

108TH CONGRESS
1ST SESSION

H. R. 1

AN ACT

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

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1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLES.**

4 (a) DIVISION A.—Division A of this Act may be cited
 5 as the “Medicare Prescription Drug and Modernization
 6 Act of 2003”.

7 (b) DIVISION B.—Division B of this Act may be cited
 8 as the “Health Savings and Affordability Act of 2003”.

9 **SEC. 2. ORGANIZATION OF ACT INTO DIVISIONS; AMEND-**
 10 **MENTS TO SOCIAL SECURITY ACT; REF-**
 11 **ERENCES TO BIPA AND SECRETARY; TABLE**
 12 **OF CONTENTS.**

13 (a) DIVISIONS.—This Act is organized into two divi-
 14 sions as follows:

15 (1) DIVISION A—Medicare Prescription Drug
 16 and Modernization Act of 2003.

17 (2) DIVISION B—Health Savings and Afford-
 18 ability Act of 2003.

19 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Ex-
 20 cept as otherwise specifically provided, whenever in divi-
 21 sion A of this Act an amendment is expressed in terms
 22 of an amendment to or repeal of a section or other provi-
 23 sion, the reference shall be considered to be made to that
 24 section or other provision of the Social Security Act.

25 (c) BIPA; SECRETARY.—In division A of this Act:

1 (1) BIPA.—The term “BIPA” means the
2 Medicare, Medicaid, and SCHIP Benefits Improve-
3 ment and Protection Act of 2000, as enacted into
4 law by section 1(a)(6) of Public Law 106–554.

5 (2) SECRETARY.—The term “Secretary” means
6 the Secretary of Health and Human Services.

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

Sec. 1. Short titles.

Sec. 2. Organization of Act into divisions; amendments to Social Security Act;
references to BIPA and Secretary; table of contents.

**DIVISION A—MEDICARE PRESCRIPTION DRUG AND
MODERNIZATION ACT OF 2003**

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Establishment of a medicare prescription drug benefit.

Sec. 102. Offering of qualified prescription drug coverage under Medicare Ad-
vantage and enhanced fee-for-service (EFFS) program.

Sec. 103. Medicaid amendments.

Sec. 104. Medigap transition.

Sec. 105. Medicare prescription drug discount card and assistance program.

Sec. 106. Disclosure of return information for purposes of carrying out medi-
care catastrophic prescription drug program.

Sec. 107. State Pharmaceutical Assistance Transition Commission.

Sec. 108. Additional requirements for annual financial report and oversight on
medicare program, including prescription drug spending.

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND
MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

Sec. 200. Medicare modernization and revitalization.

Subtitle A—Medicare Enhanced Fee-for-Service Program

Sec. 201. Establishment of enhanced fee-for-service (EFFS) program under
medicare.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

Sec. 211. Implementation of medicare advantage program.

Sec. 212. Medicare advantage improvements.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

Sec. 221. Competition program beginning in 2006.

CHAPTER 3—ADDITIONAL REFORMS

- Sec. 231. Making permanent change in medicare advantage reporting deadlines and annual, coordinated election period.
- Sec. 232. Avoiding duplicative State regulation.
- Sec. 233. Specialized medicare advantage plans for special needs beneficiaries.
- Sec. 234. Medicare MSAs.
- Sec. 235. Extension of reasonable cost contracts.
- Sec. 236. Extension of municipal health service demonstration projects.
- Sec. 237. Study of performance-based payment systems.

Subtitle C—Application of FEHBP-Style Competitive Reforms

Sec. 241. Application of FEHBP-style competitive reform beginning in 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

- Sec. 301. Medicare secondary payor (MSP) provisions.
- Sec. 302. Competitive acquisition of certain items and services.
- Sec. 303. Competitive acquisition of covered outpatient drugs and biologicals.
- Sec. 304. Demonstration project for use of recovery audit contractors.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

- Sec. 401. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.
- Sec. 402. Immediate establishment of uniform standardized amount in rural and small urban areas.
- Sec. 403. Establishment of essential rural hospital classification.
- Sec. 404. More frequent update in weights used in hospital market basket.
- Sec. 405. Improvements to critical access hospital program.
- Sec. 406. Redistribution of unused resident positions.
- Sec. 407. Two-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under prospective payment system for hospital outpatient department services.
- Sec. 408. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.
- Sec. 409. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.
- Sec. 410. Improvement in payments to retain emergency capacity for ambulance services in rural areas.
- Sec. 411. Two-year increase for home health services furnished in a rural area.
- Sec. 412. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
- Sec. 413. GAO study of geographic differences in payments for physicians' services.
- Sec. 414. Treatment of missing cost reporting periods for sole community hospitals.
- Sec. 415. Extension of telemedicine demonstration project.
- Sec. 416. Adjustment to the medicare inpatient hospital PPS wage index to revise the labor-related share of such index.
- Sec. 417. Medicare incentive payment program improvements for physician scarcity.
- Sec. 418. Rural hospice demonstration project.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

- Sec. 501. Revision of acute care hospital payment updates.
- Sec. 502. Recognition of new medical technologies under inpatient hospital PPS.
- Sec. 503. Increase in Federal rate for hospitals in Puerto Rico.
- Sec. 504. Wage index adjustment reclassification reform .
- Sec. 505. MedPAC report on specialty hospitals.

Subtitle B—Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services.
- Sec. 512. Coverage of hospice consultation services.
- Sec. 513. Correction of Trust Fund holdings.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

- Sec. 601. Revision of updates for physicians' services.
- Sec. 602. Studies on access to physicians' services.
- Sec. 603. MedPAC report on payment for physicians' services.
- Sec. 604. Inclusion of podiatrists and dentists under private contracting authority.
- Sec. 605. Establishment of floor on work geographic adjustment.

SUBTITLE B—PREVENTIVE SERVICES

- Sec. 611. Coverage of an initial preventive physical examination.
- Sec. 612. Coverage of cholesterol and blood lipid screening.
- Sec. 613. Waiver of deductible for colorectal cancer screening tests.
- Sec. 614. Improved payment for certain mammography services.

Subtitle C—Other Services

- Sec. 621. Hospital outpatient department (HOPD) payment reform.
- Sec. 622. Payment for ambulance services.
- Sec. 623. Renal dialysis services.
- Sec. 624. One-year moratorium on therapy caps; provisions relating to reports.
- Sec. 625. Adjustment to payments for services furnished in ambulatory surgical centers.
- Sec. 626. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
- Sec. 627. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 628. Part B deductible.
- Sec. 629. Extension of coverage of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases in the home.
- Sec. 630. Medicare coverage of diabetes laboratory diagnostic tests.
- Sec. 631. Demonstration project for coverage of certain prescription drugs and biologics.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 701. Update in home health services.
- Sec. 702. Establishment of reduced copayment for a home health service episode of care for certain beneficiaries.
- Sec. 703. MedPAC study on medicare margins of home health agencies.
- Sec. 704. Demonstration project to clarify the definition of homebound.

Subtitle B—Direct Graduate Medical Education

- Sec. 711. Extension of update limitation on high cost programs.

Subtitle C—Chronic Care Improvement

- Sec. 721. Voluntary chronic care improvement under traditional fee-for-service.
- Sec. 722. Chronic care improvement under medicare advantage and enhanced fee-for-service programs.
- Sec. 723. Institute of Medicine report.
- Sec. 724. MedPAC report.

Subtitle D—Other Provisions

- Sec. 731. Modifications to medicare payment advisory commission (MedPAC).
- Sec. 732. Demonstration project for medical adult day care services.
- Sec. 733. Improvements in national and local coverage determination process to respond to changes in technology.
- Sec. 734. Treatment of certain physician pathology services.
- Sec. 735. Clinical investigation of medicare pancreatic islet cell transplants.
- Sec. 736. Demonstration project for consumer-directed chronic outpatient services.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

- Sec. 801. Establishment of Medicare Benefits Administration.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

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

Subtitle B—Contracting Reform

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

Subtitle C—Education and Outreach

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

Subtitle D—Appeals and Recovery

- Sec. 931. Transfer of responsibility for medicare appeals.
- Sec. 932. Process for expedited access to review.
- Sec. 933. Revisions to medicare appeals process.
- Sec. 934. Prepayment review.
- Sec. 935. Recovery of overpayments.
- Sec. 936. Provider enrollment process; right of appeal.
- Sec. 937. Process for correction of minor errors and omissions without pursuing appeals process.
- Sec. 938. Prior determination process for certain items and services; advance beneficiary notices.

Subtitle V—Miscellaneous Provisions

- Sec. 941. Policy development regarding evaluation and management (E & M) documentation guidelines.
- Sec. 942. Improvement in oversight of technology and coverage.
- Sec. 943. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.
- Sec. 944. EMTALA improvements.
- Sec. 945. Emergency Medical Treatment and Active Labor Act (EMTALA) technical advisory group.
- Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.
- Sec. 947. Application of OSHA bloodborne pathogens standard to certain hospitals.
- Sec. 948. BIPA-related technical amendments and corrections.
- Sec. 949. Conforming authority to waive a program exclusion.
- Sec. 950. Treatment of certain dental claims.
- Sec. 951. Furnishing hospitals with information to compute dsh formula.
- Sec. 952. Revisions to reassignment provisions.
- Sec. 953. Other provisions.
- Sec. 954. Temporary suspension of OASIS requirement for collection of data on non-medicare and non-medicaid patients.

TITLE X—MEDICAID

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

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

- Sec. 1101. 30-month stay-of-effectiveness period.
- Sec. 1102. Forfeiture of 180-day exclusivity period.
- Sec. 1103. Bioavailability and bioequivalence.
- Sec. 1104. Conforming amendments.

Subtitle B—Federal Trade Commission Review

- Sec. 1111. Definitions.
- Sec. 1112. Notification of agreements.
- Sec. 1113. Filing deadlines.

Sec. 1114. Disclosure exemption.
 Sec. 1115. Enforcement.
 Sec. 1116. Rulemaking.
 Sec. 1117. Savings clause.
 Sec. 1118. Effective date.

Subtitle C—Importation of Prescription Drugs

Sec. 1121. Importation of prescription drugs.

**DIVISION B—HEALTH SAVINGS AND AFFORDABILITY ACT
OF 2003**

TITLE XII—HEALTH SAVINGS SECURITY ACCOUNTS AND HEALTH
SAVINGS ACCOUNTS

Sec. 1201. Short title.
 Sec. 1202. Health savings security accounts and health savings accounts.
 Sec. 1203. Disposition of unused health benefits in cafeteria plans and flexible
spending arrangements.
 Sec. 1204. Exception to information reporting requirements related to certain
health arrangements.

1 **DIVISION A—MEDICARE PRE-**
 2 **SCRIPTION DRUG AND MOD-**
 3 **ERNIZATION ACT OF 2003**

4 **TITLE I—MEDICARE**
 5 **PRESCRIPTION DRUG BENEFIT**

6 **SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION**
 7 **DRUG BENEFIT.**

8 (a) IN GENERAL.—Title XVIII is amended—
 9 (1) by redesignating part D as part F; and
 10 (2) by inserting after part C the following new
 11 part:

1 “PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT
2 PROGRAM

3 **“SEC. 1860D-1. BENEFITS; ELIGIBILITY; ENROLLMENT; AND**
4 **COVERAGE PERIOD.**

5 “(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG
6 COVERAGE THROUGH ENROLLMENT IN PLANS.—Subject
7 to the succeeding provisions of this part, each individual
8 who is entitled to benefits under part A or is enrolled
9 under part B is entitled to obtain qualified prescription
10 drug coverage (described in section 1860D-2(a)) as fol-
11 lows:

12 “(1) MEDICARE-RELATED PLANS.—

13 “(A) MEDICARE ADVANTAGE.—If the indi-
14 vidual is eligible to enroll in a Medicare Advan-
15 tage plan that provides qualified prescription
16 drug coverage under section 1851(j), the indi-
17 vidual may enroll in such plan and obtain cov-
18 erage through such plan.

19 “(B) EFFS PLANS.—If the individual is
20 eligible to enroll in an EFFS plan that provides
21 qualified prescription drug coverage under part
22 E under section 1860E-2(d), the individual
23 may enroll in such plan and obtain coverage
24 through such plan.

1 “(C) MA-EFFS PLAN; MA-EFFS Rx
2 PLAN.—For purposes of this part, the term
3 ‘MA-EFFS plan’ means a Medicare Advantage
4 plan under part C and an EFFS plan under
5 part E and the term ‘MA-EFFS Rx plan’
6 means a MA-EFFS plan insofar as such plan
7 provides qualified prescription drug coverage.

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

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

14 “(b) GENERAL ELECTION PROCEDURES.—

15 “(1) IN GENERAL.—An individual eligible to
16 make an election under subsection (a) may elect to
17 enroll in a prescription drug plan under this part, or
18 elect the option of qualified prescription drug cov-
19 erage under a MA-EFFS Rx plan under part C or
20 part E, and to change such election only in such
21 manner and form as may be prescribed by regula-
22 tions of the Administrator of the Medicare Benefits
23 Administration (appointed under section 1809(b))
24 (in this part referred to as the ‘Medicare Benefits

1 Administrator’) and only during an election period
2 prescribed in or under this subsection.

3 “(2) ELECTION PERIODS.—

4 “(A) IN GENERAL.—Except as provided in
5 this paragraph, the election periods under this
6 subsection shall be the same as the coverage
7 election periods under the Medicare Advantage
8 and EFFS programs under section 1851(e), in-
9 cluding—

10 “(i) annual coordinated election peri-
11 ods; and

12 “(ii) special election periods.

13 In applying the last sentence of section
14 1851(e)(4) (relating to discontinuance of an
15 election during the first year of eligibility)
16 under this subparagraph, in the case of an elec-
17 tion described in such section in which the indi-
18 vidual had elected or is provided qualified pre-
19 scription drug coverage at the time of such first
20 enrollment, the individual shall be permitted to
21 enroll in a prescription drug plan under this
22 part at the time of the election of coverage
23 under the original fee-for-service plan.

24 “(B) INITIAL ELECTION PERIODS.—

1 “(i) INDIVIDUALS CURRENTLY COV-
2 ERED.—In the case of an individual who is
3 entitled to benefits under part A or en-
4 rolled under part B as of October 1, 2005,
5 there shall be an initial election period of
6 6 months beginning on that date.

7 “(ii) INDIVIDUAL COVERED IN FU-
8 TURE.—In the case of an individual who is
9 first entitled to benefits under part A or
10 enrolled under part B after such date,
11 there shall be an initial election period
12 which is the same as the initial enrollment
13 period under section 1837(d).

14 “(C) ADDITIONAL SPECIAL ELECTION PE-
15 RIODS.—The Administrator shall establish spe-
16 cial election periods—

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

20 “(ii) in cases described in section
21 1837(h) (relating to errors in enrollment),
22 in the same manner as such section applies
23 to part B;

24 “(iii) in the case of an individual who
25 meets such exceptional conditions (includ-

1 ing conditions provided under section
2 1851(e)(4)(D)) as the Administrator may
3 provide; and

4 “(iv) in cases of individuals (as deter-
5 mined by the Administrator) who become
6 eligible for prescription drug assistance
7 under title XIX under section 1935(d).

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

12 “(4) ADDITIONAL INFORMATION.—In order to
13 promote the efficient marketing of prescription drug
14 plans and MA-EFFS plans, the Administrator may
15 provide information to the sponsors and organiza-
16 tions offering such plans about individuals eligible to
17 enroll in such plans.

18 “(c) GUARANTEED ISSUE; COMMUNITY RATING; AND
19 NONDISCRIMINATION.—

20 “(1) GUARANTEED ISSUE.—

21 “(A) IN GENERAL.—An eligible individual
22 who is eligible to elect qualified prescription
23 drug coverage under a prescription drug plan or
24 MA-EFFS Rx plan at a time during which elec-
25 tions are accepted under this part with respect

1 to the plan shall not be denied enrollment based
2 on any health status-related factor (described in
3 section 2702(a)(1) of the Public Health Service
4 Act) or any other factor.

5 “(B) MEDICARE ADVANTAGE LIMITATIONS
6 PERMITTED.—The provisions of paragraphs (2)
7 and (3) (other than subparagraph (C)(i), relat-
8 ing to default enrollment) of section 1851(g)
9 (relating to priority and limitation on termi-
10 nation of election) shall apply to PDP sponsors
11 under this subsection.

12 “(2) COMMUNITY-RATED PREMIUM.—

13 “(A) IN GENERAL.—In the case of an indi-
14 vidual who enrolls under a prescription drug
15 plan or in a MA-EFFS Rx plan during the in-
16 dividual’s initial enrollment period under this
17 part or maintains (as determined under sub-
18 paragraph (C)) continuous prescription drug
19 coverage since the date the individual first
20 qualifies to elect prescription drug coverage
21 under this part, a PDP sponsor or entity offer-
22 ing a prescription drug plan or MA-EFFS Rx
23 plan and in which the individual is enrolled may
24 not deny, limit, or condition the coverage or
25 provision of covered prescription drug benefits

1 or vary or increase the premium under the plan
2 based on any health status-related factor de-
3 scribed in section 2702(a)(1) of the Public
4 Health Service Act or any other factor.

5 “(B) LATE ENROLLMENT PENALTY.—In
6 the case of an individual who does not maintain
7 such continuous prescription drug coverage (as
8 described in subparagraph (C)), a PDP sponsor
9 or an entity offering a MA-EFFS Rx plan may
10 (notwithstanding any provision in this title) ad-
11 just the premium otherwise applicable with re-
12 spect to qualified prescription drug coverage in
13 a manner that reflects additional actuarial risk
14 involved. Such a risk shall be established
15 through an appropriate actuarial opinion of the
16 type described in subparagraphs (A) through
17 (C) of section 2103(c)(4). The Administrator
18 shall provide a mechanism for assisting such
19 sponsors and entities in identifying eligible indi-
20 viduals who have (or have not) maintained such
21 continuous prescription drug coverage.

22 “(C) CONTINUOUS PRESCRIPTION DRUG
23 COVERAGE.—An individual is considered for
24 purposes of this part to be maintaining contin-
25 uous prescription drug coverage on and after

1 the date the individual first qualifies to elect
2 prescription drug coverage under this part if
3 the individual establishes that as of such date
4 the individual is covered under any of the fol-
5 lowing prescription drug coverage and before
6 the date that is the last day of the 63-day pe-
7 riod that begins on the date of termination of
8 the particular prescription drug coverage in-
9 volved (regardless of whether the individual
10 subsequently obtains any of the following pre-
11 scription drug coverage):

12 “(i) COVERAGE UNDER PRESCRIPTION
13 DRUG PLAN OR MA-EFFS RX PLAN.—Quali-
14 fied prescription drug coverage under a
15 prescription drug plan or under a MA-
16 EFFS Rx plan.

17 “(ii) MEDICAID PRESCRIPTION DRUG
18 COVERAGE.—Prescription drug coverage
19 under a medicaid plan under title XIX, in-
20 cluding through the Program of All-inclu-
21 sive Care for the Elderly (PACE) under
22 section 1934, or through a demonstration
23 project under part C that demonstrates the
24 application of capitation payment rates for
25 frail elderly medicare beneficiaries through

1 the use of an interdisciplinary team and
2 through the provision of primary care serv-
3 ices to such beneficiaries by means of such
4 a team at the nursing facility involved.

5 “(iii) PRESCRIPTION DRUG COVERAGE
6 UNDER GROUP HEALTH PLAN.—Any out-
7 patient prescription drug coverage under a
8 group health plan, including a health bene-
9 fits plan under the Federal Employees
10 Health Benefit Plan under chapter 89 of
11 title 5, United States Code, and a qualified
12 retiree prescription drug plan as defined in
13 section 1860D–8(f)(1), but only if (subject
14 to subparagraph (E)(ii)) the coverage pro-
15 vides benefits at least equivalent to the
16 benefits under a qualified prescription drug
17 plan.

18 “(iv) PRESCRIPTION DRUG COVERAGE
19 UNDER CERTAIN MEDIGAP POLICIES.—
20 Coverage under a medicare supplemental
21 policy under section 1882 that provides
22 benefits for prescription drugs (whether or
23 not such coverage conforms to the stand-
24 ards for packages of benefits under section
25 1882(p)(1)), but only if the policy was in

1 effect on January 1, 2006, and if (subject
2 to subparagraph (E)(ii)) the coverage pro-
3 vides benefits at least equivalent to the
4 benefits under a qualified prescription drug
5 plan.

6 “(v) STATE PHARMACEUTICAL ASSIST-
7 ANCE PROGRAM.—Coverage of prescription
8 drugs under a State pharmaceutical assist-
9 ance program, but only if (subject to sub-
10 paragraph (E)(ii)) the coverage provides
11 benefits at least equivalent to the benefits
12 under a qualified prescription drug plan.

13 “(vi) VETERANS’ COVERAGE OF PRE-
14 SCRIPTON DRUGS.—Coverage of prescrip-
15 tion drugs for veterans under chapter 17
16 of title 38, United States Code, but only if
17 (subject to subparagraph (E)(ii)) the cov-
18 erage provides benefits at least equivalent
19 to the benefits under a qualified prescrip-
20 tion drug plan.

21 “(D) CERTIFICATION.—For purposes of
22 carrying out this paragraph, the certifications
23 of the type described in sections 2701(e) of the
24 Public Health Service Act and in section
25 9801(e) of the Internal Revenue Code shall also

1 include a statement for the period of coverage
2 of whether the individual involved had prescrip-
3 tion drug coverage described in subparagraph
4 (C).

5 “(E) DISCLOSURE.—

6 “(i) IN GENERAL.—Each entity that
7 offers coverage of the type described in
8 clause (iii), (iv), (v), or (vi) of subpara-
9 graph (C) shall provide for disclosure, con-
10 sistent with standards established by the
11 Administrator, of whether such coverage
12 provides benefits at least equivalent to the
13 benefits under a qualified prescription drug
14 plan.

15 “(ii) WAIVER OF LIMITATIONS.—An
16 individual may apply to the Administrator
17 to waive the requirement that coverage of
18 such type provide benefits at least equiva-
19 lent to the benefits under a qualified pre-
20 scription drug plan, if the individual estab-
21 lishes that the individual was not ade-
22 quately informed that such coverage did
23 not provide such level of benefits.

24 “(F) CONSTRUCTION.—Nothing in this
25 section shall be construed as preventing the

1 disenrollment of an individual from a prescrip-
2 tion drug plan or a MA-EFFS Rx plan based
3 on the termination of an election described in
4 section 1851(g)(3), including for non-payment
5 of premiums or for other reasons specified in
6 subsection (d)(3), which takes into account a
7 grace period described in section
8 1851(g)(3)(B)(i).

9 “(3) NONDISCRIMINATION.—A PDP sponsor
10 that offers a prescription drug plan in an area des-
11 ignated under section 1860D–4(b)(5) shall make
12 such plan available to all eligible individuals residing
13 in the area without regard to their health or eco-
14 nomic status or their place of residence within the
15 area.

16 “(d) EFFECTIVE DATE OF ELECTIONS.—

17 “(1) IN GENERAL.—Except as provided in this
18 section, the Administrator shall provide that elec-
19 tions under subsection (b) take effect at the same
20 time as the Administrator provides that similar elec-
21 tions under section 1851(e) take effect under section
22 1851(f).

23 “(2) NO ELECTION EFFECTIVE BEFORE 2006.—

24 In no case shall any election take effect before Janu-
25 ary 1, 2006.

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

4 “(A) termination of coverage under both
5 part A and part B; and

6 “(B) termination of elections described in
7 section 1851(g)(3) (including failure to pay re-
8 quired premiums).

9 **“SEC. 1860D-2. REQUIREMENTS FOR QUALIFIED PRESCRIP-**
10 **TION DRUG COVERAGE.**

11 “(a) REQUIREMENTS.—

12 “(1) IN GENERAL.—For purposes of this part
13 and part C and part E, the term ‘qualified prescrip-
14 tion drug coverage’ means either of the following:

15 “(A) STANDARD COVERAGE WITH ACCESS
16 TO NEGOTIATED PRICES.—Standard coverage
17 (as defined in subsection (b)) and access to ne-
18 gotiated prices under subsection (d).

19 “(B) ACTUARIALLY EQUIVALENT COV-
20 ERAGE WITH ACCESS TO NEGOTIATED
21 PRICES.—Coverage of covered outpatient drugs
22 which meets the alternative coverage require-
23 ments of subsection (c) and access to negotiated
24 prices under subsection (d), but only if it is ap-

1 proved by the Administrator, as provided under
2 subsection (c).

3 “(2) PERMITTING ADDITIONAL OUTPATIENT
4 PRESCRIPTION DRUG COVERAGE.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B), nothing in this part shall be con-
7 strued as preventing qualified prescription drug
8 coverage from including coverage of covered
9 outpatient drugs that exceeds the coverage re-
10 quired under paragraph (1), but any such addi-
11 tional coverage shall be limited to coverage of
12 covered outpatient drugs.

13 “(B) DISAPPROVAL AUTHORITY.—The Ad-
14 ministrators shall review the offering of qualified
15 prescription drug coverage under this part or
16 part C or E. If the Administrator finds, in the
17 case of a qualified prescription drug coverage
18 under a prescription drug plan or a MA-EFFS
19 Rx plan, that the organization or sponsor offer-
20 ing the coverage is engaged in activities in-
21 tended to discourage enrollment of classes of el-
22 igible medicare beneficiaries obtaining coverage
23 through the plan on the basis of their higher
24 likelihood of utilizing prescription drug cov-
25 erage, the Administrator may terminate the

1 contract with the sponsor or organization under
2 this part or part C or E.

3 “(3) APPLICATION OF SECONDARY PAYOR PRO-
4 VISIONS.—The provisions of section 1852(a)(4) shall
5 apply under this part in the same manner as they
6 apply under part C.

7 “(b) STANDARD COVERAGE.—For purposes of this
8 part, the ‘standard coverage’ is coverage of covered out-
9 patient drugs (as defined in subsection (f)) that meets the
10 following requirements:

11 “(1) DEDUCTIBLE.—The coverage has an an-
12 nual deductible—

13 “(A) for 2006, that is equal to \$250; or

14 “(B) for a subsequent year, that is equal
15 to the amount specified under this paragraph
16 for the previous year increased by the percent-
17 age specified in paragraph (5) for the year in-
18 volved.

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

22 “(2) 80:20 BENEFIT STRUCTURE.—

23 “(A) 20 PERCENT COINSURANCE.—The
24 coverage has cost-sharing (for costs above the
25 annual deductible specified in paragraph (1)

1 and up to the initial coverage limit under para-
2 graph (3)) that is—

3 “(i) equal to 20 percent; or

4 “(ii) is actuarially equivalent (using
5 processes established under subsection (e))
6 to an average expected payment of 20 per-
7 cent of such costs.

