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108TH CONGRESS
1ST SESSION

H. R. 2606

To amend title XVIII of the Social Security Act to provide prescription drug coverage under the Medicare Program, to make improvements in Medicare payment for rural providers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 25, 2003

Mr. THOMPSON of California (for himself, Mr. STENHOLM, Mr. TANNER, Mr. TURNER of Texas, Mr. BERRY, Mr. BISHOP of Georgia, Mr. BOYD, Mr. DAVIS of Tennessee, Mr. FORD, Mr. HOLDEN, Mr. ISRAEL, Mr. JOHN, Mr. LUCAS of Kentucky, Mr. MATHESON, Mr. MCINTYRE, Mr. MICHAUD, Mr. MOORE, Mr. POMEROY, Mr. SCOTT of Georgia, Mr. LIPINSKI, Mr. ALEXANDER, and Mr. CARDOZA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to provide prescription drug coverage under the Medicare Program, to make improvements in Medicare payment for rural providers, 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:

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

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Subtitle A—Medicare Voluntary Prescription Drug Delivery Program

Sec. 101. Medicare voluntary prescription drug delivery program.

''PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

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

''Subpart 1—Establishment of Voluntary Prescription Drug Delivery Program

''Sec. 1860D–1. Establishment of voluntary prescription drug delivery program.
''Sec. 1860D–2. Enrollment under program.
''Sec. 1860D–3. Election of a Medicare Prescription Drug plan.
''Sec. 1860D–4. Providing information to beneficiaries.
''Sec. 1860D–5. Beneficiary protections.
''Sec. 1860D–6. Prescription drug benefits.
''Sec. 1860D–7. Requirements for entities offering Medicare Prescription Drug plans; establishment of standards.

''Subpart 2—Prescription Drug Delivery System

''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.
''Sec. 1860D–13. Approval of proposed Medicare Prescription Drug plans.
''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.
''Sec. 1860D–21. Direct subsidy for sponsor of a qualified retiree prescription drug plan for plan enrollees eligible for, but not enrolled in, this part.

''Subpart 3—Miscellaneous Provisions

''Sec. 1860D–25. Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
''Sec. 1860D–26. Other related provisions.
Sec. 102. Study and report on permitting part B only individuals to enroll in medicare voluntary prescription drug delivery program.
Sec. 103. Rules relating to medigap policies that provide prescription drug coverage.
Sec. 104. Medicaid and other amendments related to low-income beneficiaries.
Sec. 105. Expansion of membership and duties of Medicare Payment Advisory Commission (MedPAC).
Sec. 106. Study regarding variations in spending and drug utilization.

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.

Subtitle C—Standards for Electronic Prescribing

Sec. 121. Standards for electronic prescribing.

Subtitle D—Other Provisions

Sec. 131. Additional requirements for annual financial report and oversight on medicare program.
Sec. 132. Trustees' report on medicare's unfunded obligations.

TITLE II—MEDICAREADVANTAGE

Subtitle A—MedicareAdvantage Competition

Sec. 201. Eligibility, election, and enrollment.
Sec. 202. Benefits and beneficiary protections.
Sec. 203. Payments to MedicareAdvantage organizations.
Sec. 204. Submission of bids; premiums.
Sec. 205. Special rules for prescription drug benefits.
Sec. 206. Facilitating employer participation.
Sec. 207. Administration by the Center for Medicare Choices.
Sec. 208. Conforming amendments.
Sec. 209. Effective date.

Subtitle B—Preferred Provider Organizations

Sec. 211. Establishment of MedicareAdvantage preferred provider program option.

Subtitle C—Other Managed Care Reforms

Sec. 221. Extension of reasonable cost contracts.
Sec. 222. Specialized Medicare+Choice plans for special needs beneficiaries.
Sec. 223. Payment by PACE providers for medicare and medicaid services furnished by noncontract providers.
Sec. 224. Institute of Medicine evaluation and report on health care performance measures.
Sec. 225. Expanding the work of medicare quality improvement organizations to include parts C and D.

TITLE III—CENTER FOR MEDICARE CHOICES

Sec. 301. Establishment of the Center for Medicare Choices.
Sec. 302. Miscellaneous administrative provisions.

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.
Sec. 402. Adjustment to the medicare inpatient hospital PPS wage index to revise the labor-related share of such index.
Sec. 403. Medicare inpatient hospital payment adjustment for low-volume hospitals.
Sec. 404. Fairness in the medicare disproportionate share hospital (DSH) adjustment for rural hospitals.
Sec. 405. Critical access hospital (CAH) improvements.

Sec. 406. Authorizing use of arrangements to provide core hospice services in certain circumstances.
Sec. 407. Services provided to hospice patients by nurse practitioners, clinical nurse specialists, and physician assistants.
Sec. 408. Authority to include costs of training of psychologists in payments to hospitals under medicare.
Sec. 409. Revision of Federal rate for hospitals in Puerto Rico.
Sec. 410. Authority regarding geriatric fellowships.
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.
Sec. 412. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.
Sec. 413. GAO study and report on appropriateness of payments under the prospective payment system for inpatient hospital services.

Subtitle B—Provisions Relating to Part B

Sec. 421. Establishment of floor on geographic adjustments of payments for physicians' services.
Sec. 422. Medicare incentive payment program improvements.
Sec. 423. Increase in renal dialysis composite rate.
Sec. 424. 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.
Sec. 425. Increase in payments for certain services furnished by small rural and sole community hospitals under medicare prospective payment system for hospital outpatient department services.
Sec. 426. Increase for ground ambulance services furnished in a rural area.
Sec. 427. Ensuring appropriate coverage of air ambulance services under ambulance fee schedule.
Sec. 428. Treatment of certain clinical diagnostic laboratory tests furnished by a sole community hospital.
Sec. 429. Improvement in rural health clinic reimbursement.
Sec. 430. Elimination of consolidated billing for certain services under the medicare PPS for skilled nursing facility services.
Sec. 431. Freeze in payments for certain items of durable medical equipment and certain orthotics; establishment of quality standards and accreditation requirements for DME providers.
Sec. 432. Application of coinsurance and deductible for clinical diagnostic laboratory tests.
Sec. 433. Basing medicare payments for covered outpatient drugs on market prices.
Sec. 434. Indexing part B deductible to inflation.
Sec. 435. Revisions to reassignment provisions.
Sec. 436. Extension of treatment of certain physician pathology services under medicare.
Sec. 437. Adequate reimbursement for outpatient pharmacy therapy under the hospital outpatient PPS.
Sec. 438. Limitation of application of functional equivalence standard.
Sec. 439. Medicare coverage of routine costs associated with certain clinical trials.
Sec. 440. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
Sec. 441. Demonstration of coverage of chiropractic services under medicare.

