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108TH CONGRESS
1ST SESSION

# S. 1

# AN ACT

To amend title XVIII of the Social Security Act to provide for a voluntary prescription drug benefit under the medicare program and to strengthen and improve the medicare program, and for other purposes.

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

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

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

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

(c) BIPA; SECRETARY.—In this Act:

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

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

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

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''PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

''Sec. 1860D. Definitions; treatment of references to provisions in MedicareAdvantage program.

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''Sec. 1860D–3. Election of a Medicare Prescription Drug plan.
''Sec. 1860D–4. Providing information to beneficiaries.
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"Sec. 1860D–7. Requirements for entities offering Medicare Prescription Drug plans; establishment of standards.

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"Sec. 1860D–10. Establishment of service areas.
"Sec. 1860D–11. Publication of risk adjusters.
"Sec. 1860D–12. Submission of bids for proposed Medicare Prescription Drug plans.
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"Sec. 1860D–14. Computation of monthly standard prescription drug coverage premiums.
"Sec. 1860D–15. Computation of monthly national average premium.
"Sec. 1860D–16. Payments to eligible entities.
"Sec. 1860D–17. Computation of monthly beneficiary obligation.
"Sec. 1860D–18. Collection of monthly beneficiary obligation.
"Sec. 1860D–19. Premium and cost-sharing subsidies for low-income individuals.
"Sec. 1860D–20. Reinsurance payments for expenses incurred in providing prescription drug coverage above the annual out-of-pocket threshold.
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# TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

## Subtitle A—Medicare Voluntary Prescription Drug Delivery Program

### SEC. 101. MEDICARE VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM.

(a) ESTABLISHMENT.—Title XVIII (42 U.S.C. 1395 et seq.) is amended by redesignating part D as part E and by inserting after part C the following new part:

"PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

"DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS IN MEDICAREADVANTAGE PROGRAM

"SEC. 1860D. (a) DEFINITIONS.—In this part:

"(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Center for Medicare Choices as established under section 1808.

"(2) COVERED DRUG.—

"(A) IN GENERAL.—Except as provided in subparagraphs (B), (C), and (D), the term 'covered drug' means—

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

"(ii) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section; or

"(iii) insulin described in subparagraph (C) of such section (including syringes, and necessary medical supplies associated with the administration of insulin, as defined by the Administrator);

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

"(B) EXCLUSIONS.—

"(i) IN GENERAL.—The term 'covered drug' does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise re-

stricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

"(ii) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered drug under this part shall not be so considered if payment for such drug is available under part A or B, but shall be so considered if such payment is not available under part A or B or because benefits under such parts have been exhausted.

"(C) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered drug under this part shall not be so considered under a plan if the plan excludes the drug under a formulary and such exclusion is not successfully resolved under subsection (d) or (e)(2) of section 1860D–5.

"(D) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A Medicare Prescription Drug plan or a MedicareAdvantage plan may

exclude from qualified prescription drug coverage any covered drug—

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

"(ii) which are not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860D–5(e).

"(3) ELIGIBLE BENEFICIARY.—The term 'eligible beneficiary' means an individual who is entitled to, or enrolled for, benefits under part A and enrolled under part B (other than a dual eligible individual, as defined in section 1860D–19(a)(4)(E)).

"(4) ELIGIBLE ENTITY.—The term 'eligible entity' means any risk-bearing entity that the Administrator determines to be appropriate to provide eligible beneficiaries with the benefits under a Medicare Prescription Drug plan, including—

"(A) a pharmaceutical benefit management company;

"(B) a wholesale or retail pharmacist delivery system;

"(C) an insurer (including an insurer that offers medicare supplemental policies under section 1882);

"(D) any other risk-bearing entity; or

"(E) any combination of the entities described in subparagraphs (A) through (D).

"(5) INITIAL COVERAGE LIMIT.—The term 'initial coverage limit' means the limit as established under section 1860D–6(c)(3), or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage.

"(6) MEDICAREADVANTAGE ORGANIZATION; MEDICAREADVANTAGE PLAN.—The terms 'MedicareAdvantage organization' and 'MedicareAdvantage plan' have the meanings given such terms in subsections (a)(1) and (b)(1), respectively, of section 1859 (relating to definitions relating to MedicareAdvantage organizations).

"(7) MEDICARE PRESCRIPTION DRUG PLAN.—The term 'Medicare Prescription Drug plan' means prescription drug coverage that is offered under a policy, contract, or plan—

"(A) that has been approved under section 1860D–13; and

"(B) by an eligible entity pursuant to, and in accordance with, a contract between the Administrator and the entity under section 1860D–7(b).

"(8) PRESCRIPTION DRUG ACCOUNT.—The term 'Prescription Drug Account' means the Prescription Drug Account (as established under section 1860D–25) in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

"(9) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' means the coverage described in section 1860D–6(a)(1).

"(10) STANDARD PRESCRIPTION DRUG COVERAGE.—The term 'standard prescription drug coverage' means the coverage described in section 1860D–6(c).

"(b) APPLICATION OF MEDICAREADVANTAGE PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a Medicare Prescription Drug plan and an eligible entity, unless otherwise provided in this part such provisions shall be applied as if—

"(1) any reference to a MedicareAdvantage plan included a reference to a Medicare Prescription Drug plan;

"(2) any reference to a provider-sponsored organization included a reference to an eligible entity;

"(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D–7(b); and

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

"Subpart 1—Establishment of Voluntary Prescription Drug Delivery Program

"ESTABLISHMENT OF VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

"SEC. 1860D–1. (a) PROVISION OF BENEFIT.—

"(1) IN GENERAL.—The Administrator shall provide for and administer a voluntary prescription drug delivery program under which each eligible beneficiary enrolled under this part shall be provided with access to qualified prescription drug coverage as follows:

"(A) MEDICAREADVANTAGE ENROLLEES RECEIVE COVERAGE THROUGH MEDICAREADVANTAGE PLAN.—

"(i) IN GENERAL.—Except as provided in clause (ii), an eligible beneficiary who is enrolled under this part and enrolled in a MedicareAdvantage plan offered by a MedicareAdvantage organization shall receive coverage of benefits under this part through such plan.

"(ii) EXCEPTION FOR ENROLLEES IN MEDICAREADVANTAGE MSA PLANS.—An eligible beneficiary who is enrolled under this part and enrolled in an MSA plan under part C shall receive coverage of benefits under this part through enrollment in a Medicare Prescription Drug plan that is offered in the geographic area in which the beneficiary resides. For purposes of this part, the term 'MSA plan' has the meaning given such term in section 1859(b)(3).

"(iii) EXCEPTION FOR ENROLLEES IN MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—An eligible beneficiary who is enrolled under this part and enrolled in a private fee-for-service plan under part C shall—

"(i) receive benefits under this part through such plan if the plan provides qualified prescription drug coverage; and

"(ii) if the plan does not provide qualified prescription drug coverage, receive coverage of benefits under this part through enrollment in a Medicare Prescription Drug plan that is offered in the geographic area in which the beneficiary resides. For purposes of this part, the term 'private fee-for-service plan' has the meaning given such term in section 1859(b)(2).

"(B) FEE-FOR-SERVICE ENROLLEES RECEIVE COVERAGE THROUGH A MEDICARE PRESCRIPTION DRUG PLAN.—An eligible beneficiary who is enrolled under this part but is not enrolled in a MedicareAdvantage plan (except for an MSA plan or a private fee-for-service plan that does not provide qualified prescription drug coverage) shall receive coverage of benefits under this part through enrollment in a Medicare Prescription Drug plan that is offered in

the geographic area in which the beneficiary resides.

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

"(3) SCOPE OF BENEFITS.—Pursuant to section 1860D–6(b)(3)(C), the program established under this part shall provide for coverage of all therapeutic categories and classes of covered drugs (although not necessarily for all drugs within such categories and classes).

"(4) PROGRAM TO BEGIN IN 2006.—The Administrator shall establish the program under this part in a manner so that benefits are first provided beginning on January 1, 2006.

"(b) ACCESS TO ALTERNATIVE PRESCRIPTION DRUG COVERAGE.—In the case of an eligible beneficiary who has creditable prescription drug coverage (as defined in section 1860D–2(b)(1)(F)), such beneficiary—

"(1) may continue to receive such coverage and not enroll under this part; and

"(2) pursuant to section 1860D–2(b)(1)(C), is permitted to subsequently enroll under this part without any penalty and obtain access to qualified

prescription drug coverage in the manner described in subsection (a) if the beneficiary involuntarily loses such coverage.

"(c) FINANCING.—The costs of providing benefits under this part shall be payable from the Prescription Drug Account.

"ENROLLMENT UNDER PROGRAM

"SEC. 1860D–2. (a) ESTABLISHMENT OF ENROLLMENT PROCESS.—

"(1) PROCESS SIMILAR TO PART B ENROLLMENT.—The Administrator shall establish a process through which an eligible beneficiary (including an eligible beneficiary enrolled in a MedicareAdvantage plan offered by a MedicareAdvantage organization) may make an election to enroll under this part. Such process shall be similar to the process for enrollment in part B under section 1837, including the deeming provisions of such section.

"(2) CONDITION OF ENROLLMENT.—An eligible beneficiary must be enrolled under this part in order to be eligible to receive access to qualified prescription drug coverage.

"(b) SPECIAL ENROLLMENT PROCEDURES.—

"(1) LATE ENROLLMENT PENALTY.—

"(A) INCREASE IN MONTHLY BENEFICIARY OBLIGATION.—Subject to the succeeding provi-

sions of this paragraph, in the case of an eligible beneficiary whose coverage period under this part began pursuant to an enrollment after the beneficiary's initial enrollment period under part B (determined pursuant to section 1837(d)) and not pursuant to the open enrollment period described in paragraph (2), the Administrator shall establish procedures for increasing the amount of the monthly beneficiary obligation under section 1860D–17 applicable to such beneficiary by an amount that the Administrator determines is actuarially sound for each full 12-month period (in the same continuous period of eligibility) in which the eligible beneficiary could have been enrolled under this part but was not so enrolled.

"(B) PERIODS TAKEN INTO ACCOUNT.—For purposes of calculating any 12-month period under subparagraph (A), there shall be taken into account—

"(i) the months which elapsed between the close of the eligible beneficiary's initial enrollment period and the close of the enrollment period in which the beneficiary enrolled; and

"(ii) in the case of an eligible beneficiary who reenrolls under this part, the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which the beneficiary reenrolled.

"(C) PERIODS NOT TAKEN INTO ACCOUNT.—

"(i) IN GENERAL.—For purposes of calculating any 12-month period under subparagraph (A), subject to clause (ii), there shall not be taken into account months for which the eligible beneficiary can demonstrate that the beneficiary had creditable prescription drug coverage (as defined in subparagraph (F)).

"(ii) BENEFICIARY MUST INVOLUNTARILY LOSE COVERAGE.—Clause (i) shall only apply with respect to coverage—

"(I) in the case of coverage described in clause (ii) of subparagraph (F), if the plan terminates, ceases to provide, or reduces the value of the prescription drug coverage under such plan to below the actuarial value of

standard prescription drug coverage (as determined under section 1860D–6(f));

"(II) in the case of coverage described in clause (i), (iii), or (iv) of subparagraph (F), if the beneficiary is involuntarily disenrolled or becomes ineligible for such coverage; or

"(III) in the case of a beneficiary with coverage described in clause (v) of subparagraph (F), if the issuer of the policy terminates coverage under the policy.

"(D) PERIODS TREATED SEPARATELY.—Any increase in an eligible beneficiary's monthly beneficiary obligation under subparagraph (A) with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which the beneficiary may have.

"(E) CONTINUOUS PERIOD OF ELIGIBILITY.—

"(i) IN GENERAL.—Subject to clause (ii), for purposes of this paragraph, an eligible beneficiary's 'continuous period of eli-

gibility' is the period that begins with the first day on which the beneficiary is eligible to enroll under section 1836 and ends with the beneficiary's death.

"(ii) SEPARATE PERIOD.—Any period during all of which an eligible beneficiary satisfied paragraph (1) of section 1836 and which terminated in or before the month preceding the month in which the beneficiary attained age 65 shall be a separate 'continuous period of eligibility' with respect to the beneficiary (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this paragraph).

"(F) CREDITABLE PRESCRIPTION DRUG COVERAGE DEFINED.—Subject to subparagraph (G), for purposes of this part, the term 'creditable prescription drug coverage' means any of the following:

"(i) DRUG-ONLY COVERAGE UNDER MEDICAID.—Coverage of covered outpatient drugs (as defined in section 1927) under title XIX or a waiver under 1115 that is provided to an individual who is not

a dual eligible individual (as defined in section 1860D–19(a)(4)(E)).

"(ii) PRESCRIPTION DRUG COVERAGE UNDER A GROUP HEALTH PLAN.—Any outpatient prescription drug 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–20(e)(4)).

"(iii) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program.

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

"(v) 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) REQUIREMENT FOR CREDITABLE COVERAGE.—Coverage described in clauses (i) through (v) of subparagraph (F) shall not be considered to be creditable coverage under this part unless the coverage provides coverage of the cost of prescription drugs the actuarial value of which (as defined by the Administrator) to the beneficiary equals or exceeds the actuarial value of standard prescription drug coverage (as determined under section 1860D–6(f)).

"(H) DISCLOSURE.—

"(i) IN GENERAL.—Each entity that offers coverage of the type described in clause (ii) (iii), (iv), or (v) of subparagraph (F) shall provide for disclosure, consistent with standards established by the Administrator, of whether the coverage provides coverage of the cost of prescription drugs the actuarial value of which (as defined by the Administrator) to the beneficiary

equals or exceeds the actuarial value of standard prescription drug coverage (as determined under section 1860D–6(f)).

"(ii) WAIVER OF LIMITATIONS.—An individual may apply to the Administrator to waive the application of subparagraph (G) if the individual establishes that the individual was not adequately informed that the coverage the beneficiary was enrolled in did not provide the level of benefits required in order for the coverage to be considered creditable coverage under subparagraph (F).

"(2) INITIAL ELECTION PERIODS.—

"(A) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES IN WHICH LATE ENROLLMENT PROCEDURES DO NOT APPLY.—In the case of an individual who is an eligible beneficiary as of November 1, 2005, there shall be an open enrollment period of 6 months beginning on that date under which such beneficiary may enroll under this part without the application of the late enrollment procedures established under paragraph (1)(A).

"(B) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who becomes an eligible beneficiary after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

"(3) SPECIAL ENROLLMENT PERIOD FOR BENEFICIARIES WHO INVOLUNTARILY LOSE CREDITABLE PRESCRIPTION DRUG COVERAGE.—

"(A) ESTABLISHMENT.—The Administrator shall establish a special open enrollment period (as described in subparagraph (B)) for an eligible beneficiary that loses creditable prescription drug coverage.

"(B) SPECIAL OPEN ENROLLMENT PERIOD.—The special open enrollment period described in this subparagraph is the 63-day period that begins on—

"(i) in the case of a beneficiary with coverage described in clause (ii) of paragraph (1)(F), the later of the date on which the plan terminates, ceases to provide, or substantially reduces (as defined by the Administrator) the value of the prescription drug coverage under such plan or

the date the beneficiary is provided with notice of such termination or reduction;

"(ii) in the case of a beneficiary with coverage described in clause (i), (iii), or (iv) of paragraph (1)(F), the later of the date on which the beneficiary is involuntarily disenrolled or becomes ineligible for such coverage or the date the beneficiary is provided with notice of such loss of eligibility; or

"(iii) in the case of a beneficiary with coverage described in clause (v) of paragraph (1)(F), the latter of the date on which the issuer of the policy terminates coverage under the policy or the date the beneficiary is provided with notice of such termination.

"(c) PERIOD OF COVERAGE.—

"(1) IN GENERAL.—Except as provided in paragraph (2) and subject to paragraph (3), an eligible beneficiary's coverage under the program under this part shall be effective for the period provided in section 1838, as if that section applied to the program under this part.

"(2) OPEN AND SPECIAL ENROLLMENT.—

"(A) OPEN ENROLLMENT.—An eligible beneficiary who enrolls under the program under this part pursuant to subsection (b)(2) shall be entitled to the benefits under this part beginning on January 1, 2006.

"(B) SPECIAL ENROLLMENT.—Subject to paragraph (3), an eligible beneficiary who enrolls under the program under this part pursuant to subsection (b)(3) shall be entitled to the benefits under this part beginning on the first day of the month following the month in which such enrollment occurs.

"(3) LIMITATION.—Coverage under this part shall not begin prior to January 1, 2006.

"(d) TERMINATION.—

"(1) IN GENERAL.—The causes of termination specified in section 1838 shall apply to this part in the same manner as such causes apply to part B.

"(2) COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PART A OR B.—

"(A) IN GENERAL.—In addition to the causes of termination specified in paragraph (1), the Administrator shall terminate an individual's coverage under this part if the indi-

vidual is no longer enrolled in both parts A and B.

"(B) EFFECTIVE DATE.—The termination described in subparagraph (A) shall be effective on the effective date of termination of coverage under part A or (if earlier) under part B.

"(3) PROCEDURES REGARDING TERMINATION OF A BENEFICIARY UNDER A PLAN.—The Administrator shall establish procedures for determining the status of an eligible beneficiary's enrollment under this part if the beneficiary's enrollment in a Medicare Prescription Drug plan offered by an eligible entity under this part is terminated by the entity for cause (pursuant to procedures established by the Administrator under section 1860D–3(a)(1)).

"ELECTION OF A MEDICARE PRESCRIPTION DRUG PLAN

"SEC. 1860D–3. (a) IN GENERAL.—

"(1) PROCESS.—

"(A) ELECTION.—

"(i) IN GENERAL.—The Administrator shall establish a process through which an eligible beneficiary who is enrolled under this part but not enrolled in a MedicareAdvantage plan (except for an MSA plan or a private fee-for-service plan that does not provide qualified prescription

drug coverage) offered by a MedicareAdvantage organization—

"(I) shall make an election to enroll in any Medicare Prescription Drug plan that is offered by an eligible entity and that serves the geographic area in which the beneficiary resides; and

"(II) may make an annual election to change the election under this clause.

"(ii) CLARIFICATION REGARDING ENROLLMENT.—The process established under clause (i) shall include, in the case of an eligible beneficiary who is enrolled under this part but who has failed to make an election of a Medicare Prescription Drug plan in an area, for the enrollment in any Medicare Prescription Drug plan that has been designated by the Administrator in the area. The Administrator shall establish a process for designating a plan or plans in order to carry out the preceding sentence.

"(B) REQUIREMENTS FOR PROCESS.—In establishing the process under subparagraph (A), the Administrator shall—

"(i) use rules similar to the rules for enrollment, disenrollment, and termination of enrollment with a MedicareAdvantage plan under section 1851, including—

"(I) the establishment of special election periods under subsection (e)(4) of such section; and

"(II) the application of the guaranteed issue and renewal provisions of section 1851(g) (other than clause (i) and the second sentence of clause (ii) of paragraph (3)(C), relating to default enrollment); and

"(ii) coordinate enrollments, disenrollments, and terminations of enrollment under part C with enrollments, disenrollments, and terminations of enrollment under this part.

"(2) FIRST ENROLLMENT PERIOD FOR PLAN ENROLLMENT.—The process developed under paragraph (1) shall ensure that eligible beneficiaries who enroll under this part during the open enrollment

period under section 1860D–2(b)(2) are permitted to elect an eligible entity prior to January 1, 2006, in order to ensure that coverage under this part is effective as of such date.

"(b) ENROLLMENT IN A MEDICAREADVANTAGE PLAN.—

"(1) IN GENERAL.—An eligible beneficiary who is enrolled under this part and enrolled in a MedicareAdvantage plan (except for an MSA plan or a private fee-for-service plan that does not provide qualified prescription drug coverage) offered by a MedicareAdvantage organization shall receive access to such coverage under this part through such plan.

"(2) RULES.—Enrollment in a MedicareAdvantage plan is subject to the rules for enrollment in such plan under section 1851.

"(c) INFORMATION TO ENTITIES TO FACILITATE ENROLLMENT.—Notwithstanding any other provision of law, the Administrator may provide to each eligible entity with a contract under this part such information about eligible beneficiaries as the Administrator determines to be necessary to facilitate efficient enrollment by such beneficiaries with such entities. The Administrator may provide such information only so long as and to the extent necessary to carry out such objective.

"PROVIDING INFORMATION TO BENEFICIARIES

"SEC. 1860D–4. (a) ACTIVITIES.—

"(1) IN GENERAL.—The Administrator shall conduct activities that are designed to broadly disseminate information to eligible beneficiaries (and prospective eligible beneficiaries) regarding the coverage provided under this part.

"(2) SPECIAL RULE FOR FIRST ENROLLMENT UNDER THE PROGRAM.—The activities described in paragraph (1) shall ensure that eligible beneficiaries are provided with such information at least 30 days prior to the first enrollment period described in section 1860D–3(a)(2).

"(b) REQUIREMENTS.—

"(1) IN GENERAL.—The activities described in subsection (a) shall—

"(A) be similar to the activities performed by the Administrator under section 1851(d);

"(B) be coordinated with the activities performed by—

"(i) the Administrator under such section; and

"(ii) the Secretary under section 1804; and

"(C) provide for the dissemination of information comparing the plans offered by eligible entities under this part that are available to eligible beneficiaries residing in an area.

"(2) COMPARATIVE INFORMATION.—The comparative information described in paragraph (1)(C) shall include a comparison of the following:

"(A) BENEFITS.—The benefits provided under the plan and the formularies and grievance and appeals processes under the plan.

"(B) MONTHLY BENEFICIARY OBLIGATION.—The monthly beneficiary obligation under the plan.

"(C) QUALITY AND PERFORMANCE.—The quality and performance of the eligible entity offering the plan.

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

"(E) CONSUMER SATISFACTION SURVEYS.—The results of consumer satisfaction surveys regarding the plan and the eligible entity offering such plan (conducted pursuant to section 1860D–5(h).

"(F) ADDITIONAL INFORMATION.—Such additional information as the Administrator may prescribe.

"BENEFICIARY PROTECTIONS

"SEC. 1860D–5. (a) DISSEMINATION OF INFORMATION.—

"(1) GENERAL INFORMATION.—An eligible entity offering a Medicare Prescription Drug plan shall disclose, in a clear, accurate, and standardized form to each enrollee at the time of enrollment, and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

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

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

"(C) Copayments, coinsurance, and deductible requirements.

"(D) Grievance and appeals processes.

The information described in the preceding sentence shall also be made available on request to prospective enrollees during open enrollment periods.

"(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to en-

roll in a Medicare Prescription Drug plan, the eligible entity offering such plan shall provide information similar (as determined by the Administrator) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

"(3) RESPONSE TO BENEFICIARY QUESTIONS.—An eligible entity offering a Medicare Prescription Drug plan shall have a mechanism for providing on a timely basis specific information to enrollees upon request, including information on the coverage of specific drugs and changes in its formulary.

"(4) CLAIMS INFORMATION.—An eligible entity offering a Medicare Prescription Drug plan must furnish to enrolled individuals in a form easily understandable to such individuals—

"(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 the initial coverage limit and annual out-of-pocket limit for the current year (except that such notice need not be provided more often than monthly).

"(5) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The provisions of section 1851(h) shall apply to marketing material and application forms under this part in the same manner as such provisions apply to marketing material and application forms under part C.

"(b) ACCESS TO COVERED DRUGS.—

"(1) ACCESS TO NEGOTIATED PRICES FOR PRESCRIPTION DRUGS.—An eligible entity offering a Medicare Prescription Drug plan shall have in place procedures to ensure that beneficiaries are not charged more than the negotiated price of a covered drug. Such procedures shall include the issuance of a card (or other technology) that may be used by an enrolled beneficiary for the purchase of prescription drugs for which coverage is not otherwise provided under the Medicare Prescription Drug plan.

"(2) ASSURING PHARMACY ACCESS.—

"(A) IN GENERAL.—An eligible entity offering a Medicare 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 (as determined by the Administrator and including ade-

quate emergency access) for enrolled beneficiaries, in accordance with standards established by the Administrator under section 1860D–7(g) that ensure such convenient access. Such standards shall take into account reasonable distances to pharmacy services in urban and rural areas and access to pharmacy services of the Indian Health Service and Indian tribes and tribal organizations.

"(B) USE OF POINT-OF-SERVICE SYSTEM.—An eligible entity offering a Medicare Prescription Drug plan shall establish an optional point-of-service method of operation under which—

"(i) the plan provides access to any or all pharmacies that are not participating pharmacies in its network; and

"(ii) the plan may charge beneficiaries through adjustments in copayments any additional costs associated with the point-of-service option.

The additional copayments so charged shall not count toward the application of section 1860D–6(c).

"(C) LEVEL PLAYING FIELD.—An eligible entity offering a Medicare Prescription Drug plan shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order, and may permit a differential amount to be paid by such enrollees.

"(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If an eligible entity offering a Medicare Prescription Drug plan uses a formulary, the following requirements must be met:

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

"(i) IN GENERAL.—The eligible entity must establish a pharmacy and therapeutic committee that develops and reviews the formulary.

"(ii) COMPOSITION.—A pharmacy and therapeutic committee shall include at least 1 academic expert, at least 1 practicing physician, and at least 1 practicing pharmacist, all of whom have expertise in the care of elderly or disabled persons, and a

majority of the members of such committee shall consist of individuals who are a practicing physician or a practicing pharmacist (or both).

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

"(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 drugs (as defined by the Administrator), although not necessarily for all drugs within such categories and classes.

"(ii) REQUIREMENT.—In defining therapeutic categories and classes of covered drugs pursuant to clause (i), the Administrator shall use—

"(I) the compendia referred to section 1927(g)(1)(B)(i); and

"(II) other recognized sources of drug classifications and categorizations determined appropriate by the Administrator.

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

"(E) NOTICE BEFORE REMOVING DRUGS FROM FORMULARY.—Any removal of a drug from a formulary shall take effect only after appropriate notice is made available to beneficiaries, physicians, and pharmacists.

"(F) APPEALS AND EXCEPTIONS TO APPLICATION.—The eligible entity must have, as part of the appeals process under subsection (e), a process for timely appeals for denials of coverage based on such application of the formulary.

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

"(1) IN GENERAL.—An eligible entity shall have in place the following with respect to covered drugs:

"(A) A cost-effective drug utilization management program, including incentives to reduce costs when appropriate.

"(B) Quality assurance measures to reduce medical errors and adverse drug interactions and to improve medication use, which—

"(i) shall include a medication therapy management program described in paragraph (2); and

"(ii) may include beneficiary education programs, counseling, medication refill reminders, and special packaging.

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

Nothing in this section shall be construed as impairing an eligible entity from applying cost management tools (including differential payments) under all methods of operation.

"(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

"(A) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy manage-

ment and medication administration that is designed to assure, with respect to beneficiaries with chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure) or multiple prescriptions, that covered drugs under the Medicare Prescription Drug plan are appropriately used to optimize therapeutic outcomes through improved medication use and to achieve therapeutic goals and reduce the risk of adverse events, including adverse drug interactions.

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

"(i) enhanced beneficiary understanding of such appropriate use through beneficiary education, counseling, and other appropriate means;

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

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

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

"(D) CONSIDERATIONS IN PHARMACY FEES.—The eligible entity offering a Medicare Prescription Drug plan shall take into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program.

"(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—The eligible entity offering a Medicare Prescription Drug plan shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered drug shall inform the beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost generic drug covered under the plan that is therapeutically equivalent and bioequivalent.

"(d) GRIEVANCE MECHANISM, COVERAGE DETERMINATIONS, AND RECONSIDERATIONS.—

"(1) IN GENERAL.—An eligible entity shall provide meaningful procedures for hearing and resolving grievances between the eligible entity (including any entity or individual through which the eligible entity provides covered benefits) and enrollees with Medicare Prescription Drug plans of the eligible entity under this part in accordance with section 1852(f).

"(2) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—The requirements of paragraphs (1) through (3) of section 1852(g) shall apply to an eligible entity with respect to covered benefits under the Medicare Prescription Drug plan it offers under this part in the same manner as such requirements apply to a MedicareAdvantage organization with respect to benefits it offers under a MedicareAdvantage plan under part C.

"(3) REQUEST FOR REVIEW OF TIERED FORMULARY DETERMINATIONS.—In the case of a Medicare Prescription Drug plan offered by an eligible entity that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, an individual who is enrolled in the plan may request coverage of a nonpreferred drug under

the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition is not as effective for the individual or has adverse effects for the individual.

"(e) APPEALS.—

"(1) IN GENERAL.—Subject to paragraph (2), the requirements of paragraphs (4) and (5) of section 1852(g) shall apply to an eligible entity with respect to drugs not included on any formulary in a manner that is similar (as determined by the Administrator) to the manner that such requirements apply to a MedicareAdvantage organization with respect to benefits it offers under a MedicareAdvantage plan under part C.

"(2) FORMULARY DETERMINATIONS.—An individual who is enrolled in a Medicare Prescription Drug plan offered by an eligible entity may appeal to obtain coverage for a covered drug that is not on a formulary of the entity under the terms applicable for a formulary drug if the prescribing physician determines that the formulary drug for treatment of the same condition is not as effective for the individual or has adverse effects for the individual.

"(f) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—Insofar as an eligible entity maintains individually identifiable medical records or other health information regarding eligible beneficiaries enrolled in the Medicare Prescription Drug plan offered by the entity, the entity shall have in place procedures to—

"(1) safeguard the privacy of any individually identifiable beneficiary information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

"(2) maintain such records and information in a manner that is accurate and timely;

"(3) ensure timely access by such beneficiaries to such records and information; and

"(4) otherwise comply with applicable laws relating to patient privacy and confidentiality.

"(g) UNIFORM MONTHLY PLAN PREMIUM.—An eligible entity shall ensure that the monthly plan premium for a Medicare Prescription Drug plan charged under this part is the same for all eligible beneficiaries enrolled in the plan. Such requirement shall not apply to enrollees of a Medicare Prescription Drug plan who are enrolled in

the plan pursuant to a contractual agreement between the plan and an employer or other group health plan that provides employment-based retiree health coverage (as defined in section 1860D–20(d)(4)(B)) if the premium amount is the same for all such enrollees under such agreement.

"(h) CONSUMER SATISFACTION SURVEYS.—An eligible entity shall conduct consumer satisfaction surveys with respect to the plan and the entity. The Administrator shall establish uniform requirements for such surveys.

"PRESCRIPTION DRUG BENEFITS

"SEC. 1860D–6. (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 (c)) and access to negotiated prices under subsection (e).

"(B) ACTUARIALLY EQUIVALENT PRESCRIPTION DRUG COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Coverage of covered drugs which meets the alternative coverage requirements of subsection (d) and access to negotiated prices under subsection (e), but only if

it is approved by the Administrator as provided under subsection (d).

"(2) PERMITTING ADDITIONAL PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B) and section 1860D–13(c)(2), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered drugs that exceeds the coverage required under paragraph (1).

"(B) REQUIREMENT.—An eligible entity may not offer a Medicare Prescription Drug plan that provides additional benefits pursuant to subparagraph (A) in an area unless the eligible entity offering such plan also offers a Medicare Prescription Drug plan in the area that only provides the coverage of prescription drugs that is required under paragraph (1).

"(3) COST CONTROL MECHANISMS.—In providing qualified prescription drug coverage, the entity offering the Medicare Prescription Drug plan or the MedicareAdvantage plan may use a variety of cost control mechanisms, including the use of formularies, tiered copayments, selective contracting

with providers of prescription drugs, and mail order pharmacies.

"(b) 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.

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

"(1) DEDUCTIBLE.—

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

"(i) for 2006, that is equal to $275; 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 (5) for the year involved.

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

"(2) LIMITS ON COST-SHARING.—The coverage has cost-sharing (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is equal to 50 percent or that is actuarially consistent (using processes established under subsection (f)) with an average expected payment of 50 percent of such costs.

"(3) INITIAL COVERAGE LIMIT.—

"(A) IN GENERAL.—Subject to 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 $4,500; 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 (5) for the year involved.

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

"(4) LIMITATION ON OUT-OF-POCKET EXPENDITURES BY BENEFICIARY.—

"(A) IN GENERAL.—The coverage provides benefits with cost-sharing that is equal to 10 percent after the individual has incurred costs (as described in subparagraph (C)) for covered drugs in a year equal to the annual out-of-pocket limit specified in subparagraph (B).

"(B) ANNUAL OUT-OF-POCKET LIMIT.—

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

"(I) for 2006, is equal to $3,700; 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 (5) for the year involved.

"(ii) ROUNDING.—Any amount determined under clause (i)(II) that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

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

"(i) incurred costs shall only include costs incurred, with respect to covered drugs, for the annual deductible (described in paragraph (1)), cost-sharing (described in paragraph (2)), and amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3) (including costs incurred for covered drugs described in section 1860D(a)(2)(C)); and

"(ii) such costs shall be treated as incurred only if they are paid by the individual (or by another individual, such as a family member, on behalf of the individual), under section 1860D–19 (but only with respect to the percentage of such costs that the individual is responsible for under that section), under title XIX, or under a State pharmaceutical assistance program and the individual (or other individual) is not reimbursed through insurance or otherwise, a group health plan, or

other third-party payment arrangement for such costs.

"(D) INFORMATION REGARDING THIRD-PARTY REIMBURSEMENT.—In order to ensure compliance with the requirements of subparagraph (C)(ii), the Administrator is authorized to establish procedures, in coordination with the Secretary of Treasury and the Secretary of Labor, for determining whether costs for individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement, and for alerting the entities in which such individuals are enrolled about such reimbursement arrangements. An entity with a contract under this part may also periodically ask individuals enrolled in a plan offered by the entity whether the individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Administrator and determined through a process established by the Administrator) shall constitute grounds for ter-

mination of enrollment under section 1860D–2(d).

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

"(d) ALTERNATIVE COVERAGE REQUIREMENTS.—A Medicare Prescription Drug plan or MedicareAdvantage plan may provide a different prescription drug benefit design from the standard prescription drug coverage described in subsection (c) so long as the Administrator determines (based on an actuarial analysis by the Administrator) that the following requirements are met and the plan applies for, and receives, the approval of the Administrator for such benefit design:

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

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

so determined) 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 (as determined under subsection (f)) exceeds the actuarial value of the amounts associated with the application of section 1860D–17(c) and reinsurance payments under section 1860D–20 with respect to such coverage.

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

"(i) such initial coverage limit minus the deductible under subsection (c)(1); and

"(ii) the percentage specified in subsection (c)(2).

Benefits other than qualified prescription drug coverage shall not be taken into account for purposes of this paragraph.

"(2) DEDUCTIBLE AND LIMITATION ON OUT-OF-POCKET EXPENDITURES BY BENEFICIARIES MAY NOT VARY.—The coverage may not vary the deductible under subsection (c)(1) for the year or the limitation on out-of-pocket expenditures by beneficiaries described in subsection (c)(4) for the year.

"(e) ACCESS TO NEGOTIATED PRICES.—

"(1) ACCESS.—

"(A) IN GENERAL.—Under qualified prescription drug coverage offered by an eligible entity or a MedicareAdvantage organization, the entity or organization shall provide beneficiaries with access to negotiated prices used for payment for covered drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of the deductible, any cost-sharing, or an initial coverage limit (described in subsection (c)(3)). For purposes of this part, the term 'negotiated prices' includes all dis-

counts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations.

"(B) MEDICAID RELATED PROVISIONS.—Insofar as a State elects to provide medical assistance under title XIX for a drug based on the prices negotiated under a Medicare Prescription Drug plan under this part—

"(i) the medical assistance for such a drug shall be disregarded for purposes of a rebate agreement entered into under section 1927 which would otherwise apply to the provision of medical assistance for the drug under title XIX; and

"(ii) the prices negotiated under a Medicare Prescription Drug plan with respect to covered drugs, under a MedicareAdvantage plan with respect to such drugs, or under a qualified retiree prescription drug plan (as defined in section 1860D–20(e)(4)) with respect to such drugs, on behalf of eligible beneficiaries, 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) CARDS OR OTHER TECHNOLOGY.—

"(A) IN GENERAL.—In providing the access under paragraph (1), the eligible entity or MedicareAdvantage organization shall issue a card or use other technology pursuant to section 1860D–5(b)(1).

"(B) NATIONAL STANDARDS.—

"(i) DEVELOPMENT.—The Administrator shall provide for the development of national standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with parts C and D 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 Administrator shall consult with the National Council for Prescription Drug Programs and other standard-setting organizations determined appropriate by the Administrator.

"(iii) IMPLEMENTATION.—The Administrator shall implement the standards developed under clause (i) by January 1, 2008.

"(3) DISCLOSURE.—The eligible entity offering a Medicare Prescription Drug plan and the MedicareAdvantage organization offering a MedicareAdvantage plan shall disclose to the Administrator (in a manner specified by the Administrator) the extent to which discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made available to the entity or organization by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Administrator under this paragraph in the same manner as such provisions apply to information disclosed under such section.

"(4) AUDITS AND REPORTS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part, in addition to any protections against fraud and abuse provided under section 1860D–7(f)(1), the Administrator may periodically audit the financial statements and

records of an eligible entity offering a Medicare Prescription Drug plan and a MedicareAdvantage organization offering a MedicareAdvantage plan with the auditor of the Administrator's choice.

"(f) ACTUARIAL VALUATION; DETERMINATION OF ANNUAL PERCENTAGE INCREASES.—

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

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

"(i) an actuarial valuation of standard prescription drug coverage and of the reinsurance payments under section 1860D–20;

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

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

"(B) for determining annual percentage increases described in subsection (c)(5).

Such processes shall take into account any effect that providing actuarially equivalent prescription drug coverage rather than standard prescription drug coverage has on drug utilization.

"(2) USE OF OUTSIDE ACTUARIES.—Under the processes under paragraph (1)(A), eligible entities and MedicareAdvantage organizations may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values, but the Administrator shall determine whether such actuarial values meet the requirements under subsection (c)(1).

"REQUIREMENTS FOR ENTITIES OFFERING MEDICARE PRESCRIPTION DRUG PLANS; ESTABLISHMENT OF STANDARDS

"SEC. 1860D–7. (a) GENERAL REQUIREMENTS.—An eligible entity offering a Medicare Prescription Drug plan shall meet the following requirements:

"(1) LICENSURE.—Subject to subsection (c), the entity 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 Medicare Prescription Drug plan.

"(2) ASSUMPTION OF FINANCIAL RISK.—

"(A) IN GENERAL.—Subject to subparagraph (B) and subsections (d)(2) and (e) of section 1860D–13, to the extent that the entity

is at risk pursuant to such section 1860D–16, the entity assumes financial risk on a prospective basis for the benefits that it offers under a Medicare Prescription Drug plan and that is not covered under section 1860D–20.

"(B) REINSURANCE PERMITTED.—To the extent that the entity is at risk pursuant to section 1860D–16, the entity may obtain insurance or make other arrangements for the cost of coverage provided to any enrolled member under this part.

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

"(b) CONTRACT REQUIREMENTS.—The Administrator shall not permit an eligible beneficiary to elect a Medicare Prescription Drug plan offered by an eligible entity under this part, and the entity shall not be eligible for payments under section 1860D–16 or 1860D–20, unless the Administrator has entered into a contract under this subsection with the entity with respect to the offering of such plan. Such a contract with an entity may cover

more than 1 Medicare Prescription Drug plan. Such contract shall provide that the entity 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.

"(c) WAIVER OF CERTAIN REQUIREMENTS IN ORDER TO ENSURE BENEFICIARY CHOICE.—

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

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

"(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under this subsection, the provisions

of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply.

"(4) REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying the provisions of section 1855(a)(2) under this subsection to Medicare Prescription Drug plans and eligible entities—

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

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

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

"(1) ESTABLISHMENT AND PUBLICATION.—The Administrator, 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.—An eligible entity that is not licensed by a State under subsection (a)(1) and for which a waiver application has

been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Administrator shall establish certification procedures for such eligible entities 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 an entity is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the eligible entity to meet other requirements imposed under this part for an eligible entity.

"(f) INCORPORATION OF CERTAIN MEDICAREADVANTAGE CONTRACT REQUIREMENTS.—The following provisions of section 1857 shall apply, subject to subsection (c)(4), to contracts under this section in the same manner as they apply to contracts under section 1857(a):

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

"(2) INTERMEDIATE SANCTIONS.—Section 1857(g), except that in applying such section—

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

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

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

"(g) OTHER STANDARDS.—The Administrator shall establish by regulation other standards (not described in subsection (d)) for eligible entities and Medicare Prescription Drug plans consistent with, and to carry out, this part. The Administrator shall publish such regulations by January 1, 2005.

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

"(1) IN GENERAL.—Subject to paragraph (2), the Administrator shall periodically review the standards established under this section and, based on such review, may revise such standards if the Administrator determines such revision to be appropriate.

"(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Administrator may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, signifi-

cant regulatory requirements on an eligible entity or a Medicare Prescription Drug plan.

"(h) RELATION TO STATE LAWS.—

"(1) IN GENERAL.—The standards established under this part shall supersede any State law or regulation (including standards described in paragraph (2)) with respect to Medicare Prescription Drug plans which are offered by eligible entities under this part—

"(A) to the extent such law or regulation is inconsistent with such standards; and

"(B) in the same manner as such laws and regulations are superseded under section 1856(b)(3).

"(2) STANDARDS SPECIFICALLY SUPERSEDED.—State standards relating to the following are superseded under this section:

"(A) Benefit requirements, including requirements relating to cost-sharing and the structure of formularies.

"(B) Premiums.

"(C) Requirements relating to inclusion or treatment of providers.

"(D) Coverage determinations (including related appeals and grievance processes).

"(E) Requirements relating to marketing materials and summaries and schedules of benefits regarding a Medicare Prescription Drug plan.

"(3) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.—No State may impose a premium tax or similar tax with respect to—

"(A) monthly beneficiary obligations paid to the Administrator for Medicare Prescription Drug plans under this part; or

"(B) any payments made by the Administrator under this part to an eligible entity offering such a plan.

"Subpart 2—Prescription Drug Delivery System

"ESTABLISHMENT OF SERVICE AREAS

"SEC. 1860D–10. (a) ESTABLISHMENT.—

"(1) INITIAL ESTABLISHMENT.—Not later than April 15, 2005, the Administrator shall establish and publish the service areas in which Medicare Prescription Drug plans may offer benefits under this part.

"(2) PERIODIC REVIEW AND REVISION OF SERVICE AREAS.—The Administrator shall periodically review the service areas applicable under this section and, based on such review, may revise such

service areas if the Administrator determines such revision to be appropriate.

"(b) REQUIREMENTS FOR ESTABLISHMENT OF SERVICE AREAS.—

"(1) IN GENERAL.—The Administrator shall establish the service areas under subsection (a) in a manner that—

"(A) maximizes the availability of Medicare Prescription Drug plans to eligible beneficiaries; and

"(B) minimizes the ability of eligible entities offering such plans to favorably select eligible beneficiaries.

"(2) ADDITIONAL REQUIREMENTS.—The Administrator shall establish the service areas under subsection (a) consistent with the following requirements:

"(A) There shall be at least 10 service areas.

"(B) Each service area must include at least 1 State.

"(C) The Administrator may not divide States so that portions of the State are in different service areas.

"(D) To the extent possible, the Administrator shall include multistate metropolitan statistical areas in a single service area. The Administrator may divide metropolitan statistical areas where it is necessary to establish service areas of such size and geography as to maximize the participation of Medicare Prescription Drug plans.

"(3) MAY CONFORM TO MEDICAREADVANTAGE PREFERRED PROVIDER REGIONS.—The Administrator may conform the service areas established under this section to the preferred provider regions established under section 1858(a)(3).

"PUBLICATION OF RISK ADJUSTERS

"SEC. 1860D–11. (a) PUBLICATION.—Not later than April 15 of each year (beginning in 2005), the Administrator shall publish the risk adjusters established under subsection (b) to be used in computing—

"(1) the amount of payment to Medicare Prescription Drug plans in the subsequent year under section 1860D–16(a), insofar as it is attributable to standard prescription drug coverage (or actuarially equivalent prescription drug coverage); and

"(2) the amount of payment to MedicareAdvantage plans in the subsequent year under section 1858A(c), insofar as it is attributable

to standard prescription drug coverage (or actuarially equivalent prescription drug coverage).

"(b) ESTABLISHMENT OF RISK ADJUSTERS.—

"(1) IN GENERAL.—Subject to paragraph (2), the Administrator shall establish an appropriate methodology for adjusting the amount of payment to plans referred to in subsection (a) to take into account variation in costs based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner as to not result in a change in the aggregate payments described in paragraphs (1) and (2) of subsection (a).

"(2) CONSIDERATIONS.—In establishing the methodology under paragraph (1), the Administrator may take into account the similar methodologies used under section 1853(a)(3) to adjust payments to MedicareAdvantage organizations.

"(3) DATA COLLECTION.—In order to carry out this subsection, the Administrator shall require—

"(A) eligible entities to submit data regarding drug claims that can be linked at the beneficiary level to part A and part B data and such other information as the Administrator determines necessary; and

"(B) MedicareAdvantage organizations (except MSA plans or a private fee-for-service plan that does not provide qualified prescription drug coverage) to submit data regarding drug claims that can be linked to other data that such organizations are required to submit to the Administrator and such other information as the Administrator determines necessary.

"SUBMISSION OF BIDS FOR PROPOSED MEDICARE PRESCRIPTION DRUG PLANS

"SEC. 1860D–12. (a) SUBMISSION.—

"(1) IN GENERAL.—Each eligible entity that intends to offer a Medicare Prescription Drug plan in an area in a year (beginning with 2006) shall submit to the Administrator, at such time in the previous year and in such manner as the Administrator may specify, such information as the Administrator may require, including the information described in subsection (b).

"(2) ANNUAL SUBMISSION.—An eligible entity shall submit the information required under paragraph (1) with respect to a Medicare Prescription Drug plan that the entity intends to offer on an annual basis.

"(b) INFORMATION DESCRIBED.—The information described in this subsection includes information on each of the following:

"(1) The benefits under the plan (as required under section 1860D–6).

"(2) The actuarial value of the qualified prescription drug coverage.

"(3) The amount of the monthly plan premium under the plan, including an actuarial certification of—

"(A) the actuarial basis for such monthly plan premium;

"(B) the portion of such monthly plan premium attributable to standard prescription drug coverage or actuarially equivalent prescription drug coverage and, if applicable, to benefits that are in addition to such coverage; and

"(C) the reduction in such monthly plan premium resulting from the payments provided under section 1860D–20.

"(4) The service area for the plan.

"(5) Whether the entity plans to use any funds in the plan stabilization reserve fund in the Prescription Drug Account that are available to the entity to stabilize or reduce the monthly plan premium sub-

mitted under paragraph (3), and if so, the amount in such reserve fund that is to be used.

"(6) Such other information as the Administrator may require to carry out this part.

"(c) OPTIONS REGARDING SERVICE AREAS.—

"(1) IN GENERAL.—The service area of a Medicare Prescription Drug plan shall be either—

"(A) the entire area of 1 of the service areas established by the Administrator under section 1860D–10; or

"(B) the entire area covered by the medicare program.

"(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed as prohibiting an eligible entity from submitting separate bids in multiple service areas as long as each bid is for a single service area.

"APPROVAL OF PROPOSED MEDICARE PRESCRIPTION DRUG PLANS

"SEC. 1860D–13. (a) APPROVAL.—

"(1) IN GENERAL.—The Administrator shall review the information filed under section 1860D–12 and shall approve or disapprove the Medicare Prescription Drug plan.

"(2) REQUIREMENTS FOR APPROVAL.—The Administrator may not approve a Medicare Prescrip-

tion Drug plan unless the following requirements are met:

"(A) COMPLIANCE WITH REQUIREMENTS.—The plan and the entity offering the plan comply with the requirements under this part.

"(B) APPLICATION OF FEHBP STANDARD.—(i) The portion of the monthly plan premium submitted under section 1860D–12(b) that is attributable to standard prescription drug coverage reasonably and equitably reflects the actuarial value of the standard prescription drug coverage less the actuarial value of the reinsurance payments under section 1860D–20 and the amount of any funds in the plan stabilization reserve fund in the Prescription Drug Account used to stabilize or reduce the monthly plan premium.

"(ii) If the plan provides additional prescription drug coverage pursuant to section 1860D–6(a)(2), the monthly plan premium reasonably and equitably reflects the actuarial value of the coverage provided less the actuarial value of the reinsurance payments under section 1860D–20 and the amount of any funds in the

1 plan stabilization reserve fund in the Prescrip-
2 tion Drug Account used to stabilize or reduce
3 the monthly plan premium.
4 "(b) NEGOTIATION.—In exercising the authority
5 under subsection (a), the Administrator shall have the au-
6 thority to—
7 "(1) negotiate the terms and conditions of the
8 proposed monthly plan premiums submitted and
9 other terms and conditions of a proposed plan; and
10 "(2) disapprove, or limit enrollment in, a pro-
11 posed plan based on—
12 "(A) the costs to beneficiaries under the
13 plan;
14 "(B) the quality of the coverage and bene-
15 fits under the plan;
16 "(C) the adequacy of the network under
17 the plan;
18 "(D) the average aggregate projected cost
19 of covered drugs under the plan relative to
20 other Medicare Prescription Drug plans and
21 MedicareAdvantage plans; or
22 "(E) other factors determined appropriate
23 by the Administrator.
24 "(c) SPECIAL RULES FOR APPROVAL.—The Adminis-
25 trator may approve a Medicare Prescription Drug plan

submitted under section 1860D–12 only if the benefits under such plan—

"(1) include the required benefits under section 1860D–6(a)(1); and

"(2) are not designed in such a manner that the Administrator finds is likely to result in favorable selection of eligible beneficiaries.

"(d) ACCESS TO COMPETITIVE COVERAGE.—

"(1) NUMBER OF CONTRACTS.—The Administrator, consistent with the requirements of this part and the goal of containing costs under this title, shall, with respect to a year, approve at least 2 contracts to offer a Medicare Prescription Drug plan in each service area (established under section 1860D–10) for the year.

"(2) AUTHORITY TO REDUCE RISK TO ENSURE ACCESS.—

"(A) IN GENERAL.—Subject to subparagraph (B), if the Administrator determines, with respect to an area, that the access required under paragraph (1) is not going to be provided in the area during the subsequent year, the Administrator shall—

"(i) adjust the percents specified in paragraphs (2) and (4) of section 1860D–16(b) in an area in a year; or

"(ii) increase the percent specified in section 1860D–20(c)(1) in an area in a year.

The administrator shall exercise the authority under the preceding sentence only so long as (and to the extent) necessary to assure the access guaranteed under paragraph (1).

"(B) REQUIREMENTS FOR USE OF AUTHORITY.—In exercising authority under subparagraph (A), the Administrator—

"(i) shall not provide for the full underwriting of financial risk for any eligible entity;

"(ii) shall not provide for any underwriting of financial risk for a public eligible entity with respect to the offering of a nationwide Medicare Prescription Drug plan; and

"(iii) shall seek to maximize the assumption of financial risk by eligible entities to ensure fair competition among Medicare Prescription Drug plans.

"(C) REQUIREMENT TO ACCEPT 2 FULL-RISK QUALIFIED BIDS BEFORE EXERCISING AUTHORITY.—The Administrator may not exercise the authority under subparagraph (A) with respect to an area and year if 2 or more qualified bids are submitted by eligible entities to offer a Medicare Prescription Drug plan in the area for the year under paragraph (1) before the application of subparagraph (A).

"(D) REPORTS.—The Administrator, in each annual report to Congress under section 1808(c)(1)(D), shall include information on the exercise of authority under subparagraph (A). The Administrator also shall include such recommendations as may be appropriate to limit the exercise of such authority.

"(e) GUARANTEED ACCESS.—

"(1) ACCESS.—In order to assure access to qualified prescription drug coverage in an area, the Administrator shall take the following steps:

"(A) DETERMINATION.—Not later than September 1 of each year (beginning in 2005) and for each area (established under section 1860D–10), the Administrator shall make a determination as to whether the access required

under subsection (d)(1) is going to be provided in the area during the subsequent year. Such determination shall be made after the Administrator has exercised the authority under subsection (d)(2).

"(B) CONTRACT WITH AN ENTITY TO PROVIDE COVERAGE IN AN AREA.—Subject to paragraph (3), if the Administrator makes a determination under subparagraph (A) that the access required under subsection (d)(1) is not going to be provided in an area during the subsequent year, the Administrator shall enter into a contract with an entity to provide eligible beneficiaries enrolled under this part (and not, except for an MSA plan or a private fee-for-service plan that does not provide qualified prescription drug coverage enrolled in a MedicareAdvantage plan) and residing in the area with standard prescription drug coverage (including access to negotiated prices for such beneficiaries pursuant to section 1860D–6(e)) during the subsequent year. An entity may be awarded a contract for more than 1 of the areas for which the Administrator is required to enter into a contract under this paragraph but

the Administrator may enter into only 1 such contract in each such area.

"(C) REQUIREMENT TO ACCEPT 2 REDUCED-RISK QUALIFIED BIDS BEFORE ENTERING INTO CONTRACT.—The Administrator may not enter into a contract under subparagraph (B) with respect to an area and year if 2 or more qualified bids are submitted by eligible entities to offer a Medicare Prescription Drug plan in the area for the year after the Administrator has exercised the authority under subsection (d)(2) in the area for the year.

"(D) ENTITY REQUIRED TO MEET BENEFICIARY PROTECTION AND OTHER REQUIREMENTS.—An entity with a contract under subparagraph (B) shall meet the requirements described in section 1860D–5 and such other requirements determined appropriate by the Administrator.

"(E) 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 subparagraph (B).

"(2) MONTHLY BENEFICIARY OBLIGATION FOR ENROLLMENT.—

"(A) IN GENERAL.—In the case of an eligible beneficiary receiving access to qualified prescription drug coverage through enrollment with an entity with a contract under paragraph (1)(B), the monthly beneficiary obligation of such beneficiary for such enrollment shall be an amount equal to the applicable percent (as determined under section 1860D–17(c)) of the monthly national average premium (as computed under section 1860D–15) for the area for the year, as adjusted using the geographic adjuster under subparagraph (B).

"(B) ESTABLISHMENT OF GEOGRAPHIC ADJUSTER.—The Administrator shall establish an appropriate methodology for adjusting the monthly beneficiary obligation (as computed under subparagraph (A)) for the year in an area to take into account differences in drug prices among areas. In establishing such methodology, the Administrator may take into account differences in drug utilization between eligible beneficiaries in an area and eligible beneficiaries in other areas and the results of the

ongoing study required under section 106 of the Prescription Drug and Medicare Improvement Act of 2003. Any such adjustment 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 Administrator had not applied such adjustment.

''(3) PAYMENTS UNDER THE CONTRACT.—

''(A) IN GENERAL.—A contract entered into under paragraph (1)(B) shall provide for—

''(i) payment for the negotiated costs of covered drugs provided to eligible beneficiaries enrolled with the entity; and

''(ii) payment of prescription management fees that are tied to performance requirements established by the Administrator for the management, administration, and delivery of the benefits under the contract.

''(B) PERFORMANCE REQUIREMENTS.—The performance requirements established by the Administrator pursuant to subparagraph (A)(ii) shall include the following:

''(i) The entity contains costs to the Prescription Drug Account and to eligible

beneficiaries enrolled under this part and with the entity.

"(ii) The entity provides such beneficiaries with quality clinical care.

"(iii) The entity provides such beneficiaries with quality services.

"(C) ENTITY ONLY AT RISK TO THE EXTENT OF THE FEES TIED TO PERFORMANCE REQUIREMENTS.—An entity with a contract under paragraph (1)(B) shall only be at risk for the provision of benefits under the contract to the extent that the management fees paid to the entity are tied to performance requirements under subparagraph (A)(ii).

"(4) ELIGIBLE ENTITY THAT SUBMITTED A BID FOR THE AREA NOT ELIGIBLE TO BE AWARDED THE CONTRACT.—An eligible entity that submitted a bid to offer a Medicare Prescription Drug plan for an area for a year under section 1860D–12, including a bid submitted after the Administrator has exercised the authority under subsection (d)(2), may not be awarded a contract under paragraph (1)(B) for that area and year. The previous sentence shall apply to an entity that was awarded a contract under paragraph (1)(B) for the area in the previous

year and submitted such a bid under section 1860D–12 for the year.

"(5) TERM OF CONTRACT.—A contract entered into under paragraph (1)(B) shall be for a 1-year period. Such contract may provide for renewal at the discretion of the Administrator if the Administrator is required to enter into a contract under such paragraph with respect to the area covered by such contract for the subsequent year.

"(6) ENTITY NOT PERMITTED TO MARKET OR BRAND THE CONTRACT.—An entity with a contract under paragraph (1)(B) may not engage in any marketing or branding of such contract.

"(7) RULES FOR AREAS WHERE ONLY 1 COMPETITIVELY BID PLAN WAS APPROVED.—In the case of an area where (before the application of this subsection) only 1 Medicare Prescription Drug plan was approved for a year—

"(A) the plan may (at the option of the plan) be offered in the area for the year (under rules applicable to such plans under this part and not under this subsection);

"(B) eligible beneficiaries described in paragraph (1)(B) may receive access to qualified prescription drug coverage through enroll-

ment in the plan or with an entity with a contract under paragraph (1)(B); and

"(C) for purposes of applying section 1860D–3(a)(1)(A)(ii), such plan shall be the plan designated in the area under such section.

"(f) TWO-YEAR CONTRACTS.—Except for a contract entered into under subsection (e)(1)(B), a contract approved under this part shall be for a 2-year period.

"COMPUTATION OF MONTHLY STANDARD PRESCRIPTION DRUG COVERAGE PREMIUMS

"SEC. 1860D–14. (a) IN GENERAL.—For each year (beginning with 2006), the Administrator shall compute a monthly standard prescription drug coverage premium for each Medicare Prescription Drug plan approved under section 1860D–13 and for each MedicareAdvantage plan.

"(b) REQUIREMENTS.—The monthly standard prescription drug coverage premium for a plan for a year shall be equal to—

"(1) in the case of a plan offered by an eligible entity or MedicareAdvantage organization that provides standard prescription drug coverage or an actuarially equivalent prescription drug coverage and does not provide additional prescription drug coverage pursuant to section 1860D–6(a)(2), the monthly plan premium approved for the plan under section 1860D–13 for the year; and

"(2) in the case of a plan offered by an eligible entity or MedicareAdvantage organization that provides additional prescription drug coverage pursuant to section 1860D–6(a)(2)—

"(A) an amount that reflects only the actuarial value of the standard prescription drug coverage offered under the plan; or

"(B) if determined appropriate by the Administrator, the monthly plan premium approved under section 1860D–13 for the year for the Medicare Prescription Drug plan (or, if applicable, the MedicareAdvantage plan) that, as required under section 1860D–6(a)(2)(B) for a Medicare Prescription Drug plans and a MedicareAdvantage plan—

"(i) is offered by such entity or organization in the same area as the plan; and

"(ii) does not provide additional prescription drug coverage pursuant to such section.

"COMPUTATION OF MONTHLY NATIONAL AVERAGE PREMIUM

"SEC. 1860D–15. (a) COMPUTATION.—

"(1) IN GENERAL.—For each year (beginning with 2006) the Administrator shall compute a monthly national average premium equal to the aver-

age of the monthly standard prescription drug coverage premium for each Medicare Prescription Drug plan and each MedicareAdvantage plan (as computed under section 1860D–14). Such premium may be adjusted pursuant to any methodology determined under subsection (b), as determined appropriate by the Administrator.

"(2) WEIGHTED AVERAGE.—The monthly national average premium computed under paragraph (1) shall be a weighted average, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the previous year.

"(b) GEOGRAPHIC ADJUSTMENT.—The Administrator shall establish an appropriate methodology for adjusting the monthly national average premium (as computed under subsection (a)) for the year in an area to take into account differences in prices for covered drugs among different areas. In establishing such methodology, the Administrator may take into account differences in drug utilization between eligible beneficiaries in that area and other eligible beneficiaries and the results of the ongoing study required under section 106 of the Prescription Drug and Medicare Improvement Act of 2003. Any such adjustment shall be applied in a manner as to not result in a

1 change in aggregate payments made under this part than
2 would have been made if the Administrator had not ap-
3 plied such adjustment.

4 "(c) SPECIAL RULE FOR 2006.—For purposes of ap-
5 plying this section for 2006, the Administrator shall estab-
6 lish procedures for determining the weighted average
7 under subsection (a)(2) for 2005.

8 "PAYMENTS TO ELIGIBLE ENTITIES

9 "SEC. 1860D–16. (a) PAYMENT OF MONTHLY PLAN
10 PREMIUMS.—For each year (beginning with 2006), the
11 Administrator shall pay to each entity offering a Medicare
12 Prescription Drug plan in which an eligible beneficiary is
13 enrolled an amount equal to the full amount of the month-
14 ly plan premium approved for the plan under section
15 1860D–13 on behalf of each eligible beneficiary enrolled
16 in such plan for the year, as adjusted using the risk ad-
17 justers that apply to the standard prescription drug cov-
18 erage published under section 1860D–11.

19 "(b) PORTION OF TOTAL PAYMENTS OF MONTHLY
20 PLAN PREMIUMS SUBJECT TO RISK.—

21 "(1) NOTIFICATION OF SPENDING UNDER THE
22 PLAN.—

23 "(A) IN GENERAL.—For each year (begin-
24 ning in 2007), the eligible entity offering a
25 Medicare Prescription Drug plan shall notify
26 the Administrator of the following:

"(i) TOTAL ACTUAL COSTS.—The total amount of costs that the entity incurred in providing standard prescription drug coverage (or prescription drug coverage that is actuarially equivalent pursuant to section 1860D–6(a)(1)(B)) for all enrollees under the plan in the previous year.

"(ii) AMOUNTS RESULTING IN ACTUAL COSTS.—With respect to the total amount under clause (i) for the year—

"(I) the aggregate amount of payments made by the entity to pharmacies and other entities with respect to such coverage for such enrollees; and

"(II) the aggregate amount of discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity with respect to such coverage for such enrollees.

"(B) CERTAIN EXPENSES NOT INCLUDED.—The amount under subparagraph (A)(i) may not include—

"(i) administrative expenses incurred in providing the coverage described in subparagraph (A)(i);

"(ii) amounts expended on providing additional prescription drug coverage pursuant to section 1860D–6(a)(2);

"(iii) amounts expended for which the entity is subsequently provided with reinsurance payments under section 1860D–20; or

"(iv) discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity with respect to coverage described in subparagraph (A)(i).

"(2) ADJUSTMENT OF PAYMENT.—

"(A) NO ADJUSTMENT IF ALLOWABLE COSTS WITHIN RISK CORRIDOR.—If the allowable costs (specified in paragraph (3)) for the plan for the year are not more than the first threshold upper limit of the risk corridor (specified in paragraph (4)(A)(iii)) and are not less than the first threshold lower limit of the risk corridor (specified in paragraph (4)(A)(i)) for the plan for the year, then no additional pay-

ments shall be made by the Administrator and no payments shall be made by (or collected from) the eligible entity offering the plan.

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

"(i) IN GENERAL.—If the allowable costs for the plan for the year are more than the first threshold upper limit of the risk corridor for the plan for the year, then the Administrator shall increase the total of the monthly payments made to the entity offering the plan for the year under subsection (a) by an amount equal to the sum of—

"(I) the applicable percent (as defined in subparagraph (D)) of such allowable costs which are more than such first threshold upper limit of the risk corridor and not more than the second threshold upper limit of the risk corridor for the plan for the year (as specified under paragraph (4)(A)(iv)); and

"(II) 90 percent of such allowable costs which are more than such second threshold upper limit of the risk corridor.

"(ii) SPECIAL TRANSITIONAL CORRIDOR FOR 2006 AND 2007.—If the Administrator determines with respect to 2006 or 2007 that at least 60 percent of Medicare Prescription Drug plans and MedicareAdvantage Plans (excluding MSA plans or private fee-for-service plans that do not provide qualified prescription drug coverage) have allowable 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 that such plans represent at least 60 percent of eligible beneficiaries enrolled under this part, clause (i)(I) shall be applied by substituting '90 percent' for 'applicable percent'.

"(C) PLAN PAYMENT IF ALLOWABLE COSTS BELOW LOWER LIMIT OF RISK CORRIDOR.—If the allowable costs for the plan for the year are less than the first threshold lower

limit of the risk corridor for the plan for the year, then the entity offering the plan shall a make a payment to the Administrator of an amount (or the Administrator shall otherwise recover from the plan an amount) equal to—

"(i) the applicable percent (as so defined) of such allowable costs which are less than such first threshold lower limit of the risk corridor and not less than the second threshold lower limit of the risk corridor for the plan for the year (as specified under paragraph (4)(A)(ii)); and

"(ii) 90 percent of such allowable costs which are less than such second threshold lower limit of the risk corridor.

"(D) APPLICABLE PERCENT DEFINED.—For purposes of this paragraph, the term 'applicable percent' means—

"(i) for 2006 and 2007, 75 percent; and

"(ii) for 2008 and subsequent years, 50 percent.

"(3) ESTABLISHMENT OF ALLOWABLE COSTS.—For each year, the Administrator shall establish the allowable costs for each Medicare Pre-

scription Drug plan for the year. The allowable costs for a plan for a year shall be equal to the amount described in paragraph (1)(A)(i) for the plan for the year.

"(4) ESTABLISHMENT OF RISK CORRIDORS.—

"(A) IN GENERAL.—For each year (beginning with 2006), the Administrator shall establish a risk corridor for each Medicare Prescription Drug 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 Medicare Prescription Drug plan offered by an eligible entity in a year—

"(i) in the case of a plan offered by an eligible entity that provides standard prescription drug coverage or actuarially equivalent prescription drug coverage and does not provide additional prescription drug coverage pursuant to section 1860D–6(a)(2), an amount equal to the total of the monthly plan premiums paid to such entity for such plan for the year pursuant to subsection (a), reduced by the percentage specified in subparagraph (D); and

"(ii) in the case of a plan offered by an eligible entity that provides additional prescription drug coverage pursuant to section 1860D–6(a)(2), an amount equal to the total of the monthly plan premiums paid to such entity for such plan for the year pursuant to subsection (a) that are related to standard prescription drug coverage (determined using the rules under section 1860D–14(b)), reduced by the percentage specified in subparagraph (D).

"(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 Administrator, 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, 5.0 percent;

"(II) for 2008 through 2011, 10 percent

"(III) for 2012 and subsequent years, a percentage established by the Administrator 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 paragraph (2) of section 1860D–13(d), the Administrator may reduce the applicable first or second threshold risk percentage in an area in a year in order to ensure the access to plans required under paragraph (1) of such section.

"(D) TARGET AMOUNT NOT TO INCLUDE ADMINISTRATIVE EXPENSES NEGOTIATED BETWEEN THE ADMINISTRATOR AND THE ENTITY OFFERING THE PLAN.—For each year (beginning in 2006), the Administrator and the entity offering a Medicare Prescription Drug plan shall negotiate, as part of the negotiation process described in section 1860D–13(b) during the previous year, the percentage of the payments to the entity under subsection (a) with respect to the plan that are attributable and reasonably incurred for administrative expenses for providing standard prescription drug cov-

erage or actuarially equivalent prescription drug coverage in the year.

"(5) PLANS AT RISK FOR ENTIRE AMOUNT OF ADDITIONAL PRESCRIPTION DRUG COVERAGE.—An eligible entity that offers a Medicare Prescription Drug plan that provides additional prescription drug coverage pursuant to section 1860D–6(a)(2) shall be at full financial risk for the provision of such additional coverage.

"(6) NO EFFECT ON ELIGIBLE BENEFICIARIES.—No change in payments made by reason of this subsection shall affect the beneficiary obligation under section 1860D–17 for the year in which such change in payments is made.

"(7) DISCLOSURE OF INFORMATION.—

"(A) IN GENERAL.—Each contract under this part shall provide that—

"(i) the entity offering a Medicare Prescription Drug plan shall provide the Administrator with such information as the Administrator determines is necessary to carry out this section; and

"(ii) the Administrator shall have the right to inspect and audit any books and records of the eligible entity that pertain to

the information regarding costs provided to the Administrator under paragraph (1).

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

"(c) STABILIZATION RESERVE FUND.—

"(1) ESTABLISHMENT.—

"(A) IN GENERAL.—There is established, within the Prescription Drug Account, a stabilization reserve fund in which the Administrator shall deposit amounts on behalf of eligible entities in accordance with paragraph (2) and such amounts shall be made available by the Secretary for the use of eligible entities in contract year 2008 and subsequent contract years in accordance with paragraph (3).

"(B) REVERSION OF UNUSED AMOUNTS.—Any amount in the stabilization reserve fund established under subparagraph (A) that is not expended by an eligible entity in accordance with paragraph (3) or that was deposited for

the use of an eligible entity that no longer has a contract under this part shall revert for the use of the Prescription Drug Account.

"(2) DEPOSIT OF AMOUNTS FOR 5 YEARS.—

"(A) IN GENERAL.—If the target amount for a Medicare Prescription Drug plan for 2006, 2007, 2008, 2009, or 2010 (as determined under subsection (b)(4)(B)) exceeds the applicable costs for the plan for the year by more than 3 percent, then—

"(i) the entity offering the plan shall make a payment to the Administrator of an amount (or the Administrator shall otherwise recover from the plan an amount) equal to the portion of such excess that is in excess of 3 percent of the target amount; and

"(ii) the Administrator shall deposit an amount equal to the amount collected or otherwise recovered under clause (i) in the stabilization reserve fund on behalf of the eligible entity offering such plan.

"(B) APPLICABLE COSTS.—For purposes of subparagraph (A), the term 'applicable costs' means, with respect to a Medicare Prescription

Drug plan and year, an amount equal the sum of—

"(i) the allowable costs for the plan and year (as determined under subsection (b)(3)(A); and

"(ii) the total amount by which monthly payments to the plan were reduced (or otherwise recovered from the plan) for the year under subsection (b)(2)(C).

"(3) USE OF RESERVE FUND TO STABILIZE OR REDUCE MONTHLY PLAN PREMIUMS.—

"(A) IN GENERAL.—For any contract year beginning after 2007, an eligible entity offering a Medicare Prescription Drug plan may use funds in the stabilization reserve fund in the Prescription Drug Account that were deposited in such fund on behalf of the entity to stabilize or reduce monthly plan premiums submitted under section 1860D–12(b)(3).

"(B) PROCEDURES.—The Administrator shall establish procedures for—

"(i) reducing monthly plan premiums submitted under section 1860D–12(b)(3) pursuant to subparagraph (A); and

"(ii) making payments from the plan stabilization reserve fund in the Prescription Drug Account to eligible entities that inform the Secretary under section 1860D–12(b)(5) of the entity's intent to use funds in such reserve fund to reduce such premiums.

"(d) PORTION OF PAYMENTS OF MONTHLY PLAN PREMIUMS ATTRIBUTABLE TO ADMINISTRATIVE EXPENSES TIED TO PERFORMANCE REQUIREMENTS.—

"(1) IN GENERAL.—The Administrator shall establish procedures to adjust the portion of the payments made to an entity under subsection (a) that are attributable to administrative expenses (as determined pursuant to subsection (b)(4)(D)) to ensure that the entity meets the performance requirements described in clauses (ii) and (iii) of section 1860D–13(e)(4)(B).

"(2) NO EFFECT ON ELIGIBLE BENEFICIARIES.—No change in payments made by reason of this subsection shall affect the beneficiary obligation under section 1860D–17 for the year in which such change in payments is made.

"(e) PAYMENT TERMS.—

"(1) ADMINISTRATOR PAYMENTS.—Payments to an entity offering a Medicare Prescription Drug plan under this section shall be made in a manner determined by the Administrator and based upon the manner in which payments are made under section 1853(a) (relating to payments to MedicareAdvantage organizations).

"(2) PLAN PAYMENTS.—The Administrator shall establish a process for collecting (or other otherwise recovering) amounts that an entity offering a Medicare Prescription Drug plan is required to make to the Administrator under this section.

"(f) PAYMENTS TO MEDICAREADVANTAGE PLANS.—For provisions related to payments to MedicareAdvantage organizations offering MedicareAdvantage plans for qualified prescription drug coverage made available under the plan, see section 1858A(c).

"(g) SECONDARY PAYER PROVISIONS.—The provisions of section 1862(b) shall apply to the benefits provided under this part.

"COMPUTATION OF MONTHLY BENEFICIARY OBLIGATION

"SEC. 1860D–17. (a) BENEFICIARIES ENROLLED IN A MEDICARE PRESCRIPTION DRUG PLAN.—In the case of an eligible beneficiary enrolled under this part and in a Medicare Prescription Drug plan, the monthly beneficiary

obligation for enrollment in such plan in a year shall be determined as follows:

"(1) MONTHLY PLAN PREMIUM EQUALS MONTHLY NATIONAL AVERAGE PREMIUM.—If the amount of the monthly plan premium approved by the Administrator under section 1860D–13 for a Medicare Prescription Drug plan for the year is equal to the monthly national average premium (as computed under section 1860D–15) for the area for the year, the monthly beneficiary obligation of the eligible beneficiary in that year shall be an amount equal to the applicable percent (as determined in subsection (c)) of the amount of such monthly national average premium.

"(2) MONTHLY PLAN PREMIUM LESS THAN MONTHLY NATIONAL AVERAGE PREMIUM.—If the amount of the monthly plan premium approved by the Administrator under section 1860D–13 for the Medicare Prescription Drug plan for the year is less than the monthly national average premium (as computed under section 1860D–15) for the area for the year, the monthly beneficiary obligation of the eligible beneficiary in that year shall be an amount equal to—

"(A) the applicable percent of the amount of such monthly national average premium; minus

"(B) the amount by which such monthly national average premium exceeds the amount of the monthly plan premium approved by the Administrator for the plan.

"(3) MONTHLY PLAN PREMIUM EXCEEDS MONTHLY NATIONAL AVERAGE PREMIUM.—If the amount of the monthly plan premium approved by the Administrator under section 1860D–13 for a Medicare Prescription Drug plan for the year exceeds the monthly national average premium (as computed under section 1860D–15) for the area for the year, the monthly beneficiary obligation of the eligible beneficiary in that year shall be an amount equal to the sum of—

"(A) the applicable percent of the amount of such monthly national average premium; plus

"(B) the amount by which the monthly plan premium approved by the Administrator for the plan exceeds the amount of such monthly national average premium.

"(b) BENEFICIARIES ENROLLED IN A MEDICAREADVANTAGE PLAN.—In the case of an eligible

1 beneficiary that is enrolled in a MedicareAdvantage plan
2 (except for an MSA plan or a private fee-for-service plan
3 that does not provide qualified prescription drug cov-
4 erage), the Medicare monthly beneficiary obligation for
5 qualified prescription drug coverage shall be determined
6 pursuant to section 1858A(d).

7 ''(c) APPLICABLE PERCENT.—For purposes of this
8 section, except as provided in section 1860D–19 (relating
9 to premium subsidies for low-income individuals), the ap-
10 plicable percent for any year is the percentage equal to
11 a fraction—

12 ''(1) the numerator of which is 30 percent; and

13 ''(2) the denominator of which is 100 percent
14 minus a percentage equal to—

15 ''(A) the total reinsurance payments which
16 the Administrator estimates will be made under
17 section 1860D–20 to qualifying entities de-
18 scribed in subsection (e)(3) of such section dur-
19 ing the year; divided by

20 ''(B) the sum of—

21 ''(i) the amount estimated under sub-
22 paragraph (A) for the year; and

23 ''(ii) the total payments which the Ad-
24 ministrator estimates will be made under
25 sections 1860D–16 and 1858A(c) during

the year that relate to standard prescription drug coverage (or actuarially equivalent prescription drug coverage).

"COLLECTION OF MONTHLY BENEFICIARY OBLIGATION

"SEC. 1860D–18. (a) COLLECTION OF AMOUNT IN SAME MANNER AS PART B PREMIUM.—

"(1) IN GENERAL.—Subject to paragraph (2), the amount of the monthly beneficiary obligation (determined under section 1860D–17) applicable to an eligible beneficiary under this part (after application of any increase under section 1860D–2(b)(1)(A)) shall be collected and credited to the Prescription Drug Account in the same manner as the monthly premium determined under section 1839 is collected and credited to the Federal Supplementary Medical Insurance Trust Fund under section 1840.

"(2) PROCEDURES FOR SPONSOR TO PAY OBLIGATION ON BEHALF OF RETIREE.—The Administrator shall establish procedures under which an eligible beneficiary enrolled in a Medicare Prescription Drug plan may elect to have the sponsor (as defined in paragraph (5) of section 1860D–20(e)) of employment-based retiree health coverage (as defined in paragraph (4)(B) of such section) in which the beneficiary is enrolled pay the amount of the monthly

beneficiary obligation applicable to the beneficiary under this part directly to the Administrator.

"(b) INFORMATION NECESSARY FOR COLLECTION.—In order to carry out subsection (a), the Administrator shall transmit to the Commissioner of Social Security—

"(1) by the beginning of each year, the name, social security account number, monthly beneficiary obligation owed by each individual enrolled in a Medicare Prescription Drug plan for each month during the year, and other information determined appropriate by the Administrator; and

"(2) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

"(c) COLLECTION FOR BENEFICIARIES ENROLLED IN A MEDICAREADVANTAGE PLAN.—For provisions related to the collection of the monthly beneficiary obligation for qualified prescription drug coverage under a MedicareAdvantage plan, see section 1858A(e).

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

"SEC. 1860D–19. (a) AMOUNT OF SUBSIDIES.—

"(1) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR QUALIFIED MEDICARE BENEFICIARIES.—In the case of a qualified medicare beneficiary (as defined in paragraph (4)(A))—

"(A) section 1860D–17 shall be applied—

"(i) in subsection (c), by substituting '0 percent' for the applicable percent that would otherwise apply under such subsection; and

"(ii) in subsection (a)(3)(B), by substituting 'the amount of the monthly plan premium for the Medicare Prescription Drug plan with the lowest monthly plan premium in the area that the beneficiary resides' for 'the amount of such monthly national average premium', but only if there is no Medicare Prescription Drug plan offered in the area in which the individual resides that has a monthly plan premium for the year that is equal to or less than the monthly national average premium (as computed under section 1860D–15) for the area for the year;

"(B) the annual deductible applicable under section 1860D–6(c)(1) in a year shall be reduced to $0;

"(C) section 1860D–6(c)(2) shall be applied by substituting '2.5 percent' for '50 percent' each place it appears;

"(D) such individual shall be responsible for cost-sharing for the cost of any covered drug provided in the year (after the individual has reached the initial coverage limit described in section 1860D–6(c)(3) and before the individual has reached the annual out-of-pocket limit under section 1860D–6(c)(4)(A)), that is equal to 5.0 percent; and

"(E) section 1860D–6(c)(4)(A) shall be applied by substituting '2.5 percent' for '10 percent'.

In no case may the application of subparagraph (A) result in a monthly beneficiary obligation that is below 0.

"(2) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR SPECIFIED LOW INCOME MEDICARE BENEFICIARIES AND QUALIFYING INDIVIDUALS.—In the case of a specified low income medicare beneficiary (as defined in paragraph (4)(B)) or a qualifying individual (as defined in paragraph (4)(C))—

"(A) section 1860D–17 shall be applied—

"(i) in subsection (c), by substituting '0 percent' for the applicable percent that

would otherwise apply under such subsection; and

"(ii) in subsection (a)(3)(B), by substituting 'the amount of the monthly plan premium for the Medicare Prescription Drug plan with the lowest monthly plan premium in the area that the beneficiary resides' for 'the amount of such monthly national average premium', but only if there is no Medicare Prescription Drug plan offered in the area in which the individual resides that has a monthly plan premium for the year that is equal to or less than the monthly national average premium (as computed under section 1860D–15) for the area for the year;

"(B) the annual deductible applicable under section 1860D–6(c)(1) in a year shall be reduced to $0;

"(C) section 1860D–6(c)(2) shall be applied by substituting '5.0 percent' for '50 percent' each place it appears;

"(D) such individual shall be responsible for cost-sharing for the cost of any covered drug provided in the year (after the individual

has reached the initial coverage limit described in section 1860D–6(c)(3) and before the individual has reached the annual out-of-pocket limit under section 1860D–6(c)(4)(A)), that is equal to 10.0 percent; and

"(E) section 1860D–6(c)(4)(A) shall be applied by substituting '2.5 percent' for '10 percent'.

In no case may the application of subparagraph (A) result in a monthly beneficiary obligation that is below 0.

"(3) SLIDING SCALE PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR SUBSIDY-ELIGIBLE INDIVIDUALS.—

"(A) IN GENERAL.—In the case of a subsidy-eligible individual (as defined in paragraph (4)(D))—

"(i) section 1860D–17 shall be applied—

"(I) in subsection (c), by substituting 'subsidy percent' for the applicable percentage that would otherwise apply under such subsection; and

"(II) in subparagraphs (A) and (B) of subsection (a)(3), by sub-

stituting 'the amount of the monthly plan premium for the Medicare Prescription Drug plan with the lowest monthly plan premium in the area that the beneficiary resides' for 'the amount of such monthly national average premium', but only if there is no Medicare Prescription Drug plan offered in the area in which the individual resides that has a monthly plan premium for the year that is equal to or less than the monthly national average premium (as computed under section 1860D–15) for the area for the year; and

''(ii) the annual deductible applicable under section 1860D–6(c)(1)—

''(I) for 2006, shall be reduced to $50; and

''(II) for a subsequent year, shall be reduced to the amount specified under this clause for the previous year increased by the percentage specified in section 1860D–6(c)(5) for the year involved;

"(iii) section 1860D–6(c)(2) shall be applied by substituting '10.0 percent' for '50 percent' each place it appears;

"(iv) such individual shall be responsible for cost-sharing for the cost of any covered drug provided in the year (after the individual has reached the initial coverage limit described in section 1860D–6(c)(3) and before the individual has reached the annual out-of-pocket limit under section 1860D–6(c)(4)(A)), that is equal to 20.0 percent; and

"(v) such individual shall be responsible for the cost-sharing described in section 1860D–6(c)(4)(A).

In no case may the application of clause (i) result in a monthly beneficiary obligation that is below 0.

"(B) SUBSIDY PERCENT DEFINED.—For purposes of subparagraph (A)(i), the term 'subsidy percent' means, with respect to a State, a percent determined on a linear sliding scale ranging from—

"(i) 0 percent with respect to a subsidy-eligible individual residing in the State

whose income does not exceed 135 percent of the poverty line; to

"(ii) the highest percentage that would otherwise apply under section 1860D–17 in the service area in which the subsidy-eligible individual resides, in the case of a subsidy-eligible individual residing in the State whose income equals 160 percent of the poverty line.

"(4) DEFINITIONS.—In this part:

"(A) QUALIFIED MEDICARE BENEFICIARY.—Subject to subparagraph (H), the term 'qualified medicare beneficiary' means an individual who—

"(i) is enrolled under this part, including an individual who is enrolled under a MedicareAdvantage plan;

"(ii) is eligible for medicare cost-sharing described in section 1905(p)(3) under the State plan under title XIX (or under a waiver of such plan), on the basis of being described in section 1905(p)(1), as determined under such plan (or under a waiver of plan); and

"(iii) is not—

"(I) a specified low-income medicare beneficiary;

"(II) a qualifying individual; or

"(III) a dual eligible individual.