8 “(B) USE OF TIERS.—Nothing in this part
9 shall be construed as preventing a PDP sponsor
10 from applying tiered copayments, so long as
11 such tiered copayments are consistent with sub-
12 paragraph (A).

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

17 “(A) for 2006, that is equal to \$2,000; or

18 “(B) for a subsequent year, that is equal
19 to the amount specified in this paragraph for
20 the previous year, increased by the annual per-
21 centage increase described in paragraph (5) for
22 the year involved.

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

1 “(4) CATASTROPHIC PROTECTION.—

2 “(A) IN GENERAL.—Notwithstanding para-
3 graph (3), the coverage provides benefits with
4 no cost-sharing after the individual has in-
5 curred costs (as described in subparagraph (C))
6 for covered outpatient drugs in a year equal to
7 the annual out-of-pocket threshold specified in
8 subparagraph (B).

9 “(B) ANNUAL OUT-OF-POCKET THRESH-
10 OLD.—

11 “(i) IN GENERAL.—For purposes of
12 this part, the ‘annual out-of-pocket thresh-
13 old’ specified in this subparagraph is equal
14 to \$3,500 (subject to adjustment under
15 clause (ii) and subparagraph (D)).

16 “(ii) INFLATION INCREASE.—For a
17 year after 2006, the dollar amount speci-
18 fied in clause (i) shall be increased by the
19 annual percentage increase described in
20 paragraph (5) for the year involved. Any
21 amount determined under the previous
22 sentence that is not a multiple of \$100
23 shall be rounded to the nearest multiple of
24 \$100.

1 “(C) APPLICATION.—In applying subpara-
2 graph (A)—

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

10 “(ii) such costs shall be treated as in-
11 curred only if they are paid by the indi-
12 vidual (or by another individual, such as a
13 family member, on behalf of the indi-
14 vidual), under section 1860D–7, under title
15 XIX, or under a State pharmaceutical as-
16 sistance program and the individual (or
17 other individual) is not reimbursed through
18 insurance or otherwise, a group health
19 plan, or other third-party payment ar-
20 rangement (other than under such title or
21 such program) for such costs.

22 “(D) ADJUSTMENT OF ANNUAL OUT-OF-
23 POCKET THRESHOLDS.—

24 “(i) IN GENERAL.—Subject to clause
25 (vii), for each enrollee in a prescription

1 drug plan or in a MA-EFFS Rx plan
2 whose adjusted gross income exceeds the
3 income threshold as defined in clause (ii)
4 for a year, the annual out-of-pocket thresh-
5 old otherwise determined under subpara-
6 graph (B) for such year shall be increased
7 by an amount equal to the percentage
8 specified in clause (iii), multiplied by the
9 lesser of—

10 “(I) the amount of such excess;

11 or

12 “(II) the amount by which the
13 income threshold limit exceeds the in-
14 come threshold.

15 Any amount determined under the previous
16 sentence that is not a multiple of \$100
17 shall be rounded to the nearest multiple of
18 \$100.

19 “(ii) INCOME THRESHOLD.—For pur-
20 poses of clause (i)—

21 “(I) IN GENERAL.—Subject to
22 subclause (II), the term ‘income
23 threshold’ means \$60,000 and the
24 term ‘income threshold limit’ means
25 \$200,000.

1 “(II) INCOME INFLATION AD-
2 JUSTMENT.—In the case of a year be-
3 ginning after 2006, each of the dollar
4 amounts in subclause (I) shall be in-
5 creased by an amount equal to such
6 dollar amount multiplied by the cost-
7 of-living adjustment determined under
8 section 1(f)(3) of the Internal Rev-
9 enue Code of 1986 for such year, de-
10 termined by substituting ‘calendar
11 year 2005’ for ‘calendar year 1992’.
12 If any amount increased under the
13 previous sentence is not a multiple of
14 \$100, such amount shall be rounded
15 to the nearest multiple of \$100.

16 “(iii) PERCENTAGE.—The percentage
17 specified in this clause for a year is a frac-
18 tion (expressed as a percentage) equal to—

19 “(I) the annual out-of-pocket
20 threshold for a year under subpara-
21 graph (B) (determined without regard
22 to this subparagraph), divided by

23 “(II) the income threshold under
24 clause (ii) for that year.

1 If any percentage determined under the
2 previous sentence that is not a multiple of
3 $\frac{1}{10}$ th of 1 percentage point, such percent-
4 age shall be rounded to the nearest mul-
5 tiple of $\frac{1}{10}$ th of 1 percentage point.

6 “(iv) USE OF MOST RECENT RETURN
7 INFORMATION.—For purposes of clause (i)
8 for an enrollee for a year, except as pro-
9 vided in clause (v), the adjusted gross in-
10 come of an individual shall be based on the
11 most recent information disclosed to the
12 Secretary under section 6109(l)(19) of the
13 Internal Revenue Code of 1986 before the
14 beginning of that year.

15 “(v) INDIVIDUAL ELECTION TO
16 PRESENT MOST RECENT INFORMATION RE-
17 GARDING INCOME.—The Secretary shall
18 provide, in coordination with the Secretary
19 of the Treasury, a procedure under which,
20 for purposes of applying this subparagraph
21 for a calendar year, instead of using the
22 information described in clause (iv), an en-
23 rollee may elect to use more recent infor-
24 mation, including information with respect

1 to a taxable year ending in such calendar
2 year. Such process shall—

3 “(I) require the enrollee to pro-
4 vide the Secretary with a copy of the
5 relevant portion of the more recent re-
6 turn to be used under this clause;

7 “(II) provide for the Medicare
8 Beneficiary Ombudsman (under sec-
9 tion 1810) offering assistance to such
10 enrollees in presenting such informa-
11 tion and the toll-free number under
12 such section being a point of contact
13 for beneficiaries to inquire as to how
14 to present such information;

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

20 “(IV) provide for the payment by
21 the Secretary (in a manner specified
22 by the Secretary) to the enrollee of an
23 amount equal to the excess of the ben-
24 efit payments that would have been
25 payable under the plan if the more re-

1 cent return information were used,
2 over the benefit payments that were
3 made under the plan.

4 In the case of a payment under subclause
5 (III) for an enrollee under a prescription
6 drug plan, the PDP sponsor of the plan
7 shall pay to the Secretary the amount so
8 paid, less the applicable reinsurance
9 amount that would have applied under sec-
10 tion 1860D–8(c)(1)(B) if such payment
11 had been treated as an allowable cost
12 under such section. Such plan payment
13 shall be deposited in the Treasury to the
14 credit of the Medicare Prescription Drug
15 Account in the Federal Supplementary
16 Medical Insurance Trust Fund (under sec-
17 tion 1841).

18 “(vi) DISSEMINATION OF INFORMA-
19 TION ON PROCESS.—The Secretary shall
20 provide, through the annual medicare
21 handbook under section 1804(a), for a
22 general description of the adjustment of
23 annual out-of-pocket thresholds provided
24 under this subparagraph, including the
25 process for adjustment based upon more

1 recent information and the confidentiality
2 provisions of subparagraph (F), and shall
3 provide for dissemination of a table for
4 each year that sets forth the amount of the
5 adjustment that is made under clause (i)
6 based on the amount of an enrollee’s ad-
7 justed gross income.

8 “(vii) ENROLLEE OPT-OUT.—The Sec-
9 retary shall provide a procedure whereby,
10 if an enrollee elects to have the maximum
11 annual out-of-pocket threshold applied
12 under this subparagraph for a year, the
13 Secretary shall not request any informa-
14 tion regarding the enrollee under subpara-
15 graph (E) for that year.

16 “(E) REQUESTING INFORMATION ON EN-
17 ROLLEES.—

18 “(i) IN GENERAL.—The Secretary
19 shall, periodically as required to carry out
20 subparagraph (D), transmit to the Sec-
21 retary of the Treasury a list of the names
22 and TINs of enrollees in prescription drug
23 plans (or in MA-EFFS Rx plans) and re-
24 quest that such Secretary disclose to the
25 Secretary information under subparagraph

1 (A) of section 6103(l)(19) of the Internal
2 Revenue Code of 1986 with respect to
3 those enrollees for a specified taxable year
4 for application in a particular calendar
5 year.

6 “(ii) DISCLOSURE TO PLAN SPON-
7 SORS.—In the case of a specified taxpayer
8 (as defined in section 6103(l)(19)(B) of
9 the Internal Revenue Code of 1986) who is
10 enrolled in a prescription drug plan or in
11 an MA-EFFS Rx plan or an individual
12 who makes an election under subparagraph
13 (D)(vii), the Secretary shall disclose to the
14 entity that offers the plan the annual out-
15 of-pocket threshold applicable to such indi-
16 vidual under subparagraph (D).

17 “(F) MAINTAINING CONFIDENTIALITY OF
18 INFORMATION.—

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

1 “(ii) CRIMINAL AND CIVIL PENALTIES
2 FOR UNAUTHORIZED DISCLOSURE.—A per-
3 son who makes an unauthorized disclosure
4 of information disclosed under section
5 6103(l)(19) of the Internal Revenue Code
6 of 1986 (including disclosure of any in-
7 crease in an annual out-of-pocket threshold
8 under subparagraph (D)) shall be subject
9 to penalty to the extent provided under—

10 “(I) section 7213 of such Code
11 (relating to criminal penalty for unau-
12 thorized disclosure of information);

13 “(II) section 7213A of such Code
14 (relating to criminal penalty for unau-
15 thorized inspection of returns or re-
16 turn information);

17 “(III) section 7431 of such Code
18 (relating to civil damages for unau-
19 thorized inspection or disclosure of re-
20 turns and return information);

21 “(IV) any other provision of the
22 Internal Revenue Code of 1986; or

23 “(V) any other provision of law.

24 “(iii) APPLICATION OF ADDITIONAL
25 CIVIL MONETARY PENALTY FOR UNAU-

1 THORIZED DISCLOSURES.—In addition to
2 any penalty otherwise provided under law,
3 any person who makes an unauthorized
4 disclosure of such information shall be sub-
5 ject to a civil monetary penalty of not to
6 exceed \$10,000 for each such unauthorized
7 disclosure. The provisions of section 1128A
8 (other than subsections (a) and (b)) shall
9 apply to civil money penalties under this
10 subparagraph in the same manner as they
11 apply to a penalty or proceeding under sec-
12 tion 1128A(a).

13 “(G) INFORMATION REGARDING THIRD-
14 PARTY REIMBURSEMENT.—In order to ensure
15 compliance with the requirements of subpara-
16 graph (C)(ii), the Administrator is authorized
17 to establish procedures, in coordination with the
18 Secretary of Treasury and the Secretary of
19 Labor, for determining whether costs for indi-
20 viduals are being reimbursed through insurance
21 or otherwise, a group health plan, or other
22 third-party payment arrangement, and for
23 alerting the sponsors and organization that
24 offer the plans in which such individuals are en-
25 rolled about such reimbursement arrangements.

1 A PDP sponsor or Medicare Advantage or
2 EFFS organization may also periodically ask
3 individuals enrolled in a prescription drug plan
4 or MA-EFFS Rx plan offered by the sponsor or
5 organization whether the individuals have or ex-
6 pect to receive such third-party reimbursement.
7 A material misrepresentation of the information
8 described in the preceding sentence by an indi-
9 vidual (as defined in standards set by the Ad-
10 ministrator and determined through a process
11 established by the Administrator) shall con-
12 stitute grounds for termination of enrollment
13 under section 1860D–1(d)(3).

14 “(5) ANNUAL PERCENTAGE INCREASE.—For
15 purposes of this part, the annual percentage increase
16 specified in this paragraph for a year is equal to the
17 annual percentage increase in average per capita ag-
18 gregate expenditures for covered outpatient drugs in
19 the United States for medicare beneficiaries, as de-
20 termined by the Administrator for the 12-month pe-
21 riod ending in July of the previous year.

22 “(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A
23 prescription drug plan or MA-EFFS Rx plan may provide
24 a different prescription drug benefit design from the
25 standard coverage described in subsection (b) so long as

1 the Administrator determines (based on an actuarial anal-
2 ysis approved by the Administrator) that the following re-
3 quirements are met and the plan applies for, and receives,
4 the approval of the Administrator for such benefit design:

5 “(1) ASSURING AT LEAST ACTUARIALLY EQUIV-
6 ALENT COVERAGE.—

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

12 “(B) ASSURING EQUIVALENT UNSUB-
13 SIDIZED VALUE OF COVERAGE.—The unsub-
14 sidized value of the coverage is at least equal to
15 the unsubsidized value of standard coverage.
16 For purposes of this subparagraph, the unsub-
17 sidized value of coverage is the amount by
18 which the actuarial value of the coverage (as
19 determined under subsection (e)) exceeds the
20 actuarial value of the subsidy payments under
21 section 1860D–8 with respect to such coverage.

22 “(C) ASSURING STANDARD PAYMENT FOR
23 COSTS AT INITIAL COVERAGE LIMIT.—The cov-
24 erage is designed, based upon an actuarially
25 representative pattern of utilization (as deter-

1 mined under subsection (e)), to provide for the
2 payment, with respect to costs incurred that are
3 equal to the initial coverage limit under sub-
4 section (b)(3), of an amount equal to at least
5 the product of—

6 “(i) the amount by which the initial
7 coverage limit described in subsection
8 (b)(3) exceeds the deductible described in
9 subsection (b)(1); and

10 “(ii) 100 percent minus the cost-shar-
11 ing percentage specified in subsection
12 (b)(2)(A)(i).

13 “(2) CATASTROPHIC PROTECTION.—The cov-
14 erage provides for beneficiaries the catastrophic pro-
15 tection described in subsection (b)(4).

16 “(d) ACCESS TO NEGOTIATED PRICES.—

17 “(1) IN GENERAL.—Under qualified prescrip-
18 tion drug coverage offered by a PDP sponsor or an
19 entity offering a MA-EFFS Rx plan, the sponsor or
20 entity shall provide beneficiaries with access to nego-
21 tiated prices (including applicable discounts) used
22 for payment for covered outpatient drugs, regardless
23 of the fact that no benefits may be payable under
24 the coverage with respect to such drugs because of
25 the application of cost-sharing or an initial coverage

1 limit (described in subsection (b)(3)). Insofar as a
2 State elects to provide medical assistance under title
3 XIX to a beneficiary enrolled under such title and
4 under a prescription drug plan or MA-EFFS Rx
5 plan for a drug based on the prices negotiated by a
6 prescription drug plan or MA-EFFS Rx plan under
7 this part, the requirements of section 1927 shall not
8 apply to such drugs. The prices negotiated by a pre-
9 scription drug plan under this part, by a MA-EFFS
10 Rx plan with respect to covered outpatient drugs, or
11 by a qualified retiree prescription drug plan (as de-
12 fined in section 1860D–8(f)(1)) with respect to such
13 drugs on behalf of individuals entitled to benefits
14 under part A or enrolled under part B, shall (not-
15 withstanding any other provision of law) not be
16 taken into account for the purposes of establishing
17 the best price under section 1927(c)(1)(C).

18 “(2) DISCLOSURE.—The PDP sponsor or entity
19 offering a MA-EFFS Rx plan shall disclose to the
20 Administrator (in a manner specified by the Admin-
21 istrator) the extent to which discounts or rebates or
22 other remuneration or price concessions made avail-
23 able to the sponsor or organization by a manufac-
24 turer are passed through to enrollees through phar-
25 macies and other dispensers or otherwise. The provi-

1 sions of section 1927(b)(3)(D) shall apply to infor-
2 mation disclosed to the Administrator under this
3 paragraph in the same manner as such provisions
4 apply to information disclosed under such section.

5 “(3) AUDITS AND REPORTS.—To protect
6 against fraud and abuse and to ensure proper disclo-
7 sures and accounting under this part, in addition to
8 any protections against fraud and abuse provided
9 under section 1860D–4(b)(3)(C), the Administrator
10 may periodically audit the financial statements and
11 records of PDP sponsor or entities offering a MA-
12 EFFS Rx plan.

13 “(e) ACTUARIAL VALUATION; DETERMINATION OF
14 ANNUAL PERCENTAGE INCREASES.—

15 “(1) PROCESSES.—For purposes of this section,
16 the Administrator shall establish processes and
17 methods—

18 “(A) for determining the actuarial valu-
19 ation of prescription drug coverage, including—

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

23 “(ii) the use of generally accepted ac-
24 tuarial principles and methodologies; and

1 “(iii) applying the same methodology
2 for determinations of alternative coverage
3 under subsection (c) as is used with re-
4 spect to determinations of standard cov-
5 erage under subsection (b); and

6 “(B) for determining annual percentage in-
7 creases described in subsection (b)(5).

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

11 “(2) USE OF OUTSIDE ACTUARIES.—Under the
12 processes under paragraph (1)(A), PDP sponsors
13 and entities offering MA-EFFS Rx plans may use
14 actuarial opinions certified by independent, qualified
15 actuaries to establish actuarial values, but the Ad-
16 ministrator shall determine whether such actuarial
17 values meet the requirements under subsection
18 (c)(1).

19 “(f) COVERED OUTPATIENT DRUGS DEFINED.—

20 “(1) IN GENERAL.—Except as provided in this
21 subsection, for purposes of this part, the term ‘cov-
22 ered outpatient drug’ means—

23 “(A) a drug that may be dispensed only
24 upon a prescription and that is described in

1 subparagraph (A)(i) or (A)(ii) of section
2 1927(k)(2); or

3 “(B) a biological product described in
4 clauses (i) through (iii) of subparagraph (B) of
5 such section or insulin described in subpara-
6 graph (C) of such section and medical supplies
7 associated with the injection of insulin (as de-
8 fined in regulations of the Secretary),

9 and such term includes a vaccine licensed under sec-
10 tion 351 of the Public Health Service Act and any
11 use of a covered outpatient drug for a medically ac-
12 cepted indication (as defined in section 1927(k)(6)).

13 “(2) EXCLUSIONS.—

14 “(A) IN GENERAL.—Such term does not
15 include drugs or classes of drugs, or their med-
16 ical uses, which may be excluded from coverage
17 or otherwise restricted under section
18 1927(d)(2), other than subparagraph (E) there-
19 of (relating to smoking cessation agents), or
20 under section 1927(d)(3).

21 “(B) AVOIDANCE OF DUPLICATE COV-
22 ERAGE.—A drug prescribed for an individual
23 that would otherwise be a covered outpatient
24 drug under this part shall not be so considered
25 if payment for such drug is available under part

1 A or B for an individual entitled to benefits
2 under part A and enrolled under part B.

3 “(3) APPLICATION OF FORMULARY RESTRIC-
4 TIONS.—A drug prescribed for an individual that
5 would otherwise be a covered outpatient drug under
6 this part shall not be so considered under a plan if
7 the plan excludes the drug under a formulary and
8 such exclusion is not successfully appealed under
9 section 1860D–3(f)(2).

10 “(4) APPLICATION OF GENERAL EXCLUSION
11 PROVISIONS.—A prescription drug plan or MA-
12 EFFS Rx plan may exclude from qualified prescrip-
13 tion drug coverage any covered outpatient drug—

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

16 “(B) which are not prescribed in accord-
17 ance with the plan or this part.

18 Such exclusions are determinations subject to recon-
19 sideration and appeal pursuant to section 1860D–
20 3(f).

21 **“SEC. 1860D–3. BENEFICIARY PROTECTIONS FOR QUALI-**
22 **FIED PRESCRIPTION DRUG COVERAGE.**

23 “(a) GUARANTEED ISSUE, COMMUNITY-RATED PRE-
24 MIUMS, ACCESS TO NEGOTIATED PRICES, AND NON-
25 DISCRIMINATION.—For provisions requiring guaranteed

1 issue, community-rated premiums, access to negotiated
2 prices, and nondiscrimination, see sections 1860D–
3 1(c)(1), 1860D–1(c)(2), 1860D–2(d), and 1860D–6(b),
4 respectively.

5 “(b) DISSEMINATION OF INFORMATION.—

6 “(1) GENERAL INFORMATION.—A PDP sponsor
7 shall disclose, in a clear, accurate, and standardized
8 form to each enrollee with a prescription drug plan
9 offered by the sponsor under this part at the time
10 of enrollment and at least annually thereafter, the
11 information described in section 1852(c)(1) relating
12 to such plan. Such information includes the fol-
13 lowing:

14 “(A) Access to specific covered outpatient
15 drugs, including access through pharmacy net-
16 works.

17 “(B) How any formulary used by the spon-
18 sor functions, including the drugs included in
19 the formulary.

20 “(C) Co-payments and deductible require-
21 ments, including the identification of the tiered
22 or other co-payment level applicable to each
23 drug (or class of drugs).

24 “(D) Grievance and appeals procedures.

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

3 “(2) DISCLOSURE UPON REQUEST OF GENERAL
4 COVERAGE, UTILIZATION, AND GRIEVANCE INFORMA-
5 TION.—Upon request of an individual eligible to en-
6 roll under a prescription drug plan, the PDP spon-
7 sor shall provide the information described in section
8 1852(e)(2) (other than subparagraph (D)) to such
9 individual.

10 “(3) RESPONSE TO BENEFICIARY QUESTIONS.—
11 Each PDP sponsor offering a prescription drug plan
12 shall have a mechanism for providing specific infor-
13 mation to enrollees upon request. The sponsor shall
14 make available on a timely basis, through an Inter-
15 net website and in writing upon request, information
16 on specific changes in its formulary.

17 “(4) CLAIMS INFORMATION.—Each PDP spon-
18 sor offering a prescription drug plan must furnish to
19 each enrollee in a form easily understandable to such
20 enrollees an explanation of benefits (in accordance
21 with section 1806(a) or in a comparable manner)
22 and a notice of the benefits in relation to initial cov-
23 erage limit and the annual out-of-pocket threshold
24 applicable to such enrollee for the current year,
25 whenever prescription drug benefits are provided

1 under this part (except that such notice need not be
2 provided more often than monthly).

3 “(c) ACCESS TO COVERED BENEFITS.—

4 “(1) ASSURING PHARMACY ACCESS.—

5 “(A) PARTICIPATION OF ANY WILLING
6 PHARMACY.—A PDP sponsor and an entity of-
7 fering a MA-EFFS Rx plan shall permit the
8 participation of any pharmacy that meets terms
9 and conditions that the plan has established.

10 “(B) DISCOUNTS ALLOWED FOR NETWORK
11 PHARMACIES.—A prescription drug plan and a
12 MA-EFFS Rx plan may, notwithstanding sub-
13 paragraph (A), reduce coinsurance or copay-
14 ments for its enrolled beneficiaries below the
15 level otherwise provided for covered outpatient
16 drugs dispensed through in-network phar-
17 macies, but in no case shall such a reduction re-
18 sult in an increase in payments made by the
19 Administrator under section 1860D–8 to a
20 plan.

21 “(C) CONVENIENT ACCESS FOR NETWORK
22 PHARMACIES.—The PDP sponsor of the pre-
23 scription drug plan and the entity offering a
24 MA-EFFS Rx plan shall secure the participa-
25 tion in its network of a sufficient number of

1 pharmacies that dispense (other than by mail
2 order) drugs directly to patients to ensure con-
3 venient access (consistent with rules of the Ad-
4 ministrator). The Administrator shall establish
5 convenient access rules under this subpara-
6 graph that are no less favorable to enrollees
7 than the rules for convenient access to phar-
8 macies of the Secretary of Defense established
9 as of June 1, 2003, for purposes of the
10 TRICARE Retail Pharmacy (TRRx) program.
11 Such rules shall include adequate emergency ac-
12 cess for enrolled beneficiaries.

13 “(D) LEVEL PLAYING FIELD.—Such a
14 sponsor shall permit enrollees to receive benefits
15 (which may include a 90-day supply of drugs or
16 biologicals) through a community pharmacy,
17 rather than through mail order, with any dif-
18 ferential in charge paid by such enrollees.

19 “(E) NOT REQUIRED TO ACCEPT INSUR-
20 ANCE RISK.—The terms and conditions under
21 subparagraph (A) may not require participating
22 pharmacies to accept insurance risk as a condi-
23 tion of participation.

24 “(2) USE OF STANDARDIZED TECHNOLOGY.—

1 “(A) IN GENERAL.—The PDP sponsor of
2 a prescription drug plan and an entity offering
3 a MA-EFFS Rx plan shall issue (and reissue,
4 as appropriate) such a card (or other tech-
5 nology) that may be used by an enrollee to as-
6 sure access to negotiated prices under section
7 1860D–2(d) for the purchase of prescription
8 drugs for which coverage is not otherwise pro-
9 vided under the plan.

10 “(B) STANDARDS.—

11 “(i) DEVELOPMENT.—The Adminis-
12 trator shall provide for the development or
13 utilization of uniform standards relating to
14 a standardized format for the card or
15 other technology referred to in subpara-
16 graph (A). Such standards shall be com-
17 patible with standards established under
18 part C of title XI.

19 “(ii) APPLICATION OF ADVISORY TASK
20 FORCE.—The advisory task force estab-
21 lished under subsection (d)(3)(B)(ii) shall
22 provide recommendations to the Adminis-
23 trator under such subsection regarding the
24 standards developed under clause (i).

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

6 “(A) PHARMACY AND THERAPEUTIC (P&T)
7 COMMITTEE.—The sponsor or entity must es-
8 tablish a pharmacy and therapeutic committee
9 that develops and reviews the formulary. Such
10 committee shall include at least one practicing
11 physician and at least one practicing phar-
12 macist independent and free of conflict with re-
13 spect to the committee both with expertise in
14 the care of elderly or disabled persons and a
15 majority of its members shall consist of individ-
16 uals who are practicing physicians or practicing
17 pharmacists (or both).

18 “(B) FORMULARY DEVELOPMENT.—In de-
19 veloping and reviewing the formulary, the com-
20 mittee shall—

21 “(i) base clinical decisions on the
22 strength of scientific evidence and stand-
23 ards of practice, including assessing peer-
24 reviewed medical literature, such as ran-
25 domized clinical trials, pharmacoeconomic

1 studies, outcomes research data, and on
2 such other information as the committee
3 determines to be appropriate; and

4 “(ii) shall take into account whether
5 including in the formulary particular cov-
6 ered outpatient drugs has therapeutic ad-
7 vantages in terms of safety and efficacy.

8 “(C) INCLUSION OF DRUGS IN ALL THERA-
9 PEUTIC CATEGORIES.—The formulary must in-
10 clude drugs within each therapeutic category
11 and class of covered outpatient drugs (although
12 not necessarily for all drugs within such cat-
13 egories and classes). In establishing such class-
14 es, the committee shall take into account the
15 standards published in the United States Phar-
16 macopeia-Drug Information. The committee
17 shall make available to the enrollees under the
18 plan through the Internet or otherwise the
19 bases for the exclusion of coverage of any drug
20 from the formulary.