Sec. 442. Medicare health care quality demonstration programs.
Sec. 443. Medicare complex clinical care management payment demonstration.
Sec. 444. Medicare fee-for-service care coordination demonstration program.
Sec. 445. GAO study of geographic differences in payments for physicians' services.

Subtitle C—Provisions Relating to Parts A and B

Sec. 451. Increase for home health services furnished in a rural area.
Sec. 452. Limitation on reduction in area wage adjustment factors under the prospective payment system for home health services.
Sec. 453. Clarifications to certain exceptions to medicare limits on physician referrals.
Sec. 454. Demonstration program for substitute adult day services.
Sec. 455. Medicare secondary payor (MSP) provisions.

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.
Sec. 502. Compliance with changes in regulations and policies.
Sec. 503. Report on legal and regulatory inconsistencies.

Subtitle B—Appeals Process Reform

Sec. 511. Submission of plan for transfer of responsibility for medicare appeals.
Sec. 512. Expedited access to judicial review.
Sec. 513. Expedited review of certain provider agreement determinations.
Sec. 514. Revisions to medicare appeals process.
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.
Sec. 516. Appeals by providers when there is no other party available.
Sec. 517. Provider access to review of local coverage determinations.

Subtitle C—Contracting Reform

Sec. 521. Increased flexibility in medicare administration.

Subtitle D—Education and Outreach Improvements

Sec. 531. Provider education and technical assistance.
Sec. 532. Access to and prompt responses from medicare contractors.
Sec. 533. Reliance on guidance.
Sec. 534. Medicare provider ombudsman.
Sec. 535. Beneficiary outreach demonstration programs.

Subtitle E—Review, Recovery, and Enforcement Reform

Sec. 541. Prepayment review.
Sec. 542. Recovery of overpayments.
Sec. 543. Process for correction of minor errors and omissions on claims without pursuing appeals process.
Sec. 544. Authority to waive a program exclusion.

TITLE VI—OTHER PROVISIONS

Sec. 601. Increase in medicaid DSH allotments for fiscal years 2004 and 2005.
Sec. 602. Increase in floor for treatment as an extremely low DSH State under the medicaid program for fiscal years 2004 and 2005.
Sec. 603. Increased reporting requirements to ensure the appropriateness of payment adjustments to disproportionate share hospitals under the medicaid program.
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.
Sec. 605. Assistance with coverage of legal immigrants under the medicaid program and SCHIP.
Sec. 606. Establishment of consumer ombudsman account.
Sec. 607. GAO study regarding impact of assets test for low-income beneficiaries.
Sec. 608. Health care infrastructure improvement.
Sec. 609. Capital infrastructure revolving loan program.
Sec. 610. Federal reimbursement of emergency health services furnished to undocumented aliens.
Sec. 611. Increase in appropriation to the health care fraud and abuse control account.
Sec. 612. Increase in civil penalties under the False Claims Act.
Sec. 613. Increase in civil monetary penalties under the Social Security Act.
Sec. 614. Extension of customs user fees.

TITLE VII—ACCESS TO AFFORDABLE PHARMACEUTICALS

Sec. 701. Short title.
Sec. 702. 30-month stay-of-effectiveness period.
Sec. 703. Forfeiture of 180-day exclusivity period.
Sec. 704. Bioavailability and bioequivalence.
Sec. 705. Remedies for infringement.
Sec. 706. Conforming amendments.

TITLE VIII—IMPORTATION OF PRESCRIPTION DRUGS

Sec. 801. Importation of prescription drugs.

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 de-

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

''(ii) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered drug under this part shall not be so con-

sidered 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.

''(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 cov-

erage 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 provisions 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 eligibility' 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 through a waiver under 1115 where covered outpatient drugs are the sole medical assistance benefit.

''(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 para-

graph (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 individual 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 enroll 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 adequate 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 both urban and rural areas.

''(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).

"(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 phar-

macist, 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 cov-

ered 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 management 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 for-

mulary, 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.

''(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 15 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 without regard to whether the individual or another person, including a State program or other third-party coverage, has paid for such costs, except that only the applicable percent (specified in subparagraph (D)) of the amount of portion of such costs that are paid or reimbursed through insurance, a group health plan, or other third-party payment arrangement for such costs shall not be counted.

''(D) APPLICABLE PERCENT DEFINED.—

''(i) IN GENERAL.—For purposes of subparagraph (C)(ii), but subject to clause (ii), the applicable percent specified in this subparagraph is—

''(I) for years before 2010, 25 percent;

"(II) for 2011, 2012, 2013, 2014, and 2015, 50 percent; and

"(III) for any year thereafter, 100 percent.

"(ii) SECRETARIAL LIMITATION ON TOTAL EXPENDITURES.—The Secretary, in consultation with the Office of Management and Budget, shall estimate at the time of enactment of this part, the aggregate budget outlays that will result during the 10-fiscal-year period beginning with fiscal year 2004 from the enactment of the Prescription Drug and Medicare Improvement Act of 2003. If such estimate exceeds $400,000,000,000, the Secretary shall provide for such proportional reductions in the percentages specified in clause (i) as the Secretary determines to be necessary to assure that such aggregate budget outlays during such period do not exceed such amount.