"(B) SPECIFIED LOW INCOME MEDICARE BENEFICIARY.—Subject to subparagraph (H), the term 'specified low income medicare beneficiary' means an individual who—

"(i) is enrolled under this part, including an individual who is enrolled under a MedicareAdvantage plan;

"(ii) is eligible for medicare cost-sharing described in section 1905(p)(3)(A)(ii) under the State plan under title XIX (or under a waiver of such plan), on the basis of being described in section 1902(a)(10)(E)(iii), as determined under such plan (or under a waiver of plan); and

"(iii) is not—

"(I) a qualified medicare beneficiary;

"(II) a qualifying individual; or

"(III) a dual eligible individual.

"(C) QUALIFYING INDIVIDUAL.—Subject to subparagraph (H), the term 'qualifying individual' means an individual who—

"(i) is enrolled under this part, including an individual who is enrolled under a MedicareAdvantage plan;

"(ii) is eligible for medicare cost-sharing described in section 1905(p)(3)(A)(ii) under the State plan under title XIX (or under a waiver of such plan), on the basis of being described in section 1902(a)(10)(E)(iv) (without regard to any termination of the application of such section under title XIX), as determined under such plan (or under a waiver of such plan); and

"(iii) is not—

"(I) a qualified medicare beneficiary;

"(II) a specified low-income medicare beneficiary; or

"(III) a dual eligible individual.

"(D) SUBSIDY-ELIGIBLE INDIVIDUAL.—Subject to subparagraph (H), the term 'subsidy-eligible individual' means an individual—

"(i) who is enrolled under this part, including an individual who is enrolled under a MedicareAdvantage plan;

"(ii) whose income is less than 160 percent of the poverty line; and

"(iii) who is not—

"(I) a qualified medicare beneficiary;

"(II) a specified low-income medicare beneficiary;

"(III) a qualifying individual; or

"(IV) a dual eligible individual.

"(E) DUAL ELIGIBLE INDIVIDUAL.—

"(i) IN GENERAL.—The term 'dual eligible individual' means an individual who is—

"(I) enrolled under title XIX or under a waiver under section 1115 of the requirements of such title for medical assistance that is not less than the medical assistance provided to an individual described in section 1902(a)(10)(A)(i) and includes covered outpatient drugs (as such term is

defined for purposes of section 1927); and

"(II) entitled to benefits under part A and enrolled under part B.

"(ii) INCLUSION OF MEDICALLY NEEDY.—Such term includes an individual described in section 1902(a)(10)(C).

"(F) POVERTY LINE.—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.

"(G) ELIGIBILITY DETERMINATIONS.—Beginning on November 1, 2005, the determination of whether an individual residing in a State is an individual described in subparagraph (A), (B), (C), (D), or (E) and, for purposes of paragraph (3), the amount of an individual's income, shall be determined under the State medicaid plan for the State under section 1935(a). In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator.

"(H) NONAPPLICATION TO DUAL ELIGIBLE INDIVIDUALS AND TERRITORIAL RESIDENTS.—In the case of an individual who is a dual eligible individual or an individual who is not a resident of the 50 States or the District of Columbia—

"(i) the subsidies provided under this section shall not apply; and

"(ii) in the case of such an individual who is not a resident of the 50 States or the District of Columbia, such individual may be provided with medical assistance for covered outpatient drugs (as such term is defined for purposes of section 1927) in accordance with section 1935 under the State medicaid program under title XIX.

"(I) UPDATE OF ASSET OR RESOURCE TEST.—With respect to eligibility determinations for premium and cost-sharing subsidies under this section that are made on or after January 1, 2009, such determinations shall be made (to the extent a State, as of such date, has not already eliminated the application of an asset or resource test under section

1905(p)(1)(C)) in accordance with the following:

"(i) SELF-DECLARATION OF VALUE.—

"(I) IN GENERAL.—A State shall permit an individual applying for such subsidies to declare and certify by signature under penalty of perjury on the application form that the value of the individual's assets or resources (or the combined value of the individual's assets or resources and the assets or resources of the individual's spouse), as determined under section 1613 for purposes of the supplemental security income program, does not exceed $10,000 ($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).

"(II) ANNUAL ADJUSTMENT.—Beginning on January 1, 2010, and for each subsequent year, the dollar amounts specified in subclause (I) for the preceding year shall be increased by the percentage increase in the Con-

sumer Price Index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.

"(ii) METHODOLOGY FLEXIBILITY.—Nothing in clause (i) shall be construed as prohibiting a State in making eligibility determinations for premium and cost-sharing subsidies under this section from using asset or resource methodologies that are less restrictive than the methodologies used under 1613 for purposes of the supplemental security income program.

"(J) DEVELOPMENT OF MODEL DECLARATION FORM.—The Secretary shall—

"(i) develop a model, simplified application form for individuals to use in making a self-declaration of assets or resources in accordance with subparagraph (I)(i); and

"(ii) provide such form to States and, for purposes of outreach under section 1144, the Commissioner of Social Security.".

1 "(b) RULES IN APPLYING COST-SHARING SUB-
2 SIDIES.—Nothing in this section shall be construed as pre-
3 venting an eligible entity offering a Medicare Prescription
4 Drug plan or a MedicareAdvantage organization offering
5 a MedicareAdvantage plan from waiving or reducing the
6 amount of the deductible or other cost-sharing otherwise
7 applicable pursuant to section 1860D–6(a)(2).

8 "(c) ADMINISTRATION OF SUBSIDY PROGRAM.—The
9 Administrator shall establish a process whereby, in the
10 case of an individual eligible for a cost-sharing subsidy
11 under subsection (a) who is enrolled in a Medicare Pre-
12 scription Drug plan or a MedicareAdvantage plan—

13 "(1) the Administrator provides for a notifica-
14 tion of the eligible entity or MedicareAdvantage or-
15 ganization involved that the individual is eligible for
16 a cost-sharing subsidy and the amount of the sub-
17 sidy under such subsection;

18 "(2) the entity or organization involved reduces
19 the cost-sharing otherwise imposed by the amount of
20 the applicable subsidy and submits to the Adminis-
21 trator information on the amount of such reduction;
22 and

23 "(3) the Administrator periodically and on a
24 timely basis reimburses the entity or organization
25 for the amount of such reductions.

The reimbursement under paragraph (3) 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 provisions providing for eligibility determinations and additional Federal payments for expenditures related to providing prescription drug coverage for dual eligible individuals and territorial residents under the medicaid program, see section 1935.

"REINSURANCE PAYMENTS FOR EXPENSES INCURRED IN PROVIDING PRESCRIPTION DRUG COVERAGE ABOVE THE ANNUAL OUT-OF-POCKET THRESHOLD

"SEC. 1860D–20. (a) REINSURANCE PAYMENTS.—

"(1) IN GENERAL.—Subject to section 1860D–21(b), the Administrator shall provide in accordance with this section for payment to a qualifying entity of the reinsurance payment amount (as specified in subsection (c)(1)) for costs incurred by the entity in providing prescription drug coverage for a qualifying covered individual after the individual has reached the annual out-of-pocket threshold specified in section 1860D–6(c)(4)(B) for the year.

"(2) BUDGET AUTHORITY.—This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Ad-

ministrator to provide for the payment of amounts provided under this section.

"(b) NOTIFICATION OF SPENDING UNDER THE PLAN FOR COSTS INCURRED IN PROVIDING PRESCRIPTION DRUG COVERAGE ABOVE THE ANNUAL OUT-OF-POCKET THRESHOLD.—

"(1) IN GENERAL.—Each qualifying entity shall notify the Administrator of the following with respect to a qualifying covered individual for a coverage year:

"(A) TOTAL ACTUAL COSTS.—The total amount (if any) of costs that the qualifying entity incurred in providing prescription drug coverage for the individual in the year after the individual had reached the annual out-of-pocket threshold specified in section 1860D–6(c)(4)(B) for the year.

"(B) AMOUNTS RESULTING IN ACTUAL COSTS.—With respect to the total amount under subparagraph (A) for the year—

"(i) the aggregate amount of payments made by the entity to pharmacies and other entities with respect to such coverage for such enrollees; and

"(ii) the aggregate amount of discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity with respect to such coverage for such enrollees.

"(2) CERTAIN EXPENSES NOT INCLUDED.—The amount under paragraph (1)(A) may not include—

"(A) administrative expenses incurred in providing the coverage described in paragraph (1)(A);

"(B) amounts expended on providing additional prescription drug coverage pursuant to section 1860D–6(a)(2); or

"(C) discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity with respect to coverage described in paragraph (1)(A).

"(3) RESTRICTION ON USE OF INFORMATION.—The restriction specified in section 1860D–16(b)(7)(B) shall apply to information disclosed or obtained pursuant to the provisions of this section.

"(c) REINSURANCE PAYMENT AMOUNT.—

"(1) IN GENERAL.—The reinsurance payment amount under this subsection for a qualifying cov-

ered individual for a coverage year is an amount equal to 80 percent (or 65 percent with respect to a qualifying covered individual described in subsection (e)(2)(D)) of the allowable costs (as specified in paragraph (2)) incurred by the qualifying entity with respect to the individual and year.

"(2) ESTABLISHMENT OF ALLOWABLE COSTS.—In the case of a qualifying entity that has incurred costs described in subsection (b)(1)(A) with respect to a qualifying covered individual for a coverage year, the Administrator shall establish the allowable costs for the individual and year. Such allowable costs shall be equal to the amount described in such subsection for the individual and year.

"(d) PAYMENT METHODS.—

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

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

"(e) DEFINITIONS.—In this section:

"(1) COVERAGE YEAR.—The term 'coverage year' means a calendar year in which covered drugs are dispensed if a claim for payment is made under the plan for such drugs, regardless of when the claim is paid.

"(2) QUALIFYING COVERED INDIVIDUAL.—The term 'qualifying covered individual' means an individual who—

"(A) is enrolled in this part and in a Medicare Prescription Drug plan;

"(B) is enrolled in this part and in a MedicareAdvantage plan (except for an MSA plan or a private fee-for-service plan that does not provide qualified prescription drug coverage);

"(C) is eligible for, but not enrolled in, the program under this part, and is covered under a qualified retiree prescription drug plan; or

"(D) is eligible for, but not enrolled in, the program under this part, and is covered under

a qualified State pharmaceutical assistance program.

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

"(A) An eligible entity offering a Medicare Prescription Drug plan under this part.

"(B) A MedicareAdvantage organization offering a MedicareAdvantage plan under part C (except for an MSA plan or a private fee-for-service plan that does not provide qualified prescription drug coverage).

"(C) The sponsor of a qualified retiree prescription drug plan.

"(D) A State offering a qualified State pharmaceutical assistance program.

"(4) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—

"(A) IN GENERAL.—The term 'qualified retiree prescription drug plan' means employment-based retiree health coverage if, with respect to a qualifying covered individual who is

covered under the plan, the following requirements are met:

"(i) ATTESTATION OF ACTUARIAL VALUE OF COVERAGE.—The sponsor of the plan shall, annually or at such other time as the Administrator may require, provide the Administrator an attestation, in accordance with the procedures established under section 1860D–6(f), that the actuarial value of prescription drug coverage under the plan is at least equal to the actuarial value of standard prescription drug coverage.

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

"(B) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-

based retiree health coverage' means health insurance or other coverage, whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation, of health care costs for retired individuals (or for such individuals and their spouses and dependents) based on their status as former employees or labor union members.

"(5) QUALIFIED STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—

"(A) IN GENERAL.—The term 'qualified State pharmaceutical assistance program' means a State pharmaceutical assistance program if, with respect to a qualifying covered individual who is covered under the program, the following requirements are met:

"(i) ASSURANCE.—The State offering the program shall, annually or at such other times as the Administrator may require, provide the Administrator an attestation that, in accordance with the procedures established under section 1860D–6(f), that—

"(I) the actuarial value of prescription drug coverage under the pro-

gram is at least equal to the actuarial value of standard prescription drug coverage; and

"(II) the actuarial value of subsidies to individuals provided under the program are at least equal to the actuarial value of the subsidies that would apply under section 1860D–19 if the individual was enrolled under this part rather than under the program.

"(ii) DISCLOSURE OF INFORMATION.—The State complies with the requirements described in clauses (i) and (ii) of section 1860D–16(b)(7)(A).

"(B) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—For purposes of subparagraph (A), the term 'State pharmaceutical assistance program' means a program—

"(i) that is in operation as of the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003;

"(ii) that is sponsored and financed by a State; and

"(iii) that provides coverage for outpatient drugs for individuals in the State who meet income- and resource-related qualifications specified under such program.

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

"(f) DISTRIBUTION OF REINSURANCE PAYMENT AMOUNTS.—

"(1) IN GENERAL.—Any sponsor meeting the requirements of subsection (e)(3) with respect to a quarter in a calendar year, but which is not an employer, shall distribute the reinsurance payments received for such quarter under subsection (c) to the employers contributing to the qualified retiree prescription drug plan maintained by such sponsor during that quarter, in the manner described in paragraphs (2) and (3).

"(2) ALLOCATION.—The reinsurance payments to be distributed pursuant to paragraph (1) shall be allocated proportionally among all employers who contribute to the plan during the quarter with respect to which the payments are received. The share allocated to each employer contributing to the plan

during a quarter shall be determined by multiplying the total reinsurance payments received by the sponsor for the quarter by a fraction, the numerator of which is the total contributions made by an employer for that quarter, and the denominator of which is the total contributions required to be made to the plan by all employers for that quarter. Any share allocated to an employer required to contribute for a quarter who does not make the contributions required for that quarter on or before the date due shall be retained by the sponsor for the benefit of the plan as a whole.

"(3) TIMING.—Reinsurance payments required to be distributed to employers pursuant to this subsection shall be distributed as soon as practicable after received by the sponsor, but in no event later than the end of the quarter immediately following the quarter in which such reinsurance payments are received by the sponsor.

"(4) REGULATIONS.—The Secretary shall promulgate regulations providing that any sponsor subject to the requirements of this subsection who fails to meet such requirements shall not be eligible for a payment under this section.

"DIRECT SUBSIDY FOR SPONSOR OF A QUALIFIED RETIREE PRESCRIPTION DRUG PLAN FOR PLAN ENROLLEES ELIGIBLE FOR, BUT NOT ENROLLED IN, THIS PART

"SEC. 1860D–21. (a) DIRECT SUBSIDY.—

"(1) IN GENERAL.—The Administrator shall provide for the payment to a sponsor of a qualified retiree prescription drug plan (as defined in section 1860D–20(e)(4)) for each qualifying covered individual (described in subparagraph (C) of section 1860D–20(e)(2)) enrolled in the plan for each month for which such individual is so enrolled.

"(2) AMOUNT OF PAYMENT.—

"(A) IN GENERAL.—The amount of the payment under paragraph (1) shall be an amount equal to the direct subsidy percent determined for the year of the monthly national average premium for the area for the year (determined under section 1860D–15), as adjusted using the risk adjusters that apply to the standard prescription drug coverage published under section 1860D–11.

"(B) DIRECT SUBSIDY PERCENT.—For purposes of subparagraph (A), the term 'direct

subsidy percent' means the percentage equal to—

"(i) 100 percent; minus

"(ii) the applicable percent for the year (as determined under section 1860D–17(c).

"(b) PAYMENT METHODS.—

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

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

"DIRECT SUBSIDIES FOR QUALIFIED STATE OFFERING A STATE PHARMACEUTICAL ASSISTANCE PROGRAM FOR PROGRAM ENROLLEES ELIGIBLE FOR, BUT NOT ENROLLED IN, THIS PART

"SEC. 1860D–22. (a) DIRECT SUBSIDY.—

"(1) IN GENERAL.—The Administrator shall provide for the payment to a State offering a qualified State pharmaceutical assistance program (as de-

fined in section 1860D–20(e)(6)) for each qualifying covered individual (described in subparagraph (D) of section 1860D–(e)(2)) enrolled in the program for each month for which such individual is so enrolled.

"(2) AMOUNT OF PAYMENT.—

"(A) IN GENERAL.—The amount of the payment under paragraph (1) shall be an amount equal to the amount of payment for the area and year made under section 1860D–21(a)(2).

"(b) ADDITIONAL SUBSIDY.—

"(1) IN GENERAL.—The Administrator shall provide for the payment to a State offering a qualified State pharmaceutical program (as defined in section 1860D–20(e)(6)) for each applicable low-income individual enrolled in the program for each month for which such individual is so enrolled.

"(2) AMOUNT OF PAYMENT.—

"(A) IN GENERAL.—The amount of the payment under paragraph (1) shall be the amount the Administrator estimates would have been made to an entity or organization under section 1860D–19 with respect to the applicable low-income individual if such individual was enrolled in this part and under a Medicare Pre-

scription Drug plan or a MedicareAdvantage plan.

"(B) MAXIMUM PAYMENTS.—In no case may the amount of the payment determined under subparagraph (A) with respect to an applicable low-income individual exceed, as estimated by the Administrator, the average amounts made in a year under section 1860D–19 on behalf of an eligible beneficiary enrolled under this part with income that is the same as the income of the applicable low-income individual.

"(3) APPLICABLE LOW-INCOME INDIVIDUAL.—For purposes of this subsection, the term 'applicable low-income individual' means an individual who is both—

"(A) a qualifying covered individual (described in subparagraph (D) of section 1860D–(e)(2)); and

"(B) a qualified medicare beneficiary, a specified low income medicare beneficiary, or a subsidy-eligible individual, as such terms are defined in section 1860D–19(a)(4).

"(c) PAYMENT METHODS.—

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

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

"(d) CONSTRUCTION.—Nothing in this section or section 1860D–20 shall effect the provisions of section 1860D–26(b).

"Subpart 3—Miscellaneous Provisions

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

"SEC. 1860D–25. (a) ESTABLISHMENT.—

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

"(2) FUNDS.—The Account shall consist of such gifts and bequests as may be made as provided

in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, the 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.

"(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 to eligible entities under section 1860D–16;

"(B) payments under 1860D–19 for low-income subsidy payments for cost-sharing;

"(C) reinsurance payments under section 1860D–20;

"(D) payments to sponsors of qualified retiree prescription drug plans under section 1860D–21;

"(E) payments to MedicareAdvantage organizations for the provision of qualified pre-

scription drug coverage under section 1858A(c); and

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

"(2) 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) APPROPRIATIONS TO COVER BENEFITS AND ADMINISTRATIVE COSTS.—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 and transfers made from the Account in the year.

"OTHER RELATED PROVISIONS

"SEC. 1860D–26. (a) RESTRICTION ON ENROLLMENT IN A MEDICARE PRESCRIPTION DRUG PLAN OFFERED BY A SPONSOR OF EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—

"(1) IN GENERAL.—In the case of a Medicare Prescription Drug plan offered by an eligible entity that is a sponsor (as defined in paragraph (5) of section 1860D–20(e)) of employment-based retiree health coverage (as defined in paragraph (4)(B) of such section), notwithstanding any other provision of

this part and in accordance with regulations of the Administrator, the entity offering the plan may restrict the enrollment of eligible beneficiaries enrolled under this part to eligible beneficiaries who are enrolled in such coverage.

"(2) LIMITATION.—The sponsor of the employment-based retiree health coverage described in paragraph (1) may not offer enrollment in the Medicare Prescription Drug plan described in such paragraph based on the health status of eligible beneficiaries enrolled for such coverage.

"(b) COORDINATION WITH STATE PHARMACEUTICAL ASSISTANCE PROGRAMS.—

"(1) IN GENERAL.—An eligible entity offering a Medicare Prescription Drug plan, or a MedicareAdvantage organization offering a MedicareAdvantage plan (other than an MSA plan or a private fee-for-service plan that does not provide qualified prescription drug coverage), may enter into an agreement with a State pharmaceutical assistance program described in paragraph (2) to coordinate the coverage provided under the plan with the assistance provided under the State pharmaceutical assistance program.

"(2) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DESCRIBED.—For purposes of paragraph (1), a State pharmaceutical assistance program described in this paragraph is a program that has been established pursuant to a waiver under section 1115 or otherwise.

"(c) REGULATIONS TO CARRY OUT THIS PART.—

"(1) AUTHORITY FOR INTERIM FINAL REGULATIONS.—The Secretary may promulgate initial regulations implementing this part in interim final form without prior opportunity for public comment.

"(2) FINAL REGULATIONS.—A final regulation reflecting public comments must be published within 1 year of the interim final regulation promulgated under paragraph (1).".

"(d) WAIVER AUTHORITY.—The Secretary shall have authority similar to the waiver authority under section 1857(i) to facilitate the offering of Medicare Prescription Drug plans by employer or other group health plans as part of employment-based retiree health coverage (as defined in section 1860D–20(d)(4)(B)), including the authority to establish separate premium amounts for enrollees in a Medicare Prescription Drug plan by reason of such coverage.".

(b) CONFORMING AMENDMENTS TO FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841 (42 U.S.C. 1395t) is amended—

(1) in the last sentence of subsection (a)—

(A) by striking ''and'' before ''such amounts''; and

(B) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Prescription Drug Account established by section 1860D–25'';

(2) in subsection (g), by inserting after ''by this part,'' the following: ''the payments provided for under part D (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund),'';

(3) in subsection (h), by inserting after ''1840(d)'' the following: ''and sections 1860D–18 and 1858A(e) (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund)''; and

(4) in subsection (i), by inserting after ''section 1840(b)(1)'' the following: '', sections 1860D–18 and 1858A(e) (in which case the payments shall be

made from the Prescription Drug Account in the Trust Fund),''.

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

(d) 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 Act.

**SEC. 102. STUDY AND REPORT ON PERMITTING PART B ONLY INDIVIDUALS TO ENROLL IN MEDICARE VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM.**

(a) STUDY.—The Administrator of the Center for Medicare Choices (as established under section 1808 of the Social Security Act, as added by section 301(a)) shall conduct a study on the need for rules relating to permitting individuals who are enrolled under part B of title XVIII of the Social Security Act but are not entitled to benefits under part A of such title to buy into the medicare

1 voluntary prescription drug delivery program under part
2 D of such title (as so added).

3 (b) REPORT.—Not later than January 1, 2005, the
4 Administrator of the Center for Medicare Choices shall
5 submit a report to Congress on the study conducted under
6 subsection (a), together with any recommendations for leg-
7 islation that the Administrator determines to be appro-
8 priate as a result of such study.

9 **SEC. 103. RULES RELATING TO MEDIGAP POLICIES THAT**
10 **PROVIDE PRESCRIPTION DRUG COVERAGE.**

11 (a) RULES RELATING TO MEDIGAP POLICIES THAT
12 PROVIDE PRESCRIPTION DRUG COVERAGE.—Section
13 1882 (42 U.S.C. 1395ss) is amended by adding at the end
14 the following new subsection:

15 ''(v) RULES RELATING TO MEDIGAP POLICIES THAT
16 PROVIDE PRESCRIPTION DRUG COVERAGE.—

17 ''(1) PROHIBITION ON SALE, ISSUANCE, AND
18 RENEWAL OF POLICIES THAT PROVIDE PRESCRIP-
19 TION DRUG COVERAGE TO PART D ENROLLEES.—

20 ''(A) IN GENERAL.—Notwithstanding any
21 other provision of law, on or after January 1,
22 2006, no medicare supplemental policy that
23 provides coverage of expenses for prescription
24 drugs may be sold, issued, or renewed under

this section to an individual who is enrolled under part D.

"(B) PENALTIES.—The penalties described in subsection (d)(3)(A)(ii) shall apply with respect to a violation of subparagraph (A).

"(2) ISSUANCE OF SUBSTITUTE POLICIES IF THE POLICYHOLDER OBTAINS PRESCRIPTION DRUG COVERAGE UNDER PART D.—

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

"(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as 'A', 'B', 'C', 'D', 'E', 'F' (including the benefit package classified as 'F' with a high deductible feature, as described in subsection (p)(11)), or 'G' (under the standards established under subsection (p)(2)) and that is offered and is available for issuance to new enrollees by such issuer;

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

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

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy during the open enrollment period established under section 1860D–2(b)(2) and who submits evidence that they meet the requirements under subparagraph (B) along with the application for such medicare supplemental policy.

"(B) INDIVIDUAL DESCRIBED.—An individual described in this subparagraph is an individual who—

"(i) enrolls in the medicare prescription drug delivery program under part D; and

"(ii) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as 'H', 'I', or 'J' (including the benefit package classified as 'J' with a high deductible feature, as described in section 1882(p)(11)) under the standards referred to in subparagraph

(A)(i) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

"(C) ENFORCEMENT.—The provisions of subparagraph (A) shall be enforced as though they were included in subsection (s).

"(3) NOTICE REQUIRED TO BE PROVIDED TO CURRENT POLICYHOLDERS WITH PRESCRIPTION DRUG COVERAGE.—No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer provides written notice during the 60-day period immediately preceding the period established for the open enrollment period established under section 1860D–2(b)(2), to each individual who is a policyholder or certificate holder of a medicare supplemental policy issued by that issuer that provides some coverage of expenses for prescription drugs (at the most recent available address of that individual) of—

"(A) the ability to enroll in a new medicare supplemental policy pursuant to paragraph (2); and

"(B) the fact that, so long as such individual retains coverage under such policy, the

individual shall be ineligible for coverage of prescription drugs under part D.''.

(b) 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 an eligible entity under part D 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 an eligible entity under part D of such Act, as added by section 101, as a condition for issuing such policy.

**SEC. 104. MEDICAID AND OTHER AMENDMENTS RELATED TO LOW-INCOME BENEFICIARIES.**

(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

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

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

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

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

(b) NEW SECTION.—

(1) IN GENERAL.—Title XIX (42 U.S.C. 1396 et seq.) is amended—

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

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

"SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

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

"(1) DETERMINATION OF ELIGIBILITY FOR TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE CARD PROGRAM FOR ELIGIBLE LOW-INCOME BENEFICIARIES.—For purposes of section 1807A, submit to the Secretary an eligibility plan under which the State—

"(A) establishes eligibility standards consistent with the provisions of that section;

"(B) establishes procedures for providing presumptive eligibility for eligible low-income beneficiaries (as defined in section 1807A(i)(2)) under that section;

"(C) makes determinations of eligibility and income for purposes of identifying eligible low-income beneficiaries (as so defined) under that section; and

"(D) communicates to the Secretary determinations of eligibility or discontinuation of eligibility under that section for purposes of notifying prescription drug card sponsors under that section of the identity of eligible medicare low-income beneficiaries.

"(2) DETERMINATION OF ELIGIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF TITLE XVIII FOR LOW-INCOME INDIVIDUALS.—Beginning November 1, 2005, for purposes of section 1860D–19—

"(A) make determinations of eligibility for premium and cost-sharing subsidies under and in accordance with such section;

"(B) establish procedures for providing presumptive eligibility for individuals eligible for subsidies under that section;

"(C) inform the Administrator of the Center for Medicare Choices of such determinations in cases in which such eligibility is established; and

"(D) otherwise provide such Administrator with such information as may be required to carry out part D of title XVIII (including section 1860D–19).

"(3) AGREEMENT TO ESTABLISH INFORMATION AND ENROLLMENT SITES AT SOCIAL SECURITY FIELD OFFICES.—Enter into an agreement with the Commissioner of Social Security to use all Social Security field offices located in the State as information and enrollment sites for making the eligibility determinations required under paragraphs (1) and (2).

"(4) SCREEN AND ENROLL INDIVIDUALS ELIGIBLE FOR MEDICARE COST-SHARING.—As part of making an eligibility determination required under paragraph (1) or (2), screen an individual who applies for such a determination for eligibility for medical assistance for any medicare cost-sharing de-

scribed in section 1905(p)(3) and, if the individual is eligible for any such medicare cost-sharing, enroll the individual under the State plan (or under a waiver of such plan).

"(b) FEDERAL SUBSIDY OF ADMINISTRATIVE COSTS.—

"(1) ENHANCED MATCH FOR ELIGIBILITY DETERMINATIONS.—Subject to paragraphs (2) and (4), with respect to calendar quarters beginning on or after January 1, 2004, the amounts expended by a State in carrying out subsection (a) are expenditures reimbursable under section 1903(a)(7) except that, in applying such section with respect to such expenditures incurred for—

"(A) such calendar quarters occurring in fiscal year 2004 or 2005, '75 percent' shall be substituted for '50 per centum';

"(B) calendar quarters occurring in fiscal year 2006, '70 percent' shall be substituted for '50 per centum';

"(C) calendar quarters occurring in fiscal year 2007, '65 percent' shall be substituted for '50 per centum'; and

"(D) calendar quarters occurring in fiscal year 2008 or any fiscal year thereafter, '60 percent' shall be substituted for '50 per centum'.

"(2) 100 PERCENT MATCH FOR ELIGIBILITY DETERMINATIONS FOR SUBSIDY-ELIGIBLE INDIVIDUALS.—In the case of amounts expended by a State on or after November 1, 2005, to determine whether an individual is a subsidy-eligible individual for purposes of section 1860D–19, such expenditures shall be reimbursed under section 1903(a)(7) by substituting '100 percent' for '50 per centum'.

"(3) ENHANCED MATCH FOR UPDATES OR IMPROVEMENTS TO ELIGIBILITY DETERMINATION SYSTEMS.—With respect to calendar quarters occurring in fiscal year 2004, 2005, or 2006, the Secretary, in addition to amounts otherwise paid under section 1903(a), shall pay to each State which has a plan approved under this title, for each such quarter an amount equal to 90 percent of so much of the sums expended during such quarter as are attributable to the design, development, acquisition, or installation of improved eligibility determination systems (including hardware and software for such systems) in order to carry out the requirements of subsection (a) and section 1807A(h)(1). No payment shall be made

to a State under the preceding sentence unless the State's improved eligibility determination system—

"(A) satisfies such standards for improvement as the Secretary may establish; and

"(B) complies, and is compatible, with the standards established under part C of title XI and any regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(4) COORDINATION.—The State shall provide the Secretary with such information as may be necessary to properly allocate expenditures described in paragraph (1), (2), or (3) that may otherwise be made for similar eligibility determinations or expenditures.

"(c) FEDERAL PAYMENT OF MEDICARE PART B PREMIUM FOR STATES PROVIDING PRESCRIPTION DRUG COVERAGE FOR DUAL ELIGIBLE INDIVIDUALS.—

"(1) IN GENERAL.—Subject to paragraph (4) and notwithstanding section 1905(b), in the case of a State that provides medical assistance for covered drugs (as such term is defined in section 1860D(a)(2)) to dual eligible individuals under this title that satisfies the minimum standards described

in paragraph (2), the Federal medical assistance percentage shall be 100 percent for medicare cost-sharing described in section 1905(p)(3)(A)(ii) (relating to premiums under section 1839) for individuals—

"(A) who are dual eligible individuals or qualified medicare beneficiaries; and

"(B) whose income is at least the income required for an individual to be an eligible individual under section 1611 for purposes of the supplemental security income program (as determined under section 1612), but does not exceed 100 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved.

"(2) MINIMUM STANDARDS DESCRIBED.—For purposes of paragraph (1), the minimum standards described in this paragraph are the following:

"(A) In providing medical assistance for dual eligible individuals for such covered drugs, the State satisfies the requirements of this title (including limitations on cost-sharing imposed under section 1916) applicable to the provision of medical assistance for prescribed drugs to dual eligible individuals.

"(B) In providing medical assistance for dual eligible individuals for such covered drugs, the State provides such individuals with beneficiary protections that the Secretary determines are equivalent to the beneficiary protections applicable under section 1860D–5 to eligible entities offering a Medicare Prescription Drug plan under part D of title XVIII.

"(C) In providing medical assistance for dual eligible individuals for such covered drugs, the State does not impose a limitation on the number of prescriptions an individual may have filled.

"(3) NONAPPLICATION.—Section 1927(d)(2)(E) shall not apply to a State for purposes of providing medical assistance for covered drugs (as such term is defined in section 1860D(a)(2)) to dual eligible individuals that satisfies the minimum standards described in paragraph (2).

"(4) LIMITATION.—Paragraph (1) shall not apply to any State before January 1, 2006.

"(d) FEDERAL PAYMENT OF MEDICARE PART A COST-SHARING FOR CERTAIN STATES.—

"(1) IN GENERAL.—Subject to paragraph (2) and notwithstanding section 1905(b), in the case of

a State that, as of the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003, provides medical assistance for individuals described in section 1902(a)(10)(A)(ii))(X), the Federal medical assistance percentage shall be 100 percent for medicare cost-sharing described in subparagraphs (B) and (C) of section 1905(p)(3) (relating to coinsurance and deductibles established under title XVIII) for the individuals provided medical assistance under section 1902(a)(10)(A)(ii)(X), but only—

"(A) with respect to such medicare cost-sharing that is incurred under part A of title XVIII; and

"(B) for so long as the State elects to provide medical assistance under section 1902(a)(10)(A)(ii)(X).

"(2) LIMITATION.—Paragraph (1) shall not apply to any State before January 1, 2006.

"(e) TREATMENT OF TERRITORIES.—

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

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

"(B) if the State establishes a plan described in paragraph (2), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be further increased by the amount specified in paragraph (3).

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

"(A) provides medical assistance with respect to the provision of covered drugs (as defined in section 1860D(a)(2)) to individuals described in subparagraph (A), (B), (C), or (D) of section 1860D–19(a)(3); and

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

"(3) INCREASED AMOUNT.—

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

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

"(ii) the amount specified in section 1108(g)(1) for that State, divided by the

sum of the amounts specified in such section for all such States.

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

"(i) the last 3 quarters of fiscal year 2006, is equal to $37,500,000;

"(ii) fiscal year 2007, is equal to $50,000,000; and

"(iii) any subsequent fiscal year, is equal to the aggregate amount specified in this subparagraph for the previous fiscal year increased by the annual percentage increase specified in section 1860D–6(c)(5) for the calendar year beginning in such fiscal year.

"(4) NONAPPLICATION.—Section 1927(d)(2)(E) shall not apply to a State described in paragraph (1) for purposes of providing medical assistance described in paragraph (2)(A).

"(5) 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.

"(f) DEFINITIONS.—For purposes of this section, the terms 'qualified medicare beneficiary', 'subsidy-eligible individual', and 'dual eligible individual' have the meanings given such terms in subparagraphs (A), (D), and (E), respectively, of section 1860D–19(a)(4).".

(2) CONFORMING AMENDMENTS.—

(A) Section 1905(b) (42 U.S.C. 1396d(b)) is amended by inserting "and subsections (c)(1) and (d)(1) of section 1935" after "1933(d)".

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

(3) TRANSFER OF FEDERALLY ASSUMED PORTIONS OF MEDICARE COST-SHARING.—

(A) TRANSFER OF ASSUMPTION OF PART B PREMIUM FOR STATES PROVIDING PRESCRIPTION DRUG COVERAGE FOR DUAL ELIGIBLE INDIVIDUALS TO THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841(f) (42 U.S.C. 1395t(f)) is amended—

(i) by inserting "(1)" after "(f)"; and

(ii) by adding at the end the following new paragraph:

"(2) There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Treasury amounts which the Secretary of Health and Human Services shall have certified are equivalent to the amounts determined under section 1935(c)(1) with respect to all States for a fiscal year.".

(B) TRANSFER OF ASSUMPTION OF PART A COST-SHARING FOR CERTAIN STATES.—Section 1817(g) (42 U.S.C. 1395i(g)) is amended—

(i) by inserting "(1)" after "(g)"; and

(ii) by adding at the end the following new paragraph:

"(2) There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Treasury amounts which the Secretary of Health and Human Services shall have certified are equivalent to the amounts determined under section 1935(d)(1) with respect to certain States for a fiscal year.".

(4) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)), as amended by section 111(b), is amended—

(A) by striking "and" at the end of subclause (IV);

(B) by striking the period at the end of subclause (V) and inserting "; and"; and

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

"(VI) any prices charged which are negotiated under a Medicare Prescription Drug plan under part D of title XVIII with respect to covered drugs, under a MedicareAdvantage plan under part C of such title with respect to such drugs, or under a qualified retiree prescription drug plan (as defined in section 1860D–20(f)(1)) with respect to such drugs, on behalf of eligible beneficiaries (as defined in section 1860D(a)(3).".

(c) EXTENSION OF MEDICARE COST-SHARING FOR PART B PREMIUM FOR QUALIFYING INDIVIDUALS THROUGH 2008.—

(1) IN GENERAL.—Section 1902(a)(10)(E)(iv) (42 U.S.C. 1396a(a)(10)(E)(iv)) is amended to read as follows:

"(iv) subject to sections 1933 and 1905(p)(4), for making medical assistance available (but only for premiums payable with respect to months during the period beginning with January 1998, and ending with December

2008) for medicare cost-sharing described in section 1905(p)(3)(A)(ii) for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) and is at least 120 percent, but less than 135 percent, of the official poverty line (referred to in such section) for a family of the size involved and who are not otherwise eligible for medical assistance under the State plan;''.

(2) TOTAL AMOUNT AVAILABLE FOR ALLOCATION.—Section 1933(c) (42 U.S.C. 1396u–3(c)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (D), by striking ''and'' at the end;

(ii) in subparagraph (E)—

(I) by striking ''fiscal year 2002'' and inserting ''each of fiscal years 2002 through 2008''; and

(II) by striking the period and inserting ''; and''; and

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

"(F) the first quarter of fiscal year 2009, $100,000,000."; and

(B) in paragraph (2)(A), by striking "the sum of" and all that follows through "1902(a)(10)(E)(iv)(II) in the State; to" and inserting "twice the total number of individuals described in section 1902(a)(10)(E)(iv) in the State; to".

(d) 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 prescription drug assistance card program under section 1807A, or for premium and cost-sharing subsidies under section 1860D–19" 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 prescription drug assistance card program under section 1807A, or premium and cost-sharing subsidies under section 1860D–19" 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 the transitional prescription drug assistance card program under section 1807A, or for premium and cost-sharing subsidies for low-income individuals under section 1860D–19" after "1933";

(B) in paragraph (2), by inserting ", program, and subsidies" after "medical assistance"; and

(C) by adding at the end the following:

"(3) AGREEMENTS TO ESTABLISH INFORMATION AND ENROLLMENT SITES AT SOCIAL SECURITY FIELD OFFICES.—

"(A) IN GENERAL.—The Commissioner shall enter into an agreement with each State operating a State plan under title XIX (including under a waiver of such plan) to establish information and enrollment sites within all the Social Security field offices located in the State for purposes of—

"(i) the State determining the eligibility of individuals residing in the State for medical assistance for payment of the cost of medicare cost-sharing under the medicaid program pursuant to sections 1902(a)(10)(E) and 1933, the transitional prescription drug assistance card program under section 1807A, or premium and cost-sharing subsidies under section 1860D–19; and

"(ii) enrolling individuals who are determined eligible for such medical assistance, program, or subsidies in the State plan (or waiver), the transitional prescription drug assistance card program under section 1807A, or the appropriate category for premium and cost-sharing subsidies under section 1860D–19.

"(B) AGREEMENT TERMS.—The Secretary and the Commissioner jointly shall develop terms for the State agreements required under subparagraph (A) that shall specify the responsibilities of the State and the Commissioner in the establishment and operation of such sites.

"(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Commissioner, such sums as may be necessary to carry out this paragraph.".

(e) REPORT REGARDING VOLUNTARY ENROLLMENT OF DUAL ELIGIBLE INDIVIDUALS IN PART D.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains such recommendations for legislation as the Secretary determines are necessary in order to establish a voluntary option for dual eligible individuals (as defined in 1860D–19(a)(4)(E) of the Social Security Act (as added by section 101)) to enroll under part D of title XVIII of such Act for prescription drug coverage.

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

(a) EXPANSION OF MEMBERSHIP.—

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

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

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

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

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

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

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

(B) COMMENCEMENT OF TERMS.—Such terms shall begin on January 1, 2005.

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

"(D) VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM.—Specifically, the Commission shall review, with respect to the voluntary prescription drug delivery program under part D, competition among eligible entities offering Medicare Prescription Drug plans and beneficiary access to such plans and covered drugs, particularly in rural areas. As part of such review, the Commission shall hold 3 field hearings in 2007.".

**SEC. 106. STUDY REGARDING VARIATIONS IN SPENDING AND DRUG UTILIZATION.**

(a) STUDY.—The Secretary shall study on an ongoing basis variations in spending and drug utilization under part D of title XVIII of the Social Security Act for covered drugs to determine the impact of such variations on premiums imposed by eligible entities offering Medicare Prescription Drug plans under that part. In conducting such study, the Secretary shall examine the impact of geographic adjustments of the monthly national average premium under section 1860D–15 of such Act on—

(1) maximization of competition under part D of title XVIII of such Act; and

(2) the ability of eligible entities offering Medicare Prescription Drug plans to contain costs for covered drugs.

(b) REPORT.—Beginning with 2007, the Secretary shall submit annual reports to Congress on the study required under subsection (a).

**SEC. 107. LIMITATION ON PRESCRIPTION DRUG BENEFITS OF MEMBERS OF CONGRESS.**

(a) LIMITATION ON BENEFITS.—Notwithstanding any other provision of law, during calendar year 2004, the actuarial value of the prescription drug benefit of any Member of Congress enrolled in a health benefits plan under chapter 89 of title 5, United States Code, may not exceed the actuarial value of any prescription drug benefit under title XVIII of the Social Security Act passed by the 1st session of the 108th Congress and enacted in law.

(b) REGULATIONS.—The Office of Personnel Management shall promulgate regulations to carry out this section.

**SEC. 108. PROTECTING SENIORS WITH CANCER.**

Any eligible beneficiary (as defined in section 1860D(3) of the Social Security Act) who is diagnosed with cancer shall be protected from high prescription drug costs in the following manner:

(1) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN INCOME BELOW 100 PERCENT OF THE FEDERAL POVERTY LINE.—If the individual is a qualified medicare beneficiary (as defined in section 1860D–19(a)(4) of such Act), such individual shall receive the full premium subsidy and reduction of cost-sharing described in section 1860D–19(a)(1) of such Act, including the payment of—

(A) no deductible;

(B) no monthly beneficiary premium for at least one Medicare Prescription Drug plan available in the area in which the individual resides; and

(C) reduced cost-sharing described in subparagraphs (C), (D), and (E) of section 1860D–19(a)(1) of such Act.

(2) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN INCOME BETWEEN 100 AND 135 PERCENT OF THE FEDERAL POVERTY LINE.—If the individual is a specified low income medicare beneficiary (as defined in paragraph 1860D–19(4)(B) of such Act) or a qualifying individual (as defined in paragraph 1860D–19(4)(C) of such Act) who is diagnosed with cancer, such individual shall receive the full premium subsidy and reduction of cost-sharing described in

section 1860D–19(a)(2) of such Act, including payment of—

(A) no deductible;

(B) no monthly premium for any Medicare Prescription Drug plan described paragraph (1) or (2) of section 1860D–17(a) of such Act; and

(C) reduced cost-sharing described in subparagraphs (C), (D), and (E) of section 1860D–19(a)(2) of such Act.

(3) SUBSIDY-ELIGIBLE INDIVIDUALS WITH INCOME BETWEEN 135 PERCENT AND 160 PERCENT OF THE FEDERAL POVERTY LEVEL.—If the individual is a subsidy-eligible individual (as defined in section 1860D–19(a)(4)(D) of such Act) who is diagnosed with cancer, such individual shall receive sliding scale premium subsidy and reduction of cost-sharing for subsidy-eligible individuals, including payment of—

(A) for 2006, a deductible of only $50;

(B) only a percentage of the monthly premium (as described in section 1860D–19(a)(3)(A)(i)); and

(C) reduced cost-sharing described in clauses (iii), (iv), and (v) of section 1860D–19(a)(3)(A).

(4) ELIGIBLE BENEFICIARIES WITH INCOME ABOVE 160 PERCENT OF THE FEDERAL POVERTY LEVEL.—If an individual is an eligible beneficiary (as defined in section 1860D(3) of such Act), is not described in paragraphs (1) through (3), and is diagnosed with cancer, such individual shall have access to qualified prescription drug coverage (as described in section 1860D–6(a)(1) of such Act), including payment of—

(A) for 2006, a deductible of $275;

(B) the limits on cost-sharing described section 1860D–6(c)(2) of such Act up to, for 2006, an initial coverage limit of $4,500; and

(C) for 2006, an annual out-of-pocket limit of $3,700 with 10 percent cost-sharing after that limit is reached.

**SEC. 109. PROTECTING SENIORS WITH CARDIOVASCULAR DISEASE, CANCER, OR ALZHEIMER'S DISEASE.**

Any eligible beneficiary (as defined in section 1860D(3) of the Social Security Act) who is diagnosed with cardiovascular disease, cancer, diabetes or Alzheimer's disease shall be protected from high prescription drug costs in the following manner:

(1) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN INCOME BELOW 100 PERCENT OF THE FEDERAL

1 POVERTY LINE.—If the individual is a qualified
2 medicare beneficiary (as defined in section 1860D–
3 19(a)(4) of such Act), such individual shall receive
4 the full premium subsidy and reduction of cost-shar-
5 ing described in section 1860D–19(a)(1) of such
6 Act, including the payment of—
7 (A) no deductible;
8 (B) no monthly beneficiary premium for at
9 least one Medicare Prescription Drug plan
10 available in the area in which the individual re-
11 sides; and
12 (C) reduced cost-sharing described in sub-
13 paragraphs (C), (D), and (E) of section
14 1860D–19(a)(1) of such Act.
15 (2) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN
16 INCOME BETWEEN 100 AND 135 PERCENT OF THE
17 FEDERAL POVERTY LINE.—If the individual is a
18 specified low income medicare beneficiary (as defined
19 in paragraph 1860D–19(4)(B) of such Act) or a
20 qualifying individual (as defined in paragraph
21 1860D–19(4)(C) of such Act) who is diagnosed with
22 cardiovascular disease, cancer, or Alzheimer's dis-
23 ease, such individual shall receive the full premium
24 subsidy and reduction of cost-sharing described in

section 1860D–19(a)(2) of such Act, including payment of—

(A) no deductible;

(B) no monthly premium for any Medicare Prescription Drug plan described paragraph (1) or (2) of section 1860D–17(a) of such Act; and

(C) reduced cost-sharing described in subparagraphs (C), (D), and (E) of section 1860D–19(a)(2) of such Act.

(3) SUBSIDY-ELIGIBLE INDIVIDUALS WITH INCOME BETWEEN 135 PERCENT AND 160 PERCENT OF THE FEDERAL POVERTY LEVEL.—If the individual is a subsidy-eligible individual (as defined in section 1860D–19(a)(4)(D) of such Act) who is diagnosed with cardiovascular disease, cancer, or Alzheimer's disease, such individual shall receive sliding scale premium subsidy and reduction of cost-sharing for subsidy-eligible individuals, including payment of—

(A) for 2006, a deductible of only $50;

(B) only a percentage of the monthly premium (as described in section 1860D–19(a)(3)(A)(i)); and

(C) reduced cost-sharing described in clauses (iii), (iv), and (v) of section 1860D–19(a)(3)(A).

(4) ELIGIBLE BENEFICIARIES WITH INCOME ABOVE 160 PERCENT OF THE FEDERAL POVERTY LEVEL.—If an individual is an eligible beneficiary (as defined in section 1860D(3) of such Act), is not described in paragraphs (1) through (3), and is diagnosed with cardiovascular disease, cancer, or Alzheimer's disease, such individual shall have access to qualified prescription drug coverage (as described in section 1860D–6(a)(1) of such Act), including payment of—

(A) for 2006, a deductible of $275;

(B) the limits on cost-sharing described section 1860D–6(c)(2) of such Act up to, for 2006, an initial coverage limit of $4,500; and

(C) for 2006, an annual out-of-pocket limit of $3,700 with 10 percent cost-sharing after that limit is reached.

**SEC. 110. REVIEW AND REPORT ON CURRENT STANDARDS OF PRACTICE FOR PHARMACY SERVICES PROVIDED TO PATIENTS IN NURSING FACILITIES.**

(a) REVIEW.—

(1) IN GENERAL.—The Secretary shall conduct a thorough review of the current standards of prac-

tice for pharmacy services provided to patients in nursing facilities.

(2) SPECIFIC MATTERS REVIEWED.—In conducting the review under paragraph (1), the Secretary shall—

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

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

(b) REPORT.—

(1) IN GENERAL.—Not later than the date that is 18 months after the date of enactment of this Act, the Secretary shall submit a report to Congress on the study conducted under subsection (a)(1), together with any recommendations for legislation that the Administrator determines to be appropriate as a result of such study.

(2) CONTENTS.—The report submitted under paragraph (1) shall contain—

(A) a detailed 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

(B) 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.

**SEC. 110A. MEDICATION THERAPY MANAGEMENT ASSESSMENT PROGRAM.**

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish an assessment program to contract with qualified pharmacists to provide medication therapy management services to eligible beneficiaries who receive care under the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act to eligible beneficiaries.

(2) SITES.—The Secretary shall designate 6 geographic areas, each containing not less than 3 sites, at which to conduct the assessment program under this section. At least 2 geographic areas designated under this paragraph shall be located in rural areas.

(3) DURATION.—The Secretary shall conduct the assessment program under this section for a 1-year period.

(4) IMPLEMENTATION.—The Secretary shall implement the program not later than January 1, 2005, but may not implement the assessment program before October 1, 2004.

(b) PARTICIPANTS.—Any eligible beneficiary who resides in an area designated by the Secretary as an assessment site under subsection (a)(2) may participate in the assessment program under this section if such beneficiary identifies a qualified pharmacist who agrees to furnish medication therapy management services to the eligible beneficiary under the assessment program.

(c) CONTRACTS WITH QUALIFIED PHARMACISTS.—

(1) IN GENERAL.—The Secretary shall enter into a contract with qualified pharmacists to provide medication therapy management services to eligible beneficiaries residing in the area served by the qualified pharmacist.

(2) NUMBER OF QUALIFIED PHARMACISTS.—The Secretary may contract with more than 1 qualified pharmacist at each site.

(d) PAYMENT TO QUALIFIED PHARMACISTS.—

(1) IN GENERAL.—Under an contract entered into under subsection (c), the Secretary shall pay qualified pharmacists a fee for providing medication therapy management services.

(2) ASSESSMENT OF PAYMENT METHODOLOGIES.—The Secretary shall, in consultation with national pharmacist and pharmacy associations, design the fee paid under paragraph (1) to test various payment methodologies applicable with respect to medication therapy management services, including a payment methodology that applies a relative value scale and fee-schedule with respect to such services that take into account the differences in—

(A) the time required to perform the different types of medication therapy management services;

(B) the level of risk associated with the use of particular outpatient prescription drugs or groups of drugs; and

(C) the health status of individuals to whom such services are provided.

(e) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund es-

tablished 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 assessment program under this section.

(2) BUDGET NEUTRALITY.—In conducting the assessment 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 assessment 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.; 1395 et seq.) as may be necessary for the purpose of carrying out the assessment program under this section.

(g) AVAILABILITY OF DATA.—During the period in which the assessment program is conducted, the Secretary annually shall make available data regarding—

(1) the geographic areas and sites designated under subsection (a)(2);

(2) the number of eligible beneficiaries participating in the program under subsection (b) and the level and types medication therapy management services used by such beneficiaries;

(3) the number of qualified pharmacists with contracts under subsection (c), the location of such pharmacists, and the number of eligible beneficiaries served by such pharmacists; and

(4) the types of payment methodologies being tested under subsection (d)(2).

(h) REPORT.—

(1) IN GENERAL.—Not later than 6 months after the completion of the assessment program under this section, the Secretary shall submit to Congress a final report summarizing the final outcome of the program and evaluating the results of the program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(2) ASSESSMENT OF PAYMENT METHODOLOGIES.—The final report submitted under paragraph (1) shall include an assessment of the feasibility and appropriateness of the various payment methodologies tested under subsection (d)(2).

(i) DEFINITIONS.—In this section:

(1) MEDICATION THERAPY MANAGEMENT SERVICES.—The term ''medication therapy management services'' means services or programs furnished by a qualified pharmacist to an eligible beneficiary, indi-

1 vidually or on behalf of a pharmacy provider, which
2 are designed—
3 (A) to ensure that medications are used
4 appropriately by such individual;
5 (B) to enhance the individual's under-
6 standing of the appropriate use of medications;
7 (C) to increase the individual's compliance
8 with prescription medication regimens;
9 (D) to reduce the risk of potential adverse
10 events associated with medications; and
11 (E) to reduce the need for other costly
12 medical services through better management of
13 medication therapy.
14 (2) ELIGIBLE BENEFICIARY.—The term ''eligi-
15 ble beneficiary'' means an individual who is—
16 (A) entitled to (or enrolled for) benefits
17 under part A and enrolled for benefits under
18 part B of the Social Security Act (42 U.S.C.
19 1395c et seq.; 1395j et seq.);
20 (B) not enrolled with a Medicare+Choice
21 plan or a MedicareAdvantage plan under part
22 C; and
23 (C) receiving, in accordance with State law
24 or regulation, medication for—

(i) the treatment of asthma, diabetes, or chronic cardiovascular disease, including an individual on anticoagulation or lipid reducing medications; or

(ii) such other chronic diseases as the Secretary may specify.

(3) QUALIFIED PHARMACIST.—The term ''qualified pharmacist'' means an individual who is a licensed pharmacist in good standing with the State Board of Pharmacy.

# Subtitle B—Medicare Prescription Drug Discount Card and Transitional Assistance for Low-Income Beneficiaries

## SEC. 111. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE FOR LOW-INCOME BENEFICIARIES.

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

''MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM

''SEC. 1807. (a) ESTABLISHMENT.—There is established a medicare prescription drug discount card endorsement program under which the Secretary shall—

"(1) endorse prescription drug discount card programs offered by prescription drug card sponsors that meet the requirements of this section; and

"(2) make available to eligible beneficiaries information regarding such endorsed programs.

"(b) ELIGIBILITY, ELECTION OF PROGRAM, AND ENROLLMENT FEES.—

"(1) ELIGIBILITY AND ELECTION OF PROGRAM.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall establish procedures—

"(i) for identifying eligible beneficiaries; and

"(ii) under which such beneficiaries may make an election to enroll in any prescription drug discount card program endorsed under this section and disenroll from such a program.

"(B) LIMITATION.—An eligible beneficiary may not be enrolled in more than 1 prescription drug discount card program at any time.

"(2) ENROLLMENT FEES.—

"(A) IN GENERAL.—A prescription drug card sponsor may charge an annual enrollment

fee to each eligible beneficiary enrolled in a prescription drug discount card program offered by such sponsor.

"(B) AMOUNT.—No enrollment fee charged under subparagraph (A) may exceed $25.

"(C) UNIFORM ENROLLMENT FEE.—A prescription drug card sponsor shall ensure that the enrollment fee for a prescription drug discount card program endorsed under this section is the same for all eligible medicare beneficiaries enrolled in the program.

"(D) COLLECTION.—Any enrollment fee shall be collected by the prescription drug card sponsor.

"(c) PROVIDING INFORMATION TO ELIGIBLE BENEFICIARIES.—

"(1) PROMOTION OF INFORMED CHOICE.—

"(A) BY THE SECRETARY.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which compares the costs and benefits of such programs. Such dissemination shall

be coordinated with the dissemination of educational information on other medicare options.

"(B) BY PRESCRIPTION DRUG CARD SPONSORS.—Each prescription drug card sponsor shall make available to each eligible beneficiary (through the Internet and otherwise) information—

"(i) that the Secretary identifies as being necessary to promote informed choice among endorsed prescription drug discount card programs by eligible beneficiaries, including information on enrollment fees, negotiated prices for prescription drugs charged to beneficiaries, and services relating to prescription drugs offered under the program;

"(ii) on how any formulary used by such sponsor functions.

"(2) USE OF MEDICARE TOLL-FREE NUMBER.—The Secretary shall provide through the 1–800–MEDICARE toll free telephone number for the receipt and response to inquiries and complaints concerning the medicare prescription drug discount card endorsement program established under this section

and prescription drug discount card programs endorsed under such program.

"(d) BENEFICIARY PROTECTIONS.—

"(1) IN GENERAL.—Each prescription drug discount card program endorsed under this section shall meet such requirements as the Secretary identifies to protect and promote the interest of eligible beneficiaries, including requirements that—

"(A) relate to appeals by eligible beneficiaries and marketing practices; and

"(B) ensure that beneficiaries are not charged more than the lower of the negotiated retail price or the usual and customary price.

"(2) ENSURING PHARMACY ACCESS.—Each prescription drug card sponsor offering a prescription drug discount card program endorsed under this section 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 (as determined by the Secretary and including adequate emergency access) for enrolled beneficiaries. Such standards shall take into account reasonable distances to pharmacy services in urban and rural areas and access to phar-

1 macy services of the Indian Health Service and In-
2 dian tribes and tribal organizations.
3 "(3) QUALITY ASSURANCE.—Each prescription
4 drug card sponsor offering a prescription drug dis-
5 count card program endorsed under this section
6 shall have in place adequate procedures for assuring
7 that quality service is provided to eligible bene-
8 ficiaries enrolled in a prescription drug discount
9 card program offered by such sponsor.
10 "(4) CONFIDENTIALITY OF ENROLLEE
11 RECORDS.—Insofar as a prescription drug card
12 sponsor maintains individually identifiable medical
13 records or other health information regarding eligi-
14 ble beneficiaries enrolled in a prescription drug dis-
15 count card program endorsed under this section, the
16 prescription drug card sponsor shall have in place
17 procedures to safeguard the privacy of any individ-
18 ually identifiable beneficiary information in a man-
19 ner that the Secretary determines is consistent with
20 the Federal regulations (concerning the privacy of
21 individually identifiable health information) promul-
22 gated under section 264(c) of the Health Insurance
23 Portability and Accountability Act of 1996.
24 "(5) NO OTHER FEES.—A prescription drug
25 card sponsor may not charge any fee to an eligible

1 beneficiary under a prescription drug discount card
2 program endorsed under this section other than an
3 enrollment fee charged under subsection (b)(2)(A).
4 ''(6) PRICES.—
5 ''(A) AVOIDANCE OF HIGH PRICED
6 DRUGS.—A prescription drug card sponsor may
7 not recommend switching an eligible beneficiary
8 to a drug with a higher negotiated price absent
9 a recommendation by a licensed health profes-
10 sional that there is a clinical indication with re-
11 spect to the patient for such a switch.
12 ''(B) PRICE STABILITY.—Negotiated prices
13 charged for prescription drugs covered under a
14 prescription drug discount card program en-
15 dorsed under this section may not change more
16 frequently than once every 60 days.
17 ''(e) PRESCRIPTION DRUG BENEFITS.—
18 ''(1) IN GENERAL.—Each prescription drug
19 card sponsor may only provide benefits that relate to
20 prescription drugs (as defined in subsection (i)(2))
21 under a prescription drug discount card program en-
22 dorsed under this section.
23 ''(2) SAVINGS TO ELIGIBLE BENEFICIARIES.—
24 ''(A) IN GENERAL.—Subject to subpara-
25 graph (D), each prescription drug card sponsor

shall provide eligible beneficiaries who enroll in a prescription drug discount card program offered by such sponsor that is endorsed under this section with access to negotiated prices used by the sponsor with respect to prescription drugs dispensed to eligible beneficiaries.

"(B) INAPPLICABILITY OF MEDICAID BEST PRICE RULES.—The requirements of section 1927 relating to manufacturer best price shall not apply to the negotiated prices for prescription drugs made available under a prescription drug discount card program endorsed under this section.

"(C) GUARANTEED ACCESS TO NEGOTIATED PRICES.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures to ensure that eligible beneficiaries have access to the negotiated prices for prescription drugs provided under subparagraph (A).

"(D) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an eligible beneficiary that would otherwise be a covered drug under this section shall not be so consid-

ered under a prescription drug discount card program if the program excludes the drug under a formulary.

"(3) BENEFICIARY SERVICES.—Each prescription drug discount card program endorsed under this section shall provide pharmaceutical support services, such as education, counseling, and services to prevent adverse drug interactions.

"(4) DISCOUNT CARDS.—Each prescription drug card sponsor shall issue a card to eligible beneficiaries enrolled in a prescription drug discount card program offered by such sponsor that the beneficiary may use to obtain benefits under the program.

"(f) SUBMISSION OF APPLICATIONS FOR ENDORSEMENT AND APPROVAL.—

"(1) SUBMISSION OF APPLICATIONS FOR ENDORSEMENT.—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, such information as the Secretary may require.

"(2) APPROVAL.—The Secretary shall review the information submitted under paragraph (1) and

shall determine whether to endorse the prescription drug discount card program to which such information relates. The Secretary may not approve a program unless the program and prescription drug card sponsor offering the program comply with the requirements under this section.

"(g) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a prescription drug card sponsor offering a prescription drug discount card program uses a formulary, the following requirements must be met:

"(1) PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

"(A) IN GENERAL.—The eligible entity must establish a pharmacy and therapeutic committee that develops and reviews the formulary.

"(B) COMPOSITION.—A pharmacy and therapeutic committee shall include at least 1 academic expert, at least 1 practicing physician, and at least 1 practicing pharmacist, all of whom have expertise in the care of elderly or disabled persons, and a majority of the members of such committee shall consist of individ-

uals who are a practicing physician or a practicing pharmacist (or both).

"(2) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall 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 such other information as the committee determines to be appropriate.

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

"(A) IN GENERAL.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (as defined by the Secretary), although not necessarily for all drugs within such categories and classes.

"(B) REQUIREMENT.—In defining therapeutic categories and classes of covered outpatient drugs pursuant to subparagraph (A), the Secretary shall use the compendia referred to section 1927(g)(1)(B)(i) or other recognized sources for categorizing drug therapeutic categories and classes.

"(4) PROVIDER EDUCATION.—The committee shall establish policies and procedures to educate and inform health care providers concerning the formulary.

"(5) NOTICE BEFORE REMOVING DRUGS FROM FORMULARY.—Any removal of a drug from a formulary shall take effect only after appropriate notice is made available to beneficiaries and pharmacies.

"(h) FRAUD AND ABUSE PREVENTION.—

"(1) IN GENERAL.—The Secretary shall provide appropriate oversight to ensure compliance of endorsed programs with the requirements of this section, including verification of the negotiated prices and services provided.

"(2) DISQUALIFICATION FOR ABUSIVE PRACTICES.—The Secretary may implement intermediate sanctions and may revoke the endorsement of a program that the Secretary determines no longer meets the requirements of this section or that has engaged in false or misleading marketing practices.

"(3) AUTHORITY WITH RESPECT TO CIVIL MONEY PENALTIES.—The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for any violation of this section. The provisions of section 1128A (other than subsections (a)

and (b)) 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).

"(4) REPORTING TO SECRETARY.—Each prescription drug card sponsor offering a prescription drug discount card program endorsed under this section shall report information relating to program performance, use of prescription drugs by eligible beneficiaries enrolled in the program, financial information of the sponsor, and such other information as the Secretary may specify. The Secretary may not disclose any proprietary data reported under this paragraph.

"(5) DRUG UTILIZATION REVIEW.—The Secretary may use claims data from parts A and B for purposes of conducting a drug utilization review program.

"(i) DEFINITIONS.—In this section:

"(1) ELIGIBLE BENEFICIARY.—

"(A) IN GENERAL.—The term 'eligible beneficiary' means an individual who—

"(i) is entitled to, or enrolled for, benefits under part A and enrolled under part B; and

"(ii) is not a dual eligible individual (as defined in subparagraph (B)).

"(B) DUAL ELIGIBLE INDIVIDUAL.—

"(i) IN GENERAL.—The term 'dual eligible individual' means an individual who is—

"(I) enrolled under title XIX or under a waiver under section 1115 of the requirements of such title for medical assistance that is not less than the medical assistance provided to an individual described in section 1902(a)(10)(A)(i) and includes covered outpatient drugs (as such term is defined for purposes of section 1927); and

"(II) entitled to benefits under part A and enrolled under part B.

"(ii) INCLUSION OF MEDICALLY NEEDY.—Such term includes an individual described in section 1902(a)(10)(C).

"(2) PRESCRIPTION DRUG.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'prescription drug' means—

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

"(ii) a biological product or insulin described in subparagraph (B) or (C) of such section (including syringes, and necessary medical supplies associated with the administration of insulin, as defined by the Secretary),

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

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

"(3) NEGOTIATED PRICE.—The term 'negotiated price' includes all discounts, direct or indirect

subsidies, rebates, price concessions, and direct or indirect remunerations.

"(4) PRESCRIPTION DRUG CARD SPONSOR.—The term 'prescription drug card sponsor' means any entity with demonstrated experience and expertise in operating a prescription drug discount card program, an insurance program that provides coverage for prescription drugs, or a similar program that the Secretary determines to be appropriate to provide eligible beneficiaries with the benefits under a prescription drug discount card program endorsed by the Secretary under this section, including—

"(A) a pharmaceutical benefit management company;

"(B) a wholesale or retail pharmacist delivery system;

"(C) an insurer (including an insurer that offers medicare supplemental policies under section 1882);

"(D) any other entity; or

"(E) any combination of the entities described in subparagraphs (A) through (D).

"TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE CARD PROGRAM FOR ELIGIBLE LOW-INCOME BENEFICIARIES

"SEC. 1807A. (a) ESTABLISHMENT.—

"(1) IN GENERAL.—There is established a program under which the Secretary shall award contracts to prescription drug card sponsors offering a prescription drug discount card that has been endorsed by the Secretary under section 1807 under which such sponsors shall offer a prescription drug assistance card program to eligible low-income beneficiaries in accordance with the requirements of this section.

"(2) APPLICATION OF DISCOUNT CARD PROVISIONS.—Except as otherwise provided in this section, the provisions of section 1807 shall apply to the program established under this section.

"(b) ELIGIBILITY, ELECTION OF PROGRAM, AND ENROLLMENT FEES.—

"(1) ELIGIBILITY AND ELECTION OF PROGRAM.—

"(A) IN GENERAL.—Subject to the succeeding provisions of this paragraph, the enrollment procedures established under section 1807(b)(1)(A)(ii) shall apply for purposes of this section.

"(B) ENROLLMENT OF ANY ELIGIBLE LOW-INCOME BENEFICIARY.—Each prescription drug card sponsor offering a prescription drug

assistance card program under this section shall permit any eligible low-income beneficiary to enroll in such program if it serves the geographic area in which the beneficiary resides.

"(C) SIMULTANEOUS ENROLLMENT IN PRESCRIPTION DRUG DISCOUNT CARD PROGRAM.—An eligible low-income beneficiary who enrolls in a prescription drug assistance card program offered by a prescription drug card sponsor under this section shall be simultaneously enrolled in a prescription drug discount card program offered by such sponsor.

"(2) WAIVER OF ENROLLMENT FEES.—

"(A) IN GENERAL.—A prescription drug card sponsor may not charge an enrollment fee to any eligible low-income beneficiary enrolled in a prescription drug discount card program offered by such sponsor.

"(B) PAYMENT BY SECRETARY.—Under a contract awarded under subsection (f)(2), the Secretary shall pay to each prescription drug card sponsor an amount equal to any enrollment fee charged under section 1807(b)(2)(A) on behalf of each eligible low-income beneficiary enrolled in a prescription drug discount card

program under paragraph (1)(C) offered by such sponsor.

"(c) ADDITIONAL BENEFICIARY PROTECTIONS.—

"(1) PROVIDING INFORMATION TO ELIGIBLE LOW-INCOME BENEFICIARIES.—In addition to the information provided to eligible beneficiaries under section 1807(c), the prescription drug card sponsor shall—

"(A) periodically notify each eligible low-income beneficiary enrolled in a prescription drug assistance card program offered by such sponsor of the amount of coverage for prescription drugs remaining under subsection (d)(2)(A); and

"(B) notify each eligible low-income beneficiary enrolled in a prescription drug assistance card program offered by such sponsor of the grievance and appeals processes under the program.

"(2) CONVENIENT ACCESS IN LONG-TERM CARE FACILITIES.—For purposes of determining whether convenient access has been provided under section 1807(d)(2) with respect to eligible low-income beneficiaries enrolled in a prescription drug assistance card program, the Secretary may only make a deter-

mination that such access has been provided if an appropriate arrangement is in place for eligible low-income beneficiaries who are in a long-term care facility (as defined by the Secretary) to receive prescription drug benefits under the program.

"(3) COORDINATION OF BENEFITS.—

"(A) IN GENERAL.—The Secretary shall establish procedures under which eligible low-income beneficiaries who are enrolled for coverage described in subparagraph (B) and enrolled in a prescription drug assistance card program have access to the prescription drug benefits available under such program.

"(B) COVERAGE DESCRIBED.—Coverage described in this subparagraph is as follows:

"(i) Coverage of prescription drugs under a State pharmaceutical assistance program.

"(ii) Enrollment in a Medicare+Choice plan under part C.

"(4) GRIEVANCE MECHANISM.—Each prescription drug card sponsor with a contract under this section shall provide in accordance with section 1852(f) meaningful procedures for hearing and resolving grievances between the prescription drug

card sponsor (including any entity or individual through which the prescription drug card sponsor provides covered benefits) and enrollees in a prescription drug assistance card program offered by such sponsor.

"(5) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—

"(A) IN GENERAL.—The requirements of paragraphs (1) through (3) of section 1852(g) shall apply with respect to covered benefits under a prescription drug assistance card program under this section in the same manner as such requirements apply to a Medicare+Choice organization with respect to benefits it offers under a Medicare+Choice plan under part C.

"(B) REQUEST FOR REVIEW OF TIERED FORMULARY DETERMINATIONS.—In the case of a prescription drug assistance card program offered by a prescription drug card sponsor that provides for tiered pricing for drugs included within a formulary and provides lower prices for preferred drugs included within the formulary, an eligible low-income beneficiary who is enrolled in the program may request coverage of a nonpreferred drug under the terms applicable

for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition is not as effective for the eligible low-income beneficiary or has adverse effects for the eligible low-income beneficiary.

"(C) FORMULARY DETERMINATIONS.—An eligible low-income beneficiary who is enrolled in a prescription drug assistance card program offered by a prescription drug card sponsor may appeal to obtain coverage for a covered drug that is not on a formulary of the entity if the prescribing physician determines that the formulary drug for treatment of the same condition is not as effective for the eligible low-income beneficiary or has adverse effects for the eligible low-income beneficiary.

"(6) APPEALS.—

"(A) IN GENERAL.—Subject to subparagraph (B), a prescription drug card sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to drugs not included on any formulary in a similar manner (as determined by the Secretary) as such requirements apply to a Medicare+Choice

organization with respect to benefits it offers under a Medicare+Choice plan under part C.

"(B) FORMULARY DETERMINATIONS.—An eligible low-income beneficiary who is enrolled in a prescription drug assistance card program offered by a prescription drug card sponsor may appeal to obtain coverage for a covered drug that is not on a formulary of the entity if the prescribing physician determines that the formulary drug for treatment of the same condition is not as effective for the eligible low-income beneficiary or has adverse effects for the eligible low-income beneficiary.

"(C) APPEALS AND EXCEPTIONS TO APPLICATION.—The prescription drug card sponsor must have, as part of the appeals process under this paragraph, a process for timely appeals for denials of coverage based on the application of the formulary.

"(d) PRESCRIPTION DRUG BENEFITS.—

"(1) IN GENERAL.—Subject to paragraph (5), all the benefits available under a prescription drug discount card program offered by a prescription drug card sponsor and endorsed under section 1807 shall be available to eligible low-income beneficiaries

enrolled in a prescription drug assistance card program offered by such sponsor.

"(2) ASSISTANCE FOR ELIGIBLE LOW-INCOME BENEFICIARIES.—

"(A) $600 ANNUAL ASSISTANCE.—Subject to subparagraphs (B) and (C) and paragraph (5), each prescription drug card sponsor with a contract under this section shall provide coverage for the first $600 of expenses for prescription drugs incurred during each calendar year by an eligible low-income beneficiary enrolled in a prescription drug assistance card program offered by such sponsor.

"(B) COINSURANCE.—

"(i) IN GENERAL.—The prescription drug card sponsor shall determine an amount of coinsurance to collect from each eligible low-income beneficiary enrolled in a prescription drug assistance card program offered by such sponsor for which coverage is available under subparagraph (A).

"(ii) AMOUNT.—The amount of coinsurance collected under clause (i) shall be at least 10 percent of the negotiated price

of each prescription drug dispensed to an eligible low-income beneficiary.

"(iii) CONSTRUCTION.—Amounts collected under clause (i) shall not be counted against the total amount of coverage available under subparagraph (A).

"(C) REDUCTION FOR LATE ENROLLMENT.—For each month during a calendar quarter in which an eligible low-income beneficiary is not enrolled in a prescription drug assistance card program offered by a prescription drug card sponsor with a contract under this section, the amount of assistance available under subparagraph (A) shall be reduced by $50.

"(D) CREDITING OF UNUSED BENEFITS TOWARD FUTURE YEARS.—The dollar amount of coverage described in subparagraph (A) shall be increased by any amount of coverage described in such subparagraph that was not used during the previous calendar year.

"(E) WAIVER TO ENSURE PROVISION OF BENEFIT.—The Secretary may waive such requirements of this section and section 1807 as may be necessary to ensure that each eligible

low-income beneficiaries has access to the assistance described in subparagraph (A).

"(3) ADDITIONAL DISCOUNTS.—A prescription drug card sponsor with a contract under this section shall provide each eligible low-income beneficiary enrolled in a prescription drug assistance program offered by the sponsor with access to negotiated prices that reflect a minimum average discount of at least 20 percent of the average wholesale price for prescription drugs covered under that program.

"(4) ASSISTANCE CARDS.—Each prescription drug card sponsor shall permit eligible low-income beneficiaries enrolled in a prescription drug assistance card program offered by such sponsor to use the discount card issued under section 1807(e)(4) to obtain benefits under the program.

"(5) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an eligible low-income beneficiary that would otherwise be a covered drug under this section shall not be so considered under a prescription drug assistance card program if the program excludes the drug under a formulary and such exclusion is not successfully resolved under paragraph (4), (5), or (6) of subsection (c).

"(e) REQUIREMENTS FOR PRESCRIPTION DRUG CARD SPONSORS THAT OFFER PRESCRIPTION DRUG ASSISTANCE CARD PROGRAMS.—

"(1) IN GENERAL.—Each prescription drug card sponsor shall—

"(A) process claims made by eligible low-income beneficiaries;

"(B) negotiate with brand name and generic prescription drug manufacturers and others for low prices on prescription drugs;

"(C) track individual beneficiary expenditures in a format and periodicity specified by the Secretary; and

"(D) perform such other functions as the Secretary may assign.

"(2) DATA EXCHANGES.—Each prescription drug card sponsor shall receive data exchanges in a format specified by the Secretary and shall maintain real-time beneficiary files.

"(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—The prescription drug card sponsor offering the prescription drug assistance card program shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered drug shall inform the eligible

low-income beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest priced generic drug covered under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy or other dispenser.

"(f) SUBMISSION OF BIDS AND AWARDING OF CONTRACTS.—

"(1) SUBMISSION OF BIDS.—Each prescription drug card sponsor that seeks to offer a prescription drug assistance card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, such information as the Secretary may require.

"(2) AWARDING OF CONTRACTS.—The Secretary shall review the information submitted under paragraph (1) and shall determine whether to award a contract to the prescription drug card sponsor offering the program to which such information relates. The Secretary may not approve a program unless the program and prescription drug card sponsor offering the program comply with the requirements under this section.

"(3) NUMBER OF CONTRACTS.—There shall be no limit on the number of prescription drug card

sponsors that may be awarded contracts under paragraph (2).

"(4) CONTRACT PROVISIONS.—

"(A) DURATION.—A contract awarded under paragraph (2) shall be for the lifetime of the program under this section.

"(B) WITHDRAWAL.—A prescription drug card sponsor that desires to terminate the contract awarded under paragraph (2) may terminate such contract without penalty if such sponsor gives notice—

"(i) to the Secretary 90 days prior to the termination of such contract; and

"(ii) to each eligible low-income beneficiary that is enrolled in a prescription drug assistance card program offered by such sponsor 60 days prior to such termination.

"(C) SERVICE AREA.—The service area under the contract shall be the same as the area served by the prescription drug card sponsor under section 1807.

"(5) SIMULTANEOUS APPROVAL OF DISCOUNT CARD AND ASSISTANCE PROGRAMS.—A prescription drug card sponsor may submit an application for en-

dorsement under section 1807 as part of the bid submitted under paragraph (1) and the Secretary may approve such application at the same time as the Secretary awards a contract under this section.

"(g) PAYMENTS TO PRESCRIPTION DRUG CARD SPONSORS.—

"(1) IN GENERAL.—The Secretary shall pay to each prescription drug card sponsor offering a prescription drug assistance card program in which an eligible low-income beneficiary is enrolled an amount equal to the amount agreed to by the Secretary and the sponsor in the contract awarded under subsection (f)(2).

"(2) PAYMENT FROM PART B TRUST FUND.—The costs of providing benefits under this section shall be payable from the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

"(h) ELIGIBILITY DETERMINATIONS MADE BY STATES; PRESUMPTIVE ELIGIBILITY.—States shall perform the functions described in section 1935(a)(1).

"(i) APPROPRIATIONS.—There are appropriated from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 such sums as may be necessary to carry out the program under this section.

"(j) DEFINITIONS.—In this section:

"(1) ELIGIBLE BENEFICIARY; NEGOTIATED PRICE; PRESCRIPTION DRUG.—The terms 'eligible beneficiary', 'negotiated price', and 'prescription drug' have the meanings given those terms in section 1807(i).

"(2) ELIGIBLE LOW-INCOME BENEFICIARY.—The term 'eligible low-income beneficiary' means an individual who—

"(A) is an eligible beneficiary (as defined in section 1807(i)); and

"(B) is described in clause (iii) or (iv) of section 1902(a)(10)(E) or in section 1905(p)(1).

"(3) PRESCRIPTION DRUG CARD SPONSOR.—The term 'prescription drug card sponsor' has the meaning given that term in section 1807(i), except that such sponsor shall also be an entity that the Secretary determines is—

"(A) is appropriate to provide eligible low-income beneficiaries with the benefits under a prescription drug assistance card program under this section; and

"(B) is able to manage the monetary assistance made available under subsection (d)(2);

"(C) agrees to submit to audits by the Secretary; and

"(D) provides such other assurances as the Secretary may require.

"(4) STATE.—The term 'State' has the meaning given such term for purposes of title XIX.".

(b) EXCLUSION OF PRICES FROM DETERMINATION OF BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

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

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

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

"(V) any negotiated prices charged under the medicare prescription drug discount card endorsement program under section 1807 or under the transitional prescription drug assistance card program for eligible low-income beneficiaries under section 1807A.".

(c) EXCLUSION OF PRESCRIPTION DRUG ASSISTANCE CARD COSTS FROM DETERMINATION OF PART B

MONTHLY PREMIUM.—Section 1839(g) of the Social Security Act (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 prescription drug assistance card program under section 1807A.''.

(d) REGULATIONS.—

(1) AUTHORITY FOR INTERIM FINAL REGULATIONS.—The Secretary may promulgate initial regulations implementing sections 1807 and 1807A of the Social Security Act (as added by this section) in interim final form without prior opportunity for public comment.

(2) FINAL REGULATIONS.—A final regulation reflecting public comments must be published within 1 year of the interim final regulation promulgated under paragraph (1).

(3) EXEMPTION FROM THE PAPERWORK REDUCTION ACT.—The promulgation of the regulations under this subsection and the administration the

programs established by sections 1807 and 1807A of the Social Security Act (as added by this section) shall be made without regard to chapter 35 of title 44, United States Code (commonly known as the ''Paperwork Reduction Act'').

(e) IMPLEMENTATION; TRANSITION.—

(1) IMPLEMENTATION.—The Secretary shall implement the amendments made by this section in a manner that discounts are available to eligible beneficiaries under section 1807 of the Social Security Act and assistance is available to eligible low-income beneficiaries under section 1807A of such Act not later than January 1, 2004.

(2) TRANSITION.—The Secretary shall provide for an appropriate transition and discontinuation of the programs under section 1807 and 1807A of the Social Security Act. Such transition and discontinuation shall ensure that such programs continue to operate until the date on which the first enrollment period under part D ends.

# Subtitle C—Standards for Electronic Prescribing

**SEC. 121. STANDARDS FOR ELECTRONIC PRESCRIBING.**

Title XI (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART D—ELECTRONIC PRESCRIBING

"STANDARDS FOR ELECTRONIC PRESCRIBING

"SEC. 1180. (a) STANDARDS.—

"(1) DEVELOPMENT AND ADOPTION.—

"(A) IN GENERAL.—The Secretary shall develop or adopt standards for transactions and data elements for such transactions (in this section referred to as 'standards') to enable the electronic transmission of medication history, eligibility, benefit, and other prescription information.

"(B) CONSULTATION.—In developing and adopting the standards under subparagraph (A), the Secretary shall consult with representatives of physicians, hospitals, pharmacists, standard setting organizations, pharmacy benefit managers, beneficiary information exchange networks, technology experts, and representatives of the Departments of Veterans Affairs and Defense and other interested parties.

"(2) OBJECTIVE.—Any standards developed or adopted under this part shall be consistent with the objectives of improving—

"(A) patient safety; and

"(B) the quality of care provided to patients.

"(3) REQUIREMENTS.—Any standards developed or adopted under this part shall comply with the following:

"(A) PATIENT MAY REQUEST A WRITTEN PRESCRIPTION.—The standards provide that—

"(i) a prescription shall be written and not transmitted electronically if the patient makes such a request; and

"(ii) no additional charges may be imposed on the patient for making such a request.

"(B) PATIENT-SPECIFIC MEDICATION HISTORY, ELIGIBILITY, BENEFIT, AND OTHER PRESCRIPTION INFORMATION.—

"(i) IN GENERAL.—The standards shall accommodate electronic transmittal of patient-specific medication history, eligibility, benefit, and other prescription information among prescribing and dispensing professionals at the point of care.

"(ii) REQUIRED INFORMATION.—The information described in clause (i) shall include the following:

"(I) Information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medication history of the patient that may be relevant to the appropriate prescription for that patient.

"(II) Cost-effective alternatives (if any) to the drug prescribed.

"(III) Information on eligibility and benefits, including the drugs included in the applicable formulary and any requirements for prior authorization.

"(IV) Information on potential interactions with drugs listed on the medication history, graded by severity of the potential interaction.

"(V) Other information to improve the quality of patient care and to reduce medical errors.

"(C) UNDUE BURDEN.—The standards shall be designed so that, to the extent practicable, the standards do not impose an undue

administrative burden on the practice of medicine, pharmacy, or other health professions.

"(D) COMPATIBILITY WITH ADMINISTRATIVE SIMPLIFICATION AND PRIVACY LAWS.—The standards shall be—

"(i) consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; and

"(ii) compatible with the standards adopted under part C.

"(4) TRANSFER OF INFORMATION.—The Secretary shall develop and adopt standards for transferring among prescribing and insurance entities and other necessary entities appropriate standard data elements needed for the electronic exchange of medication history, eligibility, benefit, and other prescription drug information and other health information determined appropriate in compliance with the standards adopted or modified under this part.

"(b) TIMETABLE FOR ADOPTION OF STANDARDS.—

"(1) IN GENERAL.—The Secretary shall adopt the standards under this part by January 1, 2006.

"(2) ADDITIONS AND MODIFICATIONS TO STANDARDS.—The Secretary shall, in consultation with appropriate representatives of interested parties, review the standards developed or adopted under this part and adopt modifications to the standards (including additions to the standards), as determined appropriate. Any addition or modification to such standards shall be completed in a manner which minimizes the disruption and cost of compliance.

"(c) COMPLIANCE WITH STANDARDS.—

"(1) REQUIREMENT FOR ALL INDIVIDUALS AND ENTITIES THAT TRANSMIT OR RECEIVE PRESCRIPTIONS ELECTRONICALLY.—

"(A) IN GENERAL.—Individuals or entities that transmit or receive prescriptions electronically shall comply with the standards adopted or modified under this part.

"(B) RELATION TO STATE LAWS.—The standards adopted or modified under this part shall supersede any State law or regulations pertaining to the electronic transmission of medication history, eligibility, benefit and prescription information.