21 “(D) PROVIDER AND PATIENT EDU-
22 CATION.—The committee shall establish policies
23 and procedures to educate and inform health
24 care providers and enrollees concerning the for-
25 mulary.

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

9 “(F) PERIODIC EVALUATION OF PROTO-
10 COLS.—In connection with the formulary, a pre-
11 scription drug plan shall provide for the peri-
12 odic evaluation and analysis of treatment proto-
13 cols and procedures.

14 “(G) GRIEVANCES AND APPEALS RELAT-
15 ING TO APPLICATION OF FORMULARIES.—For
16 provisions relating to grievances and appeals of
17 coverage, see subsections (e) and (f).

18 “(d) COST AND UTILIZATION MANAGEMENT; QUAL-
19 ITY ASSURANCE; MEDICATION THERAPY MANAGEMENT
20 PROGRAM.—

21 “(1) IN GENERAL.—The PDP sponsor or entity
22 offering a MA-EFFS Rx plan shall have in place, di-
23 rectly or through appropriate arrangements, with re-
24 spect to covered outpatient drugs—

1 “(A) an effective cost and drug utilization
2 management program, including medically ap-
3 propriate incentives to use generic drugs and
4 therapeutic interchange, when appropriate;

5 “(B) quality assurance measures and sys-
6 tems to reduce medical errors and adverse drug
7 interactions, including side-effects, and improve
8 medication use, including a medication therapy
9 management program described in paragraph
10 (2) and for years beginning with 2007, an elec-
11 tronic prescription program described in para-
12 graph (3); and

13 “(C) a program to control fraud, abuse,
14 and waste.

15 Nothing in this section shall be construed as impair-
16 ing a PDP sponsor or entity from utilizing cost
17 management tools (including differential payments)
18 under all methods of operation.

19 “(2) MEDICATION THERAPY MANAGEMENT PRO-
20 GRAM.—

21 “(A) IN GENERAL.—A medication therapy
22 management program described in this para-
23 graph is a program of drug therapy manage-
24 ment and medication administration that may
25 be furnished by a pharmacy provider and that

1 is designed to assure, with respect to bene-
2 ficiaries at risk for potential medication prob-
3 lems, such as beneficiaries with complex or
4 chronic diseases (such as diabetes, asthma, hy-
5 pertension, and congestive heart failure) or
6 multiple prescriptions, that covered outpatient
7 drugs under the prescription drug plan are ap-
8 propriately used to optimize therapeutic out-
9 comes through improved medication use and re-
10 duce the risk of adverse events, including ad-
11 verse drug interactions. Such programs may
12 distinguish between services in ambulatory and
13 institutional settings.

14 “(B) ELEMENTS.—Such program may in-
15 clude—

16 “(i) enhanced beneficiary under-
17 standing to promote the appropriate use of
18 medications by beneficiaries and to reduce
19 the risk of potential adverse events associ-
20 ated with medications, through beneficiary
21 education, counseling, case management,
22 disease state management programs, and
23 other appropriate means;

24 “(ii) increased beneficiary adherence
25 with prescription medication regimens

1 through medication refill reminders, special
2 packaging, and other compliance programs
3 and other appropriate means; and

4 “(iii) detection of patterns of overuse
5 and underuse of prescription drugs.

6 “(C) DEVELOPMENT OF PROGRAM IN CO-
7 OPERATION WITH LICENSED PHARMACISTS.—

8 The program shall be developed in cooperation
9 with licensed and practicing pharmacists and
10 physicians.

11 “(D) CONSIDERATIONS IN PHARMACY

12 FEES.—The PDP sponsor of a prescription
13 drug program and an entity offering a MA-
14 EFFS Rx plan shall take into account, in es-
15 tablishing fees for pharmacists and others pro-
16 viding services under the medication therapy
17 management program, the resources and time
18 used in implementing the program. Each such
19 sponsor or entity shall disclose to the Adminis-
20 trator upon request the amount of any such
21 management or dispensing fees and such fees
22 shall be confidential in the same manner as pro-
23 vided under section 1927(b)(3)(D) for informa-
24 tion disclosed under section 1927(b)(3)(A).

25 “(3) ELECTRONIC PRESCRIPTION PROGRAM.—

1 “(A) IN GENERAL.—An electronic prescrip-
2 tion drug program described in this paragraph
3 is a program that includes at least the following
4 components, consistent with uniform standards
5 established under subparagraph (B):

6 “(i) ELECTRONIC TRANSMITTAL OF
7 PRESCRIPTIONS.—Prescriptions must be
8 written and transmitted electronically
9 (other than by facsimile), except in emer-
10 gency cases and other exceptional cir-
11 cumstances recognized by the Adminis-
12 trator.

13 “(ii) PROVISION OF INFORMATION TO
14 PRESCRIBING HEALTH CARE PROFES-
15 SIONAL.—The program provides for the
16 electronic transmittal to the prescribing
17 health care professional of information
18 that includes—

19 “(I) information (to the extent
20 available and feasible) on the drug or
21 drugs being prescribed for that pa-
22 tient and other information relating to
23 the medical history or condition of the
24 patient that may be relevant to the

1 appropriate prescription for that pa-
2 tient;

3 “(II) cost-effective alternatives (if
4 any) for the use of the drug pre-
5 scribed; and

6 “(III) information on the drugs
7 included in the applicable formulary.

8 To the extent feasible, such program shall
9 permit the prescribing health care profes-
10 sional to provide (and be provided) related
11 information on an interactive, real-time
12 basis.

13 “(B) STANDARDS.—

14 “(i) DEVELOPMENT.—The Adminis-
15 trator shall provide for the development of
16 uniform standards relating to the elec-
17 tronic prescription drug program described
18 in subparagraph (A). Such standards shall
19 be compatible with standards established
20 under part C of title XI.

21 “(ii) ADVISORY TASK FORCE.—In de-
22 veloping such standards and the standards
23 described in subsection (c)(2)(B)(i) the Ad-
24 ministrator shall establish a task force that
25 includes representatives of physicians, hos-

1 pitals, pharmacies, beneficiaries, pharmacy
2 benefit managers, individuals with exper-
3 tise in information technology, and phar-
4 macy benefit experts of the Departments
5 of Veterans Affairs and Defense and other
6 appropriate Federal agencies to provide
7 recommendations to the Administrator on
8 such standards, including recommenda-
9 tions relating to the following:

10 “(I) The range of available com-
11 puterized prescribing software and
12 hardware and their costs to develop
13 and implement.

14 “(II) The extent to which such
15 standards and systems reduce medica-
16 tion errors and can be readily imple-
17 mented by physicians, pharmacies,
18 and hospitals.

19 “(III) Efforts to develop uniform
20 standards and a common software
21 platform for the secure electronic
22 communication of medication history,
23 eligibility, benefit, and prescription in-
24 formation.

1 “(IV) Efforts to develop and pro-
2 mote universal connectivity and inter-
3 operability for the secure electronic
4 exchange of such information.

5 “(V) The cost of implementing
6 such systems in the range of hospital
7 and physician office settings and
8 pharmacies, including hardware, soft-
9 ware, and training costs.

10 “(VI) Implementation issues as
11 they relate to part C of title XI, and
12 current Federal and State prescribing
13 laws and regulations and their impact
14 on implementation of computerized
15 prescribing.

16 “(iii) DEADLINES.—

17 “(I) The Administrator shall con-
18 stitute the task force under clause (ii)
19 by not later than April 1, 2004.

20 “(II) Such task force shall sub-
21 mit recommendations to Adminis-
22 trator by not later than January 1,
23 2005.

24 “(III) The Administrator shall
25 provide for the development and pro-

1 mulgation, by not later than January
2 1, 2006, of national standards relat-
3 ing to the electronic prescription drug
4 program described in clause (ii). Such
5 standards shall be issued by a stand-
6 ards organization accredited by the
7 American National Standards Insti-
8 tute (ANSI) and shall be compatible
9 with standards established under part
10 C of title XI.

11 “(4) TREATMENT OF ACCREDITATION.—Section
12 1852(e)(4) (relating to treatment of accreditation)
13 shall apply to prescription drug plans under this
14 part with respect to the following requirements, in
15 the same manner as they apply to plans under part
16 C with respect to the requirements described in a
17 clause of section 1852(e)(4)(B):

18 “(A) Paragraph (1) (including quality as-
19 surance), including medication therapy manage-
20 ment program under paragraph (2).

21 “(B) Subsection (c)(1) (relating to access
22 to covered benefits).

23 “(C) Subsection (g) (relating to confiden-
24 tiality and accuracy of enrollee records).

1 “(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL
2 PRICES FOR EQUIVALENT DRUGS.—Each PDP spon-
3 sor and each entity offering a MA-EFFS Rx plan
4 shall provide that each pharmacy or other dispenser
5 that arranges for the dispensing of a covered out-
6 patient drug shall inform the beneficiary at the time
7 of purchase of the drug of any differential between
8 the price of the prescribed drug to the enrollee and
9 the price of the lowest cost available generic drug
10 covered under the plan that is therapeutically equiv-
11 alent and bioequivalent.

12 “(e) GRIEVANCE MECHANISM, COVERAGE DETER-
13 MINATIONS, AND RECONSIDERATIONS.—

14 “(1) IN GENERAL.—Each PDP sponsor shall
15 provide meaningful procedures for hearing and re-
16 solving grievances between the organization (includ-
17 ing any entity or individual through which the spon-
18 sor provides covered benefits) and enrollees with pre-
19 scription drug plans of the sponsor under this part
20 in accordance with section 1852(f).

21 “(2) APPLICATION OF COVERAGE DETERMINA-
22 TION AND RECONSIDERATION PROVISIONS.—A PDP
23 sponsor shall meet the requirements of paragraphs
24 (1) through (3) of section 1852(g) with respect to
25 covered benefits under the prescription drug plan it

1 offers under this part in the same manner as such
2 requirements apply to an organization with respect
3 to benefits it offers under a plan under part C.

4 “(3) REQUEST FOR REVIEW OF TIERED FOR-
5 MULARY DETERMINATIONS.—In the case of a pre-
6 scription drug plan offered by a PDP sponsor or a
7 MA-EFFS Rx plan that provides for tiered cost-
8 sharing for drugs included within a formulary and
9 provides lower cost-sharing for preferred drugs in-
10 cluded within the formulary, an individual who is en-
11 rolled in the plan may request coverage of a nonpre-
12 ferred drug under the terms applicable for preferred
13 drugs if the prescribing physician determines that
14 the preferred drug for treatment of the same condi-
15 tion either would not be as effective for the indi-
16 vidual or would have adverse effects for the indi-
17 vidual or both.

18 “(f) APPEALS.—

19 “(1) IN GENERAL.—Subject to paragraph (2), a
20 PDP sponsor shall meet the requirements of para-
21 graphs (4) and (5) of section 1852(g) with respect
22 to drugs (including a determination related to the
23 application of tiered cost-sharing described in sub-
24 section (e)(3)) in the same manner as such require-

1 ments apply to an organization with respect to bene-
2 fits it offers under a plan under part C.

3 “(2) FORMULARY DETERMINATIONS.—An indi-
4 vidual who is enrolled in a prescription drug plan of-
5 fered by a PDP sponsor or in a MA-EFFS Rx plan
6 may appeal to obtain coverage for a covered out-
7 patient drug that is not on a formulary of the spon-
8 sor or entity offering the plan if the prescribing phy-
9 sician determines that the formulary drug for treat-
10 ment of the same condition either would not be as
11 effective for the individual or would have adverse ef-
12 fects for the individual or both.

13 “(g) CONFIDENTIALITY AND ACCURACY OF EN-
14 ROLLEE RECORDS.—A PDP sponsor that offers a pre-
15 scription drug plan shall meet the requirements of section
16 1852(h) with respect to enrollees under the plan in the
17 same manner as such requirements apply to an organiza-
18 tion with respect to enrollees under part C. A PDP spon-
19 sor shall be treated as a business associate for purposes
20 of the provisions of subpart E of part 164 of title 45, Code
21 of Federal Regulations, adopted pursuant to the authority
22 of the Secretary under section 264(c) of the Health Insur-
23 ance Portability and Accountability Act of 1996 (42 U.S.
24 C. 1320d-2 note).

1 **“SEC. 1860D–4. REQUIREMENTS FOR AND CONTRACTS WITH**
2 **PRESCRIPTION DRUG PLAN (PDP) SPONSORS.**

3 “(a) GENERAL REQUIREMENTS.—Each PDP sponsor
4 of a prescription drug plan shall meet the following re-
5 quirements:

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

11 “(2) ASSUMPTION OF FINANCIAL RISK FOR UN-
12 SUBSIDIZED COVERAGE.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (B) and section 1860D–5(d)(2), the enti-
15 ty assumes full financial risk on a prospective
16 basis for qualified prescription drug coverage
17 that it offers under a prescription drug plan
18 and that is not covered under section 1860D–
19 8.

20 “(B) REINSURANCE PERMITTED.—The en-
21 tity may obtain insurance or make other ar-
22 rangements for the cost of coverage provided to
23 any enrollee.

24 “(3) SOLVENCY FOR UNLICENSED SPONSORS.—
25 In the case of a sponsor that is not described in
26 paragraph (1), the sponsor shall meet solvency

1 standards established by the Administrator under
2 subsection (d).

3 “(b) CONTRACT REQUIREMENTS.—

4 “(1) IN GENERAL.—The Administrator shall
5 not permit the election under section 1860D–1 of a
6 prescription drug plan offered by a PDP sponsor
7 under this part, and the sponsor shall not be eligible
8 for payments under section 1860D–7 or 1860D–8,
9 unless the Administrator has entered into a contract
10 under this subsection with the sponsor with respect
11 to the offering of such plan. Such a contract with
12 a sponsor may cover more than one prescription
13 drug plan. Such contract shall provide that the spon-
14 sor agrees to comply with the applicable require-
15 ments and standards of this part and the terms and
16 conditions of payment as provided for in this part.

17 “(2) NEGOTIATION REGARDING TERMS AND
18 CONDITIONS.—The Administrator shall have the
19 same authority to negotiate the terms and conditions
20 of prescription drug plans under this part as the Di-
21 rector of the Office of Personnel Management has
22 with respect to health benefits plans under chapter
23 89 of title 5, United States Code. In negotiating the
24 terms and conditions regarding premiums for which
25 information is submitted under section 1860D–

1 6(a)(2), the Administrator shall take into account
2 the subsidy payments under section 1860D–8.

3 “(3) INCORPORATION OF CERTAIN MEDICARE
4 ADVANTAGE CONTRACT REQUIREMENTS.—The fol-
5 lowing provisions of section 1857 shall apply, subject
6 to subsection (c)(5), to contracts under this section
7 in the same manner as they apply to contracts under
8 section 1857(a):

9 “(A) MINIMUM ENROLLMENT.—Para-
10 graphs (1) and (3) of section 1857(b), except
11 that the requirement of such paragraph (1)
12 shall be waived during the first contract year
13 with respect to an organization in a region.

14 “(B) CONTRACT PERIOD AND EFFECTIVE-
15 NESS.—Paragraphs (1) through (3) and (5) of
16 section 1857(e).

17 “(C) PROTECTIONS AGAINST FRAUD AND
18 BENEFICIARY PROTECTIONS.—Section 1857(d).

19 “(D) ADDITIONAL CONTRACT TERMS.—
20 Section 1857(e); except that in applying section
21 1857(e)(2) under this part—

22 “(i) such section shall be applied sepa-
23 rately to costs relating to this part (from
24 costs under part C and part E);

1 “(ii) in no case shall the amount of
2 the fee established under this subpara-
3 graph for a plan exceed 20 percent of the
4 maximum amount of the fee that may be
5 established under subparagraph (B) of
6 such section; and

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

10 “(E) INTERMEDIATE SANCTIONS.—Section
11 1857(g).

12 “(F) PROCEDURES FOR TERMINATION.—
13 Section 1857(h).

14 “(4) RULES OF APPLICATION FOR INTER-
15 MEDIATE SANCTIONS.—In applying paragraph
16 (3)(E)—

17 “(A) the reference in section
18 1857(g)(1)(B) to section 1854 is deemed a ref-
19 erence to this part; and

20 “(B) the reference in section
21 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall
22 not be applied.

23 “(5) SERVICE AREA REQUIREMENT.—For pur-
24 poses of this part, the Administrator shall designate
25 at least 10 areas covering the entire United States

1 and to the extent practicable shall be consistent with
2 EFFS regions established under section 1860E–
3 1(a)(2).

4 “(c) WAIVER OF CERTAIN REQUIREMENTS TO EX-
5 PAND CHOICE.—

6 “(1) IN GENERAL.—In the case of an entity
7 that seeks to offer a prescription drug plan in a
8 State, the Administrator shall waive the requirement
9 of subsection (a)(1) that the entity be licensed in
10 that State if the Administrator determines, based on
11 the application and other evidence presented to the
12 Administrator, that any of the grounds for approval
13 of the application described in paragraph (2) have
14 been met.

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

21 “(3) APPLICATION OF WAIVER PROCEDURES.—
22 With respect to an application for a waiver (or a
23 waiver granted) under this subsection, the provisions
24 of subparagraphs (E), (F), and (G) of section
25 1855(a)(2) shall apply.

1 “(4) LICENSURE DOES NOT SUBSTITUTE FOR
2 OR CONSTITUTE CERTIFICATION.—The fact that an
3 entity is licensed in accordance with subsection
4 (a)(1) does not deem the entity to meet other re-
5 quirements imposed under this part for a PDP spon-
6 sor.

7 “(5) REFERENCES TO CERTAIN PROVISIONS.—
8 For purposes of this subsection, in applying provi-
9 sions of section 1855(a)(2) under this subsection to
10 prescription drug plans and PDP sponsors—

11 “(A) any reference to a waiver application
12 under section 1855 shall be treated as a ref-
13 erence to a waiver application under paragraph
14 (1); and

15 “(B) any reference to solvency standards
16 shall be treated as a reference to solvency
17 standards established under subsection (d).

18 “(d) SOLVENCY STANDARDS FOR NON-LICENSED
19 SPONSORS.—

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

1 “(2) COMPLIANCE WITH STANDARDS.—Each
2 PDP sponsor that is not licensed by a State under
3 subsection (a)(1) and for which a waiver application
4 has been approved under subsection (c) shall meet
5 solvency and capital adequacy standards established
6 under paragraph (1). The Administrator shall estab-
7 lish certification procedures for such PDP sponsors
8 with respect to such solvency standards in the man-
9 ner described in section 1855(c)(2).

10 “(e) RELATION TO STATE LAWS.—

11 “(1) IN GENERAL.—The standards established
12 under this part shall supersede any State law or reg-
13 ulation (other than State licensing laws or State
14 laws relating to plan solvency, except as provided in
15 subsection (d)) with respect to prescription drug
16 plans which are offered by PDP sponsors under this
17 part.

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

1 **“SEC. 1860D-5. PROCESS FOR BENEFICIARIES TO SELECT**
2 **QUALIFIED PRESCRIPTION DRUG COVERAGE.**

3 “(a) IN GENERAL.—The Administrator shall estab-
4 lish a process for the selection of the prescription drug
5 plan or MA-EFFS Rx plan through which eligible individ-
6 uals elect qualified prescription drug coverage under this
7 part.

8 “(b) ELEMENTS.—Such process shall include the fol-
9 lowing:

10 “(1) Annual, coordinated election periods, in
11 which such individuals can change the qualifying
12 plans through which they obtain coverage, in accord-
13 ance with section 1860D-1(b)(2).

14 “(2) Active dissemination of information to pro-
15 mote an informed selection among qualifying plans
16 based upon price, quality, and other features, in the
17 manner described in (and in coordination with) sec-
18 tion 1851(d), including the provision of annual com-
19 parative information, maintenance of a toll-free hot-
20 line, and the use of non-Federal entities.

21 “(3) Coordination of elections through filing
22 with the entity offering a MA-EFFS Rx plan or a
23 PDP sponsor, in the manner described in (and in co-
24 ordination with) section 1851(c)(2).

25 “(4) Informing each enrollee before the begin-
26 ning of each year of the annual out-of-pocket thresh-

1 old applicable to the enrollee for that year under sec-
2 tion 1860D–2(b)(4) at such time.

3 “(c) MA-EFFS RX ENROLLEE MAY ONLY OBTAIN
4 BENEFITS THROUGH THE PLAN.—An individual who is
5 enrolled under a MA-EFFS Rx plan may only elect to re-
6 ceive qualified prescription drug coverage under this part
7 through such plan.

8 “(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED
9 PRESCRIPTION DRUG COVERAGE.—

10 “(1) CHOICE OF AT LEAST TWO PLANS IN EACH
11 AREA.—

12 “(A) IN GENERAL.—The Administrator
13 shall assure that each individual who is entitled
14 to benefits under part A or enrolled under part
15 B and who is residing in an area in the United
16 States has available, consistent with subpara-
17 graph (B), a choice of enrollment in at least
18 two qualifying plans (as defined in paragraph
19 (5)) in the area in which the individual resides,
20 at least one of which is a prescription drug
21 plan.

22 “(B) REQUIREMENT FOR DIFFERENT
23 PLAN SPONSORS.—The requirement in subpara-
24 graph (A) is not satisfied with respect to an
25 area if only one PDP sponsor or one entity that

1 offers a MA-EFFS Rx plan offers all the quali-
2 fying plans in the area.

3 “(2) GUARANTEEING ACCESS TO COVERAGE.—

4 In order to assure access under paragraph (1) and
5 consistent with paragraph (3), the Administrator
6 may provide partial underwriting of risk for a PDP
7 sponsor to expand the service area under an existing
8 prescription drug plan to adjoining or additional
9 areas or to establish such a plan (including offering
10 such a plan on a regional or nationwide basis), but
11 only so long as (and to the extent) necessary to as-
12 sure the access guaranteed under paragraph (1).

13 “(3) LIMITATION ON AUTHORITY.—In exer-
14 cising authority under this subsection, the Adminis-
15 trator—

16 “(A) shall not provide for the full under-
17 writing of financial risk for any PDP sponsor;
18 and

19 “(B) shall seek to maximize the assump-
20 tion of financial risk by PDP sponsors or enti-
21 ties offering a MA-EFFS Rx plan.

22 “(4) REPORTS.—The Administrator shall, in
23 each annual report to Congress under section
24 1809(f), include information on the exercise of au-
25 thority under this subsection. The Administrator

1 also shall include such recommendations as may be
2 appropriate to minimize the exercise of such author-
3 ity, including minimizing the assumption of financial
4 risk.

5 “(5) QUALIFYING PLAN DEFINED.—For pur-
6 poses of this subsection, the term ‘qualifying plan’
7 means a prescription drug plan or a MA-EFFS Rx
8 plan.

9 **“SEC. 1860D-6. SUBMISSION OF BIDS AND PREMIUMS.**

10 “(a) SUBMISSION OF BIDS, PREMIUMS, AND RE-
11 LATED INFORMATION.—

12 “(1) IN GENERAL.—Each PDP sponsor shall
13 submit to the Administrator the information de-
14 scribed in paragraph (2) in the same manner as in-
15 formation is submitted by an organization under sec-
16 tion 1854(a)(1).

17 “(2) INFORMATION SUBMITTED.—The informa-
18 tion described in this paragraph is the following:

19 “(A) COVERAGE PROVIDED.—Information
20 on the qualified prescription drug coverage to
21 be provided.

22 “(B) ACTUARIAL VALUE.—Information on
23 the actuarial value of the coverage.

1 “(C) BID AND PREMIUM.—Information on
2 the bid and the premium for the coverage, in-
3 cluding an actuarial certification of—

4 “(i) the actuarial basis for such bid
5 and premium;

6 “(ii) the portion of such bid and pre-
7 mium attributable to benefits in excess of
8 standard coverage;

9 “(iii) the reduction in such bid result-
10 ing from the reinsurance subsidy payments
11 provided under section 1860D–8(a)(2);
12 and

13 “(iv) the reduction in such premium
14 resulting from the direct and reinsurance
15 subsidy payments provided under section
16 1860D–8.

17 “(D) ADDITIONAL INFORMATION.—Such
18 other information as the Administrator may re-
19 quire to carry out this part.

20 “(3) REVIEW OF INFORMATION; NEGOTIATION
21 AND APPROVAL OF PREMIUMS.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), the Administrator shall review the
24 information filed under paragraph (2) for the
25 purpose of conducting negotiations under sec-

1 tion 1860D–4(b)(2) (relating to using OPM-like
2 authority under the FEHBP). The Adminis-
3 trator, using the information provided (includ-
4 ing the actuarial certification under paragraph
5 (2)(C)) shall approve the premium submitted
6 under this subsection only if the premium accu-
7 rately reflects both (i) the actuarial value of the
8 benefits provided, and (ii) the 73 percent aver-
9 age subsidy provided under section 1860D–8
10 for the standard benefit. The Administrator
11 shall apply actuarial principles to approval of a
12 premium under this part in a manner similar to
13 the manner in which those principles are ap-
14 plied in establishing the monthly part B pre-
15 mium under section 1839.

16 “(B) EXCEPTION.—In the case of a plan
17 described in section 1851(a)(2)(C), the provi-
18 sions of subparagraph (A) shall not apply and
19 the provisions of paragraph (5)(B) of section
20 1854(a), prohibiting the review, approval, or
21 disapproval of amounts described in such para-
22 graph, shall apply to the negotiation and rejec-
23 tion of the monthly bid amounts and proportion
24 referred to in subparagraph (A).

25 “(b) UNIFORM BID AND PREMIUM.—

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

5 “(2) CONSTRUCTION.—Nothing in paragraph
6 (1) shall be construed as preventing the imposition
7 of a late enrollment penalty under section 1860D–
8 1(c)(2)(B).

9 “(c) COLLECTION.—

10 “(1) BENEFICIARY’S OPTION OF PAYMENT
11 THROUGH WITHHOLDING FROM SOCIAL SECURITY
12 PAYMENT OR USE OF ELECTRONIC FUNDS TRANS-
13 FER MECHANISM.—In accordance with regulations, a
14 PDP sponsor shall permit each enrollee, at the en-
15 rollee’s option, to make payment of premiums under
16 this part to the sponsor through withholding from
17 benefit payments in the manner provided under sec-
18 tion 1840 with respect to monthly premiums under
19 section 1839 or through an electronic funds transfer
20 mechanism (such as automatic charges of an ac-
21 count at a financial institution or a credit or debit
22 card account) or otherwise. All premium payments
23 that are withheld under this paragraph shall be
24 credited to the Medicare Prescription Drug Trust

1 Fund and shall be paid to the PDP sponsor in-
2 volved.

3 “(2) OFFSETTING.—Reductions in premiums
4 for coverage under parts A and B as a result of a
5 selection of a MA-EFFS Rx plan may be used to re-
6 duce the premium otherwise imposed under para-
7 graph (1).