"(E) 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 termination 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 subpara-

graph, 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 discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations and shall reflect prices that are no higher than the prices negotiated by the Secretary under subparagraph (B).

"(B) SECRETARIAL NEGOTIATED PRICE.—Notwithstanding any otherprovision of this

part, the Secretary shall, consistent with the requirements of this part and the goals of providing quality care and containing costs under this part, negotiate contracts with manufacturers of covered outpatient prescription drugs that provide for the maximum prices that may be charged to individuals enrolled under this part by participating pharmacies for dispensing such drugs to such individuals.

"(C) 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, the requirements of section 1927 shall not apply to such drugs. 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.

''(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.

''(i) 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

plan stabilization reserve fund in the Prescription Drug Account used to stabilize or reduce the monthly plan premium.

''(b) NEGOTIATION.—In exercising the authority under subsection (a), the Administrator shall have the authority to—

''(1) negotiate the terms and conditions of the proposed monthly plan premiums submitted and other terms and conditions of a proposed plan; and

''(2) disapprove, or limit enrollment in, a proposed plan based on—

''(A) the costs to beneficiaries under the plan;

''(B) the quality of the coverage and benefits under the plan;

''(C) the adequacy of the network under the plan; or

''(D) other factors determined appropriate by the Administrator.

''(c) SPECIAL RULES FOR APPROVAL.—The Administrator 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. An entity with a contract under this part shall meet the requirements described in section 1860D–5 and such

other requirements determined appropriate by the Administrator.

''(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) CONTRACT TO BE AVAILABLE IN DESIGNATED AREA FOR 2 YEARS.—Notwithstanding paragraph (1), if the Administrator enters into a contract with an entity with respect to an area designated under subparagraph (B) of such paragraph for a year, the following rules shall apply:

''(A) The contract shall be for a 2-year period.

''(B) The Secretary is not required to make the determination under paragraph (1)(A) with respect to the second year of the contract for the area.

''(C) During the second year of the contract, an eligible beneficiary residing in the area may continue to receive standard prescription drug coverage (including access to negotiated prices for such beneficiaries pursuant to section 1860D-6(e)) under such contract or through any Medicare Prescription Drug plan that is available in the area.

''(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 enrollment 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 (including a contract under) 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 plan 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 average 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 change in aggregate payments made under this part than would have been made if the Administrator had not applied such adjustment.

''(c) SPECIAL RULE FOR 2006.—For purposes of applying this section for 2006, the Administrator shall establish procedures for determining the weighted average under subsection (a)(2) for 2005.

''PAYMENTS TO ELIGIBLE ENTITIES

''SEC. 1860D–16. (a) PAYMENT OF MONTHLY PLAN PREMIUMS.—For each year (beginning with 2006), the Administrator shall pay to each entity offering a Medicare Prescription Drug plan in which an eligible beneficiary is enrolled an amount equal to the full amount of the monthly plan premium approved for the plan under section 1860D–13 on behalf of each eligible beneficiary enrolled in such plan for the year, as adjusted using the risk adjusters that apply to the standard prescription drug coverage published under section 1860D–11.

''(b) PORTION OF TOTAL PAYMENTS OF MONTHLY PLAN PREMIUMS SUBJECT TO RISK.—

''(1) NOTIFICATION OF SPENDING UNDER THE PLAN.—

''(A) IN GENERAL.—For each year (beginning in 2007), the eligible entity offering a Medicare Prescription Drug plan shall notify 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) ACTUAL COSTS FOR SPECIFIC DRUGS.—With respect to the total amount under clause (i) for the year, a breakdown of—

''(I) each covered drug that constitutes a portion of such amount;

''(II) the negotiated price for the eligible entity for each such drug;

''(III) the number of prescriptions; and

''(IV) the average beneficiary coinsurance rate for a each covered drug that constitutes a portion of such amount.

''(B) CERTAIN EXPENSES NOT INCLUDED.—The amounts under clauses (i) and (ii)(II) of subparagraph (A) 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); or

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

''(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 payments 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 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.—

"(A) IN GENERAL.—For each year, the Administrator shall establish the allowable costs for each Medicare Prescription 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, adjusted under subparagraph (B)(ii).

"(B) REPRICING OF COSTS.—

"(i) CALCULATION OF AVERAGE PLAN COST.—Utilizing the information obtained under paragraph (1)(A)(ii) and section 1860D–20(b)(1)(B), for each year (beginning with 2006), the Administrator shall

establish an average negotiated price with respect to all Medicare Prescription Drug plans for each covered drug.

''(ii) ADJUSTMENT IF ACTUAL COSTS EXCEED AVERAGE COSTS.—With respect to a Medicare Prescription Drug plan for a year, the Administrator shall reduce the amount described in paragraph (1)(A)(i) for the plan for the year to the extent such amount is based on costs of specific covered drugs furnished under the plan in the year (as specified under paragraph (1)(A)(ii)) for which the negotiated prices are greater than the average negotiated price for the covered drug for the year (as determined under clause (i)).

''(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 sec-

tion 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, 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 pur-

poses 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 (begin-

ning 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 coverage 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 eligi-

ble 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 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 quali-

fied 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 beneficiary that is 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), the Medicare monthly beneficiary obligation for qualified prescription drug coverage shall be determined pursuant to section 1858A(d).

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

''(1) the numerator of which is 27.5 percent; and

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

''(A) the total reinsurance payments which the Administrator estimates will be made under

section 1860D–20 to qualifying entities described in subsection (e)(3) of such section during the year; divided by

"(B) the sum of—

"(i) the amount estimated under subparagraph (A) for the year; and

"(ii) the total payments which the Administrator estimates will be made under 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 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;

''(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; and

''(ii) is described in section 1905(p)(1).

''(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; and

''(ii) is described in section 1902(a)(10)(E)(iii).

''(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; and

''(ii) is described in section 1902(a)(10)(E)(iv) (without regard to any

termination of the application of such section under title XIX).

''(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; or

''(III) a qualifying individual.

''(E) 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.

''(F) 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), or (D) 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.

