is amended by striking the last item and inserting the following:

"Sec. 223. Health savings accounts.

"Sec. 224. Cross reference.".

(k) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2003.

SEC. 1202. EXCLUSION FROM GROSS INCOME OF CERTAIN FEDERAL SUBSIDIES FOR PRESCRIPTION DRUG PLANS.

(a) IN GENERAL.—Part III of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after section 139 the following new section:

"SEC. 139A. FEDERAL SUBSIDIES FOR PRESCRIPTION DRUG PLANS.

"Gross income shall not include any special subsidy payment received under section 1860D–22 of the Social Security Act. This section shall not be taken into account for purposes of determining whether any deduction is allowable with respect to any cost taken into account in determining such payment.".

(b) ALTERNATIVE MINIMUM TAX RELIEF.—Section 56(g)(4)(B) of such Code is amended by inserting "or 139A" after "section 114".

(c) CONFORMING AMENDMENT.—The table of sections for part III of subchapter B of chapter 1 of such Code is amended by inserting after the item relating to section 139 the following new item:

"Sec. 139A. Federal subsidies for prescription drug plans.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years ending after the date of the enactment of this Act.

SEC. 1203. EXCEPTION TO INFORMATION REPORTING REQUIREMENTS RELATED TO CERTAIN HEALTH ARRANGEMENTS.

(a) IN GENERAL.—Section 6041 of the Internal Revenue Code of 1986 (relating to information at source) is amended by adding at the end the following new subsection:

"(f) SECTION DOES NOT APPLY TO CERTAIN HEALTH ARRANGEMENTS.—This section shall not apply to any payment for medical care (as defined in section 213(d)) made under—

"(1) a flexible spending arrangement (as defined in section 106(c)(2)), or

"(2) a health reimbursement arrangement which is treated as employer-provided coverage under an accident or health plan for purposes of section 106.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to payments made after December 31, 2002.

Speaker of the House of Representatives.

Vice President of the United States and President of the Senate.