8 “(d) ACCEPTANCE OF REFERENCE PREMIUM
9 AMOUNT AS FULL PREMIUM FOR SUBSIDIZED LOW-IN-
10 COME INDIVIDUALS IF NO STANDARD (OR EQUIVALENT)
11 COVERAGE IN AN AREA.—

12 “(1) IN GENERAL.—If there is no standard pre-
13 scription drug coverage (as defined in paragraph
14 (2)) offered in an area, in the case of an individual
15 who is eligible for a premium subsidy under section
16 1860D–7 and resides in the area, the PDP sponsor
17 of any prescription drug plan offered in the area
18 (and any entity offering a MA-EFFS Rx plan in the
19 area) shall accept the reference premium amount
20 (under paragraph (3)) as payment in full for the
21 premium charge for qualified prescription drug cov-
22 erage.

23 “(2) STANDARD PRESCRIPTION DRUG COV-
24 ERAGE DEFINED.—For purposes of this subsection,
25 the term ‘standard prescription drug coverage’

1 means qualified prescription drug coverage that is
2 standard coverage or that has an actuarial value
3 equivalent to the actuarial value for standard cov-
4 erage.

5 “(3) REFERENCE PREMIUM AMOUNT DE-
6 FINED.—For purposes of this subsection, the term
7 ‘reference premium amount’ means, with respect to
8 qualified prescription drug coverage offered under—

9 “(A) a prescription drug plan that—

10 “(i) provides standard coverage (or al-
11 ternative prescription drug coverage the
12 actuarial value is equivalent to that of
13 standard coverage), the plan’s PDP pre-
14 mium; or

15 “(ii) provides alternative prescription
16 drug coverage the actuarial value of which
17 is greater than that of standard coverage,
18 the plan’s PDP premium multiplied by the
19 ratio of (I) the actuarial value of standard
20 coverage, to (II) the actuarial value of the
21 alternative coverage;

22 “(B) an EFFS plan, the EFFS monthly
23 prescription drug beneficiary premium (as de-
24 fined in section 1860E–4(a)(3)(B)); or

1 “(C) a Medicare Advantage, the Medicare
2 Advantage monthly prescription drug bene-
3 ficiary premium (as defined in section
4 1854(b)(2)(B)).

5 For purposes of subparagraph (A), the term ‘PDP
6 premium’ means, with respect to a prescription drug
7 plan, the premium amount for enrollment under the
8 plan under this part (determined without regard to
9 any low-income subsidy under section 1860D-7 or
10 any late enrollment penalty under section 1860D-
11 1(c)(2)(B)).

12 **“SEC. 1860D-7. PREMIUM AND COST-SHARING SUBSIDIES**
13 **FOR LOW-INCOME INDIVIDUALS.**

14 “(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS
15 WITH INCOME BELOW 150 PERCENT OF FEDERAL POV-
16 ERTY LEVEL.—

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

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

4 “(B) subject to subsection (c), to the sub-
5 stitution for the beneficiary cost-sharing de-
6 scribed in paragraphs (1) and (2) of section
7 1860D–2(b) (up to the initial coverage limit
8 specified in paragraph (3) of such section) of
9 amounts that do not exceed \$2 for a multiple
10 source or generic drug (as described in section
11 1927(k)(7)(A)) and \$5 for a non-preferred
12 drug.

13 “(2) SLIDING SCALE PREMIUM SUBSIDY FOR
14 INDIVIDUALS WITH INCOME ABOVE 135, BUT BELOW
15 150 PERCENT, OF FEDERAL POVERTY LEVEL.—In
16 the case of a subsidy eligible individual who is deter-
17 mined to have income that exceeds 135 percent, but
18 does not exceed 150 percent, of the Federal poverty
19 level, the individual is entitled under this section to
20 an income-related premium subsidy determined on a
21 linear sliding scale ranging from 100 percent of the
22 amount described in subsection (b)(1) for individuals
23 with incomes at 135 percent of such level to 0 per-
24 cent of such amount for individuals with incomes at
25 150 percent of such level.

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

6 “(4) DETERMINATION OF ELIGIBILITY.—

7 “(A) SUBSIDY ELIGIBLE INDIVIDUAL DE-
8 FINED.—For purposes of this section, subject
9 to subparagraph (D), the term ‘subsidy eligible
10 individual’ means an individual who—

11 “(i) is eligible to elect, and has elect-
12 ed, to obtain qualified prescription drug
13 coverage under this part;

14 “(ii) has income below 150 percent of
15 the Federal poverty line; and

16 “(iii) meets the resources requirement
17 described in subparagraph (D).

18 “(B) DETERMINATIONS.—The determina-
19 tion of whether an individual residing in a State
20 is a subsidy eligible individual and the amount
21 of such individual’s income shall be determined
22 under the State medicaid plan for the State
23 under section 1935(a) or by the Social Security
24 Administration. In the case of a State that does
25 not operate such a medicaid plan (either under

1 title XIX or under a statewide waiver granted
2 under section 1115), such determination shall
3 be made under arrangements made by the Ad-
4 ministrator. There are authorized to be appro-
5 priated to the Social Security Administration
6 such sums as may be necessary for the deter-
7 mination of eligibility under this subparagraph.

8 “(C) INCOME DETERMINATIONS.—For pur-
9 poses of applying this section—

10 “(i) income shall be determined in the
11 manner described in section
12 1905(p)(1)(B); and

13 “(ii) the term ‘Federal poverty line’
14 means the official poverty line (as defined
15 by the Office of Management and Budget,
16 and revised annually in accordance with
17 section 673(2) of the Omnibus Budget
18 Reconciliation Act of 1981) applicable to a
19 family of the size involved.

20 “(D) RESOURCE STANDARD APPLIED TO
21 BE BASED ON THREE TIMES SSI RESOURCE
22 STANDARD.—The resource requirement of this
23 subparagraph is that an individual’s resources
24 (as determined under section 1613 for purposes

1 of the supplemental security income program)
2 do not exceed—

3 “(i) for 2006 three times the max-
4 imum amount of resources that an indi-
5 vidual may have and obtain benefits under
6 that program; and

7 “(ii) for a subsequent year the re-
8 source limitation established under this
9 clause for the previous year increased by
10 the annual percentage increase in the con-
11 sumer price index (all items; U.S. city av-
12 erage) as of September of such previous
13 year.

14 Any resource limitation established under clause
15 (ii) that is not a multiple of \$10 shall be round-
16 ed to the nearest multiple of \$10.

17 “(E) TREATMENT OF TERRITORIAL RESI-
18 DENTS.—In the case of an individual who is not
19 a resident of the 50 States or the District of
20 Columbia, the individual is not eligible to be a
21 subsidy eligible individual but may be eligible
22 for financial assistance with prescription drug
23 expenses under section 1935(e).

24 “(F) TREATMENT OF CONFORMING
25 MEDIGAP POLICIES.—For purposes of this sec-

1 tion, the term ‘qualified prescription drug cov-
2 erage’ includes a medicare supplemental policy
3 described in section 1860D–8(b)(4).

4 “(5) INDEXING DOLLAR AMOUNTS.—

5 “(A) FOR 2007.—The dollar amounts ap-
6 plied under paragraphs (1)(B) for 2007 shall be
7 the dollar amounts specified in such paragraph
8 increased by the annual percentage increase de-
9 scribed in section 1860D–2(b)(5) for 2007.

10 “(B) FOR SUBSEQUENT YEARS.—The dol-
11 lar amounts applied under paragraph (1)(B) for
12 a year after 2007 shall be the amounts (under
13 this paragraph) applied under paragraph (1)(B)
14 for the preceding year increased by the annual
15 percentage increase described in section
16 1860D–2(b)(5) (relating to growth in medicare
17 prescription drug costs per beneficiary) for the
18 year involved.

19 “(b) PREMIUM SUBSIDY AMOUNT.—

20 “(1) IN GENERAL.—The premium subsidy
21 amount described in this subsection for an individual
22 residing in an area is the benchmark premium
23 amount (as defined in paragraph (2)) for qualified
24 prescription drug coverage offered by the prescrip-

1 tion drug plan or the MA-EFFS Rx plan in which
2 the individual is enrolled.

3 “(2) BENCHMARK PREMIUM AMOUNT DE-
4 FINED.—For purposes of this subsection, the term
5 ‘benchmark premium amount’ means, with respect
6 to qualified prescription drug coverage offered
7 under—

8 “(A) a prescription drug plan that—

9 “(i) provides standard coverage (or al-
10 ternative prescription drug coverage the
11 actuarial value of which is equivalent to
12 that of standard coverage), the premium
13 amount for enrollment under the plan
14 under this part (determined without regard
15 to any subsidy under this section or any
16 late enrollment penalty under section
17 1860D–1(c)(2)(B)); or

18 “(ii) provides alternative prescription
19 drug coverage the actuarial value of which
20 is greater than that of standard coverage,
21 the premium amount described in clause
22 (i) multiplied by the ratio of (I) the actu-
23 arial value of standard coverage, to (II)
24 the actuarial value of the alternative cov-
25 erage; or

1 “(B) a MA-EFFS Rx plan, the portion of
2 the premium amount that is attributable to
3 statutory drug benefits (described in section
4 1853(a)(1)(A)(ii)(II)).

5 “(c) RULES IN APPLYING COST-SHARING SUB-
6 SIDIES.—

7 “(1) IN GENERAL.—In applying subsection
8 (a)(1)(B), nothing in this part shall be construed as
9 preventing a plan or provider from waiving or reduc-
10 ing the amount of cost-sharing otherwise applicable.

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

16 “(3) APPLICATION OF INDEXING RULES.—The
17 provisions of subsection (a)(5) shall apply to the dol-
18 lar amount specified in paragraph (2) in the same
19 manner as they apply to the dollar amounts specified
20 in subsections (a)(1)(B).

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

1 “(1) the Administrator provides for a notifica-
2 tion of the PDP sponsor or the entity offering the
3 MA-EFFS Rx plan involved that the individual is el-
4 igible for a subsidy and the amount of the subsidy
5 under subsection (a);

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

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

14 The reimbursement under paragraph (3) with respect to
15 cost-sharing subsidies may be computed on a capitated
16 basis, taking into account the actuarial value of the sub-
17 sidies and with appropriate adjustments to reflect dif-
18 ferences in the risks actually involved.

19 “(e) RELATION TO MEDICAID PROGRAM.—

20 “(1) IN GENERAL.—For provisions providing
21 for eligibility determinations, and additional financ-
22 ing, under the medicaid program, see section 1935.

23 “(2) MEDICAID PROVIDING WRAP AROUND BEN-
24 EFITS.—The coverage provided under this part is
25 primary payor to benefits for prescribed drugs pro-

1 vided under the medicaid program under title XIX
2 consistent with section 1935(d)(1).

3 “(3) COORDINATION.—The Administrator shall
4 develop and implement a plan for the coordination
5 of prescription drug benefits under this part with
6 the benefits provided under the medicaid program
7 under title XIX, with particular attention to insur-
8 ing coordination of payments and prevention of
9 fraud and abuse. In developing and implementing
10 such plan, the Administrator shall involve the Sec-
11 retary, the States, the data processing industry,
12 pharmacists, and pharmaceutical manufacturers,
13 and other experts.

14 **“SEC. 1860D-8. SUBSIDIES FOR ALL MEDICARE BENE-**
15 **FICIARIES FOR QUALIFIED PRESCRIPTION**
16 **DRUG COVERAGE.**

17 “(a) SUBSIDY PAYMENT.—In order to reduce pre-
18 mium levels applicable to qualified prescription drug cov-
19 erage for all medicare beneficiaries consistent with an
20 overall subsidy level of 73 percent, to reduce adverse selec-
21 tion among prescription drug plans and MA-EFFS Rx
22 plans, and to promote the participation of PDP sponsors
23 under this part, the Administrator shall provide in accord-
24 ance with this section for payment to a qualifying entity
25 (as defined in subsection (b)) of the following subsidies:

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

7 “(2) SUBSIDY THROUGH REINSURANCE.—In
8 the case of an enrollee enrolled for a month in a pre-
9 scription drug plan or a MA-EFFS Rx plan, the re-
10 insurance payment amount (as defined in subsection
11 (c)), which in the aggregate is 30 percent of the
12 total payments made by qualifying entities for stand-
13 ard coverage under the respective plan, for excess
14 costs incurred in providing qualified prescription
15 drug coverage—

16 “(A) for enrollees with a prescription drug
17 plan under this part; and

18 “(B) for enrollees with a MA-EFFS Rx
19 plan.

20 “(3) EMPLOYER AND UNION FLEXIBILITY.—In
21 the case of an individual who is a participant or ben-
22 eficiary in a qualified retiree prescription drug plan
23 (as defined in subsection (f)(1)) and who is not en-
24 rolled in a prescription drug plan or in a MA-EFFS

1 Rx plan, the special subsidy payments under sub-
2 section (f)(3).

3 This section constitutes budget authority in advance of ap-
4 propriations Acts and represents the obligation of the Ad-
5 ministrator to provide for the payment of amounts pro-
6 vided under this section.

7 “(b) QUALIFYING ENTITY DEFINED.—For purposes
8 of this section, the term ‘qualifying entity’ means any of
9 the following that has entered into an agreement with the
10 Administrator to provide the Administrator with such in-
11 formation as may be required to carry out this section:

12 “(1) A PDP sponsor offering a prescription
13 drug plan under this part.

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

15 “(3) The sponsor of a qualified retiree prescrip-
16 tion drug plan (as defined in subsection (f)).

17 “(c) REINSURANCE PAYMENT AMOUNT.—

18 “(1) IN GENERAL.—Subject to subsection
19 (d)(1)(B) and paragraph (4), the reinsurance pay-
20 ment amount under this subsection for a qualifying
21 covered individual (as defined in paragraph (5)) for
22 a coverage year (as defined in subsection (h)(2)) is
23 equal to the sum of the following:

24 “(A) REINSURANCE BETWEEN INITIAL RE-
25 INSURANCE THRESHOLD AND THE INITIAL COV-

1 ERAGE LIMIT.—For the portion of the individ-
2 ual’s gross covered prescription drug costs (as
3 defined in paragraph (3)) for the year that ex-
4 ceeds the initial reinsurance threshold specified
5 in paragraph (4), but does not exceed the initial
6 coverage limit specified in section 1860D–
7 2(b)(3), an amount equal to 20 percent of the
8 allowable costs (as defined in paragraph (2)) at-
9 tributable to such gross covered prescription
10 drug costs.

11 “(B) REINSURANCE ABOVE ANNUAL OUT-
12 OF-POCKET THRESHOLD.—For the portion of
13 the individual’s gross covered prescription drug
14 costs for the year that exceeds the annual out-
15 of-pocket threshold specified in 1860D–
16 2(b)(4)(B), an amount equal to 80 percent of
17 the allowable costs attributable to such gross
18 covered prescription drug costs.

19 “(2) ALLOWABLE COSTS.—For purposes of this
20 section, the term ‘allowable costs’ means, with re-
21 spect to gross covered prescription drug costs under
22 a plan described in subsection (b) offered by a quali-
23 fying entity, the part of such costs that are actually
24 paid (net of discounts, chargebacks, and average
25 percentage rebates) under the plan, but in no case

1 more than the part of such costs that would have
2 been paid under the plan if the prescription drug
3 coverage under the plan were standard coverage.

4 “(3) GROSS COVERED PRESCRIPTION DRUG
5 COSTS.—For purposes of this section, the term
6 ‘gross covered prescription drug costs’ means, with
7 respect to an enrollee with a qualifying entity under
8 a plan described in subsection (b) during a coverage
9 year, the costs incurred under the plan (including
10 costs attributable to administrative costs) for cov-
11 ered prescription drugs dispensed during the year,
12 including costs relating to the deductible, whether
13 paid by the enrollee or under the plan, regardless of
14 whether the coverage under the plan exceeds stand-
15 ard coverage and regardless of when the payment
16 for such drugs is made.

17 “(4) INITIAL REINSURANCE THRESHOLD.—The
18 initial reinsurance threshold specified in this para-
19 graph—

20 “(A) for 2006, is equal to \$1,000; or

21 “(B) for a subsequent year, is equal to the
22 payment threshold specified in this paragraph
23 for the previous year, increased by the annual
24 percentage increase described in section
25 1860D–2(b)(5) for the year involved.

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

4 “(5) QUALIFYING COVERED INDIVIDUAL DE-
5 FINED.—For purposes of this subsection, the term
6 ‘qualifying covered individual’ means an individual
7 who—

8 “(A) is enrolled with a prescription drug
9 plan under this part; or

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

11 “(d) ADJUSTMENT OF PAYMENTS.—

12 “(1) ADJUSTMENT OF REINSURANCE PAY-
13 MENTS TO ASSURE 30 PERCENT LEVEL OF SUBSIDY
14 THROUGH REINSURANCE.—

15 “(A) ESTIMATION OF PAYMENTS.—The
16 Administrator shall estimate—

17 “(i) the total payments to be made
18 (without regard to this subsection) during
19 a year under subsections (a)(2) and (c);
20 and

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

1 “(B) ADJUSTMENT.—The Administrator
2 shall proportionally adjust the payments made
3 under subsections (a)(2) and (c) for a coverage
4 year in such manner so that the total of the
5 payments made under such subsections for the
6 year is equal to 30 percent of the total pay-
7 ments described in subparagraph (A)(ii).

8 “(2) RISK ADJUSTMENT FOR DIRECT SUB-
9 SIDIES.—To the extent the Administrator deter-
10 mines it appropriate to avoid risk selection, the pay-
11 ments made for direct subsidies under subsection
12 (a)(1) are subject to adjustment based upon risk
13 factors specified by the Administrator. Any such risk
14 adjustment shall be designed in a manner as to not
15 result in a change in the aggregate payments made
16 under such subsection.

17 “(e) PAYMENT METHODS.—

18 “(1) IN GENERAL.—Payments under this sec-
19 tion shall be based on such a method as the Admin-
20 istrator determines. The Administrator may estab-
21 lish a payment method by which interim payments
22 of amounts under this section are made during a
23 year based on the Administrator’s best estimate of
24 amounts that will be payable after obtaining all of
25 the information.

1 “(2) SOURCE OF PAYMENTS.—Payments under
2 this section shall be made from the Medicare Pre-
3 scription Drug Trust Fund.

4 “(f) RULES RELATING TO QUALIFIED RETIREE PRE-
5 SCRIPTION DRUG PLAN.—

6 “(1) DEFINITION.—For purposes of this sec-
7 tion, the term ‘qualified retiree prescription drug
8 plan’ means employment-based retiree health cov-
9 erage (as defined in paragraph (4)(A)) if, with re-
10 spect to an individual who is a participant or bene-
11 ficiary under such coverage and is eligible to be en-
12 rolled in a prescription drug plan or a MA-EFFS Rx
13 plan under this part, the following requirements are
14 met:

15 “(A) ACTUARIAL EQUIVALENCE TO STAND-
16 ARD COVERAGE.—The Administrator deter-
17 mines (based on an actuarial analysis approved
18 by the Administrator) that coverage provides at
19 least the same actuarial value as standard cov-
20 erage. Such determination may be made on an
21 annual basis.

22 “(B) AUDITS.—The sponsor (or the ad-
23 ministrator, if designated by the sponsor) and
24 the plan shall maintain, and afford the Admin-
25 istrator access to, such records as the Adminis-

1 trator may require for purposes of audits and
2 other oversight activities necessary to ensure
3 the adequacy of prescription drug coverage and
4 the accuracy of payments made.

5 “(C) PROVISION OF CERTIFICATION OF
6 PRESCRIPTION DRUG COVERAGE.—The sponsor
7 of the plan shall provide for issuance of certifi-
8 cations of the type described in section 1860D–
9 1(e)(2)(D).

10 “(2) LIMITATION ON BENEFIT ELIGIBILITY.—
11 No payment shall be provided under this section
12 with respect to a participant or beneficiary in a
13 qualified retiree prescription drug plan unless the in-
14 dividual is—

15 “(A) is covered under the plan; and

16 “(B) is eligible to obtain qualified prescrip-
17 tion drug coverage under section 1860D–1 but
18 did not elect such coverage under this part (ei-
19 ther through a prescription drug plan or
20 through a MA-EFFS Rx plan).

21 “(3) EMPLOYER AND UNION SPECIAL SUBSIDY
22 AMOUNTS.—

23 “(A) IN GENERAL.—For purposes of sub-
24 section (a), the special subsidy payment amount
25 under this paragraph for a qualifying covered

1 retiree(as defined in paragraph (6)) for a cov-
2 erage year (as defined in subsection (h)) en-
3 rolled in a qualifying entity described in sub-
4 section (b)(3) under a qualified retiree prescrip-
5 tion drug plan is, for the portion of the individ-
6 ual’s gross covered prescription drug costs for
7 the year that exceeds the deductible amount
8 specified in subparagraph (B), an amount equal
9 to, subject to subparagraph (D), 28 percent of
10 the allowable costs attributable to such gross
11 covered prescription drug costs, but only to the
12 extent such costs exceed the deductible under
13 subparagraph (B) and do not exceed the cost
14 limit under such subparagraph in the case of
15 any such individual for the plan year.

16 “(B) DEDUCTIBLE AND COST LIMIT APPLI-
17 CABLE.—Subject to subparagraph (C)—

18 “(i) the deductible under this sub-
19 paragraph is equal to \$250 for plan years
20 that end in 2006; and

21 “(ii) the cost limit under this subpara-
22 graph is equal to \$5,000 for plan years
23 that end in 2006.

24 “(C) INDEXING.—The deductible and cost
25 limit amounts specified in subparagraphs (B)

1 for a plan year that ends after 2006 shall be
2 adjusted in the same manner as the annual de-
3 ductible under section 1860D-2(b)(1) is annu-
4 ally adjusted under such section.

5 “(4) RELATED DEFINITIONS.—As used in this
6 section:

7 “(A) EMPLOYMENT-BASED RETIREE
8 HEALTH COVERAGE.—The term ‘employment-
9 based retiree health coverage’ means health in-
10 surance or other coverage of health care costs
11 for individuals eligible to enroll in a prescription
12 drug plan or MA-EFFS Rx plan under this
13 part (or for such individuals and their spouses
14 and dependents) under a group health plan (in-
15 cluding such a plan that is established or main-
16 tained under or pursuant to one or more collec-
17 tive bargaining agreements or that is offered
18 under chapter 89 of title 5, United States
19 Code) based on their status as retired partici-
20 pants in such plan.

21 “(B) QUALIFYING COVERED RETIREE.—
22 The term ‘qualifying covered retiree’ means an
23 individual who is eligible to obtain qualified pre-
24 scription drug coverage under section 1860D-1
25 but did not elect such coverage under this part

1 (either through a prescription drug plan or
2 through a MA-EFFS Rx plan) but is covered
3 under a qualified retiree prescription drug plan.

4 “(C) SPONSOR.—The term ‘sponsor’
5 means a plan sponsor, as defined in section
6 3(16)(B) of the Employee Retirement Income
7 Security Act of 1974.

8 “(5) CONSTRUCTION.—Nothing in this sub-
9 section shall be construed as—

10 “(A) precluding an individual who is cov-
11 ered under employment-based retiree health
12 coverage from enrolling in a prescription drug
13 plan or in a MA-EFFS plan;

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

20 “(C) preventing such employment-based
21 retiree health coverage from providing coverage
22 for retirees—

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

1 “(ii) who are not covered under a
2 qualified retiree prescription plan but who
3 are enrolled in a prescription drug plan or
4 a MA-EFFS Rx plan, that is supplemental
5 to the benefits provided under such pre-
6 scription drug plan or MA-EFFS Rx plan,
7 except that any such supplemental cov-
8 erage (not including payment of any pre-
9 mium referred to in subparagraph (B))
10 shall be treated as primary coverage to
11 which section 1862(b)(2)(A)(i) is deemed
12 to apply.

13 “(g) COMPUTATION OF NATIONAL AVERAGE MONTH-
14 LY BID AMOUNT.—

15 “(1) IN GENERAL.—For each year (beginning
16 with 2006) the Administrator shall compute a na-
17 tional average monthly bid amount equal to the av-
18 erage of the benchmark bid amounts for each pre-
19 scription drug plan and for each MA-EFFS Rx plan
20 (as computed under paragraph (2), but excluding
21 plans described in section 1851(a)(2)(C))) adjusted
22 under paragraph (4) to take into account reinsur-
23 ance payments.

24 “(2) BENCHMARK BID AMOUNT DEFINED.—For
25 purposes of this subsection, the term ‘benchmark bid

1 amount’ means, with respect to qualified prescrip-
2 tion drug coverage offered under—

3 “(A) a prescription drug plan that—

4 “(i) provides standard coverage (or al-
5 ternative prescription drug coverage the
6 actuarial value of which is equivalent to
7 that of standard coverage), the PDP bid;
8 or

9 “(ii) provides alternative prescription
10 drug coverage the actuarial value of which
11 is greater than that of standard coverage,
12 the PDP bid multiplied by the ratio of (I)
13 the actuarial value of standard coverage, to
14 (II) the actuarial value of the alternative
15 coverage; or

16 “(B) a MA-EFFS Rx plan, the portion of
17 the bid amount that is attributable to statutory
18 drug benefits (described in section
19 1853(a)(1)(A)(ii)(II)).

20 For purposes of subparagraph (A), the term ‘PDP
21 bid’ means, with respect to a prescription drug plan,
22 the bid amount for enrollment under the plan under
23 this part (determined without regard to any low-in-
24 come subsidy under section 1860D–7 or any late en-
25 rollment penalty under section 1860D–1(c)(2)(B)).

1 “(3) WEIGHTED AVERAGE.—

2 “(A) IN GENERAL.—The monthly national
3 average monthly bid amount computed under
4 paragraph (1) shall be a weighted average, with
5 the weight for each plan being equal to the av-
6 erage number of beneficiaries enrolled under
7 such plan in the previous year.

8 “(B) SPECIAL RULE FOR 2006.—For pur-
9 poses of applying this subsection for 2006, the
10 Administrator shall establish procedures for de-
11 termining the weighted average under subpara-
12 graph (A) for 2005.

13 “(4) ADJUSTMENT TO ADD BACK IN VALUE OF
14 REINSURANCE SUBSIDIES.—The adjustment under
15 this paragraph, to take into account reinsurance
16 payments under subsection (c) making up 30 per-
17 cent of total payments, is such an adjustment as will
18 make the national average monthly bid amount rep-
19 resent represent 100 percent, instead of representing
20 70 percent, of average payments under this part.