"(G) NONAPPLICATION TO DUAL ELIGIBLE INDIVIDUALS AND TERRITORIAL RESIDENTS.—In the case of 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) such individuals 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.

"(b) RULES IN APPLYING COST-SHARING SUBSIDIES.—Nothing in this section shall be construed as preventing an eligible entity offering a Medicare Prescription

Drug plan or a MedicareAdvantage organization offering a MedicareAdvantage plan from waiving or reducing the amount of the deductible or other cost-sharing otherwise applicable pursuant to section 1860D–6(a)(2).

''(c) ADMINISTRATION OF SUBSIDY PROGRAM.—The Administrator shall establish a process whereby, in the case of an individual eligible for a cost-sharing subsidy under subsection (a) who is enrolled in a Medicare Prescription Drug plan or a MedicareAdvantage plan—

''(1) the Administrator provides for a notification of the eligible entity or MedicareAdvantage organization involved that the individual is eligible for a cost-sharing subsidy and the amount of the subsidy under such subsection;

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

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

The reimbursement under paragraph (3) may be computed on a capitated basis, taking into account the actu-

arial 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 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 Administrator 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) ACTUAL COSTS FOR SPECIFIC DRUGS.—With respect to the total amount under subparagraph (A) for the year, a breakdown of—

''(i) each covered drug that constitutes a portion of such amount;

''(ii) the negotiated price for the qualifying entity for each such drug;

''(iii) the number of prescriptions; and

''(iv) the average beneficiary coinsurance rate for a each covered drug that constitutes a portion of such amount.

''(2) CERTAIN EXPENSES NOT INCLUDED.—The amounts under subparagraphs (A) and (B)(ii) of paragraph (1) may not include—

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

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

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

''(2) ALLOWABLE COSTS.—

"(A) IN GENERAL.—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, adjusted under subparagraph (B).

"(B) REPRICING OF COSTS IF ACTUAL COSTS EXCEED AVERAGE COSTS.—The Administrator shall reduce the amount described in subsection (b)(1)(A) with respect to a qualifying covered individual for a coverage year to the extent such amount is based on costs of specific covered drugs furnished under the plan in the year (as specified under subsection (b)(1)(B)) that are greater than the average cost for the covered drug for the year (as determined under section 1860D–16(b)(3)(A)).

"(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); or

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

''(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.

''(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) ASSURANCE.—The sponsor of the plan shall annually attest, and provide such assurances as the Administrator may require, that the coverage meets or exceeds the requirements for qualified prescription drug coverage.

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

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

''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.

"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 prescription 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).''.

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

(b) REPORT.—Not later than January 1, 2005, the Administrator of the Center for Medicare Choices shall submit a report to Congress on the study conducted under subsection (a), together with any recommendations for leg-

islation that the Administrator determines to be appropriate as a result of such study.

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

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

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

''(1) PROHIBITION ON SALE, ISSUANCE, AND RENEWAL OF POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE TO PART D ENROLLEES.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, on or after January 1, 2006, no medicare supplemental policy that provides coverage of expenses for prescription 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 in a manner that is similar to the manner in which presumptive eligibility is provided to children and pregnant women under this title;

"(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 in a manner that is similar to the manner in which presumptive eligibility is provided to children and pregnant women under this title;

"(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).

"(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 pur-

poses 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) and to the design, development, acquisition or installation of improved data systems necessary to track prescription drug spending for purposes of implementing section 1935(c). 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 ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALLY ELIGIBLE BENEFICIARIES.—

''(1) IN GENERAL.—For purpose of section 1903(a)(1) for a State for a calendar quarter in a year (beginning with 2006) the amount computed under this subsection is equal to the product of the following:

''(A) STANDARD PRESCRIPTION DRUG COVERAGE UNDER MEDICARE.—With respect to individuals who are residents of the State, who are entitled to, or enrolled for, benefits under part A of title XVIII, or are enrolled under part

B of title XVIII and are receiving medical assistance under subparagraph (A)(i), (A)(ii), or (C) of section 1902(a)(10) (or as the result of the application of section 1902(f)) that includes covered outpatient drugs (as defined for purposes of section 1927) under the State plan under this title (including such a plan operated under a waiver under section 1115)—

''(i) the total amounts attributable to such individuals in the quarter under section 1860D–19 (relating to premium and cost-sharing subsidies for low-income medicare beneficiaries); and

''(ii) the actuarial value of standard prescription drug coverage (as determined under section 1860D–6(f)) provided to such individuals in the quarter.

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

''(C) PHASE-OUT PROPORTION.—Subject to subparagraph (D), the phase-out proportion for a quarter in—

"(i) 2006 is 100 percent;

"(ii) 2007 is 95 percent;

"(iii) 2008 or 2009, is 90 percent;

"(iv) 2010 is 85 percent; or

"(v) 2011, 2012, or 2013 is 80 percent.

"(d) MEDICAID AS SECONDARY PAYOR.—In the case of an individual who is entitled to a Medicare Prescription Drug plan under part D or drug coverage under a MedicareAdvantage plan, and medical assistance including covered outpatient drugs under this title, medical assistance shall continue to be provided under this title for covered outpatient drugs to the extent payment is not made under the Medicare Prescription Drug plan or a MedicareAdvantage plan.

"(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 $22,500,000;

"(ii) fiscal year 2007, is equal to $30,000,000; 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) DEFINITION.—For purposes of this section, the term 'subsidy-eligible individual' has the meaning given

that term in subparagraph (D) of section 1860D–19(a)(4).''.

(2) CONFORMING AMENDMENTS.—

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

(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) 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''; and

(B) in paragraph (2), by inserting '', program, and subsidies'' after ''medical assistance''.

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 Com-

mission 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.''.

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).

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 dis-

count 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; and

''(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 both urban and rural areas.

"(3) QUALITY ASSURANCE.—Each prescription drug card sponsor offering a prescription drug discount card program endorsed under this section shall have in place adequate procedures for assuring that quality service is provided to eligible beneficiaries enrolled in a prescription drug discount card program offered by such sponsor.