"(2) TIMETABLE FOR COMPLIANCE.—

"(A) INITIAL COMPLIANCE.—

"(i) IN GENERAL.—Not later than 24 months after the date on which an initial standard is adopted under this part, each individual or entity to whom the standard applies shall comply with the standard.

"(ii) SPECIAL RULE FOR SMALL HEALTH PLANS.—In the case of a small health plan, as defined by the Secretary for purposes of section 1175(b)(1)(B), clause (i) shall be applied by substituting '36 months' for '24 months'.

"(d) CONSULTATION WITH ATTORNEY GENERAL.—The Secretary shall consult with the Attorney General before developing, adopting, or modifying a standard under this part to ensure that the standard accommodates secure electronic transmission of prescriptions for controlled substances in a manner that minimizes the possibility of violations under the Comprehensive Drug Abuse Prevention and Control Act of 1970 and related Federal laws.

"(e) NO REQUIREMENT TO TRANSMIT OR RECEIVE PRESCRIPTIONS ELECTRONICALLY.—Nothing in this part shall be construed to require an individual or entity to transmit or receive prescriptions electronically.

"GRANTS TO HEALTH CARE PROVIDERS TO IMPLEMENT ELECTRONIC PRESCRIPTION PROGRAMS

"SEC. 1180A. (a) IN GENERAL.—The Secretary is authorized to make grants to health care providers for the purpose of assisting such entities to implement electronic prescription programs that comply with the standards adopted or modified under this part.

"(b) APPLICATION.—No grant may be made under this section except pursuant to a grant application that is submitted in a time, manner, and form approved by the Secretary.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for each of fiscal years 2006, 2007, and 2008, such sums as may be necessary to carry out this section.".

# Subtitle D—Other Provisions

**SEC. 131. ADDITIONAL REQUIREMENTS FOR ANNUAL FINANCIAL REPORT AND OVERSIGHT ON MEDICARE PROGRAM.**

(a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i) is amended by adding at the end the following new subsection:

"(l) COMBINED REPORT ON OPERATION AND STATUS OF THE TRUST FUND AND THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND (INCLUD-

ING THE PRESCRIPTION DRUG ACCOUNT).—In addition to the duty of the Board of Trustees to report to Congress under subsection (b), on the date the Board submits the report required under subsection (b)(2), the Board shall submit to Congress a report on the operation and status of the Trust Fund and the Federal Supplementary Medical Insurance Trust Fund established under section 1841 (including the Prescription Drug Account within such Trust Fund), in this subsection referred to as the 'Trust Funds'. Such report shall include the following information:

"(1) OVERALL SPENDING FROM THE GENERAL FUND OF THE TREASURY.—A statement of total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury to the Trust Funds, separately stated in terms of the total amount and in terms of the percentage such amount bears to all other amounts obligated from such General Revenues during such fiscal year, for each of the following amounts:

"(A) MEDICARE BENEFITS.—The amount expended for payment of benefits covered under this title.

"(B) ADMINISTRATIVE AND OTHER EXPENSES.—The amount expended for payments

not related to the benefits described in subparagraph (A).

"(2) HISTORICAL OVERVIEW OF SPENDING.—From the date of the inception of the program of insurance under this title through the fiscal year involved, a statement of the total amounts referred to in paragraph (1), separately stated for the amounts described in subparagraphs (A) and (B) of such paragraph.

"(3) 10-YEAR AND 50-YEAR PROJECTIONS.—An estimate of total amounts referred to in paragraph (1), separately stated for the amounts described in subparagraphs (A) and (B) of such paragraph, required to be obligated for payment for benefits covered under this title for each of the 10 fiscal years succeeding the fiscal year involved and for the 50-year period beginning with the succeeding fiscal year.

"(4) RELATION TO OTHER MEASURES OF GROWTH.—A comparison of the rate of growth of the total amounts referred to in paragraph (1), separately stated for the amounts described in subparagraphs (A) and (B) of such paragraph, to the rate of growth for the same period in—

"(A) the gross domestic product;

"(B) health insurance costs in the private sector;

"(C) employment-based health insurance costs in the public and private sectors; and

"(D) other areas as determined appropriate by the Board of Trustees.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to fiscal years beginning on or after the date of enactment of this Act.

(c) CONGRESSIONAL HEARINGS.—It is the sense of Congress that the committees of jurisdiction of Congress shall hold hearings on the reports submitted under section 1817(l) of the Social Security Act (as added by subsection (a)).

**SEC. 132. TRUSTEES' REPORT ON MEDICARE'S UNFUNDED OBLIGATIONS.**

(a) REPORT.—The report submitted under sections 1817(b)(2) and 1841(b)(2) of the Social Security Act (42 U.S.C. 1395i(b)(2) and 1395t(b)(2)) during 2004 shall include an analysis of the total amount of the unfunded obligations of the Medicare program under title XVIII of the Social Security Act.

(b) MATTERS ANALYZED.—The analysis described in subsection (A) shall compare the long-term obligations of the Medicare program to the dedicated funding sources

for that program (other than general revenue transfers), including the combined obligations of the Federal Hospital Insurance Trust Fund established under section 1817 of such 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).

**SEC. 133. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.**

Subpart 3 of part D of title XVIII of the Social Security Act (as added by section 101) is amended by adding at the end the following new section:

"PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS

"SEC. 1860D–27. (a) PROHIBITION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, an eligible entity offering a Medicare Prescription Drug plan under this part or a MedicareAdvantage organization offering a MedicareAdvantage plan under part C shall not enter into a contract with any pharmacy benefit manager (in this section referred to as a 'PBM') that is owned by a pharmaceutical manufacturing company.

"(2) PROVISION OF INFORMATION.—A PBM that manages prescription drug coverage under this part or part C shall provide the following informa-

tion, on an annual basis, to the Assistant Attorney General for Antitrust of the Department of Justice and the Inspector General of the Health and Human Services Department:

"(A) The aggregate amount of any and all rebates, discounts, administrative fees, promotional allowances, and other payments received or recovered from each pharmaceutical manufacturer.

"(B) The amount of payments received or recovered from each pharmaceutical manufacturer for each of the top 50 drugs as measured by volume (as determined by the Secretary).

"(C) The percentage differential between the price the PBM pays pharmacies for a drug described in subparagraph (B) and the price the PBM charges a Medicare Prescription Drug Plan or a MedicareAdvantage organization for such drug.

"(b) FAILURE TO DISCLOSE.—

"(1) CIVIL PENALTY.—Any PBM that fails to comply with subsection (a) shall be liable for a civil penalty as determined appropriate through regulations promulgated by the Attorney General. Such

1 penalty may be recovered in a civil action brought by
2 the United States.
3 ''(2) COMPLIANCE AND EQUITABLE RELIEF.—If
4 any PBM fails to comply with subsection (a), the
5 United States district court may order compliance,
6 and may grant such other equitable relief as the
7 court in its discretion determines necessary or ap-
8 propriate, upon application of the Assistant Attorney
9 General.
10 ''(c) DISCLOSURE EXEMPTION.—Any information
11 filed with the Assistant Attorney General under subsection
12 (a)(2) shall be exempt from disclosure under section 552
13 of title 5, and no such information may be made public,
14 except as may be relevant to any administrative or judicial
15 action or proceeding. Nothing in this section is intended
16 to prevent disclosure to either body of Congress or to any
17 duly authorized committee or subcommittee of the Con-
18 gress.''.

19 **SEC. 134. OFFICE OF THE MEDICARE BENEFICIARY ADVO-**
20 **CATE.**

21 (a) ESTABLISHMENT.—Not later than 1 year after
22 the date of enactment of this Act, the Secretary shall es-
23 tablish within the Department of Health and Human
24 Services, an Office of the Medicare Beneficiary Advocate
25 (in this section referred to as the ''Office'').

(b) DUTIES.—The Office shall carry out the following activities:

(1) Establishing a toll-free telephone number for medicare beneficiaries to use to obtain information on the medicare program, and particularly with respect to the benefits provided under part D of title XVIII of the Social Security Act and the Medicare Prescription Drug plans and MedicareAdvantage plans offering such benefits. The Office shall ensure that the toll-free telephone number accommodates beneficiaries with disabilities and limited-English proficiency.

(2) Establishing an Internet website with easily accessible information regarding Medicare Prescription Drug plans and MedicareAdvantage plans and the benefits offered under such plans. The website shall—

(A) be updated regularly to reflect changes in services and benefits, including with respect to the plans offered in a region and the associated monthly premiums, benefits offered, formularies, and contact information for such plans, and to ensure that there are no broken links or errors;

(B) have printer-friendly, downloadable fact sheets on the medicare coverage options and benefits;

(C) be easy to navigate, with large print and easily recognizable links; and

(D) provide links to the websites of the eligible entities participating in part D of title XVIII.

(3) Providing regional publications to medicare beneficiaries that include regional contacts for information, and that inform the beneficiaries of the prescription drug benefit options under title XVIII of the Social Security Act, including with respect to—

(A) monthly premiums;

(B) formularies; and

(C) the scope of the benefits offered.

(4) Conducting outreach to medicare beneficiaries to inform the beneficiaries of the medicare coverage options and benefits under parts A, B, C, and D of title XVIII of the Social Security Act.

(5) Working with local benefits administrators, ombudsmen, local benefits specialists, and advocacy groups to ensure that medicare beneficiaries are aware of the medicare coverage options and benefits

under parts A, B, C, and D of title XVIII of the Social Security Act.

(c) FUNDING.—

(1) ESTABLISHMENT.—Of the amounts authorized to be appropriated under the Secretary's discretion for administrative expenditures, $2,000,000 may be used to establish the Office in accordance with this section.

(2) OPERATION.—With respect to each fiscal year occurring after the fiscal year in which the Office is established under this section, the Secretary may use, out of amounts authorized to be appropriated under the Secretary's discretion for administrative expenditures for such fiscal year, such sums as may be necessary to operate the Office in that fiscal year.

# TITLE II—MEDICAREADVANTAGE

## Subtitle A—MedicareAdvantage Competition

**SEC. 201. ELIGIBILITY, ELECTION, AND ENROLLMENT.**

Section 1851 (42 U.S.C. 1395w–21) is amended to read as follows:

"ELIGIBILITY, ELECTION, AND ENROLLMENT

"SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS THROUGH MEDICAREADVANTAGE PLANS.—

"(1) IN GENERAL.—Subject to the provisions of this section, each MedicareAdvantage eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits under this title—

"(A) through—

"(i) the original Medicare fee-for-service program under parts A and B; and

"(ii) the voluntary prescription drug delivery program under part D; or

"(B) through enrollment in a MedicareAdvantage plan under this part.

"(2) TYPES OF MEDICAREADVANTAGE PLANS THAT MAY BE AVAILABLE.—A MedicareAdvantage plan may be any of the following types of plans of health insurance:

"(A) COORDINATED CARE PLANS.—Coordinated care plans which provide health care services, including health maintenance organization plans (with or without point of service options) and plans offered by provider-sponsored organizations (as defined in section 1855(d)).

"(B) COMBINATION OF MSA PLAN AND CONTRIBUTIONS TO MEDICAREADVANTAGE MSA.—An MSA plan, as defined in section 1859(b)(3), and a contribution into a

MedicareAdvantage medical savings account (MSA).

"(C) PRIVATE FEE-FOR-SERVICE PLANS.—A MedicareAdvantage private fee-for-service plan, as defined in section 1859(b)(2).

"(3) MEDICAREADVANTAGE ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—Subject to subparagraph (B), in this title, the term 'MedicareAdvantage eligible individual' means an individual who is entitled to (or enrolled for) benefits under part A, enrolled under part B, and enrolled under part D.

"(B) SPECIAL RULE FOR END-STAGE RENAL DISEASE.—Such term shall not include an individual medically determined to have end-stage renal disease, except that—

"(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice or a MedicareAdvantage plan may continue to be enrolled in that plan; and

"(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan or a MedicareAdvantage plan under clause

(i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in section 1851(e)(4)(A), then the individual will be treated as a 'MedicareAdvantage eligible individual' for purposes of electing to continue enrollment in another MedicareAdvantage plan.

''(b) SPECIAL RULES.—

''(1) RESIDENCE REQUIREMENT.—

''(A) IN GENERAL.—Except as the Secretary may otherwise provide and except as provided in subparagraph (C), an individual is eligible to elect a MedicareAdvantage plan offered by a MedicareAdvantage organization only if the plan serves the geographic area in which the individual resides.

''(B) CONTINUATION OF ENROLLMENT PERMITTED.—Pursuant to rules specified by the Secretary, the Secretary shall provide that a plan may offer to all individuals residing in a geographic area the option to continue enrollment in the plan, notwithstanding that the individual no longer resides in the service area of the plan, so long as the plan provides that indi-

viduals exercising this option have, as part of the basic benefits described in section 1852(a)(1)(A), reasonable access within that geographic area to the full range of basic benefits, subject to reasonable cost-sharing liability in obtaining such benefits.

"(C) CONTINUATION OF ENROLLMENT PERMITTED WHERE SERVICE CHANGED.—Notwithstanding subparagraph (A) and in addition to subparagraph (B), if a MedicareAdvantage organization eliminates from its service area a MedicareAdvantage payment area that was previously within its service area, the organization may elect to offer individuals residing in all or portions of the affected area who would otherwise be ineligible to continue enrollment the option to continue enrollment in a MedicareAdvantage plan it offers so long as—

"(i) the enrollee agrees to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively at facilities designated by the organization within the plan service area; and

"(ii) there is no other MedicareAdvantage plan offered in the area in which the enrollee resides at the time of the organization's election.

"(2) SPECIAL RULE FOR CERTAIN INDIVIDUALS COVERED UNDER FEHBP OR ELIGIBLE FOR VETERANS OR MILITARY HEALTH BENEFITS.—

"(A) FEHBP.—An individual who is enrolled in a health benefit plan under chapter 89 of title 5, United States Code, is not eligible to enroll in an MSA plan until such time as the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted policies which will ensure that the enrollment of such individuals in such plans will not result in increased expenditures for the Federal Government for health benefit plans under such chapter.

"(B) VA AND DOD.—The Secretary may apply rules similar to the rules described in subparagraph (A) in the case of individuals who are eligible for health care benefits under chapter 55 of title 10, United States Code, or under chapter 17 of title 38 of such Code.

"(3) LIMITATION ON ELIGIBILITY OF QUALIFIED MEDICARE BENEFICIARIES AND OTHER MEDICAID BENEFICIARIES TO ENROLL IN AN MSA PLAN.—An individual who is a qualified medicare beneficiary (as defined in section 1905(p)(1)), a qualified disabled and working individual (described in section 1905(s)), an individual described in section 1902(a)(10)(E)(iii), or otherwise entitled to medicare cost-sharing under a State plan under title XIX is not eligible to enroll in an MSA plan.

"(4) COVERAGE UNDER MSA PLANS ON A DEMONSTRATION BASIS.—

"(A) IN GENERAL.—An individual is not eligible to enroll in an MSA plan under this part—

"(i) on or after January 1, 2004, unless the enrollment is the continuation of such an enrollment in effect as of such date; or

"(ii) as of any date if the number of such individuals so enrolled as of such date has reached 390,000.

Under rules established by the Secretary, an individual is not eligible to enroll (or continue enrollment) in an MSA plan for a year unless the

individual provides assurances satisfactory to the Secretary that the individual will reside in the United States for at least 183 days during the year.

"(B) EVALUATION.—The Secretary shall regularly evaluate the impact of permitting enrollment in MSA plans under this part on selection (including adverse selection), use of preventive care, access to care, and the financial status of the Trust Funds under this title.

"(C) REPORTS.—The Secretary shall submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted under subparagraph (B).

"(c) PROCESS FOR EXERCISING CHOICE.—

"(1) IN GENERAL.—The Secretary shall establish a process through which elections described in subsection (a) are made and changed, including the form and manner in which such elections are made and changed. Such elections shall be made or changed only during coverage election periods specified under subsection (e) and shall become effective as provided in subsection (f).

"(2) COORDINATION THROUGH MEDICAREADVANTAGE ORGANIZATIONS.—

"(A) ENROLLMENT.—Such process shall permit an individual who wishes to elect a MedicareAdvantage plan offered by a MedicareAdvantage organization to make such election through the filing of an appropriate election form with the organization.

"(B) DISENROLLMENT.—Such process shall permit an individual, who has elected a MedicareAdvantage plan offered by a MedicareAdvantage organization and who wishes to terminate such election, to terminate such election through the filing of an appropriate election form with the organization.

"(3) DEFAULT.—

"(A) INITIAL ELECTION.—

"(i) IN GENERAL.—Subject to clause (ii), an individual who fails to make an election during an initial election period under subsection (e)(1) is deemed to have chosen the original medicare fee-for-service program option.

"(ii) SEAMLESS CONTINUATION OF COVERAGE.—The Secretary may establish

procedures under which an individual who is enrolled in a Medicare+Choice plan or another health plan (other than a MedicareAdvantage plan) offered by a MedicareAdvantage organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the MedicareAdvantage plan offered by the organization (or, if the organization offers more than 1 such plan, such plan or plans as the Secretary identifies under such procedures).

"(B) CONTINUING PERIODS.—An individual who has made (or is deemed to have made) an election under this section is considered to have continued to make such election until such time as—

"(i) the individual changes the election under this section; or

"(ii) the MedicareAdvantage plan with respect to which such election is in effect is discontinued or, subject to subsection (b)(1)(B), no longer serves the area in which the individual resides.

"(d) PROVIDING INFORMATION TO PROMOTE INFORMED CHOICE.—

"(1) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to medicare beneficiaries (and prospective medicare beneficiaries) on the coverage options provided under this section in order to promote an active, informed selection among such options.

"(2) PROVISION OF NOTICE.—

"(A) OPEN SEASON NOTIFICATION.—At least 15 days before the beginning of each annual, coordinated election period (as defined in subsection (e)(3)(B)), the Secretary shall mail to each MedicareAdvantage eligible individual residing in an area the following:

"(i) GENERAL INFORMATION.—The general information described in paragraph (3).

"(ii) LIST OF PLANS AND COMPARISON OF PLAN OPTIONS.—A list identifying the MedicareAdvantage plans that are (or will be) available to residents of the area and information described in paragraph (4) concerning such plans. Such informa-

tion shall be presented in a comparative form.

"(iii) ADDITIONAL INFORMATION.—Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1804.

"(B) NOTIFICATION TO NEWLY ELIGIBLE MEDICAREADVANTAGE ELIGIBLE INDIVIDUALS.—To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial MedicareAdvantage enrollment period for an individual described in subsection (e)(1), mail to the individual the information described in subparagraph (A).

"(C) FORM.—The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

"(D) PERIODIC UPDATING.—The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of

MedicareAdvantage plans, the benefits under such plans, and the MedicareAdvantage monthly basic beneficiary premium, MedicareAdvantage monthly beneficiary premium for enhanced medical benefits, and MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage for such plans.

"(3) GENERAL INFORMATION.—General information under this paragraph, with respect to coverage under this part during a year, shall include the following:

"(A) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—A general description of the benefits covered under parts A and B of the original medicare fee-for-service program, including—

"(i) covered items and services;

"(ii) beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts; and

"(iii) any beneficiary liability for balance billing.

"(B) CATASTROPHIC COVERAGE AND COMBINED DEDUCTIBLE.—A description of the cat-

astrophic coverage and unified deductible applicable under the plan.

"(C) OUTPATIENT PRESCRIPTION DRUG COVERAGE BENEFITS.—The information required under section 1860D–4 with respect to coverage for prescription drugs under the plan.

"(D) ELECTION PROCEDURES.—Information and instructions on how to exercise election options under this section.

"(E) RIGHTS.—A general description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program (including such rights under part D) and the MedicareAdvantage program and the right to be protected against discrimination based on health status-related factors under section 1852(b).

"(F) INFORMATION ON MEDIGAP AND MEDICARE SELECT.—A general description of the benefits, enrollment rights, and other requirements applicable to medicare supplemental policies under section 1882 and provisions relating to medicare select policies described in section 1882(t).

"(G) POTENTIAL FOR CONTRACT TERMINATION.—The fact that a MedicareAdvantage organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract, under this part, and the effect of such a termination, nonrenewal, or service area reduction may have on individuals enrolled with the MedicareAdvantage plan under this part.

"(4) INFORMATION COMPARING PLAN OPTIONS.—Information under this paragraph, with respect to a MedicareAdvantage plan for a year, shall include the following:

"(A) BENEFITS.—The benefits covered under the plan, including the following:

"(i) Covered items and services beyond those provided under the original medicare fee-for-service program option.

"(ii) Beneficiary cost-sharing for any items and services described in clause (i) and paragraph (3)(A)(i), including information on the unified deductible under section 1852(a)(1)(C).

"(iii) The maximum limitations on out-of-pocket expenses under section 1852(a)(1)(C).

"(iv) In the case of an MSA plan, differences in cost-sharing, premiums, and balance billing under such a plan compared to under other MedicareAdvantage plans.

"(v) In the case of a MedicareAdvantage private fee-for-service plan, differences in cost-sharing, premiums, and balance billing under such a plan compared to under other MedicareAdvantage plans.

"(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

"(vii) The extent to which an enrollee may select among in-network providers and the types of providers participating in the plan's network.

"(viii) The organization's coverage of emergency and urgently needed care.

"(ix) The comparative information described in section 1860D–4(b)(2) relating

to prescription drug coverage under the plan.

"(B) PREMIUMS.—

"(i) IN GENERAL.—The MedicareAdvantage monthly basic beneficiary premium and MedicareAdvantage monthly beneficiary premium for enhanced medical benefits, if any, for the plan or, in the case of an MSA plan, the MedicareAdvantage monthly MSA premium.

"(ii) REDUCTIONS.—The reduction in part B premiums, if any.

"(iii) NATURE OF THE PREMIUM FOR ENHANCED MEDICAL BENEFITS.—Whether the MedicareAdvantage monthly premium for enhanced benefits is optional or mandatory.

"(C) SERVICE AREA.—The service area of the plan.

"(D) QUALITY AND PERFORMANCE.—Plan quality and performance indicators for the benefits under the plan (and how such indicators compare to quality and performance indicators under the original medicare fee-for-service pro-

gram under parts A and B and under the voluntary prescription drug delivery program under part D in the area involved), including—

"(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan's service area);

"(ii) information on medicare enrollee satisfaction;

"(iii) information on health outcomes; and

"(iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

"(5) MAINTAINING A TOLL-FREE NUMBER AND INTERNET SITE.—The Secretary shall maintain a toll-free number for inquiries regarding MedicareAdvantage options and the operation of this part in all areas in which MedicareAdvantage plans are offered and an Internet site through which individuals may electronically obtain information on such options and MedicareAdvantage plans.

"(6) USE OF NON-FEDERAL ENTITIES.—The Secretary may enter into contracts with non-Federal entities to carry out activities under this subsection.

"(7) PROVISION OF INFORMATION.—A MedicareAdvantage organization shall provide the Secretary with such information on the organization and each MedicareAdvantage plan it offers as may be required for the preparation of the information referred to in paragraph (2)(A).

"(e) COVERAGE ELECTION PERIODS.—

"(1) INITIAL CHOICE UPON ELIGIBILITY TO MAKE ELECTION IF MEDICAREADVANTAGE PLANS AVAILABLE TO INDIVIDUAL.—If, at the time an individual first becomes eligible to elect to receive benefits under part B or D (whichever is later), there is 1 or more MedicareAdvantage plans offered in the area in which the individual resides, the individual shall make the election under this section during a period specified by the Secretary such that if the individual elects a MedicareAdvantage plan during the period, coverage under the plan becomes effective as of the first date on which the individual may receive such coverage.

"(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5), the following rules shall apply:

"(A) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2005.—At any time during the period beginning January 1, 1998, and ending on December 31, 2005, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

"(B) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 6 MONTHS DURING 2006.—

"(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), at any time during the first 6 months of 2006, or, if the individual first becomes a MedicareAdvantage eligible individual during 2006, during the first 6 months during 2006 in which the individual is a MedicareAdvantage eligible individual, a MedicareAdvantage eligible individual may change the election under subsection (a)(1).

"(ii) LIMITATION OF 1 CHANGE.—An individual may exercise the right under

clause (i) only once. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under the first sentence of paragraph (4).

"(C) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN SUBSEQUENT YEARS.—

"(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), at any time during the first 3 months of 2007 and each subsequent year, or, if the individual first becomes a MedicareAdvantage eligible individual during 2007 or any subsequent year, during the first 3 months of such year in which the individual is a MedicareAdvantage eligible individual, a MedicareAdvantage eligible individual may change the election under subsection (a)(1).

"(ii) LIMITATION OF 1 CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR.—An individual may exercise the right under clause (i) only once during the

applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

"(D) CONTINUOUS OPEN ENROLLMENT FOR INSTITUTIONALIZED INDIVIDUALS.—At any time during 2006 or any subsequent year, in the case of a MedicareAdvantage eligible individual who is institutionalized (as defined by the Secretary), the individual may elect under subsection (a)(1)—

"(i) to enroll in a MedicareAdvantage plan; or

"(ii) to change the MedicareAdvantage plan in which the individual is enrolled.

"(3) ANNUAL, COORDINATED ELECTION PERIOD.—

"(A) IN GENERAL.—Subject to paragraph (5), each individual who is eligible to make an election under this section may change such

election during an annual, coordinated election period.

"(B) ANNUAL, COORDINATED ELECTION PERIOD.—For purposes of this section, the term 'annual, coordinated election period' means, with respect to a year before 2003 and after 2006, the month of November before such year and with respect to 2003, 2004, 2005, and 2006, the period beginning on November 15 and ending on December 31 of the year before such year.

"(C) MEDICAREADVANTAGE HEALTH INFORMATION FAIRS.—During the fall season of each year (beginning with 2006), in conjunction with the annual coordinated election period defined in subparagraph (B), the Secretary shall provide for a nationally coordinated educational and publicity campaign to inform MedicareAdvantage eligible individuals about MedicareAdvantage plans and the election process provided under this section.

"(D) SPECIAL INFORMATION CAMPAIGN IN 2005.—During the period beginning on November 15, 2005, and ending on December 31, 2005, the Secretary shall provide for an edu-

cational and publicity campaign to inform MedicareAdvantage eligible individuals about the availability of MedicareAdvantage plans, and eligible organizations with risk-sharing contracts under section 1876, offered in different areas and the election process provided under this section.

"(4) SPECIAL ELECTION PERIODS.—Effective on and after January 1, 2006, an individual may discontinue an election of a MedicareAdvantage plan offered by a MedicareAdvantage organization other than during an annual, coordinated election period and make a new election under this section if—

"(A)(i) the certification of the organization or plan under this part has been terminated, or the organization or plan has notified the individual of an impending termination of such certification; or

"(ii) the organization has terminated or otherwise discontinued providing the plan in the area in which the individual resides, or has notified the individual of an impending termination or discontinuation of such plan;

"(B) the individual is no longer eligible to elect the plan because of a change in the indi-

vidual's place of residence or other change in circumstances (specified by the Secretary, but not including termination of the individual's enrollment on the basis described in clause (i) or (ii) of subsection (g)(3)(B));

"(C) the individual demonstrates (in accordance with guidelines established by the Secretary) that—

"(i) the organization offering the plan substantially violated a material provision of the organization's contract under this part in relation to the individual (including the failure to provide an enrollee on a timely basis medically necessary care for which benefits are available under the plan or the failure to provide such covered care in accordance with applicable quality standards); or

"(ii) the organization (or an agent or other entity acting on the organization's behalf) materially misrepresented the plan's provisions in marketing the plan to the individual; or

"(D) the individual meets such other exceptional conditions as the Secretary may provide.

Effective on and after January 1, 2006, an individual who, upon first becoming eligible for benefits under part A at age 65, enrolls in a MedicareAdvantage plan under this part, the individual may discontinue the election of such plan, and elect coverage under the original fee-for-service plan, at any time during the 12-month period beginning on the effective date of such enrollment.

"(5) SPECIAL RULES FOR MSA PLANS.—Notwithstanding the preceding provisions of this subsection, an individual—

"(A) may elect an MSA plan only during—

"(i) an initial open enrollment period described in paragraph (1);

"(ii) an annual, coordinated election period described in paragraph (3)(B); or

"(iii) the month of November 1998;

"(B) subject to subparagraph (C), may not discontinue an election of an MSA plan except during the periods described in clause (ii) or (iii) of subparagraph (A) and under the first sentence of paragraph (4); and

"(C) who elects an MSA plan during an annual, coordinated election period, and who never previously had elected such a plan, may revoke such election, in a manner determined by the Secretary, by not later than December 15 following the date of the election.

"(6) OPEN ENROLLMENT PERIODS.—Subject to paragraph (5), a MedicareAdvantage organization—

"(A) shall accept elections or changes to elections during the initial enrollment periods described in paragraph (1), during the period beginning on November 15, 2005, and ending on December 31, 2005, and during the annual, coordinated election period under paragraph (3) for each subsequent year, and during special election periods described in the first sentence of paragraph (4); and

"(B) may accept other changes to elections at such other times as the organization provides.

"(f) EFFECTIVENESS OF ELECTIONS AND CHANGES OF ELECTIONS.—

"(1) DURING INITIAL COVERAGE ELECTION PERIOD.—An election of coverage made during the initial coverage election period under subsection

(e)(1)(A) shall take effect upon the date the individual becomes entitled to (or enrolled for) benefits under part A, enrolled under part B, and enrolled under part D, except as the Secretary may provide (consistent with sections 1838 and 1860D–2)) in order to prevent retroactive coverage.

''(2) DURING CONTINUOUS OPEN ENROLLMENT PERIODS.—An election or change of coverage made under subsection (e)(2) shall take effect with the first day of the first calendar month following the date on which the election or change is made.

''(3) ANNUAL, COORDINATED ELECTION PERIOD.—An election or change of coverage made during an annual, coordinated election period (as defined in subsection (e)(3)(B)) in a year shall take effect as of the first day of the following year.

''(4) OTHER PERIODS.—An election or change of coverage made during any other period under subsection (e)(4) shall take effect in such manner as the Secretary provides in a manner consistent (to the extent practicable) with protecting continuity of health benefit coverage.

''(g) GUARANTEED ISSUE AND RENEWAL.—

''(1) IN GENERAL.—Except as provided in this subsection, a MedicareAdvantage organization shall

provide that at any time during which elections are accepted under this section with respect to a MedicareAdvantage plan offered by the organization, the organization will accept without restrictions individuals who are eligible to make such election.

"(2) PRIORITY.—If the Secretary determines that a MedicareAdvantage organization, in relation to a MedicareAdvantage plan it offers, has a capacity limit and the number of MedicareAdvantage eligible individuals who elect the plan under this section exceeds the capacity limit, the organization may limit the election of individuals of the plan under this section but only if priority in election is provided—

"(A) first to such individuals as have elected the plan at the time of the determination; and

"(B) then to other such individuals in such a manner that does not discriminate, on a basis described in section 1852(b), among the individuals (who seek to elect the plan).

The preceding sentence shall not apply if it would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with

regulations of the Secretary, of the medicare population in the service area of the plan.

"(3) LIMITATION ON TERMINATION OF ELECTION.—

"(A) IN GENERAL.—Subject to subparagraph (B), a MedicareAdvantage organization may not for any reason terminate the election of any individual under this section for a MedicareAdvantage plan it offers.

"(B) BASIS FOR TERMINATION OF ELECTION.—A MedicareAdvantage organization may terminate an individual's election under this section with respect to a MedicareAdvantage plan it offers if—

"(i) any MedicareAdvantage monthly basic beneficiary premium, MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage, or MedicareAdvantage monthly beneficiary premium for required or optional enhanced medical benefits required with respect to such plan are not paid on a timely basis (consistent with standards under section 1856 that provide for a

grace period for late payment of such premiums);

"(ii) the individual has engaged in disruptive behavior (as specified in such standards); or

"(iii) the plan is terminated with respect to all individuals under this part in the area in which the individual resides.

"(C) CONSEQUENCE OF TERMINATION.—

"(i) TERMINATIONS FOR CAUSE.—Any individual whose election is terminated under clause (i) or (ii) of subparagraph (B) is deemed to have elected to receive benefits under the original medicare fee-for-service program option.

"(ii) TERMINATION BASED ON PLAN TERMINATION OR SERVICE AREA REDUCTION.—Any individual whose election is terminated under subparagraph (B)(iii) shall have a special election period under subsection (e)(4)(A) in which to change coverage to coverage under another MedicareAdvantage plan. Such an individual who fails to make an election during such period is deemed to have chosen to

change coverage to the original medicare fee-for-service program option.

"(D) ORGANIZATION OBLIGATION WITH RESPECT TO ELECTION FORMS.—Pursuant to a contract under section 1857858., each MedicareAdvantage organization receiving an election form under subsection (c)(2) shall transmit to the Secretary (at such time and in such manner as the Secretary may specify) a copy of such form or such other information respecting the election as the Secretary may specify.

"(h) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—

"(1) SUBMISSION.—No marketing material or application form may be distributed by a MedicareAdvantage organization to (or for the use of) MedicareAdvantage eligible individuals unless—

"(A) at least 45 days (or 10 days in the case described in paragraph (5)) before the date of distribution the organization has submitted the material or form to the Secretary for review; and

"(B) the Secretary has not disapproved the distribution of such material or form.

"(2) REVIEW.—The standards established under section 1856 shall include guidelines for the review of any material or form submitted and under such guidelines the Secretary shall disapprove (or later require the correction of) such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.

"(3) DEEMED APPROVAL (1-STOP SHOPPING).—In the case of material or form that is submitted under paragraph (1)(A) to the Secretary or a regional office of the Department of Health and Human Services and the Secretary or the office has not disapproved the distribution of marketing material or form under paragraph (1)(B) with respect to a MedicareAdvantage plan in an area, the Secretary is deemed not to have disapproved such distribution in all other areas covered by the plan and organization except with regard to that portion of such material or form that is specific only to an area involved.

"(4) PROHIBITION OF CERTAIN MARKETING PRACTICES.—Each MedicareAdvantage organization shall conform to fair marketing standards, in relation to MedicareAdvantage plans offered under this

part, included in the standards established under section 1856. Such standards—

"(A) shall not permit a MedicareAdvantage organization to provide for cash or other monetary rebates as an inducement for enrollment or otherwise (other than as an additional benefit described in section 1854(g)(1)(C)(i)); and

"(B) may include a prohibition against a MedicareAdvantage organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual.

"(5) SPECIAL TREATMENT OF MARKETING MATERIAL FOLLOWING MODEL MARKETING LANGUAGE.—In the case of marketing material of an organization that uses, without modification, proposed model language specified by the Secretary, the period specified in paragraph (1)(A) shall be reduced from 45 days to 10 days.

"(i) EFFECT OF ELECTION OF MEDICAREADVANTAGE PLAN OPTION.—

"(1) PAYMENTS TO ORGANIZATIONS.—Subject to sections 1852(a)(5), 1853(h), 1853(i), 1886(d)(11), and 1886(h)(3)(D), payments under a contract with a MedicareAdvantage organization

under section 1853(a) with respect to an individual electing a MedicareAdvantage plan offered by the organization shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under parts A, B, and D for items and services furnished to the individual.

"(2) ONLY ORGANIZATION ENTITLED TO PAYMENT.—Subject to sections 1853(f), 1853(h), 1853(i), 1857(f)(2), 1886(d)(11), and 1886(h)(3)(D), only the MedicareAdvantage organization shall be entitled to receive payments from the Secretary under this title for services furnished to the individual.".

**SEC. 202. BENEFITS AND BENEFICIARY PROTECTIONS.**

Section 1852 (42 U.S.C. 1395w–22) is amended to read as follows:

"BENEFITS AND BENEFICIARY PROTECTIONS

"SEC. 1852. (a) BASIC BENEFITS.—

"(1) IN GENERAL.—Except as provided in section 1859(b)(3) for MSA plans, each MedicareAdvantage plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

"(A) those items and services (other than hospice care) for which benefits are available

under parts A and B to individuals residing in the area served by the plan;

"(B) except as provided in paragraph (2)(D), qualified prescription drug coverage under part D to individuals residing in the area served by the plan;

"(C) a maximum limitation on out-of-pocket expenses and a unified deductible; and

"(D) additional benefits required under section 1854(d)(1).

"(2) SATISFACTION OF REQUIREMENT.—

"(A) IN GENERAL.—A MedicareAdvantage plan (other than an MSA plan) offered by a MedicareAdvantage organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—

"(i) the sum of such payment amount and any cost-sharing provided for under the plan; is equal to at least

"(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and

B (including any balance billing permitted under such parts).

"(B) REFERENCE TO RELATED PROVISIONS.—For provisions relating to—

"(i) limitations on balance billing against MedicareAdvantage organizations for noncontract providers, see sections 1852(k) and 1866(a)(1)(O); and

"(ii) limiting actuarial value of enrollee liability for covered benefits, see section 1854(f).

"(C) ELECTION OF UNIFORM COVERAGE POLICY.—In the case of a MedicareAdvantage organization that offers a MedicareAdvantage plan in an area in which more than 1 local coverage policy is applied with respect to different parts of the area, the organization may elect to have the local coverage policy for the part of the area that is most beneficial to MedicareAdvantage enrollees (as identified by the Secretary) apply with respect to all MedicareAdvantage enrollees enrolled in the plan.

"(D) SPECIAL RULE FOR PRIVATE FEE-FOR-SERVICE PLANS.—

"(i) IN GENERAL.—A private fee-for-service plan may elect not to provide qualified prescription drug coverage under part D to individuals residing in the area served by the plan.

"(ii) AVAILABILITY OF DRUG COVERAGE FOR ENROLLEES.—If a beneficiary enrolls in a plan making the election described in clause (i), the beneficiary may enroll for drug coverage under part D with an eligible entity under such part.

"(3) ENHANCED MEDICAL BENEFITS.—

"(A) BENEFITS INCLUDED SUBJECT TO SECRETARY'S APPROVAL.—Each MedicareAdvantage organization may provide to individuals enrolled under this part, other than under an MSA plan (without affording those individuals an option to decline the coverage), enhanced medical benefits that the Secretary may approve. The Secretary shall approve any such enhanced medical benefits unless the Secretary determines that including such enhanced medical benefits would substantially discourage enrollment by MedicareAdvantage eligible individuals with the organization.

"(B) AT ENROLLEES' OPTION.—A MedicareAdvantage organization may not provide, under an MSA plan, enhanced medical benefits that cover the deductible described in section 1859(b)(2)(B). In applying the previous sentence, health benefits described in section 1882(u)(2)(B) shall not be treated as covering such deductible.

"(C) APPLICATION TO MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—Nothing in this paragraph shall be construed as preventing a MedicareAdvantage private fee-for-service plan from offering enhanced medical benefits that include payment for some or all of the balance billing amounts permitted consistent with section 1852(k) and coverage of additional services that the plan finds to be medically necessary.

"(D) RULE FOR APPROVAL OF MEDICAL AND PRESCRIPTION DRUG BENEFITS.—Notwithstanding the preceding provisions of this paragraph, the Secretary may not approve any enhanced medical benefit that provides for the coverage of any prescription drug (other than that relating to prescription drugs covered

under the original medicare fee-for-service program option).

"(4) ORGANIZATION AS SECONDARY PAYER.—Notwithstanding any other provision of law, a MedicareAdvantage organization may (in the case of the provision of items and services to an individual under a MedicareAdvantage plan under circumstances in which payment under this title is made secondary pursuant to section 1862(b)(2)) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section—

"(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services; or

"(B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services.

"(5) NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—If there is a national coverage determination or legislative change in benefits required to be provided under this part made in the period beginning on the date of an

announcement under section 1853(b) and ending on the date of the next announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a MedicareAdvantage organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the benchmark amount announced under section 1853(b)(1)(A) at the beginning of such period, then, unless otherwise required by law—

"(A) such determination or legislative change in benefits shall not apply to contracts under this part until the first contract year that begins after the end of such period; and

"(B) if such coverage determination or legislative change provides for coverage of additional benefits or coverage under additional circumstances, section 1851(i)(1) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

The projection under the previous sentence shall be based on an analysis by the Secretary of the actu-

arial costs associated with the coverage determination or legislative change in benefits.

"(6) AUTHORITY TO PROHIBIT RISK SELECTION.—The Secretary shall have the authority to disapprove any MedicareAdvantage plan that the Secretary determines is designed to attract a population that is healthier than the average population residing in the service area of the plan.

"(7) UNIFIED DEDUCTIBLE DEFINED.—In this part, the term 'unified deductible' means an annual deductible amount that is applied in lieu of the inpatient hospital deductible under section 1813(b)(1) and the deductible under section 1833(b). Nothing in this part shall be construed as preventing a MedicareAdvantage organization from requiring coinsurance or a copayment for inpatient hospital services after the unified deductible is satisfied, subject to the limitation on enrollee liability under section 1854(f).

"(b) ANTIDISCRIMINATION.—

"(1) BENEFICIARIES.—

"(A) IN GENERAL.—A MedicareAdvantage organization may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled

with the organization under this part, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

"(B) CONSTRUCTION.—Except as provided under section 1851(a)(3)(B), subparagraph (A) shall not be construed as requiring a MedicareAdvantage organization to enroll individuals who are determined to have end-stage renal disease.

"(2) PROVIDERS.—A MedicareAdvantage organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

"(c) DISCLOSURE REQUIREMENTS.—

"(1) DETAILED DESCRIPTION OF PLAN PROVISIONS.—A MedicareAdvantage organization shall

disclose, in clear, accurate, and standardized form to each enrollee with a MedicareAdvantage plan offered by the organization under this part at the time of enrollment and at least annually thereafter, the following information regarding such plan:

"(A) SERVICE AREA.—The plan's service area.

"(B) BENEFITS.—Benefits offered under the plan, including information described section 1852(a)(1) (relating to benefits under the original medicare fee-for-service program option, the maximum limitation in out-of-pocket expenses and the unified deductible, and qualified prescription drug coverage under part D, respectively) and exclusions from coverage and, if it is an MSA plan, a comparison of benefits under such a plan with benefits under other MedicareAdvantage plans.

"(C) ACCESS.—The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits for such option).

"(D) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan.

"(E) EMERGENCY COVERAGE.—Coverage of emergency services, including—

"(i) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

"(ii) the process and procedures of the plan for obtaining emergency services; and

"(iii) the locations of—

"(I) emergency departments; and

"(II) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

"(F) ENHANCED MEDICAL BENEFITS.—Enhanced medical benefits available from the organization offering the plan, including—

"(i) whether the enhanced medical benefits are optional;

"(ii) the enhanced medical benefits covered; and

"(iii) the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits.

"(G) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in non-payment.

"(H) PLAN GRIEVANCE AND APPEALS PROCEDURES.—All plan appeal or grievance rights and procedures.

"(I) QUALITY ASSURANCE PROGRAM.—A description of the organization's quality assurance program under subsection (e).

"(2) DISCLOSURE UPON REQUEST.—Upon request of a MedicareAdvantage eligible individual, a MedicareAdvantage organization must provide the following information to such individual:

"(A) The general coverage information and general comparative plan information made available under clauses (i) and (ii) of section 1851(d)(2)(A).

"(B) Information on procedures used by the organization to control utilization of services and expenditures.

"(C) Information on the number of grievances, reconsiderations, and appeals and on the disposition in the aggregate of such matters.

"(D) An overall summary description as to the method of compensation of participating physicians.

"(E) The information described in subparagraphs (A) through (C) in relation to the qualified prescription drug coverage provided by the organization.

"(d) ACCESS TO SERVICES.—

"(1) IN GENERAL.—A MedicareAdvantage organization offering a MedicareAdvantage plan may select the providers from whom the benefits under the plan are provided so long as—

"(A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

"(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

"(C) the plan provides for reimbursement with respect to services which are covered under

subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

"(i) the services were not emergency services (as defined in paragraph (3)), but—

"(I) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition; and

"(II) it was not reasonable given the circumstances to obtain the services through the organization;

"(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan's service area; or

"(iii) the services are maintenance care or post-stabilization care covered under the guidelines established under paragraph (2);

"(D) the organization provides access to appropriate providers, including credentialed

specialists, for medically necessary treatment and services; and

"(E) coverage is provided for emergency services (as defined in paragraph (3)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization.

"(2) GUIDELINES RESPECTING COORDINATION OF POST-STABILIZATION CARE.—A MedicareAdvantage plan shall comply with such guidelines as the Secretary may prescribe relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after the enrollee has been determined to be stable under section 1867.

"(3) DEFINITION OF EMERGENCY SERVICES.—In this subsection—

"(A) IN GENERAL.—The term 'emergency services' means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

"(i) are furnished by a provider that is qualified to furnish such services under this title; and

"(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

"(B) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

"(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

"(ii) serious impairment to bodily functions; or

"(iii) serious dysfunction of any bodily organ or part.

"(4) ASSURING ACCESS TO SERVICES IN MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—In addition to any other requirements under this part, in the case of a MedicareAdvantage private fee-for-service plan,

the organization offering the plan must demonstrate to the Secretary that the organization has sufficient number and range of health care professionals and providers willing to provide services under the terms of the plan. The Secretary shall find that an organization has met such requirement with respect to any category of health care professional or provider if, with respect to that category of provider—

"(A) the plan has established payment rates for covered services furnished by that category of provider that are not less than the payment rates provided for under part A, B, or D for such services; or

"(B) the plan has contracts or agreements (other than deemed contracts or agreements under subsection (j)(6), with a sufficient number and range of providers within such category to provide covered services under the terms of the plan,

or a combination of both. The previous sentence shall not be construed as restricting the persons from whom enrollees under such a plan may obtain covered benefits, 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.

''(e) QUALITY ASSURANCE PROGRAM.—

''(1) IN GENERAL.—Each MedicareAdvantage organization must have arrangements, consistent with any regulation, for an ongoing quality assurance program for health care services it provides to individuals enrolled with MedicareAdvantage plans of the organization.

''(2) ELEMENTS OF PROGRAM.—

''(A) IN GENERAL.—The quality assurance program of an organization with respect to a MedicareAdvantage plan (other than a MedicareAdvantage private fee-for-service plan or a nonnetwork MSA plan) it offers shall—

''(i) stress health outcomes and provide for the collection, analysis, and reporting of data (in accordance with a quality measurement system that the Secretary

recognizes) that will permit measurement of outcomes and other indices of the quality of MedicareAdvantage plans and organizations;

''(ii) monitor and evaluate high volume and high risk services and the care of acute and chronic conditions;

''(iii) provide access to disease management and chronic care services;

''(iv) provide access to preventive benefits and information for enrollees on such benefits;

''(v) evaluate the continuity and coordination of care that enrollees receive;

''(vi) be evaluated on an ongoing basis as to its effectiveness;

''(vii) include measures of consumer satisfaction;

''(viii) provide the Secretary with such access to information collected as may be appropriate to monitor and ensure the quality of care provided under this part;

''(ix) provide review by physicians and other health care professionals of the proc-

ess followed in the provision of such health care services;

"(x) provide for the establishment of written protocols for utilization review, based on current standards of medical practice;

"(xi) have mechanisms to detect both underutilization and overutilization of services;

"(xii) after identifying areas for improvement, establish or alter practice parameters;

"(xiii) take action to improve quality and assesses the effectiveness of such action through systematic followup; and

"(xiv) make available information on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options (in such form and on such quality and outcomes measures as the Secretary determines to be appropriate).

Such program shall include a separate focus (with respect to all the elements described in

this subparagraph) on racial and ethnic minorities.

"(B) ELEMENTS OF PROGRAM FOR ORGANIZATIONS OFFERING MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS, AND NONNETWORK MSA PLANS.—The quality assurance program of an organization with respect to a MedicareAdvantage private fee-for-service plan or a nonnetwork MSA plan it offers shall—

"(i) meet the requirements of clauses (i) through (viii) of subparagraph (A);

"(ii) insofar as it provides for the establishment of written protocols for utilization review, base such protocols on current standards of medical practice; and

"(iii) have mechanisms to evaluate utilization of services and inform providers and enrollees of the results of such evaluation.

Such program shall include a separate focus (with respect to all the elements described in this subparagraph) on racial and ethnic minorities.

"(C) DEFINITION OF NONNETWORK MSA PLAN.—In this subsection, the term 'nonnet-

work MSA plan' means an MSA plan offered by a MedicareAdvantage organization that does not provide benefits required to be provided by this part, in whole or in part, through a defined set of providers under contract, or under another arrangement, with the organization.

"(3) EXTERNAL REVIEW.—

"(A) IN GENERAL.—Each MedicareAdvantage organization shall, for each MedicareAdvantage plan it operates, have an agreement with an independent quality review and improvement organization approved by the Secretary to perform functions of the type described in paragraphs (4)(B) and (14) of section 1154(a) with respect to services furnished by MedicareAdvantage plans for which payment is made under this title. The previous sentence shall not apply to a MedicareAdvantage private fee-for-service plan or a nonnetwork MSA plan that does not employ utilization review.

"(B) NONDUPLICATION OF ACCREDITATION.—Except in the case of the review of quality complaints, and consistent with subparagraph (C), the Secretary shall ensure that the external review activities conducted under sub-

paragraph (A) are not duplicative of review activities conducted as part of the accreditation process.

"(C) WAIVER AUTHORITY.—The Secretary may waive the requirement described in subparagraph (A) in the case of an organization if the Secretary determines that the organization has consistently maintained an excellent record of quality assurance and compliance with other requirements under this part.

"(4) TREATMENT OF ACCREDITATION.—

"(A) IN GENERAL.—The Secretary shall provide that a MedicareAdvantage organization is deemed to meet all the requirements described in any specific clause of subparagraph (B) if the organization is accredited (and periodically reaccredited) by a private accrediting organization under a process that the Secretary has determined assures that the accrediting organization applies and enforces standards that meet or exceed the standards established under section 1856 to carry out the requirements in such clause.

"(B) REQUIREMENTS DESCRIBED.—The provisions described in this subparagraph are the following:

"(i) Paragraphs (1) and (2) of this subsection (relating to quality assurance programs).

"(ii) Subsection (b) (relating to anti-discrimination).

"(iii) Subsection (d) (relating to access to services).

"(iv) Subsection (h) (relating to confidentiality and accuracy of enrollee records).

"(v) Subsection (i) (relating to information on advance directives).

"(vi) Subsection (j) (relating to provider participation rules).

"(C) TIMELY ACTION ON APPLICATIONS.—The Secretary shall determine, within 210 days after the date the Secretary receives an application by a private accrediting organization and using the criteria specified in section 1865(b)(2), whether the process of the private accrediting organization meets the requirements with respect to any specific clause in subpara-

graph (B) with respect to which the application is made. The Secretary may not deny such an application on the basis that it seeks to meet the requirements with respect to only one, or more than one, such specific clause.

"(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 1857, including the authority to terminate contracts with MedicareAdvantage organizations under subsection (c)(2) of such section.

"(5) REPORT TO CONGRESS.—

"(A) IN GENERAL.—The Secretary shall submit to Congress a biennial report regarding how quality assurance programs conducted under this subsection focus on racial and ethnic minorities.

"(B) CONTENTS OF REPORT.—Each such report shall include the following:

"(i) A description of the means by which such programs focus on such racial and ethnic minorities.

"(ii) An evaluation of the impact of such programs on eliminating health disparities and on improving health outcomes,

1 continuity and coordination of care, man-
2 agement of chronic conditions, and con-
3 sumer satisfaction.
4 ''(iii) Recommendations on ways to re-
5 duce clinical outcome disparities among ra-
6 cial and ethnic minorities.
7 ''(f) GRIEVANCE MECHANISM.—Each
8 MedicareAdvantage organization must provide meaningful
9 procedures for hearing and resolving grievances between
10 the organization (including any entity or individual
11 through which the organization provides health care serv-
12 ices) and enrollees with MedicareAdvantage plans of the
13 organization under this part.
14 ''(g) COVERAGE DETERMINATIONS, RECONSIDER-
15 ATIONS, AND APPEALS.—
16 ''(1) DETERMINATIONS BY ORGANIZATION.—
17 ''(A) IN GENERAL.—A MedicareAdvantage
18 organization shall have a procedure for making
19 determinations regarding whether an individual
20 enrolled with the plan of the organization under
21 this part is entitled to receive a health service
22 under this section and the amount (if any) that
23 the individual is required to pay with respect to
24 such service. Subject to paragraph (3), such

procedures shall provide for such determination to be made on a timely basis.

"(B) EXPLANATION OF DETERMINATION.—Such a determination that denies coverage, in whole or in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

"(2) RECONSIDERATIONS.—

"(A) IN GENERAL.—The organization shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved. The reconsideration shall be within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

"(B) PHYSICIAN DECISION ON CERTAIN RECONSIDERATIONS.—A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treat-

ment who is other than a physician involved in the initial determination.

"(3) EXPEDITED DETERMINATIONS AND RECONSIDERATIONS.—

"(A) RECEIPT OF REQUESTS.—

"(i) ENROLLEE REQUESTS.—An enrollee in a MedicareAdvantage plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the MedicareAdvantage organization.

"(ii) PHYSICIAN REQUESTS.—A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

"(B) ORGANIZATION PROCEDURES.—

"(i) IN GENERAL.—The MedicareAdvantage organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal timeframe for making a de-

termination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

"(ii) EXPEDITION REQUIRED FOR PHYSICIAN REQUESTS.—In the case of a request for an expedited determination or reconsideration made under subparagraph (A)(ii), the organization shall expedite the determination or reconsideration if the request indicates that the application of the normal timeframe for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

"(iii) TIMELY RESPONSE.—In cases described in clauses (i) and (ii), the organization shall notify the enrollee (and the physician involved, as appropriate) of the determination or reconsideration under time limitations established by the Secretary, but not later than 72 hours of the time of receipt of the request for the deter-

mination or reconsideration (or receipt of the information necessary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

"(4) INDEPENDENT REVIEW OF CERTAIN COVERAGE DENIALS.—The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. The provisions of section 1869(c)(5) shall apply to independent outside entities under contract with the Secretary under this paragraph.

"(5) APPEALS.—An enrollee with a MedicareAdvantage plan of a MedicareAdvantage organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is $1,000 or

more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g), and both the individual and the organization shall be entitled to be parties to that judicial review. In applying subsections (b) and (g) of section 205 as provided in this paragraph, and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

''(h) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—Insofar as a MedicareAdvantage organization maintains medical records or other health information regarding enrollees under this part, the MedicareAdvantage organization shall establish procedures—

''(1) to safeguard the privacy of any individually identifiable enrollee information;

''(2) to maintain such records and information in a manner that is accurate and timely; and

''(3) to assure timely access of enrollees to such records and information.

"(i) INFORMATION ON ADVANCE DIRECTIVES.—Each MedicareAdvantage organization shall meet the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

"(j) RULES REGARDING PROVIDER PARTICIPATION.—

"(1) PROCEDURES.—Insofar as a MedicareAdvantage organization offers benefits under a MedicareAdvantage plan through agreements with physicians, the organization shall establish reasonable procedures relating to the participation (under an agreement between a physician and the organization) of physicians under such a plan. Such procedures shall include—

"(A) providing notice of the rules regarding participation;

"(B) providing written notice of participation decisions that are adverse to physicians; and

"(C) providing a process within the organization for appealing such adverse decisions, including the presentation of information and views of the physician regarding such decision.

"(2) CONSULTATION IN MEDICAL POLICIES.—A MedicareAdvantage organization shall consult with

1 physicians who have entered into participation
2 agreements with the organization regarding the or-
3 ganization's medical policy, quality, and medical
4 management procedures.

5 "(3) PROHIBITING INTERFERENCE WITH PRO-
6 VIDER ADVICE TO ENROLLEES.—

7 "(A) IN GENERAL.—Subject to subpara-
8 graphs (B) and (C), a MedicareAdvantage orga-
9 nization (in relation to an individual enrolled
10 under a MedicareAdvantage plan offered by the
11 organization under this part) shall not prohibit
12 or otherwise restrict a covered health care pro-
13 fessional (as defined in subparagraph (D)) from
14 advising such an individual who is a patient of
15 the professional about the health status of the
16 individual or medical care or treatment for the
17 individual's condition or disease, regardless of
18 whether benefits for such care or treatment are
19 provided under the plan, if the professional is
20 acting within the lawful scope of practice.

21 "(B) CONSCIENCE PROTECTION.—Sub-
22 paragraph (A) shall not be construed as requir-
23 ing a MedicareAdvantage plan to provide, reim-
24 burse for, or provide coverage of a counseling or

referral service if the MedicareAdvantage organization offering the plan—

"(i) objects to the provision of such service on moral or religious grounds; and

"(ii) in the manner and through the written instrumentalities such MedicareAdvantage organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

"(C) CONSTRUCTION.—Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

"(D) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term 'health care professional' means a physician (as defined in section 1861(r)) or other health care professional if coverage for the professional's services is provided under the

MedicareAdvantage plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, licensed pharmacist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

"(4) LIMITATIONS ON PHYSICIAN INCENTIVE PLANS.—

"(A) IN GENERAL.—No MedicareAdvantage organization may operate any physician incentive plan (as defined in subparagraph (B)) unless the following requirements are met:

"(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

"(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization—

"(I) provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or group; and

"(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

"(iii) The organization provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this subparagraph.

"(B) PHYSICIAN INCENTIVE PLAN DEFINED.—In this paragraph, the term 'physician incentive plan' means any compensation arrangement between a MedicareAdvantage organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization under this part.

"(5) LIMITATION ON PROVIDER INDEMNIFICATION.—A MedicareAdvantage organization may not provide (directly or indirectly) for a health care professional, provider of services, or other entity providing health care services (or group of such professionals, providers, or entities) to indemnify the organization against any liability resulting from a civil action brought for any damage caused to an enrollee with a MedicareAdvantage plan of the organization

under this part by the organization's denial of medically necessary care.

"(6) SPECIAL RULES FOR MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—For purposes of applying this part (including subsection (k)(1)) and section 1866(a)(1)(O), a hospital (or other provider of services), a physician or other health care professional, or other entity furnishing health care services is treated as having an agreement or contract in effect with a MedicareAdvantage organization (with respect to an individual enrolled in a MedicareAdvantage private fee-for-service plan it offers), if—

"(A) the provider, professional, or other entity furnishes services that are covered under the plan to such an enrollee; and

"(B) before providing such services, the provider, professional, or other entity —

"(i) has been informed of the individual's enrollment under the plan; and

"(ii) either—

"(I) has been informed of the terms and conditions of payment for such services under the plan; or

"(II) is given a reasonable opportunity to obtain information concerning such terms and conditions,

in a manner reasonably designed to effect informed agreement by a provider.

The previous sentence shall only apply in the absence of an explicit agreement between such a provider, professional, or other entity and the MedicareAdvantage organization.

"(k) TREATMENT OF SERVICES FURNISHED BY CERTAIN PROVIDERS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), a physician or other entity (other than a provider of services) that does not have a contract establishing payment amounts for services furnished to an individual enrolled under this part with a MedicareAdvantage organization described in section 1851(a)(2)(A) shall accept as payment in full for covered services under this title that are furnished to such an individual the amounts that the physician or other entity could collect if the individual were not so enrolled. Any penalty or other provision of law that applies to such a payment with respect to an individual entitled to benefits under this title (but not enrolled with a MedicareAdvantage organization

under this part) also applies with respect to an individual so enrolled.

"(2) APPLICATION TO MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—

"(A) BALANCE BILLING LIMITS UNDER MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS IN CASE OF CONTRACT PROVIDERS.—

"(i) IN GENERAL.—In the case of an individual enrolled in a MedicareAdvantage private fee-for-service plan under this part, a physician, provider of services, or other entity that has a contract (including through the operation of subsection (j)(6)) establishing a payment rate for services furnished to the enrollee shall accept as payment in full for covered services under this title that are furnished to such an individual an amount not to exceed (including any deductibles, coinsurance, copayments, or balance billing otherwise permitted under the plan) an amount equal to 115 percent of such payment rate.

"(ii) PROCEDURES TO ENFORCE LIMITS.—The MedicareAdvantage organization

that offers such a plan shall establish procedures, similar to the procedures described in section 1848(g)(1)(A), in order to carry out clause (i).

"(iii) ASSURING ENFORCEMENT.—If the MedicareAdvantage organization fails to establish and enforce procedures required under clause (ii), the organization is subject to intermediate sanctions under section 1857(g).

"(B) ENROLLEE LIABILITY FOR NONCONTRACT PROVIDERS.—For provisions—

"(i) establishing a minimum payment rate in the case of noncontract providers under a MedicareAdvantage private fee-for-service plan, see section 1852(a)(2); or

"(ii) limiting enrollee liability in the case of covered services furnished by such providers, see paragraph (1) and section 1866(a)(1)(O).

"(C) INFORMATION ON BENEFICIARY LIABILITY.—

"(i) IN GENERAL.—Each MedicareAdvantage organization that offers a MedicareAdvantage private fee-for-

service plan shall provide that enrollees under the plan who are furnished services for which payment is sought under the plan are provided an appropriate explanation of benefits (consistent with that provided under parts A, B, and D, and, if applicable, under medicare supplemental policies) that includes a clear statement of the amount of the enrollee's liability (including any liability for balance billing consistent with this subsection) with respect to payments for such services.

''(ii) ADVANCE NOTICE BEFORE RECEIPT OF INPATIENT HOSPITAL SERVICES AND CERTAIN OTHER SERVICES.—In addition, such organization shall, in its terms and conditions of payments to hospitals for inpatient hospital services and for other services identified by the Secretary for which the amount of the balance billing under subparagraph (A) could be substantial, require the hospital to provide to the enrollee, before furnishing such services and if the hospital imposes balance billing under subparagraph (A)—

"(I) notice of the fact that balance billing is permitted under such subparagraph for such services; and

"(II) a good faith estimate of the likely amount of such balance billing (if any), with respect to such services, based upon the presenting condition of the enrollee.

"(l) RETURN TO HOME SKILLED NURSING FACILITIES FOR COVERED POST-HOSPITAL EXTENDED CARE SERVICES.—

"(1) ENSURING RETURN TO HOME SNF.—

"(A) IN GENERAL.—In providing coverage of post-hospital extended care services, a MedicareAdvantage plan shall provide for such coverage through a home skilled nursing facility if the following conditions are met:

"(i) ENROLLEE ELECTION.—The enrollee elects to receive such coverage through such facility.

"(ii) SNF AGREEMENT.—The facility has a contract with the MedicareAdvantage organization for the provision of such services, or the facility agrees to accept substantially similar payment under the same

terms and conditions that apply to similarly situated skilled nursing facilities that are under contract with the MedicareAdvantage organization for the provision of such services and through which the enrollee would otherwise receive such services.

"(B) MANNER OF PAYMENT TO HOME SNF.—The organization shall provide payment to the home skilled nursing facility consistent with the contract or the agreement described in subparagraph (A)(ii), as the case may be.

"(2) NO LESS FAVORABLE COVERAGE.—The coverage provided under paragraph (1) (including scope of services, cost-sharing, and other criteria of coverage) shall be no less favorable to the enrollee than the coverage that would be provided to the enrollee with respect to a skilled nursing facility the post-hospital extended care services of which are otherwise covered under the MedicareAdvantage plan.

"(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to do the following:

"(A) To require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under part A for medicare beneficiaries not enrolled in a MedicareAdvantage plan.

"(B) To prevent a skilled nursing facility from refusing to accept, or imposing conditions upon the acceptance of, an enrollee for the receipt of post-hospital extended care services.

"(4) DEFINITIONS.—In this subsection:

"(A) HOME SKILLED NURSING FACILITY.—The term 'home skilled nursing facility' means, with respect to an enrollee who is entitled to receive post-hospital extended care services under a MedicareAdvantage plan, any of the following skilled nursing facilities:

"(i) SNF RESIDENCE AT TIME OF ADMISSION.—The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of such post-hospital extended care services.

"(ii) SNF IN CONTINUING CARE RETIREMENT COMMUNITY.—A skilled nursing facility that is providing such services

through a continuing care retirement community (as defined in subparagraph (B)) which provided residence to the enrollee at the time of such admission.

"(iii) SNF RESIDENCE OF SPOUSE AT TIME OF DISCHARGE.—The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from such hospital.

"(B) CONTINUING CARE RETIREMENT COMMUNITY.—The term 'continuing care retirement community' means, with respect to an enrollee in a MedicareAdvantage plan, an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period.".

**SEC. 203. PAYMENTS TO MEDICAREADVANTAGE ORGANIZATIONS.**

Section 1853 (42 U.S.C. 1395w–23) is amended to read as follows:

"PAYMENTS TO MEDICAREADVANTAGE ORGANIZATIONS

"SEC. 1853. (a) PAYMENTS TO ORGANIZATIONS.—

"(1) MONTHLY PAYMENTS.—

"(A) IN GENERAL.—Under a contract under section 1857 and subject to subsections (f), (h), and (j) and section 1859(e)(4), the Secretary shall make, to each MedicareAdvantage organization, with respect to coverage of an individual for a month under this part in a MedicareAdvantage payment area, separate monthly payments with respect to—

"(i) benefits under the original medicare fee-for-service program under parts A and B in accordance with subsection (d); and

"(ii) benefits under the voluntary prescription drug program under part D in accordance with section 1858A and the other provisions of this part.

"(B) SPECIAL RULE FOR END-STAGE RENAL DISEASE.—The Secretary shall establish separate rates of payment to a MedicareAdvantage organization with respect to classes of individuals determined to have end-stage renal disease and enrolled in a MedicareAdvantage plan of the organization. Such rates of payment shall be actuarially equivalent to rates paid to other enrollees in the

MedicareAdvantage payment area (or such other area as specified by the Secretary). In accordance with regulations, the Secretary shall provide for the application of the seventh sentence of section 1881(b)(7) to payments under this section covering the provision of renal dialysis treatment in the same manner as such sentence applies to composite rate payments described in such sentence. In establishing such rates, the Secretary shall provide for appropriate adjustments to increase each rate to reflect the demonstration rate (including the risk adjustment methodology associated with such rate) of the social health maintenance organization end-stage renal disease capitation demonstrations (established by section 2355 of the Deficit Reduction Act of 1984, as amended by section 13567(b) of the Omnibus Budget Reconciliation Act of 1993), and shall compute such rates by taking into account such factors as renal treatment modality, age, and the underlying cause of the end-stage renal disease.

"(2) ADJUSTMENT TO REFLECT NUMBER OF ENROLLEES.—

"(A) IN GENERAL.—The amount of payment under this subsection may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled with an organization under this part and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

"(B) SPECIAL RULE FOR CERTAIN ENROLLEES.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary may make retroactive adjustments under subparagraph (A) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with a MedicareAdvantage organization under a plan operated, sponsored, or contributed to by the individual's employer or former employer (or the employer or former employer of the individual's spouse) and ending on the date on which the individual is enrolled in the organization under this part, except that for purposes of making such retroactive adjustments under this subpara-

graph, such period may not exceed 90 days.

"(ii) EXCEPTION.—No adjustment may be made under clause (i) with respect to any individual who does not certify that the organization provided the individual with the disclosure statement described in section 1852(c) at the time the individual enrolled with the organization.

"(C) EQUALIZATION OF FEDERAL CONTRIBUTION.—In applying subparagraph (A), the Secretary shall ensure that the payment to the MedicareAdvantage organization for each individual enrolled with the organization shall equal the MedicareAdvantage benchmark amount for the payment area in which that individual resides (as determined under paragraph (4)), as adjusted—

"(i) by multiplying the benchmark amount for that payment area by the ratio of—

"(I) the payment amount determined under subsection (d)(4); to

"(II) the weighted service area benchmark amount determined under subsection (d)(2); and

"(ii) using such risk adjustment factor as specified by the Secretary under subsection (b)(1)(B).

"(3) COMPREHENSIVE RISK ADJUSTMENT METHODOLOGY.—

"(A) APPLICATION OF METHODOLOGY.—The Secretary shall apply the comprehensive risk adjustment methodology described in subparagraph (B) to 100 percent of the amount of payments to plans under subsection (d)(4)(B).

"(B) COMPREHENSIVE RISK ADJUSTMENT METHODOLOGY DESCRIBED.—The comprehensive risk adjustment methodology described in this subparagraph is the risk adjustment methodology that would apply with respect to MedicareAdvantage plans offered by MedicareAdvantage organizations in 2005, except that if such methodology does not apply to groups of beneficiaries who are aged or disabled and groups of beneficiaries who have end-stage renal disease, the Secretary shall revise such methodology to apply to such groups.

"(C) UNIFORM APPLICATION TO ALL TYPES OF PLANS.—Subject to section 1859(e)(4), the comprehensive risk adjustment methodology established under this paragraph shall be applied uniformly without regard to the type of plan.

"(D) DATA COLLECTION.—In order to carry out this paragraph, the Secretary shall require MedicareAdvantage organizations to submit such data and other information as the Secretary deems necessary.

"(E) IMPROVEMENT OF PAYMENT ACCURACY.—Notwithstanding any other provision of this paragraph, the Secretary may revise the comprehensive risk adjustment methodology described in subparagraph (B) from time to time to improve payment accuracy.

"(4) ANNUAL CALCULATION OF BENCHMARK AMOUNTS.—For each year, the Secretary shall calculate a benchmark amount for each MedicareAdvantage payment area for each month for such year with respect to coverage of the benefits available under the original medicare fee-for-service program option equal to the greater of the following amounts (adjusted as appropriate for the application

of the risk adjustment methodology under paragraph (3)):

"(A) MINIMUM AMOUNT.—1/12 of the annual Medicare+Choice capitation rate determined under subsection (c)(1)(B) for the payment area for the year.

"(B) LOCAL FEE-FOR-SERVICE RATE.—The local fee-for-service rate for such area for the year (as calculated under paragraph (5)).

"(5) ANNUAL CALCULATION OF LOCAL FEE-FOR-SERVICE RATES.—

"(A) IN GENERAL.—Subject to subparagraph (B), the term 'local fee-for-service rate' means the amount of payment for a month in a MedicareAdvantage payment area for benefits under this title and associated claims processing costs for an individual who has elected to receive benefits under the original medicare fee-for-service program option and not enrolled in a MedicareAdvantage plan under this part. The Secretary shall annually calculate such amount in a manner similar to the manner in which the Secretary calculated the adjusted average per capita cost under section 1876.

"(B) REMOVAL OF MEDICAL EDUCATION COSTS FROM CALCULATION OF LOCAL FEE-FOR-SERVICE RATE.—

"(i) IN GENERAL.—In calculating the local fee-for-service rate under subparagraph (A) for a year, the amount of payment described in such subparagraph shall be adjusted to exclude from such payment the payment adjustments described in clause (ii).

"(ii) PAYMENT ADJUSTMENTS DESCRIBED.—

"(I) IN GENERAL.—Subject to subclause (II), the payment adjustments described in this subparagraph are payment adjustments which the Secretary estimates are payable during the year—

"(aa) for the indirect costs of medical education under section 1886(d)(5)(B); and

"(bb) for direct graduate medical education costs under section 1886(h).

"(II) TREATMENT OF PAYMENTS COVERED UNDER STATE HOSPITAL REIMBURSEMENT SYSTEM.—To the extent that the Secretary estimates that the amount of the local fee-for-service rates reflects payments to hospitals reimbursed under section 1814(b)(3), the Secretary shall estimate a payment adjustment that is comparable to the payment adjustment that would have been made under clause (i) if the hospitals had not been reimbursed under such section.

"(b) ANNUAL ANNOUNCEMENT OF PAYMENT FACTORS.—

"(1) ANNUAL ANNOUNCEMENT.—Beginning in 2005, at the same time as the Secretary publishes the risk adjusters under section 1860D–11, the Secretary shall annually announce (in a manner intended to provide notice to interested parties) the following payment factors:

"(A) The benchmark amount for each MedicareAdvantage payment area (as calculated under subsection (a)(4)) for the year.

"(B) The factors to be used for adjusting payments under the comprehensive risk adjustment methodology described in subsection (a)(3)(B) with respect to each MedicareAdvantage payment area for the year.

"(2) ADVANCE NOTICE OF METHODOLOGICAL CHANGES.—At least 45 days before making the announcement under paragraph (1) for a year, the Secretary shall—

"(A) provide for notice to MedicareAdvantage organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement; and

"(B) provide such organizations with an opportunity to comment on such proposed changes.

"(3) EXPLANATION OF ASSUMPTIONS.—In each announcement made under paragraph (1), the Secretary shall include an explanation of the assumptions and changes in methodology used in the announcement in sufficient detail so that MedicareAdvantage organizations can compute each payment factor described in paragraph (1).

"(c) CALCULATION OF ANNUAL MEDICARE+CHOICE CAPITATION RATES.—

"(1) IN GENERAL.—For purposes of making payments under this part for years before 2006 and for purposes of calculating the annual Medicare+Choice capitation rates under paragraph (7) beginning with such year, subject to paragraph (6)(C), each annual Medicare+Choice capitation rate, for a Medicare+Choice payment area before 2006 or a MedicareAdvantage payment area beginning with such year for a contract year consisting of a calendar year, is equal to the largest of the amounts specified in the following subparagraph (A), (B), or (C):

"(A) BLENDED CAPITATION RATE.—The sum of—

"(i) the area-specific percentage (as specified under paragraph (2) for the year) of the annual area-specific Medicare+Choice capitation rate for the MedicareAdvantage payment area, as determined under paragraph (3) for the year; and

"(ii) the national percentage (as specified under paragraph (2) for the year) of

the input-price-adjusted annual national Medicare+Choice capitation rate, as determined under paragraph (4) for the year,

multiplied by the budget neutrality adjustment factor determined under paragraph (5).

"(B) MINIMUM AMOUNT.—12 multiplied by the following amount:

"(i) For 1998, $367 (but not to exceed, in the case of an area outside the 50 States and the District of Columbia, 150 percent of the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) for the area).

"(ii) For 1999 and 2000, the minimum amount determined under clause (i) or this clause, respectively, for the preceding year, increased by the national per capita Medicare+Choice growth percentage described in paragraph (6)(A) applicable to 1999 or 2000, respectively.

"(iii)(I) Subject to subclause (II), for 2001, for any area in a Metropolitan Statistical Area with a population of more than 250,000, $525, and for any other area $475.

"(II) In the case of an area outside the 50 States and the District of Columbia, the amount specified in this clause shall not exceed 120 percent of the amount determined under clause (ii) for such area for 2000.

"(iv) For 2002 through 2013, the minimum amount specified in this clause (or clause (iii)) for the preceding year increased by the national per capita Medicare+Choice growth percentage, described in paragraph (6)(A) for that succeeding year.

"(v) For 2014 and each succeeding year, the minimum amount specified in this clause (or clause (iv)) for the preceding year increased by 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.

"(C) MINIMUM PERCENTAGE INCREASE.—

"(i) For 1998, 102 percent of the annual per capita rate of payment for 1997

determined under section 1876(a)(1)(C) for the Medicare+Choice payment area.

"(ii) For 1999 and 2000, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

"(iii) For 2001, 103 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for 2000.

"(iv) For 2002, 2003, and 2004, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

"(v) For 2005, 103 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for 2003.

"(vi) For 2006 and each succeeding year, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year, except that such rate shall be determined by substituting '102' for '103' in clause (v).

"(2) AREA-SPECIFIC AND NATIONAL PERCENTAGES.—For purposes of paragraph (1)(A)—

"(A) for 1998, the 'area-specific percentage' is 90 percent and the 'national percentage' is 10 percent;

"(B) for 1999, the 'area-specific percentage' is 82 percent and the 'national percentage' is 18 percent;

"(C) for 2000, the 'area-specific percentage' is 74 percent and the 'national percentage' is 26 percent;

"(D) for 2001, the 'area-specific percentage' is 66 percent and the 'national percentage' is 34 percent;

"(E) for 2002, the 'area-specific percentage' is 58 percent and the 'national percentage' is 42 percent; and

"(F) for a year after 2002, the 'area-specific percentage' is 50 percent and the 'national percentage' is 50 percent.

"(3) ANNUAL AREA-SPECIFIC MEDICARE+CHOICE CAPITATION RATE.—

"(A) IN GENERAL.—For purposes of paragraph (1)(A), subject to subparagraph (B), the annual area-specific Medicare+Choice capita-

tion rate for a Medicare+Choice payment area—

"(i) for 1998 is, subject to subparagraph (D), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) for the area, increased by the national per capita Medicare+Choice growth percentage for 1998 (described in paragraph (6)(A)); or

"(ii) for a subsequent year is the annual area-specific Medicare+Choice capitation rate for the previous year determined under this paragraph for the area, increased by the national per capita Medicare+Choice growth percentage for such subsequent year.

"(B) REMOVAL OF MEDICAL EDUCATION FROM CALCULATION OF ADJUSTED AVERAGE PER CAPITA COST.—

"(i) IN GENERAL.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 1998), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be

adjusted to exclude from the rate the applicable percent (specified in clause (ii)) of the payment adjustments described in subparagraph (C).

"(ii) APPLICABLE PERCENT.—For purposes of clause (i), the applicable percent for—

"(I) 1998 is 20 percent;

"(II) 1999 is 40 percent;

"(III) 2000 is 60 percent;

"(IV) 2001 is 80 percent; and

"(V) a succeeding year is 100 percent.

"(C) PAYMENT ADJUSTMENT.—

"(i) IN GENERAL.—Subject to clause (ii), the payment adjustments described in this subparagraph are payment adjustments which the Secretary estimates were payable during 1997—

"(I) for the indirect costs of medical education under section 1886(d)(5)(B); and

"(II) for direct graduate medical education costs under section 1886(h).

"(ii) TREATMENT OF PAYMENTS COVERED UNDER STATE HOSPITAL REIMBURSEMENT SYSTEM.—To the extent that the Secretary estimates that an annual per capita rate of payment for 1997 described in clause (i) reflects payments to hospitals reimbursed under section 1814(b)(3), the Secretary shall estimate a payment adjustment that is comparable to the payment adjustment that would have been made under clause (i) if the hospitals had not been reimbursed under such section.

"(D) TREATMENT OF AREAS WITH HIGHLY VARIABLE PAYMENT RATES.—In the case of a Medicare+Choice payment area for which the annual per capita rate of payment determined under section 1876(a)(1)(C) for 1997 varies by more than 20 percent from such rate for 1996, for purposes of this subsection the Secretary may substitute for such rate for 1997 a rate that is more representative of the costs of the enrollees in the area.

"(4) INPUT-PRICE-ADJUSTED ANNUAL NATIONAL MEDICARE+CHOICE CAPITATION RATE.—

"(A) IN GENERAL.—For purposes of paragraph (1)(A), the input-price-adjusted annual national Medicare+Choice capitation rate for a Medicare+Choice payment area for a year is equal to the sum, for all the types of medicare services (as classified by the Secretary), of the product (for each such type of service) of—

"(i) the national standardized annual Medicare+Choice capitation rate (determined under subparagraph (B)) for the year;

"(ii) the proportion of such rate for the year which is attributable to such type of services; and

"(iii) an index that reflects (for that year and that type of services) the relative input price of such services in the area compared to the national average input price of such services.

In applying clause (iii), the Secretary may, subject to subparagraph (C), apply those indices under this title that are used in applying (or updating) national payment rates for specific areas and localities.

"(B) NATIONAL STANDARDIZED ANNUAL MEDICARE+CHOICE CAPITATION RATE.—In subparagraph (A)(i), the 'national standardized annual Medicare+Choice capitation rate' for a year is equal to—

"(i) the sum (for all Medicare+Choice payment areas) of the product of—

"(I) the annual area-specific Medicare+Choice capitation rate for that year for the area under paragraph (3); and

"(II) the average number of medicare beneficiaries residing in that area in the year, multiplied by the average of the risk factor weights used to adjust payments under subsection (a)(1)(A) for such beneficiaries in such area; divided by

"(ii) the sum of the products described in clause (i)(II) for all areas for that year.

"(5) PAYMENT ADJUSTMENT BUDGET NEUTRALITY FACTOR.—For purposes of paragraph (1)(A), for each year, the Secretary shall determine a budget neutrality adjustment factor so that the

aggregate of the payments under this part (other than those attributable to subsections (a)(3)(C)(iii) and (i)) shall equal the aggregate payments that would have been made under this part if payment were based entirely on area-specific capitation rates.

"(6) NATIONAL PER CAPITA MEDICARE+CHOICE GROWTH PERCENTAGE DEFINED.—

"(A) IN GENERAL.—In this part, the 'national per capita Medicare+Choice growth percentage' for a year is the percentage determined by the Secretary, by March 1st before the beginning of the year involved, to reflect the Secretary's estimate of the projected per capita rate of growth in expenditures under this title for an individual entitled to (or enrolled for) benefits under part A and enrolled under part B, reduced by the number of percentage points specified in subparagraph (B) for the year. Separate determinations may be made for aged enrollees, disabled enrollees, and enrollees with end-stage renal disease.

"(B) ADJUSTMENT.—The number of percentage points specified in this subparagraph is—

"(i) for 1998, 0.8 percentage points;

"(ii) for 1999, 0.5 percentage points;

"(iii) for 2000, 0.5 percentage points;

"(iv) for 2001, 0.5 percentage points;

"(v) for 2002, 0.3 percentage points; and

"(vi) for a year after 2002, 0 percentage points.

"(C) ADJUSTMENT FOR OVER OR UNDER PROJECTION OF NATIONAL PER CAPITA MEDICARE+CHOICE GROWTH PERCENTAGE.—Beginning with rates calculated for 1999, before computing rates for a year as described in paragraph (1), the Secretary shall adjust all area-specific and national Medicare+Choice capitation rates (and beginning in 2000, the minimum amount) for the previous year for the differences between the projections of the national per capita Medicare+Choice growth percentage for that year and previous years and the current estimate of such percentage for such years.

"(7) TRANSITION TO MEDICAREADVANTAGE COMPETITION.—

"(A) IN GENERAL.—For each year (beginning with 2006) payments to MedicareAdvantage plans shall not be computed under this subsection, but instead shall be based on the payment amount determined under subsection (d).

"(B) CONTINUED CALCULATION OF CAPITATION RATES.—For each year (beginning with 2006) the Secretary shall calculate and publish the annual Medicare+Choice capitation rates under this subsection and shall use the annual Medicare+Choice capitation rate determined under subsection (c)(1) for purposes of determining the benchmark amount under subsection (a)(4).

"(d) SECRETARY'S DETERMINATION OF PAYMENT AMOUNT.—

"(1) REVIEW OF PLAN BIDS.—The Secretary shall review each plan bid submitted under section 1854(a) for the coverage of benefits under the original medicare fee-for-service program option to ensure that such bids are consistent with the requirements under this part an are based on the assumptions described in section 1854(a)(2)(A)(iii).

"(2) DETERMINATION OF WEIGHTED SERVICE AREA BENCHMARK AMOUNTS.—The Secretary shall calculate a weighted service area benchmark amount for the benefits under the original medicare fee-for-service program option for each plan equal to the weighted average of the benchmark amounts for benefits under such original medicare fee-for-service program option for the payment areas included in the service area of the plan using the assumptions described in section 1854(a)(2)(A)(iii).

"(3) COMPARISON TO BENCHMARK.—The Secretary shall determine the difference between each plan bid (as adjusted under paragraph (1)) and the weighted service area benchmark amount (as determined under paragraph (2)) for purposes of determining—

"(A) the payment amount under paragraph (4); and

"(B) the additional benefits required and MedicareAdvantage monthly basic beneficiary premiums.

"(4) DETERMINATION OF PAYMENT AMOUNT FOR ORIGINAL MEDICARE FEE-FOR-SERVICE BENEFITS.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall determine the payment amount for MedicareAdvantage plans for the benefits under the original medicare fee-for-service program option as follows:

"(i) BIDS THAT EQUAL OR EXCEED THE BENCHMARK.—In the case of a plan bid that equals or exceeds the weighted service area benchmark amount, the amount of each monthly payment to a MedicareAdvantage organization with respect to each individual enrolled in a plan shall be the weighted service area benchmark amount.