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

1 **“SEC. 1860D-9. MEDICARE PRESCRIPTION DRUG TRUST**
2 **FUND.**

3 “(a) IN GENERAL.—There is created on the books
4 of the Treasury of the United States a trust fund to be
5 known as the ‘Medicare Prescription Drug Trust Fund’
6 (in this section referred to as the ‘Trust Fund’). The
7 Trust Fund shall consist of such gifts and bequests as
8 may be made as provided in section 201(i)(1), and such
9 amounts as may be deposited in, or appropriated to, such
10 fund as provided in this part. Except as otherwise pro-
11 vided in this section, the provisions of subsections (b)
12 through (i) of section 1841 shall apply to the Trust Fund
13 in the same manner as they apply to the Federal Supple-
14 mentary Medical Insurance Trust Fund under such sec-
15 tion.

16 “(b) PAYMENTS FROM TRUST FUND.—

17 “(1) IN GENERAL.—The Managing Trustee
18 shall pay from time to time from the Trust Fund
19 such amounts as the Administrator certifies are nec-
20 essary to make—

21 “(A) payments under section 1860D-7 (re-
22 lating to low-income subsidy payments);

23 “(B) payments under section 1860D-8 (re-
24 lating to subsidy payments); and

1 “(C) payments with respect to administra-
2 tive expenses under this part in accordance with
3 section 201(g).

4 “(2) TRANSFERS TO MEDICAID ACCOUNT FOR
5 INCREASED ADMINISTRATIVE COSTS.—The Man-
6 aging Trustee shall transfer from time to time from
7 the Trust Fund to the Grants to States for Medicaid
8 account amounts the Administrator certifies are at-
9 tributable to increases in payment resulting from the
10 application of a higher Federal matching percentage
11 under section 1935(b).

12 “(c) DEPOSITS INTO TRUST FUND.—

13 “(1) LOW-INCOME TRANSFER.—There is hereby
14 transferred to the Trust Fund, from amounts appro-
15 priated for Grants to States for Medicaid, amounts
16 equivalent to the aggregate amount of the reductions
17 in payments under section 1903(a)(1) attributable to
18 the application of section 1935(c).

19 “(2) APPROPRIATIONS TO COVER GOVERNMENT
20 CONTRIBUTIONS.—There are authorized to be appro-
21 priated from time to time, out of any moneys in the
22 Treasury not otherwise appropriated, to the Trust
23 Fund, an amount equivalent to the amount of pay-
24 ments made from the Trust Fund under subsection

1 (b), reduced by the amount transferred to the Trust
2 Fund under paragraph (1).

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

8 **“SEC. 1860D-10. DEFINITIONS; APPLICATION TO MEDICARE**
9 **ADVANTAGE AND EFFS PROGRAMS; TREAT-**
10 **MENT OF REFERENCES TO PROVISIONS IN**
11 **PART C.**

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

13 “(1) COVERED OUTPATIENT DRUGS.—The term
14 ‘covered outpatient drugs’ is defined in section
15 1860D-2(f).

16 “(2) INITIAL COVERAGE LIMIT.—The term ‘ini-
17 tial coverage limit’ means such limit as established
18 under section 1860D-2(b)(3), or, in the case of cov-
19 erage that is not standard coverage, the comparable
20 limit (if any) established under the coverage.

21 “(3) MEDICARE PRESCRIPTION DRUG TRUST
22 FUND.—The term ‘Medicare Prescription Drug
23 Trust Fund’ means the Trust Fund created under
24 section 1860D-9(a).

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

5 “(5) PRESCRIPTION DRUG PLAN.—The term
6 ‘prescription drug plan’ means health benefits cov-
7 erage that—

8 “(A) is offered under a policy, contract, or
9 plan by a PDP sponsor pursuant to, and in ac-
10 cordance with, a contract between the Adminis-
11 trator and the sponsor under section 1860D-
12 4(b);

13 “(B) provides qualified prescription drug
14 coverage; and

15 “(C) meets the applicable requirements of
16 the section 1860D-3 for a prescription drug
17 plan.

18 “(6) QUALIFIED PRESCRIPTION DRUG COV-
19 ERAGE.—The term ‘qualified prescription drug cov-
20 erage’ is defined in section 1860D-2(a).

21 “(7) STANDARD COVERAGE.—The term ‘stand-
22 ard coverage’ is defined in section 1860D-2(b).

23 “(8) INSURANCE RISK.—The term ‘insurance
24 risk’ means, with respect to a participating phar-
25 macy, risk of the type commonly assumed only by

1 insurers licensed by a State and does not include
2 payment variations designed to reflect performance-
3 based measures of activities within the control of the
4 pharmacy, such as formulary compliance and generic
5 drug substitution.

6 “(b) OFFER OF QUALIFIED PRESCRIPTION DRUG
7 COVERAGE UNDER MEDICARE ADVANTAGE AND EFFS
8 PROGRAMS.—

9 “(1) AS PART OF MEDICARE ADVANTAGE
10 PLAN.—Medicare Advantage organizations are re-
11 quired to offer Medicare Advantage plans that in-
12 clude qualified prescription drug coverage under part
13 C pursuant to section 1851(j).

14 “(2) AS PART OF EFFS PLAN.—EFFS organi-
15 zations are required to offer EFFS plans that in-
16 clude qualified prescription drug coverage under part
17 E pursuant to section 1860E–2(d).

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

23 “(1) any reference to a Medicare Advantage or
24 other plan included a reference to a prescription
25 drug plan;

1 “(2) any reference to a provider-sponsored or-
2 ganization included a reference to a PDP sponsor;

3 “(3) any reference to a contract under section
4 1857 included a reference to a contract under sec-
5 tion 1860D–4(b); and

6 “(4) any reference to part C included a ref-
7 erence to this part.

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

10 “(1) REVIEW.—Within 6 months after the date
11 of the enactment of this section, the Secretary shall
12 review the current standards of practice for phar-
13 macy services provided to patients in nursing facili-
14 ties and other long-term care facilities.

15 “(2) EVALUATIONS AND RECOMMENDATIONS.—
16 Specifically in the review under paragraph (1), the
17 Secretary shall—

18 “(A) assess the current standards of prac-
19 tice, clinical services, and other service require-
20 ments generally utilized for pharmacy services
21 in the long-term care setting;

22 “(B) evaluate the impact of those stand-
23 ards with respect to patient safety, reduction of
24 medication errors and quality of care; and

1 “(C) recommend (in the Secretary’s report
2 under paragraph (3)) necessary actions and ap-
3 propriate reimbursement to ensure the provision
4 of prescription drugs to medicare beneficiaries
5 residing in nursing facilities and other long-
6 term care facilities in a manner consistent with
7 existing patient safety and quality of care
8 standards under applicable State and Federal
9 laws.

10 “(3) REPORT.—The Secretary shall submit a
11 report to the Congress on the Secretary’s findings
12 and recommendations under this subsection, includ-
13 ing a detailed description of the Secretary’s plans to
14 implement this part in a manner consistent with ap-
15 plicable State and Federal laws designed to protect
16 the safety and quality of care of patients of nursing
17 facilities and other long-term care facilities.”.

18 (b) ADDITIONAL CONFORMING CHANGES.—

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

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

4 (A) by striking “and” at the end of sub-
5 paragraph (E);

6 (B) by striking the period at the end of
7 subparagraph (F) and inserting “; and”; and

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

10 “(G) the waiver or reduction of any cost-shar-
11 ing imposed under part D of title XVIII.”.

12 (3) SUBMISSION OF LEGISLATIVE PROPOSAL.—
13 Not later than 6 months after the date of the enact-
14 ment of this Act, the Secretary of Health and
15 Human Services shall submit to the appropriate
16 committees of Congress a legislative proposal pro-
17 viding for such technical and conforming amend-
18 ments in the law as are required by the provisions
19 of this subtitle.

20 (c) STUDY ON TRANSITIONING PART B PRESCRIP-
21 TION DRUG COVERAGE.—Not later than January 1, 2005,
22 the Medicare Benefits Administrator shall submit a report
23 to Congress that makes recommendations regarding meth-
24 ods for providing benefits under part D of title XVIII of

1 the Social Security Act for outpatient prescription drugs
2 for which benefits are provided under part B of such title.

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

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

10 “(j) **AVAILABILITY OF PRESCRIPTION DRUG BENE-**
11 **FITS AND SUBSIDIES.**—

12 “(1) **OFFERING OF QUALIFIED PRESCRIPTION**
13 **DRUG COVERAGE.**—A Medicare Advantage organiza-
14 tion on and after January 1, 2006—

15 “(A) may not offer a Medicare Advantage
16 plan described in section 1851(a)(2)(A) in an
17 area unless either that plan (or another Medi-
18 care Advantage plan offered by the organization
19 in that area) includes qualified prescription
20 drug coverage; and

21 “(B) may not offer the prescription drug
22 coverage (other than that required under parts
23 A and B) to an enrollee under a Medicare Ad-
24 vantage plan, unless such drug coverage is at
25 least qualified prescription drug coverage and

1 unless the requirements of this subsection with
2 respect to such coverage are met.

3 “(2) REQUIREMENT FOR ELECTION OF PART D
4 COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION
5 DRUG COVERAGE.—For purposes of this part, an in-
6 dividual who has not elected qualified prescription
7 drug coverage under section 1860D–1(b) shall be
8 treated as being ineligible to enroll in a Medicare
9 Advantage plan under this part that offers such cov-
10 erage.

11 “(3) COMPLIANCE WITH CERTAIN ADDITIONAL
12 BENEFICIARY PROTECTIONS FOR PRESCRIPTION
13 DRUG COVERAGE.—With respect to the offering of
14 qualified prescription drug coverage by a Medicare
15 Advantage organization under this part on and after
16 January 1, 2006, the organization and plan shall
17 meet the requirements of subsections (a) through (d)
18 of section 1860D–3 in the same manner as they
19 apply to a PDP sponsor and a prescription drug
20 plan under part D and shall submit to the Adminis-
21 trator the information described in section 1860D–
22 6(a)(2). The Administrator shall waive such require-
23 ments to the extent the Administrator determines
24 that such requirements duplicate requirements oth-

1 erwise applicable to the organization or plan under
2 this part.

3 “(4) AVAILABILITY OF PREMIUM AND COST-
4 SHARING SUBSIDIES.—In the case of low-income in-
5 dividuals who are enrolled in a Medicare Advantage
6 plan that provides qualified prescription drug cov-
7 erage, premium and cost-sharing subsidies are pro-
8 vided for such coverage under section 1860D–7.

9 “(5) AVAILABILITY OF DIRECT AND REINSUR-
10 ANCE SUBSIDIES TO REDUCE BIDS AND PRE-
11 MIUMS.—Medicare Advantage organizations are pro-
12 vided direct and reinsurance subsidy payments for
13 providing qualified prescription drug coverage under
14 this part under section 1860D–8.

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

21 “(7) TRANSITION IN INITIAL ENROLLMENT PE-
22 RIOD.—Notwithstanding any other provision of this
23 part, the annual, coordinated election period under
24 subsection (e)(3)(B) for 2006 shall be the 6-month
25 period beginning with November 2005.

1 “(8) QUALIFIED PRESCRIPTION DRUG COV-
2 ERAGE; STANDARD COVERAGE.—For purposes of
3 this part, the terms ‘qualified prescription drug cov-
4 erage’ and ‘standard coverage’ have the meanings
5 given such terms in section 1860D–2.

6 “(9) SPECIAL RULES FOR PRIVATE FEE-FOR-
7 SERVICE PLANS.—With respect to a Medicare Ad-
8 vantage plan described in section 1851(a)(2)(C) that
9 offers qualified prescription drug coverage—

10 “(A) REQUIREMENTS REGARDING NEGO-
11 TIATED PRICES.—Subsections (a)(1) and (d)(1)
12 of section 1860D–2 shall not be construed to
13 require the plan to negotiate prices or discounts
14 but shall apply to the extent the plan does so.

15 “(B) MODIFICATION OF PHARMACY PAR-
16 TICIPATION REQUIREMENT.—If the plan pro-
17 vides access, without charging additional copay-
18 ments, to all pharmacies without regard to
19 whether they are participating pharmacies in a
20 network, section 1860D-3(e)(1)(A)(iii) shall not
21 apply to the plan.

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

1 “(D) NON-PARTICIPATING PHARMACY DIS-
2 CLOSURE EXCEPTION.—If the plan provides
3 coverage for drugs purchased from all phar-
4 macies, without entering into contracts or
5 agreements with pharmacies to provide drugs to
6 enrollees covered by the plan, section 1860D-
7 3(d)(5) shall not apply to the plan.”.

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

11 “(d) AVAILABILITY OF PRESCRIPTION DRUG BENE-
12 FITS AND SUBSIDIES.—

13 “(1) OFFERING OF QUALIFIED PRESCRIPTION
14 DRUG COVERAGE.—An EFFS organization—

15 “(A) may not offer an EFFS plan in an
16 area unless either that plan (or another EFFS
17 plan offered by the organization in that area)
18 includes qualified prescription drug coverage;
19 and

20 “(B) may not offer the prescription drug
21 coverage (other than that required under parts
22 A and B) to an enrollee under an EFFS plan,
23 unless such drug coverage is at least qualified
24 prescription drug coverage and unless the re-

1 requirements of this subsection with respect to
2 such coverage are met.

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

10 “(3) COMPLIANCE WITH CERTAIN ADDITIONAL
11 BENEFICIARY PROTECTIONS FOR PRESCRIPTION
12 DRUG COVERAGE.—With respect to the offering of
13 qualified prescription drug coverage by an EFFS or-
14 ganization under this part, the organization and
15 plan shall meet the requirements of subsections (a)
16 through (d) of section 1860D–3 in the same manner
17 as they apply to a PDP sponsor and a prescription
18 drug plan under part D and shall submit to the Ad-
19 ministrator the information described in section
20 1860D–6(a)(2). The Administrator shall waive such
21 requirements to the extent the Administrator deter-
22 mines that such requirements duplicate requirements
23 otherwise applicable to the organization or plan
24 under this part.

1 “(4) AVAILABILITY OF PREMIUM AND COST-
2 SHARING SUBSIDIES.—In the case of low-income in-
3 dividuals who are enrolled in an EFFS plan that
4 provides qualified prescription drug coverage, pre-
5 mium and cost-sharing subsidies are provided for
6 such coverage under section 1860D–7.

7 “(5) AVAILABILITY OF DIRECT AND REINSUR-
8 ANCE SUBSIDIES TO REDUCE BIDS AND PRE-
9 MIUMS.—EFFS organizations are provided direct
10 and reinsurance subsidy payments for providing
11 qualified prescription drug coverage under this part
12 under section 1860D–8.

13 “(6) CONSOLIDATION OF DRUG AND NON-DRUG
14 PREMIUMS.—In the case of an EFFS plan that in-
15 cludes qualified prescription drug coverage, with re-
16 spect to an enrollee in such plan there shall be a sin-
17 gle premium for both drug and non-drug coverage
18 provided under the plan.

19 “(7) QUALIFIED PRESCRIPTION DRUG COV-
20 ERAGE; STANDARD COVERAGE.—For purposes of
21 this part, the terms ‘qualified prescription drug cov-
22 erage’ and ‘standard coverage’ have the meanings
23 given such terms in section 1860D–2.”.

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

1 (1) in subsection (a)(1)—

2 (A) by inserting “(other than qualified pre-
3 scription drug benefits)” after “benefits”;

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

6 (C) by adding after and below subpara-
7 graph (B) the following:

8 “and may elect qualified prescription drug coverage
9 in accordance with section 1860D–1.”; and

10 (2) in subsection (g)(1), by inserting “and sec-
11 tion 1860D–1(c)(2)(B)” after “in this subsection”.

12 (d) EFFECTIVE DATE.—The amendments made by
13 this section apply to coverage provided on or after January
14 1, 2006.

15 **SEC. 103. MEDICAID AMENDMENTS.**

16 (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-IN-
17 COME SUBSIDIES.—

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

20 (A) by striking “and” at the end of para-
21 graph (64);

22 (B) by striking the period at the end of
23 paragraph (65) and inserting “; and”; and

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

1 “(66) provide for making eligibility determina-
2 tions under section 1935(a).”.

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

5 (A) by redesignating section 1935 as sec-
6 tion 1936; and

7 (B) by inserting after section 1934 the fol-
8 lowing new section:

9 “SPECIAL PROVISIONS RELATING TO MEDICARE

10 PRESCRIPTION DRUG BENEFIT

11 “SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGI-
12 BILITY DETERMINATIONS FOR LOW-INCOME SUB-
13 SIDIES.—As a condition of its State plan under this title
14 under section 1902(a)(66) and receipt of any Federal fi-
15 nancial assistance under section 1903(a), a State shall—

16 “(1) make determinations of eligibility for pre-
17 mium and cost-sharing subsidies under (and in ac-
18 cordance with) section 1860D-7;

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

22 “(3) otherwise provide such Administrator with
23 such information as may be required to carry out
24 part D of title XVIII (including section 1860D-7).

25 “(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE
26 COSTS.—

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

10 “(A) For expenditures attributable to costs
11 incurred during 2005, the otherwise applicable
12 Federal matching rate shall be increased by 6-
13 $\frac{2}{3}$ percent of the percentage otherwise payable
14 (but for this subsection) by the State.

15 “(B)(i) For expenditures attributable to
16 costs incurred during 2006 and each subse-
17 quent year through 2018, the otherwise applica-
18 ble Federal matching rate shall be increased by
19 the applicable percent (as defined in clause (ii))
20 of the percentage otherwise payable (but for
21 this subsection) by the State.

22 “(ii) For purposes of clause (i), the ‘appli-
23 cable percent’ for—

24 “(I) 2006 is 13- $\frac{1}{3}$ percent; or

1 “(II) a subsequent year is the applica-
2 ble percent under this clause for the pre-
3 vious year increased by $6\frac{2}{3}$ percentage
4 points.

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

9 “(2) COORDINATION.—The State shall provide
10 the Administrator with such information as may be
11 necessary to properly allocate administrative expend-
12 itures described in paragraph (1) that may otherwise
13 be made for similar eligibility determinations.”.

14 (b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID
15 RESPONSIBILITY FOR PREMIUM AND COST-SHARING SUB-
16 SIDIES FOR DUALY ELIGIBLE INDIVIDUALS.—

17 (1) IN GENERAL.—Section 1903(a)(1) (42
18 U.S.C. 1396b(a)(1)) is amended by inserting before
19 the semicolon the following: “, reduced by the
20 amount computed under section 1935(e)(1) for the
21 State and the quarter”.

22 (2) AMOUNT DESCRIBED.—Section 1935, as in-
23 serted by subsection (a)(2), is amended by adding at
24 the end the following new subsection:

1 “(c) FEDERAL ASSUMPTION OF MEDICAID PRE-
2 SCRIPTION DRUG COSTS FOR DUALY-ELIGIBLE BENE-
3 FIICIARIES.—

4 “(1) IN GENERAL.—For purposes of section
5 1903(a)(1), for a State that is one of the 50 States
6 or the District of Columbia for a calendar quarter
7 in a year (beginning with 2005) the amount com-
8 puted under this subsection is equal to the product
9 of the following:

10 “(A) MEDICARE SUBSIDIES.—The total
11 amount of payments made in the quarter under
12 section 1860D–7 (relating to premium and
13 cost-sharing prescription drug subsidies for low-
14 income medicare beneficiaries) that are attrib-
15 utable to individuals who are residents of the
16 State and are entitled to benefits with respect
17 to prescribed drugs under the State plan under
18 this title (including such a plan operating under
19 a waiver under section 1115).

20 “(B) STATE MATCHING RATE.—A propor-
21 tion computed by subtracting from 100 percent
22 the Federal medical assistance percentage (as
23 defined in section 1905(b)) applicable to the
24 State and the quarter.

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

4 “(2) PHASE-OUT PROPORTION.—For purposes
5 of paragraph (1)(C), the ‘phase-out proportion’ for
6 a calendar quarter in—

7 “(A) 2006 is 93- $\frac{1}{3}$ percent;

8 “(B) a subsequent year before 2021, is the
9 phase-out proportion for calendar quarters in
10 the previous year decreased by 6- $\frac{2}{3}$ percentage
11 points; or

12 “(C) a year after 2020 is 0 percent.”.

13 (c) MEDICAID PROVIDING WRAP-AROUND BENE-
14 FITS.—Section 1935, as so inserted and amended, is fur-
15 ther amended by adding at the end the following new sub-
16 section:

17 “(d) ADDITIONAL PROVISIONS.—

18 “(1) MEDICAID AS SECONDARY PAYOR.—In the
19 case of an individual who is entitled to qualified pre-
20 scription drug coverage under a prescription drug
21 plan under part D of title XVIII (or under a MA-
22 EFFS Rx plan under part C or E of such title) and
23 medical assistance for prescribed drugs under this
24 title, medical assistance shall continue to be provided
25 under this title (other than for copayment amounts

1 specified in section 1860D–7(a)(1)(B), notwith-
2 standing section 1916) for prescribed drugs to the
3 extent payment is not made under the prescription
4 drug plan or MA-EFFS Rx plan selected by the in-
5 dividual.

6 “(2) CONDITION.—A State may require, as a
7 condition for the receipt of medical assistance under
8 this title with respect to prescription drug benefits
9 for an individual eligible to obtain qualified prescrip-
10 tion drug coverage described in paragraph (1), that
11 the individual elect qualified prescription drug cov-
12 erage under section 1860D–1.”.

13 (d) TREATMENT OF TERRITORIES.—

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

16 (A) in subsection (a) in the matter pre-
17 ceding paragraph (1), by inserting “subject to
18 subsection (e)” after “section 1903(a)”;

19 (B) in subsection (c)(1), by inserting “sub-
20 ject to subsection (e)” after “1903(a)(1)”; and

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

23 “(e) TREATMENT OF TERRITORIES.—

1 “(1) IN GENERAL.—In the case of a State,
2 other than the 50 States and the District of Colum-
3 bia—

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

6 “(B) if the State establishes a plan de-
7 scribed in paragraph (2) (for providing medical
8 assistance with respect to the provision of pre-
9 scription drugs to medicare beneficiaries), the
10 amount otherwise determined under section
11 1108(f) (as increased under section 1108(g))
12 for the State shall be increased by the amount
13 specified in paragraph (3).

14 “(2) PLAN.—The plan described in this para-
15 graph is a plan that—

16 “(A) provides medical assistance with re-
17 spect to the provision of covered outpatient
18 drugs (as defined in section 1860D–2(f)) to
19 low-income medicare beneficiaries; and

20 “(B) assures that additional amounts re-
21 ceived by the State that are attributable to the
22 operation of this subsection are used only for
23 such assistance.

24 “(3) INCREASED AMOUNT.—

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

4 “(i) the aggregate amount specified in
5 subparagraph (B); and

6 “(ii) the amount specified in section
7 1108(g)(1) for that State, divided by the
8 sum of the amounts specified in such sec-
9 tion for all such States.

10 “(B) AGGREGATE AMOUNT.—The aggre-
11 gate amount specified in this subparagraph
12 for—

13 “(i) 2006, is equal to \$25,000,000; or

14 “(ii) a subsequent year, is equal to the
15 aggregate amount specified in this sub-
16 paragraph for the previous year increased
17 by annual percentage increase specified in
18 section 1860D–2(b)(5) for the year in-
19 volved.

20 “(4) REPORT.—The Administrator shall submit
21 to Congress a report on the application of this sub-
22 section and may include in the report such rec-
23 ommendations as the Administrator deems appro-
24 priate.”.

1 (2) CONFORMING AMENDMENT.—Section
2 1108(f) (42 U.S.C. 1308(f)) is amended by inserting
3 “and section 1935(e)(1)(B)” after “Subject to sub-
4 section (g)”.

5 (e) AMENDMENT TO BEST PRICE.—Section
6 1927(e)(1)(C)(i) (42 U.S.C. 1396r-8(e)(1)(C)(i)) is
7 amended—

8 (1) by striking “and” at the end of subclause
9 (III);

10 (2) by striking the period at the end of sub-
11 clause (IV) and inserting “; and”; and

12 (3) by adding at the end the following new sub-
13 clause:

14 “(V) any prices charged which
15 are negotiated by a prescription drug
16 plan under part D of title XVIII, by
17 a MA-EFFS Rx plan under part C or
18 E of such title with respect to covered
19 outpatient drugs, or by a qualified re-
20 tiree prescription drug plan (as de-
21 fined in section 1860D-8(f)(1)) with
22 respect to such drugs on behalf of in-
23 dividuals entitled to benefits under
24 part A or enrolled under part B of
25 such title.”.

1 **SEC. 104. MEDIGAP TRANSITION.**

2 (a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss)
3 is amended by adding at the end the following new sub-
4 section:

5 “(v) COVERAGE OF PRESCRIPTION DRUGS.—

6 “(1) IN GENERAL.—Notwithstanding any other
7 provision of law, except as provided in paragraph (3)
8 no new medicare supplemental policy that provides
9 coverage of expenses for prescription drugs may be
10 issued under this section on or after January 1,
11 2006, to an individual unless it replaces a medicare
12 supplemental policy that was issued to that indi-
13 vidual and that provided some coverage of expenses
14 for prescription drugs. Nothing in this subsection
15 shall be construed as preventing the policy holder of
16 a medicare supplemental policy issued before Janu-
17 ary 1, 2006, from continuing to receive benefits
18 under such policy on and after such date.

19 “(2) ISSUANCE OF SUBSTITUTE POLICIES FOR
20 BENEFICIARIES ENROLLED WITH A PLAN UNDER
21 PART D.—

22 “(A) IN GENERAL.—The issuer of a medi-
23 care supplemental policy—

24 “(i) may not deny or condition the
25 issuance or effectiveness of a medicare
26 supplemental policy that has a benefit

1 package classified as ‘A’, ‘B’, ‘C’, ‘D’, ‘E’,
2 ‘F’, or ‘G’ (under the standards estab-
3 lished under subsection (p)(2)) and that is
4 offered and is available for issuance to new
5 enrollees by such issuer;

6 “(ii) may not discriminate in the pric-
7 ing of such policy, because of health sta-
8 tus, claims experience, receipt of health
9 care, or medical condition; and

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

13 in the case of an individual described in sub-
14 paragraph (B) who seeks to enroll under the
15 policy not later than 63 days after the date of
16 the termination of enrollment described in such
17 paragraph and who submits evidence of the
18 date of termination or disenrollment along with
19 the application for such medicare supplemental
20 policy.

21 “(B) INDIVIDUAL COVERED.—An indi-
22 vidual described in this subparagraph is an in-
23 dividual who—

24 “(i) enrolls in a prescription drug plan
25 under part D; and

1 “(ii) at the time of such enrollment
2 was enrolled and terminates enrollment in
3 a medicare supplemental policy which has
4 a benefit package classified as ‘H’, ‘I’, or
5 ‘J’ under the standards referred to in sub-
6 paragraph (A)(i) or terminates enrollment
7 in a policy to which such standards do not
8 apply but which provides benefits for pre-
9 scription drugs.