"(4) CONFIDENTIALITY OF ENROLLEE RECORDS.—Insofar as a prescription drug card sponsor maintains individually identifiable medical records or other health information regarding eligi-

ble beneficiaries enrolled in a prescription drug discount card program endorsed under this section, the prescription drug card sponsor shall have in place procedures to safeguard the privacy of any individually identifiable beneficiary information in a manner that the Secretary determines is 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.

''(5) NO OTHER FEES.—A prescription drug card sponsor may not charge any fee to an eligible beneficiary under a prescription drug discount card program endorsed under this section other than an enrollment fee charged under subsection (b)(2)(A).

''(6) PRICES.—

''(A) AVOIDANCE OF HIGH PRICED DRUGS.—A prescription drug card sponsor may not recommend switching an eligible beneficiary to a drug with a higher negotiated price absent a recommendation by a licensed health professional that there is a clinical indication with respect to the patient for such a switch.

''(B) PRICE STABILITY.—Negotiated prices charged for prescription drugs covered under a

prescription drug discount card program endorsed under this section may not change more frequently than once every 60 days.

''(e) PRESCRIPTION DRUG BENEFITS.—

''(1) IN GENERAL.—Each prescription drug card sponsor may only provide benefits that relate to prescription drugs (as defined in subsection (i)(2)) under a prescription drug discount card program endorsed under this section.

''(2) SAVINGS TO ELIGIBLE BENEFICIARIES.—

''(A) IN GENERAL.—Subject to subparagraph (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 considered 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 bene-

ficiary 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 individuals 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 sec-

tion, 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 includes but is limited solely to 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,

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 determination 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-in-

come 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 endorsement 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));

''(B) is not a dual eligible beneficiary as defined under section 1807(i)(1)(B); and

"(C) 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—

"(A) is appropriate to provide eligible low-income beneficiaries with the benefits under a prescription drug assistance card program under this section;

"(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-in-

come 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) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—

"(i) IN GENERAL.—Except as provided in clause (ii), the standards require that prescriptions be written and transmitted electronically.

"(ii) EXCEPTIONS.—The standards shall not require a prescription to be written and transmitted electronically—

"(I) in emergency cases and other exceptional circumstances recognized by the Administrator; or

"(II) if the patient requests that the prescription not be transmitted electronically.

If a patient makes a request under subclause (II), no additional charges may be imposed on the patient for making such 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 electronic medication history, eligibility, benefit and prescription information, 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.

''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 (INCLUDING 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 in-

volved, 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 Supple-

mentary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t).

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 eli-

gible 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 individuals 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 num-

bers 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 information 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 begin-

ning 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 catastrophic 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 re-

spect 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 program 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 bene-

fits 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 educational 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 indi-

vidual 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 individual'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 mate-

rial 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 or-

ganization 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 actuarial 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 inpa-

tient 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 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.

''(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 process 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 'nonnetwork 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 subparagraph (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 subparagraph (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, continuity and coordination of care, management of chronic conditions, and consumer satisfaction.

''(iii) Recommendations on ways to reduce clinical outcome disparities among racial and ethnic minorities.

''(f) GRIEVANCE MECHANISM.—Each MedicareAdvantage organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with MedicareAdvantage plans of the organization under this part.

''(g) COVERAGE DETERMINATIONS, RECONSIDERATIONS, AND APPEALS.—

''(1) DETERMINATIONS BY ORGANIZATION.—

''(A) IN GENERAL.—A MedicareAdvantage organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that

the individual is required to pay with respect to 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 treatment 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 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.

''(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 determination 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

physicians who have entered into participation agreements with the organization regarding the organization's medical policy, quality, and medical management procedures.

''(3) PROHIBITING INTERFERENCE WITH PROVIDER ADVICE TO ENROLLEES.—

''(A) IN GENERAL.—Subject to subparagraphs (B) and (C), a MedicareAdvantage organization (in relation to an individual enrolled under a MedicareAdvantage plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

''(B) CONSCIENCE PROTECTION.—Subparagraph (A) shall not be construed as requiring a MedicareAdvantage plan to provide, reimburse 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 and each succeeding year, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

''(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 capitation 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 re-

spect 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 program option' means those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to, 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 adjustment 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 non-contiguous 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 in-

dividual 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 and payments to a MedicareAdvantage MSA under subsection (e)(1) shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such proportion as the Secretary determines reflects the relative weight that benefits under part A and under part B represents of the actuarial value of the total benefits under this title. Monthly payments otherwise payable under this section for October 2000 shall be paid on the first business day of such month. Monthly payments otherwise payable under this section for October 2001 shall be paid on the last business day of September 2001. Monthly payments otherwise payable

under this section for October 2006 shall be paid on the first business day of October 2006.

''(h) SPECIAL RULE FOR CERTAIN INPATIENT HOSPITAL STAYS.—In the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1886(d)(1)(B)) as of the effective date of the individual's—

''(1) election under this part of a MedicareAdvantage plan offered by a MedicareAdvantage organization—

''(A) payment for such services until the date of the individual's discharge shall be made 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 pro-

gram 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 enhanced 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); and

''(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 medi-

care 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 as-

sumptions 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) MSA EXCEPTION.—The Secretary shall not review, approve, or disapprove the amounts submitted under paragraph (3).

''(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 obligation 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 enhanced 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.

"(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) or (C) 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) or (C) 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 ad-

ditional 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 under this paragraph and from imposing a premium for such enhanced medical benefits.

"(2) STABILIZATION FUND.—A MedicareAdvantage organization may provide that a part of the value of an excess amount described in paragraph (1) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with such paragraph. Any of such value of the amount reserved which is not provided as additional benefits described in paragraph (1)(A) to individuals electing the MedicareAdvantage plan of the organization in accordance with such paragraph

prior to the end of such periods, shall revert for the use of such Trust Funds.

''(3) ADJUSTED COMMUNITY RATE.—For purposes of this subsection, subject to paragraph (4), the term 'adjusted community rate' for a service or services means, at the election of a 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 population 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 Con-

gress 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.