"(ii) BIDS BELOW THE BENCHMARK.—In the case of a plan bid that is less than the weighted service area benchmark amount, the amount of each monthly payment to a MedicareAdvantage organization with respect to each individual enrolled in a plan shall be the weighted service area benchmark amount reduced by the amount of any premium reduction elected by the plan under section 1854(d)(1)(A)(i).

"(B) APPLICATION OF COMPREHENSIVE RISK ADJUSTMENT METHODOLOGY.—The Secretary shall adjust the amounts determined under subparagraph (A) using the comprehensive risk adjustment methodology applicable under subsection (a)(3).

"(6) ADJUSTMENT FOR NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—If the Secretary makes a determination with respect to coverage under this title or there is a change in benefits required to be provided under this part that the Secretary projects will result in a significant increase in the costs to MedicareAdvantage organizations of providing benefits under contracts under this part (for periods after any period described in section 1852(a)(5)), the Secretary shall appropriately adjust the benchmark amounts or payment amounts (as determined by the Secretary). Such projection and adjustment shall be based on an analysis by the Secretary of the actuarial costs associated with the new benefits.

"(7) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—For purposes of this part, the term 'benefits under the original medicare fee-for-service pro-

gram option' means those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to, or enrolled for, 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.

"(e) MEDICAREADVANTAGE PAYMENT AREA DEFINED.—

"(1) IN GENERAL.—In this part, except as provided in paragraph (3), the term 'MedicareAdvantage payment area' means a county, or equivalent area specified by the Secretary.

"(2) RULE FOR ESRD BENEFICIARIES.—In the case of individuals who are determined to have end stage renal disease, the MedicareAdvantage payment area shall be a State or such other payment area as the Secretary specifies.

"(3) GEOGRAPHIC ADJUSTMENT.—

"(A) IN GENERAL.—Upon written request of the chief executive officer of a State for a contract year (beginning after 2005) made by not later than February 1 of the previous year, the Secretary shall make a geographic adjust-

ment to a MedicareAdvantage payment area in the State otherwise determined under paragraph (1)—

"(i) to a single statewide MedicareAdvantage payment area;

"(ii) to the metropolitan based system described in subparagraph (C); or

"(iii) to consolidating into a single MedicareAdvantage payment area noncontiguous counties (or equivalent areas described in paragraph (1)) within a State.

Such adjustment shall be effective for payments for months beginning with January of the year following the year in which the request is received.

"(B) BUDGET NEUTRALITY ADJUSTMENT.—In the case of a State requesting an adjustment under this paragraph, the Secretary shall initially (and annually thereafter) adjust the payment rates otherwise established under this section for MedicareAdvantage payment areas in the State in a manner so that the aggregate of the payments under this section in the State shall not exceed the aggregate payments that would have been made under this

section for MedicareAdvantage payment areas in the State in the absence of the adjustment under this paragraph.

"(C) METROPOLITAN BASED SYSTEM.—The metropolitan based system described in this subparagraph is one in which—

"(i) all the portions of each metropolitan statistical area in the State or in the case of a consolidated metropolitan statistical area, all of the portions of each primary metropolitan statistical area within the consolidated area within the State, are treated as a single MedicareAdvantage payment area; and

"(ii) all areas in the State that do not fall within a metropolitan statistical area are treated as a single MedicareAdvantage payment area.

"(D) AREAS.—In subparagraph (C), the terms 'metropolitan statistical area', 'consolidated metropolitan statistical area', and 'primary metropolitan statistical area' mean any area designated as such by the Secretary of Commerce.

"(f) SPECIAL RULES FOR INDIVIDUALS ELECTING MSA PLANS.—

"(1) IN GENERAL.—If the amount of the MedicareAdvantage monthly MSA premium (as defined in section 1854(b)(2)(D)) for an MSA plan for a year is less than 1/12 of the annual Medicare+Choice capitation rate applied under this section for the area and year involved, the Secretary shall deposit an amount equal to 100 percent of such difference in a MedicareAdvantage MSA established (and, if applicable, designated) by the individual under paragraph (2).

"(2) ESTABLISHMENT AND DESIGNATION OF MEDICAREADVANTAGE MEDICAL SAVINGS ACCOUNT AS REQUIREMENT FOR PAYMENT OF CONTRIBUTION.—In the case of an individual who has elected coverage under an MSA plan, no payment shall be made under paragraph (1) on behalf of an individual for a month unless the individual—

"(A) has established before the beginning of the month (or by such other deadline as the Secretary may specify) a MedicareAdvantage MSA (as defined in section 138(b)(2) of the Internal Revenue Code of 1986); and

"(B) if the individual has established more than 1 such MedicareAdvantage MSA, has designated 1 of such accounts as the individual's MedicareAdvantage MSA for purposes of this part.

Under rules under this section, such an individual may change the designation of such account under subparagraph (B) for purposes of this part.

"(3) LUMP-SUM DEPOSIT OF MEDICAL SAVINGS ACCOUNT CONTRIBUTION.—In the case of an individual electing an MSA plan effective beginning with a month in a year, the amount of the contribution to the MedicareAdvantage MSA on behalf of the individual for that month and all successive months in the year shall be deposited during that first month. In the case of a termination of such an election as of a month before the end of a year, the Secretary shall provide for a procedure for the recovery of deposits attributable to the remaining months in the year.

"(g) PAYMENTS FROM TRUST FUNDS.—Except as provided in section 1858A(c) (relating to payments for qualified prescription drug coverage), the payment to a MedicareAdvantage organization under this section for individuals enrolled under this part with the organization

1 and payments to a MedicareAdvantage MSA under sub-
2 section (e)(1) shall be made from the Federal Hospital In-
3 surance Trust Fund and the Federal Supplementary Med-
4 ical Insurance Trust Fund in such proportion as the Sec-
5 retary determines reflects the relative weight that benefits
6 under part A and under part B represents of the actuarial
7 value of the total benefits under this title. Monthly pay-
8 ments otherwise payable under this section for October
9 2000 shall be paid on the first business day of such month.
10 Monthly payments otherwise payable under this section
11 for October 2001 shall be paid on the last business day
12 of September 2001. Monthly payments otherwise payable
13 under this section for October 2006 shall be paid on the
14 first business day of October 2006.

15 ''(h) SPECIAL RULE FOR CERTAIN INPATIENT HOS-
16 PITAL STAYS.—In the case of an individual who is receiv-
17 ing inpatient hospital services from a subsection (d) hos-
18 pital (as defined in section 1886(d)(1)(B)) as of the effec-
19 tive date of the individual's—

20 ''(1) election under this part of a
21 MedicareAdvantage plan offered by a
22 MedicareAdvantage organization—

23 ''(A) payment for such services until the
24 date of the individual's discharge shall be made
25 under this title through the MedicareAdvantage

plan or the original medicare fee-for-service program option (as the case may be) elected before the election with such organization,

"(B) the elected organization shall not be financially responsible for payment for such services until the date after the date of the individual's discharge; and

"(C) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this part; or

"(2) termination of election with respect to a MedicareAdvantage organization under this part—

"(A) the organization shall be financially responsible for payment for such services after such date and until the date of the individual's discharge;

"(B) payment for such services during the stay shall not be made under section 1886(d) or by any succeeding MedicareAdvantage organization; and

"(C) the terminated organization shall not receive any payment with respect to the individual under this part during the period the individual is not enrolled.

"(i) SPECIAL RULE FOR HOSPICE CARE.—

"(1) INFORMATION.—A contract under this part shall require the MedicareAdvantage organization to inform each individual enrolled under this part with a MedicareAdvantage plan offered by the organization about the availability of hospice care if—

"(A) a hospice program participating under this title is located within the organization's service area; or

"(B) it is common practice to refer patients to hospice programs outside such service area.

"(2) PAYMENT.—If an individual who is enrolled with a MedicareAdvantage organization under this part makes an election under section 1812(d)(1) to receive hospice care from a particular hospice program—

"(A) payment for the hospice care furnished to the individual shall be made to the hospice program elected by the individual by the Secretary;

"(B) payment for other services for which the individual is eligible notwithstanding the individual's election of hospice care under section 1812(d)(1), including services not related to the

individual's terminal illness, shall be made by the Secretary to the MedicareAdvantage organization or the provider or supplier of the service instead of payments calculated under subsection (a); and

"(C) the Secretary shall continue to make monthly payments to the MedicareAdvantage organization in an amount equal to the value of the additional benefits required under section 1854(f)(1)(A).".

**SEC. 204. SUBMISSION OF BIDS; PREMIUMS.**

Section 1854 (42 U.S.C. 1395w–24) is amended to read as follows:

"SUBMISSION OF BIDS; PREMIUMS

"SEC. 1854. (a) SUBMISSION OF BIDS BY MEDICAREADVANTAGE ORGANIZATIONS.—

"(1) IN GENERAL.—Not later than the second Monday in September and except as provided in paragraph (3), each MedicareAdvantage organization shall submit to the Secretary, in such form and manner as the Secretary may specify, for each MedicareAdvantage plan that the organization intends to offer in a service area in the following year—

"(A) notice of such intent and information on the service area of the plan;

"(B) the plan type for each plan;

"(C) if the MedicareAdvantage plan is a coordinated care plan (as described in section 1851(a)(2)(A)) or a private fee-for-service plan (as described in section 1851(a)(2)(C)), the information described in paragraph (2) with respect to each payment area;

"(D) the enrollment capacity (if any) in relation to the plan and each payment area;

"(E) the expected mix, by health status, of enrolled individuals; and

"(F) such other information as the Secretary may specify.

"(2) INFORMATION REQUIRED FOR COORDINATED CARE PLANS AND PRIVATE FEE-FOR-SERVICE PLANS.—For a MedicareAdvantage plan that is a coordinated care plan (as described in section 1851(a)(2)(A)) or a private fee-for-service plan (as described in section 1851(a)(2)(C)), the information described in this paragraph is as follows:

"(A) INFORMATION REQUIRED WITH RESPECT TO BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—Information relating to the coverage of

benefits under the original medicare fee-for-service program option as follows:

"(i) The plan bid, which shall consist of a dollar amount that represents the total amount that the plan is willing to accept (not taking into account the application of the comprehensive risk adjustment methodology under section 1853(a)(3)) for providing coverage of the benefits under the original medicare fee-for-service program option to an individual enrolled in the plan that resides in the service area of the plan for a month.

"(ii) For the enhanced medical benefits package offered—

"(I) the adjusted community rate (as defined in subsection (g)(3)) of the package;

"(II) the portion of the actuarial value of such benefits package (if any) that will be applied toward satisfying the requirement for additional benefits under subsection (g);

"(III) the MedicareAdvantage monthly beneficiary premium for en-

hanced medical benefits (as defined in subsection (b)(2)(C));

"(IV) a description of any cost-sharing;

"(V) a description of whether the amount of the unified deductible has been lowered or the maximum limitations on out-of-pocket expenses have been decreased (relative to the levels used in calculating the plan bid);

"(VI) such other information as the Secretary considers necessary.

"(iii) The assumptions that the MedicareAdvantage organization used in preparing the plan bid with respect to numbers, in each payment area, of enrolled individuals and the mix, by health status, of such individuals.

"(B) INFORMATION REQUIRED WITH RESPECT TO PART D.—The information required to be submitted by an eligible entity under section 1860D–12, including the monthly premiums for standard coverage and any other qualified prescription drug coverage available to individuals enrolled under part D.

"(C) DETERMINING PLAN COSTS INCLUDED IN PLAN BID.—For purposes of submitting its plan bid under subparagraph (A)(i) a MedicareAdvantage plan offered by a MedicareAdvantage organization satisfies subparagraphs (A) and (C) of section 1852(a)(1) if the actuarial value of the deductibles, coinsurance, and copayments applicable on average to individuals enrolled in such plan under this part with respect to benefits under the original medicare fee-for-service program option on which that bid is based (ignoring any reduction in cost-sharing offered by such plan as enhanced medical benefits under paragraph (2)(A)(ii) or required under clause (ii) or (iii) of subsection (g)(1)(C)) equals the amount specified in subsection (f)(1)(B).

"(3) REQUIREMENTS FOR MSA PLANS.—For an MSA plan described in section 1851(a)(2)(B), the information described in this paragraph is the information that such a plan would have been required to submit under this part if the Prescription Drug and Medicare Improvements Act of 2003 had not been enacted.

"(4) REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall review the adjusted community rates (as defined in section 1854(g)(3)), the amounts of the MedicareAdvantage monthly basic premium and the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits filed under this subsection and shall approve or disapprove such rates and amounts so submitted. The Secretary shall review the actuarial assumptions and data used by the MedicareAdvantage organization with respect to such rates and amounts so submitted to determine the appropriateness of such assumptions and data.

"(B) EXCEPTION.—The Secretary shall not review, approve, or disapprove the amounts submitted under paragraph (3), or, with respect to a private fee-for-service plan (as described in section 1851(a)(2)(C)) under subparagraph (A)(i), (A)(ii)(III), or (B) of paragraph (2).

"(C) CLARIFICATION OF AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE BENEFICIARY COST-SHARING.—Under the authority under subparagraph (A), the Secretary

may disapprove the bid if the Secretary determines that the deductibles, coinsurance, or copayments applicable under the plan discourage access to covered services or are likely to result in favorable selection of MedicareAdvantage eligible individuals.

"(5) APPLICATION OF FEHBP STANDARD; PROHIBITION ON PRICE GOUGING.—Each bid amount submitted under paragraph (1) for a MedicareAdvantage plan must reasonably and equitably reflect the cost of benefits provided under that plan.

"(b) MONTHLY PREMIUMS CHARGED.—

"(1) IN GENERAL.—

"(A) COORDINATED CARE AND PRIVATE FEE-FOR-SERVICE PLANS.—The monthly amount of the premium charged to an individual enrolled in a MedicareAdvantage plan (other than an MSA plan) offered by a MedicareAdvantage organization shall be equal to the sum of the following:

"(i) The MedicareAdvantage monthly basic beneficiary premium (if any).

"(ii) The MedicareAdvantage monthly beneficiary premium for enhanced medical benefits (if any).

"(iii) The MedicareAdvantage monthly obligation for qualified prescription drug coverage (if any).

"(B) MSA PLANS.—The rules under this section that would have applied with respect to an MSA plan if the Prescription Drug and Medicare Improvements Act of 2003 had not been enacted shall continue to apply to MSA plans after the date of enactment of such Act.

"(2) PREMIUM TERMINOLOGY.—For purposes of this part:

"(A) MEDICAREADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'MedicareAdvantage monthly basic beneficiary premium' means, with respect to a MedicareAdvantage plan, the amount required to be charged under subsection (d)(2) for the plan.

"(B) MEDICAREADVANTAGE MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'MedicareAdvantage monthly beneficiary obliga-

tion for qualified prescription drug coverage' means, with respect to a MedicareAdvantage plan, the amount determined under section 1858A(d).

"(C) MEDICAREADVANTAGE MONTHLY BENEFICIARY PREMIUM FOR ENHANCED MEDICAL BENEFITS.—The term 'MedicareAdvantage monthly beneficiary premium for enhanced medical benefits' means, with respect to a MedicareAdvantage plan, the amount required to be charged under subsection (f)(2) for the plan, or, in the case of an MSA plan, the amount filed under subsection (a)(3).

"(D) MEDICAREADVANTAGE MONTHLY MSA PREMIUM.—The term 'MedicareAdvantage monthly MSA premium' means, with respect to a MedicareAdvantage plan, the amount of such premium filed under subsection (a)(3) for the plan.

"(c) UNIFORM PREMIUM.—The MedicareAdvantage monthly basic beneficiary premium, the MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage, the MedicareAdvantage monthly beneficiary premium for en-

hanced medical benefits, and the MedicareAdvantage monthly MSA premium charged under subsection (b) of a MedicareAdvantage organization under this part may not vary among individuals enrolled in the plan. Subject to the provisions of section 1858(h), such requirement shall not apply to enrollees of a MedicareAdvantage plan who are enrolled in the plan pursuant to a contractual agreement between the plan and an employer or other group health plan that provides employment-based retiree health coverage (as defined in section 1860D–20(d)(4)(B)) if the premium amount is the same for all such enrollees under such agreement.

"(d) DETERMINATION OF PREMIUM REDUCTIONS, REDUCED COST-SHARING, ADDITIONAL BENEFITS, AND BENEFICIARY PREMIUMS.—

"(1) BIDS BELOW THE BENCHMARK.—If the Secretary determines under section 1853(d)(3) that the weighted service area benchmark amount exceeds the plan bid, the Secretary shall require the plan to provide additional benefits in accordance with subsection (g).

"(2) BIDS ABOVE THE BENCHMARK.—If the Secretary determines under section 1853(d)(3) that the plan bid exceeds the weighted service area benchmark amount (determined under section

1853(d)(2)), the amount of such excess shall be the MedicareAdvantage monthly basic beneficiary premium (as defined in section 1854(b)(2)(A)).

"(e) TERMS AND CONDITIONS OF IMPOSING PREMIUMS.—Each MedicareAdvantage organization shall permit the payment of any MedicareAdvantage monthly basic premium, the MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage, and the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits on a monthly basis, may terminate election of individuals for a MedicareAdvantage plan for failure to make premium payments only in accordance with section 1851(g)(3)(B)(i), and may not provide for cash or other monetary rebates as an inducement for enrollment or otherwise (other than as an additional benefit described in subsection (g)(1)(C)(i)).

"(f) LIMITATION ON ENROLLEE LIABILITY.—

"(1) FOR BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—The sum of—

"(A) the MedicareAdvantage monthly basic beneficiary premium (multiplied by 12) and the actuarial value of the deductibles, coinsurance, and copayments (determined on the same basis as used in determining the plan's bid under

paragraph (2)(C)) applicable on average to individuals enrolled under this part with a MedicareAdvantage plan described in subparagraph (A) of section 1851(a)(2) of an organization with respect to required benefits described in section 1852(a)(1)(A); must equal

"(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals who have elected to receive benefits under the original medicare fee-for-service program option if such individuals were not members of a MedicareAdvantage organization for the year (adjusted as determined appropriate by the Secretary to account for geographic differences and for plan cost and utilization differences).

"(2) FOR ENHANCED MEDICAL BENEFITS.—If the MedicareAdvantage organization provides to its members enrolled under this part in a MedicareAdvantage plan described in subparagraph (A) of section 1851(a)(2) with respect to enhanced medical benefits relating to benefits under the original medicare fee-for-service program option, the sum of the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits (multiplied by

12) charged and the actuarial value of its deductibles, coinsurance, and copayments charged with respect to such benefits for a year must equal the adjusted community rate (as defined in subsection (g)(3)) for such benefits for the year minus the actuarial value of any additional benefits pursuant to clause (ii), (iii), or (iv) of subsection (g)(2)(C) that the plan specified under subsection (a)(2)(i)(II).

"(3) DETERMINATION ON OTHER BASIS.—If the Secretary determines that adequate data are not available to determine the actuarial value under paragraph (1)(A) or (2), the Secretary may determine such amount with respect to all individuals in the same geographic area, the State, or in the United States, eligible to enroll in the MedicareAdvantage plan involved under this part or on the basis of other appropriate data.

"(4) SPECIAL RULE FOR PRIVATE FEE-FOR-SERVICE PLANS.—With respect to a MedicareAdvantage private fee-for-service plan (other than a plan that is an MSA plan), in no event may—

"(A) the actuarial value of the deductibles, coinsurance, and copayments applicable on average to individuals enrolled under this part

with such a plan of an organization with respect to required benefits described in subparagraphs (A), (C), and (D) of section 1852(a)(1); exceed

"(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals entitled to (or enrolled for) benefits under part A and enrolled under part B if they were not members of a MedicareAdvantage organization for the year.

"(g) REQUIREMENT FOR ADDITIONAL BENEFITS.—

"(1) REQUIREMENT.—

"(A) IN GENERAL.—Each MedicareAdvantage organization (in relation to a MedicareAdvantage plan, other than an MSA plan, it offers) shall provide that if there is an excess amount (as defined in subparagraph (B)) for the plan for a contract year, subject to the succeeding provisions of this subsection, the organization shall provide to individuals such additional benefits described in subparagraph (C) as the organization may specify in a value which the Secretary determines is at least equal to the adjusted excess amount (as defined in subparagraph (D)).

"(B) EXCESS AMOUNT.—For purposes of this paragraph, the term 'excess amount' means, for an organization for a plan, is 100 percent of the amount (if any) by which the weighted service area benchmark amount (determined under section 1853(d)(2)) exceeds the plan bid (as adjusted under section 1853(d)(1)).

"(C) ADDITIONAL BENEFITS DESCRIBED.—The additional benefits described in this subparagraph are as follows:

"(i) Subject to subparagraph (F), a monthly part B premium reduction for individuals enrolled in the plan.

"(ii) Lowering the amount of the unified deductible and decreasing the maximum limitations on out-of-pocket expenses for individuals enrolled in the plan.

"(iii) A reduction in the actuarial value of plan cost-sharing for plan enrollees.

"(iv) Subject to subparagraph (E), such additional benefits as the organization may specify.

"(v) Contributing to the stabilization fund under paragraph (2).

"(vi) Any combination of the reductions and benefits described in clauses (i) through (v).

"(D) ADJUSTED EXCESS AMOUNT.—For purposes of this paragraph, the term 'adjusted excess amount' means, for an organization for a plan, is the excess amount reduced to reflect any amount withheld and reserved for the organization for the year under paragraph (2).

"(E) RULE FOR APPROVAL OF MEDICAL AND PRESCRIPTION DRUG BENEFITS.—An organization may not specify any additional benefit that provides for the coverage of any prescription drug (other than that relating to prescription drugs covered under the original medicare fee-for-service program option).

"(F) PREMIUM REDUCTIONS.—

"(i) IN GENERAL.—Subject to clause (ii), as part of providing any additional benefits required under subparagraph (A), a MedicareAdvantage organization may elect a reduction in its payments under section 1853(a)(1)(A)(i) with respect to a

MedicareAdvantage plan and the Secretary shall apply such reduction to reduce the premium under section 1839 of each enrollee in such plan as provided in section 1840(i).

"(ii) AMOUNT OF REDUCTION.—The amount of the reduction under clause (i) with respect to any enrollee in a MedicareAdvantage plan—

"(I) may not exceed 125 percent of the premium described under section 1839(a)(3); and

"(II) shall apply uniformly to each enrollee of the MedicareAdvantage plan to which such reduction applies.

"(G) UNIFORM APPLICATION.—This paragraph shall be applied uniformly for all enrollees for a plan.

"(H) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing a MedicareAdvantage organization from providing enhanced medical benefits (described in section 1852(a)(3)) that are in addition to the health care benefits otherwise required to be provided

1 under this paragraph and from imposing a pre-
2 mium for such enhanced medical benefits.
3 "(2) STABILIZATION FUND.—A
4 MedicareAdvantage organization may provide that a
5 part of the value of an excess amount described in
6 paragraph (1) be withheld and reserved in the Fed-
7 eral Hospital Insurance Trust Fund and in the Fed-
8 eral Supplementary Medical Insurance Trust Fund
9 (in such proportions as the Secretary determines to
10 be appropriate) by the Secretary for subsequent an-
11 nual contract periods, to the extent required to pre-
12 vent undue fluctuations in the additional benefits of-
13 fered in those subsequent periods by the organiza-
14 tion in accordance with such paragraph. Any of such
15 value of the amount reserved which is not provided
16 as additional benefits described in paragraph (1)(A)
17 to individuals electing the MedicareAdvantage plan
18 of the organization in accordance with such para-
19 graph prior to the end of such periods, shall revert
20 for the use of such Trust Funds.
21 "(3) ADJUSTED COMMUNITY RATE.—For pur-
22 poses of this subsection, subject to paragraph (4),
23 the term 'adjusted community rate' for a service or
24 services means, at the election of a
25 MedicareAdvantage organization, either—

"(A) the rate of payment for that service or services which the Secretary annually determines would apply to an individual electing a MedicareAdvantage plan under this part if the rate of payment were determined under a 'community rating system' (as defined in section 1302(8) of the Public Health Service Act, other than subparagraph (C)); or

"(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to such an individual, as the Secretary annually estimates is attributable to that service or services,

but adjusted for differences between the utilization characteristics of the individuals electing coverage under this part and the utilization characteristics of the other enrollees with the plan (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of individuals selecting other MedicareAdvantage coverage, or MedicareAdvantage eligible individuals in the area, in the State, or in the United States, eligible to elect MedicareAdvantage coverage under this part and the utilization characteristics of the rest of the popu-

lation in the area, in the State, or in the United States, respectively).

"(4) DETERMINATION BASED ON INSUFFICIENT DATA.—For purposes of this subsection, if the Secretary finds that there is insufficient enrollment experience to determine the average amount of payments to be made under this part at the beginning of a contract period or to determine (in the case of a newly operated provider-sponsored organization or other new organization) the adjusted community rate for the organization, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this part and may determine such a rate using data in the general commercial marketplace.

"(h) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.—No State may impose a premium tax or similar tax with respect to payments to MedicareAdvantage organizations under section 1853.

"(i) PERMITTING USE OF SEGMENTS OF SERVICE AREAS.—The Secretary shall permit a MedicareAdvantage organization to elect to apply the provisions of this section uniformly to separate segments of a service area (rather than uniformly to an entire service area) as long as such

segments are composed of 1 or more MedicareAdvantage payment areas.''.

(b) STUDY AND REPORT ON CLARIFICATION OF AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE BENEFICIARY COST-SHARING.—

(1) STUDY.—The Secretary, in consultation with beneficiaries, consumer groups, employers, and Medicare+Choice organizations, shall conduct a study to determine the extent to which the cost-sharing structures under Medicare+Choice plans under part C of title XVIII of the Social Security Act discourage access to covered services or discriminate based on the health status of Medicare+Choice eligible individuals (as defined 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 Secretary shall submit a report to Congress on the study conducted under paragraph (1) together with recommendations for such legislation and administrative actions as the Secretary considers appropriate.

**SEC. 205. SPECIAL RULES FOR PRESCRIPTION DRUG BENEFITS.**

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 PRESCRIPTION DRUG BENEFITS

"SEC. 1858A. (a) AVAILABILITY.—

"(1) PLANS REQUIRED TO PROVIDE QUALIFIED PRESCRIPTION DRUG COVERAGE TO ENROLLEES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), on and after January 1, 2006, a MedicareAdvantage organization offering a MedicareAdvantage plan (except for an MSA plan) shall make available qualified prescription drug coverage that meets the requirements for such coverage under this part and part D to each enrollee of the plan.

"(B) PRIVATE FEE-FOR-SERVICE PLANS MAY, BUT ARE NOT REQUIRED TO, PROVIDE QUALIFIED PRESCRIPTION DRUG COVERAGE.—Pursuant to section 1852(a)(2)(D), a private fee-for-service plan may elect not to provide qualified prescription drug coverage under part D to individuals residing in the area served by the plan.

"(2) REFERENCE TO PROVISION PERMITTING ADDITIONAL PRESCRIPTION DRUG COVERAGE.—For the provisions of part D, made applicable to this part pursuant to paragraph (1), that permit a plan to make available qualified prescription drug coverage that includes coverage of covered drugs that exceeds the coverage required under paragraph (1) of section 1860D–6 in an area, but only if the MedicareAdvantage organization offering the plan also offers a MedicareAdvantage plan in the area that only provides the coverage that is required under such paragraph (1), see paragraph (2) of such section.

"(3) RULE FOR APPROVAL OF MEDICAL AND PRESCRIPTION DRUG BENEFITS.—Pursuant to sections 1854(g)(1)(F) and 1852(a)(3)(D), a MedicareAdvantage organization offering a MedicareAdvantage plan that provides qualified prescription drug coverage may not make available coverage of any prescription drugs (other than that relating to prescription drugs covered under the original medicare fee-for-service program option) to an enrollee as an additional benefit or as an enhanced medical benefit.

"(b) COMPLIANCE WITH ADDITIONAL BENEFICIARY PROTECTIONS.—With respect to the offering of qualified prescription drug coverage by a MedicareAdvantage organization under a MedicareAdvantage plan, the organization and plan shall meet the requirements of section 1860D–5, including requirements relating to information dissemination and grievance and appeals, and such other requirements under part D that the Secretary determines appropriate in the same manner as such requirements apply to an eligible entity and a Medicare Prescription Drug plan under part D. The Secretary shall waive such requirements to the extent the Secretary determines that such requirements duplicate requirements otherwise applicable to the organization or the plan under this part.

"(c) PAYMENTS FOR PRESCRIPTION DRUGS.—

"(1) PAYMENT OF FULL AMOUNT OF PREMIUM TO ORGANIZATIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—For each year (beginning with 2006), the Secretary shall pay to each MedicareAdvantage organization offering a MedicareAdvantage plan that provides qualified prescription drug coverage, an amount equal to the full amount of the monthly premium submitted under section 1854(a)(2)(B) for the

year, as adjusted using the risk adjusters that apply to the standard prescription drug coverage published under section 1860D–11.

"(B) APPLICATION OF PART D RISK CORRIDOR, STABILIZATION RESERVE FUND, AND ADMINISTRATIVE EXPENSES PROVISIONS.—The provisions of subsections (b), (c), and (d) of section 1860D–16 shall apply to a MedicareAdvantage organization offering a MedicareAdvantage plan that provides qualified prescription drug coverage and payments made to such organization under subparagraph (A) in the same manner as such provisions apply to an eligible entity offering a Medicare Prescription Drug plan and payments made to such entity under subsection (a) of section 1860D–16.

"(2) PAYMENT FROM PRESCRIPTION DRUG ACCOUNT.—Payment made to MedicareAdvantage organizations under this subsection shall be made from the Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

"(d) COMPUTATION OF MEDICAREADVANTAGE MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.—In the case of a

1 MedicareAdvantage eligible individual receiving qualified
2 prescription drug coverage under a MedicareAdvantage
3 plan during a year after 2005, the MedicareAdvantage
4 monthly beneficiary obligation for qualified prescription
5 drug coverage of such individual in the year shall be deter-
6 mined in the same manner as the monthly beneficiary obli-
7 gation is determined under section 1860D–17 for eligible
8 beneficiaries enrolled in a Medicare Prescription Drug
9 plan, except that, for purposes of this subparagraph, any
10 reference to the monthly plan premium approved by the
11 Secretary under section 1860D–13 shall be treated as a
12 reference to the monthly premium for qualified prescrip-
13 tion drug coverage submitted by the MedicareAdvantage
14 organization offering the plan under section
15 1854(a)(2)(A) and approved by the Secretary.

16 ''(e) COLLECTION OF MEDICAREADVANTAGE
17 MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED
18 PRESCRIPTION DRUG COVERAGE.—The provisions of sec-
19 tion 1860D–18, including subsection (b) of such section,
20 shall apply to the amount of the MedicareAdvantage
21 monthly beneficiary obligation for qualified prescription
22 drug coverage (as determined under subsection (d)) re-
23 quired to be paid by a MedicareAdvantage eligible indi-
24 vidual enrolled in a MedicareAdvantage plan in the same
25 manner as such provisions apply to the amount of the

monthly beneficiary obligation required to be paid by an eligible beneficiary enrolled in a Medicare Prescription Drug plan under part D.

"(f) AVAILABILITY OF PREMIUM SUBSIDY AND COST-SHARING REDUCTIONS FOR LOW-INCOME ENROLLEES AND REINSURANCE PAYMENTS.—For provisions—

"(1) providing premium subsidies and cost-sharing reductions for low-income individuals receiving qualified prescription drug coverage through a MedicareAdvantage plan, see section 1860D–19; and

"(2) providing a MedicareAdvantage organization with reinsurance payments for certain expenses incurred in providing qualified prescription drug coverage through a MedicareAdvantage plan, see section 1860D–20.".

(b) TREATMENT OF REDUCTION FOR PURPOSES OF DETERMINING GOVERNMENT CONTRIBUTION UNDER PART B.—Section 1844(c) (42 U.S.C. 1395w) is amended by striking "section 1854(f)(1)(E)" and inserting "section 1854(d)(1)(A)(i)".

**SEC. 206. FACILITATING EMPLOYER PARTICIPATION.**

Section 1858(h) (as added by section 211) is amended—

(1) by inserting "(including subsection (i) of such section)" after "section 1857"; and

(2) by adding at the end the following new sentence: "In applying the authority under section 1857(i) pursuant to this subsection, the Administrator may permit MedicareAdvantage plans to establish separate premium amounts for enrollees in an employer or other group health plan that provides employment-based retiree health coverage (as defined in section 1860D–20(d)(4)(B))."

**SEC. 207. ADMINISTRATION BY THE CENTER FOR MEDICARE CHOICES.**

On and after January 1, 2006, the MedicareAdvantage program under part C of title XVIII of the Social Security Act shall be administered by the Center for Medicare Choices established under section 1808 such title (as added by section 301), and each reference to the Secretary made in such part shall be deemed to be a reference to the Administrator of the Center for Medicare Choices.

**SEC. 208. CONFORMING AMENDMENTS.**

(a) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS FOR MEDICAREADVANTAGE ORGANIZATIONS; PROVIDER-SPONSORED ORGANIZATIONS.—Section 1855 (42 U.S.C. 1395w–25) is amended—

(1) in subsection (b), in the matter preceding paragraph (1), by inserting ''subparagraphs (A), (B), and (D) of'' before ''section 1852(A)(1)''; and

(2) by striking ''Medicare+Choice'' and inserting ''MedicareAdvantage'' each place it appears.

(b) ESTABLISHMENT OF PSO STANDARDS.—Section 1856 (42 U.S.C. 1395w–26) is amended by striking ''Medicare+Choice'' and inserting ''MedicareAdvantage'' each place it appears.

(c) CONTRACTS WITH MEDICAREADVANTAGE ORGANIZATIONS.—Section 1857 (42 U.S.C. 1395w–27) is amended—

(1) in subsection (g)(1)—

(A) in subparagraph (B), by striking ''amount of the Medicare+Choice monthly basic and supplemental beneficiary premiums'' and inserting ''amounts of the MedicareAdvantage monthly basic premium and MedicareAdvantage monthly beneficiary premium for enhanced medical benefits'';

(B) in subparagraph (F), by striking ''or'' after the semicolon at the end;

(C) in subparagraph (G), by adding ''or'' after the semicolon at the end; and

(D) by inserting after subparagraph (G) the following new subparagraph:

''(H)(i) charges any individual an amount in excess of the MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage under section 1858A(d);

''(ii) provides coverage for prescription drugs that is not qualified prescription drug coverage;

''(iii) offers prescription drug coverage, but does not make standard prescription drug coverage available; or

''(iv) provides coverage for prescription drugs (other than that relating to prescription drugs covered under the original medicare fee-for-service program option described in section 1851(a)(1)(A)(i)) as an enhanced medical benefit under section 1852(a)(3)(D) or as an additional benefit under section 1854(g)(1)(F),''; and

(2) by striking ''Medicare+Choice'' and inserting ''MedicareAdvantage'' each place it appears.

(d) DEFINITIONS; MISCELLANEOUS PROVISIONS.—Section 1859 (42 U.S.C. 1395w–28) is amended—

(1) by striking subsection (c) and inserting the following new subsection:

"(c) OTHER REFERENCES TO OTHER TERMS.—

"(1) ENHANCED MEDICAL BENEFITS.—The term 'enhanced medical benefits' is defined in section 1852(a)(3)(E).

"(2) MEDICAREADVANTAGE ELIGIBLE INDIVIDUAL.—The term 'MedicareAdvantage eligible individual' is defined in section 1851(a)(3).

"(3) MEDICAREADVANTAGE PAYMENT AREA.—The term 'MedicareAdvantage payment area' is defined in section 1853(d).

"(4) NATIONAL PER CAPITA MEDICARE+CHOICE GROWTH PERCENTAGE.—The 'national per capita Medicare+Choice growth percentage' is defined in section 1853(c)(6).

"(5) MEDICAREADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM; MEDICAREADVANTAGE MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIPTION DRUG COVERAGE; MEDICAREADVANTAGE MONTHLY BENEFICIARY PREMIUM FOR ENHANCED MEDICAL BENEFITS.—The terms 'MedicareAdvantage monthly basic beneficiary premium', 'MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage',

and 'MedicareAdvantage monthly beneficiary premium for enhanced medical benefits' are defined in section 1854(b)(2).

"(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' has the meaning given such term in section 1860D(9).

"(7) STANDARD PRESCRIPTION DRUG COVERAGE.—The term 'standard prescription drug coverage' has the meaning given such term in section 1860D(10)."; and

(2) by striking "Medicare+Choice" and inserting "MedicareAdvantage" each place it appears.

(e) CONFORMING AMENDMENTS EFFECTIVE BEFORE 2006.—

(1) EXTENSION OF MSAS.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is amended by striking "January 1, 2003" and inserting "January 1, 2004".

(2) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2005.—Section 1851(e) of the Social Security Act (42 U.S.C. 1395w–21(e)) is amended—

(A) in paragraph (2)(A), by striking "THROUGH 2004" and "December 31,2004" and

inserting "THROUGH 2005" and "December 31, 2005", respectively;

(B) in the heading of paragraph (2)(B), by striking "DURING 2005" and inserting "DURING 2006";

(C) in paragraphs (2)(B)(i) and (2)(C)(i), by striking "2005" and inserting "2006" each place it appears;

(D) in paragraph (2)(D), by striking "2004" and inserting "2005"; and

(E) in paragraph (4), by striking "2005" and inserting "2006" each place it appears.

(3) UPDATE IN MINIMUM PERCENTAGE INCREASE.—Section 1853(c)(1)(C) (42 U.S.C. 1395w–23(c)(1)(C)) is amended by striking clause (iv) and inserting the following new clauses:

"(iv) For 2002, 2003, and 2004, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

"(v) For 2005, 103 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for 2003.

"(vi) For 2006 and each succeeding year, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year, except that such rate shall be determined by substituting '102' for '103' in clause (v).".

(4) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of enactment of this Act.

(e) OTHER CONFORMING AMENDMENTS.—

(1) CONFORMING MEDICARE CROSS-REFERENCES.—

(A) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking "section 1854(f)(1)(E)" and inserting "section 1854(g)(1)(C)(i)".

(B) Section 1840(i) (42 U.S.C. 1395s(i)) is amended by striking "section 1854(f)(1)(E)" and inserting "section 1854(g)(1)(C)(i)".

(C) Section 1844(c) (42 U.S.C. 1395w(c)) is amended by striking "section 1854(f)(1)(E)" and inserting "section 1854(g)(1)(C)(i)".

(D) Section 1876(k)(3)(A) (42 U.S.C. 1395mm(k)(3)(A)) is amended by inserting

"(as in effect immediately before the enactment of the Prescription Drug and Medicare Improvements Act of 2003)" after section 1853(a).

(F) Section 1876(k)(4) (42 U.S.C. 1395mm(k)(4)(A)) is amended—

(i) in subparagraph (A), by striking "section 1853(a)(3)(B)" and inserting "section 1853(a)(3)(D)"; and

(ii) in subparagraph (B), by striking "section 1854(g)" and inserting "section 1854(h)".

(G) Section 1876(k)(4)(C) (42 U.S.C. 1395mm(k)(4)(C)) in amended by inserting "(as in effect immediately before the enactment of the Prescription Drug and Medicare Improvements Act of 2003)" after "section 1851(e)(6)".

(H) Section 1894(d) (42 U.S.C. 1395eee(d)) is amended by adding at the end the following new paragraph:

"(3) APPLICATION OF PROVISIONS.—For purposes of paragraphs (1) and (2), the references to section 1853 and subsection (a)(2) of such section in such paragraphs shall be deemed to be references to

those provisions as in effect immediately before the enactment of the Prescription Drug and Medicare Improvements Act of 2003.''.

(2) CONFORMING MEDICARE TERMINOLOGY.—Title XVIII (42 U.S.C. 1395 et seq.), except for part C of such title (42 U.S.C. 1395w–21 et seq.), and title XIX (42 U.S.C. 1396 et seq.) are each amended by striking ''Medicare+Choice'' and inserting ''MedicareAdvantage'' each place it appears.

**SEC. 209. EFFECTIVE DATE.**

(a) IN GENERAL.—Except as provided in section 208(d)(3) and subsection (b), the amendments made by this title shall apply with respect to plan years beginning on and after January 1, 2006.

(b) MEDICAREADVANTAGE MSA PLANS.—Notwithstanding any provision of this title, the Secretary shall apply the payment and other rules that apply with respect to an MSA plan described in section 1851(a)(2)(B) of the Social Security Act (42 U.S.C. 1395w–21(a)(2)(B)) as if this title had not been enacted.

**SEC. 210. IMPROVEMENTS IN MEDICAREADVANTAGE BENCHMARK DETERMINATIONS.**

(a) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE

BENEFICIARIES IN CALCULATION OF MEDICAREADVANTAGE PAYMENT RATES.—

(1) FOR PURPOSES OF CALCULATING MEDICARE+CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)), as amended by section 203, is amended—

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

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

''(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2006), 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.''.

(2) FOR PURPOSES OF CALCULATING LOCAL FEE-FOR-SERVICE RATES.—Section 1853(d)(5) (42 U.S.C. 1395w–23(d)(5)), as amended by section 203, is amended—

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

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

''(C) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the local fee-for-service rate under subparagraph (A) for a year (beginning with 2006), 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 Depart-

ment of Defense or the Department of Veterans Affairs.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on and after January 1, 2006.

# Subtitle B—Preferred Provider Organizations

## SEC. 211. ESTABLISHMENT OF MEDICAREADVANTAGE PREFERRED PROVIDER PROGRAM OPTION.

(a) ESTABLISHMENT OF PREFERRED PROVIDER PROGRAM OPTION.—Section 1851(a)(2) is amended by adding at the end the following new subparagraph:

''(D) PREFERRED PROVIDER ORGANIZATION PLANS.—A MedicareAdvantage preferred provider organization plan under the program established under section 1858.''.

(b) PROGRAM SPECIFICATIONS.—Part C of title XVIII (42 U.S.C. 1395w–21 et seq.) is amended by inserting after section 1857 the following new section:

''PREFERRED PROVIDER ORGANIZATIONS

''SEC. 1858. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—Beginning on January 1, 2006, there is established a preferred provider program under which preferred provider organization plans offered by preferred provider organizations are

offered to MedicareAdvantage eligible individuals in preferred provider regions.

"(2) DEFINITIONS.—

"(A) PREFERRED PROVIDER ORGANIZATION.—The term 'preferred provider organization' means an entity with a contract under section 1857 that meets the requirements of this section applicable with respect to preferred provider organizations.

"(B) PREFERRED PROVIDER ORGANIZATION PLAN.—The term 'preferred provider organization plan' means a MedicareAdvantage 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 a preferred provider organization.

"(C) PREFERRED PROVIDER REGION.—The term 'preferred provider region' means—

"(i) a region established under paragraph (3); and

"(ii) a region that consists of the entire United States.

"(3) PREFERRED PROVIDER REGIONS.—For purposes of this part the Secretary shall establish preferred provider regions as follows:

"(A) There shall be at least 10 regions.

"(B) Each region must include at least 1 State.

"(C) The Secretary may not divide States so that portions of the State are in different regions.

"(D) To the extent possible, the Secretary shall include multistate metropolitan statistical areas in a single region. The Secretary may divide metropolitan statistical areas where it is necessary to establish regions of such size and geography as to maximize the participation of preferred provider organization plans.

"(E) The Secretary may conform the preferred provider regions to the service areas established under section 1860D–10.

"(b) ELIGIBILITY, ELECTION, AND ENROLLMENT; BENEFITS AND BENEFICIARY PROTECTIONS.—

"(1) IN GENERAL.—Except as provided in the succeeding provisions of this subsection, the provisions of sections 1851 and 1852 that apply with respect to coordinated care plans shall apply to preferred provider organization plans offered by a preferred provider organization.

"(2) SERVICE AREA.—The service area of a preferred provider organization plan shall be a preferred provider region.

"(3) AVAILABILITY.—Each preferred provider organization plan must be offered to each MedicareAdvantage eligible individual who resides in the service area of the plan.

"(4) AUTHORITY TO PROHIBIT RISK SELECTION.—The provisions of section 1852(a)(6) shall apply to preferred provider organization plans.

"(5) ASSURING ACCESS TO SERVICES IN PREFERRED PROVIDER ORGANIZATION PLANS.—

"(A) IN GENERAL.—In addition to any other requirements under this section, in the case of a preferred provider organization plan, the organization offering the plan must demonstrate to the Secretary that the organization has sufficient number and range of health care

professionals and providers willing to provide services under the terms of the plan.

"(B) DETERMINATION OF SUFFICIENT ACCESS.—The Secretary shall find that an organization has met the requirement under subparagraph (A) with respect to any category of health care professional or provider if, with respect to that category of provider the plan has contracts or agreements with a sufficient number and range of providers within such category to provide covered services under the terms of the plan.

"(C) CONSTRUCTION.—Subparagraph (B) shall not be construed as restricting—

"(i) the persons from whom enrollees under such plan may obtain covered benefits; or

"(ii) the categories of licensed health professionals or providers from whom enrollees under such a plan may obtain covered benefits if the covered services are provided to enrollees in a State where 25 percent or more of the population resides in health professional shortage areas des-

ignated pursuant to section 332 of the Public Health Service Act.

"(c) PAYMENTS TO PREFERRED PROVIDER ORGANIZATIONS.—

"(1) PAYMENTS TO ORGANIZATIONS.—

"(A) MONTHLY PAYMENTS.—

"(i) IN GENERAL.—Under a contract under section 1857 and subject to paragraph (5), subsection (e), and section 1859(e)(4), the Secretary shall make, to each preferred provider organization, with respect to coverage of an individual for a month under this part in a preferred provider region, separate monthly payments with respect to—

"(I) benefits under the original medicare fee-for-service program under parts A and B in accordance with paragraph (4); and

"(II) benefits under the voluntary prescription drug program under part D in accordance with section 1858A and the other provisions of this part.

"(ii) SPECIAL RULE FOR END-STAGE RENAL DISEASE.—The Secretary shall establish separate rates of payment applicable with respect to classes of individuals determined to have end-stage renal disease and enrolled in a preferred provider organization plan under this clause that are similar to the separate rates of payment described in section 1853(a)(1)(B).

"(B) ADJUSTMENT TO REFLECT NUMBER OF ENROLLEES.—The Secretary may retroactively adjust the amount of payment under this paragraph in a manner that is similar to the manner in which payment amounts may be retroactively adjusted under section 1853(a)(2).

"(C) COMPREHENSIVE RISK ADJUSTMENT METHODOLOGY.—The Secretary shall apply the comprehensive risk adjustment methodology described in section 1853(a)(3)(B) to 100 percent of the amount of payments to plans under paragraph (4)(D)(ii).

"(D) ADJUSTMENT FOR SPENDING VARIATIONS WITHIN A REGION.—The Secretary shall establish a methodology for adjusting the amount of payments to plans under paragraph

(4)(D)(ii) that achieves the same objective as the adjustment described in paragraph 1853(a)(2)(C).

"(2) ANNUAL CALCULATION OF BENCHMARK AMOUNTS FOR PREFERRED PROVIDER REGIONS.—For each year (beginning in 2006), the Secretary shall calculate a benchmark amount for each preferred provider region for each month for such year with respect to coverage of the benefits available under the original medicare fee-for-service program option equal to the average of each benchmark amount calculated under section 1853(a)(4) for each MedicareAdvantage payment area for the year within such region, weighted by the number of MedicareAdvantage eligible individuals residing in each such payment area for the year.

"(3) ANNUAL ANNOUNCEMENT OF PAYMENT FACTORS.—

"(A) ANNUAL ANNOUNCEMENT.—Beginning in 2005, at the same time as the Secretary publishes the risk adjusters under section 1860D–11, the Secretary shall annually announce (in a manner intended to provide notice to interested parties) the following payment factors:

"(i) The benchmark amount for each preferred provider region (as calculated under paragraph (2)(A)) for the year.

"(ii) The factors to be used for adjusting payments described under—

"(I) the comprehensive risk adjustment methodology described in paragraph (1)(C) with respect to each preferred provider region for the year; and

"(II) the methodology used for adjustment for geographic variations within such region established under paragraph (1)(D).

"(B) ADVANCE NOTICE OF METHODOLOGICAL CHANGES.—At least 45 days before making the announcement under subparagraph (A) for a year, the Secretary shall—

"(i) provide for notice to preferred provider organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement; and

"(ii) provide such organizations with an opportunity to comment on such proposed changes.

"(C) EXPLANATION OF ASSUMPTIONS.—In each announcement made under subparagraph (A), the Secretary shall include an explanation of the assumptions and changes in methodology used in the announcement in sufficient detail so that preferred provider organizations can compute each payment factor described in such subparagraph.

"(4) SECRETARY'S DETERMINATION OF PAYMENT AMOUNT FOR BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM.—The Secretary shall determine the payment amount for plans as follows:

"(A) REVIEW OF PLAN BIDS.—The Secretary shall review each plan bid submitted under subsection (d)(1) for the coverage of benefits under the original medicare fee-for-service program option to ensure that such bids are consistent with the requirements under this part and are based on the assumptions described in section 1854(a)(2)(A)(iii) that the

plan used with respect to numbers of enrolled individuals.

"(B) DETERMINATION OF PREFERRED PROVIDER REGIONAL BENCHMARK AMOUNTS.—The Secretary shall calculate a preferred provider regional benchmark amount for that plan for the benefits under the original medicare fee-for-service program option for each plan equal to the regional benchmark adjusted by using the assumptions described in section 1854(a)(2)(A)(iii) that the plan used with respect to numbers of enrolled individuals.

"(C) COMPARISON TO BENCHMARK.—The Secretary shall determine the difference between each plan bid (as adjusted under subparagraph (A)) and the preferred provider regional benchmark amount (as determined under subparagraph (B)) for purposes of determining—

"(i) the payment amount under subparagraph (D); and

"(ii) the additional benefits required and MedicareAdvantage monthly basic beneficiary premiums.

"(D) DETERMINATION OF PAYMENT AMOUNT.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary shall determine the payment amount to a preferred provider organization for a preferred provider organization plan as follows:

"(I) BIDS THAT EQUAL OR EXCEED THE BENCHMARK.—In the case of a plan bid that equals or exceeds the preferred provider regional benchmark amount, the amount of each monthly payment to the organization with respect to each individual enrolled in a plan shall be the preferred provider regional benchmark amount.

"(II) BIDS BELOW THE BENCHMARK.—In the case of a plan bid that is less than the preferred provider regional benchmark amount, the amount of each monthly payment to the organization with respect to each individual enrolled in a plan shall be the preferred provider regional benchmark amount reduced by the amount

of any premium reduction elected by the plan under section 1854(d)(1)(A)(i).

"(ii) APPLICATION OF ADJUSTMENT METHODOLOGIES.—The Secretary shall adjust the amounts determined under subparagraph (A) using the factors described in paragraph (3)(A)(ii).

"(E) FACTORS USED IN ADJUSTING BIDS AND BENCHMARKS FOR PREFERRED PROVIDER ORGANIZATIONS AND IN DETERMINING ENROLLEE PREMIUMS.—Subject to subparagraph (F), in addition to the factors used to adjust payments to plans described in section 1853(d)(6), the Secretary shall use the adjustment for geographic variation within the region established under paragraph (1)(D).

"(F) ADJUSTMENT FOR NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—The Secretary shall provide for adjustments for national coverage determinations and legislative changes in benefits applicable with respect to preferred provider organizations in the same manner as the Sec-

retary provides for adjustments under section 1853(d)(7).

"(5) PAYMENTS FROM TRUST FUND.—The payment to a preferred provider organization under this section shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in a manner similar to the manner described in section 1853(g).

"(6) SPECIAL RULE FOR CERTAIN INPATIENT HOSPITAL STAYS.—Rules similar to the rules applicable under section 1853(h) shall apply with respect preferred provider organizations.

"(7) SPECIAL RULE FOR HOSPICE CARE.—Rules similar to the rules applicable under section 1853(i) shall apply with respect to preferred provider organizations.

"(d) SUBMISSION OF BIDS BY PPOS; PREMIUMS.—

"(1) SUBMISSION OF BIDS BY PREFERRED PROVIDER ORGANIZATIONS.—

"(A) IN GENERAL.—For the requirements on submissions by MedicareAdvantage preferred provider organization plans, see section 1854(a)(1).

"(B) UNIFORM PREMIUMS.—Each bid amount submitted under subparagraph (A) for

a preferred provider organization plan in a preferred provider region may not vary among MedicareAdvantage eligible individuals residing in such preferred provider region.

"(C) APPLICATION OF FEHBP STANDARD; PROHIBITION ON PRICE GOUGING.—Each bid amount submitted under subparagraph (A) for a preferred provider organization plan must reasonably and equitably reflect the cost of benefits provided under that plan.

"(D) REVIEW.—The Secretary shall review the adjusted community rates (as defined in section 1854(g)(3)), the amounts of the MedicareAdvantage monthly basic premium and the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits filed under this paragraph and shall approve or disapprove such rates and amounts so submitted. The Secretary shall review the actuarial assumptions and data used by the preferred provider organization with respect to such rates and amounts so submitted to determine the appropriateness of such assumptions and data.

"(E) AUTHORITY TO LIMIT NUMBER OF PLANS IN A REGION.—If there are bids for

more than 3 preferred provider organization plans in a preferred provider region, the Secretary shall accept only the 3 lowest-cost credible bids for that region that meet or exceed the quality and minimum standards applicable under this section.

"(2) MONTHLY PREMIUMS CHARGED.—The amount of the monthly premium charged to an individual enrolled in a preferred provider organization plan offered by a preferred provider organization shall be equal to the sum of the following:

"(A) The MedicareAdvantage monthly basic beneficiary premium, as defined in section 1854(b)(2)(A) (if any).

"(B) The MedicareAdvantage monthly beneficiary premium for enhanced medical benefits, as defined in section 1854(b)(2)(C) (if any).

"(C) The MedicareAdvantage monthly obligation for qualified prescription drug coverage, as defined in section 1854(b)(2)(B) (if any).

"(3) DETERMINATION OF PREMIUM REDUCTIONS, REDUCED COST-SHARING, ADDITIONAL BENEFITS, AND BENEFICIARY PREMIUMS.—The rules for determining premium reductions, reduced cost-sharing, additional benefits, and beneficiary premiums

under section 1854(d) shall apply with respect to preferred provider organizations.

"(4) PROHIBITION OF SEGMENTING PREFERRED PROVIDER REGIONS.—The Secretary may not permit a preferred provider organization to elect to apply the provisions of this section uniformly to separate segments of a preferred provider region (rather than uniformly to an entire preferred provider region).

"(e) PORTION OF TOTAL PAYMENTS TO AN ORGANIZATION SUBJECT TO RISK FOR 2 YEARS.—

"(1) NOTIFICATION OF SPENDING UNDER THE PLAN.—

"(A) IN GENERAL.—For 2007 and 2008, the preferred provider organization offering a preferred provider organization plan shall notify the Secretary of the total amount of costs that the organization incurred in providing benefits covered under parts A and B of the original medicare fee-for-service program for all enrollees under the plan in the previous year.

"(B) CERTAIN EXPENSES NOT INCLUDED.—The total amount of costs specified in subparagraph (A) may not include—

"(i) subject to subparagraph (C), administrative expenses incurred in providing the benefits described in such subparagraph; or

"(ii) amounts expended on providing enhanced medical benefits under section 1852(a)(3)(D).

"(C) ESTABLISHMENT OF ALLOWABLE ADMINISTRATIVE EXPENSES.—For purposes of applying subparagraph (B)(i), the administrative expenses incurred in providing benefits described in subparagraph (A) under a preferred provider organization plan may not exceed an amount determined appropriate by the Administrator.

"(2) ADJUSTMENT OF PAYMENT.—

"(A) NO ADJUSTMENT IF COSTS WITHIN RISK CORRIDOR.—If the total amount of costs specified in paragraph (1)(A) for the plan for the year are not more than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) and are not less than the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)) for the plan for the year, then no additional payments shall

be made by the Secretary and no reduced payments shall be made to the preferred provider organization offering the plan.

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

"(i) IN GENERAL.—If the total amount of costs specified in paragraph (1)(A) for the plan for the year are more than the first threshold upper limit of the risk corridor for the plan for the year, then the Secretary shall increase the total of the monthly payments made to the preferred provider organization offering the plan for the year under subsection (c)(1)(A) by an amount equal to the sum of—

"(I) 50 percent of the amount of such total costs which are more than such first threshold upper limit of the risk corridor and not more than the second threshold upper limit of the risk corridor for the plan for the year (as specified under paragraph (3)(A)(iv)); and

"(II) 90 percent of the amount of such total costs which are more than

such second threshold upper limit of the risk corridor.

"(C) REDUCTION IN PAYMENT IF COSTS BELOW LOWER LIMIT OF RISK CORRIDOR.—If the total amount of costs specified in paragraph (1)(A) for the plan for the year are less than the first threshold lower limit of the risk corridor for the plan for the year, then the Secretary shall reduce the total of the monthly payments made to the preferred provider organization offering the plan for the year under subsection (c)(1)(A) by an amount (or otherwise recover from the plan an amount) equal to—

"(i) 50 percent of the amount of such total costs which are less than such first threshold lower limit of the risk corridor and not less than the second threshold lower limit of the risk corridor for the plan for the year (as specified under paragraph (3)(A)(ii)); and

"(ii) 90 percent of the amount of such total costs which are less than such second threshold lower limit of the risk corridor.

"(3) ESTABLISHMENT OF RISK CORRIDORS.—

"(A) IN GENERAL.—For 2006 and 2007, the Secretary shall establish a risk corridor for each preferred provider organization 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 5 percent 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 10 percent 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 preferred provider organization plan offered by a preferred provider organization in a year, an amount equal to the sum of—

"(i) the total monthly payments made to the organization for enrollees in the plan for the year under subsection (c)(1)(A); and

"(ii) the total MedicareAdvantage basic beneficiary premiums collected for such enrollees for the year under subsection (d)(2)(A).

"(4) PLANS AT RISK FOR ENTIRE AMOUNT OF ENHANCED MEDICAL BENEFITS.—A preferred provider organization that offers a preferred provider organization plan that provides enhanced medial benefits under section 1852(a)(3)(D) shall be at full financial risk for the provision of such benefits.

"(5) NO EFFECT ON ELIGIBLE BENEFICIARIES.—No change in payments made by reason of this subsection shall affect the amount of the MedicareAdvantage basic beneficiary premium that a beneficiary is otherwise required to pay under the plan for the year under subsection (d)(2)(A).

"(6) DISCLOSURE OF INFORMATION.—The provisions of section 1860D–16(b)(7), including subparagraph (B) of such section, shall apply to a preferred provider organization and a preferred provider organization plan in the same manner as such provisions apply to an eligible entity and a Medicare Prescription Drug plan under part D.

"(f) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS FOR PREFERRED PROVIDER ORGANIZATIONS.—A preferred provider organization shall be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in

each State within the preferred provider region in which it offers a preferred provider organization plan.

"(g) INAPPLICABILITY OF PROVIDER-SPONSORED ORGANIZATION SOLVENCY STANDARDS.—The requirements of section 1856 shall not apply with respect to preferred provider organizations.

"(h) CONTRACTS WITH PREFERRED PROVIDER ORGANIZATIONS.—The provisions of section 1857 shall apply to a preferred provider organization plan offered by a preferred provider organization under this section.".

(c) PREFERRED PROVIDER TERMINOLOGY DEFINED.—Section 1859(a) is amended by adding at the end the following new paragraph:

"(3) PREFERRED PROVIDER ORGANIZATION; PREFERRED PROVIDER ORGANIZATION PLAN; PREFERRED PROVIDER REGION.—The terms 'preferred provider organization', 'preferred provider organization plan', and 'preferred provider region' have the meaning given such terms in section 1858(a)(2).".

# Subtitle C—Other Managed Care Reforms

**SEC. 221. EXTENSION OF REASONABLE COST CONTRACTS.**

(a) FIVE-YEAR EXTENSION.—Section 1876(h)(5)(C) (42 U.S.C. 1395mm(h)(5)(C)) is amended by striking "2004" and inserting "2009".

(b) APPLICATION OF CERTAIN MEDICARE+CHOICE REQUIREMENTS TO COST CONTRACTS EXTENDED OR RENEWED AFTER 2003.—Section 1876(h) (42 U.S.C. 1395mm(h)(5)), as amended by subsection (a), is amended—

(1) by redesignating paragraph (5) as paragraph (6); and

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

''(5) Any reasonable cost reimbursement contract with an eligible organization under this subsection that is extended or renewed on or after the date of enactment of the Prescription Drug and Medicare Improvements Act of 2003 for plan years beginning on or after January 1, 2004, shall provide that the following provisions of the Medicare+Choice program under part C (and, on and after January 1, 2006, the provisions of the MedicareAdvantage program under such part) shall apply to such organization and such contract in a substantially similar manner as such provisions apply to Medicare+Choice organizations and Medicare+Choice plans (or, on and after January 1, 2006, MedicareAdvantage organizations and MedicareAdvantage plans, respectively) under such part:

"(A) Paragraph (1) of section 1852(e) (relating to the requirement of having an ongoing quality assurance program) and paragraph (2)(B) of such section (relating to the required elements for such a program).

"(B) Section 1852(j)(4) (relating to limitations on physician incentive plans).

"(C) Section 1854(c) (relating to the requirement of uniform premiums among individuals enrolled in the plan).

"(D) Section 1854(g), or, on and after January 1, 2006, section 1854(h) (relating to restrictions on imposition of premium taxes with respect to payments to organizations).

"(E) Section 1856(b) (regarding compliance with the standards established by regulation pursuant to such section, including the provisions of paragraph (3) of such section relating to relation to State laws).

"(F) Section 1852(a)(3)(A) (regarding the authority of organizations to include supplemental health care benefits and, on and after January 1, 2006, enhanced medical benefits under the plan subject to the approval of the Secretary).

"(G) The provisions of part C relating to timelines for benefit filings, contract renewal, and beneficiary notification.

"(H) Section 1854(e), or, on and after January 1, 2006, section 1854(f) (relating to proposed cost-sharing under the contract being subject to review by the Secretary).".

(c) PERMITTING DEDICATED GROUP PRACTICE HEALTH MAINTENANCE ORGANIZATIONS TO PARTICIPATE IN THE MEDICARE COST CONTRACT PROGRAM.—Section 1876(h)(6) of the Social Security Act (42 U.S.C. 1395mm(h)(6)), as redesignated and amended by subsections (a) and (b), is amended—

(1) in subparagraph (A), by striking "After the date of the enactment" and inserting "Except as provided in subparagraph (C), after the date of the enactment";

(2) in subparagraph (B), by striking "subparagraph (C)" and inserting "subparagraph (D)";

(3) by redesignating subparagraph (C) as subparagraph (D); and

(4) by inserting after subparagraph (B), the following new subparagraph:

"(C) Subject to paragraph (5) and subparagraph (D), the Secretary shall approve an application to enter into a reasonable cost contract under this section if—

"(i) the application is submitted to the Secretary by a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act) that, as of January 1, 2004, and except as provided in section 1301(b)(3)(B) of such Act, provides at least 85 percent of the services of a physician which are provided as basic health services through a medical group (or groups), as defined in section 1302(4) of such Act; and

"(ii) the Secretary determines that the organization meets the requirements applicable to such organizations and contracts under this section.".

**SEC. 222. SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.**

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by adding at the end the following new sentence: "Specialized Medicare+Choice plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.".

(b) SPECIALIZED MEDICARE+CHOICE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section

1859(b) (42 U.S.C. 1395w–28(b)) is amended by adding at the end the following new paragraph:

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

"(A) IN GENERAL.—The term 'specialized Medicare+Choice plans for special needs beneficiaries' means a Medicare+Choice plan that—

"(i) exclusively serves special needs beneficiaries (as defined in subparagraph (B)), or

"(ii) to the extent provided in regulations prescribed by the Secretary, disproportionately serves such special needs beneficiaries, frail elderly medicare beneficiaries, or both.

"(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare+Choice eligible individual who—

"(i) is institutionalized (as defined by the Secretary);

"(ii) is entitled to medical assistance under a State plan under title XIX; or

"(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized

Medicare+Choice plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.''.

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–28) is amended by adding at the end the following new subsection:

''(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2008, the plan may restrict the enrollment of individuals under the plan to individuals who are within 1 or more classes of special needs beneficiaries.''.

(d) REPORT TO CONGRESS.—Not later than December 31, 2006, the Secretary shall submit to Congress a report that assesses the impact of specialized Medicare+Choice plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect on the date of enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later than 1 year after the date of enactment of this Act, the Secretary shall issue final regulations to establish requirements for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

**SEC. 223. 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)''; and

(D) by striking ''members of the organization'' and inserting ''members of the organiza-

tion 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+CHOICE REQUIREMENT WITH RESPECT TO MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—Section 1852(k)(1) (relating to limitations on balance billing against Medicare+Choice 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 establishing payment amounts for services furnished to such an individual in the same manner as such section applies to Medicare+Choice 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 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)) is amended—

(A) in paragraph (64), by striking "and" at the end;

(B) in paragraph (65), by striking the period at the end and inserting "; and"; and

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

"(66) 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 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) REFERENCE IN MEDICAID STATUTE.—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+CHOICE REQUIREMENT WITH RESPECT TO MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—Section 1852(k)(1) (relating to limitations on balance billing against Medicare+Choice 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 establishing payment amounts for services furnished to such an individual in the same manner as such section applies to Medicare+Choice 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 serv-

ices covered under title XVIII furnished by non-contract 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 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)(66).".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004.

**SEC. 224. 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 enactment of this Act, the Secretary of Health and Human Services 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 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, health plans, purchasers, and consumers.

(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 of Health and Human Services, the Committees on Ways and Means and Energy and Commerce of the House of Representatives, and the Committee on Finance of the Senate 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 in the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act, the Medicare+Choice 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 $1,000,000 for purposes of conducting the evaluation and preparing the report required by this section.

**SEC. 225. 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 ", Medicare+Choice organizations and MedicareAdvantage organizations under part C, and prescription drug card sponsors and eligible entities 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, prescription drug card sponsors and eligible entities under part D, and Medicare+Choice and

MedicareAdvantage plans under part C 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.

**SEC. 226. EXTENSION OF DEMONSTRATION FOR ESRD MANAGED CARE.**

The Secretary shall extend without interruption, through December 31, 2007, the approval of the demonstration project, Contract No. H1021, under the authority of section 2355(b)(1)(B)(iv) of the Deficit Reduction Act of 1984, as amended by section 13567 of the Omnibus Reconciliation Act of 1993. Such approval shall be subject to the terms and conditions in effect for the 2002 project year with respect to eligible participants and covered benefits. The Secretary shall set the monthly capitation rate for enrollees on the basis of the reasonable medical and direct administrative costs of providing those benefits to such participants.

# Subtitle D—Evaluation of Alternative Payment and Delivery Systems

## SEC. 231. ESTABLISHMENT OF ALTERNATIVE PAYMENT SYSTEM FOR PREFERRED PROVIDER ORGANIZATIONS IN HIGHLY COMPETITIVE REGIONS.

(a) ESTABLISHMENT OF ALTERNATIVE PAYMENT SYSTEM FOR PREFERRED PROVIDER ORGANIZATIONS IN HIGHLY COMPETITIVE REGIONS.—Section 1858 (as added by section 211(b)) is amended by adding at the end the following new subsection:

"(i) ALTERNATIVE PAYMENT METHODOLOGY FOR HIGHLY COMPETITIVE REGIONS.—

"(1) ANNUAL DETERMINATION AND DESIGNATION.—

"(A) IN 2008.—In 2008, prior to the date on which the Secretary expects to publish the risk adjusters under section 1860D–11, the Secretary shall designate a limited number (but in no case fewer than 1) of preferred provider regions (other than the region described in subsection (a)(2)(C)(ii)) as highly competitive regions.

"(B) SUBSEQUENT YEARS.—For each year (beginning with 2009) the Secretary may designate a limited number of preferred provider regions (other than the region described in subsection (a)(2)(C)(ii)) as highly competitive regions in addition to any region designated as a highly competitive region under subparagraph (A).

"(C) CONSIDERATIONS.—In determining which preferred provider regions to designate as highly competitive regions under subparagraph (A) or (B), the Secretary shall consider the following:

"(i) Whether the application of this subsection to the preferred provider region would enhance the participation of preferred provider organization plans in that region.

"(ii) Whether the Secretary anticipates that there is likely to be at least 3 bids submitted under subsection (d)(1) with respect to the preferred provider region if the Secretary designates such region as a highly competitive region under subparagraph (A) or (B).

"(iii) Whether the Secretary expects that MedicareAdvantage eligible individuals will elect preferred provider organization plans in the preferred provider region if the region is designated as a highly competitive region under subparagraph (A) or (B).

"(iv) Whether the designation of the preferred provider region as a highly competitive region will permit compliance with the limitation described in paragraph (5).

In considering the matters described in clauses (i) through (iv), the Secretary shall give special consideration to preferred provider regions where no bids were submitted under subsection (d)(1) for the previous year.

"(2) EFFECT OF DESIGNATION.—If a preferred provider region is designated as a highly competitive region under subparagraph (A) or (B) of paragraph (1)—

"(A) the provisions of this subsection shall apply to such region and shall supersede the provisions of this part relating to benchmarks for preferred provider regions; and

"(B) such region shall continue to be a highly competitive region until such designation is rescinded pursuant to paragraph (5)(B)(ii).

"(3) SUBMISSION OF BIDS.—

"(A) IN GENERAL.—Notwithstanding subsection (d)(1), for purposes of applying section 1854(a)(2)(A)(i), the plan bid for a highly competitive region shall consist of a dollar amount that represents the total amount that the plan is willing to accept (not taking into account the application of the comprehensive risk adjustment methodology under section 1853(a)(3)) for providing coverage of only the benefits described in section 1852(a)(1)(A) to an individual enrolled in the plan that resides in the service area of the plan for a month.

"(B) CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as permitting a preferred provider organization plan not to provide coverage for the benefits described in section 1852(a)(1)(C).

"(4) PAYMENTS TO PREFERRED PROVIDER ORGANIZATIONS IN HIGHLY COMPETITIVE AREAS.—With respect to highly competitive regions, the following rules shall apply:

"(A) IN GENERAL.—Notwithstanding subsection (c), of the plans described in subsection (d)(1)(E), the Secretary shall substitute the second lowest bid for the benchmark applicable under subsection (c)(4).

"(B) IF THERE ARE FEWER THAN THREE BIDS.—Notwithstanding subsection (c), if there are fewer than 3 bids in a highly competitive region for a year, the Secretary shall substitute the lowest bid for the benchmark applicable under subsection (c)(4).

"(5) FUNDING LIMITATION.—

"(A) IN GENERAL.—

"(i) IN GENERAL.—The total amount expended as a result of the application of this subsection during the period or year, as applicable, may not exceed the applicable amount (as defined in clause (ii)).

"(ii) APPLICABLE AMOUNT DEFINED.—In this paragraph, the term 'applicable amount' means—

"(I) for the period beginning on January 1, 2009, and ending on September 30, 2013, the total amount that would have been expended under

this title during the period if this subsection had not been enacted plus $6,000,000,000; and

"(II) for fiscal year 2014 and any subsequent fiscal year, the total amount that would have been expended under this title during the year if this subsection had not been enacted.

"(B) APPLICATION OF LIMITATION.—If the Secretary determines that the application of this subsection will cause expenditures to exceed the applicable amount, the Secretary shall—

"(i) take appropriate steps to stay within the applicable amount, including through providing limitations on enrollment; or

"(ii) rescind the designation under subparagraph (A) or (B) of paragraph (1) of 1 or more preferred provider regions as highly competitive regions.

"(C) TRANSITION.—If the Secretary rescinds a designation under subparagraph (A) or (B) of paragraph (1) pursuant to subparagraph (B)(ii) with respect to a preferred provider re-

gion, the Secretary shall provide for an appropriate transition from the payment system applicable under this subsection to the payment system described in the other provisions of this section in that region. Any amount expended by reason of the preceding sentence shall be considered to be part of the total amount expended as a result of the application of this subsection for purposes of applying the limitation under subparagraph (A).

"(D) APPLICATION.—Notwithstanding paragraph (1)(B), on or after January 1 of the year in which the fiscal year described in subparagraph (A)(ii)(II) begins, the Secretary may designate appropriate regions under such paragraph.

"(6) LIMITATION OF JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of designations made under subparagraph (A) or (B) of paragraph (1).

"(7) SECRETARY REPORTS.—Not later than April 1 of each year (beginning in 2010), 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 clauses (i) and (ii) of paragraph (5)(B) to ensure that the application of this subsection will not cause expenditures to exceed the applicable amount described in paragraph (5)(A); and

"(B) a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that the descriptions under clauses (i), (ii), (iii), and (iv) of subparagraph (A) are reasonable, accurate, and based on generally accepted actuarial principles and methodologies.

"(8) BIENNIAL GAO REPORTS.—Not later than January 1, 2011, and biennially thereafter, the Comptroller General of the United States shall submit to the Secretary and Congress a report on the designation of highly competitive regions under this subsection and the application of the payment system under this subsection within such regions. Each report shall include—

"(A) an evaluation of—

"(i) the quality of care provided to beneficiaries enrolled in a MedicareAdvantage preferred provider plan in a highly competitive region;

"(ii) the satisfaction of beneficiaries 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 benchmark system applicable under the other provisions of this section and the payment system applicable in highly competitive regions under this subsection; and

"(C) recommendations for such legislation or administrative action as the Comptroller General determines to be appropriate.

"(9) REPORT ON BUDGET NEUTRALITY FOR FISCAL YEARS AFTER 2013.—

"(A) IN GENERAL.—If the Secretary intends to designate 1 or more regions as highly competitive regions with respect to calendar 2014 or any subsequent calendar year, the Secretary shall submit a report to Congress indicating such intent no later than April 1 of the calendar year prior to the calendar year in which the applicable designation year begins.

"(B) REQUIREMENTS.—A report submitted under subparagraph (A) shall—

"(i) specify the steps (if any) that the Secretary will take pursuant to paragraph (5)(B) to ensure that the total amount ex-

pended as a result of the application of this subsection during the year will not exceed the applicable amount for the year (as defined in paragraph (5)(A)(ii)(II)); and

"(ii) contain a certification from the Chief Actuary of the Centers for Medicare and Medicaid Services that such steps will meet the requirements of paragraph (5)(A) based on an analysis using generally accepted actuarial principles and methodologies.".

(b) CONFORMING AMENDMENT.—Section 1858(c)(3)(A)(i) (as added by section 211(b)) is amended to read as follows:

"(i) Whether each preferred provider region has been designated as a highly competitive region under subparagraph (A) or (B) of subsection (i)(1) and the benchmark amount for any preferred provider region (as calculated under paragraph (2)(A)) for the year that has not been designated as a highly competitive region.".

**SEC. 232. FEE-FOR-SERVICE MODERNIZATION PROJECTS.**

(a) ESTABLISHMENT.—

(1) REVIEW AND REPORT ON RESULTS OF EXISTING DEMONSTRATIONS.—

(A) REVIEW.—The Secretary shall conduct an empirical review of the results of the demonstrations under sections 442, 443, and 444.

(B) REPORT.—Not later than January 1, 2008, the Secretary shall submit a report to Congress on the empirical review conducted under subparagraph (A) which shall include estimates of the total costs of the demonstrations, including expenditures as a result of the provision of services provided to beneficiaries under the demonstrations that are incidental to the services provided under the demonstrations, and all other expenditures under title XVIII of the Social Security Act. The report shall also include a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that such estimates are reasonable, accurate, and based on generally accepted actuarial principles and methodologies.

(2) PROJECTS.—Beginning in 2009, the Secretary, based on the empirical review conducted under paragraph (1), shall establish projects under which medicare beneficiaries receiving benefits under

the medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act are provided with coverage of enhanced benefits or services under such program. The purpose of such projects is to evaluate whether the provision of such enhanced benefits or services to such beneficiaries—

(A) improves the quality of care provided to such beneficiaries under the medicare program;

(B) improves the health care delivery system under the medicare program; and

(C) results in reduced expenditures under the medicare program.

(2) ENHANCED BENEFITS OR SERVICES.—For purposes of this section, enhanced benefits or services shall include—

(A) preventive services not otherwise covered under title XVIII of the Social Security Act;

(B) chronic care coordination services;

(C) disease management services; or

(D) other benefits or services that the Secretary determines will improve preventive health care for medicare beneficiaries, result in improved chronic disease management, and man-

agement of complex, life-threatening, or high-cost conditions and are consistent with the goals described in subparagraphs (A), (B), and (C) of paragraph (1).

(b) PROJECT SITES AND DURATION.—

(1) IN GENERAL.—Subject to subsection (e)(2), the projects under this section shall be conducted—

(A) in a region or regions that are comparable (as determined by the Secretary) to the region or regions that are designated as a highly competitive region under subparagraph (A) or (B) of section 1858(i)(1) of the Social Security Act, as added by section 231 of this Act; and

(B) during the years that a region or regions are designated as such a highly competitive region.

(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), a comparable region does not necessarily mean the identical region.

(c) 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.) only to the extent and for such period as the Secretary determines is

1 necessary to provide for enhanced benefits or services con-
2 sistent with the projects under this section.
3 (d) BIENNIAL GAO REPORTS.—Not later than Janu-
4 ary 1, 2011, and biennially thereafter for as long as the
5 projects under this section are being conducted, the Comp-
6 troller General of the United States shall submit to the
7 Secretary and Congress a report that evaluates the
8 projects. Each report shall include—
9 (1) an evaluation of—
10 (A) the quality of care provided to bene-
11 ficiaries receiving benefits or services under the
12 projects;
13 (B) the satisfaction of beneficiaries receiv-
14 ing benefits or services under the projects;
15 (C) the costs to the medicare program
16 under the projects; and
17 (D) any improvements in the delivery of
18 health care services under the projects; and
19 (2) recommendations for such legislation or ad-
20 ministrative action as the Comptroller General deter-
21 mines to be appropriate.
22 (e) FUNDING.—
23 (1) IN GENERAL.—Payments for the costs of
24 carrying out the projects under this section shall be
25 made from the Federal Hospital Insurance Trust

Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) and the Federal Supplementary Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t), as determined appropriate by the Secretary.

(2) LIMITATION.—The total amount expended under the medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act (including all amounts expended as a result of the projects under this section) during the period or year, as applicable, may not exceed—

(A) for the period beginning on January 1, 2009, and ending on September 30, 2013, an amount equal to the total amount that would have been expended under the medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act during the period if the projects had not been conducted plus $6,000,000,000; and

(B) for fiscal year 2014 and any subsequent fiscal year, an amount equal to the total amount that would have been expended under the medicare fee-for-service program under parts A and B of such title during the year if the projects had not been conducted.

(3) MONITORING AND REPORTS.—

(A) ONGOING MONITORING BY THE SECRETARY TO ENSURE FUNDING LIMITATION IS NOT VIOLATED.—The Secretary shall continually monitor expenditures made under title XVIII of the Social Security Act by reason of the projects under this section to ensure that the limitations described in subparagraphs (A) and (B) of paragraph (2) are not violated.

(B) REPORTS.—Not later than April 1 of each year (beginning in 2010), the Secretary shall submit a report to Congress and the Comptroller General of the United States that includes—

(i) a detailed description of—

(I) the total amount expended under the medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act (including all amounts expended as a result of the projects under this section) during the previous year compared to the total amount that would have been expended under the original medicare fee-for-service program in

the year if the projects had not been conducted;

(II) the projections of the total amount expended under the medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act (including all amounts expended as a result of the projects under this section) during the year in which the report is submitted compared to the total amount that would have been expended under the original medicare fee-for-service program in the year if the projects had not been conducted;

(III) amounts remaining within the funding limitation specified in paragraph (2); and

(IV) how the Secretary will change the scope, site, and duration of the projects in subsequent years in order to ensure that the limitations described in subparagraphs (A) and (B) of paragraph (2) are not violated; and

(ii) a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that the descriptions under subclauses (I), (II), (III), and (IV) of clause (i) are reasonable, accurate, and based on generally accepted actuarial principles and methodologies.

(C) REPORT ON BUDGET NEUTRALITY FOR FISCAL YEARS AFTER 2013.—

(i) IN GENERAL.—If the Secretary intends to continue the projects under this section for fiscal year 2014 or any subsequent fiscal year, the Secretary shall submit a report to Congress indicating such intent no later than April 1 of the year prior to the year in which the fiscal year begins.

(ii) REQUIREMENTS.—A report submitted under clause (i) shall—

(I) specify the steps (if any) that the Secretary will take pursuant to paragraph (4) to ensure that the limitations described in paragraph (2)(B) will not be violated for the year; and

(II) contain a certification from the Chief Actuary of the Centers for Medicare and Medicaid Services that such steps will meet the requirements of paragraph (2) based on an analysis using generally accepted actuarial principles and methodologies.

(4) APPLICATION OF LIMITATION.—If the Secretary determines that the projects under this section will cause the limitations described in subparagraphs (A) and (B) of paragraph (2) to be violated, the Secretary shall take appropriate steps to reduce spending under the projects, including through reducing the scope, site, and duration of the projects.

(5) AUTHORITY.—Beginning in 2014, the Secretary shall make necessary spending adjustments (including pro rata reductions in payments to health care providers under the medicare program) to recoup amounts so that the limitations described in subparagraphs (A) and (B) of paragraph (2) are not violated.

# Subtitle E—National Bipartisan Commission on Medicare Reform

**SEC. 241. MEDICAREADVANTAGE GOAL; ESTABLISHMENT OF COMMISSION.**

(a) ENROLLMENT GOAL.—It is the goal of this title that, not later than January 1, 2010, at least 15 percent of individuals entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act and enrolled under part B of such title should be enrolled in a MedicareAdvantage plan, as determined by the Center for Medicare Choices.

(b) FAILURE TO ACHIEVE GOAL.—If the goal described in subsection (a) is not met by January 1, 2012, as determined by the Center for Medicare Choices, there shall be established a commission as described in section 2.

**SEC. 242. NATIONAL BIPARTISAN COMMISSION ON MEDICARE REFORM.**

(a) ESTABLISHMENT.—Upon a determination under section 241(b) that the enrollment goal has not been met, there shall be established a commission to be known as the National Bipartisan Commission on Medicare Reform (in this section referred to as the ''Commission'').

(b) DUTIES OF THE COMMISSION.—The Commission shall—

(1) review and analyze the long-term financial condition of the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(2) identify problems that threaten the financial integrity of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund established under sections 1817 and 1841 of such Act (42 U.S.C. 1395i and 1395t), including—

(A) the financial impact on the medicare program of the significant increase in the number of medicare eligible individuals; and

(B) the ability of the Federal Government to sustain the program into the future;

(3) analyze potential solutions to the problems identified under paragraph (2) that will ensure both the financial integrity of the medicare program and the provision of appropriate benefits under such program, including methods used by other nations to respond to comparable demographic patterns in eligibility for health care benefits for elderly and disabled individuals and trends in employment-related health care for retirees;

(4) make recommendations to restore the solvency of the Federal Hospital Insurance Trust Fund

and the financial integrity of the Federal Supplementary Medical Insurance Trust Fund;

(5) make recommendations for establishing the appropriate financial structure of the medicare program as a whole;

(6) make recommendations for establishing the appropriate balance of benefits covered under, and beneficiary contributions to, the medicare program;

(7) make recommendations for the time periods during which the recommendations described in paragraphs (4), (5) and (6) should be implemented;

(8) make recommendations on the impact of chronic disease and disability trends on future costs and quality of services under the current benefit, financing, and delivery system structure of the medicare program;

(9) make recommendations regarding a comprehensive approach to preserve the medicare program, including ways to increase the effectiveness of the MedicareAdvantage program and to increase MedicareAdvantage enrollment rates; and

(10) review and analyze such other matters as the Commission determines appropriate.