10 “(C) ENFORCEMENT.—The provisions of
11 paragraph (4) of subsection (s) shall apply with
12 respect to the requirements of this paragraph in
13 the same manner as they apply to the require-
14 ments of such subsection.

15 “(3) NEW STANDARDS.—In applying subsection
16 (p)(1)(E) (including permitting the NAIC to revise
17 its model regulations in response to changes in law)
18 with respect to the change in benefits resulting from
19 title I of the Medicare Prescription Drug and Mod-
20 ernization Act of 2003, with respect to policies
21 issued to individuals who are enrolled in a plan
22 under part D, the changes in standards shall only
23 provide for substituting (for the benefit packages de-
24 scribed in paragraph (2)(B)(ii) that included cov-
25 erage for prescription drugs) two benefit packages

1 that may provide for coverage of cost-sharing (other
2 than the prescription drug deductible) with respect
3 to qualified prescription drug coverage under such
4 part. The two benefit packages shall be consistent
5 with the following:

6 “(A) FIRST NEW POLICY.—The policy de-
7 scribed in this subparagraph has the following
8 benefits, notwithstanding any other provision of
9 this section relating to a core benefit package:

10 “(i) Coverage of 50 percent of the
11 cost-sharing otherwise applicable under
12 parts A and B, except coverage of 100 per-
13 cent of any cost-sharing otherwise applica-
14 ble for preventive benefits.

15 “(ii) No coverage of the part B de-
16 ductible.

17 “(iii) Coverage for all hospital coin-
18 surance for long stays (as in the current
19 core benefit package).

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

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

5 “(i) Substitute ‘75 percent’ for ‘50
6 percent’ in clause (i) of such subpara-
7 graph.

8 “(ii) Substitute ‘\$2,000’ for ‘\$4,000’
9 in clause (iv) of such subparagraph.

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

15 (b) NAIC REPORT TO CONGRESS ON MEDIGAP MOD-
16 ERNIZATION.—The Secretary shall request the National
17 Association of Insurance Commissioners to submit to Con-
18 gress, not later than 18 months after the date of the en-
19 actment of this Act, a report that includes recommenda-
20 tions on the modernization of coverage under the medigap
21 program under section 1882 of the Social Security Act (42
22 U.S.C. 1395ss).

1 **SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT**
 2 **CARD AND ASSISTANCE PROGRAM.**

3 (a) IN GENERAL.—Title XVIII is amended by insert-
 4 ing after section 1806 the following new sections:

5 “MEDICARE PRESCRIPTION DRUG DISCOUNT CARD
 6 ENDORSEMENT AND ASSISTANCE PROGRAM

7 “SEC. 1807. (a) ESTABLISHMENT OF PROGRAM.—

8 “(1) IN GENERAL.—The Secretary shall estab-
 9 lish a program—

10 “(A) to endorse prescription drug discount
 11 card programs (each such program referred to
 12 as an ‘endorsed program’) that meet the re-
 13 quirements of this section in order to provide
 14 access to prescription drug discounts through
 15 eligible entities for medicare beneficiaries
 16 throughout the United States; and

17 “(B) to provide for prescription drug ac-
 18 counts and public contributions into such ac-
 19 counts.

20 The Secretary shall make available to medicare
 21 beneficiaries information regarding endorsed pro-
 22 grams and accounts under this section.

23 “(2) LIMITED PERIOD OF OPERATION.—The
 24 Secretary shall begin—

25 “(A) the card endorsement part of the pro-
 26 gram under paragraph (1)(A) as soon as pos-

1 sible, but in no case later than 90 days after
2 the date of the enactment of this section; and

3 “(B) the prescription drug account part of
4 the program under paragraph (1)(B) as soon as
5 possible, but in no case later than September
6 2004.

7 “(3) TRANSITION.—The program under this
8 section shall continue through 2005 throughout the
9 United States. The Secretary shall provide for an
10 appropriate transition and termination of such pro-
11 gram on January 1, 2006.

12 “(4) VOLUNTARY NATURE OF PROGRAM.—
13 Nothing in this section shall be construed as requir-
14 ing an eligible beneficiary to enroll in the program
15 under this section.

16 “(b) ELIGIBLE BENEFICIARY; ELIGIBLE ENTITY;
17 PRESCRIPTION DRUG ACCOUNT.—For purposes of this
18 section:

19 “(1) ELIGIBLE BENEFICIARY.—The term ‘eligi-
20 ble beneficiary’ means an individual who is eligible
21 for benefits under part A or enrolled under part B
22 and who is not enrolled in a Medicare Advantage
23 plan that offers qualified prescription drug coverage.

24 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-
25 tity’ means any entity that the Secretary determines

1 to be appropriate to provide the benefits under this
2 section, including—

3 “(A) pharmaceutical benefit management
4 companies;

5 “(B) wholesale and retail pharmacy deliv-
6 ery systems;

7 “(C) insurers;

8 “(D) Medicare Advantage organizations;

9 “(E) other entities; or

10 “(F) any combination of the entities de-
11 scribed in subparagraphs (A) through (E).

12 “(3) PRESCRIPTION DRUG ACCOUNT.—The
13 term ‘prescription drug account’ means, with respect
14 to an eligible beneficiary, an account established for
15 the benefit of that beneficiary under section 1807A.

16 “(c) ENROLLMENT IN ENDORSED PLAN.—

17 “(1) ESTABLISHMENT OF PROCESS.—

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

22 “(B) REQUIREMENT OF ENROLLMENT.—
23 An eligible beneficiary must enroll under this
24 section for a year in order to be eligible to re-

1 ceive the benefits under this section for that
2 year.

3 “(C) LIMITATION ON ENROLLMENT.—

4 “(i) IN GENERAL.—Except as pro-
5 vided under this subparagraph and under
6 such exceptional circumstances as the Sec-
7 retary may provide, an eligible individual
8 shall have the opportunity to enroll under
9 this section during an initial, general en-
10 rollment period as soon as possible after
11 the date of the enactment of this section
12 and annually thereafter. The Secretary
13 shall specify the form, manner, and timing
14 of such election but shall permit the exer-
15 cise of such election at the time the indi-
16 vidual is eligible to enroll. The annual open
17 enrollment periods shall be coordinated
18 with those provided under the Medicare
19 Advantage program under part C.

20 “(ii) REELECTION AFTER TERMI-
21 NATION OF ENROLLMENT IN A MEDICARE
22 ADVANTAGE PLAN.—In the case of an indi-
23 vidual who is enrolled under this section
24 and who subsequently enrolls in a Medi-
25 care Advantage plan that provides quali-

1 fied prescription drug coverage under part
2 C, the individual shall be given the oppor-
3 tunity to reenroll under this section at the
4 time the individual discontinues the enroll-
5 ment under such part.

6 “(iii) LATE ENROLLMENT.—The Sec-
7 retary shall permit individuals to elect to
8 enroll under this section at times other
9 than as permitted under the previous pro-
10 visions of this paragraph.

11 “(D) TERMINATION OF ENROLLMENT.—
12 An enrollee under this section shall be
13 disenrolled—

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

17 “(ii) upon failure to pay the applicable
18 enrollment fee under subsection (f);

19 “(iii) upon termination of coverage
20 under part A or part B; or

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

1 Terminations of enrollment under this subpara-
2 graph shall be effective as specified by the Sec-
3 retary in regulations.

4 “(2) ENROLLMENT PERIODS.—

5 “(A) IN GENERAL.—Except as provided
6 under this paragraph, an eligible beneficiary
7 may not enroll in the program under this part
8 during any period after the beneficiary’s initial
9 enrollment period under part B (as determined
10 under section 1837).

11 “(B) OPEN ENROLLMENT PERIOD FOR
12 CURRENT BENEFICIARIES.—The Secretary shall
13 establish a period, which shall begin on the date
14 on which the Secretary first begins to accept
15 elections for enrollment under this section and
16 shall end not earlier than 3 months later, dur-
17 ing which any eligible beneficiary may enroll
18 under this section.

19 “(C) SPECIAL ENROLLMENT PERIOD IN
20 CASE OF TERMINATION OF COVERAGE UNDER A
21 GROUP HEALTH PLAN.—The Secretary shall
22 provide for a special enrollment period under
23 this section in the same manner as is provided
24 under section 1837(i) with respect to part B,
25 except that for purposes of this subparagraph

1 any reference to ‘by reason of the individual’s
2 (or the individual’s spouse’s) current employ-
3 ment status’ shall be treated as being deleted.

4 “(3) PERIOD OF COVERAGE.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (B) and subject to subparagraph
7 (C), an eligible beneficiary’s coverage under the
8 program under this section shall be effective for
9 the period provided under section 1838, as if
10 that section applied to the program under this
11 section.

12 “(B) ENROLLMENT DURING OPEN AND
13 SPECIAL ENROLLMENT.—Subject to subpara-
14 graph (C), an eligible beneficiary who enrolls
15 under the program under this section under
16 subparagraph (B) or (C) of paragraph (2) shall
17 be entitled to the benefits under this section be-
18 ginning on the first day of the month following
19 the month in which such enrollment occurs.

20 “(d) SELECTION OF AN ELIGIBLE ENTITY FOR AC-
21 CESS TO NEGOTIATED PRICES.—

22 “(1) PROCESS.—

23 “(A) IN GENERAL.—The Secretary shall
24 establish a process through which an eligible
25 beneficiary who is enrolled under this section

1 shall select any eligible entity, that has been
2 awarded a contract under this section and
3 serves the State in which the beneficiary re-
4 sides, to provide access to negotiated prices
5 under subsection (i).

6 “(B) RULES.—In establishing the process
7 under subparagraph (A), the Secretary shall
8 use rules similar to the rules for enrollment and
9 disenrollment with a Medicare Advantage plan
10 under section 1851 (including the special elec-
11 tion periods under subsection (e)(4) of such sec-
12 tion), including that—

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

15 “(ii) an individual shall only be per-
16 mitted (except for unusual circumstances)
17 to change the selection of the entity once
18 a year.

19 In carrying out clause (ii), the Secretary may
20 consider a change in residential setting (such as
21 placement in a nursing facility) to be an un-
22 usual circumstance.

23 “(C) DEFAULT SELECTION.—In estab-
24 lishing such process, the Secretary shall provide
25 an equitable method for selecting an eligible en-

1 tity for individuals who enroll under this section
2 and fail to make such a selection.

3 “(2) COMPETITION.—Eligible entities with a
4 contract under this section shall compete for bene-
5 ficiaries on the basis of discounts, formularies, phar-
6 macy networks, and other services provided for
7 under the contract.

8 “(e) PROVIDING ENROLLMENT, SELECTION, AND
9 COVERAGE INFORMATION TO BENEFICIARIES.—

10 “(1) ACTIVITIES.—The Secretary shall provide
11 for activities under this section to broadly dissemi-
12 nate information to eligible beneficiaries (and pro-
13 spective eligible beneficiaries) regarding enrollment
14 under this section, the selection of eligible entities,
15 and the prescription drug coverage made available
16 by eligible entities with a contract under this section.

17 “(2) SPECIAL RULE FOR FIRST ENROLLMENT
18 UNDER THE PROGRAM.—To the extent practicable,
19 the activities described in paragraph (1) shall ensure
20 that eligible beneficiaries are provided with such in-
21 formation at least 60 days prior to the first enroll-
22 ment period described in subsection (c).

23 “(f) ENROLLMENT FEE.—

24 “(1) AMOUNT.—Except as provided in para-
25 graph (3), enrollment under the program under this

1 section is conditioned upon payment of an annual
2 enrollment fee of \$30. Such fee for 2004 shall in-
3 clude any portion of 2003 in which the program is
4 implemented under this section.

5 “(2) COLLECTION OF ENROLLMENT FEE.—The
6 annual enrollment fee shall be collected and credited
7 to the Federal Supplementary Medical Insurance
8 Trust Fund in the same manner as the monthly pre-
9 mium determined under section 1839 is collected
10 and credited to such Trust Fund under section
11 1840, except that it shall be collected only 1 time
12 per year.

13 “(3) PAYMENT OF ENROLLMENT FEE BY STATE
14 FOR CERTAIN BENEFICIARIES.—

15 “(A) IN GENERAL.—The Secretary shall
16 establish an arrangement under which a State
17 may provide for payment of some or all of the
18 enrollment fee for some or all low income en-
19 rollees in the State, as specified by the State
20 under the arrangement. Insofar as such a pay-
21 ment arrangement is made with respect to an
22 enrollee, the amount of the enrollment fee shall
23 be paid directly by the State and shall not be
24 collected under paragraph (2). In carrying out
25 this paragraph, the Secretary may apply proce-

1 dures similar to that applied under state agree-
2 ments under section 1843.

3 “(B) NO FEDERAL MATCHING AVAILABLE
4 UNDER MEDICAID OR SCHIP.—Expenditures
5 made by a State described in subparagraph (A)
6 shall not be treated as State expenditures for
7 purposes of Federal matching payments under
8 titles XIX and XXI insofar as such expendi-
9 tures are for an enrollment fee under this sub-
10 section.

11 “(4) DISTRIBUTION OF PORTION OF ENROLL-
12 MENT FEE.—Of the enrollment fee collected by the
13 Secretary under this subsection with respect to a
14 beneficiary, $\frac{2}{3}$ of that fee shall be made available to
15 the eligible entity selected by the eligible beneficiary.

16 “(g) ISSUANCE OF CARD AND COORDINATION.—
17 Each eligible entity shall—

18 “(1) issue, in a uniform standard format
19 specified by the Secretary, to each enrolled ben-
20 eficiary a card and an enrollment number that
21 establishes proof of enrollment and that can be
22 used in a coordinated manner—

23 “(A) to identify the eligible entity selected
24 to provide access to negotiated prices under
25 subsection (i); and

1 “(B) to make deposits to and withdrawals
2 from a prescription drug account under section
3 1807A; and

4 “(2) provide for electronic methods to coordi-
5 nate with the accounts established under section
6 1807A.

7 “(h) ENROLLEE PROTECTIONS.—

8 “(1) GUARANTEED ISSUE AND NONDISCRIMINA-
9 TION.—

10 “(A) GUARANTEED ISSUE.—

11 “(i) IN GENERAL.—An eligible bene-
12 ficiary who is eligible to select an eligible
13 entity under subsection (b) for prescription
14 drug coverage under this section at a time
15 during which selections are accepted under
16 this section with respect to the coverage
17 shall not be denied selection based on any
18 health status-related factor (described in
19 section 2702(a)(1) of the Public Health
20 Service Act) or any other factor and may
21 not be charged any selection or other fee
22 as a condition of such acceptance.

23 “(ii) MEDICARE ADVANTAGE LIMITA-
24 TIONS PERMITTED.—The provisions of
25 paragraphs (2) and (3) (other than sub-

1 paragraph (C)(i), relating to default enroll-
2 ment) of section 1851(g) (relating to pri-
3 ority and limitation on termination of elec-
4 tion) shall apply to selection of eligible en-
5 tities under this paragraph.

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

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

15 “(2) DISSEMINATION OF INFORMATION.—

16 “(A) GENERAL INFORMATION.—An eligible
17 entity with a contract under this section shall
18 disclose, in a clear, accurate, and standardized
19 form to each eligible beneficiary who has se-
20 lected the entity to provide access to negotiated
21 prices under this section at the time of selection
22 and at least annually thereafter, the informa-
23 tion described in section 1852(c)(1) relating to
24 such prescription drug coverage. Such informa-
25 tion includes the following (in a manner de-

1 signed to permit and promote competition
2 among eligible entities):

3 “(i) Summary information regarding
4 negotiated prices (including discounts) for
5 covered outpatient drugs.

6 “(ii) Access to such prices through
7 pharmacy networks.

8 “(iii) How any formulary used by the
9 eligible entity functions.

10 “(B) DISCLOSURE UPON REQUEST OF
11 GENERAL COVERAGE, UTILIZATION, AND GRIEV-
12 ANCE INFORMATION.—Upon request of an eligi-
13 ble beneficiary, the eligible entity shall provide
14 the information described in section 1852(e)(2)
15 (other than subparagraph (D)) to such bene-
16 ficiary.

17 “(C) RESPONSE TO BENEFICIARY QUES-
18 TIONS.—Each eligible entity offering prescrip-
19 tion drug coverage under this section shall have
20 a mechanism (including a toll-free telephone
21 number) for providing upon request specific in-
22 formation (such as negotiated prices, including
23 discounts) to individuals who have selected the
24 entity. The entity shall make available, through
25 an Internet website and in writing upon re-

1 quest, information on specific changes in its
2 formulary.

3 “(D) COORDINATION WITH PRESCRIPTION
4 DRUG ACCOUNT BENEFITS.—Each such eligible
5 entity shall provide for coordination of such in-
6 formation as the Secretary may specify to carry
7 out section 1807A.

8 “(3) ACCESS TO COVERED BENEFITS.—

9 “(A) ENSURING PHARMACY ACCESS.—The
10 provisions of subsection (c)(1) of section
11 1860D–3 (other than payment provisions under
12 section 1860D–8 with respect to sponsors under
13 such subsection) shall apply to an eligible entity
14 under this section in the same manner as they
15 apply to a PDP sponsor under such section.

16 “(B) ACCESS TO NEGOTIATED PRICES FOR
17 PRESCRIPTION DRUGS.—For requirements re-
18 lating to the access of an eligible beneficiary to
19 negotiated prices (including applicable dis-
20 counts), see subsection (i).

21 “(C) REQUIREMENTS ON DEVELOPMENT
22 AND APPLICATION OF FORMULARIES.—Insofar
23 as an eligible entity with a contract under this
24 part uses a formulary, the entity shall comply
25 with the requirements of section 1860D–

1 3(e)(3), insofar as the Secretary determines
2 that such requirements can be implemented on
3 a timely basis.

4 “(4) COST AND UTILIZATION MANAGEMENT;
5 QUALITY ASSURANCE; MEDICATION THERAPY MAN-
6 AGEMENT PROGRAM.—

7 “(A) IN GENERAL.—For purposes of pro-
8 viding access to negotiated benefits under sub-
9 section (i), the eligible entity shall have in place
10 the programs and measure described in section
11 1860D–3(d), including an effective cost and
12 drug utilization management program, quality
13 assurance measures and systems, and a pro-
14 gram to control fraud, abuse, and waste, inso-
15 far as the Secretary determines that such provi-
16 sions can be implemented on a timely basis.

17 “(B) TREATMENT OF ACCREDITATION.—
18 Section 1852(e)(4) (relating to treatment of ac-
19 creditation) shall apply to the requirements for
20 an endorsed program under this section with
21 respect to the following requirements, in the
22 same manner as they apply to Medicare Advan-
23 tage plans under part C with respect to the re-
24 quirements described in a clause of section
25 1852(e)(4)(B):

1 “(i) Paragraph (3)(A) (relating to ac-
2 cess to covered benefits).

3 “(ii) Paragraph (7) (relating to con-
4 fidentiality and accuracy of enrollee
5 records).

6 “(5) GRIEVANCE MECHANISM.—Each eligible
7 entity shall provide meaningful procedures for hear-
8 ing and resolving grievances between the organiza-
9 tion consistent with the requirements of section
10 1860D–3(e) insofar as they relate to PDP sponsors
11 of prescription drug plans.

12 “(6) BENEFICIARY SERVICES.—An eligible enti-
13 ty shall provide for its enrollees pharmaceutical sup-
14 port services, such as education and counseling, and
15 services to prevent adverse drug interactions.

16 “(7) COVERAGE DETERMINATIONS AND RECON-
17 SIDERATIONS.—An eligible entity shall meet the re-
18 quirements of paragraphs (1) through (3) of section
19 1852(g) with respect to covered benefits under the
20 prescription drug coverage it offers under this sec-
21 tion in the same manner as such requirements apply
22 to a Medicare Advantage organization with respect
23 to benefits it offers under a Medicare Advantage
24 plan under part C.

1 “(8) CONFIDENTIALITY AND ACCURACY OF EN-
2 ROLLEE RECORDS.—An eligible entity shall meet the
3 requirements of section 1852(h) with respect to en-
4 rollees under this section in the same manner as
5 such requirements apply to a Medicare Advantage
6 organization with respect to enrollees under part C.
7 The eligible entity shall implement policies and pro-
8 cedures to safeguard the use and disclosure of en-
9 rollees’ individually identifiable health information in
10 a manner consistent with the Federal regulations
11 (concerning the privacy of individually identifiable
12 health information) promulgated under section
13 264(c) of the Health Insurance Portability and Ac-
14 countability Act of 1996. The eligible entity shall be
15 treated as a covered entity for purposes of the provi-
16 sions of subpart E of part 164 of title 45, Code of
17 Federal Regulations, adopted pursuant to the au-
18 thority of the Secretary under section 264(c) of the
19 Health Insurance Portability and Accountability Act
20 of 1996 (42 U.S. C. 1320d-2 note).

21 “(9) PERIODIC REPORTS AND OVERSIGHT.—
22 The eligible entity shall submit to the Secretary peri-
23 odic reports on performance, utilization, finances,
24 and such other matters as the Secretary may speci-
25 fy. The Secretary shall provide appropriate oversight

1 to ensure compliance of eligible entities with the re-
2 quirements of this subsection, including verification
3 of the discounts and services provided.

4 “(10) ADDITIONAL BENEFICIARY PROTEC-
5 TIONS.—The eligible entity meets such additional re-
6 quirements as the Secretary identifies to protect and
7 promote the interest of enrollees, including require-
8 ments that ensure that enrollees are not charged
9 more than the lower of the negotiated retail price or
10 the usual and customary price.

11 “(i) BENEFITS UNDER THE PROGRAM THROUGH
12 SAVINGS TO ENROLLEES THROUGH NEGOTIATED
13 PRICES.—

14 “(1) IN GENERAL.—Subject to paragraph (2),
15 each eligible entity with a contract under this section
16 shall provide each eligible beneficiary enrolled with
17 the entity with access to negotiated prices (including
18 applicable discounts). For purposes of this para-
19 graph, the term ‘prescription drugs’ is not limited to
20 covered outpatient drugs, but does not include any
21 over-the-counter drug that is not a covered out-
22 patient drug. The prices negotiated by an eligible en-
23 tity under this paragraph shall (notwithstanding any
24 other provision of law) not be taken into account for

1 the purposes of establishing the best price under sec-
2 tion 1927(c)(1)(C).

3 “(2) FORMULARY RESTRICTIONS.—Insofar as
4 an eligible entity with a contract under this part
5 uses a formulary, the negotiated prices (including
6 applicable discounts) for prescription drugs shall
7 only be available for drugs included in such for-
8 mulary.

9 “(3) PROHIBITION ON APPLICATION ONLY TO
10 MAIL ORDER.—The negotiated prices under this sub-
11 section shall apply to prescription drugs that are
12 available other than solely through mail order.

13 “(4) PROHIBITION ON CHARGES FOR REQUIRED
14 SERVICES.—An eligible entity (and any pharmacy
15 contracting with such entity for the provision of a
16 discount under this section) may not charge a bene-
17 ficiary any amount for any services required to be
18 provided by the entity under this section.

19 “(5) DISCLOSURE.—The eligible entity offering
20 the endorsed program shall disclose to the Secretary
21 (in a manner specified by the Secretary) the extent
22 to which discounts or rebates or other remuneration
23 or price concessions made available to the entity by
24 a manufacturer are passed through to enrollees
25 through pharmacies and other dispensers or other-

1 wise. The provisions of section 1927(b)(3)(D) shall
2 apply to information disclosed to the Secretary
3 under this paragraph in the same manner as such
4 provisions apply to information disclosed under such
5 section.

6 “(6) PUBLIC DISCLOSURE OF PHARMACEUTICAL
7 PRICES FOR EQUIVALENT DRUGS.—Each eligible en-
8 tity shall provide that each pharmacy or other dis-
9 penser that arranges for the dispensing of a covered
10 outpatient drug in connection with its endorsed pro-
11 gram shall inform the enrollee in that program at
12 the time of purchase of the drug of any differential
13 between the price of the prescribed drug to the en-
14 rollee and the price of the lowest cost available ge-
15 neric drug covered under the program that is thera-
16apeutically equivalent and bioequivalent.

17 “(j) CONTRIBUTION INTO PRESCRIPTION DRUG AC-
18 COUNT.—

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

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

23 “(B) subject to paragraph (5), deposit into
24 such account on a monthly or other periodic
25 basis an amount that, on an annual basis, is

1 equivalent to the annual Federal contribution
2 amount specified in paragraph (2) for the en-
3 rollee involved.

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

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

10 “(B) more than 135 percent, but not more
11 than 150 percent, of the poverty line, the an-
12 nual Federal contribution amount for a year is
13 \$500; or

14 “(C) more than 150 percent of the poverty
15 line, the annual Federal contribution amount
16 for a year is \$100.

17 “(3) INCOME ELIGIBILITY DETERMINATIONS.—

18 The determination of whether an individual residing
19 in a State is eligible for a contribution under para-
20 graph (1) shall be determined under the State med-
21 icaid plan for the State under section 1935(a) or by
22 the Social Security Administration. In the case of a
23 State that does not operate such a medicaid plan
24 (either under title XIX or under a statewide waiver
25 granted under section 1115), such determination

1 shall be made under arrangements made by the Sec-
2 retary. There are authorized to be appropriated to
3 the Social Security Administration such sums as
4 may be necessary for the determination of eligibility
5 under this paragraph.

6 “(4) PARTIAL YEAR.—Insofar as the provisions
7 of this subsection and section 1807A are not imple-
8 mented for all months in 2004, the annual contribu-
9 tion amount under this subsection for 2004 shall be
10 prorated to reflect the portion of that year in which
11 such provisions are in effect.

12 “(5) RESTRICTION ON CONTRIBUTIONS.—There
13 shall only be an annual Federal contribution under
14 paragraph (1) for an individual if the individual is
15 not eligible for coverage of, or assistance for, out-
16 patient prescription drugs under any of the fol-
17 lowing:

18 “(A) A medicaid plan under title XIX (in-
19 cluding under any waiver approved under sec-
20 tion 1115).

21 “(B) Enrollment under a group health
22 plan or health insurance coverage.

23 “(C) Enrollment under a medicare supple-
24 mental insurance policy.

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

4 “(E) Chapter 17 of title 38, United States
5 Code (relating to Veterans’ medical care).

6 “(F) Enrollment under a plan under chap-
7 ter 89 of title 5, United States Code (relating
8 to the Federal employees’ health benefits pro-
9 gram).

10 “(G) The Indian Health Care Improve-
11 ment Act (25 U.S.C. 1601 et seq.).

12 “(6) APPROPRIATION TO COVER NET PROGRAM
13 EXPENDITURES.—There are authorized to be appro-
14 priated from time to time, out of any moneys in the
15 Treasury not otherwise appropriated, to the Federal
16 Supplementary Medical Insurance Trust Fund es-
17 tablished under section 1841, an amount equal to
18 the amount by which the benefits and administrative
19 costs of providing the benefits under this section ex-
20 ceed the sum of the portion of the enrollment fees
21 retained by the Secretary.