(a) 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 MedicareAdvantage eligible individual receiving qualified prescription drug coverage under a MedicareAdvantage plan during a year after 2005, the MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage of such individual in the year shall be determined in the same manner as the monthly beneficiary obligation is determined under section 1860D–17 for eligible beneficiaries enrolled in a Medicare Prescription Drug plan, except that, for purposes of this subparagraph, any reference to the monthly plan premium approved by the Secretary under section 1860D–13 shall be treated as a reference to the monthly premium for qualified prescription drug coverage submitted by the MedicareAdvantage organization offering the plan under section 1854(a)(2)(A) and approved by the Secretary.

"(e) COLLECTION OF MEDICAREADVANTAGE MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.—The provisions of section 1860D–18, including subsection (b) of such section, shall apply to the amount of the MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage (as determined under subsection (d)) re-

quired to be paid by a MedicareAdvantage eligible individual enrolled in a MedicareAdvantage plan in the same 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 by inserting ''(including subsection (i) of such section)'' after ''section 1857''.

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 cov-

erage' 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) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of enactment of this Act.

(f) 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).

(E) 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)''.

(F) Section 1876(k)(4)(C) (42 U.S.C. 1395mm(k)(4)(C)) is 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)''.

(G) 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.

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 organiza-

tion' 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 pre-

ferred 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 subpara-

graph (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 the persons from whom enrollees under such a plan may obtain covered benefits.

''(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 Secretary 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 to 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 dis-

approve 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 medical 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 plan for special needs beneficiaries' means a Medicare+Choice plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

''(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare+Choice eligible individual who—

''(i) is institutionalized (as defined by the Secretary);

''(ii) is entitled to medical assistance under a State plan under title XIX; or

''(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare+Choice plan described in sub-

paragraph (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.

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 and Medicaid Services.

''(b) ADMINISTRATOR AND DEPUTY ADMINISTRATOR.—

''(1) ADMINISTRATOR.—

''(A) IN GENERAL.—The Center for Medicare Choices shall be headed by an Adminis-

trator (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 delega-

tions, 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 and 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 appro-

priate. 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 AND MEDICAID SERVICES.—

''(A) IN GENERAL.—The Secretary, the Administrator of the Center for Medicare Choices, and the Administrator of the Centers for Medicare and 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 and 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 and Medicaid Services transfers to the Administrator such information and data in the possession of the Administrator of the Centers for Medicare and 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 Adminis-

trator of the Centers for Medicare and Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare and 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).

''(B) DUTIES.—The Medicare Ombudsman shall—

''(i) receive complaints, grievances, and requests for information submitted by a medicare beneficiary, with respect to any aspect of the medicare program;

''(ii) provide assistance with respect to complaints, grievances, and requests referred to in clause (i), including—

''(I) assistance in collecting relevant information for such beneficiaries, to seek an appeal of a decision or determination made by a fiscal

intermediary, carrier, Medicare-Advan-tage organization, an eligible entity under part D, or the Secretary; and

''(II) assistance to such beneficiaries with any problems arising from disenrollment from a MedicareAdvantage plan under part C or a prescription drug plan under part D; and

''(iii) submit annual reports to Congress, 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 Administrator 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 top-

ics 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 pri-

vate 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 and 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 and 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 the succeeding provisions of this clause, for discharges''; and

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

''(II) For discharges occurring during fiscal year 2004, the operating standardized amount for hospitals located other than in a large urban area shall be increased by ½ of the difference between the operating standardized amount determined under subclause (I) for hospitals located in large urban areas for such fiscal year and such amount determined (without regard to this subclause) for other hospitals for such fiscal year.

''(III) For discharges occurring in a fiscal year beginning with fiscal year 2005, the Secretary shall compute an operating standardized amount for hospitals located in any area within the United States and within each region equal to the operating standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2006, 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) 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 which is'';

(C) in clause (i)—

(i) in the matter preceding subclause (I), by inserting ''for fiscal years before fiscal year 2005,'' 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 2005,'' 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 2004, for hospitals located in all areas, to the product of—

''(I) the applicable operating 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 2004.—

"(I) IN GENERAL.—Except as provided in subclause (II), for discharges occurring on or after October 1, 2003, 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 2004), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in clause (iii)) for discharges occurring during that cost reporting period which is equal to the applicable percentage increase (determined under clause (ii)) in the amount paid to such hospital under this section for such discharges.

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

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

"(II) low-volume hospitals that have the lowest number of discharges during a cost reporting period receive the highest percentage increases in payments due to the application of this paragraph; and

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

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

"(I) the Secretary determines had an average of less than 2,000 discharges (determined with respect to all patients and not just individuals receiving benefits under this title) during the 3 most recent cost report-

ing 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, 2003, 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, 2003," after "April 1, 2001,"; and

(II) by inserting "or, for discharges occurring on or after October 1, 2003, is equal to the percent determined in accordance with the applicable formula described in clause (vii)" after "clause (xiii)";

(ii) in subclause (III)—

(I) by inserting ''and before October 1, 2003,'' after ''April 1, 2001,''; and

(II) by inserting ''or, for discharges occurring on or after October 1, 2003, 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, 2003,'' after ''April 1, 2001,''; and

(II) by inserting ''or, for discharges occurring on or after October 1, 2003, 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, 2003,'' after ''April 1, 2001,''; and

(II) by inserting ''or, for discharges occurring on or after October

1, 2003, 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, 2003,'' after ''April 1, 2001,''; and

(II) by inserting ''or, for discharges occurring on or after October 1, 2003, 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, 2003, 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, 2003.

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, 2003.

(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, 2004.

(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, 2004.

(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 inpa-

tient critical access facility services furnished on or after January 1, 2004.

(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, 2003, 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.

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-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.''.

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

''(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after October 1, 2003.

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 who 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) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to hospice care furnished on or after October 1, 2003.