(c) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 17 members, of whom—

(A) four shall be appointed by the President;

(B) six shall be appointed by the Majority Leader of the Senate, in consultation with the Minority Leader of the Senate, of whom not more than 4 shall be of the same political party;

(C) six shall be appointed by the Speaker of the House of Representatives, in consultation with the Minority Leader of the House of Representatives, of whom not more than 4 shall be of the same political party; and

(D) one, who shall serve as Chairperson of the Commission, shall be appointed jointly by the President, Majority Leader of the Senate, and the Speaker of the House of Representatives.

(2) DEADLINE FOR APPOINTMENT.—Members of the Commission shall be appointed by not later than October 1, 2012.

(3) TERMS OF APPOINTMENT.—The term of any member appointed under paragraph (1) shall be for the life of the Commission.

(4) MEETINGS.—The Commission shall meet at the call of the Chairperson or a majority of its members.

(5) QUORUM.—A quorum for purposes of conducting the business of the Commission shall consist of 8 members of the Commission, except that 4 members may conduct a hearing under subsection (e).

(6) VACANCIES.—A vacancy in the membership of the Commission shall be filled, not later than 30 days after the Commission is given notice of the vacancy, in the same manner in which the original appointment was made. Such a vacancy shall not affect the power of the remaining members to carry out the duties of the Commission.

(7) COMPENSATION.—Members of the Commission shall receive no additional pay, allowances, or benefits by reason of their service on the Commission.

(8) EXPENSES.—Each member of the Commission shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

(d) STAFF AND SUPPORT SERVICES.—

(1) EXECUTIVE DIRECTOR.—

(A) APPOINTMENT.—The Chairperson shall appoint an executive director of the Commission.

(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule under title 5, United States Code.

(2) STAFF.—With the approval of the Commission, the executive director may appoint such personnel as the executive director considers appropriate.

(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

(4) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(5) PHYSICAL FACILITIES.—The Administrator of the General Services Administration shall locate

suitable office space for the operation of the Commission. The facilities shall serve as the headquarters of the Commission and shall include all necessary equipment and incidentals required for the proper functioning of the Commission.

(e) POWERS OF COMMISSION.—

(1) HEARINGS AND OTHER ACTIVITIES.—The Commission may hold such hearings and undertake such other activities as the Commission determines to be necessary to carry out its duties under this section.

(2) STUDIES BY GAO.—Upon the request of the Commission, the Comptroller General shall conduct such studies or investigations as the Commission determines to be necessary to carry out its duties under this section.

(3) COST ESTIMATES BY CONGRESSIONAL BUDGET OFFICE AND OFFICE OF THE CHIEF ACTUARY OF THE CENTERS FOR MEDICARE & MEDICAID.—

(A) IN GENERAL.—The Director of the Congressional Budget Office or the Chief Actuary of the Center for Medicare & Medicaid Services, or both, shall provide to the Commission, upon the request of the Commission, such

cost estimates as the Commission determines to be necessary to carry out its duties under this section.

(B) REIMBURSEMENTS.—The Commission shall reimburse the Director of the Congressional Budget Office for expenses relating to the employment in the office of the Director of such additional staff as may be necessary for the Director to comply with requests by the Commission under subparagraph (A).

(4) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the Commission, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the Commission to assist the Commission in carrying out its duties under this section. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

(5) TECHNICAL ASSISTANCE.—Upon the request of the Commission, the head of a Federal agency shall provide such technical assistance to the Commission as the Commission determines to be necessary to carry out its duties under this section.

(6) USE OF MAILS.—The Commission may use the United States mails in the same manner and

under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

(7) OBTAINING INFORMATION.—The Commission may secure directly from any Federal agency information necessary to enable it to carry out its duties under this section, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairperson of the Commission, the head of each such agency shall furnish such information to the Commission.

(8) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

(9) PRINTING.—For purposes of costs relating to printing and binding, including the cost of personnel detailed from the Government Printing Office, the Commission shall be deemed to be a committee of Congress.

(f) REPORT.—Not later than April 1, 2014, the Commission shall submit to the President and Congress a report and an implementation bill that shall contain a de-

tailed statement of only those recommendations, findings, and conclusions of the Commission that receive the approval of at least 11 members of the Commission.

(g) TERMINATION.—The Commission shall terminate on the date that is 30 days after the date on which the report and implementation bill is submitted under subsection (f).

**SEC. 243. CONGRESSIONAL CONSIDERATION OF REFORM PROPOSALS.**

(a) DEFINITIONS.—In this section:

(1) IMPLEMENTATION BILL.—The term ''implementation bill'' means only a bill that is introduced as provided under subsection (b), and contains the proposed legislation included in the report submitted to Congress under section 242(f), without modification.

(2) CALENDAR DAY.—The term ''calendar day'' means a calendar day other than 1 on which either House is not in session because of an adjournment of more than 3 days to a date certain.

(b) INTRODUCTION; REFERRAL; AND REPORT OR DISCHARGE.—

(1) INTRODUCTION.—On the first calendar day on which both Houses are in session immediately following the date on which the report is submitted to

Congress under section 242(f), a single implementation bill shall be introduced (by request)—

(A) in the Senate by the Majority Leader of the Senate, for himself and the Minority Leader of the Senate, or by Members of the Senate designated by the Majority Leader and Minority Leader of the Senate; and

(B) in the House of Representatives by the Speaker of the House of Representatives, for himself and the Minority Leader of the House of Representatives, or by Members of the House of Representatives designated by the Speaker and Minority Leader of the House of Representatives.

(2) REFERRAL.—The implementation bills introduced under paragraph (1) shall be referred to any appropriate committee of jurisdiction in the Senate and any appropriate committee of jurisdiction in the House of Representatives. A committee to which an implementation bill is referred under this paragraph may report such bill to the respective House without amendment.

(3) REPORT OR DISCHARGE.—If a committee to which an implementation bill is referred has not reported such bill by the end of the 15th calendar day

after the date of the introduction of such bill, such committee shall be immediately discharged from further consideration of such bill, and upon being reported or discharged from the committee, such bill shall be placed on the appropriate calendar.

(c) FLOOR CONSIDERATION.—

(1) IN GENERAL.—When the committee to which an implementation bill is referred has reported, or has been discharged under subsection (b)(3), it is at any time thereafter in order (even though a previous motion to the same effect has been disagreed to) for any Member of the respective House to move to proceed to the consideration of the implementation bill, and all points of order against the implementation bill (and against consideration of the implementation bill) are waived. The motion is highly privileged in the House of Representatives and is privileged in the Senate. The motion is not subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the implementation bill is agreed to, the

implementation bill shall remain the unfinished business of the respective House until disposed of.

(2) AMENDMENTS.—An implementation bill may not be amended in the Senate or the House of Representatives.

(3) DEBATE.—Debate on the implementation bill, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 20 hours, which shall be divided equally between those favoring and those opposing the resolution. A motion further to limit debate is in order and not debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommit the implementation bill is not in order. A motion to reconsider the vote by which the implementation bill is agreed to or disagreed to is not in order.

(4) VOTE ON FINAL PASSAGE.—Immediately following the conclusion of the debate on an implementation bill, and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the appropriate House, the vote on final passage of the implementation bill shall occur.

(5) RULINGS OF THE CHAIR ON PROCEDURE.—Appeals from the decisions of the Chair relating to

the application of the rules of the Senate or the House of Representatives, as the case may be, to the procedure relating to an implementation bill shall be decided without debate.

(d) COORDINATION WITH ACTION BY OTHER HOUSE.—If, before the passage by 1 House of an implementation bill of that House, that House receives from the other House an implementation bill, then the following procedures shall apply:

(1) NONREFERRAL.—The implementation bill of the other House shall not be referred to a committee.

(2) VOTE ON BILL OF OTHER HOUSE.—With respect to an implementation bill of the House receiving the implementation bill—

(A) the procedure in that House shall be the same as if no implementation bill had been received from the other House; but

(B) the vote on final passage shall be on the implementation bill of the other House.

(e) RULES OF SENATE AND HOUSE OF REPRESENTATIVES.—This section is enacted by Congress—

(1) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed a part of the rules

of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of an implementation bill described in subsection (a), 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 either House to change the rules (so far as relating to the procedure 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. 244. AUTHORIZATION OF APPROPRIATIONS.**

There are authorized to be appropriated such sums as may be necessary to carry out this subtitle for each of fiscal years 2012 through 2013.

# TITLE III—CENTER FOR MEDICARE CHOICES

**SEC. 301. ESTABLISHMENT OF THE CENTER FOR MEDICARE CHOICES.**

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by section 111, is amended by inserting after 1806 the following new section:

"ESTABLISHMENT OF THE CENTER FOR MEDICARE CHOICES

"SEC. 1808. (a) ESTABLISHMENT.—By not later than March 1, 2004, the Secretary shall establish within

the Department of Health and Human Services the Center for Medicare Choices, which shall be separate from the Centers for Medicare & Medicaid Services.

"(b) ADMINISTRATOR AND DEPUTY ADMINISTRATOR.—

"(1) ADMINISTRATOR.—

"(A) IN GENERAL.—The Center for Medicare Choices shall be headed by an Administrator (in this section referred to as the 'Administrator') who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall report directly to the Secretary.

"(B) COMPENSATION.—The Administrator shall be paid at the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Administrator shall be appointed for a term of 5 years. In any case in which a successor does not take office at the end of an Administrator's term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator appointed to a term of office after the commencement of such term

may serve under such appointment only for the remainder of such term.

"(D) GENERAL AUTHORITY.—The Administrator shall be responsible for the exercise of all powers and the discharge of all duties of the Center for Medicare Choices, and shall have authority and control over all personnel and activities thereof.

"(E) RULEMAKING AUTHORITY.—The Administrator may prescribe such rules and regulations as the Administrator determines necessary or appropriate to carry out the functions of the Center for Medicare Choices. The regulations prescribed by the Administrator shall be subject to the rulemaking procedures established under section 553 of title 5, United States Code.

"(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL UNITS.—The Administrator may establish, alter, consolidate, or discontinue such organizational units or components within the Center for Medicare Choices as the Administrator considers necessary or appropriate, except that this subparagraph shall not apply

with respect to any unit, component, or provision provided for by this section.

"(G) AUTHORITY TO DELEGATE.—The Administrator may assign duties, and delegate, or authorize successive redelegations of, authority to act and to render decisions, to such officers and employees of the Center for Medicare Choices as the Administrator may find necessary. Within the limitations of such delegations, redelegations, or assignments, all official acts and decisions of such officers and employees shall have the same force and effect as though performed or rendered by the Administrator.

"(2) DEPUTY ADMINISTRATOR.—

"(A) IN GENERAL.—There shall be a Deputy Administrator of the Center for Medicare Choices who shall be appointed by the Administrator.

"(B) COMPENSATION.—The Deputy Administrator shall be paid at the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Deputy Administrator shall be appointed for a term of 5 years. In any case in which a successor does not take office at the end of a Deputy Administrator's term of office, such Deputy Administrator may continue in office until the entry upon office of such a successor. A Deputy Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) DUTIES.—The Deputy Administrator shall perform such duties and exercise such powers as the Administrator shall from time to time assign or delegate. The Deputy Administrator shall be the Acting Administrator of the Center for Medicare Choices during the absence or disability of the Administrator and, unless the President designates another officer of the Government as Acting Administrator, in the event of a vacancy in the office of the Administrator.

"(3) SECRETARIAL COORDINATION OF PROGRAM ADMINISTRATION.—The Secretary shall ensure appropriate coordination between the Administrator

and the Administrator of the Centers for Medicare & Medicaid Services in carrying out the programs under this title.

"(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

"(1) DUTIES.—

"(A) GENERAL DUTIES.—The Administrator shall carry out parts C and D, including—

"(i) negotiating, entering into, and enforcing, contracts with plans for the offering of MedicareAdvantage plans under part C, including the offering of qualified prescription drug coverage under such plans; and

"(ii) negotiating, entering into, and enforcing, contracts with eligible entities for the offering of Medicare Prescription Drug plans under part D.

"(B) OTHER DUTIES.—The Administrator shall carry out any duty provided for under part C or D, including duties relating to—

"(i) reasonable cost contracts with eligible organizations under section 1876(h); and

"(ii) demonstration projects carried out in part or in whole under such parts, including the demonstration project carried out through a MedicareAdvantage (formerly Medicare+Choice) project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of an interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved.

"(C) NONINTERFERENCE.—In order to promote competition under parts C and D, the Administrator, in carrying out the duties required under this section, may not, to the extent possible, interfere in any way with negotiations between eligible entities, MedicareAdvantage organizations, hospitals, physicians, other entities or individuals furnishing items and services under this title (including contractors for such items and services), and drug manufacturers, wholesalers, or other suppliers of covered drugs

"(D) ANNUAL REPORTS.—Not later than March 31 of each year, the Administrator shall submit to Congress and the President a report on the administration of the voluntary prescription drug delivery program under this part during the previous fiscal year.

"(2) MANAGEMENT STAFF.—

"(A) IN GENERAL.—The Administrator, with the approval of the Secretary, may employ, such management staff as determined appropriate. Any such manager shall be required to have demonstrated, by their education and experience (either in the public or private sector), superior expertise in the following areas:

"(i) The review, negotiation, and administration of health care contracts.

"(ii) The design of health care benefit plans.

"(iii) Actuarial sciences.

"(iv) Compliance with health plan contracts.

"(v) Consumer education and decision making.

"(B) COMPENSATION.—

"(i) IN GENERAL.—Subject to clause (ii), the Administrator shall establish the rate of pay for an individual employed under subparagraph (A).

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

"(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

"(A) IN GENERAL.—The Secretary, the Administrator of the Center for Medicare Choices, and the Administrator of the Centers for Medicare & Medicaid Services shall establish an appropriate transition of responsibility in order to redelegate the administration of part C from the Secretary and the Administrator of the Centers for Medicare & Medicaid Services to the Administrator of the Center for Medicare Choices as is appropriate to carry out the purposes of this section.

"(B) TRANSFER OF DATA AND INFORMATION.—The Secretary shall ensure that the Administrator of the Centers for Medicare & Medicaid Services transfers to the Administrator such information and data in the possession of the Administrator of the Centers for Medicare & Medicaid Services as the Administrator requires to carry out the duties described in paragraph (1).

"(C) CONSTRUCTION.—Insofar as a responsibility of the Secretary or the Administrator of the Centers for Medicare & Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare & Medicaid Services in this title or title XI with respect to such responsibility is deemed to be a reference to the Administrator.

"(d) OFFICE OF BENEFICIARY ASSISTANCE.—

"(1) ESTABLISHMENT.—The Secretary shall establish within the Center for Medicare Choices an Office of Beneficiary Assistance to carry out functions relating to medicare beneficiaries under this title, including making determinations of eligibility of individuals for benefits under this title, providing

for enrollment of medicare beneficiaries under this title, and the functions described in paragraph (2). The Office shall be a separate operating division within the Center for Medicare Choices.

"(2) DISSEMINATION OF INFORMATION ON BENEFITS AND APPEALS RIGHTS.—

"(A) DISSEMINATION OF BENEFITS INFORMATION.—The Office of Beneficiary Assistance shall disseminate to medicare beneficiaries, by mail, by posting on the Internet site of the Center for Medicare Choices, and through the toll-free telephone number provided for under section 1804(b), information with respect to the following:

"(i) Benefits, and limitations on payment (including cost-sharing, stop-loss provisions, and formulary restrictions) under parts C and D.

"(ii) Benefits, and limitations on payment under parts A, and B, including information on medicare supplemental policies under section 1882.

"(iii) Other areas determined to be appropriate by the Administrator.

Such information shall be presented in a manner so that medicare beneficiaries may compare benefits under parts A, B, and D, and medicare supplemental policies with benefits under MedicareAdvantage plans under part C.

"(B) DISSEMINATION OF APPEALS RIGHTS INFORMATION.—The Office of Beneficiary Assistance shall disseminate to medicare beneficiaries in the manner provided under subparagraph (A) a description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program under parts A and B, the MedicareAdvantage program under part C, and the voluntary prescription drug delivery program under part D.

"(3) MEDICARE OMBUDSMAN.—

"(A) IN GENERAL.—Within the Office of Beneficiary Assistance, there shall be a Medicare Ombudsman, appointed by the Secretary from among individuals with expertise and experience in the fields of health care and advocacy, to carry out the duties described in subparagraph (B).

1 "(B) DUTIES.—The Medicare Ombudsman
2 shall—
3 "(i) receive complaints, grievances,
4 and requests for information submitted by
5 a medicare beneficiary, with respect to any
6 aspect of the medicare program;
7 "(ii) provide assistance with respect to
8 complaints, grievances, and requests re-
9 ferred to in clause (i), including—
10 "(I) assistance in collecting rel-
11 evant information for such bene-
12 ficiaries, to seek an appeal of a deci-
13 sion or determination made by a fiscal
14 intermediary, carrier,
15 MedicareAdvantage organization, an
16 eligible entity under part D, or the
17 Secretary; and
18 "(II) assistance to such bene-
19 ficiaries with any problems arising
20 from disenrollment from a
21 MedicareAdvantage plan under part C
22 or a prescription drug plan under part
23 D; and
24 "(iii) submit annual reports to Con-
25 gress, the Secretary, and the Medicare

Competitive Policy Advisory Board describing the activities of the Office, and including such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

"(C) COORDINATION WITH STATE OMBUDSMAN PROGRAMS AND CONSUMER ORGANIZATIONS.—The Medicare Ombudsman shall, to the extent appropriate, coordinate with State medical Ombudsman programs, and with State- and community-based consumer organizations, to—

"(i) provide information about the medicare program; and

"(ii) conduct outreach to educate medicare beneficiaries with respect to manners in which problems under the medicare program may be resolved or avoided.

"(e) MEDICARE COMPETITIVE POLICY ADVISORY BOARD.—

"(1) ESTABLISHMENT.—There is established within the Center for Medicare Choices the Medicare Competitive Policy Advisory Board (in this section referred to as the 'Board'). The Board shall advise, consult with, and make recommendations to the Ad-

ministrator with respect to the administration of parts C and D, including the review of payment policies under such parts.

"(2) REPORTS.—

"(A) IN GENERAL.—With respect to matters of the administration of parts C and D, the Board shall submit to Congress and to the Administrator such reports as the Board determines appropriate. Each such report may contain such recommendations as the Board determines appropriate for legislative or administrative changes to improve the administration of such parts, including the stability and solvency of the programs under such parts and the topics described in subparagraph (B). Each such report shall be published in the Federal Register.

"(B) TOPICS DESCRIBED.—Reports required under subparagraph (A) may include the following topics:

"(i) FOSTERING COMPETITION.—Recommendations or proposals to increase competition under parts C and D for services furnished to medicare beneficiaries.

"(ii) EDUCATION AND ENROLLMENT.—Recommendations for the improvement of efforts to provide medicare beneficiaries information and education on the program under this title, and specifically parts C and D, and the program for enrollment under the title.

"(iii) QUALITY.—Recommendations on ways to improve the quality of benefits provided under plans under parts C and D.

"(iv) DISEASE MANAGEMENT PROGRAMS.—Recommendations on the incorporation of disease management programs under parts C and D.

"(v) RURAL ACCESS.—Recommendations to improve competition and access to plans under parts C and D in rural areas.

"(C) MAINTAINING INDEPENDENCE OF BOARD.—The Board shall directly submit to Congress reports required under subparagraph (A). No officer or agency of the United States may require the Board to submit to any officer or agency of the United States for approval, comments, or review, prior to the submission to Congress of such reports.

"(3) DUTY OF ADMINISTRATOR.—With respect to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report is submitted, the Administrator shall submit to Congress and the President an analysis of recommendations made by the Board in such report. Each such analysis shall be published in the Federal Register.

"(4) MEMBERSHIP.—

"(A) APPOINTMENT.—Subject to the succeeding provisions of this paragraph, the Board shall consist of 7 members to be appointed as follows:

"(i) Three members shall be appointed by the President.

"(ii) Two members shall be appointed by the Speaker of the House of Representatives, with the advice of the chairman and the ranking minority member of the Committees on Ways and Means and on Energy and Commerce of the House of Representatives.

"(iii) Two members shall be appointed by the President pro tempore of the Senate with the advice of the chairman and the

ranking minority member of the Committee on Finance of the Senate.

"(B) QUALIFICATIONS.—The members shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education and experience in health care benefits management, exceptionally qualified to perform the duties of members of the Board.

"(C) PROHIBITION ON INCLUSION OF FEDERAL EMPLOYEES.—No officer or employee of the United States may serve as a member of the Board.

"(5) COMPENSATION.—Members of the Board shall receive, for each day (including travel time) they are engaged in the performance of the functions of the Board, compensation at rates not to exceed the daily equivalent to the annual rate in effect for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(6) TERMS OF OFFICE.—

"(A) IN GENERAL.—The term of office of members of the Board shall be 3 years.

"(B) TERMS OF INITIAL APPOINTEES.—As designated by the President at the time of appointment, of the members first appointed—

"(i) one shall be appointed for a term of 1 year;

"(ii) three shall be appointed for terms of 2 years; and

"(iii) three shall be appointed for terms of 3 years.

"(C) REAPPOINTMENTS.—Any person appointed as a member of the Board may not serve for more than 8 years.

"(D) VACANCY.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Board shall be filled in the manner in which the original appointment was made.

"(7) CHAIR.—The Chair of the Board shall be elected by the members. The term of office of the Chair shall be 3 years.

"(8) MEETINGS.—The Board shall meet at the call of the Chair, but in no event less than 3 times during each fiscal year.

"(9) DIRECTOR AND STAFF.—

"(A) APPOINTMENT OF DIRECTOR.—The Board shall have a Director who shall be appointed by the Chair.

"(B) IN GENERAL.—With the approval of the Board, the Director may appoint such additional personnel as the Director considers appropriate.

"(C) ASSISTANCE FROM THE ADMINISTRATOR.—The Administrator shall make available to the Board such information and other assistance as it may require to carry out its functions.

"(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

"(f) FUNDING.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription

Drug Account), such sums as are necessary to carry out this section.''.

(b) USE OF CENTRAL, TOLL-FREE NUMBER (1–800–MEDICARE).—Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by adding at the end the following: ''By not later than 1 year after the date of the enactment of the Prescription Drug and Medicare Improvement Act of 2003, the Secretary shall provide, through the toll-free number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.''.

**SEC. 302. MISCELLANEOUS ADMINISTRATIVE PROVISIONS.**

(a) ADMINISTRATOR AS MEMBER AND CO-SECRETARY OF THE BOARD OF TRUSTEES OF THE MEDICARE TRUST FUNDS.—The fifth sentence of sections 1817(b) and 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each amended by striking ''shall serve as the Secretary'' and inserting ''and the Administrator of the Center for Medicare Choices shall serve as the Co-Secretaries''.

(b) 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 March 1, 2004.

# TITLE IV—MEDICARE FEE-FOR-SERVICE IMPROVEMENTS

## Subtitle A—Provisions Relating to Part A

### 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 applicable 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) APPLICATION TO SUBSECTION (D) PUERTO RICO HOSPITALS.—Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking ''and'' after the comma at the end;

(B) in clause (ii)—

(i) in the matter preceding subclause (I), by inserting ''and before October 1, 2003'' after ''October 1, 1997''; and

(ii) in the matter following clause (III), by striking the period at the end and inserting '', and''; and

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

''(iii) for discharges in a fiscal year beginning on or after October 1, 2003, 50 percent of the national standardized rate (determined under paragraph (3)(D)(iii)) for hospitals located in any area.'';

(2) in subparagraph (C)—

(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:

''(II) For discharges in 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 an urban area, increased by the applicable percentage increase under subsection (b)(3)(B) for fiscal year 2004.

''(III) For discharges in a fiscal year after fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in any are of Puerto Rico that is equal to the average standardized amount computed under subclause (II) or this subclause for the previous fiscal year, increased by the applicable percentage increase under subsection (b)(3)(B), adjusted to reflect the most recent case mix data.'';

(B) in clause (ii), by inserting ''(or for fiscal year 2004 and thereafter, the 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''.

(c) CONFORMING AMENDMENTS.—

(1) COMPUTING DRG-SPECIFIC RATES.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

(A) in the heading, by striking ''IN DIFFERENT AREAS'';

(B) in the matter preceding clause (i), by striking ‘‘, each of’’;

(C) in clause (i)—

(i) in the matter preceding subclause (I), by inserting ‘‘for fiscal years before fiscal year 2004,’’ before ‘‘for hospitals’’; and

(ii) in subclause (II), by striking ‘‘and’’ after the semicolon at the end;

(D) in clause (ii)—

(i) in the matter preceding subclause (I), by inserting ‘‘for fiscal years before fiscal year 2004,’’ before ‘‘for hospitals’’; and

(ii) in subclause (II), by striking the period at the end and inserting ‘‘; and’’; and

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

‘‘(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

‘‘(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

"(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.".

(2) TECHNICAL CONFORMING SUNSET.—Section 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting ", for fiscal years before fiscal year 1997," before "a regional adjusted DRG prospective payment rate"; and

(B) in subparagraph (D), in the matter preceding clause (i), by inserting ", for fiscal years before fiscal year 1997," before "a regional DRG prospective payment rate for each region,".

**SEC. 402. ADJUSTMENT TO THE MEDICARE INPATIENT HOSPITAL PPS WAGE INDEX TO REVISE THE LABOR-RELATED SHARE OF SUCH INDEX.**

(a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(1) by striking "WAGE LEVELS.—The Secretary" and inserting "WAGE LEVELS.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary"; and

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

"(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2005.—

"(I) IN GENERAL.—Except as provided in 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).

"(II) HOLD HARMLESS FOR CERTAIN HOSPITALS.—If the application of subclause (I) would result in lower payments to a hospital than would otherwise be made, then this subparagraph shall be applied as if this clause had not been enacted.".

(b) WAIVING BUDGET NEUTRALITY.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended by subsection (a), is amended by adding at the end of clause (i) the following new sentence: "The Secretary shall apply the previous sentence for any period as if the amendments made by section 402(a) of the Prescription Drug and Medicare Improvement Act of 2003 had not been enacted.".

**SEC. 403. MEDICARE INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.**

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

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

"(A) PAYMENT ADJUSTMENT.—

"(i) IN GENERAL.—Notwithstanding any other provision of this section, for each cost reporting period (beginning with the cost reporting period that begins in fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in clause (iii)) for discharges occurring during that cost reporting period which is equal to the applicable percentage increase (determined under clause (ii)) in the amount paid to such hospital under this section for such discharges.

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

"(I) no percentage increase in payments under this paragraph ex-

ceeds 25 percent of the amount of payment that would (but for this paragraph) otherwise be made to a low-volume hospital under this section for each discharge;

"(II) low-volume hospitals that have the lowest number of discharges during a cost reporting period receive the highest percentage increases in payments due to the application of this paragraph; and

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

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

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

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

"(B) PROHIBITING CERTAIN REDUCTIONS.—Notwithstanding subsection (e), the

Secretary shall not reduce the payment amounts under this section to offset the increase in payments resulting from the application of subparagraph (A).''.

**SEC. 404. FAIRNESS IN THE MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT FOR RURAL HOSPITALS.**

(a) EQUALIZING DSH PAYMENT AMOUNTS.—

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

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

(A) in clause (iv)—

(i) in subclause (II)—

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

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

ble formula described in clause (vii)'' after ''clause (xiii)'';

(ii) in subclause (III)—

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

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

(iii) in subclause (IV)—

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

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

(iv) in subclause (V)—

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

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

(v) in subclause (VI)—

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

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

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

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking ''For purposes'' and inserting

"With respect to discharges occurring before October 1, 2004, for purposes".

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

**SEC. 404A. MEDPAC STUDY AND REPORT REGARDING MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT PAYMENTS.**

(a) STUDY.—The Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) (in this section referred to as "MedPAC") shall conduct a study to determine, with respect to additional payment amounts paid to subsection (d) hospitals under section 1886(d)(5)(F) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F))—

(1) whether such payments should be made in the same manner as payments are made with respect to graduate medical education under title XVIII and with respect to hospitals that serve a disproportionate share of low-income patients under the medicaid program; and

(2) whether to add costs attributable to uncompensated care to the formula for determining such payment amounts.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, MedPAC shall submit a report to Congress on the study conducted under subsection (a), together with such recommendations for legislation as MedPAC determines are appropriate.

**SEC. 405. CRITICAL ACCESS HOSPITAL (CAH) IMPROVEMENTS.**

(a) PERMITTING CAHS TO ALLOCATE SWING BEDS AND ACUTE CARE INPATIENT BEDS SUBJECT TO A TOTAL LIMIT OF 25 BEDS.—

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

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

(2) CONFORMING AMENDMENT.—Section 1820(f) (42 U.S.C. 1395i–4(f)) is amended by striking "and the number of beds used at any time for

acute care inpatient services does not exceed 15 beds''.

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

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

(1) ELIMINATION.—

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

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

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

(c) 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 to costs incurred for services provided on or after January 1, 2005.

(d) AUTHORIZATION OF PERIODIC INTERIM PAYMENT (PIP).—

(1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is amended—

(A) in subparagraph (C), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (D), by adding ''and'' after the semicolon at the end; and

(C) by inserting after subparagraph (D) the following new subparagraph:

''(E) inpatient critical access hospital services;''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for inpatient critical access facility services furnished on or after January 1, 2005.

(e) EXCLUSION OF NEW CAHS FROM PPS HOSPITAL WAGE INDEX CALCULATION.—Section 1886(d)(3)(E)(i) (42 U.S.C. 1395ww(d)(3)(E)(i)), as amended by section 402, is amended by inserting after the first sentence the following new sentence: ''In calculating the hospital wage levels under the preceding sentence applicable with respect to cost reporting periods beginning on or after January 1, 2004, the Secretary shall exclude the wage levels of any facility that became a critical access hospital prior to the cost reporting period for which such hospital wage levels are calculated.''.

(f) PROVISIONS RELATED TO CERTAIN RURAL GRANTS.—

(1) SMALL RURAL HOSPITAL IMPROVEMENT PROGRAM.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended—

(A) by redesignating paragraph (3)(F) as paragraph (5) and redesignating and indenting appropriately; and

(B) by inserting after paragraph (3) the following new paragraph:

"(4) SMALL RURAL HOSPITAL IMPROVEMENT PROGRAM.—

"(A) GRANTS TO HOSPITALS.—The Secretary may award grants to hospitals that have submitted applications in accordance with subparagraph (B) to assist eligible small rural hospitals (as defined in paragraph (3)(B)) in meeting the costs of reducing medical errors, increasing patient safety, protecting patient privacy, and improving hospital quality and performance.

"(B) APPLICATION.—A hospital seeking a grant under this paragraph shall submit an application to the Secretary on or before such date and in such form and manner as the Secretary specifies.

"(C) AMOUNT OF GRANT.—A grant to a hospital under this paragraph may not exceed $50,000.

"(D) USE OF FUNDS.—A hospital receiving a grant under this paragraph may use the funds for the purchase of computer software and hardware, the education and training of hospital staff, and obtaining technical assistance.".

(2) AUTHORIZATION FOR APPROPRIATIONS.—Section 1820(j) (42 U.S.C. 1395i–4(j)) is amended to read as follows:

"(j) AUTHORIZATION OF APPROPRIATIONS.—

"(1) HI TRUST FUND.—There are authorized to be appropriated from the Federal Hospital Insurance Trust Fund for making grants to all States under—

"(A) subsection (g), $25,000,000 in each of the fiscal years 1998 through 2002; and

"(B) paragraphs (1) and (2) of subsection (g), $40,000,000 in each of the fiscal years 2004 through 2008.

"(2) GENERAL REVENUES.—There are authorized to be appropriated from amounts in the Treasury not otherwise appropriated for making grants to all States under subsection (g)(4), $25,000,000 in each of the fiscal years 2004 through 2008.".

(3) REQUIREMENT THAT STATES AWARDED GRANTS CONSULT WITH THE STATE HOSPITAL ASSOCIATION AND RURAL HOSPITALS ON THE MOST APPROPRIATE WAYS TO USE SUCH GRANTS.—

(A) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i–4(g)), as amended by paragraph (1), is amended by adding at the end the following new paragraph:

''(6) REQUIRED CONSULTATION FOR STATES AWARDED GRANTS.—A State awarded a grant under paragraph (1) or (2) 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) EFFECTIVE DATE AND APPLICATION.—The amendment made by subparagraph (A) shall take effect on the date of enactment of this Act and shall apply to grants awarded on or after such date and to grants awarded prior to such date to the extent that funds under such grants have not been obligated as of such date.

(g) EXCLUSION OF CERTAIN BEDS FROM BED COUNT AND REMOVAL OF BARRIERS TO ESTABLISHMENT OF DISTINCT PART UNITS.—

(1) EXCLUSION OF CERTAIN BEDS FROM BED COUNT.—Section 1820(c)(2) (42 U.S.C. 1395i–4(c)(2)) is amended by adding at the end the following:

"(E) EXCLUSION OF CERTAIN BEDS FROM BED COUNT.—In determining the number of beds of a facility 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 of a distinct part psychiatric or rehabilitation unit (described in the matter following clause (v) of section 1886(d)(1)(B)) of the facility, except that the total number of beds that are not taken into account pursuant to this subparagraph with respect to a facility shall not exceed 25.".

(2) REMOVING BARRIERS TO ESTABLISHMENT OF DISTINCT PART UNITS BY CRITICAL ACCESS HOSPITALS.—Section 1886(d)(1)(B) (42 U.S.C. 195ww(d)(1)(B)) is amended by striking "a distinct part of the hospital (as defined by the Secretary)" in the matter following cause (v) and inserting "a distinct part (as defined by the Secretary) of the hospital or of a critical access hospital".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to determinations with respect to distinct part unit status, and with respect to designations, that are made on or after October 1, 2003.

**SEC. 406. 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-rou-

tinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.''.

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

''(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after October 1, 2004.

**SEC. 407. SERVICES PROVIDED TO HOSPICE PATIENTS BY NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND PHYSICIAN ASSISTANTS.**

(a) IN GENERAL.—Section 1812(d)(2)(A) (42 U.S.C. 1395d(d)(2)(A) in the matter following clause (i)(II), is amended—

(1) by inserting ''or services described in section 1861(s)(2)(K)'' after ''except that clause (i) shall not apply to physicians' services''; and

(2) by inserting '', or by a physician assistant, nurse practitioner, or clinical nurse specialist whom

is not an employee of the hospice program, and who the individual identifies as the health care provider having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care,'' after the ''(if not an employee of the hospice program)''.

(b) PERMITTING NURSE PRACTITIONERS, PHYSICIAN ASSISTANTS, AND CLINICAL NURSE SPECIALIST TO REVIEW HOSPICE PLANS OF CARE.—Section 1814(a)(7)(B) is amended by inserting ''(or by a physician assistant, nurse practitioner or clinical nurse specialist who is not an employee of the hospice program, and whom the individual identifies as the health care provider having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care)'' after ''and is periodically reviewed by the individual's attending physician''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care furnished on or after October 1, 2004.

**SEC. 408. AUTHORITY TO INCLUDE COSTS OF TRAINING OF PSYCHOLOGISTS IN PAYMENTS TO HOSPITALS UNDER MEDICARE.**

Effective for cost reporting periods beginning on or after October 1, 2004, for purposes of payments to hospitals under the medicare program under title XVIII of the Social Security Act for costs of approved educational activities (as defined in section 413.85 of title 42 of the Code of Federal Regulations), such approved educational activities shall include professional educational training programs, recognized by the Secretary, for psychologists.

**SEC. 409. REVISION OF 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 Sep-

tember 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) between October 1, 1987, and September 30, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

''(ii) on or after October 1, 1997, and before October 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

''(iii) on or after October 1, 2004, and before October 1, 2009, the applicable Puerto Rico percentage is 0 percent and the applicable Federal percentage is 100 percent; and

''(iv) on or after October 1, 2009, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent.''.

**SEC. 410. 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. 411. CLARIFICATION OF CONGRESSIONAL INTENT REGARDING THE COUNTING OF RESIDENTS IN A NONPROVIDER SETTING AND A TECHNICAL AMENDMENT REGARDING THE 3-YEAR ROLLING AVERAGE AND THE IME RATIO.**

(a) CLARIFICATION OF REQUIREMENTS FOR COUNTING RESIDENTS TRAINING IN NONPROVIDER SETTING.—

(1) D–GME.—Section 1886(h)(4)(E) (42 U.S.C. 1395ww(h)(4)(E)) is amended by adding at the end the following new sentence: For purposes of the preceding sentence time shall only be counted from the effective date of a written agreement between the hospital and the entity owning or operating a nonprovider setting. The effective date of such written agreement shall be determined in accordance with generally accepted accounting principles. All, or substantially all, of the costs for the training program in that setting shall be defined as the residents' stipends and benefits and other costs, if any, as determined by the parties.''.

(2) IME.—Section 1886(d)(5)(B)(iv) (42 U.S.C. 1395ww(d)(5)(B)(iv)) is amended by adding at the end the following new sentence: For purposes of the preceding sentence time shall only be counted from the effective date of a written agreement between the hospital and the entity owning or oper-

ating a nonprovider setting. The effective date of such written agreement shall be determined in accordance with generally accepted accounting principles. All, or substantially all, of the costs for the training program in that setting shall be defined as the residents' stipends and benefits and other costs, if any, as determined by the parties.''.

(b) LIMITING ONE-YEAR LAG IN THE INDIRECT MEDICAL EDUCATION (IME) RATIO AND THREE-YEAR ROLLING AVERAGE IN RESIDENT COUNT FOR IME AND FOR DIRECT GRADUATE MEDICAL EDUCATION (D–GME) TO MEDICAL RESIDENCY PROGRAMS.—

(1) IME RATIO AND IME ROLLING AVERAGE.—Section 1886(d)(5)(B)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(vi)) is amended by adding at the end the following new sentence: ''For cost reporting periods beginning during fiscal years beginning on or after October 1, 2004, subclauses (I) and (II) shall be applied only with respect to a hospital's approved medical residency training programs in the fields of allopathic and osteopathic medicine.''.

(2) D–GME ROLLING AVERAGE.—Section 1886(h)(4)(G) of the Social Security Act (42 U.S.C.

1395ww(h)(4)(G)) is amended by adding at the end the following new clause:

"(iv) APPLICATION FOR FISCAL YEAR 2004 AND SUBSEQUENT YEARS.—For cost reporting periods beginning during fiscal years beginning on or after October 1, 2004, clauses (i) through (iii) shall be applied only with respect to a hospital's approved medical residency training program in the fields of allopathic and osteopathic medicine.".

**SEC. 412. 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)) is amended—

(1) in subparagraph (R), by striking "and" at the end;

(2) in subparagraph (S), by striking the period and inserting ", and"; and

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

"(T) 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—

"(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 a 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 6 months after the date of enactment of this Act) to medicare participation agreements in effect (or entered into) on or after such date.

**SEC. 413. GAO STUDY AND REPORT ON APPROPRIATENESS OF PAYMENTS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES.**

(a) STUDY.—The Comptroller General of the United States, using the most current data available, shall conduct a study to determine—

(1) 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

(2) 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.

(b) REPORT.—Not later than 24 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) together with such recommendations for legislative and administrative action as the Comptroller General determines appropriate.

**SEC. 414. 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 that furnish rural community hospital services to medicare beneficiaries.

(2) DESIGNATION OF RCHS.—

(A) APPLICATION.—Each hospital that is located in a demonstration area described in subparagraph (C) 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.

(B) DESIGNATION.—The Secretary shall designate any hospital that is located in a dem-

onstration area described in subparagraph (C), submits an application in accordance with subparagraph (A), and meets the other requirements of this section as a rural community hospital for purposes of the demonstration program.

(C) DEMONSTRATION AREAS.—There shall be four demonstration areas within this program. Two of these demonstration areas described in this subparagraph shall include Kansas and Nebraska.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period.

(4) 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) INPATIENT HOSPITAL SERVICES.—The amount of payment under the demonstration program for 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, at the elec-

tion of the hospital in the application referred to in subsection (a)(2)(A)—

(A) the reasonable costs of providing such services, without regard to the amount of the customary or other charge; or

(B) the amount of payment provided for under the prospective payment system for inpatient hospital services under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)).

(2) OUTPATIENT SERVICES.—The amount of payment under the demonstration program for outpatient services furnished in a rural community hospital is, at the election of the hospital in the application referred to in subsection (a)(2)(A)—

(A) the reasonable costs of providing such services, without regard to the amount of the customary or other charge and any limitation under section 1861(v)(1)(U) of the Social Security Act (42 U.S.C. 1395x(v)(1)(U)); or

(B) the amount of payment provided for under the prospective payment system for covered OPD services under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

(3) HOME HEALTH SERVICES.—In determining payments under the demonstration program for

home health services furnished by a qualified RCH-based home health agency (as defined in paragraph (2))—

(A) the agency may make a one-time election to waive application of the prospective payment system established under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to such services furnished by the agency; and

(B) in the case of such an election, payment shall be made on the basis of the reasonable costs incurred in furnishing such services as determined under section 1861(v) of the Social Security Act (42 U.S.C. 1395x(v)), but without regard to the amount of the customary or other charges with respect to such services or the limitations established under paragraph (1)(L) of such section.

(4) CONSOLIDATED BILLING.—The Secretary shall permit consolidated billing under section 1842(b)(6)(E) of the Social Security Act (42 U.S.C. 1395u(b)(6)(E)).

(5) EXEMPTION FROM 30 PERCENT REDUCTION IN REIMBURSEMENT FOR BAD DEBT.—In determining the reasonable costs for rural community

hospitals, section 1861(v)(1)(T) of the Social Security Act (42 U.S.C. 1395x(v)(1)(T)) shall not apply.

(6) BENEFICIARY COST-SHARING FOR OUTPATIENT SERVICES.—The amounts of beneficiary cost-sharing for outpatient services furnished in a rural community hospital under the demonstration program shall be as follows:

(A) For items and services that would have been paid under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) if provided by a hospital, the amount of cost-sharing determined under paragraph (8) of such section.

(B) For items and services that would have been paid under section 1833(h) of such Act (42 U.S.C. 1395l(h)) if furnished by a provider or supplier, no cost-sharing shall apply.

(C) For all other items and services, the amount of cost-sharing that would apply to the item or service under the methodology that would be used to determine payment for such item or service if provided by a physician, provider, or supplier, as the case may be.

(7) RETURN ON EQUITY.—

(A) IN GENERAL.—Notwithstanding subparagraph (P)(i) and (S)(i) of section

1861(v)(1) of the Social Security Act (42 U.S.C. 1395x(v)(1)) and section 1886(g)(2) of such Act (42 U.S.C. 1395ww(g)(2)), in determining the reasonable costs of the services described in subclause (II) furnished by a rural community hospital for payment of a return on equity capital at a rate of return equal to 150 percent of the average specified in section 1861(v)(1)(P)(i) of such Act (42 U.S.C. 1395x(v)(1)(P)(i)).

(B) SERVICES DESCRIBED.—The services referred to in subclause (I) are rural community hospital services.

(C) DISREGARD OF PROPRIETARY PROVIDER STATUS.—Payment under the demonstration program shall be made without regard to whether a provider is a proprietary provider.

(8) REMOVING BARRIERS TO ESTABLISHMENT OF DISTINCT PART UNITS BY RCH FACILITIES.—Notwithstanding section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)), the Secretary shall permit rural community hospitals to establish distinct part units for purposes of applying such section.

(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) and the Federal Supplementary Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t), in such proportion as the Secretary determines to be appropriate, 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 titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 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 sec-

tion, 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.—

(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 subparagraph (B), has less than 51 acute care inpatient beds, as reported in its most recent cost report;

(iii) makes available 24-hour emergency care services;

(iv) subject to subparagraph (C), has a provider agreement in effect with the Secretary and is open to the public as of January 1, 2003; and

(v) applies to the Secretary for such designation.

(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.

(C) TYPES OF HOSPITALS THAT MAY PARTICIPATE.—Subparagraph (1)(D) shall not be construed to prohibit any of the following from qualifying as a rural community hospital:

(i) A replacement facility (as defined by the Secretary in regulations in effect on January 1, 2003) with the same service area (as defined by the Secretary in regulations in effect on such date).

(ii) A facility obtaining a new provider number pursuant to a change of ownership.

(iii) A facility which has a binding written agreement with an outside, unrelated party for the construction, reconstruction, lease, rental, or financing of a building as of January 1, 2003.

(D) INCLUSION OF CAHS.—Nothing in this subsection shall be construed as prohibiting a critical access hospital from qualifying as a rural community hospital if the critical access hospital meets the conditions otherwise applicable to hospitals under section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e)) and section 1866 of such Act (42 U.S.C. 1395cc).

(2) QUALIFIED RCH-BASED HOME HEALTH AGENCY DEFINED.—The term ''qualified RCH-based home health agency'' is a home health agency that is a provider-based entity (as defined in section 404 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106–554; Appendix F, 114 Stat. 2763A–506)) of a rural community hospital that is located—

(A) in a county in which no main or branch office of another home health agency is located; or

(B) at least 35 miles from any main or branch office of another home health agency.

**SEC. 415. CRITICAL ACCESS HOSPITAL IMPROVEMENT DEMONSTRATION PROGRAM.**

(a) ESTABLISHMENT OF CRITICAL ACCESS HOSPITAL DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program to test various methods to improve the critical access hospital program under section 1820 of the Social Security Act (42 U.S.C. 1395i–4).

(2) CRITICAL ACCESS HOSPITAL IMPROVEMENT.—In conducting the demonstration program under this section, the Secretary shall apply rules with respect to critical access hospitals participating in the program as follows:

(A) EXCLUSION OF CERTAIN BEDS FROM BED COUNT.—In determining the number of beds of a facility for purposes of applying the bed limitations referred to in subsections (c)(2)(B)(iii) and (f) of section 1820 of the Social Security Act (42 U.S.C. 1395i–4), the Secretary shall not take into account any bed of a distinct part psychiatric or rehabilitation unit (described in the matter following clause (v) of section 1886(d)(1)(B) of such Act (42 U.S.C. 1395ww(d)(1)(B))) of the facility, except that the total number of beds that are not taken into account pursuant to this subparagraph with respect to a facility shall not exceed 10.

(B) EXCLUSION FROM HOME HEALTH PPS.—Notwithstanding section 1895 of the Social Security Act (42 U.S.C. 1395fff), in determining payments under the demonstration program for home health services furnished by a home health agency that is owned and operated by a critical access hospital participating in the demonstration program—

(i) the agency may make an election to waive application of the prospective payment system established under such section to such services furnished by the agency; and

(ii) in the case of such an election, payment shall be made on the basis of the reasonable costs incurred in furnishing such services as determined under section 1861(v), but without regard to the amount of the customary or other charges with respect to such services or the limitations established under paragraph (1)(L) of such section.

(C) EXEMPTION OF CAH FACILITIES FROM PPS.—Notwithstanding section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e)), in

determining payments under this part for covered skilled nursing facility services furnished by a skilled nursing facility that is a distinct part unit of a critical access hospital participating in the demonstration program or is owned and operated by a critical access hospital participating in the demonstration program—

(i) the prospective payment system established under such section shall not apply; and

(ii) payment shall be made on the basis of the reasonable costs incurred in furnishing such services as determined under section 1861(v) of such Act (42 U.S.C. 1395x(v)), but without regard to the amount of the customary or other charges with respect to such services.

(D) CONSOLIDATED BILLING.—The Secretary shall permit consolidated billing under section 1842(b)(6)(E) of the Social Security Act (42 U.S.C. 1395u(b)(6)(E)).

(E) EXEMPTION OF CERTAIN DISTINCT PART PSYCHIATRIC OR REHABILITATION UNITS FROM COST LIMITS.—Notwithstanding section 1886(b) of the Social Security Act (42 U.S.C.

1395ww(b)), in determining payments under the demonstration program for inpatient hospital services furnished by a distinct part psychiatric or rehabilitation unit (described in the matter following section 1886(d)(1)(B)(v) of such Act (42 U.S.C. 1395ww(d)(1)(B)(v))) of a critical access hospital participating in the demonstration program—

(i) the limits imposed under the preceding paragraphs of this subsection shall not apply; and

(ii) payment shall be made on the basis of the reasonable costs incurred in furnishing such services as determined under section 1861(v) of such Act (42 U.S.C. 1395x(v)), but without regard to the amount of the customary or other charges with respect to such services.

(F) RETURN ON EQUITY.—

(i) IN GENERAL.—Notwithstanding subparagraph (P)(i) and (S)(i) of section 1861(v)(1) of the Social Security Act (42 U.S.C. 1395x(v)(1)) and section 1886(g)(2) of such Act (42 U.S.C. 1395ww(g)(2)), in determining the reason-

able costs of the services described in subclause (II) furnished by a critical access hospital participating in the demonstration program for payment of a return on equity capital at a rate of return equal to 150 percent of the average specified in section 1861(v)(1)(P)(i) of such Act (42 U.S.C. 1395x(v)(1)(P)(i)).

(ii) SERVICES DESCRIBED.—The services referred to in subclause (I) are inpatient critical access hospital services, outpatient critical access hospital services, extended care services, posthospital extended care services, home health services, ambulance services, and inpatient hospital services.

(iii) DISREGARD OF PROPRIETARY PROVIDER STATUS.—Payment under the demonstration program shall be made without regard to whether a provider is a proprietary provider.

(G) REMOVING BARRIERS TO ESTABLISHMENT OF DISTINCT PART UNITS BY CAH FACILITIES.—Notwithstanding section 1886(d)(1)(B) of the Social Security Act (42

U.S.C. 1395ww(d)(1)(B)), the Secretary shall permit critical access hospitals participating in the demonstration program to establish distinct part units for purposes of applying such section.

(3) PARTICIPATION OF CAHS.—

(A) APPLICATION.—Each critical access hospital that is located in a demonstration area described in subparagraph (C) 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.

(B) PARTICIPATION.—The Secretary shall permit any critical access hospital that is located in a demonstration area described in subparagraph (C), submits an application in accordance with subparagraph (A), and meets the other requirements of this section to participate in the demonstration program.

(C) DEMONSTRATION AREAS.—There shall be four demonstration areas within this program. Two of these demonstration areas de-

scribed in this subparagraph shall include Kansas and Nebraska.

(4) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period.

(5) 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) 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) and the Federal Supplementary Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t), in such proportion as the Secretary determines to be appropriate, 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 dem-

onstration program under this section was not implemented.

(c) 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.; 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(d) 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.

**SEC. 416. TREATMENT OF GRANDFATHERED LONG-TERM CARE HOSPITALS.**

(a) IN GENERAL.—The last sentence of section 1886(d)(1)(B) is amended by inserting ", and the Secretary may not impose any special conditions on the operation, size, number of beds, or location of any hospital so classified for continued participation under this title or title XIX or for continued classification as a hospital described in clause (iv)" before the period at the end.

(b) TREATMENT OF PROPOSED REVISION.—The Secretary shall not adopt the proposed revision to section 412.22(f) of title 42, Code of Federal Regulations con-

tained in 68 Federal Register 27154 (May 19, 2003) or any revision reaching the same or substantially the same result as such revision.

(c) EFFECTIVE DATE.—The amendment made by, and provisions of, this section shall apply to cost reporting periods ending on or after December 31, 2002.

**SEC. 417. TREATMENT OF CERTAIN ENTITIES FOR PURPOSES OF PAYMENTS UNDER THE MEDICARE PROGRAM.**

(a) PAYMENTS TO HOSPITALS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, effective for discharges occurring on or after October 1, 2003, for purposes of making payments to hospitals (as defined in section 1886(d) and 1833(t) of the Social Security Act (42 U.S.C. 1395(d)) under the medicare program under title XVIII of such Act (42 U.S.C. 1395 et seq.), Iredell County, North Carolina, and Rowan County, North Carolina, are deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina, South Carolina Metropolitan Statistical Area.

(2) BUDGET NEUTRAL WITHIN NORTH CAROLINA.—The Secretary shall adjust the area wage index referred to in paragraph (1) with respect to payments to hospitals located in North Carolina in

a manner which assures that the total payments made under section 1886(d) of the Social Security Act (42 U.S.C., 1395(ww)(d)) in a fiscal year for the operating cost of inpatient hospital services are not greater or less than the total of such payments that would have been made in the year if this subsection had not been enacted.

(b) PAYMENTS TO SKILLED NURSING FACILITIES AND HOME HEALTH AGENCIES.—

(1) IN GENERAL.—Notwithstanding any other provision of law, effective beginning October 1, 2003, for purposes of making payments to skilled nursing facilities (SNFs) and home health agencies (as defined in sections 1861(j) and 1861(o) of the Social Security Act (42 U.S.C. 1395x(j); 1395x(o)) under the medicare program under title XVIII of such Act, Iredell County, North Carolina, and Rowan County, North Carolina, are deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina, South Carolina Metropolitan Statistical Area.

(2) APPLICATION AND BUDGET NEUTRAL WITHIN NORTH CAROLINA.—Effective for fiscal year 2004, the skilled nursing facility PPS and home health PPS rates for Iredell County, North Carolina,

and Rowan County, North Carolina, will be updated by the prefloor, prereclassified hospital wage index available for the Charlotte-Gastonia-Rock Hill, North Carolina, South Carolina Metropolitan Statistical Area. This subsection shall be implemented in a budget neutral manner, using a methodology that ensures that the total amount of expenditures for skilled nursing facility services and home health services in a year does not exceed the total amount of expenditures that would have been made in the year if this subsection had not been enacted. Required adjustments by reason of the preceding sentence shall be done with respect to skilled nursing facilities and home health agencies located in North Carolina.

(c) CONSTRUCTION.—The provisions of this section shall have no effect on the amount of payments made under title XVIII of the Social Security Act to entities located in States other than North Carolina.

**SEC. 418. 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 striking ''on or after October 1, 2002'' and inserting ''during fiscal year 2003''; 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) during each of fiscal years 2004 and 2005, 'c' is equal to 1.36; and

''(IX) on or after October 1, 2005, 'c' is equal to 1.355.''.

(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 Prescription Drug and Medicare Improvement Act of 2003'' after ''2000''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to discharges occurring on or after October 1, 2003.

**SEC. 419. CALCULATION OF WAGE INDICES FOR HOSPITALS.**

Notwithstanding any other provision of law, in the calculation of a wage index in a State for purposes of making payments for discharges occurring during fiscal year 2004, the Secretary may waive such other criteria for reclassification, as deemed appropriate by the Secretary.

**SEC. 420. CONFORMING CHANGES REGARDING FEDERALLY QUALIFIED HEALTH CENTERS.**

Section 1833(a)(3) (42 U.S.C. 1395l(a)(3)) is amended by inserting ''(which regulations shall exclude any cost incurred for the provision of services pursuant to a contract with an eligible entity (as defined in section 1860D(4)) operating a Medicare Prescription Drug plan or with an entity with a contract under section 1860D–13(e), for which payment is made by the entity)'' after ''the Secretary may prescribe in regulations''.

**SEC. 420A. INCREASE FOR HOSPITALS WITH DISPROPORTIONATE INDIGENT CARE REVENUES.**

(a) DISPROPORTIONATE SHARE ADJUSTMENT PERCENTAGE.—Section 1886(d)(5)(F)(iii) (42 U.S.C. 1395ww(d)(5)(F)(iii)) is amended by striking ''35 percent'' and inserting ''35 percent (or, for discharges occurring on or after October 1, 2003, 40 percent)''.

(b) CAPITAL COSTS.—Section 1886(g)(1)(B) (42 U.S.C. 1395ww(g)(1)(B)) is amended—

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

(2) in clause (iv), by striking the period at the end and inserting '', and''; and

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

''(v) in the case of cost reporting periods beginning on or after October 1, 2003, shall provide for a disproportionate share adjustment in the same manner as section 1886(d)(5)(F)(iii).''.

**SEC. 420B. TREATMENT OF GRANDFATHERED LONG-TERM CARE HOSPITALS.**

(a) IN GENERAL.—The last sentence of section 1886(d)(1)(B) is amended by inserting '', and the Secretary may not impose any special conditions on the operation, size, number of beds, or location of any hospital so classified for continued participation under this title or title XIX or for continued classification as a hospital described in clause (iv)'' before the period at the end.

(b) TREATMENT OF PROPOSED REVISION.—The Secretary shall not adopt the proposed revision to section 412.22(f) of title 42, Code of Federal Regulations contained in 68 Federal Register 27154 (May 19, 2003) or any revision reaching the same or substantially the same result as such revision.

(c) EFFECTIVE DATE.—The amendment made by, and provisions of, this section shall apply to cost reporting periods ending on or after December 31, 2002.

# Subtitle B—Provisions Relating to Part B

**SEC. 421. ESTABLISHMENT OF FLOOR ON GEOGRAPHIC ADJUSTMENTS OF PAYMENTS FOR PHYSICIANS' SERVICES.**

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

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

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

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

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

any locality for which such geographic index is less than the work floor index.

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

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

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

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

**SEC. 422. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS.**

(a) PROCEDURES FOR SECRETARY, AND NOT PHYSICIANS, TO DETERMINE WHEN BONUS PAYMENTS UNDER MEDICARE INCENTIVE PAYMENT PROGRAM SHOULD BE

MADE.—Section 1833(m) (42 U.S.C. 1395l(m)) is amended—

(1) by inserting "(1)" after "(m)"; and

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

"(2) The Secretary shall establish procedures under which the Secretary, and not the physician furnishing the service, is responsible for determining when a payment is required to be made under paragraph (1).".

(b) EDUCATIONAL PROGRAM REGARDING THE MEDICARE INCENTIVE PAYMENT PROGRAM.—The Secretary shall establish and implement an ongoing educational program to provide education to physicians under the medicare program on the medicare incentive payment program under section 1833(m) of the Social Security Act (42 U.S.C. 1395l(m)).

(c) ONGOING GAO STUDY AND ANNUAL REPORT ON THE MEDICARE INCENTIVE PAYMENT PROGRAM.—

(1) ONGOING STUDY.—The Comptroller General of the United States shall conduct an ongoing study on the medicare incentive payment program under section 1833(m) of the Social Security Act (42 U.S.C. 1395l(m)). Such study shall focus on whether such program increases the access of medicare beneficiaries who reside in an area that is des-

ignated (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 to physicians' services under the medicare program.

(2) ANNUAL REPORTS.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Comptroller General of the United States shall submit to Congress a report on the study conducted under paragraph (1), together with recommendations as the Comptroller General considers appropriate.

**SEC. 423. EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND TREATMENT OF CERTAIN SOLE COMMUNITY HOSPITALS TO LIMIT DECLINE IN PAYMENT UNDER THE OPD PPS.**

(a) SMALL RURAL HOSPITALS.—Section 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended by inserting "and during 2006" after "2004,".

(b) SOLE COMMUNITY HOSPITALS.—Section 1833(t)(7)(D) (42 U.S.C. 1395l(t)(7)(D)) is amended by adding at the end the following:

"(iii) TEMPORARY TREATMENT FOR SOLE COMMUNITY HOSPITALS.—In the case of a sole community hospital (as de-

fined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished in 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.''.

**SEC. 424. INCREASE IN PAYMENTS FOR CERTAIN SERVICES FURNISHED BY SMALL RURAL AND SOLE COMMUNITY HOSPITALS UNDER MEDICARE PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.**

(a) INCREASE.—

(1) IN GENERAL.—In the case of an applicable covered OPD service (as defined in paragraph (2)) that is furnished by a hospital described in clause (i) or (iii) of paragraph (7)(D) of section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), as amended by section 424, on or after January 1, 2005, and before January 1, 2008, the Secretary shall increase the medicare OPD fee schedule amount (as determined under paragraph (4)(A) of such section) that is applicable for such service in that year (determined without regard to any increase under this section in a previous year) by 5 percent.

(2) APPLICABLE COVERED OPD SERVICES DEFINED.—For purposes of this section, the term ''applicable covered OPD service'' means a covered clinic or emergency room visit that is classified within the groups of covered OPD services (as defined in paragraph (1)(B) of section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t))) established under paragraph (2)(B) of such section.

(b) NO EFFECT ON COPAYMENT AMOUNT.—The Secretary shall compute the copayment amount for applicable covered OPD services under section 1833(t)(8)(A) of the Social Security Act (42 U.S.C. 1395l(t)(8)(A)) as if this section had not been enacted.

(c) NO EFFECT ON INCREASE UNDER HOLD HARMLESS OR OUTLIER PROVISIONS.—The Secretary shall apply the temporary hold harmless provision under clause (i) and (iii) of paragraph (7)(D) of section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) and the outlier provision under paragraph (5) of such section as if this section had not been enacted.

(d) WAIVING BUDGET NEUTRALITY AND NO REVISION OR ADJUSTMENTS.—The Secretary shall not make any revision or adjustment under subparagraph (A), (B), or (C) of section 1833(t)(9) of the Social Security Act (42

U.S.C. 1395l(t)(9)) because of the application of subsection (a)(1).

(e) NO EFFECT ON PAYMENTS AFTER INCREASE PERIOD ENDS.—The Secretary shall not take into account any payment increase provided under subsection (a)(1) in determining payments for covered OPD services (as defined in paragraph (1)(B) of section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t))) under such section that are furnished after January 1, 2008.

(f) TECHNICAL AMENDMENT.—Section 1833(t)(2)(B) (42 U.S.C. 1395l(t)(2)(B)) is amended by inserting ''(and periodically revise such groups pursuant to paragraph (9)(A))'' after ''establish groups''.

**SEC. 425. TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.**

Section 1834(l) (42 U.S.C. 1395m(l)), as amended by section 405(b)(2), is amended by adding at the end the following new paragraphs:

''(10) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

''(A) IN GENERAL.—Notwithstanding any other provision of this subsection, in the case of ground ambulance services furnished on or after January 1, 2005, and before January 1,

2008, 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 application of any increase under such paragraph, shall be increased by 5 percent; and

"(ii) an area not described in clause (i), the fee schedule established under this section shall provide that the rate for the service otherwise established shall be increased by 2 percent.

"(B) APPLICATION OF INCREASED PAYMENTS AFTER 2007.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished on or after the period specified in such subparagraph.

"(11) CONVERSION FACTOR ADJUSTMENTS.—The Secretary shall not adjust downward the conversion factor in any year because of an evaluation of the prior year conversion factor.".

**SEC. 426. ENSURING APPROPRIATE COVERAGE OF AIR AMBULANCE SERVICES UNDER AMBULANCE FEE SCHEDULE.**

(a) COVERAGE.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by section 426, is amended by adding at the end the following new paragraph:

"(11) ENSURING APPROPRIATE COVERAGE OF AIR AMBULANCE SERVICES.—

"(A) IN GENERAL.—The regulations described in section 1861(s)(7) shall ensure that air ambulance services (as defined in subparagraph (C)) are reimbursed under this subsection at the air ambulance rate if the air ambulance service—

"(i) is medically 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) MEDICALLY NECESSARY.—An air ambulance service shall be considered to be medically necessary for purposes of subparagraph (A)(i) if such service is requested—

"(i) by a physician or a hospital in accordance with the physician's or hospital's responsibilities under section 1867 (commonly known as the Emergency Medical Treatment and Active Labor Act);

"(ii) as a result of a protocol established by a State or regional emergency medical service (EMS) agency;

"(iii) by a physician, nurse practitioner, physician assistant, registered nurse, or emergency medical responder who reasonably determines or certifies that the patient's condition is such that the time needed to transport the individual by land or the lack of an appropriate ground ambulance, significantly increases the medical risks for the individual; or

"(iv) by a Federal or State agency to relocate patients following a natural disaster, an act of war, or a terrorist attack.

"(C) AIR AMBULANCE SERVICES DEFINED.—For purposes of this paragraph, the term 'air ambulance service' means fixed wing and rotary wing 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)(11)," after "but".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2005.

**SEC. 427. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED BY A SOLE COMMUNITY HOSPITAL.**

Notwithstanding subsections (a), (b), and (h) of section 1833 of the Social Security Act (42 U.S.C. 1395*l*) and section 1834(d)(1) of such Act (42 U.S.C. 1395m(d)(1)), in the case of a clinical diagnostic laboratory test covered under part B of title XVIII of such Act that is furnished in 2005 or 2006 by a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of such Act (42 U.S.C. 1395ww(d)(5)(D)(iii))) as part of services furnished to patients of the hospital, the following rules shall apply:

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

(2) NO BENEFICIARY COST-SHARING.—Notwithstanding section 432, no coinsurance, deductible, co-

payment, or other cost-sharing otherwise applicable under such part B shall apply with respect to such test.

**SEC. 428. IMPROVEMENT IN RURAL HEALTH CLINIC REIMBURSEMENT.**

Section 1833(f) (42 U.S.C. 1395*l*(f)) is amended—

(1) in paragraph (1), by striking ", and" at the end and inserting a semicolon;

(2) in paragraph (2)—

(A) by striking "in a subsequent year" and inserting "in 1989 through 2004"; and

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

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

"(3) in 2005, at $80 per visit; and

"(4) in a subsequent year, at the limit established under this subsection for the previous year increased by the percentage increase in the MEI (as so defined) applicable to primary care services (as so defined) furnished as of the first day of that year.".

**SEC. 429. ELIMINATION OF CONSOLIDATED BILLING FOR CERTAIN SERVICES UNDER THE MEDICARE PPS FOR SKILLED NURSING FACILITY SERVICES.**

(a) CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Section 1888(e) (42 U.S.C. 1395yy(e)) is amended—

(1) in paragraph (2)(A)(i)(II), by striking ''clauses (ii) and (iii)'' and inserting ''clauses (ii), (iii), and (iv)''; and

(2) by adding at the end of paragraph (2)(A) 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 a physician or practitioner not affiliated with a rural

health clinic or a Federally qualified health center.''.

(b) CERTAIN SERVICES FURNISHED BY AN ENTITY JOINTLY OWNED BY HOSPITALS AND CRITICAL ACCESS HOSPITALS.—For purposes of applying section 411.15(p)–(3)(iii) of title 42 of the Code of Federal Regulations, the Secretary shall treat an entity that is 100 percent owned as a joint venture by 2 Medicare-participating hospitals or critical access hospitals as a Medicare-participating hospital or a critical access hospital.

(c) TECHNICAL AMENDMENTS.—Sections 1842(b)(6)(E) and 1866(a)(1)(H)(ii) (42 U.S.C. 1395u(b)(6)(E); 1395cc(a)(1)(H)(ii)) are each amended by striking ''section 1888(e)(2)(A)(ii)'' and inserting ''clauses (ii), (iii), and (iv) of section 1888(e)(2)(A)''.

(d) EFFECTIVE DATE.—The amendments made by this section and the provision of subsection (b) shall apply to services furnished on or after January 1, 2005.

**SEC. 430. FREEZE IN PAYMENTS FOR CERTAIN ITEMS OF DURABLE MEDICAL EQUIPMENT AND CERTAIN ORTHOTICS; ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DME PROVIDERS.**

(a) FREEZE FOR DME.—Section 1834(a)(14) (42 U.S.C. 1395m(a)(14)) is amended—

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

(2) in subparagraph (F)—

(A) by striking ''a subsequent year'' and inserting ''2003''; and

(B) by striking ''the previous year.'' and inserting ''2002;''; and

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

''(G) for each of the years 2004 through 2010—

''(i) 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; and

''(H) for a subsequent year, the percentage increase described in subparagraph (B) for the year involved.''.

(b) FREEZE FOR OFF-THE-SHELF ORTHOTICS.—Section 1834(h)(4)(A) of the Social Security Act (42 U.S.C. 1395m(h)(4)(A)) is amended—

(1) in clause (vii), by striking ''and'' at the end;

(2) in clause (viii), by striking ''a subsequent year'' and inserting ''2003''; and

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

''(ix) for each of the years 2004 through 2010—

''(I) in the case of orthotics that have not been custom-fabricated, 0 percent; and

''(II) in the case of prosthetics, prosthetic devices, and custom-fabricated orthotics, the percentage increase described in clause (viii) for the year involved; and

''(x) for 2011 and each subsequent year, the percentage increase described in clause (viii) for the year involved;''.

(c) ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT PROVIDERS.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

(1) by redesignating paragraph (17), as added by section 4551(c)(1) of the Balanced Budget Act of 1997 (111 Stat. 458), as paragraph (19); and

(2) 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 providers of durable medical equipment throughout the United States that are developed by recognized independent accreditation organizations (as designated under subparagraph (B)(i)) and with which such providers shall be required to comply in order to—

"(i) participate in the program under this title;

"(ii) furnish any item or service described in subparagraph (D) for which payment is made under this part; and

"(iii) receive or retain a provider or supplier number used to submit claims for reimbursement for any item or service de-

scribed in subparagraph (D) for which payment may be made under this title.

"(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS.—

"(i) IN GENERAL.—Not later that the date that is 6 months after the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003, the Secretary shall designate independent accreditation organizations for purposes of subparagraph (A).

"(ii) CONSULTATION.—In determining which independent accreditation organizations to designate under clause (i), the Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of physicians, practitioners, suppliers, and manufacturers to review (and advise the Secretary concerning) selection of accrediting organizations and the quality standards of such organizations.

"(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 covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection, other than items used in infusion, and inhalation drugs used in conjunction with durable medical equipment.

"(E) PHASED-IN IMPLEMENTATION.—The application of the quality standards described in subparagraph (A) shall be phased-in over a period that does not exceed 3 years.".

**SEC. 431. APPLICATION OF COINSURANCE AND DEDUCTIBLE FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.**

(a) COINSURANCE.—

(1) IN GENERAL.—Section 1833(a) (42 U.S.C. 1395*l*(a)) is amended—

(A) in paragraph (1)(D)(i), by striking "(or 100 percent, in the case of such tests for which payment is made on an assignment-related basis)"; and

(B) in paragraph (2)(D)(i), by striking "(or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866)".

(2) CONFORMING AMENDMENT.—The third sentence of section 1866(a)(2)(A) of the Social Security Act (42 U.S.C. 1395cc(a)(2)(A) is amended by striking "and with respect to clinical diagnostic laboratory tests for which payment is made under part B".

(b) DEDUCTIBLE.—Section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)) is amended—

(1) by striking paragraph (3); and

(2) by redesignating paragraphs (4), (5), and (6) as paragraphs (3), (4), and (5), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2004.

**SEC. 432. BASING MEDICARE PAYMENTS FOR COVERED OUTPATIENT DRUGS ON MARKET PRICES.**

(a) MEDICARE MARKET BASED PAYMENT AMOUNT.—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—

''(A) in the case of a drug or biological furnished prior to January 1, 2004, 95 percent of the average wholesale price; and

''(B) in the case of a drug or biological furnished on or after January 1, 2004, the payment amount specified in—

''(i) in the case of such a drug or biological that is first available for payment under this part on or before April 1, 2003, paragraph (4); and

''(ii) in the case of such a drug or biological that is first available for payment under this part after such date, paragraph (5).''; and

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

''(4)(A) Subject to subparagraph (C), the payment amount specified in this paragraph for a year for a drug or biological is an amount equal to the lesser of—

''(i) the average wholesale price for the drug or biological; or

''(ii) the amount determined under subparagraph (B)

"(B)(i) Subject to clause (ii), the amount determined under this subparagraph is an amount equal to—

"(I) in the case of a drug or biological furnished in 2004, 85 percent of the average wholesale price for the drug or biological (determined as of April 1, 2003); and

"(II) in the case of a drug or biological furnished in 2005 or a subsequent year, the amount determined under this subparagraph 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.

"(ii) In the case of a vaccine described in subparagraph (A) or (B) of section 1861(s)(10), the amount determined under this subparagraph is an amount equal to the average wholesale price for the drug or biological.

"(C)(i) The Secretary shall establish a process under which the Secretary determines, for such drugs or biologicals as the Secretary determines appropriate, whether the widely available market price to physicians or suppliers for the drug or biological furnished in a year is different from the payment amount established under subparagraph (B) for the year. Such determination shall be based on the information described in clause (ii) as the Secretary determines appropriate.

"(ii) The information described in this clause is the following information:

"(I) Any report on drug or biological market prices by the Inspector General of the Department of Health and Human Services or the Comptroller General of the United States that is made available after December 31, 1999.

"(II) A review of drug or biological market prices by the Secretary, which may include information on such market prices from insurers, private health plans, manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physicians, suppliers, or any other source the Secretary determines appropriate.

"(III) Data and information submitted by the manufacturer of the drug or biological or by another entity.

"(IV) Other data and information as determined appropriate by the Secretary.

"(iii) If the Secretary makes a determination under clause (i) with respect to the widely available market price for a drug or biological for a year, the following provisions shall apply:

"(I) Subject to clause (iv), the amount determined under this subparagraph shall be substituted for the amount determined under subparagraph (B) for purposes of applying subparagraph (A)(ii)(I) for the year and all subsequent years.

"(II) The Secretary may make subsequent determinations under clause (i) with respect to the widely available market price for the drug or biological.

"(III) If the Secretary does not make a subsequent determination under clause (i) with respect to the widely available market price for the drug or biological for a year, the amount determined under this subparagraph shall be an amount equal to the amount determined under this subparagraph for the previous year increased by the percentage increase described in subparagraph (B)(i)(II) for the year involved.

"(iv) If the first determination made under clause (i) with respect to the widely available market price for a drug or biological would result in a payment amount in a year that is more than 15 percent less than the amount determined under subparagraph (B) for the drug or biological for the previous year (or, for 2004, the payment amount determined under paragraph (1)(A), determined

as of April 1, 2003), the Secretary shall provide for a transition to the amount determined under clause (i) so that the payment amount is reduced in annual increments equal to 15 percent of the payment amount in such previous year until the payment amount is equal to the amount determined under clause (i), as increased each year by the percentage increase described in subparagraph (B)(i)(II) for the year. The preceding sentence shall not apply to a drug or biological where a generic version of the drug or biological first enters the market on or after January 1, 2004 (even if the generic version of the drug or biological is not marketed under the chemical name of such drug or biological).

''(5) In the case of a drug or biological that is first available for payment under this part after April 1, 2003, the following rules shall apply:

''(A) As a condition of obtaining a code to report such new drug or biological and to receive payment under this part, a manufacturer shall provide the Secretary (in a time, manner, and form approved by the Secretary) with data and information on prices at which the manufacturer estimates physicians and suppliers will be able to routinely obtain the drug or biological in the market during the first year that the drug or biological is available for pay-

ment under this part and such additional information that the manufacturer determines appropriate.

"(B) During the year that the drug or biological is first available for payment under this part, the manufacturer of the drug or biological shall provide the Secretary (in a time, manner, and form approved by the Secretary) with updated information on the actual market prices paid by such physicians or suppliers for the drug or biological in the year.

"(C) The amount specified in this paragraph for a drug or biological for the year described in subparagraph (B) is equal to an amount determined by the Secretary based on the information provided under subparagraph (A) and other information that the Secretary determines appropriate.

"(D) The amount specified in this paragraph for a drug or biological for the year after the year described in subparagraph (B) is equal to an amount determined by the Secretary based on the information provided under subparagraph (B) and other information that the Secretary determines appropriate.

"(E) The amount specified in this paragraph for a drug or biological for the year beginning after

the year described in subparagraph (D) and each subsequent year is equal to the lesser of—

"(i) the average wholesale price for the drug or biological; or

"(ii) the amount determined—

"(I) by the Secretary under paragraph (4)(C)(i) with respect to the widely available market price for the drug or biological for the year, if such paragraph was applied by substituting 'the payment determined under paragraph (5)(E)(ii)(II) for the year' for 'established under subparagraph (B) for the year'; and

"(II) if no determination described in subclause (I) is made for the drug or biological for the year, under this subparagraph with respect to the drug or biological for the previous year increased by the percentage increase described in paragraph (4)(B)(i)(II) for the year involved.".

(b) ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINISTRATION OF DRUGS AND BIOLOGICALS.—

(1) ADJUSTMENT IN PHYSICIAN 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 the following new clause:

''(iv) EXEMPTION FROM BUDGET NEUTRALITY IN 2004.—Any additional expenditures under this part that are attributable to subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004.''; and

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

''(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR DRUG ADMINISTRATION SERVICES FOR 2004.—In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished in 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 administration services; and

"(ii) meets criteria established by the Secretary for acceptance of such surveys.".

(2) 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 the date of enactment of this Act, 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 anticancer chemotherapeutic agent 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 if the Secretary determines such modification 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).

(3) 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 disproportionately reduced relative to the practice expense relative value units of services not deter-

mined under such methodology, as a result of the amendments to such Act made by paragraph (1).

(4) ADMINISTRATION OF BLOOD CLOTTING FACTORS.—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (a)(2), is amended by adding at the end the following new paragraph:

''(6)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2004, 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' (GAO–03–184), provide for a separate payment for the administration of such blood clotting factors in an amount that the Secretary determines to be appropriate.

''(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2004, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraphs (4) and (5) 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 433

of the Prescription Drug and Medicare Improvement Act of 2003 had not been enacted.

"(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2005 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 described in paragraph (4)(B)(i)(II) for the year involved.".

(5) INCREASE IN COMPOSITE RATE FOR END STAGE RENAL DISEASE FACILITIES.—Section 1881(b) (42 U.S.C. 1395rr(b) is amended—

(A) in paragraph (7), by adding at the end the following new sentence: "In the case of dialysis services furnished in 2004 or a subsequent year, the composite rate for such services shall be determined under paragraph (12)."; and

(B) by adding at the end the following new paragraph:

"(12)(A) In the case of dialysis services furnished during 2004, the composite rate for such services shall be the composite rate that would otherwise apply under paragraph (7) for the year increased by an amount to ensure (as estimated by the Secretary) that—

"(i) the sum of the total amount of—

"(I) the composite rate payments for such services for the year, as increased under this paragraph; and

"(II) the payments for drugs and biologicals (other than erythropoetin) furnished in connection with the furnishing of renal dialysis services and separately billed by renal dialysis facilities under paragraphs (4) and (5) of section 1842(o) for the year; is equal to

"(ii) the sum of the total amount of the composite rate payments under paragraph (7) for the year and the payments for the separately billed drugs and biologicals described in clause (i)(II) that would have been made if the amendments made by section 433 of the Prescription Drug and Medicare Improvement Act of 2003 had not been enacted.

"(B) Subject to subparagraph (E), in the case of dialysis services furnished in 2005, the composite rate for such services shall be an amount equal to the composite rate established under subparagraph (A), increased by 0.05 percent and further increased by 1.6 percent.

"(C) Subject to subparagraph (E), in the case of dialysis services furnished in 2006, the composite rate for such services shall be an amount equal to the composite

rate established under subparagraph (B), increased by 0.05 percent and further increased by 1.6 percent.

"(D) Subject to subparagraph (E), in the case of dialysis services furnished in 2007 and all subsequent years, the composite rate for such services shall be an amount equal to the composite rate established under this paragraph for the previous year, increased by 0.05 percent.

"(E) If the Secretary implements a reduction in the payment amount under paragraph (4)(C) or (5) for a drug or biological described in subparagraph (A)(i)(II) for a year after 2004, the Secretary shall, as estimated by the Secretary—

"(i) increase the composite rate for dialysis services furnished in such year in the same manner that the composite rate for such services for 2004 was increased under subparagraph (A); and

"(ii) increase the percentage increase under subparagraph (C) or (D) (as applicable) for years after the year described in clause (i) to ensure that such increased percentage would result in expenditures equal to the sum of the total composite rate payments for such services for such years and the total payments for drugs and biologicals described in subparagraph (A)(i)(II) is equal to the sum of the total amount of the composite rate payments under

this paragraph for such years and the payments for the drugs and biologicals described in subparagraph (A)(i)(II) that would have been made if the reduction in payment amount described in subparagraph had not been made.

"(F) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under this paragraph.".

(6) HOME INFUSION DRUGS.—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (a)(2) and paragraph (4), is amended by adding at the end the following new paragraph:

"(7)(A) Subject to subparagraph (B), in the case of infusion drugs and biologicals furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, the Secretary may make separate payments for furnishing such drugs and biologicals in an amount determined by the Secretary if the Secretary determines such separate payment to be appropriate.

"(B) In determining the amount of any separate payment under subparagraph (A) for a year, the Secretary shall ensure that the total amount of payments under this part for such infusion drugs and biologicals for the year

1 and such separate payments for the year does not exceed
2 the total amount of payments that would have been made
3 under this part for the year for such infusion drugs and
4 biologicals if section 433 of the Prescription Drug and
5 Medicare Improvement Act of 2003 had not been en-
6 acted.''.

7 (7) INHALATION DRUGS.—Section 1842(o) (42
8 U.S.C. 1395u(o)), as amended by subsection (a)(2)
9 and paragraphs (4) and (6), is amended by adding
10 at the end the following new paragraph:

11 ''(8)(A) Subject to subparagraph (B), in the case of
12 inhalation drugs and biologicals furnished through durable
13 medical equipment covered under section 1861(n) on or
14 after January 1, 2004, the Secretary may increase pay-
15 ments for such equipment under section 1834(a) and may
16 make separate payments for furnishing such drugs and
17 biologicals if the Secretary determines such increased or
18 separate payments are necessary to appropriately furnish
19 such equipment and drugs and biologicals to beneficiaries.

20 ''(B) The total amount of any increased payments
21 and separate payments under subparagraph (A) for a year
22 may not exceed an amount equal to 10 percent of the
23 amount (as estimated by the Secretary) by which—

24 ''(i) the total amount of payments that would
25 have been made for such drugs and biologicals for

the year if section 433 of the Prescription Drug and Medicare Improvement Act of 2003 had not been enacted; exceeds

"(ii) the total amount of payments for such drugs and biologicals under paragraphs (4) and (5).".

(8) PHARMACY DISPENSING FEE FOR CERTAIN DRUGS AND BIOLOGICALS.—Section 1842(o)(2) (42 U.S.C. 1395u(o)(2)) is amended to read as follows:

"(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary—

"(A) 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, shall pay a dispensing fee determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts) to the pharmacy; and

"(B) in the case of a drug or biological not described in subparagraph (A), may pay a dispensing fee determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts) to the pharmacy.".

(9) PAYMENT FOR CHEMOTHERAPY DRUGS PURCHASED BUT NOT ADMINISTERED BY PHYSICIANS.—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (a)(2) and paragraphs (4), (6) and (7), is amended by adding at the end the following new paragraph:

''(9)(A) Subject to subparagraph (B), the Secretary may increase (in an amount determined appropriate) the amount of payments to physicians for anticancer chemotherapeutic drugs or biologicals that would otherwise be made under this part in order to compensate such physicians for anticancer chemotherapeutic drugs or biologicals that are purchased by physicians with a reasonable intent to administer to an individual enrolled under this part but which cannot be administered to such individual despite the reasonable efforts of the physician.

''(B) The total amount of increased payments made under subparagraph (A) in a year (as estimated by the Secretary) may not exceed an amount equal to 1 percent of the total amount of payments made under paragraphs (4) and (5) for such anticancer chemotherapeutic drugs or biologicals furnished by physicians in such year (as estimated by the Secretary).''.

(c) LINKAGE OF REVISED DRUG PAYMENTS AND INCREASES FOR DRUG ADMINISTRATION.—The Secretary shall not implement the revisions in payment amounts for a category of drug or biological as a result of the amendments made by subsection (a) unless the Secretary concurrently implements the adjustments to payment amounts for administration of such category of drug or biological for which the Secretary is required to make an adjustment, as specified in the amendments made by, and provisions of, subsection (b).