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

23 “(1) COVERED OUTPATIENT DRUG.—

1 “(A) IN GENERAL.—Except as provided in
2 this paragraph, for purposes of this section, the
3 term ‘covered outpatient drug’ means—

4 “(i) a drug that may be dispensed
5 only upon a prescription and that is de-
6 scribed in subparagraph (A)(i) or (A)(ii) of
7 section 1927(k)(2); or

8 “(ii) a biological product described in
9 clauses (i) through (iii) of subparagraph
10 (B) of such section or insulin described in
11 subparagraph (C) of such section and med-
12 ical supplies associated with the injection
13 of insulin (as defined in regulations of the
14 Secretary),

15 and such term includes a vaccine licensed under
16 section 351 of the Public Health Service Act
17 and any use of a covered outpatient drug for a
18 medically accepted indication (as defined in sec-
19 tion 1927(k)(6)).

20 “(B) EXCLUSIONS.—

21 “(i) IN GENERAL.—Such term does
22 not include drugs or classes of drugs, or
23 their medical uses, which may be excluded
24 from coverage or otherwise restricted
25 under section 1927(d)(2), other than sub-

1 paragraph (E) thereof (relating to smoking
2 cessation agents), or under section
3 1927(d)(3).

4 “(ii) AVOIDANCE OF DUPLICATE COV-
5 ERAGE.—A drug prescribed for an indi-
6 vidual that would otherwise be a covered
7 outpatient drug under this section shall
8 not be so considered if payment for such
9 drug is available under part A or B for an
10 individual entitled to benefits under part A
11 and enrolled under part B.

12 “(C) APPLICATION OF FORMULARY RE-
13 STRICTIONS.—A drug prescribed for an indi-
14 vidual that would otherwise be a covered out-
15 patient drug under this section shall not be so
16 considered under an endorsed program if the el-
17 igible entity offering the program excludes the
18 drug under a formulary and a review of such
19 exclusion is not successfully resolved under sub-
20 section (h)(5).

21 “(D) APPLICATION OF GENERAL EXCLU-
22 SION PROVISIONS.—An eligible entity offering
23 an endorsed program may exclude from quali-
24 fied prescription drug coverage any covered out-
25 patient drug—

1 “(i) for which payment would not be
2 made if section 1862(a) applied to part D;

3 or

4 “(ii) which are not prescribed in ac-
5 cordance with the program or this section.

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

8 “(2) POVERTY LINE.—The term ‘poverty line’
9 means the income official poverty line (as defined by
10 the Office of Management and Budget, and revised
11 annually in accordance with section 673(2) of the
12 Omnibus Budget Reconciliation Act of 1981) appli-
13 cable to a family of the size involved.

14 “(1) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated such sums as may be
16 necessary to carry out this section and section 1807A.

17 “(m) INTERIM, FINAL REGULATORY AUTHORITY.—
18 In order to carry out this section and section 1807A in
19 a timely manner, the Secretary may promulgate regula-
20 tions that take effect on an interim basis, after notice and
21 pending opportunity for public comment.

22 “PRESCRIPTION DRUG ACCOUNTS

23 “SEC. 1807A. “(a) ESTABLISHMENT OF AC-
24 COUNTS.—

25 “(1) IN GENERAL.—The Secretary shall estab-
26 lish and maintain for each eligible beneficiary who is

1 enrolled under section 1807 at the time of enroll-
2 ment a prescription drug account (in this section
3 and section 1807 referred to as an ‘account’).

4 “(2) RESERVE ACCOUNTS.—In cases described
5 in subsections (b)(3)(A), (b)(3)(B)(i), and
6 (b)(3)(B)(ii)(I), the Secretary shall establish and
7 maintain for each surviving spouse who is not en-
8 rolled under section 1807 a reserve prescription drug
9 account (in this section referred to as an ‘reserve ac-
10 count’).

11 “(3) ACCOUNTHOLDER DEFINED.—In this sec-
12 tion and section 1807A, the term ‘accountholder’
13 means an individual for whom an account or reserve
14 account has been established under this section.

15 “(4) EXPENDITURES FROM ACCOUNT.—Noth-
16 ing in this section shall be construed as requiring
17 the Federal Government to obligate funds for
18 amounts in any account until such time as a with-
19 drawal from such account is authorized under this
20 section.

21 “(b) USE OF ACCOUNTS.—

22 “(1) APPLICATION OF ACCOUNT.—Except as
23 provided in this subsection, amounts credited to an
24 account shall only be used for the purchase of cov-
25 ered outpatient drugs for the accountholder. Any

1 amounts remaining at the end of a year remain
2 available for expenditures in succeeding years.

3 “(2) ACCOUNT RULES FOR PUBLIC AND PRI-
4 VATE CONTRIBUTIONS.—The Secretary shall estab-
5 lish a ongoing process for the determination of the
6 amount in each account that is attributable to public
7 and private contributions (including spousal rollover
8 contributions) based on the following rules:

9 “(A) TREATMENT OF EXPENDITURES.—

10 Expenditures from the account shall—

11 “(i) first be counted against any pub-
12 lic contribution; and

13 “(ii) next be counted against private
14 contributions.

15 “(B) TREATMENT OF SPOUSAL ROLLOVER
16 CONTRIBUTIONS.—With respect to any spousal
17 rollover contribution, the portions of such con-
18 tribution that were attributable to public and
19 private contributions at the time of its distribu-
20 tion under subsection (b)(3) shall be treated
21 under this paragraph as if it were a direct pub-
22 lic or private contribution, respectively, into the
23 account of the spouse.

24 “(3) DEATH OF ACCOUNTHOLDER.—In the case
25 of the death of an accountholder, the balance in any

1 account (taking into account liabilities accrued be-
2 fore the time of death) shall be distributed as fol-
3 lows:

4 “(A) TREATMENT OF PUBLIC CONTRIBU-
5 TIONS.—If the accountholder is married at the
6 time of death, the amount in the account that
7 is attributable to public contributions shall be
8 credited to the account (if any) of the surviving
9 spouse of the accountholder (or, if the surviving
10 spouse is not an eligible beneficiary, into a re-
11 serve account to be held for when that spouse
12 becomes an eligible beneficiary).

13 “(B) TREATMENT OF PRIVATE CONTRIBU-
14 TIONS.—The amount in the account that is at-
15 tributable to private contributions shall be dis-
16 tributed as follows:

17 “(i) DESIGNATION OF DIS-
18 TRIBUTE.—If the accountholder has
19 made a designation, in a form and manner
20 specified by the Secretary, for the distribu-
21 tion of some or all of such amount, such
22 amount shall be distributed in accordance
23 with the designation. Such designation
24 may provide for the distribution into an

1 account (including a reserve account) of a
2 surviving spouse.

3 “(ii) ABSENCE OF DESIGNATION.—In-
4 sofar as the accountholder has not made
5 such a designation—

6 “(I) SURVIVING SPOUSE.—If the
7 accountholder was married at the time
8 of death, the remainder shall be cred-
9 ited to an account (including a reserve
10 account) of the accountholder’s sur-
11 viving spouse.

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

17 “(4) USE OF ACCOUNT FOR PREMIUMS FOR EN-
18 ROLLMENT IN A MEDICARE ADVANTAGE PLAN.—
19 During any period in which an accountholder is en-
20 rolled in a Medicare Advantage plan under part C,
21 the balance in the account may be used and applied
22 only to reimburse the amount of the premium (if
23 any) established for enrollment under the plan.

24 “(5) APPLICATION TO MEDICAID EXPENSES IN
25 CERTAIN CASES.—

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

5 “(B) APPLICATION TOWARDS
6 SPENDDOWN.—In the case of an accountholder
7 who is applying for such medical assistance and
8 who would, but for the application of subpara-
9 graph (A), be eligible for such assistance—

10 “(i) subparagraph (A) shall not apply;

11 and

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

17 “(c) AMOUNTS CREDITED IN ACCOUNT.—The Sec-
18 retary shall credit to a prescription drug account of an
19 eligible beneficiary the following amounts:

20 “(1) PUBLIC CONTRIBUTIONS.—The following
21 contributions (each referred to in this section as a
22 ‘public contribution’):

23 “(A) FEDERAL CONTRIBUTIONS.—Federal
24 contributions provided under subsection (d).

1 “(B) STATE CONTRIBUTIONS.—Contribu-
2 tions made by a State under subsection (f).

3 “(2) SPOUSAL ROLLOVER CONTRIBUTION.—A
4 distribution from a deceased spouse under sub-
5 section (b)(3) (referred to in this section as a ‘spous-
6 al rollover contribution’).

7 “(3) PRIVATE CONTRIBUTIONS.—The following
8 contributions (each referred to in this section as a
9 ‘private contribution’):

10 “(A) EMPLOYER AND INDIVIDUAL CON-
11 TRIBUTIONS.—Contributions made under sub-
12 section (e).

13 “(B) OTHER INDIVIDUAL CONTRIBU-
14 TIONS.—Contributions made by accountholder
15 other than under subsection (e).

16 “(C) CONTRIBUTIONS BY NONPROFIT OR-
17 GANIZATIONS.—Contributions made by a chari-
18 table, not-for-profit organization (that may be a
19 religious organization).

20 Except as provided in this subsection, no amounts may
21 be contributed to, or credited to, a prescription drug ac-
22 count.

23 “(d) FEDERAL CONTRIBUTION.—For Federal con-
24 tributions in the case of accountholders, see section
25 1807(j).

1 “(e) EMPLOYER AND INDIVIDUAL CONTRIBU-
2 TIONS.—

3 “(1) EMPLOYMENT-RELATED CONTRIBUTION.—

4 “(A) IN GENERAL.—In the case of any
5 accountholder who is a beneficiary or partici-
6 pant in a group health plan (including a multi-
7 employer plan), whether as an employee, former
8 employee or otherwise, including as a dependent
9 of an employee or former employee, the plan
10 may make a contribution into the
11 accountholder’s account (but not into a reserve
12 account of the accountholder).

13 “(B) LIMITATION.—The total amount that
14 may be contributed under subparagraph (A)
15 under a plan to an account during any year
16 may not exceed \$5,000.

17 “(C) CONDITION.—A group health plan
18 may condition a contribution with respect to an
19 accountholder under this paragraph on the
20 accountholder’s enrollment under section 1807
21 with an eligible entity that is recognized or ap-
22 proved by that plan.

23 “(2) OTHER INDIVIDUALS.—

24 “(A) IN GENERAL.—Any individual may
25 also contribute to the account of that individual

1 or the account of any other individual under
2 this subsection.

3 “(B) LIMITATION.—The total amount that
4 may be contributed to an account under sub-
5 paragraph (A) during any year may not exceed
6 \$5,000, regardless of who makes such contribu-
7 tion.

8 “(3) NO CONTRIBUTION PERMITTED TO RE-
9 SERVE ACCOUNT.—No contribution may be made
10 under this subsection to a reserve account.

11 “(4) FORM AND MANNER OF CONTRIBUTION.—
12 The Secretary shall specify the form and manner of
13 contributions under this subsection.

14 “(f) STATE CONTRIBUTIONS.—

15 “(1) IN GENERAL.—A State may enter into ar-
16 rangements with the Secretary for the crediting of
17 amounts for accountholders.

18 “(2) FORM AND MANNER OF CONTRIBUTION.—
19 The Secretary shall specify the form and manner of
20 contributions under this subsection.

21 “(3) MEDICAID TREATMENT.—Amounts cred-
22 ited under this subsection shall not be treated as
23 medical assistance for purposes of title XIX or child
24 health assistance for purposes of title XXI for indi-

1 viduals who are not qualifying low income enroll-
2 ees.”.

3 (b) EXCLUSION OF COSTS FROM DETERMINATION OF
4 PART B MONTHLY PREMIUM.—Section 1839(g) (42
5 U.S.C. 1395r(g)) is amended—

6 (1) by striking “attributable to the application
7 of section” and inserting “attributable to—

8 “(1) the application of section”;

9 (2) by striking the period and inserting “;
10 and”; and

11 (3) by adding at the end the following new
12 paragraph:

13 “(2) the Voluntary Medicare Outpatient Pre-
14 scription Drug Discount and Security Program
15 under sections 1807 and 1807A.”.

16 (c) STATE ELIGIBILITY DETERMINATIONS.—Section
17 1935, as added by section 103(a)(2), is amended—

18 (1) in subsection (a)(1), by inserting “and of
19 eligibility for an annual Federal contribution amount
20 under section 1807A(j)(2)” before the semicolon;
21 and

22 (2) in subsection (a)(3), by inserting “and sec-
23 tions 1807 and 1807A” after “1860D–7”).

24 (d) REPORT ON PROGRESS IN IMPLEMENTATION OF
25 PRESCRIPTION DRUG BENEFIT.—Not later than March 1,

1 2005, the Administrator shall submit a report to Congress
2 on the progress that has been made in implementing the
3 prescription drug benefit under this title. The Adminis-
4 trator shall include in the report specific steps that have
5 been taken, and that need to be taken, to ensure a timely
6 start of the program on January 1, 2006.

7 **SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR**
8 **PURPOSES OF CARRYING OUT MEDICARE**
9 **CATASTROPHIC PRESCRIPTION DRUG PRO-**
10 **GRAM.**

11 (a) DISCLOSURE.—

12 (1) IN GENERAL.—Subsection (l) of section
13 6103 of the Internal Revenue Code of 1986 (relating
14 to disclosure of returns and return information for
15 purposes other than tax administration) is amended
16 by adding at the end the following new paragraph:

17 “(19) DISCLOSURE OF RETURN INFORMATION
18 FOR PURPOSES OF CARRYING OUT MEDICARE CATA-
19 STROPHIC PRESCRIPTION DRUG PROGRAM.—

20 “(A) IN GENERAL.—The Secretary may,
21 upon written request from the Secretary of
22 Health and Human Services under section
23 1860D–2(b)(4)(E)(i) of the Social Security Act,
24 disclose to officers and employees of the De-
25 partment of Health and Human Services with

1 respect to a specified taxpayer for the taxable
2 year specified by the Secretary of Health and
3 Human Services in such request—

4 “(i) the taxpayer identity information
5 with respect to such taxpayer, and

6 “(ii) the adjusted gross income of
7 such taxpayer for the taxable year (or, if
8 less, the income threshold limit specified in
9 section 1860D–2(b)(4)(D)(ii) for the cal-
10 endar year specified by such Secretary in
11 such request).

12 “(B) SPECIFIED TAXPAYER.—For pur-
13 poses of this paragraph, the term ‘specified tax-
14 payer’ means any taxpayer who—

15 “(i) is identified by the Secretary of
16 Health and Human Services in the request
17 referred to in subparagraph (A), and

18 “(ii) either—

19 “(I) has an adjusted gross in-
20 come for the taxable year referred to
21 in subparagraph (A) in excess of the
22 income threshold specified in section
23 1860D–2(b)(4)(D)(ii) of such Act for
24 the calendar year referred to in such
25 subparagraph, or

1 “(II) is identified by such Sec-
2 retary under subparagraph (A) as
3 being an individual who elected to use
4 more recent information under section
5 1860D–2(b)(4)(D)(v) of such Act.

6 “(C) JOINT RETURNS.—In the case of a
7 joint return, the Secretary shall, for purposes of
8 applying this paragraph, treat each spouse as a
9 separate taxpayer having an adjusted gross in-
10 come equal to one-half of the adjusted gross in-
11 come determined with respect to such return.

12 “(D) RESTRICTION ON USE OF DISCLOSED
13 INFORMATION.—Return information disclosed
14 under subparagraph (A) may be used by offi-
15 cers and employees of the Department of
16 Health and Human Services only for the pur-
17 pose of administering the prescription drug ben-
18 efit under title XVIII of the Social Security
19 Act. Such officers and employees may disclose
20 the annual out-of-pocket threshold which ap-
21 plies to an individual under such part to the en-
22 tity that offers the plan referred to in section
23 1860D–2(b)(4)(E)(ii) of such Act in which such
24 individual is enrolled. Such sponsor may use

1 (1) IN GENERAL.—There is established, as of
2 the first day of the third month beginning after the
3 date of the enactment of this Act, a State Pharma-
4 ceutical Assistance Transition Commission (in this
5 section referred to as the “Commission”) to develop
6 a proposal for addressing the unique transitional
7 issues facing State pharmaceutical assistance pro-
8 grams, and program participants, due to the imple-
9 mentation of the medicare prescription drug pro-
10 gram under part D of title XVIII of the Social Secu-
11 rity Act.

12 (2) DEFINITIONS.—For purposes of this sec-
13 tion:

14 (A) STATE PHARMACEUTICAL ASSISTANCE
15 PROGRAM DEFINED.—The term “State pharma-
16 ceutical assistance program” means a program
17 (other than the medicaid program) operated by
18 a State (or under contract with a State) that
19 provides as of the date of the enactment of this
20 Act assistance to low-income medicare bene-
21 ficiaries for the purchase of prescription drugs.

22 (B) PROGRAM PARTICIPANT.—The term
23 “program participant” means a low-income
24 medicare beneficiary who is a participant in a
25 State pharmaceutical assistance program.

1 (b) COMPOSITION.—The Commission shall include
2 the following:

3 (1) A representative of each governor of each
4 State that the Secretary identifies as operating on a
5 statewide basis a State pharmaceutical assistance
6 program that provides for eligibility and benefits
7 that are comparable or more generous than the low-
8 income assistance eligibility and benefits offered
9 under part D of title XVIII of the Social Security
10 Act.

11 (2) Representatives from other States that the
12 Secretary identifies have in operation other State
13 pharmaceutical assistance programs, as appointed by
14 the Secretary.

15 (3) Representatives of organizations that have
16 an inherent interest in program participants or the
17 program itself, as appointed by the Secretary but
18 not to exceed the number of representatives under
19 paragraphs (1) and (2).

20 (4) Representatives of Medicare Advantage or-
21 ganizations and other private health insurance plans,
22 as appointed by the Secretary.

23 (5) The Secretary (or the Secretary's designee)
24 and such other members as the Secretary may speci-
25 fy

1 The Secretary shall designate a member to serve as chair
2 of the Commission and the Commission shall meet at the
3 call of the chair.

4 (c) DEVELOPMENT OF PROPOSAL.—The Commission
5 shall develop the proposal described in subsection (a) in
6 a manner consistent with the following principles:

7 (1) Protection of the interests of program par-
8 ticipants in a manner that is the least disruptive to
9 such participants and that includes a single point of
10 contact for enrollment and processing of benefits.

11 (2) Protection of the financial and flexibility in-
12 terests of States so that States are not financially
13 worse off as a result of the enactment of this title.

14 (3) Principles of medicare modernization pro-
15 vided under title II of this Act.

16 (d) REPORT.—By not later than January 1, 2005,
17 the Commission shall submit to the President and the
18 Congress a report that contains a detailed proposal (in-
19 cluding specific legislative or administrative recommenda-
20 tions, if any) and such other recommendations as the
21 Commission deems appropriate.

22 (e) SUPPORT.—The Secretary shall provide the Com-
23 mission with the administrative support services necessary
24 for the Commission to carry out its responsibilities under
25 this section.

1 (f) TERMINATION.—The Commission shall terminate
2 30 days after the date of submission of the report under
3 subsection (d).

4 **SEC. 108. ADDITIONAL REQUIREMENTS FOR ANNUAL FI-**
5 **NANCIAL REPORT AND OVERSIGHT ON MEDI-**
6 **CARE PROGRAM, INCLUDING PRESCRIPTION**
7 **DRUG SPENDING.**

8 (a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i)
9 is amended by adding at the end the following new sub-
10 section:

11 “(1) COMBINED REPORT ON OPERATION AND STATUS
12 OF THE TRUST FUND, THE FEDERAL SUPPLEMENTARY
13 MEDICAL INSURANCE TRUST FUND, AND MEDICARE
14 PRESCRIPTION DRUG TRUST FUND.—

15 “(1) IN GENERAL.—In addition to the duty of
16 the Board of Trustees to report to Congress under
17 subsection (b), on the date the Board submits the
18 report required under subsection (b)(2), the Board
19 shall submit to Congress a report on the operation
20 and status of the Trust Fund, the Federal Supple-
21 mentary Medical Insurance Trust Fund established
22 under section 1841, and the Medicare Prescription
23 Drug Trust Fund under section 1860D–9(a) (in this
24 subsection collectively referred to as the ‘Trust

1 Funds'). Such report shall included the following in-
2 formation:

3 “(A) OVERALL SPENDING FROM THE GEN-
4 ERAL FUND OF THE TREASURY.—A statement
5 of total amounts obligated during the preceding
6 fiscal year from the General Revenues of the
7 Treasury to the Trust Funds for payment for
8 benefits covered under this title, stated in terms
9 of the total amount and in terms of the per-
10 centage such amount bears to all other amounts
11 obligated from such General Revenues during
12 such fiscal year.

13 “(B) HISTORICAL OVERVIEW OF SPEND-
14 ING.—From the date of the inception of the
15 program of insurance under this title through
16 the fiscal year involved, a statement of the total
17 amounts referred to in subparagraph (A).

18 “(C) 10-YEAR AND 75-YEAR PROJEC-
19 TIONS.—An estimate of total amounts referred
20 to in subparagraph (A) required to be obligated
21 for payment for benefits covered under this title
22 for each of the 10 fiscal years succeeding the
23 fiscal year involved and for the 75-year period
24 beginning with the succeeding fiscal year.

1 “(D) RELATION TO GDP GROWTH.—A
2 comparison of the rate of growth of the total
3 amounts referred to in subparagraph (A) to the
4 rate of growth in the gross domestic product for
5 the same period.

6 “(2) PUBLICATION.—Each report submitted
7 under paragraph (1) shall be published jointly by the
8 Committee on Ways and Means and the Committee
9 on Energy and Commerce as a public document and
10 shall be made available by such Committees on the
11 Internet.”.

12 (b) EFFECTIVE DATE.—The amendment made by
13 subsection (a) shall apply with respect to fiscal years be-
14 ginning on or after the date of the enactment of this Act.

15 **TITLE II—MEDICARE ENHANCED**
16 **FEE-FOR-SERVICE AND MEDI-**
17 **CARE ADVANTAGE PRO-**
18 **GRAMS; MEDICARE COMPETI-**
19 **TION**

20 **SEC. 200. MEDICARE MODERNIZATION AND REVITALIZA-**
21 **TION.**

22 This title provides for—

23 (1) establishment of the medicare enhanced fee-
24 for-service (EFFS) program under which medicare
25 beneficiaries are provided access to a range of en-

1 hanced fee-for-service (FFS) plans that may use
 2 preferred provider networks to offer an enhanced
 3 range of benefits;

4 (2) establishment of a Medicare Advantage pro-
 5 gram that offers improved managed care plans with
 6 coordinated care; and

7 (3) competitive bidding, in the style of the Fed-
 8 eral Employees Health Benefits program (FEHBP),
 9 among enhanced fee-for-service plans and Medicare
 10 Advantage plans in order to promote greater effi-
 11 ciency and responsiveness to medicare beneficiaries.

12 **Subtitle A—Medicare Enhanced**
 13 **Fee-for-Service Program**

14 **SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-SERV-**
 15 **ICE (FFS) PROGRAM UNDER MEDICARE.**

16 (a) IN GENERAL.—Title XVIII, as amended by sec-
 17 tion 101(a), is amended—

18 (1) by redesignating part E as part F; and

19 (2) by inserting after part D the following new
 20 part:

21 “PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

22 “OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS

23 THROUGHOUT THE UNITED STATES

24 “SEC. 1860E-1. (a) ESTABLISHMENT OF PRO-
 25 GRAM.—

1 “(1) IN GENERAL.—The Administrator shall es-
2 tablish under this part beginning January 1, 2006,
3 an enhanced fee-for-service program under which en-
4 hanced fee-for-service plans (as defined in subsection
5 (b)) are offered to EFFS-eligible individuals (as so
6 defined) in EFFS regions throughout the United
7 States.

8 “(2) EFFS REGIONS.—For purposes of this
9 part the Administrator shall establish EFFS regions
10 throughout the United States by dividing the entire
11 United States into at least 10 such regions. Before
12 establishing such regions, the Administrator shall
13 conduct a market survey and analysis, including an
14 examination of current insurance markets, to deter-
15 mine how the regions should be established. The re-
16 gions shall be established in a manner to take into
17 consideration maximizing full access for all EFFS-
18 eligible individuals, especially those residing in rural
19 areas.

20 “(b) DEFINITIONS.—For purposes of this part:

21 “(1) EFFS ORGANIZATION.—The ‘EFFS orga-
22 nization’ means an entity that the Administrator
23 certifies as meeting the requirements and standards
24 applicable to such organization under this part.

1 “(2) ENHANCED FEE-FOR-SERVICE PLAN; EFFS
2 PLAN.—The terms ‘enhanced fee-for-service plan’
3 and ‘EFFS plan’ mean health benefits coverage of-
4 fered under a policy, contract, or plan by an EFFS
5 organization pursuant to and in accordance with a
6 contract pursuant to section 1860E–4(c), but only if
7 the plan provides either fee-for-service coverage de-
8 scribed in the following subparagraph (A) or pre-
9 ferred provider coverage described in the following
10 subparagraph (B):

11 “(A) FEE-FOR-SERVICE COVERAGE.—The
12 plan—

13 “(i) reimburses hospitals, physicians,
14 and other providers at a rate determined
15 by the plan on a fee-for-service basis with-
16 out placing the provider at financial risk;

17 “(ii) does not vary such rates for such
18 a provider based on utilization relating to
19 such provider; and

20 “(iii) does not restrict the selection of
21 providers among those who are lawfully au-
22 thorized to provide the covered services
23 and agree to accept the terms and condi-
24 tions of payment established by the plan.

1 respect to the plan and EFFS organization offering the
2 plan.

3 “(b) AVAILABLE TO ALL EFFS BENEFICIARIES IN
4 THE ENTIRE REGION.—With respect to an EFFS plan
5 offered in an EFFS region—

6 “(1) IN GENERAL.—The plan must be offered
7 to all EFFS-eligible individuals residing in the re-
8 gion.

9 “(2) ASSURING ACCESS TO SERVICES.—The
10 plan shall comply with the requirements of section
11 1852(d)(4).

12 “(c) BENEFITS.—

13 “(1) IN GENERAL.—Each EFFS plan shall pro-
14 vide to members enrolled in the plan under this part
15 benefits, through providers and other persons that
16 meet the applicable requirements of this title and
17 part A of title XI—

18 “(A) for the items and services described
19 in section 1852(a)(1);

20 “(B) that are uniform for the plan for all
21 EFFS eligible individuals residing in the same
22 EFFS region;

23 “(C) that include a single deductible appli-
24 cable to benefits under parts A and B and in-

1 “(1) REQUIREMENT.—

2 “(A) EFFS MONTHLY BID AMOUNT.—For
3 each year (beginning with 2006), an EFFS or-
4 ganization shall submit to the Administrator an
5 EFFS monthly bid amount for each EFFS
6 plan offered in each region. Each such bid is re-
7 ferred to in this section as the ‘EFFS monthly
8 bid amount’.