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 hos-

pitals 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 September 30, 1997, 25 percent)'' and inserting ''the applicable Federal percentage (specified in subparagraph (E))''; and

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

''(E) For purposes of subparagraph (A), for discharges occurring—

''(i) 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. AUTHORITY REGARDING GERIATRIC FELLOWSHIPS.

The Secretary shall have the authority to clarify that geriatric training programs are eligible for 2 years of fellowship support for purposes of making payments for direct graduate medical education under subsection (h) of

section 1886 of the Social Security Act (42 U.S.C. 1395ww) and indirect medical education under subsection (d)(5)(B) of such section 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 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.''.

(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, 2003, subclauses (I) and (II) shall be applied only with respect to a hospital's approved medical residency training pro-

grams 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, 2003, 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.

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. 1395*l*(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. 1395*l*(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. 1395*l*(m)). Such study shall focus on whether such program increases the access of medicare beneficiaries who reside 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 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. INCREASE IN RENAL DIALYSIS COMPOSITE RATE.

Notwithstanding any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2005 and 2006, the composite rate for such services shall be increased by 1.6 percent under section 1881(b)(12) of

such Act (42 U.S.C. 1395rr(b)(7)), as added by section 433(b)(5).

SEC. 424. 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 striking ''2004'' and inserting ''2006''.

(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 defined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished in 2004, 2005, or 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. 425. 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. 1395*l*(t)), as amended by section 424, on or after January 1, 2004, 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. 1395*l*(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. 1395*l*(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. 1395*l*(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. 1395*l*(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. 1395*l*(t))) under such section that are furnished after January 1, 2008.

(f) TECHNICAL AMENDMENT.—Section 1833(t)(2)(B) (42 U.S.C. 1395*l*(t)(2)(B)) is amended by inserting ''(and periodically revise such groups pursuant to paragraph (9)(A))'' after ''establish groups''.

SEC. 426. INCREASE FOR GROUND AMBULANCE SERVICES FURNISHED IN A RURAL AREA.

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 paragraph:

''(10) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES FURNISHED IN A RURAL AREA.—

''(A) IN GENERAL.—Notwithstanding any other provision of this subsection, in the case of ground ambulance services furnished on or after January 1, 2004, and before January 1, 2008, for which the transportation originates in a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section, with respect to both the payment rate for service and the payment rate for mileage, shall provide that such rates otherwise established, after application of any increase under such paragraph, shall be increased by 5 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.''.

SEC. 427. 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, 2004.

SEC. 428. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED BY A SOLE COMMUNITY HOSPITAL.

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

furnished to patients of the hospital, the following rules shall apply:

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

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

SEC. 429. 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 2003"; 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 2004, 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. 430. 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, 2004.

SEC. 431. 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 described 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 Sec-

retary 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. 432. 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. 1395*l*(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. 433. 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 payment 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 deter-

mining 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 So-

cial 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 determined 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 pursuant to section

423 of the Prescription Drug and Medicare Improvement Act of 2003.

''(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.

''(D) Subject to subparagraph (E), in the case of dialysis services furnished in 2007 or a subsequent year, the composite rate for such services shall be an amount equal to the composite rate established under this paragraph for the previous year (determined as if such section 423 had not been enacted), 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 and such separate payments for the year does not exceed the total amount of payments that would have been made under this part for the year for such infusion drugs and biologicals if section 433 of the Prescription Drug and Medicare Improvement Act of 2003 had not been enacted.''.

(7) INHALATION DRUGS.—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (a)(2) and paragraphs (4) and (6), is amended by adding at the end the following new paragraph:

''(8)(A) Subject to subparagraph (B), in the case of inhalation drugs and biologicals furnished through durable medical equipment covered under section 1861(n) on or after January 1, 2004, the Secretary may increase payments for such equipment under section 1834(a) and may make separate payments for furnishing such drugs and biologicals if the Secretary determines such increased or separate payments are necessary to appropriately furnish such equipment and drugs and biologicals to beneficiaries.

''(B) The total amount of any increased payments and separate payments under subparagraph (A) for a year may not exceed an amount equal to 10 percent of the amount (as estimated by the Secretary) by which—

''(i) the total amount of payments that would 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 adjust-

ments 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. 434. INDEXING PART B DEDUCTIBLE TO INFLATION.

The first sentence of section 1833(b) (42 U.S.C. 1395*l*(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. 435. 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. 436. 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 2004 or 2005'' before the period at the end.

SEC. 437. 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 de-

termined 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 organization (as defined in subclause (IV)) to conduct a study to determine the hospital acquisition 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 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;

''(ii) 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; and

''(iii) 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. 438. 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 affect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are phar-

maceutically equivalent and bioequvalent, as determined by the Commissioner of Food and Drugs.''.

SEC. 439. 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) EFFECTIVE DATE.—This section shall apply to clinical trials begun on or after January 1, 2005.

SEC. 440. 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 period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the first day of the month following the month in which the individual enrolls.

SEC. 441. 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 Con-

gress 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 pro-

gram 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. 442. 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 January 1, 2006, under the MedicareAdvantage program) under part C.

''(2) HEALTH CARE GROUP.—

''(A) IN GENERAL.—The term 'health care group' means—

''(i) a group of physicians that is organized at least in part for the purpose of

providing physician's services under this title;

"(ii) an integrated health care delivery system that delivers care through coordinated hospitals, clinics, home health agencies, ambulatory surgery centers, skilled nursing facilities, rehabilitation facilities and clinics, and employed, independent, or contracted physicians; or

"(iii) an organization representing regional coalitions of groups or systems described in clause (i) or (ii).

"(B) INCLUSION.—As the Secretary determines appropriate, a health care group may include a hospital or any other individual or entity furnishing items or services for which payment may be made under this title that is affiliated with the health care group under an arrangement structured so that such hospital, individual, or entity participates in a demonstration project under this section.

"(3) PHYSICIAN.—Except as otherwise provided for by the Secretary, the term 'physician' means any individual who furnishes services that may be paid for as physicians' services under this title.