(d) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW.—

(1) DRUGS.—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (a)(2) and paragraphs (4), (6), (7), and (9) of subsection (b), is amended by adding at the end the following new paragraph:

''(10) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraph (2) or paragraphs (4) through (9).''.

(2) PHYSICIAN FEE SCHEDULE.—Section 1848(i)(1) (42 U.S.C. 1395w–4(i)(1)) is amended—

(A) in subparagraph (D), by striking "and" at the end;

(B) in subparagraph (E), by striking the period at the end and inserting ", and"; and

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

"(F) adjustments in practice expense relative value units under subsection (c)(2)(H).".

(3) MULTIPLE CHEMOTHERAPY AGENTS AND OTHER SERVICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL.—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) and (3) of subsection (b).

(e) STUDIES AND REPORTS.—

(1) GAO STUDY AND REPORT ON BENEFICIARY ACCESS TO DRUGS AND BIOLOGICALS.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study that examines the impact the provisions of, and the amendments made by, this section have on access by medicare beneficiaries to drugs and biologicals covered under the medicare program.

(B) REPORT.—Not later than January 1, 2006, the Comptroller General shall submit a report to Congress on the study conducted under subparagraph (A) together with such recommendations as the Comptroller General determines to be appropriate.

(2) STUDY AND REPORT BY THE HHS INSPECTOR GENERAL ON MARKET PRICES OF DRUGS AND BIOLOGICALS.—

(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct 1 or more studies that—

(i) examine the market prices that drugs and biologicals covered under the medicare program are widely available to physicians and suppliers; and

(ii) compare such widely available market prices to the payment amount for such drugs and biologicals under section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o).

(B) REQUIREMENT.—In conducting the study under subparagraph (A), the Inspector General shall focus on those drugs and biologicals that represent the largest portions of

expenditures under the medicare program for drugs and biologicals.

(C) REPORT.—The Inspector General shall prepare a report on any study conducted under subparagraph (A).

**SEC. 433. 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 2005, $125 for 2006, and for 2007 and thereafter, the amount in effect for the previous year, increase by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year, rounded to the nearest dollar''.

**SEC. 434. REVISIONS TO REASSIGNMENT PROVISIONS.**

(a) IN GENERAL.—Section 1842(b)(6)(A)(ii) (42 U.S.C. 1395u(b)(6)(A)(ii)) is amended to read as follows: ''(ii) where the service was provided under a contractual arrangement between such physician or other person and an entity (as defined by the Secretary), to the entity if under such arrangement such entity submits the bill for such service and such 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 enactment of this Act.

**SEC. 435. 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'' before the period at the end.

**SEC. 436. ADEQUATE REIMBURSEMENT FOR OUTPATIENT PHARMACY THERAPY UNDER THE HOSPITAL OUTPATIENT PPS.**

(a) SPECIAL RULES FOR DRUGS AND BIOLOGICALS.—Section 1833(t) (42 U.S.C. 1395(t)) is amended—

(1) by redesignating paragraph (13) as paragraph (14); and

(2) by inserting after paragraph (12) the following new paragraph:

"(13) SPECIAL RULES FOR CERTAIN DRUGS AND BIOLOGICALS.—

"(A) BEFORE 2007.—

"(i) IN GENERAL.—Notwithstanding paragraph (6), but subject to clause (ii), with respect to a separately payable drug or biological described in subparagraph (D) furnished on or after January 1, 2005, and before January 1, 2007, hospitals shall be reimbursed as follows:

"(I) DRUGS AND BIOLOGICALS FURNISHED AS PART OF A CURRENT OPD SERVICE.—The amount of payment for a drug or biological described in subparagraph (D) provided as a part of a service that was a covered OPD service on May 1, 2003, shall be the applicable percentage (as defined in subparagraph (C)) of the average wholesale price for the drug or biological that would have been determined under section 1842(o) on such date.

"(II) DRUGS AND BIOLOGICALS FURNISHED AS PART OF OTHER OPD

SERVICES.—The amount of payment for a drug or biological described in subparagraph (D) provided as part of any other covered OPD service shall be the applicable percentage (as defined in subparagraph (C)) of the average wholesale price that would have been determined under section 1842(o) on May 1, 2003, if payment for such a drug or biological could have been made under this part on that date.

"(ii) UPDATE FOR 2006.—For 2006, the amounts determined under clauses (i) and (ii) shall be the amount established for 2005 increased by 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) AFTER 2007.—

"(i) ONGOING STUDY AND REPORTS ON ADEQUATE REIMBURSEMENTS.—

"(I) STUDY.—The Secretary shall contract with an eligible organi-

zation (as defined in subclause (IV)) to conduct a study to determine the hospital acquisition, pharmacy services, and handling costs for each individual drug or biological described in subparagraph (D).

"(II) STUDY REQUIREMENTS.—The study conducted under subclause (I) shall—

"(aa) be accurate to within 3 percent of true mean hospital acquisition and handling costs for each drug and biological at the 95 percent confidence level;

"(bb) begin not later than January 1, 2005; and

"(cc) be updated annually for changes in hospital costs and the addition of newly marketed products.

"(III) REPORTS.—Not later than January 1 of each year (beginning with 2006), the Secretary shall submit to Congress a report on the study conducted under clause (i) together

with recommendations for such legislative or administrative action as the Secretary determines to be appropriate.

"(IV) ELIGIBLE ORGANIZATION DEFINED.—In this clause, the term 'eligible organization' means a private, nonprofit organization within the meaning of section 501(c) of the Internal Revenue Code.

"(ii) ESTABLISHMENT OF PAYMENT METHODOLOGY.—Notwithstanding paragraph (6), the Secretary, in establishing a payment methodology on or after the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003, shall take into consideration the findings of the study conducted under clause (i)(I) in determining payment amounts for each drug and biological provided as part of a covered OPD service furnished on or after January 1, 2007.

"(C) APPLICABLE PERCENTAGE DEFINED.—In this paragraph, the term 'applicable percentage' means—

"(i) with respect to a biological product (approved under a biologics license application under section 351 of the Public Health Service Act), a single source drug (as defined in section 1927(k)(7)(A)(iv)), or an orphan product designated under section 526 of the Food, Drug, and Cosmetic Act to which the prospective payment system established under this subsection did not apply under the final rule for 2003 payments under such system, 94 percent;

"(ii) with respect to an innovator multiple source drug (as defined in section 1927(k)(7)(A)(ii)), 91 percent; and

"(iii) with respect to a noninnovator multiple source drug (as defined in as defined in section 1927(k)(7)(A)(iii)), 71 percent.

"(D) DRUGS AND BIOLOGICALS DESCRIBED.—A drug or biological described in this paragraph is any drug or biological—

"(i) for which the amount of payment was determined under paragraph (6) prior to January 1, 2005; and

"(ii)(I) which is assigned to a drug specific ambulatory payment classification on or after the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003; or

"(II) that would have been reimbursed under paragraph (6) but for the application of this paragraph.".

(b) EXCEPTIONS 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 the budget neutrality adjustment required by the preceding sentence for fiscal years 2005 and 2006, the Secretary shall not take into account any expenditures that would not have been made but for the application of paragraph (13).".

**SEC. 437. 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.—Paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Prescription Drug and Medicare Improvement 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 bioequvalent,

as determined by the Commissioner of Food and Drugs.

**SEC. 438. MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS.**

(a) IN GENERAL.—With respect to the coverage of routine costs of care for beneficiaries participating in a qualifying clinical trial, as set forth on the date of the enactment of this Act in National Coverage Determination 30–1 of the Medicare Coverage Issues Manual, the Secretary shall deem clinical trials conducted in accordance with an investigational device exemption approved under section 520(g) of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j(g)) to be automatically qualified for such coverage.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as authorizing or requiring the Secretary to modify the regulations set forth on the date of the enactment of this Act at subpart B of part 405 of title 42, Code of Federal Regulations, or subpart A of part 411 of such title, relating to coverage of, and payment for, a medical device that is the subject of an investigational device exemption by the Food and Drug Administration (except as may be necessary to implement subsection (a)).

(c) LIMITATION OF EXPENDITURES IN YEARS PRIOR TO 2014.—

(1) IN GENERAL.—The Secretary shall ensure that the total amount of expenditures under title XVIII of the Social Security Act (including amounts expended by reason of this section) in a year prior to 2014 does not exceed the sum of—

(A) the total amount of expenditures under such title XVIII that would have made if this section had not been enacted; and

(B) the applicable amount.

(2) APPLICABLE AMOUNT.—For purposes of paragraph (1), the term ''applicable amount'' means—

(A) for 2005, $32,000,000;

(B) for 2006, $34,000,000;

(C) for 2007, $36,000,000;

(D) for 2008, $38,000,000;

(E) for 2009, $40,000,000;

(F) for 2010, $42,000,000;

(G) for 2011, $44,000,000;

(H) for 2012, $48,000,000; and

(I) for 2013, $50,000,000.

(3) STEPS TO ENSURE FUNDING LIMITATION NOT VIOLATED.—If the Secretary determines that

the application of this section will result in the funding limitation described in paragraph (1) being violated for any year, the Secretary shall take appropriate steps to stay within such funding limitation, including through limiting the number of clinical trials deemed under subsection (a) and only covering a portion of the routine costs described in such subsection.

(d) EFFECTIVE DATE.—This section shall apply to clinical trials begun on or after January 1, 2005.

**SEC. 439. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILITARY RETIREES; SPECIAL ENROLLMENT PERIOD.**

(a) WAIVER OF PENALTY.—

(1) IN GENERAL.—Section 1839(b) (42 U.S.C. 1395r(b)) is amended by adding at the end the following new sentence: ''No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, who enrolls under this part during 2002, 2003, 2004, or 2005 and who demonstrates to the Secretary before December 31, 2005, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary 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 2005. The Secretary shall establish a method for providing rebates of premium penalties paid for months on or after January 2005 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 enactment of this Act, is 65 years of age or older, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act, and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin 1 year after the date of the enactment of this Act and shall end on December 31, 2005.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment pe-

riod 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. 440. 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 MedicareAdvantage 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 6 demonstration sites.

(B) GEOGRAPHIC DIVERSITY.—Of the sites described in subparagraph (A)—

(i) 3 shall be in rural areas; and

(ii) 3 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 3 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).

**SEC. 441. 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 a beneficiary who is enrolled in the original medicare fee-for-service program under parts A and B or a beneficiary in a staff model or dedicated group model health maintenance organization under the Medicare+Choice program (or, on and after

1 January 1, 2006, under the MedicareAdvantage pro-
2 gram) under part C.
3 ''(2) HEALTH CARE GROUP.—
4 ''(A) IN GENERAL.—The term 'health care
5 group' means—
6 ''(i) a group of physicians that is or-
7 ganized at least in part for the purpose of
8 providing physician's services under this
9 title;
10 ''(ii) an integrated health care delivery
11 system that delivers care through coordi-
12 nated hospitals, clinics, home health agen-
13 cies, ambulatory surgery centers, skilled
14 nursing facilities, rehabilitation facilities
15 and clinics, and employed, independent, or
16 contracted physicians; or
17 ''(iii) an organization representing re-
18 gional coalitions of groups or systems de-
19 scribed in clause (i) or (ii).
20 ''(B) INCLUSION.—As the Secretary deter-
21 mines appropriate, a health care group may in-
22 clude a hospital or any other individual or enti-
23 ty furnishing items or services for which pay-
24 ment may be made under this title that is affili-
25 ated with the health care group under an ar-

rangement 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 traditional fee-for-service program under parts A and B or the package of benefits available through a staff model or a dedicated group model health maintenance organization 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.

1 ''(f) BUDGET NEUTRALITY.—With respect to the 5-
2 year period of the demonstration program under sub-
3 section (b), the aggregate expenditures under this title for
4 such period shall not exceed the aggregate expenditures
5 that would have been expended under this title if the pro-
6 gram established under this section had not been imple-
7 mented.

8 ''(g) NOTICE REQUIREMENTS.—In the case of an in-
9 dividual that receives health care items or services under
10 a demonstration program carried out under this section,
11 the Secretary shall ensure that such individual is notified
12 of any waivers of coverage or payment rules that are appli-
13 cable to such individual under this title as a result of the
14 participation of the individual in such program.

15 ''(h) PARTICIPATION AND SUPPORT BY FEDERAL
16 AGENCIES.—In carrying out the demonstration program
17 under this section, the Secretary may direct—

18 ''(1) the Director of the National Institutes of
19 Health to expand the efforts of the Institutes to
20 evaluate current medical technologies and improve
21 the foundation for evidence-based practice;

22 ''(2) the Administrator of the Agency for
23 Healthcare Research and Quality to, where possible
24 and appropriate, use the program under this section
25 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.

"(i) IMPLEMENTATION.—The Secretary shall not implement the demonstration program before October 1, 2004.".

**SEC. 442. MEDICARE COMPLEX CLINICAL CARE MANAGEMENT PAYMENT DEMONSTRATION.**

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program to make the medicare program more responsive to needs of eligible beneficiaries by promoting continuity of care, helping stabilize medical conditions, preventing or minimizing acute exacerbations of chronic conditions,

and reducing adverse health outcomes, such as adverse drug interactions related to polypharmacy.

(2) SITES.—The Secretary shall designate 6 sites at which to conduct the demonstration program under this section, of which at least 3 shall be in an urban area and at least 1 shall be in a rural area. One of the sites shall be located in the State of Arkansas.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 3-year period.

(4) IMPLEMENTATION.—The Secretary shall not implement the demonstration program before October 1, 2004.

(b) PARTICIPANTS.—Any eligible beneficiary who resides in an area designated by the Secretary as a demonstration site under subsection (a)(2) may participate in the demonstration program under this section if such beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the eligible beneficiary under the demonstration program.

(c) PRINCIPAL CARE PHYSICIAN RESPONSIBILITIES.—The Secretary shall enter into an agreement with each principal care physician who agrees to manage the complex clinical care of an eligible beneficiary under sub-

section (b) under which the principal care physician shall—

(1) serve as the primary contact of the eligible beneficiary in accessing items and services for which payment may be made under the medicare program;

(2) maintain medical information related to care provided by other health care providers who provide health care items and services to the eligible beneficiary, including clinical reports, medication and treatments prescribed by other physicians, hospital and hospital outpatient services, skilled nursing home care, home health care, and medical equipment services;

(3) monitor and advocate for the continuity of care of the eligible beneficiary and the use of evidence-based guidelines;

(4) promote self-care and family caregiver involvement where appropriate;

(5) have appropriate staffing arrangements to conduct patient self-management and other care coordination activities as specified by the Secretary;

(6) refer the eligible beneficiary to community services organizations and coordinate the services of such organizations with the care provided by health care providers; and

(7) meet such other complex care management requirements as the Secretary may specify.

(d) COMPLEX CLINICAL CARE MANAGEMENT FEE.—

(1) PAYMENT.—Under an agreement entered into under subsection (c), the Secretary shall pay to each principal care physician, on behalf of each eligible beneficiary under the care of that physician, the complex clinical care management fee developed by the Secretary under paragraph (2).

(2) DEVELOPMENT OF FEE.—The Secretary shall develop a complex care management fee under this paragraph that is paid on a monthly basis and which shall be payment in full for all the functions performed by the principal care physician under the demonstration program, including any functions performed by other qualified practitioners acting on behalf of the physician, appropriate staff under the supervision of the physician, and any other person under a contract with the physician, including any person who conducts patient self-management and caregiver education under subsection (c)(4).

(e) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Supplementary 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 would have 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.; 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(g) 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.

(h) DEFINITIONS.—In this section:

(1) ACTIVITY OF DAILY LIVING.—The term ''activity of daily living'' means eating, toiling, transferring, bathing, dressing, and continence.

(2) CHRONIC CONDITION.—The term ''chronic condition'' means a biological, physical, or mental condition that is likely to last a year or more, for which there is no known cure, for which there is a need for ongoing medical care, and which may affect an individual's ability to carry out activities of daily living or instrumental activities of daily living, or both.

(3) ELIGIBLE BENEFICIARY.—The term ''eligible beneficiary'' means any individual who—

(A) is enrolled for benefits under part B of the medicare program;

(B) has at least 4 complex medical conditions (one of which may be cognitive impairment); and

(C) has—

(i) an inability to self-manage their care; or

(ii) a functional limitation defined as an impairment in 1 or more activity of daily living or instrumental activity of daily living.

(4) INSTRUMENTAL ACTIVITY OF DAILY LIVING.—The term ''instrumental activity of daily living'' means meal preparation, shopping, house-

keeping, laundry, money management, telephone use, and transportation use.

(5) MEDICARE PROGRAM.—The term ''medicare program'' means the health care program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(6) PRINCIPAL CARE PHYSICIAN.—The term ''principal care physician'' means the physician with primary responsibility for overall coordination of the care of an eligible beneficiary (as specified in a written plan of care) who may be a primary care physician or a specialist.

**SEC. 443. MEDICARE FEE-FOR-SERVICE CARE COORDINATION DEMONSTRATION PROGRAM.**

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program to contract with qualified care management organizations to provide health risk assessment and care management services to eligible beneficiaries who receive care under the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act to eligible beneficiaries.

(2) SITES.—The Secretary shall designate 6 sites at which to conduct the demonstration program

under this section. In selecting sites under this paragraph, the Secretary shall give preference to sites located in rural areas.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period.

(4) IMPLEMENTATION.—The Secretary shall not implement the demonstration program before October 1, 2004.

(b) PARTICIPANTS.—Any eligible beneficiary who resides in an area designated by the Secretary as a demonstration site under subsection (a)(2) may participate in the demonstration program under this section if such beneficiary identifies a care management organization who agrees to furnish care management services to the eligible beneficiary under the demonstration program.

(c) CONTRACTS WITH CMOS.—

(1) IN GENERAL.—The Secretary shall enter into a contract with care management organizations to provide care management services to eligible beneficiaries residing in the area served by the care management organization.

(2) CANCELLATION.—The Secretary may cancel a contract entered into under paragraph (1) if the care management organization does not meet nego-

tiated savings or quality outcomes targets for the year.

(3) NUMBER OF CMOS.—The Secretary may contract with more than 1 care management organization in a geographic area.

(d) PAYMENT TO CMOS.—

(1) PAYMENT.—Under an contract entered into under subsection (c), the Secretary shall pay care management organizations a fee for which the care management organization is partially at risk based on bids submitted by care management organizations.

(2) PORTION OF PAYMENT AT RISK.—The Secretary shall establish a benchmark for quality and cost against which the results of the care management organization are to be measured. The Secretary may not pay a care management organization the portion of the fee described in paragraph (1) that is at risk unless the Secretary determines that the care management organization has met the agreed upon savings and outcomes targets for the year.

(e) 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) and the Federal Supplementary Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t), in such proportion as the Secretary determines to be appropriate, 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.

(f) WAIVER AUTHORITY.—

(1) IN GENERAL.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(2) WAIVER OF MEDIGAP PREEMPTIONS.—The Secretary shall waive any provision of section 1882 of the Social Security Act that would prevent an in-

surance carrier described in subsection (h)(3)(D) from participating in the demonstration program under this section.

(g) 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.

(h) DEFINITIONS.—In this section:

(1) CARE MANAGEMENT SERVICES.—The term ''care management services'' means services that are furnished to an eligible beneficiary (as defined in paragraph (2)) by a care management organization (as defined in paragraph (3)) in accordance with guidelines established by the Secretary that are consistent with guidelines established by the American Geriatrics Society.

(2) ELIGIBLE BENEFICIARY.—The term ''eligible beneficiary'' means an individual who is—

(A) entitled to (or enrolled for) benefits under part A and enrolled for benefits under part B of the Social Security Act (42 U.S.C. 1395c et seq.; 1395j et seq.);

(B) not enrolled with a Medicare+Choice plan or a MedicareAdvantage plan under part C; and

(C) at high-risk (as defined by the Secretary, but including eligible beneficiaries with multiple sclerosis or another disabling chronic condition, eligible beneficiaries residing in a nursing home or at risk for nursing home placement, or eligible beneficiaries eligible for assistance under a State plan under title XIX).

(3) CARE MANAGEMENT ORGANIZATION.—The term ''care management organization'' means an organization that meets such qualifications as the Secretary may specify and includes any of the following:

(A) A physician group practice, hospital, home health agency, or hospice program.

(B) A disease management organization.

(C) A Medicare+Choice or MedicareAdvantage organization.

(D) Insurance carriers offering medicare supplemental policies under section 1882 of the Social Security Act (42 U.S.C. 1395ss).

(E) Such other entity as the Secretary determines to be appropriate.

**SEC. 444. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.**

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians' services in different geographic areas. Such study shall include—

(1) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(2) an evaluation of the measures used for such adjustment, including the frequency of revisions;

(3) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component;

(4) an evaluation of whether there is a sound economic basis for the implementation of the adjustment under subparagraphs (E) and (F) of section 1848(e)(1) of the Social Security Act (42 U.S.C.

1395w–4(e)(1)), as added by section 421, in those areas in which the adjustment applies;

(5) an evaluation of the effect of such adjustment on physician location and retention in areas affected by such adjustment, taking into account—

(A) differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas; and

(B) the mobility of physicians, including specialists, over the last decade;

(6) an evaluation of the appropriateness of extending such adjustment or making such adjustment permanent;

(7) an evaluation of the adjustment of the work geographic practice cost index required under section 1848(e)(1)(A)(iii) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(A)(iii)) to reflect ¼ of the area cost difference in physician work;

(8) an evaluation of the effect of the adjustment described in paragraph (7) on physician location and retention in higher than average cost-of-living areas, taking into account difference in recruitment costs and retention rates for physicians, including specialists; and

(9) an evaluation of the appropriateness of the ¼ adjustment for the work geographic practice cost index.''.

(b) REPORT.—Not later than 1 year 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). 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. 445. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.**

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 13951(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: ''and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2005.

**SEC. 446. IMPROVEMENT OF OUTPATIENT VISION SERVICES UNDER PART B.**

(a) COVERAGE UNDER PART B.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

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

(2) in subparagraph (V)(iii), by adding ''and'' after the semicolon at the end; and

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

''(W) vision rehabilitation services (as defined in subsection (ww)(1));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Vision Rehabilitation Services; Vision Rehabilitation Professional

''(ww)(1)(A) The term 'vision rehabilitation services' means rehabilitative services (as determined by the Secretary in regulations) furnished—

''(i) to an individual diagnosed with a vision impairment (as defined in paragraph (6));

''(ii) pursuant to a plan of care established by a qualified physician (as defined in subparagraph (C)) or by a qualified occupational therapist that is periodically reviewed by a qualified physician;

"(iii) in an appropriate setting (including the home of the individual receiving such services if specified in the plan of care); and

"(iv) by any of the following individuals:

"(I) A qualified physician.

"(II) A qualified occupational therapist.

"(III) A vision rehabilitation professional (as defined in paragraph (2)) while under the general supervision (as defined in subparagraph (D)) of a qualified physician.

"(B) In the case of vision rehabilitation services furnished by a vision rehabilitation professional, the plan of care may only be established and reviewed by a qualified physician.

"(C) The term 'qualified physician' means—

"(i) a physician (as defined in subsection (r)(1)) who is an ophthalmologist; or

"(ii) a physician (as defined in subsection (r)(4) (relating to a doctor of optometry)).

"(D) The term 'general supervision' means, with respect to a vision rehabilitation professional, overall direction and control of that professional by the qualified physician who established the plan of care for the individual, but the presence of the qualified physician is not required

during the furnishing of vision rehabilitation services by that professional to the individual.

"(2) The term 'vision rehabilitation professional' means any of the following individuals:

"(A) An orientation and mobility specialist (as defined in paragraph (3)).

"(B) A rehabilitation teacher (as defined in paragraph (4)).

"(C) A low vision therapist (as defined in paragraph (5)).

"(3) The term 'orientation and mobility specialist' means an individual who—

"(A) if a State requires licensure or certification of orientation and mobility specialists, is licensed or certified by that State as an orientation and mobility specialist;

"(B)(i) holds a baccalaureate or higher degree from an accredited college or university in the United States (or an equivalent foreign degree) with a concentration in orientation and mobility; and

"(ii) has successfully completed 350 hours of clinical practicum under the supervision of an orientation and mobility specialist and has furnished not less than 9 months of supervised full-time orientation and mobility services;

"(C) has successfully completed the national examination in orientation and mobility administered by the Academy for Certification of Vision Rehabilitation and Education Professionals; and

"(D) meets such other criteria as the Secretary establishes.

"(4) The term 'rehabilitation teacher' means an individual who—

"(A) if a State requires licensure or certification of rehabilitation teachers, is licensed or certified by the State as a rehabilitation teacher;

"(B)(i) holds a baccalaureate or higher degree from an accredited college or university in the United States (or an equivalent foreign degree) with a concentration in rehabilitation teaching, or holds such a degree in a health field; and

"(ii) has successfully completed 350 hours of clinical practicum under the supervision of a rehabilitation teacher and has furnished not less than 9 months of supervised full-time rehabilitation teaching services;

"(C) has successfully completed the national examination in rehabilitation teaching administered by the Academy for Certification of Vision Rehabilitation and Education Professionals; and

"(D) meets such other criteria as the Secretary establishes.

"(5) The term 'low vision therapist' means an individual who—

"(A) if a State requires licensure or certification of low vision therapists, is licensed or certified by the State as a low vision therapist;

"(B)(i) holds a baccalaureate or higher degree from an accredited college or university in the United States (or an equivalent foreign degree) with a concentration in low vision therapy, or holds such a degree in a health field; and

"(ii) has successfully completed 350 hours of clinical practicum under the supervision of a physician, and has furnished not less than 9 months of supervised full-time low vision therapy services;

"(C) has successfully completed the national examination in low vision therapy administered by the Academy for Certification of Vision Rehabilitation and Education Professionals; and

"(D) meets such other criteria as the Secretary establishes.

"(6) The term 'vision impairment' means vision loss that constitutes a significant limitation of visual capability resulting from disease, trauma, or a congenital or degen-

erative condition that cannot be corrected by conventional means, including refractive correction, medication, or surgery, and that is manifested by 1 or more of the following:

"(A) Best corrected visual acuity of less than 20/60, or significant central field defect.

"(B) Significant peripheral field defect including homonymous or heteronymous bilateral visual field defect or generalized contraction or constriction of field.

"(C) Reduced peak contrast sensitivity in conjunction with a condition described in subparagraph (A) or (B).

"(D) Such other diagnoses, indications, or other manifestations as the Secretary may determine to be appropriate.".

(c) PAYMENT UNDER PART B.—

(1) PHYSICIAN FEE SCHEDULE.—Section 1848(j)(3) (42 U.S.C. 1395w–4(j)(3)) is amended by inserting "(2)(W)," after "(2)(S),".

(2) CARVE OUT FROM HOSPITAL OUTPATIENT DEPARTMENT PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting "vision rehabilitation services (as defined in section 1861(ww)(1)) or" after "does not include".

(3) CLARIFICATION OF BILLING REQUIREMENTS.—The first sentence of section 1842(b)(6) of such Act (42 U.S.C. 1395u(b)(6)) is amended—

(A) by striking ''and'' before ''(G)''; and

(B) by inserting before the period the following: '', and (H) in the case of vision rehabilitation services (as defined in section 1861(ww)(1)) furnished by a vision rehabilitation professional (as defined in section 1861(ww)(2)) while under the general supervision (as defined in section 1861(ww)(1)(D)) of a qualified physician (as defined in section 1861(ww)(1)(C)), payment shall be made to (i) the qualified physician or (ii) the facility (such as a rehabilitation agency, a clinic, or other facility) through which such services are furnished under the plan of care if there is a contractual arrangement between the vision rehabilitation professional and the facility under which the facility submits the bill for such services''.

(d) PLAN OF CARE.—Section 1835(a)(2) (42 U.S.C. 1395n(a)(2)) is amended—

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

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

(3) by inserting after subparagraph (F) the following new subparagraph:

"(G) in the case of vision rehabilitation services, (i) such services are or were required because the individual needed vision rehabilitation services, (ii) an individualized, written plan for furnishing such services has been established (I) by a qualified physician (as defined in section 1861(ww)(1)(C)), (II) by a qualified occupational therapist, or (III) in the case of such services furnished by a vision rehabilitation professional, by a qualified physician, (iii) the plan is periodically reviewed by the qualified physician, and (iv) such services are or were furnished while the individual is or was under the care of the qualified physician.".

(e) RELATIONSHIP TO REHABILITATION ACT OF 1973.—The provision of vision rehabilitation services under the medicare program under title XVIII (42 U.S.C. 1395 et seq.) shall not be taken into account for any purpose under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.).

(f) EFFECTIVE DATE.—

(1) INTERIM, FINAL REGULATIONS.—The Secretary shall publish a rule under this section in the Federal Register by not later than 180 days after the date of enactment of this Act to carry out the provisions of this section. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period for public comment of not less than 60 days.

(2) CONSULTATION.—The Secretary shall consult with the National Vision Rehabilitation Cooperative, the Association for Education and Rehabilitation of the Blind and Visually Impaired, the Academy for Certification of Vision Rehabilitation and Education Professionals, the American Academy of Ophthalmology, the American Occupational Therapy Association, the American Optometric Association, and such other qualified professional and consumer organizations as the Secretary determines appropriate in promulgating regulations to carry out this section.

**SEC. 447. 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. 448. COVERAGE OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES UNDER PART B OF THE MEDICARE PROGRAM.**

(a) COVERAGE OF SERVICES.—

(1) IN GENERAL.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(A) in subparagraph (U), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (V)(iii), by inserting ''and'' after the semicolon at the end; and

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

"(W) marriage and family therapist services (as defined in subsection (ww)(1)) and mental health counselor services (as defined in subsection (ww)(3));".

(2) DEFINITIONS.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Marriage and Family Therapist Services; Marriage and Family Therapist; Mental Health Counselor Services; Mental Health Counselor

"(ww)(1) The term 'marriage and family therapist services' means services performed by a marriage and family therapist (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses, which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

"(2) The term 'marriage and family therapist' means an individual who—

"(A) possesses a master's or doctoral degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law;

"(B) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and

"(C) in the case of an individual performing services in a State that provides for licensure or certification of marriage and family therapists, is licensed or certified as a marriage and family therapist in such State.

"(3) The term 'mental health counselor services' means services performed by a mental health counselor (as defined in paragraph (4)) for the diagnosis and treatment of mental illnesses which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

"(4) The term 'mental health counselor' means an individual who—

"(A) possesses a master's or doctor's degree in mental health counseling or a related field;

"(B) after obtaining such a degree has performed at least 2 years of supervised mental health counselor practice; and

"(C) in the case of an individual performing services in a State that provides for licensure or certification of mental health counselors or professional counselors, is licensed or certified as a mental health counselor or professional counselor in such State.".

(3) PROVISION FOR PAYMENT UNDER PART B.—Section 1832(a)(2)(B) (42 U.S.C. 1395k(a)(2)(B)) is amended by adding at the end the following new clause:

"(v) marriage and family therapist services and mental health counselor services;".

(4) AMOUNT OF PAYMENT.—Section 1833(a)(1) (42 U.S.C. 1395*l*(a)(1)) is amended—

(A) by striking "and (U)" and inserting "(U)"; and

(B) by inserting before the semicolon at the end the following: ", and (V) with respect to marriage and family therapist services and mental health counselor services under section

1861(s)(2)(W), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under subparagraph (L)''.

(5) EXCLUSION OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES FROM SKILLED NURSING FACILITY PROSPECTIVE PAYMENT SYSTEM.—Section 1888(e)(2)(A)(ii) (42 U.S.C. 1395yy(e)(2)(A)(ii)), as amended in section 301(a), is amended by inserting ''marriage and family therapist services (as defined in subsection (ww)(1)), mental health counselor services (as defined in section 1861(ww)(3)),'' after ''qualified psychologist services,''.

(6) INCLUSION OF MARRIAGE AND FAMILY THERAPISTS AND MENTAL HEALTH COUNSELORS AS PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.—Section 1842(b)(18)(C) (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clauses:

''(vii) A marriage and family therapist (as defined in section 1861(ww)(2)).

''(viii) A mental health counselor (as defined in section 1861(ww)(4)).''.

(b) COVERAGE OF CERTAIN MENTAL HEALTH SERVICES PROVIDED IN CERTAIN SETTINGS.—

(1) RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1861(aa)(1)(B) (42 U.S.C. 1395x(aa)(1)(B)) is amended by striking ''or by a clinical social worker (as defined in subsection (hh)(1)),'' and inserting '', by a clinical social worker (as defined in subsection (hh)(1)), by a marriage and family therapist (as defined in subsection (ww)(2)), or by a mental health counselor (as defined in subsection (ww)(4)),''.

(2) HOSPICE PROGRAMS.—Section 1861(dd)(2)(B)(i)(III) (42 U.S.C. 1395x(dd)(2)(B)(i)(III)) is amended by inserting ''or a marriage and family therapist (as defined in subsection (ww)(2))'' after ''social worker''.

(c) AUTHORIZATION OF MARRIAGE AND FAMILY THERAPISTS TO DEVELOP DISCHARGE PLANS FOR POST-HOSPITAL SERVICES.—Section 1861(ee)(2)(G) (42 U.S.C. 1395x(ee)(2)(G)) is amended by inserting ''marriage and family therapist (as defined in subsection (ww)(2)),'' after ''social worker,''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to services furnished on or after January 1, 2004.

**SEC. 449. MEDICARE DEMONSTRATION PROJECT FOR DIRECT ACCESS TO PHYSICAL THERAPY SERVICES.**

(a) IN GENERAL.—The Secretary shall conduct a demonstration project under this section (in this section referred to as the ''project'') to demonstrate the impact of allowing medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as comprehensive rehabilitation facility services on—

(1) costs under the medicare program under title XVIII of the Social Security Act; and

(2) the satisfaction of beneficiaries receiving such services.

(b) DEADLINE FOR ESTABLISHMENT; DURATION; SITES.—

(1) DEADLINE.—The Secretary shall establish the project not later than 1 year after the date of enactment of this Act.

(2) DURATION; SITES.—The project shall—

(A) be conducted for a period of 3 years;

(B) include sites in at least 5 States; and

(C) to the extent feasible, be conducted on a statewide basis in each State included under subparagraph (B).

(3) EARLY TERMINATION.—Notwithstanding paragraph (2)(A), the Secretary may terminate the operation of the project at a site before the end of the 3-year period specified in such paragraph if the Secretary determines, based on actual data, that the total amount expended for all services under this title for individuals at such site for a 12-month period are greater than the total amount that would have been expended for such services for such individuals for such period but for the operation of the project at such site.

(c) WAIVER OF MEDICARE REQUIREMENTS.—The Secretary shall waive compliance with such requirements of the medicare program under title XVIII of the Social Security Act to the extent and for the period the Secretary finds necessary to conduct the demonstration project.

(d) EVALUATIONS AND REPORTS.—

(1) EVALUATIONS.—

(A) IN GENERAL.—The Secretary shall conduct interim and final evaluations of the project.

(B) FOCUS.—The evaluations conducted under paragraph (1) shall—

(i) focus on the impact of the project on program costs under title XVIII of the

Social Security Act and patient satisfaction with health care items and services for which payment is made under such title; and

(ii) include comparisons, with respect to episodes of care involving direct access to physical therapy services and episodes of care involving a physician referral for such services, of—

(I) the average number of claims paid per episode for outpatient physical therapy services and physical therapy services furnished as comprehensive outpatient rehabilitation facility services;

(II) the average number of physician office visits per episode; and

(III) the average expenditures under such title per episode.

(2) INTERIM AND FINAL REPORTS.—The Secretary shall submit to the Committee on Finance of the Senate and the Committees on Ways and Means and Energy and Commerce of the House of Representatives reports on the evaluations conducted under paragraph (1) by—

(A) in the case of the report on the interim evaluation, not later than the end of the second year the project has been in operation; and

(B) in the case of the report on the final evaluation, not later than 180 days after the closing date of the project.

(3) FUNDING FOR EVALUATION.—There are authorized to be appropriated such sums as may be necessary to provide for the evaluations and reports required by this subsection.

(e) DEFINITIONS.—In this section:

(1) COMPREHENSIVE OUTPATIENT REHABILITATION SERVICES.—Subject to paragraph (2), the term ''comprehensive outpatient rehabilitation services'' has the meaning given to such term in section 1861(cc) of the Social Security Act (42 U.S.C. 1395x(cc)).

(2) DIRECT ACCESS.—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—

(A) without regard to any requirement that—

(i) an individual be under the care of (or referred by) a physician; or

(ii) services be provided under the supervision of a physician; and

(B) by allowing a physician or a qualified physical therapist to satisfy any requirement for—

(i) certification and recertification; and

(ii) establishment and periodic review of a plan of care.

(3) FEE-FOR-SERVICE MEDICARE BENEFICIARY.—The term ''fee-for-service medicare beneficiary'' means an individual who—

(A) is enrolled under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.); and

(B) is not enrolled in—

(i) a Medicare+Choice plan under part C of such title (42 U.S.C. 1395w–21 et seq.);

(ii) a plan offered by an eligible organization under section 1876 of such Act (42 U.S.C. 1395mm);

(iii) a program of all-inclusive care for the elderly (PACE) under section 1894 of such Act (42 U.S.C. 1395eee); or

(iv) a social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203).

(4) OUTPATIENT PHYSICAL THERAPY SERVICES.—Subject to paragraph (2), the term ''outpatient physical therapy services'' has the meaning given to such term in section 1861(p) of the Social Security Act (42 U.S.C. 1395x(p)), except that such term shall not include the speech-language pathology services described in the fourth sentence of such section.

(5) PHYSICIAN.—The term ''physician'' has the meaning given to such term in section 1861(r)(1) of such Act (42 U.S.C. 1395x(r)(1)).

(6) QUALIFIED PHYSICAL THERAPIST.—The term ''qualified physical therapist'' has the meaning given to such term for purposes of section 1861(p)

of such Act (42 U.S.C. 1395x(p)), as in effect on the date of enactment of this Act.

**SEC. 450. DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND.**

(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of enactment of this Act, the Secretary shall conduct a two-year demonstration project under part B of title XVIII of the Social Security Act under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be homebound for purposes of receiving home health services under the medicare program.

(b) MEDICARE BENEFICIARY DESCRIBED.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if the beneficiary—

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

(2) requires the individual to receive assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the individual's life;

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

(4) requires technological assistance or the assistance of another person to leave the home.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

(d) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000.

(e) DATA.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program.

(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e) and shall include—

(1) an examination of whether the provision of home health services to medicare beneficiaries under the project—

(A) adversely effects the provision of home health services under the medicare program; or

(B) directly causes an unreasonable increase of expenditures under the medicare program for the provision of such services that is directly attributable to such clarification;

(2) the specific data evidencing the amount of any increase in expenditures that is a directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the medicare program; and

(3) specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to the medicare program.

(g) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent

and for such period as the Secretary determines is necessary to conduct demonstration projects.

(h) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the medicare program.

(i) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

(j) DEFINITIONS.—In this section:

(1) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual who is enrolled under part B of title XVIII of the Social Security Act.

(2) HOME HEALTH SERVICES.—The term ''home health services'' has the meaning given such term in section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ''activities of daily living'' means eating, toileting, transferring, bathing, and dressing.

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

**SEC. 450A. DEMONSTRATION PROJECT FOR EXCLUSION OF BRACHYTHERAPY DEVICES FROM PROSPECTIVE PAYMENT SYSTEM FOR OUTPATIENT HOSPITAL SERVICES.**

(a) DEMONSTRATION PROJECT.—The Secretary shall conduct a demonstration project under part B of title XVIII of the Social Security Act under which brachytherapy devices shall be excluded from the prospective payment system for outpatient hospital services under the medicare program and, notwithstanding section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), the amount of payment for a device of brachytherapy furnished under the demonstration project shall be equal to the hospital's charges for each device furnished, adjusted to cost.

(b) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY DEVICES.—The Secretary shall create additional groups of covered OPD services that classify devices of brachytherapy furnished under the demonstration project separately from the other services (or group of

services) paid for under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium–103 and iodine–125 devices.

(c) DURATION.—The Secretary shall conduct the demonstration project under this section for the 3-year period beginning on the date that is 90 days after the date of enactment of this Act.

(d) REPORT.—Not later than January 1, 2007, the Secretary shall submit to Congress a report on the demonstration project conducted under this section. The report shall include an evaluation of patient outcomes under the demonstration project, as well as an analysis of the cost effectiveness of the demonstration project.

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

(f) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Supplementary 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 project under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration project 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 project under this section was not implemented.

**SEC. 450B. REIMBURSEMENT FOR TOTAL BODY ORTHOTIC MANAGEMENT FOR CERTAIN NURSING HOME PATIENTS.**

(a) IN GENERAL.—Not later than 60 days after the date of the enactment of this Act, the Secretary shall issue product codes that qualified practioners and suppliers may use to receive reimbursement under section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) for qualified total body orthotic management devices used for the treatment of nonambulatory individuals with severe musculoskeletal conditions who are in the full-time care of skilled nursing facilities (as defined in section 1861(j) of such Act (42 U.S.C. 1395x(j))). In issuing such codes, the Secretary shall take all steps necessary to prevent fraud and abuse.

(b) QUALIFIED TOTAL BODY ORTHOTIC MANAGEMENT DEVICE.—For purposes of this section, the term ''qualified total body orthotic management device'' means a medically-prescribed device which—

(1) consists of custom fitted individual braces with adjustable points at the hips, knee, ankle, elbow, and wrist, but only if—

(A) the individually adjustable braces are attached to a frame which is an integral component of the device and cannot function or be used apart from the frame; and

(B) the frame is designed such that it serves no purpose without the braces; and

(2) is designed to—

(A) improve function;

(B) retard progression of musculoskeletal deformity; or

(C) restrict, eliminate, or assist in the functioning of lower and upper extremities and pelvic, spinal, and cervical regions of the body affected by injury, weakness, or deformity,

of an individual for whom stabilization of affected areas of the body, or relief of pressure points, is required for medical reasons.

**SEC. 450C. AUTHORIZATION OF REIMBURSEMENT FOR ALL MEDICARE PART B SERVICES FURNISHED BY CERTAIN INDIAN HOSPITALS AND CLINICS.**

(a) IN GENERAL.—Section 1880(e) (42 U.S.C. 1395qq(e)) is amended—

(1) in paragraph (1)(A), by striking ''for services described in paragraph (2)'' and inserting ''for all items and services for which payment may be made under such part'';

(2) by striking paragraph (2); and

(3) by redesignating paragraph (3) as paragraph (2).

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after October 1, 2004.

**SEC. 450D. COVERAGE OF CARDIOVASCULAR SCREENING TESTS.**

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (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) cardiovascular screening tests (as defined in subsection (ww)(1));".

(b) SERVICES DESCRIBED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Cardiovascular Screening Tests

"(ww)(1) The term 'cardiovascular screening tests' means the following diagnostic tests for the early detection of cardiovascular disease:

"(A) Tests for the determination of cholesterol levels.

"(B) Tests for the determination of lipid levels of the blood.

"(C) Such other tests for cardiovascular disease as the Secretary may approve.

"(2)(A) Subject to subparagraph (B), the Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cardiovascular screening tests.

"(B) With respect to the frequency of cardiovascular screening tests approved by the Secretary under subparagraph (A), in no case may the frequency of such tests be more often than once every 2 years.".

(c) FREQUENCY.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

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

(2) by striking the semicolon at the end of subparagraph (I) and inserting '', and''; and

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

''(J) in the case of a cardiovascular screening test (as defined in section 1861(ww)(1)), which is performed more frequently than is covered under section 1861(ww)(2).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

**SEC. 450E. MEDICARE COVERAGE OF SELF-INJECTED BIOLOGICALS.**

(a) COVERAGE.—

(1) IN GENERAL.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

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

(B) in subparagraph (V), by inserting ''and'' at the end; and

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

"(W)(i) a self-injected biological (which is approved by the Food and Drug Administration) that is prescribed as a complete replacement for a drug or biological (including the same biological for which payment is made under this title when it is furnished incident to a physicians' service) that would otherwise be described in subparagraph (A) or (B) and that is furnished during 2004 or 2005; and

"(ii) a self-injected drug that is used to treat multiple sclerosis;".

(2) CONFORMING AMENDMENT.—Subparagraphs (A) and (B) of section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) are each amended by inserting ", except for any drug or biological described in subparagraph (W)," after "which".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to drugs and biologicals furnished on or after January 1, 2004 and before January 1, 2006.

**SEC. 450F. EXTENSION OF MEDICARE SECONDARY PAYER RULES FOR INDIVIDUALS WITH END-STAGE RENAL DISEASE.**

Section 1862(b)(1)(C) (42 U.S.C. 1395y(b)(1)(C)) is amended—

(1) in the last sentence, by inserting ", and before January 1, 2004" after "prior to such date)"; and

(2) by adding at the end the following new sentence: "Effective for items and services furnished on or after January 1, 2004 (with respect to periods beginning on or after June 1, 2002), clauses (i) and (ii) shall be applied by substituting '36-month' for '12-month' each place it appears in the first sentence.

**SEC. 450G. REQUIRING THE INTERNAL REVENUE SERVICE TO DEPOSIT INSTALLMENT AGREEMENT AND OTHER FEES IN THE TREASURY AS MISCELLANEOUS RECEIPTS.**

Notwithstanding any other provision of law, the Secretary of the Treasury is required to deposit in the Treasury as miscellaneous receipts any fee receipts, including fees from installment agreements and restructured installment agreements, collected under the authority provided by Section 3 of the Administrative Provisions of the Internal Revenue Service of Public Law 103–329, the Treasury, Postal Service and General Government Appropriations Act, 1995. Fees collected under this section shall be available for use by the Internal Revenue Service only to

the extent that such authority is provided in advance in an appropriations Act.

**SEC. 450H INCREASING TYPES OF ORIGINATING TELEHEALTH SITES AND FACILITATING THE PROVISION OF TELEHEALTH SERVICES ACROSS STATE LINES.**

(a) INCREASING TYPES OF ORIGINATING SITES.—Section 1834(m)(4)(C)(ii) (42 U.S.C. 1395m(m)(4)(C)(ii)) is amended by adding at the end the following new subclauses:

"(VI) A skilled nursing facility (as defined in section 1819(a)).

"(VII) An assisted-living facility (as defined by the Secretary).

"(VIII) A board-and-care home (as defined by the Secretary).

"(IX) A county of community health clinic (as defined by the Secretary).

"(X) A community mental health center (as described in section 1861(ff)(2)(B)).

"(XI) A long-term care facility (as defined by the Secretary).

"(XII) A facility operated by the Indian Health Service or by an Indian tribe, tribal organization, or an urban Indian organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)) directly, or under contract or other arrangement.".

(b) FACILITATING THE PROVISION OF TELEHEALTH SERVICES ACROSS STATE LINES.—

(1) IN GENERAL.—For purposes of expediting the provision of telehealth services for which payment is made under the medicare program under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), across State lines, the Secretary shall, in consultation with representatives of States, physicians, health care practitioners, and patient advocates, encourage and facilitate the adoption of State provisions allowing for multistate practitioner licensure across State lines.

(2) DEFINITIONS.—In this subsection:

(A) TELEHEALTH SERVICE.—The term "telehealth service" has the meaning given that term in subparagraph (F)(i) of section

1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)).

(B) PHYSICIAN, PRACTITIONER.—The terms ''physician'' and ''practitioner'' have the meaning given those terms in subparagraphs (D) and (E), respectively, of such section.

(C) MEDICARE PROGRAM.—The term ''medicare program'' means the program of health insurance administered by the Secretary under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

**SEC. 450I. DEMONSTRATION PROJECT FOR COVERAGE OF SURGICAL FIRST ASSISTING SERVICES OF CERTIFIED REGISTERED NURSE FIRST ASSISTANTS.**

(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 surgical first assisting services furnished by a certified registered nurse first assistant to medicare beneficiaries.

(b) 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.

(c) PAYMENT RATES.—Payment under the demonstration project for surgical first assisting services furnished by a certified registered nurse first assistant shall be made at the rate of 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under sec-

tion 1848(b) of the Social Security Act (42 U.S.C. 1395w–4(b)) for the same services if furnished by a physician.

(d) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in 5 States selected by the Secretary.

(e) DURATION.—The Secretary shall conduct the demonstration project for the 3-year period beginning on the date that is 90 days after the date of the enactment of this Act.

(f) REPORT.—Not later than January 1, 2007, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient outcomes under the project, as well as an analysis of the cost effectiveness of the project.

(g) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Supplementary 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 project under this section.

(2) BUDGET NEUTRALITY.—In conducting the project 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 project under this section was not implemented.

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

**SEC. 450J. EQUITABLE TREATMENT FOR CHILDREN'S HOSPITALS.**

(a) IN GENERAL.—Section 1833(t)(7)(D)(ii) (42 U.S.C. 1395l(t)(7)(D)(ii)) is amended to read as follows:

"(ii) PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN'S HOSPITALS.—

"(I) IN GENERAL.—Subject to subclause (II), in the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

"(II) SPECIAL RULE FOR CERTAIN CHILDREN'S HOSPITALS.—In the case of a hospital described in section 1886(d)(1)(B)(iii) that is located in a State with a reimbursement system under section 1814(b)(3), but that is not reimbursed under such system, for covered OPD services furnished on or after October 1, 2003, and for which the PPS amount is less than the greater of the pre-BBA amount or the reasonable operating and capital costs without reductions of the hospital in providing such services, the amount of payment under this subsection shall be increased by the amount of such difference.".

**SEC. 450K. TREATMENT OF PHYSICIANS' SERVICES FURNISHED IN ALASKA.**

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

(1) in paragraph (1), in the matter preceding subparagraph (A), by striking "paragraph (2)" and inserting "paragraphs (2) and (4)"; and

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

"(4) TREATMENT OF PHYSICIANS' SERVICES FURNISHED IN ALASKA.—

"(A) IN GENERAL.—With respect to physicians' services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, the fee schedule for such services shall be determined as follows:

"(i) Subject to clause (ii), the payment amount for a service furnished in a year shall be an amount equal to—

"(I) in the case of services furnished in calendar year 2004, 90 percent of the VA Alaska fee schedule amount for the service for fiscal year 2001; and

"(II) in the case of services furnished in calendar year 2005, the amount determined under subclause (I) for 2004, increased by the annual update determined under subsection (d) for the year involved.

"(ii) In the case of a service for which there was no VA Alaska fee schedule

amount for fiscal year 2001, the payment amount shall be an amount equal to the sum of—

"(I) the amount of payment for the service that would otherwise apply under this section; plus

"(II) an amount equal to the applicable percent (as described in subparagraph (C)) of the amount described in subclause (I).

"(B) VA ALASKA FEE SCHEDULE AMOUNT.—For purposes of this paragraph, the term 'VA Alaska fee schedule amount' means the amount that was paid by the Department of Veterans Affairs in Alaska in fiscal year 2001 for non-Department of Veterans Affairs physicians' services associated with either outpatient or inpatient care provided to individuals eligible for hospital care or medical services under chapter 17 of title 38, United States Code, at a non-Department facility (as that term is defined in section 1701(4) of such title 38.

"(C) APPLICABLE PERCENT.—For purposes of this paragraph, the term 'applicable percent' means the weighted average percentage

(based on claims under this section) by which the fiscal year 2001 VA Alaska fee schedule amount for physicians' services exceeded the amount of payment for such services under this section that applied in Alaska in 2001.''.

**SEC. 450L. DEMONSTRATION PROJECT TO EXAMINE WHAT WEIGHT LOSS WEIGHT MANAGEMENT SERVICES CAN COST EFFECTIVELY REACH THE SAME RESULT AS THE NIH DIABETES PRIMARY PREVENTION TRIAL STUDY: A 50 PERCENT REDUCTION IN THE RISK FOR TYPE 2 DIABETES FOR INDIVIDUALS WHO HAVE IMPAIRED GLUCOSE TOLERANCE AND ARE OBESE.**

(a) IN GENERAL.—Inasmuch as the NIH Diabetes Primary Prevention Trial study proved that the risk of type 2 diabetes could be cut in half when the Institute of Medicine definition of successful weight loss (5 percent weight loss maintained for a year) is achieved by individuals at risk for type 2 diabetes due to obesity and impaired glucose tolerance, the Secretary shall conduct a demonstration project to examine the cost effectiveness and health benefits of providing group weight loss management services to achieve the same result for beneficiaries under the medicare program under title XVIII of the So-

cial Security Act who are obese and have impaired glucose tolerance.

(b) LIMITATION.—The cost of the group weight loss management services provided under subsection (a) shall not exceed the cost per recipient per year of the medical nutritional therapy benefit currently available to medicare beneficiaries.

(c) SCOPE OF SERVICES.—

(1) DURATION.—The project shall be conducted for a period of 2 fiscal years.

(2) SITES.—The Secretary shall designate the sites at which to conduct the demonstration program under this section. In selecting sites under this paragraph, the Secretary shall give preference to sites located in—

(A) rural areas; or

(B) areas that have a high concentration of Native Americans with type 2 diabetes.

(3) FUNDING.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying

out the demonstration program under this section.

(B) LIMITATION.—The total amount of the payments that may be made under this section shall not exceed $2,500,000 for each fiscal year in which the project is conducted under paragraph (1).

(d) COVERAGE AS MEDICARE PART B SERVICES.—

(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, medical nutrition therapy services furnished under the project shall be considered to be services covered under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.).

(2) PAYMENT.—Payment for such services shall be made at a rate of 80 percent of the lesser of the actual charge for the services or 85 percent of the fee schedule amount provided under section 1848 of the Social Security Act (42 U.S.C. 139w–4) for the same services if such services were furnished by a physician.

(3) APPLICATION OF LIMITS OF BILLING.—The provisions of section 1842(b)(18) of the Social Security Act (42 U.S.C. 1395u(b)(18)) shall apply to a group weight loss management professional fur-

nishing services under the project in the same manner as they to a practitioner described in subparagraph (C) of such section furnishing services under title XVIII of such Act.

(e) REPORTS.—The Secretary shall submit to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate interim reports on the project and a final report on the project not later than the date that is 6 months after the date on which the project concludes. The final report shall include an evaluation of the impact of the use of group weight loss management services as part of medical nutrition therapy on medicare beneficiaries and on the medicare program, including any impact on reducing costs under the program and improving the health of beneficiaries.

(f) DEFINITIONS.—For purposes of this section:

(1) The term ''obesity'' means that an individual has a Body Mass Index (BMI) of 30 and above.

(2) GROUP WEIGHT LOSS MANAGEMENT SERVICES.—The term ''group weight loss management services'' means comprehensive services furnished to individuals who have been diagnosed and referred by

a physician as having impaired glucose tolerance and who are obese that consist of—

(A) assessment and treatment based on the needs of individuals as determined by a group weight loss management professional; or

(B) a specific program or method that has demonstrated its efficacy to produce and maintain weight loss through results published in peer-reviewed scientific journals using recognized research methods and statistical analysis that provides—

(i) assessment of current body weight and recording of weight status at each meeting session;

(ii) provision of a healthy eating plan;

(iii) provision of an activity plan;

(iv) provision of a behavior modification plan; and

(v) a weekly group support meeting.

(3) GROUP WEIGHT LOSS MANAGEMENT PROFESSIONAL.—The term ''group weight loss management professional'' means an individual who has completed training to provide a program or method that has completed clinical trials and has dem-

onstrated its efficacy through publications in peer-reviewed scientific journals who—

(A)(i) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) in nutrition social work, psychology with experience in behavioral modification methods to reduce obesity; or

(ii) has completed a curriculum of training for a specific behavioral based weight management program as described in section (4)(A)(2) and recommended in the NIH Clinical Guidelines on Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, chapter 4, section H, parts 1, 2, 3, 4, and pursuant to guidelines by the Secretary; and

(B)(i) is licensed or certified as a group weight loss management professional by the State in which the services are performed; or

(ii) is certified by an organization that meets such criteria as the Secretary establishes with—

(I) national organizations representing consumers such as the American Obesity Association and the elderly; and

(II) such other organizations as the Secretary determines appropriate.

# Subtitle C—Provisions Relating to Parts A and B

**SEC. 451. INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.**

(a) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) on or after October 1, 2004, and before October 1, 2006, 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. 452. LIMITATION ON REDUCTION IN AREA WAGE ADJUSTMENT FACTORS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR HOME HEALTH SERVICES.**

Section 1895(b)(4)(C) (42 U.S.C. 1395fff(b)(4)(C)) is amended—

(1) by striking ''FACTORS.—The Secretary'' and inserting ''FACTORS.—

''(i) IN GENERAL.—Subject to clause (ii), the Secretary''; and

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

''(ii) LIMITATION ON REDUCTION IN FISCAL YEAR 2005 AND 2006.—For fiscal years 2005 and 2006, the area wage adjustment factor applicable to home health services furnished in an area in the fiscal year may not be more that 3 percent less than the area wage adjustment factor applicable to home health services for the area for the previous year.''.

**SEC. 453. 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

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

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

(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 hospital that is primarily or exclusively engaged in the care and treatment of one of the following:

''(i) patients with a cardiac condition;

"(ii) patients with an orthopedic condition;

"(iii) patients receiving a surgical procedure; or

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

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

"(i) determined by the Secretary—

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

"(II) under development as of such date;

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

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

(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;

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

"(C) the Secretary determines, with respect to such entity, that such services would not be available in such area but for the ownership or investment interest.".

(b) EFFECTIVE DATE.—Subject to paragraph (2), the amendments made by this section shall apply to referrals made for designated health services on or after January 1, 2004.

(c) APPLICATION OF EXCEPTION FOR HOSPITALS UNDER DEVELOPMENT.—For purposes of section 1877(h)(7)(B)(i)(II) of the Social Security Act, as added by subsection (a)(1)(B), in determining whether a hospital

is under development as of June 12, 2003, the Secretary shall consider—

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

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

**SEC. 454. DEMONSTRATION PROGRAM FOR SUBSTITUTE ADULT DAY SERVICES.**

(a) ESTABLISHMENT.—The Secretary shall establish a demonstration program (in this section referred to as the ''demonstration program'') under which the Secretary provides eligible medicare beneficiaries with coverage under the medicare program of substitute adult day services furnished by an adult day services facility.

(b) PAYMENT RATE FOR SUBSTITUTE ADULT DAY SERVICES.—

(1) PAYMENT RATE.—For purposes of making payments to an adult day services facility for substitute adult day services under the demonstration program, the following rules shall apply:

(A) ESTIMATION OF PAYMENT AMOUNT.—The Secretary shall estimate the amount that

would otherwise be payable to a home health agency under section 1895 of the Social Security Act (42 U.S.C. 1395fff) for all home health services described in subsection (i)(4)(B)(i) under the plan of care.

(B) AMOUNT OF PAYMENT.—Subject to paragraph (3)(B), the total amount payable for substitute adult day services under the plan of care is equal to 95 percent of the amount estimated to be payable under subparagraph (A).

(2) LIMITATION ON BALANCE BILLING.—Under the demonstration program, an adult day services facility shall accept as payment in full for substitute adult day services (including those services described in clauses (ii) through (iv) of subsection (i)(4)(B)) furnished by the facility to an eligible medicare beneficiary the amount of payment provided under the demonstration program for home health services consisting of substitute adult services.

(3) ADJUSTMENT IN CASE OF OVERUTILIZATION OF SUBSTITUTE ADULT DAY SERVICES TO ENSURE BUDGET NEUTRALITY.—The Secretary shall monitor the expenditures under the demonstration program and under title XVIII of the Social Security Act for home health services. If the Secretary

estimates that the total expenditures under the demonstration program 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 program had not been conducted, the Secretary shall adjust the rate of payment to adult day services facilities under paragraph (1)(B) in order to eliminate such excess.

(c) DEMONSTRATION PROGRAM SITES.—The demonstration program shall be conducted in not more than 3 sites selected by the Secretary.

(d) DURATION; IMPLEMENTATION.—

(1) DURATION.—The Secretary shall conduct the demonstration program for a period of 3 years.

(2) IMPLEMENTATION.—The Secretary may not implement the demonstration program before October 1, 2004.

(e) VOLUNTARY PARTICIPATION.—Participation of eligible medicare beneficiaries in the demonstration program shall be voluntary.

(f) WAIVER AUTHORITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary may waive such require-

ments of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary for the purposes of carrying out the demonstration program.

(2) MAY NOT WAIVE ELIGIBILITY REQUIREMENTS FOR HOME HEALTH SERVICES.—The Secretary may not waive the beneficiary eligibility requirements for home health services under title XVIII of the Social Security Act.

(g) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration program.

(2) REPORT.—Not later than 30 months after the commencement of the demonstration program, the Secretary shall submit to Congress a report on the evaluation conducted under paragraph (1) and shall include in the report the following:

(A) An analysis of the patient outcomes and costs of furnishing care to the eligible medicare beneficiaries participating in the demonstration program as compared to such outcomes and costs to such beneficiaries receiving only home health services under title XVIII of

the Social Security Act for the same health conditions.

(B) Such recommendations regarding the extension, expansion, or termination of the program as the Secretary determines appropriate.

(i) DEFINITIONS.—In this section:

(1) ADULT DAY SERVICES FACILITY.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the term ''adult day services facility'' means a public agency or private organization, or a subdivision of such an agency or organization, that—

(i) is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;

(ii) provides the items and services described in paragraph (4)(B); and

(iii) meets the requirements of paragraphs (2) through (8) of subsection (o).

(B) INCLUSION.—Notwithstanding subparagraph (A), the term ''adult day services facility'' shall include a home health agency in which the items and services described in

clauses (ii) through (iv) of paragraph (4)(B) are provided—

(i) by an adult day services program that is licensed or certified by a State, or accredited, to furnish such items and services in the State; and

(ii) under arrangements with that program made by such agency.

(C) WAIVER OF SURETY BOND.—The Secretary may waive the requirement of a surety bond under section 1861(o)(7) of the Social Security Act (42 U.S.C. 1395x(o)(7)) in the case of an agency or organization that provides a comparable surety bond under State law.

(2) ELIGIBLE MEDICARE BENEFICIARY.—The term ''eligible medicare beneficiary'' means an individual eligible for home health services under title XVIII of the Social Security Act.

(3) 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)).

(4) SUBSTITUTE ADULT DAY SERVICES.—

(A) IN GENERAL.—The term ''substitute adult day services'' means the items and serv-

ices described in subparagraph (B) that are furnished to an individual by an adult day services facility as a part of a plan under section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) that substitutes such services for some or all of the items and services described in subparagraph (B)(i) furnished by a home health agency under the plan, as determined by the physician establishing the plan.

(B) ITEMS AND SERVICES DESCRIBED.—The items and services described in this subparagraph are the following items and services:

(i) Items and services described in paragraphs (1) through (7) of such section 1861(m).

(ii) Meals.

(iii) A program of supervised activities designed to promote physical and mental health and furnished to the individual by the adult day services facility in a group setting for a period of not fewer than 4 and not greater than 12 hours per day.

(iv) A medication management program (as defined in subparagraph (C)).

(C) MEDICATION MANAGEMENT PROGRAM.—For purposes of subparagraph (B)(iv), the term ''medication management program'' means a program of services, including medicine screening and patient and health care provider education programs, that provides services to minimize—

(i) unnecessary or inappropriate use of prescription drugs; and

(ii) adverse events due to unintended prescription drug-to-drug interactions.

**SEC. 455. MEDPAC STUDY ON MEDICARE PAYMENTS AND EFFICIENCIES IN THE HEALTH CARE SYSTEM.**

Not later than 18 months after the date of enactment of this Act, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall provide Congress with recommendations to recognize and reward, within payment methodologies for physicians and hospitals established under the medicare program under title XVIII of the Social Security Act, efficiencies, and the lower utilization of services created by the practice of medicine in historically efficient and low-cost areas. Measures of efficiency recognized in accordance with the preceding sentence shall include—

(1) shorter hospital stays than the national average;

(2) fewer physician visits than the national average;

(3) fewer laboratory tests than the national average;

(4) a greater utilization of hospice services than the national average; and

(5) the efficacy of disease management and preventive health services.

**SEC. 456. MEDICARE COVERAGE OF KIDNEY DISEASE EDUCATION SERVICES.**

(a) COVERAGE OF KIDNEY DISEASE EDUCATION SERVICES.—

(1) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C.1395x) is amended—

(A) in subsection (s)(2)—

(i) in subparagraph (U), by striking ''and'' at the end;

(ii) in subparagraph (V)(iii), by adding ''and'' at the end; and

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

''(W) kidney disease education services (as defined in subsection (ww));''; and

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

"Kidney Disease Education Services

"(ww)(1) The term 'kidney disease education services' means educational services that are—

"(A) furnished to an individual with kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;

"(B) furnished, upon the referral of the physician managing the individual's kidney condition, by a qualified person (as defined in paragraph (2)); and

"(C) designed—

"(i) to provide comprehensive information regarding—

"(I) the management of comorbidities;

"(II) the prevention of uremic complications; and

"(III) each option for renal replacement therapy (including peritoneal dialysis, hemodialysis (including vascular access options), and transplantation); and

"(ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy.

"(2) The term 'qualified person' means—

"(A) a physician (as described in subsection (r)(1));

"(B) an individual who—

"(i) is—

"(I) a registered nurse;

"(II) a registered dietitian or nutrition professional (as defined in subsection (vv)(2));

"(III) a clinical social worker (as defined in subsection (hh)(1));

"(IV) a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)); or

"(V) a transplant coordinator; and

"(ii) meets such requirements related to experience and other qualifications that the Secretary finds necessary and appropriate for furnishing the services described in paragraph (1); or

"(C) a renal dialysis facility subject to the requirements of section 1881(b)(1) with personnel who—

"(i) provide the services described in paragraph (1); and

"(ii) meet the requirements of subparagraph (A) or (B).

"(3) The Secretary shall develop the requirements under paragraph (2)(B)(ii) after consulting with physicians, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations described in section 1881(c)(2), and other knowledgeable persons.

"(4) In promulgating regulations to carry out this subsection, the Secretary shall ensure that such regulations ensure that each beneficiary who is entitled to kidney disease education services under this title receives such services in a timely manner that ensures that the beneficiary receives the maximum benefit of those services.

"(5) The Secretary shall monitor the implementation of this subsection to ensure that beneficiaries who are eligible for kidney disease education services receive such services in the manner described in paragraph (4).".

(2) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—Section 1848(j)(3) of such Act (42 U.S.C. 1395w–4(j)(3)) is amended by inserting ", (2)(W)", after "(2)(S)".

(3) PAYMENT TO RENAL DIALYSIS FACILITIES.—Section 1881(b) of such Act (42 U.S.C. 1395rr(b)), as amended by section 433(b)(5), is further amended by adding at the end the following new paragraph:

''(13) For purposes of paragraph (7), the single composite weighted formulas determined under such paragraph shall not take into account the amount of payment for kidney disease education services (as defined in section 1861(ww)). Instead, payment for such services shall be made to the renal dialysis facility on an assignment-related basis under section 1848.''.

(4) ANNUAL REPORT TO CONGRESS.—Not later than April 1, 2004, and annually thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the number of medicare beneficiaries who are entitled to kidney disease education services (as defined in section 1861(ww) of the Social Security Act, as added by paragraph (1)) under title XVIII of such Act and who receive such services, together with such recommendations for legislative and administrative action as the Secretary determines to be appropriate to fulfill the legislative

intent that resulted in the enactment of that subsection.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004.

**SEC. 457. 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) 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).

**SEC. 458. IMPROVEMENTS IN NATIONAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.**

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the third sentence of subsection (a) by inserting ''consistent with subsection (j)'' after ''the Secretary shall ensure''; and

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

''(j) NATIONAL COVERAGE DETERMINATION PROCESS.—

''(1) 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.

"(2) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—At the end of the 6-month period (with respect to a request under paragraph (1)(A)) or 9-month period (with respect to a request under paragraph (1)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall—

"(A) make a draft of proposed decision on the request available to the public through the Medicare Internet site of the Department of Health and Human Services or other appropriate means;

"(B) provide a 30-day period for public comment on such draft;

"(C) make a final decision on the request within 60 days of the conclusion of the 30-day period referred to under subparagraph (B);

"(D) include in such final decision summaries of the public comments received and responses thereto;

"(E) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

"(F) in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coverage decision at the end of the 60-day period referred to in subparagraph (C).

"(3) NATIONAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection, the term 'national coverage determination' has the meaning given such term in section 1869(f)(1)(B).".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to national coverage determinations as of January 1, 2004.

**SEC. 459. INCREASE IN MEDICARE PAYMENT FOR CERTAIN HOME HEALTH SERVICES.**

(a) IN GENERAL.—Section 1895 of the Social Security Act (42 U.S.C. 1395fff) is amended by adding at the end the following:

"(f) INCREASE IN PAYMENT FOR SERVICES FURNISHED IN A RURAL AREA.—

"(1) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D)) on or after October 1, 2004 and before October 1, 2006, the Secretary shall increase the payment amount otherwise made under this section for such services by 10 percent.

"(2) WAIVER OF BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under this section applicable to home health services furnished during any period to offset the increase in payments resulting from the application of paragraph (1).".

(b) PAYMENT ADJUSTMENT.—Section 1895(b)(5) of the Social Security Act (42 U.S.C. 1395fff(b)(5)) is amended by adding at the end the following: "Notwithstanding this paragraph, the total amount of the additional payments or payment adjustments made under this paragraph may not exceed, with respect to fiscal year 2004, 3 percent, and, with respect to fiscal years 2005

and 2006, 4 percent, of the total payments projected or estimated to be made based on the prospective payment system under this subsection in the year involved.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after October 1, 2003.

**SEC. 460. 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) 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).

**SEC. 461. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.**

(a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

(1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(A) in subparagraph (A)(ii), by striking ''promptly (as determined in accordance with regulations)'';

(B) in subparagraph (B)—

(i) by redesignating clauses (i) through (iii) as clauses (ii) through (iv), respectively; and

(ii) by inserting before clause (ii), as so redesignated, the following new clause:

"(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall be effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98-369).

(b) CLARIFYING AMENDMENTS TO CONDITIONAL PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is further amended—

(1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence

at the end: ''An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.'';

(2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)(B)—

(A) by striking the first sentence and inserting the following: ''A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.''; and

(B) in the final sentence, by striking ''on the date such notice or other information is received'' and inserting ''on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received''; and

(3) in subparagraph (B)(iii), , as redesignated by subsection (a)(2)(B), by striking the first sentence and inserting the following: ''In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.''.

(c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking ''such'' before ''paragraphs''.

**SEC. 462. MEDICARE PANCREATIC ISLET CELL TRANSPLANT DEMONSTRATION PROJECT.**

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

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

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

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

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

**SEC. 463. INCREASE IN MEDICARE PAYMENT FOR CERTAIN HOME HEALTH SERVICES.**

(a) IN GENERAL.—Section 1895 of the Social Security Act (42 U.S.C. 1395fff) is amended by adding at the end the following:

"(f) INCREASE IN PAYMENT FOR SERVICES FURNISHED IN A RURAL AREA.—

"(1) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D)) on or after October 1, 2004, and before October 1, 2006, the Secretary shall increase the payment amount otherwise made under this section for such services by 10 percent.

"(2) WAIVER OF BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective

payment amount (or amounts) under this section applicable to home health services furnished during any period to offset the increase in payments resulting from the application of paragraph (1).''.

(b) PAYMENT ADJUSTMENT.—Section 1895(b)(5) of the Social Security Act (42 U.S. C. 1395fff(b)(5)) is amended by adding at the end the following: ''Notwithstanding this paragraph, the total amount of the additional payments or payment adjustments made under this paragraph may not exceed, with respect to fiscal year 2004, 3 percent, and, with respect to fiscal years 2005 and 2006, 4 percent, of the total payments projected or estimated to be made based on the prospective payment system under this subsection in the year involved.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after October 1, 2003.

**SEC. 464. SENSE OF THE SENATE CONCERNING MEDICARE PAYMENT UPDATE FOR PHYSICIANS AND OTHER HEALTH PROFESSIONALS.**

(a) FINDINGS.—The Senate makes the following findings:

(1) The formula by which medicare payments are updated each year for services furnished by phy-

sicians and other health professionals is fundamentally flawed.

(2) The flawed physician payment update formula is causing a continuing physician payment crisis, and, without congressional action, medicare payment rates for physicians and other practitioners are predicted to fall by 4.2 percent in 2004.

(3) A physician payment cut in 2004 would the fifth cut since 1991, and would be on top of a 5.4 percent cut in 2002, with additional cuts estimated for 2005, 2006, and 2007. From 1991 through 2003, payment rates for physicians and health professionals fell 14 percent behind practice cost inflation as measured by medicare's own conservative estimates.

(4) The sustainable growth rate (SGR) expenditure target, which is the basis for the physician payment update, is linked to the gross domestic product and penalizes physicians and other practitioners for volume increases that they cannot control and that the government actively promotes through new coverage decisions, quality improvement activities, and other initiatives that, while beneficial to patients, are not reflected in the SGR.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that medicare beneficiary access to quality care may be compromised if Congress does not take action to prevent cuts in 2004 and the following years that result from the SGR formula.

# TITLE V—MEDICARE APPEALS, REGULATORY, AND CONTRACTING IMPROVEMENTS

## Subtitle A—Regulatory Reform

### SEC. 501. RULES FOR THE PUBLICATION OF A FINAL REGULATION BASED ON THE PREVIOUS PUBLICATION OF AN INTERIM FINAL REGULATION.

(a) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

''(3)(A) With respect to the publication of a final regulation based on the previous publication of an interim final regulation—

''(i) subject to subparagraph (B), the Secretary shall publish the final regulation within the 12-month period that begins on the date of publication of the interim final regulation;

''(ii) if a final regulation is not published by the deadline established under this paragraph, the interim final regulation shall not continue in effect un-

less the Secretary publishes a notice described in subparagraph (B) by such deadline; and

"(iii) the final regulation shall include responses to comments submitted in response to the interim final regulation.

"(B) If the Secretary determines before the deadline otherwise established in this paragraph that there is good cause, specified in a notice published before such deadline, for delaying the deadline otherwise applicable under this paragraph, the deadline otherwise established under this paragraph shall be extended for such period (not to exceed 12 months) as the Secretary specifies in such notice.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of enactment of this Act and shall apply to interim final regulations published on or after such date.

(c) STATUS OF PENDING INTERIM FINAL REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary shall publish a notice in the Federal Register that provides the status of each interim final regulation that was published on or before the date of enactment of this Act and for which no final regulation has been published. Such notice shall include the date by which the Secretary plans to publish the final regulation that is based on the interim final regulation.

**SEC. 502. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.**

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh) is amended by adding at the end the following new subsection:

''(d)(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 enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(d)(1), as added by subsection (a), is amended by adding at the end the following:

"(B) A compliance action may be made against a provider of services, physician, practitioner, or other supplier with respect to noncompliance with such a substantive change only for items and services furnished on or after the effective date of the change.

"(C)(i) Except as provided in clause (ii), a substantive change may not take effect before the date that is 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 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.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of enactment of this Act.

**SEC. 503. REPORT ON LEGAL AND REGULATORY INCONSISTENCIES.**

Section 1871 (42 U.S.C. 1395hh), as amended by section 502(a)(1), is amended by adding at the end the following new subsection:

''(e)(1) Not later than 2 years after the date of 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 beneficiaries, providers of services, physicians, practitioners, and other suppliers with respect to such areas of inconsistency and conflict; and

''(B) information from medicare contractors that tracks the nature of all communications and correspondence.

''(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.''.

**SEC. 504. STREAMLINING AND SIMPLIFICATION OF MEDICARE REGULATIONS.**

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct an analysis of the regulations issued under title XVIII of the Social Security Act and related laws in order to determine how such regulations may be streamlined and simplified to increase the efficiency and effectiveness of the medicare program without harming beneficiaries or providers and to decrease the burdens the medicare payment systems impose on both beneficiaries and providers.

(b) REDUCTION IN REGULATIONS.—The Secretary, after completion of the analysis under subsection (a), shall direct the rewriting of the regulations described in subsection (a) in such a manner as to—

(1) reduce the number of words comprising all regulations by at least two-thirds by October 1, 2004, and

(2) ensure the simple, effective, and efficient operation of the medicare program.

(c) APPLICATION OF THE PAPERWORK REDUCTION ACT.—The Secretary shall apply the provisions of chapter 35 of title 44, United States Code (commonly known as the ''Paperwork Reduction Act'') to the provisions of this Act to ensure that any regulations issued to implement this Act are written in plain language, are streamlined,

promote the maximum efficiency and effectiveness of the medicare and medicaid programs without harming beneficiaries or providers, and minimize the burdens the payment systems affected by this Act impose on both beneficiaries and providers.

(d) FEASIBILITY.—If the Secretary determines that the two-thirds reduction in words by October 1, 2004 required in subsection (b)(1) is not feasible, he shall inform Congress in writing by July 1, 2004 of the reasons for its unfeasibility. He shall then establish a feasible reduction to be achieved by January 1, 2005.

# Subtitle B—Appeals Process Reform

## SEC. 511. SUBMISSION OF PLAN FOR TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) SUBMISSION OF 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 So-

cial 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 and how such transfer should be financed.

(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, including ensuring that such judges are in an office that is functionally and operationally separate from the Centers for Medicare & Medicaid Services and the Center for Medicare Choices.

(I) GEOGRAPHIC DISTRIBUTION.—The steps that should be taken to provide for an appropriate geographic distribution of administra-

tive law judges throughout the United States to ensure timely access to such judges.

(J) HIRING.—The steps that should be taken to hire administrative law judges (and support staff).

(K) PERFORMANCE STANDARDS.—The establishment of performance standards for administrative law judges with respect to timelines for decisions in cases under title XVIII of the Social Security Act.

(L) SHARED RESOURCES.—The feasibility of the Secretary entering into such arrangements with the Commissioner of Social Security as may be appropriate with respect to transferred functions under the plan 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 (as amended by sections 521 and 522 of BIPA (114 Stat. 2763A–534) and this Act).

(b) GAO EVALUATION.—The Comptroller General of the United States shall—

(1) evaluate the plan submitted under subsection (a); and

(2) not later than 6 months after such submission, submit to Congress, the Commissioner of Social Security, and the Secretary a report on such evaluation.

(c) SUBMISSION OF GAO REPORT REQUIRED BEFORE PLAN IMPLEMENTATION.—The Commissioner of Social Security and the Secretary may not implement the plan developed under subsection (a) before the date that is 6 months after the date the report required under subsection (b)(2) is submitted to the Commissioner and the Secretary.

**SEC. 512. EXPEDITED ACCESS TO JUDICIAL REVIEW.**

(a) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)) is amended—

(1) in paragraph (1)(A), by inserting ", subject to paragraph (2)," before "to judicial review of the Secretary's final decision"; and

(2) 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 a beneficiary 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 re-

view 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 1 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, physicians, practitioners, and other suppliers under this Act.

(D) REVIEW ENTITY DEFINED.—For purposes of this subsection, the term 'review entity' means an entity of up to 3 qualified reviewers

drawn from existing appeals levels other than the redetermination level.

(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 beneficiaries 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) GAO STUDY AND REPORT ON ACCESS TO JUDICIAL REVIEW.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the access of medicare beneficiaries and health care providers to judicial review of actions of the Secretary and the Department of Health and Human Services with re-

spect to items and services under title XVIII of the Social Security Act subsequent to February 29, 2000, the date of the decision of Shalala, Secretary of Health and Human Services, et al. v. Illinois Council on Long Term Care, Inc. (529 U.S. 1 (2000)).

(2) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations as the Comptroller General determines to be appropriate.

(d) 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).".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

**SEC. 513. EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.**

(a) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—

(1) IN GENERAL.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which—

(A) the remedy of termination of participation has been imposed;

(B) a sanction described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i–3(h)(2)(B)) has been imposed, but only if such sanction has been imposed on an immediate basis; or

(C) the Secretary has required a skilled nursing facility to suspend operations of a nurse aide training program.

(2) PRIORITY FOR CASES OF TERMINATION.—Under the process described in paragraph (1), priority shall be provided in cases of termination described in subparagraph (A) of such paragraph.

(b) 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 Secu-

rity Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums for fiscal year 2004 and each subsequent fiscal year as may be necessary to increase the number of administrative law judges (and their staffs) at the Departmental Appeals Board of the Department of Health and Human Services and to educate such judges and staff on long-term care issues.

**SEC. 514. REVISIONS TO MEDICARE APPEALS PROCESS.**

(a) TIMEFRAMES FOR THE COMPLETION OF THE RECORD.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by section 512(a)(2), is amended by adding at the end the following new paragraph:

"(3) TIMELY COMPLETION OF THE RECORD.—

"(A) DEADLINE.—Subject to subparagraph (B), the deadline to complete the record in a hearing before an administrative law judge or a review by the Departmental Appeals Board is 90 days after the date the request for the review or hearing is filed.

"(B) EXTENSIONS FOR GOOD CAUSE.—The person filing a request under subparagraph (A) may request an extension of such deadline

for good cause. The administrative law judge, in the case of a hearing, and the Departmental Appeals Board, in the case of a review, may extend such deadline based upon a finding of good cause to a date specified by the judge or Board, as the case may be.

"(C) DELAY IN DECISION DEADLINES UNTIL COMPLETION OF RECORD.—Notwithstanding any other provision of this section, the deadlines otherwise established under subsection (d) for the making of determinations in hearings or review under this section are 90 days after the date on which the record is complete.

"(D) COMPLETE RECORD DESCRIBED.—For purposes of this paragraph, a record is complete when the administrative law judge, in the case of a hearing, or the Departmental Appeals Board, in the case of a review, has received—

"(i) written or testimonial evidence, or both, submitted by the person filing the request,

"(ii) written or oral argument, or both,

"(iii) the decision of, and the record for, the prior level of appeal, and

"(iv) such other evidence as such judge or Board, as the case may be, determines is required to make a determination on the request.".

(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 paragraph:

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS AND REDETERMINATIONS.—A written notice of a determination on an initial determination or on a redetermination, insofar as such determination or redetermination results in a denial of a claim for benefits, shall be provided in printed form and written in a manner to be understood by the beneficiary and shall include—

"(A) the reasons for the determination, including, as appropriate—

"(i) upon request in the case of an initial determination, the provision of the policy, manual, or regulation that resulted in the denial; and

"(ii) in the case of a redetermination, a summary of the clinical or scientific evidence used in making the determination (as appropriate);

"(B) the procedures for obtaining additional information concerning the determination or redetermination; and

"(C) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination or appeal under this section.".

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)) is amended to read as follows:

"(E) EXPLANATION OF DECISION.—Any decision with respect to a reconsideration of a qualified independent contractor shall be in

writing in a manner to be understood by the beneficiary and shall include—

"(i) to the extent appropriate, a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision;

"(ii) a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section; and

"(iii) in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)) an explanation of the medical or scientific rationale for the 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 to be understood by the beneficiary 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) PREPARATION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J) (42 U.S.C. 1395ff(c)(3)(J)) is amended by striking "such information as is required for an appeal" and inserting "the record for the appeal".

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

(1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c) (42 U.S.C. 1395ff(c)) is amended—

(A) in paragraph (2)—

(i) by inserting "(except in the case of a utilization and quality control peer re-

view organization, as defined in section 1152)'' after ''means an entity or organization that''; and

(ii) by striking the period at the end and inserting the following: ''and meets the following requirements:

''(A) GENERAL REQUIREMENTS.—

''(i) The entity or organization has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing to carry out duties of a qualified independent contractor under this section on a timely basis.

''(ii) The entity or organization has provided assurances that it will conduct activities consistent with the applicable requirements of this section, including that it will not conduct any activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.

"(iii) The entity or organization meets such other requirements as the Secretary provides by regulation.

"(B) INDEPENDENCE REQUIREMENTS.—

"(i) IN GENERAL.—Subject to clause (ii), an entity or organization meets the independence requirements of this subparagraph with respect to any case if 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 (as determined under regulations).

"(ii) EXCEPTION FOR 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."; and

(B) in paragraph (3)(A), by striking ", and shall have sufficient training and expertise in medical science and legal matters to make reconsiderations under this subsection".

(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 OF 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'), each reviewing professional meets the qualifications described in paragraph (4).

"(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 (as determined under regulations).

"(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of affiliation with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

"(I) a nonaffiliated individual is not reasonably available;

"(II) the affiliated individual is not involved in the provision of items or services in the case under review;

"(III) the fact of such an affiliation is disclosed to the Secretary and the beneficiary (or authorized representative) and neither party objects; and

"(IV) the affiliated 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 such affiliation if the affiliation is disclosed to the Secretary and the beneficiary (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).

"(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 physician (allopathic or osteopathic) or health care professional who—

"(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

"(B) has medical expertise in the field of practice that is appropriate for the items or services at issue.

"(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving an individual beneficiary, 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) NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking ''12'' and inserting ''4''.

(e) IMPLEMENTATION OF CERTAIN BIPA REFORMS.—

(1) DELAY IN CERTAIN BIPA REFORMS.—Section 521(d) of BIPA (114 Stat. 2763A–543) is amended to read as follows:

''(d) EFFECTIVE DATE.—

''(1) IN GENERAL.—Except as specified in paragraph (2), the amendments made by this section shall apply with respect to initial determinations made on or after December 1, 2004.

''(2) EXPEDITED PROCEEDINGS AND RECONSIDERATION REQUIREMENTS.—For the following provisions, the amendments made by subsection (a) shall apply with respect to initial determinations made on or after October 1, 2003:

''(A) Subsection (b)(1)(F)(i) of section 1869 of the Social Security Act.

''(B) Subsection (c)(3)(C)(iii) of such section.

''(C) Subsection (c)(3)(C)(iv) of such section to the extent that it applies to expedited

reconsiderations under subsection (c)(3)(C)(iii) of such section.

"(3) TRANSITIONAL USE OF PEER REVIEW ORGANIZATIONS TO CONDUCT EXPEDITED RECONSIDERATIONS UNTIL QICS ARE OPERATIONAL.—Expedited reconsiderations of initial determinations under section 1869(c)(3)(C)(iii) of the Social Security Act shall be made by peer review organizations until qualified independent contractors are available for such expedited reconsiderations.".

(2) CONFORMING AMENDMENTS.—Section 521(c) of BIPA (114 Stat. 2763A–543) and section 1869(c)(3)(C)(iii)(III) of the Social Security Act (42 U.S.C. 1395ff(c)(3)(C)(iii)(III)), as added by section 521 of BIPA, are repealed.

(f) EFFECTIVE DATE.—The amendments made by this section 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.

(g) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by subsection (d)(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. 515. HEARING RIGHTS RELATED TO DECISIONS BY THE SECRETARY TO DENY OR NOT RENEW A MEDICARE ENROLLMENT AGREEMENT; CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.**

(a) HEARING RIGHTS.—

(1) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended by adding at the end the following new subsection:

''(j) HEARING RIGHTS IN CASES OF DENIAL OR NONRENEWAL.—The Secretary shall establish by regulation procedures under which—

''(1) there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment); and

''(2) providers of services, physicians, practitioners, and suppliers whose application to enroll (or, if applicable, to renew enrollment) are denied are provided a mechanism to appeal such denial and a deadline for consideration of such appeals.''.

(2) EFFECTIVE DATE.—The Secretary shall provide for the establishment of the procedures

under the amendment made by paragraph (1) within 18 months after the date of enactment of this Act.

(b) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—Section 1871 (42 U.S.C. 1395hh), as amended by sections 502 and 503, is amended by adding at the end the following new subsection:

''(f) The Secretary shall consult with providers of services, physicians, practitioners, and suppliers before making changes in the provider enrollment forms required of such providers, physicians, practitioners, and suppliers to be eligible to submit claims for which payment may be made under this title.''.

**SEC. 516. 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, physician, practitioner, or other 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 enactment of this Act and shall apply to items and services furnished on or after such date.

**SEC. 517. PROVIDER ACCESS TO REVIEW OF LOCAL COVERAGE DETERMINATIONS.**

(a) PROVIDER ACCESS TO REVIEW OF LOCAL COVERAGE DETERMINATIONS.—Section 1869(f)(5) (42 U.S.C. 1395ff(f)(5)) is amended to read as follows:

"(5) AGGRIEVED PARTY DEFINED.—In this section, the term 'aggrieved party' means—

"(A) with respect to a national coverage determination, an individual entitled to benefits under part A, or enrolled under part B, or both, who is in need of the items or services that are the subject of the coverage determination; and

"(B) with respect to a local coverage determination—

"(i) an individual who is entitled to benefits under part A, or enrolled under part B, or both, who is adversely affected by such a determination; or

"(ii) a provider of services, physician, practitioner, or supplier that is adversely affected by such a determination.".

(b) CLARIFICATION OF LOCAL COVERAGE DETERMINATION DEFINITION.—Section 1869(f)(2)(B) (42 U.S.C. 1395ff(f)(2)(B)) is amended by inserting ", including, where appropriate, the specific requirements and clinical indications relating to the medical necessity of an item or service" before the period at the end.

(c) REQUEST FOR LOCAL COVERAGE DETERMINATIONS BY PROVIDERS.—Section 1869 (42 U.S.C. 1395ff), as amended by section 514(d)(2)(B), is amended by adding at the end the following new subsection:

"(h) REQUEST FOR LOCAL COVERAGE DETERMINATIONS BY PROVIDERS.—

"(1) ESTABLISHMENT OF PROCESS.—The Secretary shall establish a process under which a provider of services, physician, practitioner, or supplier who certifies that they meet the requirements established in paragraph (3) may request a local coverage determination in accordance with the succeeding provisions of this subsection.

"(2) PROVIDER LOCAL COVERAGE DETERMINATION REQUEST DEFINED.—In this subsection, the term 'provider local coverage determination request' means a request, filed with the Secretary, at such time and in such form and manner as the Secretary may specify, that the Secretary, pursuant to para-

graph (4)(A), require a fiscal intermediary, carrier, or program safeguard contractor to make or revise a local coverage determination under this section with respect to an item or service.

"(3) REQUEST REQUIREMENTS.—Under the process established under paragraph (1), by not later than 30 days after the date on which a provider local coverage determination request is filed under paragraph (1), the Secretary shall determine whether such request establishes that—

"(A) there have been at least 5 reversals of redeterminations made by a fiscal intermediary or carrier after a hearing before an administrative law judge on claims submitted by the provider in at least 2 different cases before an administrative law judge;

"(B) each reversal described in subparagraph (A) involves substantially similar material facts;

"(C) each reversal described in subparagraph (A) involves the same medical necessity issue; and

"(D) at least 50 percent of the total number of claims submitted by such provider within the past year involving the substantially similar

material facts described in subparagraph (B) and the same medical necessity issue described in subparagraph (C) have been denied and have been reversed by an administrative law judge.

"(4) APPROVAL OR REJECTION OF REQUEST.—

"(A) APPROVAL OF REQUEST.—If the Secretary determines that subparagraphs (A) through (D) of paragraph (3) have been satisfied, the Secretary shall require the fiscal intermediary, carrier, or program safeguard contractor identified in the provider local coverage determination request, to make or revise a local coverage determination with respect to the item or service that is the subject of the request not later than the date that is 210 days after the date on which the Secretary makes the determination. Such fiscal intermediary, carrier, or program safeguard contractor shall retain the discretion to determine whether or not, and/or the circumstances under which, to cover the item or service for which a local coverage determination is requested. Nothing in this subsection shall be construed to require a fiscal intermediary, carrier or program safeguard contractor to develop a local coverage determina-

tion that is inconsistent with any national coverage determination, or any coverage provision in this title or in regulation, manual, or interpretive guidance of the Secretary.

"(B) REJECTION OF REQUEST.—If the Secretary determines that subparagraphs (A) through (D) of paragraph (3) have not been satisfied, the Secretary shall reject the provider local coverage determination request and shall notify the provider of services, physician, practitioner, or supplier that filed the request of the reason for such rejection and no further proceedings in relation to such request shall be conducted.".

(d) STUDY AND REPORT ON THE USE OF CONTRACTORS TO MONITOR MEDICARE APPEALS.—

(1) STUDY.—The Secretary shall conduct a study on the feasibility and advisability of requiring fiscal intermediaries and carriers to monitor and track—

(A) the subject matter and status of claims denied by the fiscal intermediary or carrier (as applicable) that are appealed under section 1869 of the Social Security Act (42 U.S.C. 1395ff), as added by section 522 of BIPA (114

Stat. 2763A–543) and amended by this Act; and

(B) any final determination made with respect to such claims.

(2) REPORT.—Not later than the date that is 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislation and administrative action as the Commission determines appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out the amendments made by subsections (a), (b), and (c).

(f) EFFECTIVE DATES.—

(1) PROVIDER ACCESS TO REVIEW OF LOCAL COVERAGE DETERMINATIONS.—The amendments made by subsections (a) and (b) shall apply to—

(A) any review of any local coverage determination filed on or after October 1, 2003;

(B) any request to make such a determination made on or after such date; or

(C) any local coverage determination made on or after such date.

(2) PROVIDER LOCAL COVERAGE DETERMINATION REQUESTS.—The amendment made by subsection (c) shall apply with respect to provider local coverage determination requests (as defined in section 1869(h)(2) of the Social Security Act, as added by subsection (c)) filed on or after the date of enactment of this Act.

**SEC. 518. REVISIONS TO APPEALS 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'';

(2) in subsection (c)(3)(C)(i), by striking ''30-day period'' and inserting ''60-day period'';

(3) in subsection (d)(1)(A), by striking ''90-day period'' and inserting ''120-day period''; and

(4) in subsection (d)(2)(A), by striking ''90-day period'' and inserting ''120-day period''.

**SEC. 519. ELIMINATION OF REQUIREMENT TO USE SOCIAL SECURITY ADMINISTRATION ADMINISTRATIVE LAW JUDGES.**

The first sentence of 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. 520. ELIMINATION OF REQUIREMENT FOR DE NOVO REVIEW BY THE DEPARTMENTAL APPEALS BOARD.**

Section 1869(d)(2) (42 U.S.C. 1395ff(d)(2)) is amended to read as follows:

"(2) DEPARTMENTAL APPEALS BOARD REVIEW.—The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.".

# Subtitle C—Contracting Reform

**SEC. 521. 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, physician, practitioner, facility, or supplier (or class of such providers of services, physicians, practitioners, facilities, 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, physician, practitioner, facility, or supplier or class of provider of services, physician, practitioner, facility, 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 beneficiary services functions 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, physicians, practitioners, facilities, 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.—Serving as a center for, and communicating to individuals entitled to benefits under part A or enrolled under part B, or both, with respect to education and outreach for those individuals, and assistance with specific issues, concerns, or problems of those individuals.

"(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, physicians, practitioners, facilities, or suppliers.

"(E) COMMUNICATION WITH PROVIDERS.—Serving as a center for, and communicating to providers of services, physicians, practitioners, facilities, and suppliers, any information or instructions furnished to the medicare administrative contractor by the Secretary, and serving as a channel of communication from such providers, physicians, practitioners, facilities, and suppliers to the Secretary.

"(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions described in subsections (e) and (f), relating to education, training, and technical assistance to providers of services, physicians, practitioners, facilities, and suppliers.

"(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 ACTIVITIES.—In entering into contracts under this section, the Secretary shall assure that activities of medicare administrative contractors do not duplicate activities carried out under contracts 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 title, the Federal Acquisition Regulation applies to contracts under this title.

"(b) CONTRACTING REQUIREMENTS.—

"(1) USE OF COMPETITIVE PROCEDURES.—

"(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acqui-

sition and procurement, the Federal Acquisition Regulation, or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section.

"(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 6 years.

"(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors without regard to any provision of law requiring competition. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide notice (whether in the Fed-

eral Register or otherwise) of any such transfer (including a description of the functions so transferred and contact information for the contractors involved) to providers of services, physicians, practitioners, facilities, and suppliers affected by the transfer.

"(D) INCENTIVES FOR QUALITY.—The Secretary may 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, and other matters as the Secretary finds pertinent.

"(3) PERFORMANCE REQUIREMENTS.—

"(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—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. 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. The Secretary shall make such performance requirements and measurement standards available to the public.

"(B) CONSIDERATIONS.—The Secretary shall include, as 1 of the standards, 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.

"(6) RETAINING DIVERSITY OF LOCAL COVERAGE DETERMINATIONS.—A contract with a medicare administrative contractor under this section to perform the function of developing local coverage determinations (as defined in section 1869(f)(2)(B)) shall provide that the contractor shall—

"(A) designate at least 1 different individual to serve as medical director for each State for which such contract performs such function;

"(B) utilize such medical director in the performance of such function; and

"(C) appoint a contractor advisory committee with respect to each such State to provide a formal mechanism for physicians in the State to be informed of, and participate in, the development of a local coverage determination in an advisory capacity.

"(c) TERMS AND CONDITIONS.—

"(1) IN GENERAL.—Subject to subsection (a)(6), a contract with any medicare administrative

contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

"(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

"(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

"(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

"(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

"(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—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 a 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.

"(4) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code (commonly known as the "False Claims Act").

"(5) INDEMNIFICATION BY SECRETARY.—

"(A) IN GENERAL.—Notwithstanding any other provision of law and subject to the succeeding provisions of this paragraph, 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 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 Secretary to be criminal in nature, fraudulent, or grossly negligent.

"(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)),

awards, and costs (including reasonable legal expenses).

"(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate a settlement. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement are conditioned upon the Secretary's prior written approval of the final settlement.

"(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

"(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.".

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract

performance requirements under section 1874A(b) of the Social Security Act (as added 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 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 sec-

tion'' 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,''; and

(II) by striking ''carrier'' and inserting ''medicare administrative contractor'';

(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), 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), by striking ''carrier'' and inserting ''medicare administrative contractor'';

(E) in paragraph (5), by striking ''contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B), shall require the carrier'' and ''carrier responses'' and inserting ''contract under section 1874A that provides for making payments under this part shall require the medi-

care administrative contractor'' and ''contractor responses'', respectively; and

(F) by striking paragraph (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 title, 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 the date specified in paragraph (1)(A), 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 during the time period 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 ACTIVITIES UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER TRANSITION CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and

any reference in such provisions to an agreement or contract shall be deemed to include agreements and contracts entered into pursuant to paragraph (2)(A).

(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 an appropriate 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 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) PROPOSAL FOR IMPLEMENTATION.—At least 1 year before the date specified in subsection (d)(1)(A), the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes a plan for an appropriate transition. The Comptroller General shall conduct an evaluation of such plan and shall submit to Con-

gress, 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.

# Subtitle D—Education and Outreach Improvements

## SEC. 531. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—The Social Security Act 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 (e), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services, physicians, practitioners, and suppliers.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of enactment of this Act.

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 521(a)(1), is amended by adding at the end the following new subsection:

"(e) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—

"(1) METHODOLOGY TO MEASURE CONTRACTOR ERROR RATES.—In order to give medicare contractors (as defined in paragraph (3)) an incentive to implement effective education and outreach programs for providers of services, physicians, practi-

tioners, and suppliers, the Secretary shall develop and implement by October 1, 2004, a methodology to measure the specific claims payment error rates of such contractors in the processing or reviewing of medicare claims.

"(2) GAO REVIEW OF METHODOLOGY.—The Comptroller General of the United States shall review, and make recommendations to the Secretary, regarding the adequacy of such methodology.

"(3) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' includes a medicare administrative contractor, a fiscal intermediary with a contract under section 1816, and a carrier with a contract under section 1842.".

(2) REPORT.—The Secretary shall submit to Congress a report that describes how the Secretary intends to use the methodology developed under section 1874A(e)(1) of the Social Security Act, as added by paragraph (1), in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses.

(c) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) INCREASED FUNDING FOR ENHANCED EDUCATION AND TRAINING THROUGH MEDICARE INTEGRITY PROGRAM.—Section 1817(k)(4) (42 U.S.C. 1395i(k)(4)) is amended—

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

(B) in subparagraph (B), by striking ''The amount appropriated'' and inserting ''Subject to subparagraph (C), the amount appropriated''; and

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

''(C) ENHANCED PROVIDER EDUCATION AND TRAINING.—

''(i) IN GENERAL.—In addition to the amount appropriated under subparagraph (B), the amount appropriated under subparagraph (A) for a fiscal year (beginning with fiscal year 2004) is increased by $35,000,000.

''(ii) USE.—The funds made available under this subparagraph shall be used only

to increase the conduct by medicare contractors of education and training of providers of services, physicians, practitioners, and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses to written and phone inquiries from providers of services, physicians, practitioners, and suppliers.''.

(2) TAILORING EDUCATION AND TRAINING FOR SMALL PROVIDERS OR SUPPLIERS.—

(A) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsection:

''(b) 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 take into consideration 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 de-

termine 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) an institutional provider of services with fewer than 25 full-time-equivalent employees; or

"(B) a physician, practitioner, or supplier with fewer than 10 full-time-equivalent employees.".

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall take effect on January 1, 2004.

(d) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (c)(2), is amended by adding at the end the following new subsections:

"(c) 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, physicians, practitioners, or suppliers for the purpose of conducting any type of audit or prepayment review.

"(d) 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.

"(e) DEFINITIONS.—For purposes of this section and section 1817(k)(4)(C), the term 'medicare contractor' includes the following:

"(1) A medicare administrative contractor with a contract under section 1874A, 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, physician, practitioner, or supplier an entity that has no authority under this title

or title XI with respect to such activities and such provider of services, physician, practitioner, or supplier.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of enactment of this Act.

**SEC. 532. ACCESS TO AND PROMPT RESPONSES FROM MEDICARE CONTRACTORS.**

(a) IN GENERAL.—Section 1874A, as added by section 521(a)(1) and as amended by section 531(b)(1), is amended by adding at the end the following new subsection:

''(f) COMMUNICATING WITH BENEFICIARIES AND PROVIDERS.—

''(1) COMMUNICATION PROCESS.—The Secretary shall develop a process for medicare contractors to communicate with beneficiaries and with providers of services, physicians, practitioners, and suppliers under this title.

''(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare contractor (as defined in paragraph (5)) shall provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries by beneficiaries, providers of services, physicians, practitioners, and suppliers 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 medicare contractors provide a toll-free telephone number at which beneficiaries, providers, physicians, practitioners, 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 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 publish in the Federal Register) standards regarding the accu-

racy, consistency, and timeliness of the information provided in response to 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 contractors, the Secretary shall consider 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) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in subsection (e)(3).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect October 1, 2004.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out section 1874A(f) of the Social Security Act, as added by subsection (a).

**SEC. 533. RELIANCE ON GUIDANCE.**

(a) IN GENERAL.—Section 1871(d), as added by section 502(a), is amended by adding at the end the following new paragraph:

"(2) If—

"(A) a provider of services, physician, practitioner, or other supplier follows written guidance provided—

"(i) by the Secretary; or

"(ii) by a medicare contractor (as defined in section 1889(e) and whether in the form of a written response to a written inquiry under section 1874A(f)(1) or otherwise) acting within the scope of the contractor's contract authority,

in response to a written inquiry with respect to the furnishing of items or services or the submission of a claim for benefits for such items or services;

"(B) the Secretary determines that—

"(i) the provider of services, physician, practitioner, or supplier has accurately presented the circumstances relating to such items, services, and claim to the Secretary or the contractor in the written guidance; and

"(ii) there is no indication of fraud or abuse committed by the provider of services, physician, practitioner, or supplier against the program under this title; and

"(C) the guidance was in error;

the provider of services, physician, practitioner, 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) relating to the provision of such items or service or such claim if the provider of services, physician, practitioner, or supplier reasonably relied on such guidance. In applying this paragraph with respect to guidance in the form of general responses to frequently asked questions, the Secretary retains authority to determine the extent to which such general responses apply to the particular circumstances of individual claims.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to penalties imposed on or after the date of enactment of this Act.

**SEC. 534. MEDICARE PROVIDER OMBUDSMAN.**

(a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following: "; MEDICARE PROVIDER OMBUDSMAN";

(2) by inserting "PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)" after "(a)";

(3) in paragraph (1), as so redesignated under paragraph (2), by striking "in this section" and inserting "in this subsection";

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

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

"(b) MEDICARE PROVIDER OMBUDSMAN.—

"(1) IN GENERAL.—By not later than 1 year after the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003, the Secretary shall appoint a Medicare Provider Ombudsman.

"(2) DUTIES.—The Medicare Provider Ombudsman shall—

"(A) provide assistance, on a confidential basis, to entities and individuals providing items and services, including covered drugs under part D, under this title with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

"(B) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

"(i) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is wide-

spread confusion in program administration), and

"(ii) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

"(3) STAFF.—The Secretary shall provide the Medicare Provider Ombudsman with appropriate staff.".

(b) FUNDING.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account)) to carry out the provisions of subsection (b) of section 1868 of the Social Security Act (42 U.S.C. 1395ee) (relating to the Medicare Provider Ombudsman), as added by subsection (a)(5), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

**SEC. 535. BENEFICIARY OUTREACH DEMONSTRATION PROGRAMS.**

(a) DEMONSTRATION ON THE PROVISION OF ADVICE AND ASSISTANCE TO MEDICARE BENEFICIARIES AT

LOCAL OFFICES OF THE SOCIAL SECURITY ADMINISTRATION.—

(1) ESTABLISHMENT.—The Secretary shall establish a demonstration program (in this subsection referred to as the ''demonstration program'') under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to medicare beneficiaries at the location of existing local offices of the Social Security Administration.

(2) LOCATIONS.—

(A) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to subparagraph (B), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by medicare beneficiaries.

(B) 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.

(3) DURATION.—The demonstration program shall be conducted over a 3-year period.

(4) EVALUATION AND REPORT.—

(A) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(i) utilization of, and beneficiary satisfaction with, the assistance provided under the program; and

(ii) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local social security offices.

(B) 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 social security offices.

(b) DEMONSTRATION ON PROVIDING PRIOR DETERMINATIONS.—

(1) ESTABLISHMENT.—By not later than 1 year after the date of enactment of this Act, the Secretary shall establish a demonstration project to

test the administrative feasibility of providing a process for medicare beneficiaries and entities and individuals furnishing such beneficiaries with items and services under title XVIII of the Social Security Act program to make a request for, and receive, a determination (after an advance beneficiary notice is issued with respect to the item or service involved but before such item or service is furnished to the beneficiary) as to whether the item or service is covered under such title consistent with the applicable requirements of section 1862(a)(1)(A) of such Act (42 U.S.C. 1395y(a)(1)(A)) (relating to medical necessity).

(2) EVALUATION AND REPORT.—

(A) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program conducted under paragraph (1).

(B) REPORT.—By not later than January 1, 2006, the Secretary shall submit to Congress a report on such evaluation together with recommendations for such legislation and administrative actions as the Secretary considers appropriate.

# Subtitle E—Review, Recovery, and Enforcement Reform

**SEC. 541. PREPAYMENT REVIEW.**

(a) IN GENERAL.—Section 1874A, as added by section 521(a)(1) and as amended by sections 531(b)(1) and 532(a), is amended by adding at the end the following new subsection:

"(g) CONDUCT OF PREPAYMENT REVIEW.—

"(1) STANDARDIZATION OF RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor shall conduct random prepayment review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

"(2) LIMITATIONS ON INITIATION OF NONRANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate nonrandom prepayment review of a provider of services, physician, practitioner, or supplier based on the initial identification by that provider of services, physician, practitioner, or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined by the Secretary).

"(3) TERMINATION OF NONRANDOM PREPAYMENT REVIEW.—The Secretary shall establish protocols or standards relating to the termination, includ-

ing termination dates, of nonrandom prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.

"(4) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review. In the case of a provider of services, physician, practitioner, or supplier with respect to which amounts were previously overpaid, nothing in this subsection shall be construed as limiting the ability of a medicare administrative contractor to 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) RANDOM PREPAYMENT REVIEW DEFINED.—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.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a)

shall take effect on the date of enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(g) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(g)(1) 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 enactment of this Act) as the Secretary shall specify. The Secretary shall develop and publish the standard protocol under such section by not later than 1 year after the date of enactment of this Act.

**SEC. 542. RECOVERY OF OVERPAYMENTS.**

(a) IN GENERAL.—Section 1874A, as added by section 521(a)(1) and as amended by sections 531(b)(1), 532(a), and 541(a), is amended by adding at the end the following new subsection:

"(h) RECOVERY OF OVERPAYMENTS.—

"(1) USE OF REPAYMENT PLANS.—

"(A) IN GENERAL.—If the repayment, within the period otherwise permitted by a provider of services, physician, practitioner, or other supplier, of an overpayment under this title meets the standards developed under subparagraph (B), subject to subparagraph (C), and the provider, physician, practitioner, or supplier requests the Secretary to enter into a repayment plan with respect to such overpayment, the Secretary shall enter into a plan with the provider, physician, practitioner, or supplier for the offset or repayment (at the election of the provider, physician, practitioner, or supplier) of such overpayment over a period of at least 1 year, but not longer than 3 years. Interest shall accrue on the balance through the period of repayment. The repayment plan shall meet terms and conditions determined to be appropriate by the Secretary.

"(B) DEVELOPMENT OF STANDARDS.—The Secretary shall develop standards for the recovery of overpayments. Such standards shall—

"(i) include a requirement that the Secretary take into account (and weigh in

favor of the use of a repayment plan) the reliance (as described in section 1871(d)(2)) by a provider of services, physician, practitioner, and supplier on guidance when determining whether a repayment plan should be offered; and

"(ii) provide for consideration of the financial hardship imposed on a provider of services, physician, practitioner, or supplier in considering such a repayment plan.

In developing standards with regard to financial hardship with respect to a provider of services, physician, practitioner, or supplier, the Secretary shall take into account the amount of the proposed recovery as a proportion of payments made to that provider, physician, practitioner, or supplier.

"(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

"(i) the Secretary has reason to suspect that the provider of services, physician, practitioner, 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, physician, practitioner, 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) NO RECOUPMENT UNTIL RECONSIDERATION EXERCISED.—In the case of a provider of services, physician, practitioner, or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration of such determination by a qualified independent contractor under section 1869(c), 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.

"(B) PAYMENT OF INTEREST.—

"(i) RETURN OF RECOUPED AMOUNT WITH INTEREST IN CASE OF REVERSAL.—Insofar as such determination on appeal against the provider of services, physician, practitioner, or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest for the period in which the amount was recouped.

"(ii) INTEREST IN CASE OF AFFIRMATION.—Insofar as the determination on such appeal is against the provider of services, physician, practitioner, or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment.

"(iii) RATE OF INTEREST.—The rate of interest under this subparagraph shall be the rate otherwise applicable under this title in the case of overpayments.

"(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section 1889(e).

"(3) 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, physician, practitioner, or supplier under this title, the contractor shall provide the provider of services, physician, practitioner, 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, physician, practitioner, or supplier under this title, the contractor shall—

"(i) give the provider of services, physician, practitioner, or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services, physician, practitioner, or supplier and permits the devel-

opment of an appropriate corrective action plan;

"(ii) inform the provider of services, physician, practitioner, or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary); and

"(iii) give the provider of services, physician, practitioner, or supplier an opportunity to provide additional information to the contractor.

"(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.

"(4) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services, physicians, practitioners, and suppliers, a process under which the Secretary provides for notice to classes of providers of services, physicians, practitioners, and suppliers served by a medicare contractor in cases in which the contractor

has identified that particular billing codes may be overutilized by that class of providers of services, physicians, practitioners, or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

"(5) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare administrative contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

"(6) 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, physician, practitioner, or supplier a consent settlement, the Secretary shall—

"(i) communicate to the provider of services, physician, practitioner, or supplier in a nonthreatening manner 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; and

"(ii) provide for a 45-day period during which the provider of services, physician, practitioner, 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, physician, practitioner, 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, physician, practitioner, 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, physician, practitioner, 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, physician, practitioner, 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, physician, practitioner, or supplier agrees not to appeal the claims involved.".

(b) EFFECTIVE DATES AND DEADLINES.—

(1) Not later than 1 year after the date of enactment of this Act, the Secretary shall first—

(A) develop standards for the recovery of overpayments under section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a);

(B) establish the process for notice of over-utilization of billing codes under section

1874A(h)(4) of the Social Security Act, as added by subsection (a); and

(C) establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1874A(h)(5) of the Social Security Act, as added by subsection (a).

(2) Section 1874A(h)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date that is 1 year after the date of enactment of this Act.

(3) Section 1874A(h)(3) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of enactment of this Act.

(4) Section 1874A(h)(6) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of enactment of this Act.

**SEC. 543. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS ON CLAIMS WITHOUT PURSUING APPEALS PROCESS.**

(a) IN GENERAL.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(e) of the Social Security Act, as added by section 531(d)(1)) and representatives of providers of services, physicians, practitioners, facilities, 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, physician, practitioner, facility, 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 enactment of this Act, the Secretary shall first develop the process under subsection (a).

**SEC. 544. 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 5 years, except that, upon the request of an administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on beneficiaries of that program, 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.''.

# Subtitle F—Other Improvements

**SEC. 551. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY AND HOSPITAL 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 and inpatient hospital 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 enactment of this Act.

**SEC. 552. 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).

**SEC. 553. EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES CONSIDERATION.**

The Secretary shall ensure, before making changes in documentation guidelines for, or clinical examples of, or codes to report evaluation and management physician services under title XVIII of Social Security Act, that the process used in developing such guidelines, examples, or codes was widely consultative among physicians, reflects a broad consensus among specialties, and would allow verification of reported and furnished services.

**SEC. 554. COUNCIL FOR TECHNOLOGY AND INNOVATION.**

Section 1868 (42 U.S.C. 1395ee), as amended by section 534(a), is amended by adding at the end the following new subsection:

"(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

"(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as 'CMS').

"(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

"(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

"(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.".

**SEC. 555. TREATMENT OF CERTAIN DENTAL CLAIMS.**

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by adding after subsection (g) the following new subsection:

"(h)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supple-

mental 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 enactment of this Act.

# TITLE VI—OTHER PROVISIONS

## SEC. 601. INCREASE IN MEDICAID DSH ALLOTMENTS FOR FISCAL YEARS 2004 AND 2005.

(a) IN GENERAL.—Section 1923(f)(4) (42 U.S.C. 1396r–4(f)(4)) is amended—

(1) in the paragraph heading, by striking "FISCAL YEARS 2001 AND 2002" and inserting "CERTAIN FISCAL YEARS";

(2) in subparagraph (A)—

(A) in clause (i)—

(i) by striking ''paragraph (2)'' and inserting ''paragraphs (2) and (3)''; and

(ii) by striking ''and'' at the end;

(B) in clause (ii), by striking the period and inserting a semicolon; and

(C) by adding at the end the following:

''(iii) for fiscal year 2004, shall be the DSH allotment determined under paragraph (3) for that fiscal year increased by the amount equal to the product of 0.50 and the difference between—

''(I) the amount that the DSH allotment would be if the DSH allotment for the State determined under clause (ii) were increased, subject to subparagraph (B) and paragraph (5), by the percentage change in the Consumer Price Index for all urban consumers (all items; U.S. city average) for each of fiscal years 2002 and 2003; and

''(II) the DSH allotment determined under paragraph (3) for the State for fiscal year 2004; and

"(iv) for fiscal year 2005, shall be the DSH allotment determined under paragraph (3) for that fiscal year increased by the amount equal to the product of 0.50 and the difference between—

"(I) the amount that the DSH allotment would be if the DSH allotment for the State determined under clause (ii) were increased, subject to subparagraph (B) and paragraph (5), by the percentage change in the Consumer Price Index for all urban consumers (all items; U.S. city average) for each of fiscal years 2002, 2003, and 2004; and

"(II) the DSH allotment determined under paragraph (3) for the State for fiscal year 2005."; and

(3) in subparagraph (C)—

(A) in the subparagraph heading, by striking "AFTER FISCAL YEAR 2002" and inserting "FOR OTHER FISCAL YEARS"; and

(B) by striking "2003 or" and inserting "2003, fiscal year 2006, or".

(b) DSH ALLOTMENT FOR THE DISTRICT OF COLUMBIA.—Section 1923(f)(4) (42 U.S.C. 1396r–4(f)(4)), as amended by paragraph (1), is amended—

(1) in subparagraph (A), by inserting ''and except as provided in subparagraph (C)'' after ''paragraph (2)'';

(2) by redesignating subparagraph (C) as subparagraph (D); and

(3) by inserting after subparagraph (B) the following:

''(C) DSH ALLOTMENT FOR THE DISTRICT OF COLUMBIA.—

''(i) IN GENERAL.—Notwithstanding subparagraph (A), the DSH allotment for the District of Columbia for fiscal year 2004, shall be determined by substituting ''49'' for ''32'' in the item in the table contained in paragraph (2) with respect to the DSH allotment for FY 00 (fiscal year 2000) for the District of Columbia, and then increasing such allotment, subject to subparagraph (B) and paragraph (5), by the percentage change in the Consumer Price Index for all urban consumers (all

items; U.S. city average) for each of fiscal years 2000, 2001, 2002, and 2003.

"(ii) NO APPLICATION TO ALLOTMENTS AFTER FISCAL YEAR 2004.—The DSH allotment for the District of Columbia for fiscal year 2003, fiscal year 2005, or any succeeding fiscal year shall be determined under paragraph (3) without regard to the DSH allotment determined under clause (i).".

(c) CONFORMING AMENDMENT.—Section 1923(f)(3) of such Act (42 U.S.C. 1396r–4(f)(3)) is amended by inserting ", paragraph (4)," after "subparagraph (B)".

(d) URBAN HEALTH PROVIDER ADJUSTMENT.—

(1) IN GENERAL.—Beginning with fiscal year 2004, notwithstanding section 1923(f) of the Social Security Act (42 U.S.C. 1396r–4(f)) and subject to paragraph (3), with respect to a State, payment adjustments made under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) to a hospital described in paragraph (2) shall be made without regard to the DSH allotment limitation for the State determined under section 1923(f) of that Act (42 U.S.C. 1396r–4(f)).

(2) HOSPITAL DESCRIBED.—A hospital is described in this paragraph if the hospital—

(A) is owned or operated by a State (as defined for purposes of title XIX of the Social Security Act), or by an instrumentality or a municipal governmental unit within a State (as so defined) as of January 1, 2003; and

(B) is located in Marion County, Indiana.

(3) LIMITATION.—The payment adjustment described in paragraph (1) for fiscal year 2004 and each fiscal year thereafter shall not exceed 175 percent of the costs of furnishing hospital services described in section 1923(g)(1)(A) of the Social Security Act (42 U.S.C. 1396r–4(g)(1)(A)).

**SEC. 602. INCREASE IN FLOOR FOR TREATMENT AS AN EXTREMELY LOW DSH STATE UNDER THE MEDICAID PROGRAM FOR FISCAL YEARS 2004 AND 2005.**

(a) IN GENERAL.—Section 1923(f)(5) (42 U.S.C. 1396r–4(f)(5)) is amended—

(1) by striking ''In the case of'' and inserting the following:

''(A) IN GENERAL.—In the case of''; and

(2) by adding at the end the following:

"(B) INCREASE IN FLOOR FOR FISCAL YEARS 2004 AND 2005.—

"(i) FISCAL YEAR 2004.—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 fiscal year 2004 shall be increased to 3 percent of the State's total amount of expenditures under such plan for such assistance during such fiscal year.

"(ii) FISCAL YEAR 2005.—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 2001, as reported to the

Administrator of the Centers for Medicare & Medicaid Services as of August 31, 2004, 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 fiscal year 2005 shall be the DSH allotment determined for the State for fiscal year 2004 (under clause (i) or paragraph (4) (as applicable)), increased by the percentage change in the consumer price index for all urban consumers (all items; U.S. city average) for fiscal year 2004.

''(iii) NO APPLICATION TO ALLOTMENTS AFTER FISCAL YEAR 2005.—The DSH allotment for any State for fiscal year 2006 or any succeeding fiscal year shall be determined under this subsection without regard to the DSH allotments determined under this subparagraph.''.

(b) ALLOTMENT ADJUSTMENT.—

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

(A) by redesignating paragraph (6) as paragraph (7); and

(B) 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 that was implemented on January 1, 1994, is revoked or terminated before the end of either such fiscal year, 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 provides for the maximum amount (permitted consistent with paragraph (3)(B)(ii)) that does not result in greater expenditures under this title than would have been made if such waiver had not been revoked or terminated.''.

(2) TREATMENT OF INSTITUTIONS FOR MENTAL DISEASES.—Section 1923(h)(1) of the Social Security Act (42 U.S.C. 1396r–4(h)(1)) is amended—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''(subject to paragraph (3))'' after ''the lesser of the following''; and

(B) by adding at the end the following new paragraph:

''(3) SPECIAL RULE.—The limitation of paragraph (1) shall not apply in the case of a State to which subsection (f)(6) applies.''.

(3) APPLICATION TO HAWAII.—Section 1923(f) (42 U.S.C. 1396r–4(f)), as amended by paragraph (1), is amended—

(A) by redesignating paragraph (7) as paragraph (8); and

(B) by inserting after paragraph (6), the following:

"(7) TREATMENT OF HAWAII AS A LOW-DSH STATE.—The Secretary shall compute a DSH allotment for the State of Hawaii for each of fiscal years 2004 and 2005 in the same manner as DSH allotments are determined with respect to those States to which paragraph (5) applies (but without regard to the requirement under such paragraph that total expenditures under the State plan for disproportionate share hospital adjustments for any fiscal year exceeds 0).".

**SEC. 603. INCREASED REPORTING REQUIREMENTS TO ENSURE THE APPROPRIATENESS OF PAYMENT ADJUSTMENTS TO DISPROPORTIONATE SHARE HOSPITALS UNDER THE MEDICAID PROGRAM.**

Section 1923 (42 U.S.C. 1396r–4) is amended by adding at the end the following new subsection:

"(j) ANNUAL REPORTS 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 submit an annual report that—

"(1) identifies 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; and

"(2) includes 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.".

**SEC. 604. 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) of the Social Security Act (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) of the Social Security Act (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.".

(c) EFFECTIVE DATE.—The amendments made by this section take effect on October 1, 2003.

**SEC. 605. ASSISTANCE WITH COVERAGE OF LEGAL IMMIGRANTS UNDER THE MEDICAID PROGRAM AND SCHIP.**

(a) MEDICAID PROGRAM.—Section 1903(v) (42 U.S.C. 1396b(v)) is amended—

(1) in paragraph (1), by striking "paragraph (2)" and inserting "paragraphs (2) and (4)"; and

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

"(4)(A) With respect to any or all of fiscal years 2005 through 2007, a State may elect (in a plan amendment under this title) to provide medical assistance under this title (including under a waiver authorized by the Secretary) for aliens who are lawfully residing in the United

States (including battered aliens described in section 431(c) of such Act) and who are otherwise eligible for such assistance, within either or both of the following eligibility categories:

"(i) PREGNANT WOMEN.—Women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

"(ii) CHILDREN.—Children (as defined under such plan), including optional targeted low-income children described in section 1905(u)(2)(B).

"(B)(i) In the case of a State that has elected to provide medical assistance to a category of aliens under subparagraph (A), no debt shall accrue under an affidavit of support against any sponsor of such an alien on the basis of provision of assistance to such category and the cost of such assistance shall not be considered as an unreimbursed cost.

"(ii) The provisions of sections 401(a), 402(b), 403, and 421 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 shall not apply to a State that makes an election under subparagraph (A).".

(b) SCHIP.—Section 2107(e)(1) (42 U.S.C. 1397gg(e)(1)) is amended by redesignating subparagraphs (C) and (D) as subparagraph (D) and (E), respectively,

and by inserting after subparagraph (B) the following new subparagraph:

"(C) Section 1903(v)(4) (relating to optional coverage of categories of permanent resident alien children), but only if the State has elected to apply such section to the category of children under title XIX and only with respect to any or all of fiscal years 2005 through 2007.".

**SEC. 606. ESTABLISHMENT OF CONSUMER OMBUDSMAN ACCOUNT.**

(a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i) is amended by adding at the end the following new subsection:

"(i) CONSUMER OMBUDSMAN ACCOUNT.—

"(1) ESTABLISHMENT.—There is hereby established in the Trust Fund an expenditure account to be known as the 'Consumer Ombudsman Account' (in this subsection referred to as the 'Account').

"(2) APPROPRIATED AMOUNTS TO ACCOUNT FOR HEALTH INSURANCE INFORMATION, COUNSELING, AND ASSISTANCE GRANTS.—

"(A) IN GENERAL.—There are hereby appropriated to the Account from the Trust Fund for each fiscal year beginning with fiscal year

2005, the amount described in subparagraph (B) for such fiscal year for the purpose of making grants under section 4360 of the Omnibus Budget Reconciliation Act of 1990.

"(B) AMOUNT DESCRIBED.—For purposes of subparagraph (A), the amount described in this subparagraph for a fiscal year is the amount equal to the product of—

"(i) $1; and

"(ii) the total number of individuals receiving benefits under this title for the calendar year ending on December 31 of the preceding fiscal year.".

(b) CONFORMING AMENDMENT.—Section 4360(g) of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 1395b–4(g)) is amended to read as follows:

"(g) FUNDING.—The Secretary shall use amounts appropriated to the Consumer Ombudsman Account in accordance with section 1817(i) of the Social Security Act for a fiscal year for making grants under this section for that fiscal year.".

**SEC. 607. GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR LOW-INCOME BENEFICIARIES.**

(a) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to

which drug utilization and access to covered drugs for an individual described in subsection (b) differs from the drug utilization and access to covered drugs of an individual who qualifies for the transitional assistance prescription drug card program under section 1807A of the Social Security Act (as added by section 111) or for the premiums and cost-sharing subsidies applicable to a qualified medicare beneficiary, a specified low-income medicare beneficiary, or a qualifying individual under section 1860D–19 of the Social Security Act (as added by section 101).

(b) INDIVIDUAL DESCRIBED.—An individual is described in this subsection if the individual does not qualify for the transitional assistance prescription drug card program under section 1807A of the Social Security Act or for the premiums and cost-sharing subsidies applicable to a qualified medicare beneficiary, a specified low-income medicare beneficiary, or a qualifying individual under section 1860D–19 of the Social Security Act solely as a result of the application of an assets test to the individual.

(c) REPORT.—Not later than September 30, 2007, the Comptroller General shall submit a report to Congress on the study conducted under subsection (a) that includes such recommendations for legislation as the Comptroller General determines are appropriate.

(d) DEFINITIONS.—In this section:

(1) COVERED DRUGS.—The term ''covered drugs'' has the meaning given that term in section 1860D(a)(D) of the Social Security Act.

(2) QUALIFIED MEDICARE BENEFICIARY; SPECIFIED LOW-INCOME MEDICARE BENEFICIARY; QUALIFYING INDIVIDUAL.—The terms ''qualified medicare beneficiary'', ''specified low-income medicare beneficiary'' and ''qualifying individual'' have the meaning given those terms under section 1860D–19 of the Social Security Act.

**SEC. 608. HEALTH CARE INFRASTRUCTURE IMPROVEMENT.**

At the end of the Social Security Act, add the following new title:

# ''TITLE XXII—HEALTH CARE INFRASTRUCTURE IMPROVEMENT

**''SEC. 2201. DEFINITIONS.**

''In this title, the following definitions apply:

''(1) ELIGIBLE PROJECT COSTS.—The term 'eligible project costs' means amounts substantially all of which are paid by, or for the account of, an obligor in connection with a project, including the cost of—

''(A) development phase activities, including planning, feasibility analysis, revenue fore-

casting, environmental study and review, permitting, architectural engineering and design work, and other preconstruction activities;

"(B) construction, reconstruction, rehabilitation, replacement, and acquisition of facilities and real property (including land related to the project and improvements to land), environmental mitigation, construction contingencies, and acquisition of equipment;

"(C) capitalized interest necessary to meet market requirements, reasonably required reserve funds, capital issuance expenses, and other carrying costs during construction;

"(D) major medical equipment determined to be appropriate by the Secretary; and

"(E) refinancing projects or activities that are otherwise eligible for financial assistance under subparagraphs (A) through (D).

"(2) FEDERAL CREDIT INSTRUMENT.—The term 'Federal credit instrument' means a secured loan, loan guarantee, or line of credit authorized to be made available under this title with respect to a project.

"(3) INVESTMENT-GRADE RATING.—The term 'investment-grade rating' means a rating category of

BBB minus, Baa3, or higher assigned by a rating agency to project obligations offered into the capital markets.

"(4) LENDER.—The term 'lender' means any non-Federal qualified institutional buyer (as defined in section 230.144A(a) of title 17, Code of Federal Regulations (or any successor regulation), known as Rule 144A(a) of the Securities and Exchange Commission and issued under the Securities Act of 1933 (15 U.S.C. 77a et seq.)), including—

"(A) a qualified retirement plan (as defined in section 4974(c) of the Internal Revenue Code of 1986) that is a qualified institutional buyer; and

"(B) a governmental plan (as defined in section 414(d) of the Internal Revenue Code of 1986) that is a qualified institutional buyer.

"(5) LINE OF CREDIT.—The term 'line of credit' means an agreement entered into by the Secretary with an obligor under section 2204 to provide a direct loan at a future date upon the occurrence of certain events.

"(6) LOAN GUARANTEE.—The term 'loan guarantee' means any guarantee or other pledge by the Secretary to pay all or part of the principal of and

interest on a loan or other debt obligation issued by an obligor and funded by a lender.

"(7) LOCAL SERVICER.—The term 'local servicer' means a State or local government or any agency of a State or local government that is responsible for servicing a Federal credit instrument on behalf of the Secretary.

"(8) OBLIGOR.—The term 'obligor' means a party primarily liable for payment of the principal of or interest on a Federal credit instrument, which party may be a corporation, partnership, joint venture, trust, or governmental entity, agency, or instrumentality.

"(9) PROJECT.—The term 'project' means any project that is designed to improve the health care infrastructure, including the construction, renovation, or other capital improvement of any hospital, medical research facility, or other medical facility or the purchase of any equipment to be used in a hospital, research facility, or other medical research facility.

"(10) PROJECT OBLIGATION.—The term 'project obligation' means any note, bond, debenture, lease, installment sale agreement, or other debt obligation issued or entered into by an obligor in con-

nection with the financing of a project, other than a Federal credit instrument.

"(11) RATING AGENCY.—The term 'rating agency' means a bond rating agency identified by the Securities and Exchange Commission as a Nationally Recognized Statistical Rating Organization.

"(12) SECURED LOAN.—The term 'secured loan' means a direct loan or other debt obligation issued by an obligor and funded by the Secretary in connection with the financing of a project under section 2203.

"(13) STATE.—The term 'State' has the meaning given the term in section 101 of title 23, United States Code.

"(14) SUBSIDY AMOUNT.—The term 'subsidy amount' means the amount of budget authority sufficient to cover the estimated long-term cost to the Federal Government of a Federal credit instrument, calculated on a net present value basis, excluding administrative costs and any incidental effects on governmental receipts or outlays in accordance with the provisions of the Federal Credit Reform Act of 1990 (2 U.S.C. 661 et seq.).

"(15) SUBSTANTIAL COMPLETION.—The term 'substantial completion' means the opening of a project to patients or for research purposes.

**"SEC. 2202. DETERMINATION OF ELIGIBILITY AND PROJECT SELECTION.**

"(a) ELIGIBILITY.—To be eligible to receive financial assistance under this title, a project shall meet the following criteria:

"(1) APPLICATION.—A State, a local servicer identified under section 2205(a), or the entity undertaking a project shall submit a project application to the Secretary.

"(2) ELIGIBLE PROJECT COSTS.—To be eligible for assistance under this title, a project shall have total eligible project costs that are reasonably anticipated to equal or exceed $40,000,000.

"(3) SOURCES OF REPAYMENTS.—Project financing shall be repayable, in whole or in part, from reliable revenue sources as described in the application submitted under paragraph (1).

"(4) PUBLIC SPONSORSHIP OF PRIVATE ENTITIES.—In the case of a project that is undertaken by an entity that is not a State or local government or an agency or instrumentality of a State or local government, the project that the entity is under-

taking shall be publicly sponsored or sponsored by an entity that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

"(b) SELECTION AMONG ELIGIBLE PROJECTS.—

"(1) ESTABLISHMENT.—The Secretary shall establish criteria for selecting among projects that meet the eligibility criteria specified in subsection (a).

"(2) SELECTION CRITERIA.—

"(A) IN GENERAL.—The selection criteria shall include the following:

"(i) The extent to which the project 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.

"(ii) The creditworthiness of the project, including a determination by the Secretary that any financing for the project has appropriate security features, such as a rate covenant, credit enhancement requirements, or debt services coverages, to ensure repayment.

"(iii) The extent to which assistance under this title would foster innovative public-private partnerships and attract private debt or equity investment.

"(iv) The likelihood that assistance under this title would enable the project to proceed at an earlier date than the project would otherwise be able to proceed.

"(v) The extent to which the project uses or results in new technologies.

"(vi) The amount of budget authority required to fund the Federal credit instrument made available under this title.

"(vii) The extent to which the project helps maintain or protect the environment.

"(B) SPECIFIC REQUIREMENTS.—The selection criteria shall require that a project applicant—

"(i) be engaged in research in the causes, prevention, and treatment of cancer;

"(ii) be designated as a cancer center for the National Cancer Institute or be designated by the State as the official cancer institute of the State; and

"(iii) be located in a State that, on the date of enactment of this title, has a population of less than 3,000,000 individuals.

"(C) RATING LETTER.—For purposes of subparagraph (A)(ii), the Secretary shall require each project applicant to provide a rating letter from at least 1 rating agency indicating that the project's senior obligations have the potential to achieve an investment-grade rating with or without credit enhancement.

**"SEC. 2203. SECURED LOANS.**

"(a) IN GENERAL.—

"(1) AGREEMENTS.—Subject to paragraphs (2) through (4), the Secretary may enter into agreements with 1 or more obligors to make secured loans, the proceeds of which shall be used—

"(A) to finance eligible project costs;

"(B) to refinance interim construction financing of eligible project costs; or

"(C) to refinance existing debt or prior project obligations;

of any project selected under section 2202.

"(2) LIMITATION ON REFINANCING OF INTERIM CONSTRUCTION FINANCING.—A loan under para-

graph (1) shall not refinance interim construction financing under paragraph (1)(B) later than 1 year after the date of substantial completion of the project.

"(3) RISK ASSESSMENT.—Before entering into an agreement for a secured loan under this subsection, the Secretary, in consultation with each rating agency providing a rating letter under section 2202(b)(2)(B), shall determine an appropriate capital reserve subsidy amount for each secured loan, taking into account such letter.

"(4) INVESTMENT-GRADE RATING REQUIREMENT.—The funding of a secured loan under this section shall be contingent on the project's senior obligations receiving an investment-grade rating, except that—

"(A) the Secretary may fund an amount of the secured loan not to exceed the capital reserve subsidy amount determined under paragraph (3) prior to the obligations receiving an investment-grade rating; and

"(B) the Secretary may fund the remaining portion of the secured loan only after the obligations have received an investment-grade rating by at least 1 rating agency.

"(b) TERMS AND LIMITATIONS.—

"(1) IN GENERAL.—A secured loan under this section with respect to a project shall be on such terms and conditions and contain such covenants, representations, warranties, and requirements (including requirements for audits) as the Secretary determines appropriate.

"(2) MAXIMUM AMOUNT.—The amount of the secured loan shall not exceed 100 percent of the reasonably anticipated eligible project costs.

"(3) PAYMENT.—The secured loan—

"(A) shall—

"(i) be payable, in whole or in part, from reliable revenue sources; and

"(ii) include a rate covenant, coverage requirement, or similar security feature supporting the project obligations; and

"(B) may have a lien on revenues described in subparagraph (A) subject to any lien securing project obligations.

"(4) INTEREST RATE.—The interest rate on the secured loan shall be not less than the yield on marketable United States Treasury securities of a similar maturity to the maturity of the secured loan on the date of execution of the loan agreement.

"(5) MATURITY DATE.—The final maturity date of the secured loan shall be not later than 30 years after the date of substantial completion of the project.

"(6) NONSUBORDINATION.—The secured loan shall not be subordinated to the claims of any holder of project obligations in the event of bankruptcy, insolvency, or liquidation of the obligor.

"(7) FEES.—The Secretary may establish fees at a level sufficient to cover all or a portion of the costs to the Federal Government of making a secured loan under this section.

"(c) REPAYMENT.—

"(1) SCHEDULE.—The Secretary shall establish a repayment schedule for each secured loan under this section based on the projected cash flow from project revenues and other repayment sources.

"(2) COMMENCEMENT.—Scheduled loan repayments of principal or interest on a secured loan under this section shall commence not later than 5 years after the date of substantial completion of the project.

"(3) SOURCES OF REPAYMENT FUNDS.—The sources of funds for scheduled loan repayments

under this section shall include any revenue generated by the project.

"(4) DEFERRED PAYMENTS.—

"(A) AUTHORIZATION.—If, at any time during the 10 years after the date of substantial completion of the project, the project is unable to generate sufficient revenues to pay the scheduled loan repayments of principal and interest on the secured loan, the Secretary may, subject to subparagraph (C), allow the obligor to add unpaid principal and interest to the outstanding balance of the secured loan.

"(B) INTEREST.—Any payment deferred under subparagraph (A) shall—

"(i) continue to accrue interest in accordance with subsection (b)(4) until fully repaid; and

"(ii) be scheduled to be amortized over the remaining term of the loan beginning not later than 10 years after the date of substantial completion of the project in accordance with paragraph (1).

"(C) CRITERIA.—

"(i) IN GENERAL.—Any payment deferral under subparagraph (A) shall be

contingent on the project meeting criteria established by the Secretary.

"(ii) REPAYMENT STANDARDS.—The criteria established under clause (i) shall include standards for reasonable assurance of repayment.

"(5) PREPAYMENT.—

"(A) USE OF EXCESS REVENUES.—Any excess revenues that remain after satisfying scheduled debt service requirements on the project obligations and secured loan and all deposit requirements under the terms of any trust agreement, bond resolution, reimbursement agreement, credit agreement, loan agreement, or similar agreement securing project obligations may be applied annually to prepay the secured loan without penalty.

"(B) USE OF PROCEEDS OF REFINANCING.—The secured loan may be prepaid at any time without penalty, regardless of whether such repayment is from the proceeds of refinancing from non-Federal funding sources.

"(6) FORGIVENESS OF INDEBTEDNESS.—The Secretary may forgive a loan secured under this title 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 project 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.

"(d) SALE OF SECURED LOANS.—

"(1) IN GENERAL.—Subject to paragraph (2), as soon as practicable after substantial completion of a project and after notifying the obligor, the Secretary may sell to another entity or reoffer into the capital markets a secured loan for the project if the Secretary determines that the sale or reoffering can be made on favorable terms.

"(2) CONSENT OF OBLIGOR.—In making a sale or reoffering under paragraph (1), the Secretary may not change the original terms and conditions of the secured loan without the written consent of the obligor.

"(e) LOAN GUARANTEES.—

"(1) IN GENERAL.—The Secretary may provide a loan guarantee to a lender in lieu of making a secured loan if the Secretary determines that the budgetary cost of the loan guarantee is substantially the same as that of a secured loan.

"(2) TERMS.—The terms of a guaranteed loan shall be consistent with the terms set forth in this section for a secured loan, except that the rate on the guaranteed loan and any prepayment features shall be negotiated between the obligor and the lender, with the consent of the Secretary.

**"SEC. 2204. LINES OF CREDIT.**

"(a) IN GENERAL.—

"(1) AGREEMENTS.—Subject to paragraphs (2) through (4), the Secretary may enter into agreements to make available lines of credit to 1 or more obligors in the form of direct loans to be made by the Secretary at future dates on the occurrence of

certain events for any project selected under section 2202.

"(2) USE OF PROCEEDS.—The proceeds of a line of credit made available under this section shall be available to pay debt service on project obligations issued to finance eligible project costs, extraordinary repair and replacement costs, operation and maintenance expenses, and costs associated with unexpected Federal or State environmental restrictions.

"(3) RISK ASSESSMENT.—Before entering into an agreement for a secured loan under this subsection, the Secretary, in consultation with each rating agency providing a rating letter under section 2202(b)(2)(B), shall determine an appropriate subsidy amount for each secured loan, taking into account such letter.

"(4) INVESTMENT-GRADE RATING REQUIREMENT.—The funding of a line of credit under this section shall be contingent on the project's senior obligations receiving an investment-grade rating from at least 1 rating agency.

"(b) TERMS AND LIMITATIONS.—

"(1) IN GENERAL.—A line of credit under this section with respect to a project shall be on such terms and conditions and contain such covenants,

representations, warranties, and requirements (including requirements for audits) as the Secretary determines appropriate.

"(2) MAXIMUM AMOUNTS.—

"(A) TOTAL AMOUNT.—The total amount of the line of credit shall not exceed 33 percent of the reasonably anticipated eligible project costs.

"(B) 1-YEAR DRAWS.—The amount drawn in any 1 year shall not exceed 20 percent of the total amount of the line of credit.

"(3) DRAWS.—Any draw on the line of credit shall represent a direct loan and shall be made only if net revenues from the project (including capitalized interest, any debt service reserve fund, and any other available reserve) are insufficient to pay the costs specified in subsection (a)(2).

"(4) INTEREST RATE.—The interest rate on a direct loan resulting from a draw on the line of credit shall be not less than the yield on 30-year marketable United States Treasury securities as of the date on which the line of credit is obligated.

"(5) SECURITY.—The line of credit—

"(A) shall—

"(i) be payable, in whole or in part, from reliable revenue sources; and

"(ii) include a rate covenant, coverage requirement, or similar security feature supporting the project obligations; and

"(B) may have a lien on revenues described in subparagraph (A) subject to any lien securing project obligations.

"(6) PERIOD OF AVAILABILITY.—The line of credit shall be available during the period beginning on the date of substantial completion of the project and ending not later than 10 years after that date.

"(7) RIGHTS OF THIRD-PARTY CREDITORS.—

"(A) AGAINST FEDERAL GOVERNMENT.—A third-party creditor of the obligor shall not have any right against the Federal Government with respect to any draw on the line of credit.

"(B) ASSIGNMENT.—An obligor may assign the line of credit to 1 or more lenders or to a trustee on the lenders' behalf.

"(8) NONSUBORDINATION.—A direct loan under this section shall not be subordinated to the claims of any holder of project obligations in the event of bankruptcy, insolvency, or liquidation of the obligor.

"(9) FEES.—The Secretary may establish fees at a level sufficient to cover all or a portion of the costs to the Federal Government of providing a line of credit under this section.

"(10) RELATIONSHIP TO OTHER CREDIT INSTRUMENTS.—A project that receives a line of credit under this section also shall not receive a secured loan or loan guarantee under section 2203 of an amount that, combined with the amount of the line of credit, exceeds 100 percent of eligible project costs.

"(c) REPAYMENT.—

"(1) TERMS AND CONDITIONS.—The Secretary shall establish repayment terms and conditions for each direct loan under this section based on the projected cash flow from project revenues and other repayment sources.

"(2) TIMING.—All scheduled repayments of principal or interest on a direct loan under this section shall commence not later than 5 years after the end of the period of availability specified in subsection (b)(6) and be fully repaid, with interest, by the date that is 25 years after the end of the period of availability specified in subsection (b)(6).

"(3) SOURCES OF REPAYMENT FUNDS.—The sources of funds for scheduled loan repayments under this section shall include reliable revenue sources.

**"SEC. 2205. PROJECT SERVICING.**

"(a) REQUIREMENT.—The State in which a project that receives financial assistance under this title is located may identify a local servicer to assist the Secretary in servicing the Federal credit instrument made available under this title.

"(b) AGENCY; FEES.—If a State identifies a local servicer under subsection (a), the local servicer—

"(1) shall act as the agent for the Secretary; and

"(2) may receive a servicing fee, subject to approval by the Secretary.

"(c) LIABILITY.—A local servicer identified under subsection (a) shall not be liable for the obligations of the obligor to the Secretary or any lender.

"(d) ASSISTANCE FROM EXPERT FIRMS.—The Secretary may retain the services of expert firms in the field of project finance to assist in the underwriting and servicing of Federal credit instruments.

**"SEC. 2206. STATE AND LOCAL PERMITS.**

''The provision of financial assistance under this title with respect to a project shall not—

''(1) relieve any recipient of the assistance 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.

**"SEC. 2207. REGULATIONS.**

''The Secretary may issue such regulations as the Secretary determines appropriate to carry out this title.

**"SEC. 2208. FUNDING.**

''(a) FUNDING.—

''(1) IN GENERAL.—There are authorized to be appropriated to carry out this title, $49,000,000 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 title, not more than $2,000,000 for each of fiscal years 2004 through 2008.

"(b) CONTRACT AUTHORITY.—Notwithstanding any other provision of law, approval by the Secretary of a Federal credit instrument that uses funds made available under this title shall be deemed to be acceptance by the United States of a contractual obligation to fund the Federal credit instrument.

"(c) AVAILABILITY.—Amounts appropriated under this section shall be available for obligation on July 1, 2004.

**"SEC. 2209. REPORT TO CONGRESS.**

"Not later than 4 years after the date of enactment of this title, the Secretary shall submit to Congress a report summarizing the financial performance of the projects that are receiving, or have received, assistance under this title, including a recommendation as to whether the objectives of this title are best served—

"(1) by continuing the program under the authority of the Secretary;

"(2) by establishing a Government corporation or Government-sponsored enterprise to administer the program; or

"(3) by phasing out the program and relying on the capital markets to fund the types of infrastructure investments assisted by this title without Federal participation.".

**SEC. 609. CAPITAL INFRASTRUCTURE REVOLVING LOAN PROGRAM.**

(a) IN GENERAL.—Part A of title XVI of the Public Health Service Act (42 U.S.C. 300q et seq.) is amended by adding at the end the following new section:

"CAPITAL INFRASTRUCTURE REVOLVING LOAN PROGRAM

"SEC. 1603. (a) AUTHORITY TO MAKE AND GUARANTEE LOANS.—

"(1) AUTHORITY TO MAKE LOANS.—The Secretary may make loans from the fund established under section 1602(d) to any rural entity for projects for capital improvements, including—

"(A) the acquisition of land necessary for the capital improvements;

"(B) the renovation or modernization of any building;

"(C) the acquisition or repair of fixed or major movable equipment; and

"(D) such other project expenses as the Secretary determines appropriate.

"(2) AUTHORITY TO GUARANTEE LOANS.—

"(A) IN GENERAL.—The Secretary may guarantee the payment of principal and interest for loans made to rural entities for projects for any capital improvement described in paragraph (1) to any non-Federal lender.

"(B) INTEREST SUBSIDIES.—In the case of a guarantee of any loan made to a rural entity under subparagraph (A), the Secretary may pay to the holder of such loan, for and on behalf of the project for which the loan was made, amounts sufficient to reduce (by not more than 3 percent) the net effective interest rate otherwise payable on such loan.

"(b) AMOUNT OF LOAN.—The principal amount of a loan directly made or guaranteed under subsection (a) for a project for capital improvement may not exceed $5,000,000.

"(c) FUNDING LIMITATIONS.—

"(1) GOVERNMENT CREDIT SUBSIDY EXPOSURE.—The total of the Government credit subsidy exposure under the Credit Reform Act of 1990 scoring protocol with respect to the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, under subsection (a) may not exceed $50,000,000 per year.

"(2) TOTAL AMOUNTS.—Subject to paragraph (1), the total of the principal amount of all loans directly made or guaranteed under subsection (a) may not exceed $250,000,000 per year.

"(d) CAPITAL ASSESSMENT AND PLANNING GRANTS.—

"(1) NONREPAYABLE GRANTS.—Subject to paragraph (2), the Secretary may make a grant to a rural entity, in an amount not to exceed $50,000, for purposes of capital assessment and business planning.

"(2) LIMITATION.—The cumulative total of grants awarded under this subsection may not exceed $2,500,000 per year.

"(e) TERMINATION OF AUTHORITY.—The Secretary may not directly make or guarantee any loan under subsection (a) or make a grant under subsection (d) after September 30, 2008.".

(b) RURAL ENTITY DEFINED.—Section 1624 of the Public Health Service Act (42 U.S.C. 300s–3) is amended by adding at the end the following new paragraph:

"(14)(A) The term 'rural entity' includes—

"(i) a rural health clinic, as defined in section 1861(aa)(2) of the Social Security Act;

"(ii) any medical facility with at least 1 bed, but with less than 50 beds, that is located in—

"(I) a county that is not part of a metropolitan statistical area; or

"(II) 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));

"(iii) a hospital that is classified as a rural, regional, or national referral center under section 1886(d)(5)(C) of the Social Security Act; and

"(iv) a hospital that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of the Social Security Act).

"(B) For purposes of subparagraph (A), the fact that a clinic, facility, or hospital has been geographically reclassified under the medicare program under title XVIII of the Social Security Act shall not preclude a hospital from being considered a rural entity under clause (i) or (ii) of subparagraph (A).".

(c) CONFORMING AMENDMENTS.—Section 1602 of the Public Health Service Act (42 U.S.C. 300q–2) is amended—

(1) in subsection (b)(2)(D), by inserting "or 1603(a)(2)(B)" after "1601(a)(2)(B)"; and

(2) in subsection (d)—

(A) in paragraph (1)(C), by striking ''section 1601(a)(2)(B)'' and inserting ''sections 1601(a)(2)(B) and 1603(a)(2)(B)''; and

(B) in paragraph (2)(A), by inserting ''or 1603(a)(2)(B)'' after ''1601(a)(2)(B)''.

**SEC. 610. FEDERAL REIMBURSEMENT OF EMERGENCY HEALTH SERVICES FURNISHED TO UNDOCUMENTED ALIENS.**

(a) TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—There is appropriated, out of any funds in the Treasury not otherwise appropriated, $250,000,000 for each of fiscal years 2005 through 2008, for the purpose of making allotments under this section to States described in paragraph (1) or (2) of subsection (b). Funds appropriated under the preceding sentence 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 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 with respect 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 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 bear the same ratio to the total amount available for allotments under this paragraph for the fiscal year as the ratio of the number of undocumented alien apprehensions in the State in that fiscal year bears to the total of such numbers for all such States for such 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 4 most recent quarterly apprehension rates for undocumented aliens in such States, as reported by the Immigration and Naturalization Service.

(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State that is described in both of paragraphs (1) and (2) from receiving an allotment under both paragraphs for a fiscal year.

(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 directly to local governments, hospitals, or other providers located in the State (including providers of services re-

ceived through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization) that provide uncompensated emergency health services furnished to undocumented aliens during that fiscal year, and to the State, such amounts (subject to the total amount available from such allotments) as the local governments, hospitals, providers, or State demonstrate were incurred for the provision of such services during that fiscal year.

(2) LIMITATION ON STATE USE OF FUNDS.—Funds paid to a State from allotments made under subsection (b) for a fiscal year may only be used for making payments to local governments, hospitals, or other providers for costs incurred in providing emergency health services to undocumented aliens or for State costs incurred with respect to the provision of emergency health services to such aliens.

(3) INCLUSION OF COSTS INCURRED WITH RESPECT TO CERTAIN ALIENS.—Uncompensated emergency health services furnished to aliens who have been allowed to enter the United States for the sole purpose of receiving emergency health services may be included in the determination of costs incurred by

a State, local government, hospital, or other provider with respect to the provision of such services.

(d) APPLICATIONS; ADVANCE PAYMENTS.—

(1) DEADLINE FOR ESTABLISHMENT OF APPLICATION PROCESS.—24 (A) IN GENERAL.—Not later than September 1, 2004, the Secretary shall establish a process under which States, local governments, hospitals, or other providers located in the State may apply for payments from allotments made under subsection (b) for a fiscal year for uncompensated emergency health services furnished to undocumented aliens during that fiscal year.

(B) INCLUSION OF MEASURES TO COMBAT FRAUD.—The Secretary shall include in the process established under subparagraph (A) measures to ensure that fraudulent payments are not made from the allotments determined under subsection (b).

(2) ADVANCE PAYMENT; RETROSPECTIVE ADJUSTMENT.—The process established under paragraph (1) shall allow 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) 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)).

(2) 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).

(3) PROVIDER.—The term ''provider'' includes a physician, any other health care professional licensed under State law, and any other entity that furnishes emergency health services, including ambulance services.

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

(5) STATE.—The term ''State'' means the 50 States and the District of Columbia.

**SEC. 611. INCREASE IN APPROPRIATION TO THE HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT.**

Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is amended—

(1) in clause (i)—

(A) in subclause (II), by striking ''and'' at the end; and

(B) by striking subclause (III), and inserting the following new subclauses:

''(III) for fiscal year 2004, the limit for fiscal year 2003 increased by $10,000,000;

''(IV) for fiscal year 2005, the limit for fiscal year 2003 increased by $15,000,000;

''(V) for fiscal year 2006, the limit for fiscal year 2003 increased by $25,000,000; and

''(VI) for each fiscal year after fiscal year 2006, the limit for fiscal year 2003.''; and

(2) in clause (ii)—

(A) in subclause (VI), by striking ''and'' at the end;

(B) in subclause (VII)—

(i) by striking ''each fiscal year after fiscal year 2002'' and inserting ''fiscal year 2003''; and

(ii) by striking the period and inserting a semicolon; and

(3) by adding at the end the following:

''(VIII) for fiscal year 2004, $170,000,000;

''(IX) for fiscal year 2005, $175,000,000;

''(X) for fiscal year 2006, $185,000,000; and

''(XI) for each fiscal year after fiscal year 2006, not less than $150,000,000 and not more than $160,000,000.''.

**SEC. 612. INCREASE IN CIVIL PENALTIES UNDER THE FALSE CLAIMS ACT.**

(a) IN GENERAL.—Section 3729(a) of title 31, United States Code, is amended—

(1) by striking ''$5,000'' and inserting ''$7,500''; and

(2) by striking ''$10,000'' and inserting ''$15,000''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to violations occurring on or after January 1, 2004.

**SEC. 613. INCREASE IN CIVIL MONETARY PENALTIES UNDER THE SOCIAL SECURITY ACT.**

(a) IN GENERAL.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)), in the matter following paragraph (7), is amended—

(1) by striking ''$10,000'' each place it appears and inserting ''$12,500'';

(2) by striking ''$15,000'' and inserting ''$18,750''; and

(3) striking ''$50,000'' and inserting ''$62,500''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to violations occurring on or after January 1, 2004.

**SEC. 614. EXTENSION OF CUSTOMS USER FEES.**

Section 13031(j)(3) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3)) is amended by striking ''September 30, 2003'' and inserting ''September 30, 2013''.

**SEC. 615. REIMBURSEMENT FOR FEDERALLY QUALIFIED HEALTH CENTERS PARTICIPATING IN MEDICARE MANAGED CARE.**

(a) REIMBURSEMENT.—

(1) IN GENERAL.—Section 1833(a)(3) (42 U.S.C. 1395*l*(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 MedicareAdvantage plan under part C pursuant to a written agreement described in section 1853(j), the amount 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)(C);".

(b) CONTINUATION OF MEDICAREADVANTAGE MONTHLY PAYMENTS.—

(1) IN GENERAL.—Section 1853 (42 U.S.C. 1395w–23), as amended by this Act, is amended by adding at the end the following new subsection:

"(j) PAYMENT RULE FOR FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—If an individual who is enrolled with a MedicareAdvantage plan under this part receives a service from a Federally qualified health center

that has a written agreement with such plan for providing such a service (including any agreement required under section 1857(e)(3))—

"(1) 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

"(2) the Secretary shall not reduce the amount of the monthly payments to the MedicareAdvantage plan made under section 1853(a) as a result of the application of paragraph (1).".

(2) CONFORMING AMENDMENTS.—

(A) Paragraphs (1) and (2) of section 1851(i) (42 U.S.C. 1395w–21(i)(1)), as amended by this Act, are each amended by inserting "1853(j)," after "1853(i),".

(B) Section 1853(c)(5) is amended by striking "subsections (a)(3)(C)(iii) and (i)" and inserting "subsections (a)(3)(C)(iii), (i), and (j)(1)".

(c) ADDITIONAL MEDICAREADVANTAGE 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 part shall require the MedicareAdvantage plan to provide, in any contract between the plan 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 provider of services that was not a Federally qualified health center.

"(B) COST-SHARING.—Under the written agreement described in subparagraph (A), a Federally qualified health center must accept the MedicareAdvantage contract price plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the contract, except that such a health center may collect any amount of cost-sharing permitted under the contract under this part, so long as the amounts of any deductible,

coinsurance, or copayment comply with the requirements under section 1854(e).''.

(d) SAFE HARBOR FROM ANTIKICKBACK PROHIBITION.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)) is amended—

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

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

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

''(G) any remuneration between a Federally qualified health center (or an entity controlled by such a health center) and a MedicareAdvantage plan pursuant to the written agreement described in section 1853(j).''.

(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. 616. PROVISION OF INFORMATION ON ADVANCE DIRECTIVES.**

Section 1804(c) of the Social Security Act (42 U.S.C. 1395b-2(c)) is amended—

(1) by redesignating paragraphs (1) through (4) as subparagraphs (A) through (D), respectively;

(2) in the matter preceding subparagraph (A), as so redesignated, by striking ''The notice'' and inserting ''(1) The notice''; and

(3) by adding at the end the following:

''(2)(A) The Secretary shall annually provide each medicare beneficiary with information concerning advance directives. Such information shall be provided by the Secretary as part of the Medicare and You handbook that is provided to each such beneficiary. Such handbook shall include a separate section on advanced directives and specific details on living wills and the durable power of attorney for health care. The Secretary shall ensure that the introductory letter that accompanies such handbook contain a statement concerning the inclusion of such information.

''(B) In this section:

''(i) The term 'advance directive' has the meaning given such term in section 1866(f)(3).

''(ii) The term 'medicare beneficiary' means an individual who is entitled to, or enrolled for, benefits under part A or enrolled under part B, of this title.''.

**SEC. 617. SENSE OF THE SENATE REGARDING IMPLEMENTATION OF THE PRESCRIPTION DRUG AND MEDICARE IMPROVEMENT ACT OF 2003.**

(a) IN GENERAL.—It is the sense of the Senate that the Committee on Finance of the Senate should hold not less than 4 hearings to monitor implementation of the Prescription Drug and Medicare Improvement Act of 2003 (hereinafter in this section referred to as the ''Act'') during which the Secretary or his designee should testify before the Committee.

(b) INITIAL HEARING.—It is the sense of the Senate that the first hearing described in subsection (a) should be held not later than 60 days after the date of the enactment the Act. At the hearing, the Secretary or his designee should submit written testimony and testify before the Committee on Finance of the Senate on the following issues:

(1) The progress toward implementation of the prescription drug discount card under section 111 of the Act.

(2) Development of the blueprint that will direct the implementation of the provisions of the Act, including the implementation of title I (Medicare Prescription Drug Benefit), title II (MedicareAdvantage), and title III (Center for Medicare Choices) of the Act.

(3) Any problems that will impede the timely implementation of the Act.

(4) The overall progress toward implementation of the Act.

(c) SUBSEQUENT HEARINGS.—It is the sense of the Senate that the additional hearings described in subsection (a) should be held in each of May 2004, October 2004, and May 2005. At each hearing, the Secretary or his designee should submit written testimony and testify before the Committee on Finance of the Senate on the following issues:

(1) Progress on implementation of title I (Medicare Prescription Drug Benefit), title II (MedicareAdvantage), and title III (Center for Medicare Choices) of the Act.

(2) Any problems that will impede timely implementation of the Act.

**SEC. 618. EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.**

The last sentence of section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as previously amended, is amended by striking ‘‘December 31, 2004, and inserting ‘‘December 31, 2006.

**SEC. 619. STUDY ON MAKING PRESCRIPTION PHARMACEUTICAL INFORMATION ACCESSIBLE FOR BLIND AND VISUALLY-IMPAIRED INDIVIDUALS.**

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall undertake a study of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually-impaired individuals.

(2) STUDY TO INCLUDE EXISTING AND EMERGING TECHNOLOGIES.—The study under paragraph (1) 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.

(b) REPORT.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to Congress on the study required under subsection (a).

(2) CONTENTS OF REPORT.—The report required under subsection (a) shall include rec-

ommendations 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. 620. 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 Act 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 Act as the ''Working Group'').

(d) APPOINTMENT.—Not later than 45 days after the date of enactment of this Act, the Speaker and Minority Leader of the House of Representatives and the Majority Leader and Minority Leader of the Senate (in this section referred to as the ''leadership'') shall each appoint individuals to serve as members of the Working Group in accordance with subsections (e), (f), and (g).

(e) MEMBERSHIP CRITERIA.—

(1) APPOINTED MEMBERS.—

(A) SEPARATE APPOINTMENTS.—The Speaker of the House of Representatives jointly with the Minority Leader of the House of Representatives, and the Majority Leader of the Senate jointly with the Minority Leader of the Senate, shall each appoint 1 member of the Working Group described in subparagraphs (A), (G), (J), (K), and (M) of paragraph (2).

(B) JOINT APPOINTMENTS.—Members of the Working Group described in subparagraphs (B), (C), (D), (E), (F), (I), and (N) of paragraph (2) shall be appointed jointly by the leadership.

(C) COMBINED APPOINTMENTS.—Members of the Working Group described in subparagraphs (H) and (L) shall be appointed in the following manner:

(i) One member of the Working Group in each of such subparagraphs shall be appointed jointly by the leadership.

(ii) The remaining appointments of the members in each of such subparagraphs shall be divided equally such that the Speaker of the House of Representatives jointly with the Minority Leader of the House of Representatives, and the Majority Leader of the Senate jointly with the Minority Leader of the Senate each appoint an equal number of members.

(2) CATEGORIES OF APPOINTED MEMBERS.—Members of the Working Group shall be appointed as follows:

(A) 2 members shall be patients or family members of patients who, at least 1 year prior to the date of enactment of this Act, have had no health insurance.

(B) 1 member shall be a representative of children.

(C) 1 member shall be a representative of the mentally ill.

(D) 1 member shall be a representative of the disabled.

(E) 1 member shall be over the age of 65 and a beneficiary under the medicare program established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(F) 1 member shall be a recipient of benefits under the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(G) 2 members shall be State health officials.

(H) 3 members shall be employers, including—

(i) 1 large employer (an employer who employed 50 or more employees on business days during the preceding calendar

year and who employed at least 50 employees on the first of the year);

(ii) 1 small employer (an employer who employed an average of at least 2 employees but less than 50 employees on business days in the preceding calendar year and who employs at least 2 employees on the first of the year); and

(iii) 1 multi-state employer.

(I) 1 member shall be a representative of labor.

(J) 2 members shall be health insurance issuers.

(K) 2 members shall be health care providers.

(L) 5 members shall be appointed as follows:

(i) 1 economist.

(ii) 1 academician.

(iii) 1 health policy researcher.

(iv) 1 individual with expertise in pharmacoeconomics.

(v) 1 health technology expert.

(M) 2 members shall be representatives of community leaders who have developed State or

local community solutions to the problems addressed by the Working Group.

(N) 1 member shall be a representative of a medical school.

(3) SECRETARY.—The Secretary, or the designee of the Secretary, shall be a member of the Working Group.

(f) PROHIBITED APPOINTMENTS.—Members of the Working Group shall not include members of Congress or other elected government officials (Federal, State, or local) other than those individuals specified in subsection (e). To the extent possible, individuals appointed to the Working Group shall have used the health care system within the previous 2 years and shall not be paid employees or representatives of associations or advocacy organizations involved in the health care system.

(g) APPOINTMENT CRITERIA.—

(1) HOUSE OF REPRESENTATIVES.—The Speaker and Minority Leader of the House of Representatives shall make the appointments described in subsection (d) in consultation with the chairperson and ranking member of the following committees of the House of Representatives:

(A) The Committee on Ways and Means.

(B) The Committee on Energy and Commerce.

(C) The Committee on Education and the Workforce.

(2) SENATE.—The Majority Leader and Minority Leader of the Senate shall make the appointments described in subsection (d) in consultation with the chairperson and ranking member of the following committees of the Senate:

(A) The Committee on Finance.

(B) The Committee on Health, Education, Labor, and Pensions.

(h) PERIOD OF APPOINTMENT.—Members of the Working Group shall be appointed for a term of 2 years. Such term is renewable and 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.

(i) APPOINTMENT 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), the leadership shall make a joint designation of the chairperson of the Working Group. If the leadership fails to make such designation within such time period, the Working Group Members shall, not later than 10 days after

the end of such time period, designate a chairperson by majority vote.

(j) SUBCOMMITTEES.—The Working Group may establish subcommittees if doing so increases the efficiency of the Working Group in completing its tasks.

(k) DUTIES.—

(1) HEARINGS.—Not later than 90 days after the date of appointment of the chairperson under subsection (i), 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 Act. 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 of enactment of this Act, the Working Group shall initiate health care community meetings throughout the United States (in this section 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 issues:

(I) The optimum way to balance costs and benefits so that affordable health coverage is available to as many people as possible.

(II) The identification of services that provide cost-effective, essential

health care services to maintain and improve health and which should be included in health care coverage.

(III) The cost of providing increased benefits.

(IV) The mechanisms to finance health care coverage, including defining the appropriate financial role for individuals, businesses, and government.

(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 ex-

pressed at the community meetings. There shall be a 90-day public comment period on such recommendations.

(l) RECOMMENDATIONS.—Not later than 120 days after the expiration of the public comment period described in subsection (k)(4)(D), the Working Group shall submit to Congress and the President a final set of recommendations.

(m) 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 privi-

leges, 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 Act. 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.

(n) 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.

(o) 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.

(p) 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.

(q) SUNSET OF WORKING GROUP.—The Working Group shall terminate when the report described in subsection (l) is submitted to Congress.

(r) ADMINISTRATION REVIEW AND COMMENTS.—Not later than 45 days after receiving the final recommendations of the Working Group under subsection (l), 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.

(s) REQUIRED CONGRESSIONAL ACTION.—Not later than 45 days after receiving the report submitted by the President under subsection (r), each committee of jurisdiction of Congress shall hold at least 1 hearing on such re-

port and on the final recommendations of the Working Group submitted under subsection (l).

(t) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this Act, other than subsection (k)(3), $3,000,000 for each of fiscal years 2004, 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 (k)(3), such sums as may be necessary for the fiscal year in which the report is required to be submitted.

**SEC. 621. GAO STUDY OF PHARMACEUTICAL PRICE CONTROLS AND PATENT PROTECTIONS IN THE G–7 COUNTRIES.**

(a) STUDY.—The Comptroller General of the United States shall conduct a study of price controls imposed on pharmaceuticals in France, Germany, Italy, Japan, the United Kingdom and Canada to review the impact such regulations have on consumers, including American consumers, and on innovation in medicine. Such study shall include—

(1) the pharmaceutical price control structure in each country for a wide range of pharmaceuticals,

compared with average pharmaceutical prices paid by Americans covered by private sector health insurance;

(2) the proportion of the cost for innovation borne by American consumers, compared with consumers in the other six countries;

(3) a review of how closely the observed prices in regulated markets correspond to the prices that efficiently distribute common costs of production (''Ramsey prices'');

(4) a review of any peer-reviewed literature that might show the health consequences to patients in the listed countries that result from the absence or delayed introduction of medicines, including the cost of not having access to medicines, in terms of lower life expectancy and lower quality of health;

(5) the impact on American consumers, in terms of reduced research into new or improved pharmaceuticals (including the cost of delaying the introduction of a significant advance in certain major diseases), if similar price controls were adopted in the United States;

(6) the existing standards under international conventions, including the World Trade Organization and the North American Free Trade Agreement, re-

garding regulated pharmaceutical prices, including any restrictions on anti-competitive laws that might apply to price regulations and how economic harm caused to consumers in markets without price regulations may be remedied;

(7) in parallel trade regimes, how much of the price difference between countries in the European Union is captured by middlemen and how much goes to benefit patients and health systems where parallel importing is significant; and

(8) how much cost is imposed on the owner of a property right from counterfeiting and from international violation of intellectual property rights for prescription medicines.