''(b) DEMONSTRATION PROJECTS.—The Secretary shall establish a 5-year demonstration program under which the Secretary shall approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care, including—

''(1) the provision of incentives to improve the safety of care provided to beneficiaries;

''(2) the appropriate use of best practice guidelines by providers and services by beneficiaries;

''(3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research;

''(4) encourage shared decision making between providers and patients;

''(5) the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources;

''(6) the appropriate use of culturally and ethnically sensitive health care delivery; and

''(7) the financial effects on the health care marketplace of altering the incentives for care delivery and changing the allocation of resources.

''(c) ADMINISTRATION BY CONTRACT.—

''(1) IN GENERAL.—Except as otherwise provided in this section, the Secretary may administer the demonstration program established under this section in a manner that is similar to the manner in which the demonstration program established under section 1866A is administered in accordance with section 1866B.

''(2) ALTERNATIVE PAYMENT SYSTEMS.—A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include proposals for the use of alternative payment systems for items and services provided to beneficiaries by the group that are designed to—

''(A) encourage the delivery of high quality care while accomplishing the objectives described in subsection (b); and

''(B) streamline documentation and reporting requirements otherwise required under this title.

''(3) BENEFITS.—A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include modifications to the package of benefits available under the 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.

"(f) BUDGET NEUTRALITY.—With respect to the 5-year period of the demonstration program under subsection (b), the aggregate expenditures under this title for such period shall not exceed the aggregate expenditures that would have been expended under this title if the pro-

gram established under this section had not been implemented.

''(g) NOTICE REQUIREMENTS.—In the case of an individual that receives health care items or services under a demonstration program carried out under this section, the Secretary shall ensure that such individual is notified of any waivers of coverage or payment rules that are applicable to such individual under this title as a result of the participation of the individual in such program.

''(h) PARTICIPATION AND SUPPORT BY FEDERAL AGENCIES.—In carrying out the demonstration program under this section, the Secretary may direct—

''(1) the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;

''(2) the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program; and

''(3) the Administrator of the Centers for Medicare and 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. 443. 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 subsection (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 Sec-

retary 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, housekeeping, 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. 444. 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 negotiated 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 Supple-

mentary 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 insurance 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. 445. 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; and

(6) an evaluation of appropriateness of extending such adjustment or making such adjustment permanent.

(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).

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, 2003, and before October 1, 2005, the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

(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 2004, 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 require-

ments 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 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 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 services 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. 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''.

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 unless 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.''.

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 Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) CONTENTS.—The plan shall include information on the following:

(A) WORKLOAD.—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes.

(B) COST PROJECTIONS AND FINANCING.—Funding levels required for fiscal year 2005 and subsequent fiscal years to carry out the functions transferred under the plan 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 and 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 administrative 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 So-

cial 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 review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days

after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

''(C) ACCESS TO JUDICIAL REVIEW.—

''(i) IN GENERAL.—If the appropriate review entity—

''(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

''(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

''(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

''(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

"(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

"(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than 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, a 'review entity' is a panel of no more than 3 members from the Departmental Appeals Board, selected for the purpose of making determinations under this paragraph.''.

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting ''(A)'' after ''(h)(1)''; and

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

''(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of

services, suppliers, and 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 respect 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 Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such 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 treat-

ment 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 review 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 rep-

resentative) 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 paragraph (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 sub-

section shall be construed to require a fiscal intermediary, carrier or program safeguard contractor to develop a local coverage determination 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.

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 perform-

ance 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 du-

plicate 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 acquisition 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 Federal 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 nec-

essary 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 offi-

cer 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 de-

scribed in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate 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 section'' and inserting ''contract under section 1874A that provides for making payments under this part''.

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking ''An agreement with an agency or organization under this section'' and inserting ''A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part''; and

(B) by striking ''such agency or organization'' and inserting ''such medicare administrative contractor'' each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

''PROVISIONS RELATING TO THE ADMINISTRATION OF PART B''.

(2) Subsection (a) is amended to read as follows:

''(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.''.

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking ''carriers'' and inserting ''medicare administrative contractors''; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking ''Each such contract shall provide that the carrier'' and inserting ''The Secretary'';

(ii) by striking ''will'' the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting ''shall'';

(iii) in subparagraph (B), in the matter before clause (i), by striking ''to the policyholders and subscribers of the carrier'' and inserting ''to the policyholders and subscribers of the medicare administrative contractor'';

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking ''if it makes determinations or payments with respect to physicians' services,''; 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 medicare 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 Congress, not later than 6 months after the date the report is received, a report on such evaluation and

shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

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.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 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, practitioners, 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 con-

tractor 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 determine program compliance and to suggest more efficient and effective means of achieving such compliance).

''(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term 'small provider of services or supplier' means—

''(A) 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 accuracy, 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.

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 ex-

tent 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 impo-

sition of sanctions where there is widespread 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.''.

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 allot-

ment 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)''.

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 and 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 and 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.''.

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 sub-

paragraph (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 bene-

ficiary, 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 mean-

ing 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 forecasting, 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), environ-

mental 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 connection 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 undertaking 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 re-

quire 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 paragraph (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 sub-

section, 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 (in-

cluding 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 substan-

tial 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.—

(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''.

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 NOT VALID 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 not valid 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 is 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 NOT VALID 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 not valid 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 ____02) is amended—

(1) in subparagraph (B), by striking clause (iv) and inserting the following:

''(iv) 180-DAY EXCLUSIVITY PERIOD.—

''(I) DEFINITIONS.—In this paragraph:

''(aa) 180-DAY EXCLUSIVITY PERIOD.—The term '180-day exclusivity period' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

''(bb) FIRST APPLICANT.—The term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) for the drug.

''(cc) SUBSTANTIALLY COMPLETE APPLICATION.—The term 'substantially complete application' means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

''(dd) TENTATIVE APPROVAL.—

''(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (E) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

''(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective ap-

proval 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 of 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-

retary the name and place of business of the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) PROHIBITION OF DISCRIMINATION.—

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

prescription drug manufactured by the drug manufacturer.

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

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

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

''(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian 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) 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.

''(p) 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)''.

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