(b) REPORT.—Not later than 1 year 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).

**SEC. 622. SENSE OF THE SENATE CONCERNING MEDICARE PAYMENT UPDATE FOR PHYSICIANS AND OTHER HEALTH PROFESSIONALS.**

(a) FINDINGS.—The Senate makes the following findings:

(1) The formula by which medicare payments are updated each year for services furnished by phy-

sicians and other health professionals is fundamentally flawed.

(2) The flawed physician payment update formula is causing a continuing physician payment crisis, and, without congressional action, medicare payment rates for physicians and other practitioners are predicted to fall by 4.2 percent in 2004.

(3) A physician payment cut in 2004 would be the fifth cut since 1991, and would be on top of a 5.4 percent cut in 2002, with additional cuts estimated for 2005, 2006, and 2007; from 1991–2003, payment rates for physicians and health professionals fell 14 percent behind practice cost inflation as measured by medicare's own conservative estimates.

(4) The sustainable growth rate (SGR) expenditure target, which is the basis for the physician payment update, is linked to the gross domestic product and penalizes physicians and other practitioners for volume increases that they cannot control and that the Government actively promotes through new coverage decisions, quality improvement activities and other initiatives that, while beneficial to patients, are not reflected in the SGR.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that medicare beneficiary access to quality care may be compromised if Congress does not take action to prevent cuts next year and the following that result from the SGR formula.

**SEC. 623. RESTORATION OF FEDERAL HOSPITAL INSURANCE TRUST FUND.**

(a) DEFINITIONS.—In this section:

(1) CLERICAL ERROR.—The term ''clerical error'' means the failure that occurred on April 15, 2001, to have transferred the correct amount from the general fund of the Treasury to the 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).

(b) CORRECTION OF TRUST FUND HOLDINGS.—

(1) IN GENERAL.—Not later than 120 days after the date of enactment of this Act, 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 of Health and Human Services, the holdings that would have been held by the Trust Fund if the clerical error 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 had not occurred; or

(ii) were issued to the Trust Fund and were redeemed by reason of the clerical error; and

(B) redeem from the Trust Fund obligations that would have been redeemed from the Trust Fund if the clerical error had not occurred.

(c) APPROPRIATION.—Not later than 120 days after the date of enactment of this Act, 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

of Health and Human Services, 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.

**SEC. 624. SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY COMMISSION.**

(a) IN GENERAL.—Title XI (42 U.S.C. 1320 et seq.) is amended by adding at the end the following new part:

"PART D—SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY COMMISSION

"SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY COMMISSION

"SEC. 1181. (a) ESTABLISHMENT.—There is hereby established the Safety Net Organizations and Patient Advisory Commission (in this section referred to as the 'Commission').

"(b) REVIEW OF HEALTH CARE SAFETY NET PROGRAMS AND REPORTING REQUIREMENTS.—

"(1) REVIEW.—The Commission shall conduct an ongoing review of the health care safety net programs (as described in paragraph (3)(C)) by—

"(A) monitoring each health care safety net program to document and analyze the effects of changes in these programs on the core health care safety net;

"(B) evaluating the impact of the Emergency Medical Treatment and Labor Act, the Health Insurance Portability and Accountability Act of 1996, the Balanced Budget Act of 1997, the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, the Medicare, Medicaid, and SCHIP Benefits Protection and Improvement Act of 2000, Prescription Drug and Medicare Improvement Act of 2003, and other forces on the capacity of the core health care safety net to continue their roles in the core health care safety net system to care for uninsured individuals, medicaid beneficiaries, and other vulnerable populations;

"(C) monitoring existing data sets to assess the status of the core health care safety net and health outcomes for vulnerable populations;

"(D) wherever possible, linking and integrating existing data systems to enhance the ability of the core health care safety net to track changes in the status of the core health care safety net and health outcomes for vulnerable populations;

"(E) supporting the development of new data systems where existing data are insufficient or inadequate;

"(F) developing criteria and indicators of impending core health care safety net failure;

"(G) establishing an early-warning system to identify impending failures of core health care safety net systems and providers;

"(H) providing accurate and timely information to Federal, State, and local policymakers on the indicators that may lead to the failure of the core health care safety net and an estimate of the projected consequences of such failures and the impact of such a failure on the community;

"(I) monitoring and providing oversight for the transition of individuals receiving supplemental security income benefits, medical assistance under title XIX, or child health assistance under title XXI who enroll with a managed care entity (as defined in section 1932(a)(1)(B)), including the review of—

"(i) the degree to which health plans have the capacity (including case management and management information system

infrastructure) to provide quality managed care services to such an individual;

"(ii) the degree to which these plans may be overburdened by adverse selection; and

"(iii) the degree to which emergency departments are used by enrollees of these plans; and

"(J) identifying and disseminating the best practices for more effective application of the lessons that have been learned.

"(2) REPORTS.—

"(A) ANNUAL REPORTS.—Not later than June 1 of each year (beginning with 2005), the Commission shall, based on the review conducted under paragraph (1), submit to the appropriate committees of Congress a report on—

"(i) the health care needs of the uninsured; and

"(ii) the financial and infrastructure stability of the Nation's core health care safety net.

"(B) AGENDA AND ADDITIONAL REVIEWS.—

"(i) AGENDA.—The Chair of the Commission shall consult periodically with the Chairpersons and Ranking Minority Members of the appropriate committees of Congress regarding the Commission's agenda and progress toward achieving the agenda.

"(ii) ADDITIONAL REVIEWS.—The Commission shall conduct additional reviews and submit additional reports to the appropriate committees of Congress on topics relating to the health care safety net programs under the following circumstances:

"(I) If requested by the Chairpersons or Ranking Minority Members of such committees.

"(II) If the Commission deems such additional reviews and reports appropriate.

"(C) AVAILABILITY OF REPORTS.—The Commission shall transmit to the Comptroller General and the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

"(3) DEFINITIONS.—In this section:

"(A) APPROPRIATE COMMITTEES OF CONGRESS.—The term 'appropriate committees of Congress' means the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committees on Finance and Health, Education, Labor, and Pensions of the Senate.

"(B) CORE HEALTH CARE SAFETY NET.—The term 'core health care safety net' means any health care provider that—

"(i) by legal mandate or explicitly adopted mission, offers access to health care services to patients, regardless of the ability of the patient to pay for such services; and

"(ii) has a case mix that is substantially comprised of patients who are uninsured, covered under the medicaid program, covered under any other public health care program, or are otherwise vulnerable populations.

Such term includes disproportionate share hospitals, Federally qualified health centers, other Federal, State, and locally supported clinics,

rural health clinics, local health departments, and providers covered under the Emergency Medical Treatment and Labor Act.

"(C) HEALTH CARE SAFETY NET PROGRAMS.—The term 'health care safety net programs' includes the following:

"(i) MEDICAID.—The medicaid program under title XIX.

"(ii) SCHIP.—The State children's health insurance program under title XXI.

"(iii) MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT PROGRAM.—The maternal and child health services block grant program under title V.

"(iv) FQHC PROGRAMS.—Each federally funded program under which a health center (as defined in section 330(1) of the Public Health Service Act), a Federally qualified health center (as defined in section 1861(aa)(4)), or a Federally-qualified health center (as defined in section 1905(l)(2)(B)) receives funds.

"(v) RHC PROGRAMS.—Each federally funded program under which a rural

health clinic (as defined in section 1861(aa)(4) or 1905(l)(1)) receives funds.

"(vi) DSH PAYMENT PROGRAMS.—Each federally funded program under which a disproportionate share hospital receives funds.

"(vii) EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT.—All care provided under section 1867 for the uninsured, underinsured, beneficiaries under title XIX, and other vulnerable individuals.

"(viii) OTHER HEALTH CARE SAFETY NET PROGRAMS.—Such term also includes any other health care program that the Commission determines to be appropriate.

"(D) VULNERABLE POPULATIONS.—The term 'vulnerable populations' includes uninsured and underinsured individuals, low-income individuals, farm workers, homeless individuals, individuals with disabilities, individuals with HIV or AIDS, and such other individuals as the Commission may designate.

"(c) MEMBERSHIP.—

"(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 13 members appointed

by the Comptroller General of the United States (in this section referred to as the 'Comptroller General'), in consultation with the appropriate committees of Congress.

"(2) QUALIFICATIONS.—

"(A) IN GENERAL.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, health care safety net research and program management, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic medicine (including emergency medicine), and other providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

"(B) INCLUSION.—The membership of the Commission shall include health professionals, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effec-

tiveness research and technology assessment. Such membership shall also include recipients of care from core health care safety net and individuals who provide and manage the delivery of care by the core health care safety net.

"(C) MAJORITY NONPROVIDERS.—Individuals who are directly involved in the provision, or management of the delivery, of items and services covered under the health care safety net programs shall not constitute a majority of the membership of the Commission.

"(D) ETHICAL DISCLOSURE.—The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members.

"(3) TERMS.—

"(A) IN GENERAL.—The terms of members of the Commission shall be for 3 years except that of the members first appointed, the Comptroller General shall designate—

"(i) four to serve a term of 1 year;

"(ii) four to serve a term of 2 years; and

"(iii) five to serve a term of 3 years.

"(B) VACANCIES.—

"(i) IN GENERAL.—A vacancy in the Commission shall be filled in the same manner in which the original appointment was made.

"(ii) APPOINTMENT.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term.

"(iii) TERMS.—A member may serve after the expiration of that member's term until a successor has taken office.

"(4) COMPENSATION.—

"(A) MEMBERS.—While serving on the business of the Commission (including travel time), a member of the Commission—

"(i) 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

"(ii) while so serving away from home and the member's regular place of busi-

ness, may be allowed travel expenses, as authorized by the Commission.

"(B) TREATMENT.—For purposes of pay (other than pay of members of the Commission) and employment benefits, rights, and privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate.

"(5) CHAIR; VICE CHAIR.—The Comptroller General shall designate a member of the Commission, at the time of appointment of the member as Chair and a member as Vice Chair for that term of appointment, except that in the case of vacancy of the Chair or Vice Chair, the Comptroller General may designate another member for the remainder of that member's term.

"(6) MEETINGS.—The Commission shall meet at the call of the Chair or upon the written request of a majority of its members.

"(d) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—Subject to such review as the Comptroller General determines necessary to ensure the efficient administration of the Commission, the Commission may—

"(1) employ and fix the compensation of an Executive Director (subject to the approval of the

Comptroller General) and such other personnel as may be necessary to carry out the duties of the Commission under this section (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

''(2) seek such assistance and support as may be required in the performance of the duties of the Commission under this section from appropriate Federal departments and agencies;

''(3) 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));

''(4) make advance, progress, and other payments which relate to the work of the Commission;

''(5) provide transportation and subsistence for persons serving without compensation; and

''(6) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

''(e) POWERS.—

''(1) OBTAINING OFFICIAL DATA.—

''(A) IN GENERAL.—The Commission may secure directly from any department or agency of the United States information necessary for

the Commission to carry the duties under this section.

"(B) REQUEST OF CHAIR.—Upon request of the Chair, the head of that department or agency shall furnish that information to the Commission on an agreed upon schedule.

"(2) DATA COLLECTION.—In order to carry out the duties of the Commission under this section, the Commission shall—

"(A) use existing information, both published and unpublished, where possible, collected and assessed either by the staff of the Commission or under other arrangements made in accordance with this section;

"(B) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate; and

"(C) adopt procedures allowing any interested party to submit information for the Commission's use in making reports and recommendations.

"(3) ACCESS OF GAO TO INFORMATION.—The Comptroller General shall have unrestricted access to all deliberations, records, and nonproprietary data

that pertains to the work of the Commission, immediately upon request. The expense of providing such information shall be borne by the General Accounting Office.

"(4) PERIODIC AUDIT.—The Commission shall be subject to periodic audit by the Comptroller General.

"(f) APPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Commission.

"(g) AUTHORIZATION OF APPROPRIATIONS.—

"(1) REQUEST FOR APPROPRIATIONS.—The Commission shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

"(2) AUTHORIZATION.—There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.".

(b) EFFECTIVE DATE.—The Comptroller General of the United States shall appoint the initial members of the Safety Net Organizations and Patient Advisory Commis-

sion established under subsection (a) not later than June 1, 2004.

**SEC. 625. URBAN HEALTH PROVIDER ADJUSTMENT.**

(a) IN GENERAL.—Beginning with fiscal year 2004, notwithstanding section 1923(f) of the Social Security Act (42 U.S.C. 1396r–4(f)) and subject to subsection (c), with respect to a State, payment adjustments made under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) to a hospital described in subsection (b) shall be made without regard to the DSH allotment limitation for the State determined under section 1923(f) of that Act (42 U.S.C. 1396r–4(f)).

(b) HOSPITAL DESCRIBED.—A hospital is described in this subsection if the hospital—

(1) is owned or operated by a State (as defined for purposes of title XIX of the Social Security Act), or by an instrumentality or a municipal governmental unit within a State (as so defined) as of January 1, 2003; and

(2) is located in Marion County, Indiana.

(c) LIMITATION.—The payment adjustment described in subsection (a) for fiscal year 2004 and each fiscal year thereafter shall not exceed 175 percent of the costs of furnishing hospital services described in section

1923(g)(1)(A) of the Social Security Act (42 U.S.C. 1396r–4(g)(1)(A)).

**SEC. 626. COMMITTEE ON DRUG COMPOUNDING.**

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish an Committee on Drug Compounding (referred to in this section as the ''Committee'') within the Food and Drug Administration on drug compounding to ensure that patients are receiving necessary, safe and accurate dosages of compounded drugs.

(b) MEMBERSHIP.—The membership of the Advisory Committee shall be appointed by the Secretary of Health and Human Services and shall include representatives of—

(1) the National Association of Boards of Pharmacy;

(2) pharmacy groups;

(3) physician groups;

(4) consumer and patient advocate groups;

(5) the United States Pharmacopoeia; and

(6) other individuals determined appropriate by the Secretary.

(c) REPORT AND RECOMMENDATIONS.—Not later than 1 year after the date of enactment of this Act, the Committee shall submit to the Secretary a report con-

cerning the recommendations of the Committee to improve and protect patient safety.

(d) TERMINATION.—The Committee shall terminate on the date that is 1 year after the date of enactment of this Act.

**SEC. 627. SENSE OF THE SENATE CONCERNING THE STRUCTURE OF MEDICARE REFORM AND THE PRESCRIPTION DRUG BENEFIT.**

(a) FINDINGS.—The Senate makes the following findings:

(1) America's seniors deserve a fiscally-strong medicare system that fulfills its promise to them and future retirees.

(2) The impending retirement of the ''baby boom'' generation will dramatically increase the costs of providing medicare benefits. Medicare costs will double relative to the size of the economy from 2 percent of GDP today to 4 percent in 2025 and double again to 8 percent of GDP in 2075. This growth will accelerate substantially when Congress adds a necessary prescription drug benefit.

(3) Medicare's current structure does not have the flexibility to quickly adapt to rapid advances in modern health care. Medicare lags far behind other insurers in providing prescription drug coverage, dis-

ease management programs, and host of other advances. Reforming medicare to create a more self-adjusting, innovative structure is essential to improve medicare's efficiency and the quality of the medical care it provides.

(4) Private-sector choice for medicare beneficiaries would provide two key benefits: It would be tailored to the needs of America's seniors, not the Government, and would create a powerful incentive for private-sector medicare plans to provide the best quality health care to seniors at the most affordable price.

(5) The method by which the national preferred provider organizations in the Federal Employees Health Benefits Program have been reimbursed has proven to be a reliable and successful mechanism for providing Members of Congress and Federal employees with excellent health care choices.

(6) Unlike the medicare payment system, which has had to be changed by Congress every few years, the Federal Employees Health Benefits Program has existed for 43 years with minimal changes from Congress.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that medicare reform legislation should:

(1) Ensure that prescription drug coverage is directed to those who need it most.

(2) Provide that Government contributions used to support MedicareAdvantage plans are based on market principles beginning in 2006 to ensure the long- and short-term viability of such options for America's seniors.

(3) Develop a payment system for the MedicareAdvantage preferred provider organizations similar to the payment system used for the national preferred provider organizations in the Federal Employees Health Benefits Program.

(4) Limit the addition of new unfunded obligations in the medicare program so that the long-term solvency of this important program is not further jeopardized.

(5) Incorporate private sector, market-based elements, that do not rely on the inefficient medicare price control structure.

(6) Keep the cost of structural changes and new benefits within the $400,000,000,000 provided for under the current Congressional Budget Resolution for implementing medicare reform and providing a prescription drug benefit.

(7) Preserve the current employer-sponsored retiree health plans and not design a benefit which has the unintended consequences of supplanting private coverage.

(8) Incorporate regulatory reform proposals to eliminate red tape and reduce costs.

(9) Restore the right of medicare beneficiaries and their doctors to work together to provide services, allow private fee for service plans to set their own premiums, and permit seniors to add their own dollars beyond the Government contribution.

**SEC. 628. SENSE OF THE SENATE REGARDING THE ESTABLISHMENT OF A NATIONWIDE PERMANENT LIFESTYLE MODIFICATION PROGRAM FOR MEDICARE BENEFICIARIES.**

(a) FINDINGS.—Congress finds that:

(1) Heart disease kills more than 500,000 Americans per year.

(2) The number and costs of interventions for the treatment of coronary disease are rising and currently cost the health care system $58,000,000,000 annually.

(3) The Medicare Lifestyle Modification Program has been operating throughout 12 States and

has been demonstrated to reduce the need for coronary procedures by 88 percent per year.

(4) The Medicare Lifestyle Modification Program is less expensive to deliver than interventional cardiac procedures and could reduce cardiovascular expenditures by $36,000,000,000 annually.

(5) Lifestyle choices such as diet and exercise affect heart disease and heart disease outcomes by 50 percent or greater.

(6) Intensive lifestyle interventions which include teams of nurses, doctors, exercise physiologists, registered dietitians, and behavioral health clinicians have been demonstrated to reduce heart disease risk factors and enhance heart disease outcomes dramatically.

(7) The National Institutes of Health estimates that 17,000,000 Americans have diabetes and the Centers for Disease Control and Prevention estimates that the number of Americans who have a diagnosis of diabetes increased 61 percent in the last decade and is expected to more than double by 2050.

(8) Lifestyle modification programs are superior to medication therapy for treating diabetes.

(9) Individuals with diabetes are now considered to have coronary disease at the date of diagnosis of their diabetic state.

(10) The Medicare Lifestyle Modification Program has been an effective lifestyle program for the reversal and treatment of heart disease.

(11) Men with prostate cancer have shown significant improvement in prostate cancer markers using a similar approach in lifestyle modification.

(12) These lifestyle changes are therefore likely to affect other chronic disease states, in addition to heart disease.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the Secretary of Health and Human Services should carry out the demonstration project known as the Lifestyle Modification Program Demonstration, as described in the Health Care Financing Administration Memorandum of Understanding entered into on November 13, 2000, on a permanent basis;

(2) the project should include as many Medicare beneficiaries as would like to participate in the project on a voluntary basis; and

(3) the project should be conducted on a national basis.

**SEC. 629. SENSE OF THE SENATE ON PAYMENT REDUCTIONS UNDER MEDICARE PHYSICIAN FEE SCHEDULE.**

(a) FINDINGS.—Congress finds that—

(1) the fees medicare pays physicians were reduced by 5.4 percent across-the-board in 2002;

(2) recent action by Congress narrowly averted another across-the-board reduction of 4.4 percent for 2003;

(3) based on current projections, the Centers for Medicare & Medicaid Services (CMS) estimates that, absent legislative or administrative action, fees will be reduced across-the-board once again in 2004 by 4.2 percent;

(4) the prospect of continued payment reductions under the medicare physician fee schedule for the foreseeable future threatens to destabilize an important element of the program, namely physician participation and willingness to accept medicare patients;

(5) the primary source of this instability is the sustainable growth rate (SGR), a system of annual

spending targets for physicians' services under medicare;

(6) the SGR system has a number of defects that result in unrealistically low spending targets, such as the use of the increase in the gross domestic product (GDP) as a proxy for increases in the volume and intensity of services provided by physicians, no tolerance for variance between growth in medicare beneficiary health care costs and our Nation's GDP, and a requirement for immediate recoupment of the difference;

(7) both administrative and legislative action are needed to return stability to the physician payment system;

(8) using the discretion given to it by medicare law, CMS has included expenditures for prescription drugs and biologicals administered incident to physicians' services under the annual spending targets without making appropriate adjustments to the targets to reflect price increases in these drugs and biologicals or the growing reliance on such therapies in the treatment of medicare patients;

(9) between 1996 and 2002, annual medicare spending on these drugs grew from $1,800,000,000

to $6,200,000,000, or from $55 per beneficiary to an estimated $187 per beneficiary;

(10) although physicians are responsible for prescribing these drugs and biologicals, neither the price of the drugs and biologicals, nor the standards of care that encourage their use, are within the control of physicians; and

(11) SGR target adjustments have not been made for cost increases due to new coverage decisions and new rules and regulations.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the Center for Medicare & Medicaid Services (CMS) should use its discretion to exclude drugs and biologicals administered incident to physician services from the sustainable growth rate (SGR) system;

(2) CMS should use its discretion to make SGR target adjustments for new coverage decisions and new rules and regulations; and

(3) in order to provide ample time for Congress to consider more fundamental changes to the SGR system, the conferees on the Prescription Drug and Medicare Improvement Act of 2003 should include in the conference agreement a provision to establish

a minimum percentage update in physician fees for the next 2 years and should consider adding provisions that would mitigate the swings in payment, such as establishing multi-year adjustments to recoup the variance and creating ''tolerance'' corridors for variations around the update target trend.

**SEC. 630. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.**

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as ''non-medicare/medicaid OASIS information'').

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the 2nd month beginning after the date as of which the Secretary has published final regulations regarding the collection

and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under

paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

**SEC. 631. EMPLOYER FLEXIBILITY.**

(a) MEDICARE.—Nothing in part D of title XVIII of the Social Security Act, as added by section 101, shall be construed as—

(1) preventing employment-based retiree health coverage (as defined in section 1860D–20(e)(4)(B) of such Act, as so added) from providing coverage that is supplemental to the benefits provided under a Medicare Prescription Drug plan under such part or a MedicareAdvantage plan under part C of such title, as amended by this Act; or

(2) requiring employment-based retiree health coverage (as so defined) that provides medical benefits to retired participants who are not eligible for medical benefits under title XVIII of the Social Security Act or under a plan maintained by a State or an agency thereof to provide medical benefits, or the same medical benefits, to retired participants who are so eligible.

(b) ADEA.—

(1) IN GENERAL.—Section 4(l) of the Age Discrimination in Employment Act of 1967 (29 U.S.C. 623(l)) is amended by adding at the end the following:

''(4) An employee benefit plan (as defined in section 3(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(3))) shall not be treated as violating subsection (a), (b), (c), or (e) solely because the plan provides medical benefits to retired participants who are not eligible for medical benefits under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or under a plan maintained by a State or an agency thereof, but does not provide medical benefits, or the same medical benefits, to retired participants who are so eligible.''

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply as of the date of the enactment of this Act.

**SEC. 632. ONE HUNDRED PERCENT FMAP FOR MEDICAL ASSISTANCE PROVIDED TO A NATIVE HAWAIIAN THROUGH A FEDERALLY-QUALIFIED HEALTH CENTER OR A NATIVE HAWAIIAN HEALTH CARE SYSTEM UNDER THE MEDICAID PROGRAM.**

(a) MEDICAID.—Section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) is amended, in the third sentence, by inserting ", and with respect to medical assistance provided to a Native Hawaiian (as defined in section 12 of the Native Hawaiian Health Care Improvement Act) through a federally-qualified health center or a Native Hawaiian health care system (as so defined) whether directly, by referral, or under contract or other arrangement between a federally-qualified health center or a Native Hawaiian health care system and another health care provider" before the period.

(b) EFFECTIVE DATE.—The amendment made by this section applies to medical assistance provided on or after the date of enactment of this Act.

**SEC. 633. 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.

**SEC. 634. GAO STUDY OF PHARMACEUTICAL PRICE CONTROLS AND PATENT PROTECTIONS IN THE G–7 COUNTRIES.**

(a) STUDY.—The Comptroller General of the United States shall conduct a study of price controls imposed on pharmaceuticals in France, Germany, Italy, Japan, the United Kingdom and Canada to review the impact such regulations have on consumers, including American consumers, and on innovation in medicine. The study shall include the following:

(1) The pharmaceutical price control structure in each country for a wide range of pharmaceuticals, compared with average pharmaceutical prices paid

by Americans covered by private sector health insurance.

(2) The proportion of the cost for innovation borne by American consumers, compared with consumers in the other 6 countries.

(3) A review of how closely the observed prices in regulated markets correspond to the prices that efficiently distribute common costs of production (''Ramsey prices'').

(4) A review of any peer-reviewed literature that might show the health consequences to patients in the listed countries that result from the absence or delayed introduction of medicines, including the cost of not having access to medicines, in terms of lower life expectancy and lower quality of health.

(5) The impact on American consumers, in terms of reduced research into new or improved pharmaceuticals (including the cost of delaying the introduction of a significant advance in certain major diseases), if similar price controls were adopted in the United States.

(6) The existing standards under international conventions, including the World Trade Organization and the North American Free Trade Agreement, regarding regulated pharmaceutical prices, including

any restrictions on anti-competitive laws that might apply to price regulations and how economic harm caused to consumers in markets without price regulations may be remedied.

(7) In parallel trade regimes, how much of the price difference between countries in the European Union is captured by middlemen and how much goes to benefit patients and health systems where parallel importing is significant.

(8) How much cost is imposed on the owner of a property right from counterfeiting and from international violations of intellectual property rights for prescription medicines.

(b) REPORT.—Not later than 1 year 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).

**SEC. 635. SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY COMMISSION.**

(a) IN GENERAL.—Title XI (42 U.S.C. 1320 et seq.) is amended by adding at the end the following new part:

1 "PART D—SAFETY NET ORGANIZATIONS AND PATIENT
2 ADVISORY COMMISSION
3 "SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY
4 COMMISSION
5 "SEC. 1181. (a) ESTABLISHMENT.—There is hereby
6 established the Safety Net Organizations and Patient Ad-
7 visory Commission (in this section referred to as the 'Com-
8 mission').
9 "(b) REVIEW OF HEALTH CARE SAFETY NET PRO-
10 GRAMS AND REPORTING REQUIREMENTS.—
11 "(1) REVIEW.—The Commission shall conduct
12 an ongoing review of the health care safety net pro-
13 grams (as described in paragraph (3)(C)) by—
14 "(A) monitoring each health care safety
15 net program to document and analyze the ef-
16 fects of changes in these programs on the core
17 health care safety net;
18 "(B) evaluating the impact of the Emer-
19 gency Medical Treatment and Labor Act, the
20 Health Insurance Portability and Accountability
21 Act of 1996, the Balanced Budget Act of 1997,
22 the Medicare, Medicaid, and SCHIP Balanced
23 Budget Refinement Act of 1999, the Medicare,
24 Medicaid, and SCHIP Benefits Protection and
25 Improvement Act of 2000, Prescription Drug

and Medicare Improvement Act of 2003, and other forces on the capacity of the core health care safety net to continue their roles in the core health care safety net system to care for uninsured individuals, medicaid beneficiaries, and other vulnerable populations;

''(C) monitoring existing data sets to assess the status of the core health care safety net and health outcomes for vulnerable populations;

''(D) wherever possible, linking and integrating existing data systems to enhance the ability of the core health care safety net to track changes in the status of the core health care safety net and health outcomes for vulnerable populations;

''(E) supporting the development of new data systems where existing data are insufficient or inadequate;

''(F) developing criteria and indicators of impending core health care safety net failure;

''(G) establishing an early-warning system to identify impending failures of core health care safety net systems and providers;

"(H) providing accurate and timely information to Federal, State, and local policymakers on the indicators that may lead to the failure of the core health care safety net and an estimate of the projected consequences of such failures and the impact of such a failure on the community;

"(I) monitoring and providing oversight for the transition of individuals receiving supplemental security income benefits, medical assistance under title XIX, or child health assistance under title XXI who enroll with a managed care entity (as defined in section 1932(a)(1)(B)), including the review of—

"(i) the degree to which health plans have the capacity (including case management and management information system infrastructure) to provide quality managed care services to such an individual;

"(ii) the degree to which these plans may be overburdened by adverse selection; and

"(iii) the degree to which emergency departments are used by enrollees of these plans; and

"(J) identifying and disseminating the best practices for more effective application of the lessons that have been learned.

"(2) REPORTS.—

"(A) ANNUAL REPORTS.—Not later than June 1 of each year (beginning with 2005), the Commission shall, based on the review conducted under paragraph (1), submit to the appropriate committees of Congress a report on—

"(i) the health care needs of the uninsured; and

"(ii) the financial and infrastructure stability of the Nation's core health care safety net.

"(B) AGENDA AND ADDITIONAL REVIEWS.—

"(i) AGENDA.—The Chair of the Commission shall consult periodically with the Chairpersons and Ranking Minority Members of the appropriate committees of Congress regarding the Commission's agenda and progress toward achieving the agenda.

"(ii) ADDITIONAL REVIEWS.—The Commission shall conduct additional re-

views and submit additional reports to the appropriate committees of Congress on topics relating to the health care safety net programs under the following circumstances:

"(I) If requested by the Chairpersons or Ranking Minority Members of such committees.

"(II) If the Commission deems such additional reviews and reports appropriate.

"(C) AVAILABILITY OF REPORTS.—The Commission shall transmit to the Comptroller General and the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

"(3) DEFINITIONS.—In this section:

"(A) APPROPRIATE COMMITTEES OF CONGRESS.—The term 'appropriate committees of Congress' means the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committees on Finance and Health, Education, Labor, and Pensions of the Senate.

"(B) CORE HEALTH CARE SAFETY NET.—The term 'core health care safety net' means any health care provider that—

"(i) by legal mandate or explicitly adopted mission, offers access to health care services to patients, regardless of the ability of the patient to pay for such services; and

"(ii) has a case mix that is substantially comprised of patients who are uninsured, covered under the medicaid program, covered under any other public health care program, or are otherwise vulnerable populations.

Such term includes disproportionate share hospitals, Federally qualified health centers, other Federal, State, and locally supported clinics, rural health clinics, local health departments, and providers covered under the Emergency Medical Treatment and Labor Act.

"(C) HEALTH CARE SAFETY NET PROGRAMS.—The term 'health care safety net programs' includes the following:

"(i) MEDICAID.—The medicaid program under title XIX.

"(ii) SCHIP.—The State children's health insurance program under title XXI.

"(iii) MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT PROGRAM.—The maternal and child health services block grant program under title V.

"(iv) FQHC PROGRAMS.—Each federally funded program under which a health center (as defined in section 330(1) of the Public Health Service Act), a Federally qualified health center (as defined in section 1861(aa)(4)), or a Federally-qualified health center (as defined in section 1905(l)(2)(B)) receives funds.

"(v) RHC PROGRAMS.—Each federally funded program under which a rural health clinic (as defined in section 1861(aa)(4) or 1905(l)(1)) receives funds.

"(vi) DSH PAYMENT PROGRAMS.—Each federally funded program under which a disproportionate share hospital receives funds.

"(vii) EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT.—All care provided under section 1867 for the unin-

sured, underinsured, beneficiaries under title XIX, and other vulnerable individuals.

"(viii) OTHER HEALTH CARE SAFETY NET PROGRAMS.—Such term also includes any other health care program that the Commission determines to be appropriate.

"(D) VULNERABLE POPULATIONS.—The term 'vulnerable populations' includes uninsured and underinsured individuals, low-income individuals, farm workers, homeless individuals, individuals with disabilities, individuals with HIV or AIDS, and such other individuals as the Commission may designate.

"(c) MEMBERSHIP.—

"(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 13 members appointed by the Comptroller General of the United States (in this section referred to as the 'Comptroller General'), in consultation with the appropriate committees of Congress.

"(2) QUALIFICATIONS.—

"(A) IN GENERAL.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, health care safety net

research and program management, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic medicine (including emergency medicine), and other providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

"(B) INCLUSION.—The membership of the Commission shall include health professionals, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effectiveness research and technology assessment. Such membership shall also include recipients of care from core health care safety net and individuals who provide and manage the delivery of care by the core health care safety net.

"(C) MAJORITY NONPROVIDERS.—Individuals who are directly involved in the provision, or management of the delivery, of items and services covered under the health care safety

net programs shall not constitute a majority of the membership of the Commission.

"(D) ETHICAL DISCLOSURE.—The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members.

"(3) TERMS.—

"(A) IN GENERAL.—The terms of members of the Commission shall be for 3 years except that of the members first appointed, the Comptroller General shall designate—

"(i) four to serve a term of 1 year;

"(ii) four to serve a term of 2 years; and

"(iii) five to serve a term of 3 years.

"(B) VACANCIES.—

"(i) IN GENERAL.—A vacancy in the Commission shall be filled in the same manner in which the original appointment was made.

"(ii) APPOINTMENT.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall

be appointed only for the remainder of that term.

"(iii) TERMS.—A member may serve after the expiration of that member's term until a successor has taken office.

"(4) COMPENSATION.—

"(A) MEMBERS.—While serving on the business of the Commission (including travel time), a member of the Commission—

"(i) 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

"(ii) while so serving away from home and the member's regular place of business, may be allowed travel expenses, as authorized by the Commission.

"(B) TREATMENT.—For purposes of pay (other than pay of members of the Commission) and employment benefits, rights, and privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate.

"(5) CHAIR; VICE CHAIR.—The Comptroller General shall designate a member of the Commission, at the time of appointment of the member as Chair and a member as Vice Chair for that term of appointment, except that in the case of vacancy of the Chair or Vice Chair, the Comptroller General may designate another member for the remainder of that member's term.

"(6) MEETINGS.—The Commission shall meet at the call of the Chair or upon the written request of a majority of its members.

"(d) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—Subject to such review as the Comptroller General determines necessary to ensure the efficient administration of the Commission, the Commission may—

"(1) employ and fix the compensation of an Executive Director (subject to the approval of the Comptroller General) and such other personnel as may be necessary to carry out the duties of the Commission under this section (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

"(2) seek such assistance and support as may be required in the performance of the duties of the

Commission under this section from appropriate Federal departments and agencies;

"(3) 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));

"(4) make advance, progress, and other payments which relate to the work of the Commission;

"(5) provide transportation and subsistence for persons serving without compensation; and

"(6) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

"(e) POWERS.—

"(1) OBTAINING OFFICIAL DATA.—

"(A) IN GENERAL.—The Commission may secure directly from any department or agency of the United States information necessary for the Commission to carry the duties under this section.

"(B) REQUEST OF CHAIR.—Upon request of the Chair, the head of that department or agency shall furnish that information to the Commission on an agreed upon schedule.

"(2) DATA COLLECTION.—In order to carry out the duties of the Commission under this section, the Commission shall—

"(A) use existing information, both published and unpublished, where possible, collected and assessed either by the staff of the Commission or under other arrangements made in accordance with this section;

"(B) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate; and

"(C) adopt procedures allowing any interested party to submit information for the Commission's use in making reports and recommendations.

"(3) ACCESS OF GAO TO INFORMATION.—The Comptroller General shall have unrestricted access to all deliberations, records, and nonproprietary data that pertains to the work of the Commission, immediately upon request. The expense of providing such information shall be borne by the General Accounting Office.

"(4) PERIODIC AUDIT.—The Commission shall be subject to periodic audit by the Comptroller General.

"(f) APPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Commission.

"(g) AUTHORIZATION OF APPROPRIATIONS.—

"(1) REQUEST FOR APPROPRIATIONS.—The Commission shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

"(2) AUTHORIZATION.—There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.".

(b) EFFECTIVE DATE.—The Comptroller General of the United States shall appoint the initial members of the Safety Net Organizations and Patient Advisory Commission established under subsection (a) not later than June 1, 2004.

**SEC. 636. ESTABLISHMENT OF PROGRAM TO PREVENT ABUSE OF NURSING FACILITY RESIDENTS.**

(a) IN GENERAL.—

(1) SCREENING OF SKILLED NURSING FACILITY AND NURSING FACILITY PROVISIONAL EMPLOYEES.—

(A) MEDICARE PROGRAM.—Section 1819(b) (42 U.S.C. 1395i–3(b)) is amended by adding at the end the following:

''(8) SCREENING OF SKILLED NURSING FACILITY WORKERS.—

''(A) BACKGROUND CHECKS OF PROVISIONAL EMPLOYEES.—Subject to subparagraph (B)(ii), after a skilled nursing facility selects an individual for a position as a skilled nursing facility worker, the facility, prior to employing such worker in a status other than a provisional status to the extent permitted under subparagraph (B)(ii), shall—

''(i) give such worker written notice that the facility is required to perform background checks with respect to provisional employees;

''(ii) require, as a condition of employment, that such worker—

''(I) provide a written statement disclosing any conviction for a rel-

evant crime or finding of patient or resident abuse;

"(II) provide a statement signed by the worker authorizing the facility to request the search and exchange of criminal records;

"(III) provide in person to the facility a copy of the worker's fingerprints or thumb print, depending upon available technology; and

"(IV) provide any other identification information the Secretary may specify in regulation;

"(iii) initiate a check of the data collection system established under section 1128E in accordance with regulations promulgated by the Secretary to determine whether such system contains any disqualifying information with respect to such worker; and

"(iv) if that system does not contain any such disqualifying information—

"(I) request through the appropriate State agency that the State initiate a State and national criminal

background check on such worker in accordance with the provisions of subsection (e)(6); and

"(II) submit to such State agency the information described in subclauses (II) through (IV) of clause (ii) not more than 7 days (excluding Saturdays, Sundays, and legal public holidays under section 6103(a) of title 5, United States Code) after completion of the check against the system initiated under clause (iii).

"(B) PROHIBITION ON HIRING OF ABUSIVE WORKERS.—

"(i) IN GENERAL.—A skilled nursing facility may not knowingly employ any skilled nursing facility worker who has any conviction for a relevant crime or with respect to whom a finding of patient or resident abuse has been made.

"(ii) PROVISIONAL EMPLOYMENT.—After complying with the requirements of clauses (i), (ii), and (iii) of subparagraph (A), a skilled nursing facility may provide for a provisional period of employment for

a skilled nursing facility worker pending completion of the check against the data collection system described under subparagraph (A)(iii) and the background check described under subparagraph (A)(iv). Subject to clause (iii), such facility shall maintain direct supervision of the covered individual during the worker's provisional period of employment.

''(iii) EXCEPTION FOR SMALL RURAL SKILLED NURSING FACILITIES.—In the case of a small rural skilled nursing facility (as defined by the Secretary), the Secretary shall provide, by regulation after consultation with providers of skilled nursing facility services and entities representing beneficiaries of such services, for an appropriate level of supervision with respect to any provisional employees employed by the facility in accordance with clause (ii). Such regulation should encourage the provision of direct supervision of such employees whenever practicable with respect to such a facility and if such super-

vision would not impose an unreasonable cost or other burden on the facility.

"(C) REPORTING REQUIREMENTS.—A skilled nursing facility shall report to the State any instance in which the facility determines that a skilled nursing facility worker has committed an act of resident neglect or abuse or misappropriation of resident property in the course of employment by the facility.

"(D) USE OF INFORMATION.—

"(i) IN GENERAL.—A skilled nursing facility that obtains information about a skilled nursing facility worker pursuant to clauses (iii) and (iv) of subparagraph (A) may use such information only for the purpose of determining the suitability of the worker for employment.

"(ii) IMMUNITY FROM LIABILITY.—A skilled nursing facility that, in denying employment for an individual selected for hiring as a skilled nursing facility worker (including during the period described in subparagraph (B)(ii)), reasonably relies upon information about such individual provided by the State pursuant to subsection (e)(6)

or section 1128E shall not be liable in any action brought by such individual based on the employment determination resulting from the information.

"(iii) CRIMINAL PENALTY.—Whoever knowingly violates the provisions of clause (i) shall be fined in accordance with title 18, United States Code, imprisoned for not more than 2 years, or both.

"(E) CIVIL PENALTY.—

"(i) IN GENERAL.—A skilled nursing facility that violates the provisions of this paragraph shall be subject to a civil penalty in an amount not to exceed—

"(I) for the first such violation, $2,000; and

"(II) for the second and each subsequent violation within any 5-year period, $5,000.

"(ii) KNOWING RETENTION OF WORKER.—In addition to any civil penalty under clause (i), a skilled nursing facility that—

"(I) knowingly continues to employ a skilled nursing facility worker

in violation of subparagraph (A) or (B); or

"(II) knowingly fails to report a skilled nursing facility worker under subparagraph (C),

shall be subject to a civil penalty in an amount not to exceed $5,000 for the first such violation, and $10,000 for the second and each subsequent violation within any 5-year period.

"(F) DEFINITIONS.—In this paragraph:

"(i) CONVICTION FOR A RELEVANT CRIME.—The term 'conviction for a relevant crime' means any Federal or State criminal conviction for—

"(I) any offense described in paragraphs (1) through (4) of section 1128(a); and

"(II) such other types of offenses as the Secretary may specify in regulations, taking into account the severity and relevance of such offenses, and after consultation with representatives of long-term care providers, representatives of long-term care employees,

consumer advocates, and appropriate Federal and State officials.

"(ii) DISQUALIFYING INFORMATION.—The term 'disqualifying information' means information about a conviction for a relevant crime or a finding of patient or resident abuse.

"(iii) FINDING OF PATIENT OR RESIDENT ABUSE.—The term 'finding of patient or resident abuse' means any substantiated finding by a State agency under subsection (g)(1)(C) or a Federal agency that a skilled nursing facility worker has committed—

"(I) an act of patient or resident abuse or neglect or a misappropriation of patient or resident property; or

"(II) such other types of acts as the Secretary may specify in regulations.

"(iv) SKILLED NURSING FACILITY WORKER.—The term 'skilled nursing facility worker' means any individual (other than a volunteer) that has access to a patient of a skilled nursing facility under an

employment or other contract, or both, with such facility. Such term includes individuals who are licensed or certified by the State to provide such services, and non-licensed individuals providing such services, as defined by the Secretary, including nurse assistants, nurse aides, home health aides, and personal care workers and attendants.''.

(B) MEDICAID PROGRAM.—Section 1919(b) (42 U.S.C. 1396r(b)) is amended by adding at the end the following new paragraph:

''(8) SCREENING OF NURSING FACILITY WORKERS.—

''(A) BACKGROUND CHECKS ON PROVISIONAL EMPLOYEES.—Subject to subparagraph (B)(ii), after a nursing facility selects an individual for a position as a nursing facility worker, the facility, prior to employing such worker in a status other than a provisional status to the extent permitted under subparagraph (B)(ii), shall—

''(i) give the worker written notice that the facility is required to perform

background checks with respect to provisional employees;

"(ii) require, as a condition of employment, that such worker—

"(I) provide a written statement disclosing any conviction for a relevant crime or finding of patient or resident abuse;

"(II) provide a statement signed by the worker authorizing the facility to request the search and exchange of criminal records;

"(III) provide in person to the facility a copy of the worker's fingerprints or thumb print, depending upon available technology; and

"(IV) provide any other identification information the Secretary may specify in regulation;

"(iii) initiate a check of the data collection system established under section 1128E in accordance with regulations promulgated by the Secretary to determine whether such system contains any disquali-

fying information with respect to such worker; and

"(iv) if that system does not contain any such disqualifying information—

"(I) request through the appropriate State agency that the State initiate a State and national criminal background check on such worker in accordance with the provisions of subsection (e)(8); and

"(II) submit to such State agency the information described in subclauses (II) through (IV) of clause (ii) not more than 7 days (excluding Saturdays, Sundays, and legal public holidays under section 6103(a) of title 5, United States Code) after completion of the check against the system initiated under clause (iii).

"(B) PROHIBITION ON HIRING OF ABUSIVE WORKERS.—

"(i) IN GENERAL.—A nursing facility may not knowingly employ any nursing facility worker who has any conviction for a relevant crime or with respect to whom a

finding of patient or resident abuse has been made.

"(ii) PROVISIONAL EMPLOYMENT.—After complying with the requirements of clauses (i), (ii), and (iii) of subparagraph (A), a nursing facility may provide for a provisional period of employment for a nursing facility worker pending completion of the check against the data collection system described under subparagraph (A)(iii) and the background check described under subparagraph (A)(iv). Subject to clause (iii), such facility shall maintain direct supervision of the worker during the worker's provisional period of employment.

"(iii) EXCEPTION FOR SMALL RURAL NURSING FACILITIES.—

"(I) IN GENERAL.—In the case of a small rural nursing facility (as defined by the Secretary), the Secretary shall provide, by regulation after consultation with providers of nursing facility services and entities representing beneficiaries of such

services, for an appropriate level of supervision with respect to any provisional employees employed by the facility in accordance with clause (ii). Such regulation should encourage the provision of direct supervision of such employees whenever practicable with respect to such a facility and if such supervision would not impose an unreasonable cost or other burden on the facility.

"(C) REPORTING REQUIREMENTS.—A nursing facility shall report to the State any instance in which the facility determines that a nursing facility worker has committed an act of resident neglect or abuse or misappropriation of resident property in the course of employment by the facility.

"(D) USE OF INFORMATION.—

"(i) IN GENERAL.—A nursing facility that obtains information about a nursing facility worker pursuant to clauses (iii) and (iv) of subparagraph (A) may use such information only for the purpose of deter-

mining the suitability of the worker for employment.

"(ii) IMMUNITY FROM LIABILITY.—A nursing facility that, in denying employment for an individual selected for hiring as a nursing facility worker (including during the period described in subparagraph (B)(ii)), reasonably relies upon information about such individual provided by the State pursuant to subsection (e)(6) or section 1128E shall not be liable in any action brought by such individual based on the employment determination resulting from the information.

"(iii) CRIMINAL PENALTY.—Whoever knowingly violates the provisions of clause (i) shall be fined in accordance with title 18, United States Code, imprisoned for not more than 2 years, or both.

"(E) CIVIL PENALTY.—

"(i) IN GENERAL.—A nursing facility that violates the provisions of this paragraph shall be subject to a civil penalty in an amount not to exceed—

"(I) for the first such violation, $2,000; and

"(II) for the second and each subsequent violation within any 5-year period, $5,000.

"(ii) KNOWING RETENTION OF WORKER.—In addition to any civil penalty under clause (i), a nursing facility that—

"(I) knowingly continues to employ a nursing facility worker in violation of subparagraph (A) or (B); or

"(II) knowingly fails to report a nursing facility worker under subparagraph (C),

shall be subject to a civil penalty in an amount not to exceed $5,000 for the first such violation, and $10,000 for the second and each subsequent violation within any 5-year period.

"(F) DEFINITIONS.—In this paragraph:

"(i) CONVICTION FOR A RELEVANT CRIME.—The term 'conviction for a relevant crime' means any Federal or State criminal conviction for—

"(I) any offense described in paragraphs (1) through (4) of section 1128(a); and

"(II) such other types of offenses as the Secretary may specify in regulations, taking into account the severity and relevance of such offenses, and after consultation with representatives of long-term care providers, representatives of long-term care employees, consumer advocates, and appropriate Federal and State officials.

"(ii) DISQUALIFYING INFORMATION.—The term 'disqualifying information' means information about a conviction for a relevant crime or a finding of patient or resident abuse.

"(iii) FINDING OF PATIENT OR RESIDENT ABUSE.—The term 'finding of patient or resident abuse' means any substantiated finding by a State agency under subsection (g)(1)(C) or a Federal agency that a nursing facility worker has committed—

"(I) an act of patient or resident abuse or neglect or a misappropriation of patient or resident property; or

"(II) such other types of acts as the Secretary may specify in regulations.

"(iv) NURSING FACILITY WORKER.—The term 'nursing facility worker' means any individual (other than a volunteer) that has access to a patient of a nursing facility under an employment or other contract, or both, with such facility. Such term includes individuals who are licensed or certified by the State to provide such services, and nonlicensed individuals providing such services, as defined by the Secretary, including nurse assistants, nurse aides, home health aides, and personal care workers and attendants.".

(2) FEDERAL RESPONSIBILITIES.—

(A) DEVELOPMENT OF STANDARD FEDERAL AND STATE BACKGROUND CHECK FORM.—The Secretary of Health and Human Services, in consultation with the Attorney General and representatives of appropriate State

agencies, shall develop a model form that a provisional employee at a nursing facility may complete and Federal and State agencies may use to conduct the criminal background checks required under sections 1819(b)(8) and 1919(b)(8) of the Social Security Act (42 U.S.C. 1395i–3(b), 1396r(b)) (as added by this section).

(B) PERIODIC EVALUATION.—The Secretary of Health and Human Services, in consultation with the Attorney General, periodically shall evaluate the background check system imposed under sections 1819(b)(8) and 1919(b)(8) of the Social Security Act (42 U.S.C. 1395i–3(b), 1396r(b)) (as added by this section) and shall implement changes, as necessary, based on available technology, to make the background check system more efficient and able to provide a more immediate response to long-term care providers using the system.

(3) NO PREEMPTION OF STRICTER STATE LAWS.—Nothing in section 1819(b)(8) or 1919(b)(8) of the Social Security Act (42 U.S.C. 1395i–3(b)(8), 1396r(b)(8)) (as so added) shall be construed to supersede any provision of State law that—

(A) specifies a relevant crime for purposes of prohibiting the employment of an individual at a long-term care facility (as defined in section 1128E(g)(6) of the Social Security Act (as added by subsection (e)) that is not included in the list of such crimes specified in such sections or in regulations promulgated by the Secretary of Health and Human Services to carry out such sections; or

(B) requires a long-term care facility (as so defined) to conduct a background check prior to employing an individual in an employment position that is not included in the positions for which a background check is required under such sections.

(4) TECHNICAL AMENDMENTS.—Effective as if included in the enactment of section 941 of BIPA (114 Stat. 2763A–585), sections 1819(b) and 1919(b) (42 U.S.C. 1395i–3(b), 1396r(b)), as amended by such section 941 are each amended by redesignating the paragraph (8) added by such section as paragraph (9).

(b) FEDERAL AND STATE REQUIREMENTS CONCERNING BACKGROUND CHECKS.—

(1) MEDICARE.—Section 1819(e) (42 U.S.C. 1395i–3(e)) is amended by adding at the end the following:

"(6) FEDERAL AND STATE REQUIREMENTS CONCERNING CRIMINAL BACKGROUND CHECKS ON SKILLED NURSING FACILITY EMPLOYEES.—

"(A) IN GENERAL.—Upon receipt of a request by a skilled nursing facility pursuant to subsection (b)(8) that is accompanied by the information described in subclauses (II) through (IV) of subsection (b)(8)(A)(ii), a State, after checking appropriate State records and finding no disqualifying information (as defined in subsection (b)(8)(F)(ii)), shall immediately submit such request and information to the Attorney General and shall request the Attorney General to conduct a search and exchange of records with respect to the individual as described in subparagraph (B).

"(B) SEARCH AND EXCHANGE OF RECORDS BY ATTORNEY GENERAL.—Upon receipt of a submission pursuant to subparagraph (A), the Attorney General shall direct a search of the records of the Federal Bureau of Investigation for any criminal history records cor-

responding to the fingerprints and other positive identification information submitted. The Attorney General shall provide any corresponding information resulting from the search to the State.

"(C) STATE REPORTING OF INFORMATION TO SKILLED NURSING FACILITY.—Upon receipt of the information provided by the Attorney General pursuant to subparagraph (B), the State shall—

"(i) review the information to determine whether the individual has any conviction for a relevant crime (as defined in subsection (b)(8)(F)(i));

"(ii) immediately report to the skilled nursing facility in writing the results of such review; and

"(iii) in the case of an individual with a conviction for a relevant crime, report the existence of such conviction of such individual to the database established under section 1128E.

"(D) FEES FOR PERFORMANCE OF CRIMINAL BACKGROUND CHECKS.—

"(i) AUTHORITY TO CHARGE FEES.—

"(I) ATTORNEY GENERAL.—The Attorney General may charge a fee to any State requesting a search and exchange of records pursuant to this paragraph and subsection (b)(8) for conducting the search and providing the records. The amount of such fee shall not exceed the lesser of the actual cost of such activities or $50. Such fees shall be available to the Attorney General, or, in the Attorney General's discretion, to the Federal Bureau of Investigation until expended.

"(II) STATE.—A State may charge a skilled nursing facility a fee for initiating the criminal background check under this paragraph and subsection (b)(8), including fees charged by the Attorney General, and for performing the review and report required by subparagraph (C). The amount of such fee shall not exceed the actual cost of such activities.

"(ii) PROHIBITION ON CHARGING.—An entity may not impose on a provisional employee or an employee any charges relating to the performance of a background check under this paragraph.

"(E) REGULATIONS.—

"(i) IN GENERAL.—In addition to the Secretary's authority to promulgate regulations under this title, the Attorney General, in consultation with the Secretary, may promulgate such regulations as are necessary to carry out the Attorney General's responsibilities under this paragraph and subsection (b)(9), including regulations regarding the security confidentiality, accuracy, use, destruction, and dissemination of information, audits and recordkeeping, and the imposition of fees.

"(ii) APPEAL PROCEDURES.—The Attorney General, in consultation with the Secretary, shall promulgate such regulations as are necessary to establish procedures by which a provisional employee or an employee may appeal or dispute the accuracy of the information obtained in a

background check conducted under this paragraph. Appeals shall be limited to instances in which a provisional employee or an employee is incorrectly identified as the subject of the background check, or when information about the provisional employee or employee has not been updated to reflect changes in the provisional employee's or employee's criminal record.

''(F) REPORT.—Not later than 2 years after the date of enactment of this paragraph, the Attorney General shall submit a report to Congress on—

''(i) the number of requests for searches and exchanges of records made under this section;

''(ii) the disposition of such requests; and

''(iii) the cost of responding to such requests.''.

(2) MEDICAID.—Section 1919(e) (42 U.S.C. 1396r(e)) is amended by adding at the end the following:

"(8) FEDERAL AND STATE REQUIREMENTS CONCERNING CRIMINAL BACKGROUND CHECKS ON NURSING FACILITY EMPLOYEES.—

"(A) IN GENERAL.—Upon receipt of a request by a nursing facility pursuant to subsection (b)(8) that is accompanied by the information described in subclauses (II) through (IV) of subsection (b)(8)(A)(ii), a State, after checking appropriate State records and finding no disqualifying information (as defined in subsection (b)(8)(F)(ii)), shall immediately submit such request and information to the Attorney General and shall request the Attorney General to conduct a search and exchange of records with respect to the individual as described in subparagraph (B).

"(B) SEARCH AND EXCHANGE OF RECORDS BY ATTORNEY GENERAL.—Upon receipt of a submission pursuant to subparagraph (A), the Attorney General shall direct a search of the records of the Federal Bureau of Investigation for any criminal history records corresponding to the fingerprints and other positive identification information submitted. The Attorney General shall provide any cor-

responding information resulting from the search to the State.

"(C) STATE REPORTING OF INFORMATION TO NURSING FACILITY.—Upon receipt of the information provided by the Attorney General pursuant to subparagraph (B), the State shall—

"(i) review the information to determine whether the individual has any conviction for a relevant crime (as defined in subsection (b)(8)(F)(i));

"(ii) immediately report to the nursing facility in writing the results of such review; and

"(iii) in the case of an individual with a conviction for a relevant crime, report the existence of such conviction of such individual to the database established under section 1128E.

"(D) FEES FOR PERFORMANCE OF CRIMINAL BACKGROUND CHECKS.—

"(i) AUTHORITY TO CHARGE FEES.—

"(I) ATTORNEY GENERAL.—The Attorney General may charge a fee to any State requesting a search and ex-

change of records pursuant to this paragraph and subsection (b)(8) for conducting the search and providing the records. The amount of such fee shall not exceed the lesser of the actual cost of such activities or $50. Such fees shall be available to the Attorney General, or, in the Attorney General's discretion, to the Federal Bureau of Investigation, until expended.

"(II) STATE.—A State may charge a nursing facility a fee for initiating the criminal background check under this paragraph and subsection (b)(8), including fees charged by the Attorney General, and for performing the review and report required by subparagraph (C). The amount of such fee shall not exceed the actual cost of such activities.

"(ii) PROHIBITION ON CHARGING.—An entity may not impose on a provisional employee or an employee any charges re-

lating to the performance of a background check under this paragraph.

"(E) REGULATIONS.—

"(i) IN GENERAL.—In addition to the Secretary's authority to promulgate regulations under this title, the Attorney General, in consultation with the Secretary, may promulgate such regulations as are necessary to carry out the Attorney General's responsibilities under this paragraph and subsection (b)(8), including regulations regarding the security, confidentiality, accuracy, use, destruction, and dissemination of information, audits and recordkeeping, and the imposition of fees.

"(ii) APPEAL PROCEDURES.—The Attorney General, in consultation with the Secretary, shall promulgate such regulations as are necessary to establish procedures by which a provisional employee or an employee may appeal or dispute the accuracy of the information obtained in a background check conducted under this paragraph. Appeals shall be limited to instances in which a provisional employee or

an employee is incorrectly identified as the subject of the background check, or when information about the provisional employee or employee has not been updated to reflect changes in the provisional employee's or employee's criminal record.

''(F) REPORT.—Not later than 2 years after the date of enactment of this paragraph, the Attorney General shall submit a report to Congress on—

''(i) the number of requests for searches and exchanges of records made under this section;

''(ii) the disposition of such requests; and

''(iii) the cost of responding to such requests.''.

(c) APPLICATION TO OTHER ENTITIES PROVIDING HOME HEALTH OR LONG-TERM CARE SERVICES.—

(1) MEDICARE.—Part D of title XVIII (42 U.S.C. 1395x et seq.) is amended by adding at the end the following:

"APPLICATION OF SKILLED NURSING FACILITY PREVENTIVE ABUSE PROVISIONS TO ANY PROVIDER OF SERVICES OR OTHER ENTITY PROVIDING HOME HEALTH OR LONG-TERM CARE SERVICES

"SEC. 1897. (a) IN GENERAL.—The requirements of subsections (b)(8) and (e)(6) of section 1819 shall apply to any provider of services or any other entity that is eligible to be paid under this title for providing home health services, hospice care (including routine home care and other services included in hospice care under this title), or long-term care services to an individual entitled to benefits under part A or enrolled under part B, including an individual provided with a Medicare+Choice plan offered by a Medicare+Choice organization under part C (in this section referred to as a 'medicare beneficiary').

"(b) SUPERVISION OF PROVISIONAL EMPLOYEES.—

"(1) IN GENERAL.—With respect to an entity that provides home health services, such entity shall be considered to have satisfied the requirements of section 1819(b)(8)(B)(ii) or 1919(b)(8)(B)(ii) if the entity meets such requirements for supervision of provisional employees of the entity as the Secretary shall, by regulation, specify in accordance with paragraph (2).

"(2) REQUIREMENTS.—The regulations required under paragraph (1) shall provide the following:

"(A) Supervision of a provisional employee shall consist of ongoing, good faith, verifiable efforts by the supervisor of the provisional employee to conduct monitoring and oversight activities to ensure the safety of a medicare beneficiary.

"(B) For purposes of subparagraph (A), monitoring and oversight activities may include (but are not limited to) the following:

"(i) Follow-up telephone calls to the medicare beneficiary.

"(ii) Unannounced visits to the medicare beneficiary's home while the provisional employee is serving the medicare beneficiary.

"(iii) To the extent practicable, limiting the provisional employee's duties to serving only those medicare beneficiaries in a home or setting where another family member or resident of the home or setting of the medicare beneficiary is present.

"(C) In promulgating such regulations, the Secretary shall take into account the staffing and geographic issues faced by small rural entities (as defined by the Secretary) that provide home health services, hospice care (including routine home care and other services included in hospice care under this title), or other long-term care services. Such regulations should encourage the provision of monitoring and oversight activities whenever practicable with respect to such an entity, and if such activities would not impose an unreasonable cost or other burden on the entity.".

(2) MEDICAID.—Section 1902(a) (42 U.S.C. 1396a), as amended by section 104(a), is amended—

(A) in paragraph (65), by striking "and" at the end;

(B) in paragraph (66), by striking the period and inserting "; and"; and

(C) by inserting after paragraph (66) the following:

"(67) provide that any entity that is eligible to be paid under the State plan for providing home health services, hospice care (including routine home

care and other services included in hospice care under title XVIII), or long-term care services for which medical assistance is available under the State plan to individuals requiring long-term care complies with the requirements of subsections (b)(8) and (e)(8) of section 1919 and section 1897(b) (in the same manner as such section applies to a medicare beneficiary).''.

(3) EXPANSION OF STATE NURSE AIDE REGISTRY.—

(A) MEDICARE.—Section 1819 (42 U.S.C. 1395i–3) is amended—

(i) in subsection (e)(2)—

(I) in the paragraph heading, by striking ''NURSE AIDE REGISTRY'' and inserting ''EMPLOYEE REGISTRY'';

(II) in subparagraph (A)—

(aa) by striking ''By not later than January 1, 1989, the'' and inserting ''The'';

(bb) by striking ''a registry of all individuals'' and inserting ''a registry of (i) all individuals''; and

(cc) by inserting before the period the following: ", (ii) all other skilled nursing facility employees with respect to whom the State has made a finding described in subparagraph (B), and (iii) any employee of any provider of services or any other entity that is eligible to be paid under this title for providing home health services, hospice care (including routine home care and other services included in hospice care under this title), or long-term care services and with respect to whom the entity has reported to the State a finding of patient neglect or abuse or a misappropriation of patient property"; and

(III) in subparagraph (C), by striking "a nurse aide" and inserting "an individual"; and

(ii) in subsection (g)(1)—

(I) by striking the first sentence of subparagraph (C) and inserting the following: ''The State shall provide, through the agency responsible for surveys and certification of skilled nursing facilities under this subsection, for a process for the receipt and timely review and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide or a skilled nursing facility employee of a resident in a skilled nursing facility, by another individual used by the facility in providing services to such a resident, or by an individual described in subsection (e)(2)(A)(iii).''; and

(II) in the fourth sentence of subparagraph (C), by inserting ''or described in subsection (e)(2)(A)(iii)'' after ''used by the facility''; and

(III) in subparagraph (D)—

(aa) in the subparagraph heading, by striking ''NURSE AIDE''; and

(bb) in clause (i), in the matter preceding subclause (I), by striking ''a nurse aide'' and inserting ''an individual''; and

(cc) in clause (i)(I), by striking ''nurse aide'' and inserting ''individual''.

(B) MEDICAID.—Section 1919 (42 U.S.C. 1396r) is amended—

(i) in subsection (e)(2)—

(I) in the paragraph heading, by striking ''NURSE AIDE REGISTRY'' and inserting ''EMPLOYEE REGISTRY'';

(II) in subparagraph (A)—

(aa) by striking ''By not later than January 1, 1989, the'' and inserting ''The'';

(bb) by striking ''a registry of all individuals'' and inserting ''a registry of (i) all individuals''; and

(cc) by inserting before the period the following: '', (ii) all other nursing facility employees with respect to whom the State

has made a finding described in subparagraph (B), and (iii) any employee of an entity that is eligible to be paid under the State plan for providing home health services, hospice care (including routine home care and other services included in hospice care under title XVIII), or long-term care services and with respect to whom the entity has reported to the State a finding of patient neglect or abuse or a misappropriation of patient property''; and

(III) in subparagraph (C), by striking ''a nurse aide'' and inserting ''an individual''; and

(ii) in subsection (g)(1)—

(I) by striking the first sentence of subparagraph (C) and inserting the following: ''The State shall provide, through the agency responsible for surveys and certification of nursing facilities under this subsection, for a process for the receipt and timely re-

view and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide or a nursing facility employee of a resident in a nursing facility, by another individual used by the facility in providing services to such a resident, or by an individual described in subsection (e)(2)(A)(iii).''; and

(II) in the fourth sentence of subparagraph (C), by inserting ''or described in subsection (e)(2)(A)(iii)'' after ''used by the facility''; and

(III) in subparagraph (D)—

(aa) in the subparagraph heading, by striking ''NURSE AIDE''; and

(bb) in clause (i), in the matter preceding subclause (I), by striking ''a nurse aide'' and inserting ''an individual''; and

(cc) in clause (i)(I), by striking ''nurse aide'' and inserting ''individual''.

(d) REIMBURSEMENT OF COSTS FOR BACKGROUND CHECKS.—The Secretary of Health and Human Services shall reimburse nursing facilities, skilled nursing facilities, and other entities for costs incurred by the facilities and entities in order to comply with the requirements imposed under sections 1819(b)(8) and 1919(b)(8) of such Act (42 U.S.C. 1395i–3(b)(8), 1396r(b)(8)), as added by this section.

(e) INCLUSION OF ABUSIVE ACTS WITHIN A LONG-TERM CARE FACILITY OR PROVIDER IN THE NATIONAL HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM.—

(1) IN GENERAL.—Section 1128E(g)(1)(A) (42 U.S.C. 1320a–7e(g)(1)(A)) is amended—

(A) by redesignating clause (v) as clause (vi); and

(B) by inserting after clause (iv), the following:

"(v) A finding of abuse or neglect of a patient or a resident of a long-term care facility, or misappropriation of such a patient's or resident's property.".

(2) COVERAGE OF LONG-TERM CARE FACILITY OR PROVIDER EMPLOYEES.—Section 1128E(g)(2) (42 U.S.C. 1320a–7e(g)(2)) is amended by inserting

1 ", and includes any individual of a long-term care
2 facility or provider (other than any volunteer) that
3 has access to a patient or resident of such a facility
4 under an employment or other contract, or both,
5 with the facility or provider (including individuals
6 who are licensed or certified by the State to provide
7 services at the facility or through the provider, and
8 nonlicensed individuals, as defined by the Secretary,
9 providing services at the facility or through the pro-
10 vider, including nurse assistants, nurse aides, home
11 health aides, individuals who provide home care, and
12 personal care workers and attendants)" before the
13 period.

14 (3) REPORTING BY LONG-TERM CARE FACILI-
15 TIES OR PROVIDERS.—

16 (A) IN GENERAL.—Section 1128E(b)(1)
17 (42 U.S.C. 1320a–7e(b)(1)) is amended by
18 striking "and health plan" and inserting ",
19 health plan, and long-term care facility or pro-
20 vider".

21 (B) CORRECTION OF INFORMATION.—Sec-
22 tion 1128E(c)(2) (42 U.S.C. 1320a–7e(c)(2)) is
23 amended by striking "and health plan" and in-
24 serting ", health plan, and long-term care facil-
25 ity or provider".

(4) ACCESS TO REPORTED INFORMATION.—Section 1128E(d)(1) (42 U.S.C. 1320a–7e(d)(1)) is amended by striking ''and health plans'' and inserting '', health plans, and long-term care facilities or providers''.

(5) MANDATORY CHECK OF DATABASE BY LONG-TERM CARE FACILITIES OR PROVIDERS.—Section 1128E(d) (42 U.S.C. 1320a–7e(d)) is amended by adding at the end the following:

''(3) MANDATORY CHECK OF DATABASE BY LONG-TERM CARE FACILITIES OR PROVIDERS.—A long-term care facility or provider shall check the database maintained under this section prior to hiring under an employment or other contract, or both, (other than in a provisional status) any individual as an employee of such a facility or provider who will have access to a patient or resident of the facility or provider (including individuals who are licensed or certified by the State to provide services at the facility or through the provider, and nonlicensed individuals, as defined by the Secretary, that will provide services at the facility or through the provider, including nurse assistants, nurse aides, home health aides, individuals who provide home care, and personal care workers and attendants).''.

(6) DEFINITION OF LONG-TERM CARE FACILITY OR PROVIDER.—Section 1128E(g) (42 U.S.C. 1320a–7e(g)) is amended by adding at the end the following:

''(6) LONG-TERM CARE FACILITY OR PROVIDER.—The term 'long-term care facility or provider' means a skilled nursing facility (as defined in section 1819(a)), a nursing facility (as defined in section 1919(a)), a home health agency, a provider of hospice care (as defined in section 1861(dd)(1)), a long-term care hospital (as described in section 1886(d)(1)(B)(iv)), an intermediate care facility for the mentally retarded (as defined in section 1905(d)), or any other facility or entity that provides, or is a provider of, long-term care services, home health services, or hospice care (including routine home care and other services included in hospice care under title XVIII), and receives payment for such services under the medicare program under title XVIII or the medicaid program under title XIX.''.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out the amendments made by this subsection, $10,200,000 for fiscal year 2004.

(f) PREVENTION AND TRAINING DEMONSTRATION PROJECT.—

(1) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish a demonstration program to provide grants to develop information on best practices in patient abuse prevention training (including behavior training and interventions) for managers and staff of hospital and health care facilities.

(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), an entity shall be a public or private nonprofit entity and prepare and submit to the Secretary of Health and Human Services an application at such time, in such manner, and containing such information as the Secretary may require.

(3) USE OF FUNDS.—Amounts received under a grant under this subsection shall be used to—

(A) examine ways to improve collaboration between State health care survey and provider certification agencies, long-term care ombudsman programs, the long-term care industry, and local community members;

(B) examine patient care issues relating to regulatory oversight, community involvement,

and facility staffing and management with a focus on staff training, staff stress management, and staff supervision;

(C) examine the use of patient abuse prevention training programs by long-term care entities, including the training program developed by the National Association of Attorneys General, and the extent to which such programs are used; and

(D) identify and disseminate best practices for preventing and reducing patient abuse.

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this subsection.

(g) EFFECTIVE DATE.—

(1) IN GENERAL.—With respect to a skilled nursing facility (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a)) or a nursing facility (as defined in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)), this section and the amendments made by this section shall take effect on the date that is the earlier of—

(A) 6 months after the effective date of final regulations promulgated to carry out this section and such amendments; or

(B) January 1, 2006.

(2) LONG-TERM CARE FACILITIES AND PROVIDERS.—With respect to a long-term care facility or provider (as defined in section 1128E(g)(6) of the Social Security Act (42 U.S.C. 1320a–7e(g)(6)) (as added by subsection (e)), this section and the amendments made by this section shall take effect on the date that is the earlier of—

(A) 18 months after the effective date of final regulations promulgated to carry out this section and such amendments; or

(B) January 1, 2007.

**SEC. 637. 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 inserting ''and'' after the comma at the end; 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.''.

# TITLE VII—ACCESS TO AFFORDABLE PHARMACEUTICALS

**SEC. 701. SHORT TITLE.**

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

**SEC. 702. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2), by striking subparagraph (B) and inserting the following:

''(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

''(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

''(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Sec-

retary informs the applicant that the application has been filed; or

"(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

"(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

"(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

"(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

"(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

"(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

"(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."; and

(2) in paragraph (5)—

(A) in subparagraph (B)—

(i) by striking "under the following" and inserting "by applying the following to each certification made under paragraph (2)(A)(vii)"; and

(ii) in clause (iii)—

(I) in the first sentence, by striking "unless" and all that follows and inserting "unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is

brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted.''; and

(II) in the second sentence—

(aa) by striking subclause (I) and inserting the following:

''(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(aa) the date on which the court enters judgment reflecting the decision; or

''(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is

the subject of the certification is invalid or not infringed;'';

(bb) by striking subclause (II) and inserting the following:

''(II) if before the expiration of such period the district court decides that the patent has been infringed—

''(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

''(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

''(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

''(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the

date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;'';

(cc) in subclause (III), by striking ''on the date of such court decision.'' and inserting ''as provided in subclause (I); or''; and

(dd) by inserting after subclause (III) the following:

''(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).'';

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(C) by inserting after subparagraph (B) the following:

"(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

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

"(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

"(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

"(aa) the drug for which the application was approved; or

"(bb) an approved method of using the drug.

"(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

"(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under subparagraph (i) or a counterclaim under subparagraph (ii).".

(b) APPLICATIONS GENERALLY.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b), by striking paragraph (3) and inserting the following:

"(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

"(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

"(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

"(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

"(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given 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

(2) in subsection (c)(3)—

(A) in the first sentence, by striking ''under the following'' and inserting ''by applying the following to each certification made under subsection (b)(2)(A)(iv)'';

(B) in subparagraph (C)—

(i) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on

which the application (excluding an amendment or supplement to the application) was submitted.'';

(ii) in the second sentence—

(I) by striking ''paragraph (3)(B)'' and inserting ''subsection (b)(3)'';

(II) by striking clause (i) and inserting the following:

''(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(I) the date on which the court enters judgment reflecting the decision; or

''(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;'';

(III) by striking clause (ii) and inserting the following:

"(ii) if before the expiration of such period the district court decides that the patent has been infringed—

"(I) if the judgment of the district court is appealed, the approval shall be made effective on—

"(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

"(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

"(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;";

(IV) in clause (iii), by striking "on the date of such court decision." and inserting "as provided in clause (i); or"; and

(V) by inserting after clause (iii), the following:

"(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii)."; and

(iii) in the third sentence, by striking "paragraph (3)(B)" and inserting "subsection (b)(3)";

(C) by redesignating subparagraph (D) as subparagraph (E); and

(D) by inserting after subparagraph (C) the following:

"(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

"(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent does not bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice given under subsection (b)(3) was received, the applicant may bring a civil action against the owner or holder (but not against any owner or holder that has brought such a civil action against that applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

"(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

"(I) IN GENERAL.—If an owner of the patent or the holder of the ap-

proved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

"(aa) the drug for which the application was approved; or

"(bb) an approved method of using the drug.

"(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

"(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil

action under clause (i) or a counterclaim under clause (ii).''.

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

''(5) The filing of an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and the failure of the owner of the patent to bring an action for infringement of a patent that is the subject of the certification before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of that section is received, shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed.''.

(d) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the amendments made by sub-

sections (a), (b), and (c) apply to any proceeding under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is pending on or after the date of enactment of this Act regardless of the date on which the proceeding was commenced or is commenced.

(2) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—The amendments made by subsections (a)(1) and (b)(1) apply with respect to any certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) after the date of enactment of this Act in an application filed under subsection (b)(2) or (j) of that section or in an amendment or supplement to an application filed under subsection (b)(2) or (j) of that section.

(3) EFFECTIVE DATE OF APPROVAL.—The amendments made by subsections (a)(2)(A)(ii)(I) and (b)(2)(B)(i) apply with respect to any patent information submitted under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) made after the date of enactment of this Act.

**SEC. 703. 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 702) is amended—

(1) in subparagraph (B), by striking clause (iv) and inserting the following:

"(iv) 180-DAY EXCLUSIVITY PERIOD.—

"(I) DEFINITIONS.—In this paragraph:

"(aa) 180-DAY EXCLUSIVITY PERIOD.—The term '180-day exclusivity period' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

"(bb) FIRST APPLICANT.—The term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) for the drug.

"(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term 'substantially complete application' means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

"(dd) TENTATIVE APPROVAL.—

"(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (E) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

"(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug

and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

"(II) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant."; and

(2) by inserting after subparagraph (C) the following:

"(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

"(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

"(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

"(aa) the earlier of the date that is—

"(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

"(BB) 30 months after the date of submission of the application of the first applicant; or

"(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted a certification qualifying the first applicant for the 180-day exclu-

sivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

"(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

"(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes

a finding that the patent is invalid or not infringed.

"(CC) The patent expires.

"(DD) The patent is withdrawn by the holder of the application approved under subsection (b).

"(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

"(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

"(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first appli-

cant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

"(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme

Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

"(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

"(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

"(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

"(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be

made effective in accordance with subparagraph (B)(iii); and

"(II) no applicant shall be eligible for a 180-day exclusivity period.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act.

(2) COLLUSIVE AGREEMENTS.—If a forfeiture event described in section 505(j)(5)(D)(i)(V) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(iv) of that Act without regard to when the first certification under section 505(j)(2)(A)(vii)(IV) of that Act for the listed drug was made.

(3) DECISION OF A COURT WHEN THE 180-DAY EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.—With respect to an application filed before, on, or

after the date of enactment of this Act for a listed drug for which a certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act and for which neither of the events described in subclause (I) or (II) of section 505(j)(5)(B)(iv) of that Act (as in effect on the day before the date of enactment of this Act) has occurred on or before the date of enactment of this Act, the term ''decision of a court'' as used in clause (iv) of section 505(j)(5)(B) of that Act means a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

**SEC. 704. 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 as-

sess 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. 705. REMEDIES FOR INFRINGEMENT.**

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

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

the court may refuse to award treble damages under section 284.''.

**SEC. 706. 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)''.

# TITLE VIII—IMPORTATION OF PRESCRIPTION DRUGS

**SEC. 801. IMPORTATION OF PRESCRIPTION DRUGS.**

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

**''SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

"(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

"(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

"(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(C) an infused drug (including a peritoneal dialysis solution);

"(D) an intravenously injected drug; or

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

"(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

"(5) WHOLESALER.—

"(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or dis-

tributor 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 safe-

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

"(d) INFORMATION AND RECORDS.—

"(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

"(A) The name and quantity of the active ingredient of the prescription drug.

"(B) A description of the dosage form of the prescription drug.

"(C) The date on which the prescription drug is shipped.

"(D) The quantity of the prescription drug that is shipped.

"(E) The point of origin and destination of the prescription drug.

"(F) The price paid by the importer for the prescription drug.

"(G) Documentation from the foreign seller specifying—

"(i) the original source of the prescription drug; and

"(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

"(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

"(I) The name, address, telephone number, and professional license number (if any) of the importer.

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

"(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

"(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

"(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

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

"(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

"(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

"(i) is approved for marketing in the United States; and

"(ii) meets all labeling requirements under this Act.

"(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

"(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

"(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

"(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

"(e) TESTING.—The regulations under subsection (b) shall require—

"(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

"(2) if the tests are conducted by the importer—

"(A) that information needed to—

"(i) authenticate the prescription drug being tested; and

"(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

"(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

"(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

"(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Sec-

1 retary the name and place of business of the establish-
2 ment.

3 "(g) SUSPENSION OF IMPORTATION.—The Secretary
4 shall require that importations of a specific prescription
5 drug or importations by a specific importer under sub-
6 section (b) be immediately suspended on discovery of a
7 pattern of importation of that specific prescription drug
8 or by that specific importer of drugs that are counterfeit
9 or in violation of any requirement under this section, until
10 an investigation is completed and the Secretary deter-
11 mines that the public is adequately protected from coun-
12 terfeit and violative prescription drugs being imported
13 under subsection (b).

14 "(h) APPROVED LABELING.—The manufacturer of a
15 prescription drug shall provide an importer written au-
16 thorization for the importer to use, at no cost, the ap-
17 proved labeling for the prescription drug.

18 "(i) PROHIBITION OF DISCRIMINATION.—

19 "(1) IN GENERAL.—It shall be unlawful for a
20 manufacturer of a prescription drug to discriminate
21 against, or cause any other person to discriminate
22 against, a pharmacist or wholesaler that purchases
23 or offers to purchase a prescription drug from the
24 manufacturer or from any person that distributes a

prescription drug manufactured by the drug manufacturer.

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

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

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

"(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian or-

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

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

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

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

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

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

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

"(2) WAIVER AUTHORITY.—

"(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under

such conditions as the Secretary determines to be appropriate.

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

"(l) STUDIES; REPORTS.—

"(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

"(A) STUDY.—

"(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

"(I) importations of prescription drugs made under the regulations under subsection (b); and

"(II) information and documentation submitted under subsection (d).

"(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

"(I) evaluate the compliance of importers with the regulations under subsection (b);

"(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

"(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

"(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

"(2) BY THE COMPTROLLER GENERAL.—

"(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

"(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

"(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

"(n) EFFECTIVENESS OF SECTION.—

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

after the date on which the Secretary submits the certification.

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

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

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

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

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

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

"(B) identifies specifically, in qualitative and quantitative terms, the benefits that would

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

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

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

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

(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)''.

(c) CONDITIONS.—This section shall become effective only if the Secretary of Health and Human Services certifies to the Congress that the implementation of this section will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

# TITLE IX—DRUG COMPETITION ACT OF 2003

**SEC. 901. SHORT TITLE.**

This title may be cited as the ''Drug Competition Act of 2003''.

**SEC. 902. FINDINGS.**

Congress finds that—

(1) prescription drug prices are increasing at an alarming rate and are a major worry of many senior citizens and American families;

(2) there is a potential for companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs to enter into financial deals that could tend to restrain trade and greatly reduce competi-

tion and increase prescription drug expenditures for American citizens; and

(3) enhancing competition among these companies can significantly reduce prescription drug expenditures for Americans.

**SEC. 903. PURPOSES.**

The purposes of this title are—

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs; and

(2) by providing timely notice, to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws of the United States.

**SEC. 904. DEFINITIONS.**

In this title:

(1) ANDA.—The term ''ANDA'' means an Abbreviated New Drug Application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(aa)).

(2) ASSISTANT ATTORNEY GENERAL.—The term ''Assistant Attorney General'' means the As-

sistant 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 approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)).

(4) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means the party that received Food and Drug Administration approval to market a brand name drug pursuant to an NDA, where that drug is the subject of an ANDA, or a party owning or controlling enforcement of any patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations of the Food and Drug Administration for that drug, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(5) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(6) GENERIC DRUG.—The term ''generic drug'' means a product that the Food and Drug Administration has approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(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 (21 U.S.C. 355(j)).

(8) NDA.—The term ''NDA'' means a New Drug Application, as defined under section 505(b) et seq. of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b) et seq.)

**SEC. 905. NOTIFICATION OF AGREEMENTS.**

(a) IN GENERAL.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(vii)(IV)) and a brand name drug company that enter into an agreement described in paragraph (2), prior to the generic drug that is the subject of the application entering the market, shall each file the agreement as required by subsection (b).

(2) DEFINITION.—An agreement described in this paragraph is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the subject of the generic drug applicant's ANDA;

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) FILING.—

(1) AGREEMENT.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that the generic drug applicant and the brand-name drug company shall not be 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 generic drug applicant and the brand name drug company enter-

ing into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this title.

(3) DESCRIPTION.—In the event that any agreement required to be filed by paragraph (1) or (2) has not been reduced to text, both the generic drug applicant and the brand name drug company shall file written descriptions of the non-textual agreement or agreements that must be filed sufficient to reveal all of the terms of the agreement or agreements.

**SEC. 906. FILING DEADLINES.**

Any filing required under section 5 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. 907. DISCLOSURE EXEMPTION.**

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this title shall be exempt from disclosure under sec-

tion 552 of title 5, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.

**SEC. 908. ENFORCEMENT.**

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this title 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 title. 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 title, 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. 909. 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 title—

(1) may define the terms used in this title;

(2) may exempt classes of persons or agreements from the requirements of this title; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this title.

**SEC. 910. 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 title shall not bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant at any time under any other provision of law, nor shall any filing under this title constitute or create a presumption of any violation of any antitrust or competition laws.

**SEC. 911. EFFECTIVE DATE.**

This title shall—

(1) take effect 30 days after the date of enactment of this title; and

(2) shall apply to agreements described in section 905 that are entered into 30 days after the date of enactment of this title.

Passed the Senate June 27 (legislative day, June 26), 2003.

Attest:

*Secretary.*

108th CONGRESS
1st Session

# S. 1

# AN ACT

To amend title XVIII of the Social Security Act to provide for a voluntary prescription drug benefit under the medicare program and to strengthen and improve the medicare program, and for other purposes.