9 “(B) FORM.—Such bid amounts shall be
10 submitted for each such plan and region in a
11 form and manner and time specified by the Ad-
12 ministrator, and shall include information de-
13 scribed in paragraph (3)(A).

14 “(2) UNIFORM BID AMOUNTS.—Each EFFS
15 monthly bid amount submitted under paragraph (1)
16 by an EFFS organization under this part for an
17 EFFS plan in an EFFS region may not vary among
18 EFFS eligible individuals residing in the EFFS re-
19 gion involved.

20 “(3) SUBMISSION OF BID AMOUNT INFORMA-
21 TION BY EFFS ORGANIZATIONS.—

22 “(A) INFORMATION TO BE SUBMITTED.—
23 The information described in this subparagraph
24 is as follows:

1 “(i) The EFFS monthly bid amount
2 for provision of all items and services
3 under this part, which amount shall be
4 based on average costs for a typical bene-
5 ficiary residing in the region, and the actu-
6 arial basis for determining such amount.

7 “(ii) The proportions of such bid
8 amount that are attributable to—

9 “(I) the provision of statutory
10 non-drug benefits (such portion re-
11 ferred to in this part as the
12 ‘unadjusted EFFS statutory non-drug
13 monthly bid amount’);

14 “(II) the provision of statutory
15 prescription drug benefits; and

16 “(III) the provision of non-statu-
17 tory benefits;

18 and the actuarial basis for determining
19 such proportions.

20 “(iii) Such additional information as
21 the Administrator may require to verify
22 the actuarial bases described in clauses (i)
23 and (ii).

24 “(B) STATUTORY BENEFITS DEFINED.—

25 For purposes of this part:

1 “(i) The term ‘statutory non-drug
2 benefits’ means benefits under section
3 1852(a)(1).

4 “(ii) The term ‘statutory prescription
5 drug benefits’ means benefits under part
6 D.

7 “(iii) The term ‘statutory benefits’
8 means statutory prescription drug benefits
9 and statutory non-drug benefits.

10 “(C) ACCEPTANCE AND NEGOTIATION OF
11 BID AMOUNTS.—The Administrator has the au-
12 thority to negotiate regarding monthly bid
13 amounts submitted under subparagraph (A)
14 (and the proportion described in subparagraph
15 (A)(ii)), and for such purpose, the Adminis-
16 trator has negotiation authority that the Direc-
17 tor of the Office of Personnel Management has
18 with respect to health benefits plans under
19 chapter 89 of title 5, United States Code. The
20 Administrator may reject such a bid amount or
21 proportion if the Administrator determines that
22 such amount or proportion is not supported by
23 the actuarial bases provided under subpara-
24 graph (A).

1 “(D) CONTRACT AUTHORITY.—The Ad-
2 ministrator may, taking into account the
3 unadjusted EFFS statutory non-drug monthly
4 bid amounts accepted under subparagraph (C),
5 enter into contracts for the offering of EFFS
6 plans by up to 3 EFFS organizations in any re-
7 gion.

8 “(b) PROVISION OF BENEFICIARY SAVINGS FOR CER-
9 TAIN PLANS.—

10 “(1) BENEFICIARY REBATE RULE.—

11 “(A) REQUIREMENT.—The EFFS plan
12 shall provide to the enrollee a monthly rebate
13 equal to 75 percent of the average per capita
14 savings (if any) described in paragraph (2) ap-
15 plicable to the plan and year involved.

16 “(B) FORM OF REBATE.—A rebate re-
17 quired under this paragraph shall be provided—

18 “(i) through the crediting of the
19 amount of the rebate towards the EFFS
20 monthly prescription drug beneficiary pre-
21 mium (as defined in section 1860E-
22 4(a)(3)(B)) and the EFFS monthly sup-
23 plemental beneficiary premium (as defined
24 in section 1860E-4(a)(3)(C));

1 “(ii) through a direct monthly pay-
2 ment (through electronic funds transfer or
3 otherwise); or

4 “(iii) through other means approved
5 by the Medicare Benefits Administrator,

6 or any combination thereof.

7 “(2) COMPUTATION OF AVERAGE PER CAPITA
8 MONTHLY SAVINGS.—For purposes of paragraph
9 (1)(A), the average per capita monthly savings re-
10 ferred to in such paragraph for an EFFE plan and
11 year is computed as follows:

12 “(A) DETERMINATION OF REGION-WIDE
13 AVERAGE RISK ADJUSTMENT.—

14 “(i) IN GENERAL.—The Medicare
15 Benefits Administrator shall determine, at
16 the same time rates are promulgated under
17 section 1853(b)(1) (beginning with 2006),
18 for each EFFE region the average of the
19 risk adjustment factors described in sub-
20 section (c)(3) to be applied to enrollees
21 under this part in that region. In the case
22 of an EFFE region in which an EFFE
23 plan was offered in the previous year, the
24 Administrator may compute such average
25 based upon risk adjustment factors applied

1 under subsection (c)(3) in that region in a
2 previous year.

3 “(ii) TREATMENT OF NEW RE-
4 GIONS.—In the case of a region in which
5 no EFFE plan was offered in the previous
6 year, the Administrator shall estimate such
7 average. In making such estimate, the Ad-
8 ministrator may use average risk adjust-
9 ment factors applied to comparable EFFE
10 regions or applied on a national basis.

11 “(B) DETERMINATION OF RISK ADJUSTED
12 BENCHMARK AND RISK-ADJUSTED BID.—For
13 each EFFE plan offered in an EFFE region,
14 the Administrator shall—

15 “(i) adjust the EFFE region-specific
16 non-drug monthly benchmark amount (as
17 defined in paragraph (3)) by the applicable
18 average risk adjustment factor computed
19 under subparagraph (A); and

20 “(ii) adjust the unadjusted EFFE
21 statutory non-drug monthly bid amount by
22 such applicable average risk adjustment
23 factor.

24 “(C) DETERMINATION OF AVERAGE PER
25 CAPITA MONTHLY SAVINGS.—The average per

1 capita monthly savings described in this sub-
2 paragraph is equal to the amount (if any) by
3 which—

4 “(i) the risk-adjusted benchmark
5 amount computed under subparagraph
6 (B)(i), exceeds

7 “(ii) the risk-adjusted bid computed
8 under subparagraph (B)(ii).

9 “(3) COMPUTATION OF EFFS REGION-SPECIFIC
10 NON-DRUG MONTHLY BENCHMARK AMOUNT.—For
11 purposes of this part, the term ‘EFFS region-spe-
12 cific non-drug monthly benchmark amount’ means,
13 with respect to an EFFS region for a month in a
14 year, an amount equal to $\frac{1}{12}$ of the average (weight-
15 ed by number of EFFS eligible individuals in each
16 payment area described in section 1853(d)) of the
17 annual capitation rate as calculated under section
18 1853(c)(1) for that area.

19 “(c) PAYMENT OF PLANS BASED ON BID
20 AMOUNTS.—

21 “(1) NON-DRUG BENEFITS.—Under a contract
22 under section 1860E-4(c) and subject to section
23 1853(g) (as made applicable under subsection (d)),
24 the Administrator shall make monthly payments
25 under this subsection in advance to each EFFS or-

1 organization, with respect to coverage of an individual
2 under this part in an EFFE region for a month, in
3 an amount determined as follows:

4 “(A) PLANS WITH BIDS BELOW BENCH-
5 MARK.—In the case of a plan for which there
6 are average per capita monthly savings de-
7 scribed in subsection (b)(2)(C), the payment
8 under this subsection is equal to the unadjusted
9 EFFE statutory non-drug monthly bid amount,
10 adjusted under paragraphs (3) and (4), plus the
11 amount of the monthly rebate computed under
12 subsection (b)(1)(A) for that plan and year.

13 “(B) PLANS WITH BIDS AT OR ABOVE
14 BENCHMARK.—In the case of a plan for which
15 there are no average per capita monthly savings
16 described in subsection (b)(2)(C), the payment
17 amount under this subsection is equal to the
18 EFFE region-specific non-drug monthly bench-
19 mark amount, adjusted under paragraphs (3)
20 and (4).

21 “(2) FOR FEDERAL DRUG SUBSIDIES.—In the
22 case in which an enrollee who elects under part D
23 to be provided qualified prescription drug coverage
24 through the plan, the EFFE organization offering
25 such plan also is entitled—

1 “(A) to direct subsidy payment under sec-
2 tion 1860D–8(a)(1);

3 “(B) to reinsurance subsidy payments
4 under section 1860D–8(a)(2); and

5 “(C) to reimbursement for premium and
6 cost-sharing reductions for low-income individ-
7 uals under section 1860D–7(e)(3).

8 “(3) DEMOGRAPHIC RISK ADJUSTMENT, IN-
9 CLUDING ADJUSTMENT FOR HEALTH STATUS.—The
10 Administrator shall adjust under paragraph (1)(A)
11 the unadjusted EFFS statutory non-drug monthly
12 bid amount and under paragraph (1)(B) the EFFS
13 region-specific non-drug monthly benchmark amount
14 for such risk factors as age, disability status, gen-
15 der, institutional status, and such other factors as
16 the Administrator determines to be appropriate, in-
17 cluding adjustment for health status under section
18 1853(a)(3) (as applied under subsection (d)), so as
19 to ensure actuarial equivalence. The Administrator
20 may add to, modify, or substitute for such adjust-
21 ment factors if such changes will improve the deter-
22 mination of actuarial equivalence.

23 “(4) ADJUSTMENT FOR INTRA-REGIONAL GEO-
24 GRAPHIC VARIATIONS.—The Administrator shall also
25 adjust such amounts in a manner to take into ac-

1 count variations in payments rates under part C
2 among the different payment areas under such part
3 included in each EFFE region.

4 “(d) APPLICATION OF ADDITIONAL PAYMENT
5 RULES.—The provisions of section 1853 (other than sub-
6 sections (a)(1)(A), (d), and (e)) shall apply to an EFFE
7 plan under this part, except as otherwise provided in this
8 section.

9 “PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIRE-
10 MENTS; ESTABLISHMENT OF STANDARDS; CON-
11 TRACTS WITH EFFE ORGANIZATIONS

12 “SEC. 1860E–4. (a) PREMIUMS.—

13 “(1) IN GENERAL.—The provisions of section
14 1854 (other than subsections (a)(6)(C) and (h)), in-
15 cluding subsection (b)(5) relating to the consolida-
16 tion of drug and non-drug beneficiary premiums and
17 subsection (c) relating to uniform bids and pre-
18 miums, shall apply to an EFFE plan under this
19 part, subject to paragraph (2).

20 “(2) CROSS-WALK.—In applying paragraph (1),
21 any reference in section 1854(b)(1)(A) or 1854(d)
22 to—

23 “(A) a Medicare Advantage monthly basic
24 beneficiary premium is deemed a reference to
25 the EFFE monthly basic beneficiary premium
26 (as defined in paragraph (3)(A));

1 “(B) a Medicare Advantage monthly pre-
2 scription drug beneficiary premium is deemed a
3 reference to the EFFS monthly prescription
4 drug beneficiary premium (as defined in para-
5 graph (3)(B)); and

6 “(C) a Medicare Advantage monthly sup-
7 plemental beneficiary premium is deemed a ref-
8 erence to the EFFS monthly supplemental ben-
9 eficiary premium (as defined in paragraph
10 (3)(C)).

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

12 “(A) EFFS MONTHLY BASIC BENEFICIARY
13 PREMIUM.—The term ‘EFFS monthly basic
14 beneficiary premium’ means, with respect to an
15 EFFS plan—

16 “(i) described in section 1860E-
17 3(c)(1)(A) (relating to plans providing re-
18 bates), zero; or

19 “(ii) described in section 1860E-
20 3(c)(1)(B), the amount (if any) by which
21 the unadjusted EFFS statutory non-drug
22 monthly bid amount exceeds the EFFS re-
23 gion-specific non-drug monthly benchmark
24 amount (as defined in section 1860E-
25 3(b)(3)).

1 “(B) EFFS MONTHLY PRESCRIPTION
2 DRUG BENEFICIARY PREMIUM.—The term
3 ‘EFFS monthly prescription drug beneficiary
4 premium’ means, with respect to an EFFS
5 plan, the portion of the aggregate monthly bid
6 amount submitted under clause (i) of section
7 1860E–3(a)(3)(A) for the year that is attrib-
8 utable under such section to the provision of
9 statutory prescription drug benefits.

10 “(C) EFFS MONTHLY SUPPLEMENTAL
11 BENEFICIARY PREMIUM.—The term ‘EFFS
12 monthly supplemental beneficiary premium’
13 means, with respect to an EFFS plan, the por-
14 tion of the aggregate monthly bid amount sub-
15 mitted under clause (i) of section 1860E–
16 3(a)(3)(A) for the year that is attributable
17 under such section to the provision of nonstatu-
18 tory benefits.

19 “(b) ORGANIZATIONAL AND FINANCIAL REQUIRE-
20 MENTS.—The provisions of section 1855 shall apply to an
21 EFFS plan offered by an EFFS organization under this
22 part.

23 “(c) STANDARDS.—The provisions of paragraphs (1),
24 (3), and (4) of section 1856(b) shall apply to an EFFS
25 plan offered by an EFFS organization under this part.

1 (b) REFERENCES.—Any reference to the program
2 under part C of title XVIII of the Social Security Act shall
3 be deemed a reference to the Medicare Advantage program
4 and, with respect to such part, any reference to
5 “Medicare+Choice” is deemed a reference to “Medicare
6 Advantage”.

7 **SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.**

8 (a) EQUALIZING PAYMENTS WITH FEE-FOR-SERV-
9 ICE.—

10 (1) IN GENERAL.—Section 1853(c)(1) (42
11 U.S.C. 1395w-23(c)(1)) is amended by adding at
12 the end the following:

13 “(D) BASED ON 100 PERCENT OF FEE-
14 FOR-SERVICE COSTS.—

15 “(i) IN GENERAL.—For 2004, the ad-
16 justed average per capita cost for the year
17 involved, determined under section
18 1876(a)(4) for the Medicare Advantage
19 payment area for services covered under
20 parts A and B for individuals entitled to
21 benefits under part A and enrolled under
22 part B who are not enrolled in a Medicare
23 Advantage under this part for the year,
24 but adjusted to exclude costs attributable
25 to payments under section 1886(h).

1 “(ii) INCLUSION OF COSTS OF VA AND
2 DOD MILITARY FACILITY SERVICES TO
3 MEDICARE-ELIGIBLE BENEFICIARIES.—In
4 determining the adjusted average per cap-
5 ita cost under clause (i) for a year, such
6 cost shall be adjusted to include the Sec-
7 retary’s estimate, on a per capita basis, of
8 the amount of additional payments that
9 would have been made in the area involved
10 under this title if individuals entitled to
11 benefits under this title had not received
12 services from facilities of the Department
13 of Veterans Affairs or the Department of
14 Defense.”.

15 (2) CONFORMING AMENDMENT.—Such section
16 is further amended, in the matter before subpara-
17 graph (A), by striking “or (C)” and inserting “(C),
18 or (D)”.

19 (b) CHANGE IN BUDGET NEUTRALITY FOR
20 BLEND.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is
21 amended—

22 (1) in paragraph (1)(A), by inserting “(for a
23 year other than 2004)” after “multiplied”; and

24 (2) in paragraph (5), by inserting “(other than
25 2004)” after “for each year”.

1 (c) INCREASING MINIMUM PERCENTAGE INCREASE
2 TO NATIONAL GROWTH RATE.—

3 (1) IN GENERAL.—Section 1853(c)(1) (42
4 U.S.C. 1395w-23(c)(1)) is amended—

5 (A) in subparagraph (A), by striking “The
6 sum” and inserting “For a year before 2005,
7 the sum”;

8 (B) in subparagraph (B)(iv), by striking
9 “and each succeeding year” and inserting “,
10 2003, and 2004”;

11 (C) in subparagraph (C)(iv), by striking
12 “and each succeeding year” and inserting “and
13 2003”; and

14 (D) by adding at the end of subparagraph
15 (C) the following new clause:

16 “(v) For 2004 and each succeeding
17 year, the greater of—

18 “(I) 102 percent of the annual
19 Medicare Advantage capitation rate
20 under this paragraph for the area for
21 the previous year; or

22 “(II) the annual Medicare Ad-
23 vantage capitation rate under this
24 paragraph for the area for the pre-
25 vious year increased by the national

1 per capita Medicare Advantage
2 growth percentage, described in para-
3 graph (6) for that succeeding year,
4 but not taking into account any ad-
5 justment under paragraph (6)(C) for
6 a year before 2004.”.

7 (2) CONFORMING AMENDMENT.—Section
8 1853(e)(6)(C) (42 U.S.C. 1395w-23(e)(6)(C)) is
9 amended by inserting before the period at the end
10 the following: “, except that for purposes of para-
11 graph (1)(C)(v)(II), no such adjustment shall be
12 made for a year before 2004”.

13 (d) INCLUSION OF COSTS OF DOD AND VA MILI-
14 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
15 BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE
16 PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C.
17 1395w-23(c)(3)) is amended—

18 (1) in subparagraph (A), by striking “subpara-
19 graph (B)” and inserting “subparagraphs (B) and
20 (E)”, and

21 (2) by adding at the end the following new sub-
22 paragraph:

23 “(E) INCLUSION OF COSTS OF DOD AND
24 VA MILITARY FACILITY SERVICES TO MEDICARE-
25 ELIGIBLE BENEFICIARIES.—In determining the

1 area-specific Medicare+Choice capitation rate
2 under subparagraph (A) for a year (beginning
3 with 2004), the annual per capita rate of pay-
4 ment for 1997 determined under section
5 1876(a)(1)(C) shall be adjusted to include in
6 the rate the Secretary's estimate, on a per cap-
7 ita basis, of the amount of additional payments
8 that would have been made in the area involved
9 under this title if individuals entitled to benefits
10 under this title had not received services from
11 facilities of the Department of Defense or the
12 Department of Veterans Affairs.”.

13 (e) EXTENDING SPECIAL RULE FOR CERTAIN INPA-
14 TIENT HOSPITAL STAYS TO REHABILITATION HOS-
15 PITALS.—

16 (1) IN GENERAL.—Section 1853(g) (42 U.S.C.
17 1395w-23(g)) is amended—

18 (A) by inserting “or from a rehabilitation
19 facility (as defined in section 1886(j)(1)(A))”
20 after “1886(d)(1)(B)”;

21 (B) in paragraph (2)(B), by inserting “or
22 section 1886(j), as the case may be,” after
23 “1886(d)”.

1 (2) EFFECTIVE DATE.—The amendments made
2 by paragraph (1) shall apply to contract years begin-
3 ning on or after January 1, 2004.

4 (f) MEDPAC STUDY OF AAPCC.—

5 (1) STUDY.—The Medicare Payment Advisory
6 Commission shall conduct a study that assesses the
7 method used for determining the adjusted average
8 per capita cost (AAPCC) under section 1876(a)(4)
9 of the Social Security Act (42 U.S.C.
10 1395mm(a)(4)) as applied under section
11 1853(e)(1)(A) of such Act (as amended by sub-
12 section (a)). Such study shall include an examination
13 of—

14 (A) the bases for variation in such costs
15 between different areas, including differences in
16 input prices, utilization, and practice patterns;

17 (B) the appropriate geographic area for
18 payment under the Medicare Advantage pro-
19 gram under part C of title XVIII of such Act;
20 and

21 (C) the accuracy of risk adjustment meth-
22 ods in reflecting differences in costs of pro-
23 viding care to different groups of beneficiaries
24 served under such program.

1 (2) REPORT.—Not later than 18 months after
2 the date of the enactment of this Act, the Commis-
3 sion shall submit to Congress a report on the study
4 conducted under paragraph (1).

5 (g) REPORT ON IMPACT OF INCREASED FINANCIAL
6 ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not
7 later than July 1, 2006, the Medicare Benefits Adminis-
8 trator shall submit to Congress a report that describes the
9 impact of additional financing provided under this Act and
10 other Acts (including the Medicare, Medicaid, and SCHIP
11 Balanced Budget Refinement Act of 1999 and BIPA) on
12 the availability of Medicare Advantage plans in different
13 areas and its impact on lowering premiums and increasing
14 benefits under such plans.

15 (h) ANNOUNCEMENT OF REVISED MEDICARE AD-
16 VANTAGE PAYMENT RATES.—Within 6 weeks after the
17 date of the enactment of this Act, the Secretary shall de-
18 termine, and shall announce (in a manner intended to pro-
19 vide notice to interested parties) Medicare Advantage capi-
20 tation rates under section 1853 of the Social Security Act
21 (42 U.S.C. 1395w–23) for 2004, revised in accordance
22 with the provisions of this section.

1 **CHAPTER 2—IMPLEMENTATION OF**
2 **COMPETITION PROGRAM**

3 **SEC. 221. COMPETITION PROGRAM BEGINNING IN 2006.**

4 (a) SUBMISSION OF EFFS-LIKE BIDDING INFORMA-
5 TION BEGINNING IN 2006.—Section 1854 (42 U.S.C.
6 1395w-24) is amended—

7 (1) by amending the section heading to read as
8 follows:

9 “PREMIUMS AND BID AMOUNT”;

10 (2) in subsection (a)(1)(A)—

11 (A) by striking “(A)” and inserting “(A)(i)
12 if the following year is before 2006,”; and

13 (B) by inserting before the semicolon at
14 the end the following: “or (ii) if the following
15 year is 2006 or later, the information described
16 in paragraph (3) or (6)(A) for the type of plan
17 involved”; and

18 (3) by adding at the end of subsection (a) the
19 following:

20 “(6) SUBMISSION OF BID AMOUNTS BY MEDI-
21 CARE ADVANTAGE ORGANIZATIONS.—

22 “(A) INFORMATION TO BE SUBMITTED.—

23 The information described in this subparagraph
24 is as follows:

25 “(i) The monthly aggregate bid
26 amount for provision of all items and serv-

1 ices under this part, which amount shall be
2 based on average costs for a typical bene-
3 ficiary residing in the area, and the actu-
4 arial basis for determining such amount.

5 “(ii) The proportions of such bid
6 amount that are attributable to—

7 “(I) the provision of statutory
8 non-drug benefits (such portion re-
9 ferred to in this part as the
10 ‘unadjusted Medicare Advantage stat-
11 utory non-drug monthly bid amount’);

12 “(II) the provision of statutory
13 prescription drug benefits; and

14 “(III) the provision of non-statu-
15 tory benefits;

16 and the actuarial basis for determining
17 such proportions.

18 “(iii) Such additional information as
19 the Administrator may require to verify
20 the actuarial bases described in clauses (i)
21 and (ii).

22 “(B) STATUTORY BENEFITS DEFINED.—

23 For purposes of this part:

1 “(i) The term ‘statutory non-drug
2 benefits’ means benefits under section
3 1852(a)(1).

4 “(ii) The term ‘statutory prescription
5 drug benefits’ means benefits under part
6 D.

7 “(iii) The term ‘statutory benefits’
8 means statutory prescription drug benefits
9 and statutory non-drug benefits.

10 “(C) ACCEPTANCE AND NEGOTIATION OF
11 BID AMOUNTS.—

12 “(i) IN GENERAL.—Subject to clause
13 (ii)—

14 “(I) the Administrator has the
15 authority to negotiate regarding
16 monthly bid amounts submitted under
17 subparagraph (A) (and the proportion
18 described in subparagraph (A)(ii)),
19 and for such purpose and subject to
20 such clause, the Administrator has ne-
21 gotiation authority that the Director
22 of the Office of Personnel Manage-
23 ment has with respect to health bene-
24 fits plans under chapter 89 of title 5,
25 United States Code; and

1 “(II) the Administrator may re-
2 ject such a bid amount or proportion
3 if the Administrator determines that
4 such amount or proportion is not sup-
5 ported by the actuarial bases provided
6 under subparagraph (A).

7 “(ii) EXCEPTION.—In the case of a
8 plan described in section 1851(a)(2)(C),
9 the provisions of clause (i) shall not apply
10 and the provisions of paragraph (5)(B),
11 prohibiting the review, approval, or dis-
12 approval of amounts described in such
13 paragraph, shall apply to the negotiation
14 and rejection of the monthly bid amounts
15 and proportion referred to in subparagraph
16 (A).”.

17 (b) PROVIDING FOR BENEFICIARY SAVINGS FOR
18 CERTAIN PLANS.—

19 (1) IN GENERAL.—Section 1854(b) (42 U.S.C.
20 1395w-24(b)) is amended—

21 (A) by adding at the end of paragraph (1)
22 the following new subparagraph:

23 “(C) BENEFICIARY REBATE RULE.—

24 “(i) REQUIREMENT.—The Medicare
25 Advantage plan shall provide to the en-

1 rollee a monthly rebate equal to 75 percent
2 of the average per capita savings (if any)
3 described in paragraph (3) applicable to
4 the plan and year involved.

5 “(iii) FORM OF REBATE.—A rebate
6 required under this subparagraph shall be
7 provided—

8 “(I) through the crediting of the
9 amount of the rebate towards the
10 Medicare Advantage monthly supple-
11 mentary beneficiary premium or the
12 premium imposed for prescription
13 drug coverage under part D;

14 “(II) through a direct monthly
15 payment (through electronic funds
16 transfer or otherwise); or

17 “(III) through other means ap-
18 proved by the Medicare Benefits Ad-
19 ministrator,

20 or any combination thereof.”; and

21 (B) by adding at the end the following new
22 paragraphs:

23 “(3) COMPUTATION OF AVERAGE PER CAPITA
24 MONTHLY SAVINGS.—For purposes of paragraph
25 (1)(C)(i), the average per capita monthly savings re-

1 ferred to in such paragraph for a Medicare Advan-
2 tage plan and year is computed as follows:

3 “(A) DETERMINATION OF STATE-WIDE AV-
4 ERAGE RISK ADJUSTMENT.—

5 “(i) IN GENERAL.—The Medicare
6 Benefits Administrator shall determine, at
7 the same time rates are promulgated under
8 section 1853(b)(1) (beginning with 2006),
9 for each State the average of the risk ad-
10 justment factors to be applied under sec-
11 tion 1853(a)(1)(A) to payment for enroll-
12 ees in that State. In the case of a State in
13 which a Medicare Advantage plan was of-
14 fered in the previous year, the Adminis-
15 trator may compute such average based
16 upon risk adjustment factors applied in
17 that State in a previous year.

18 “(ii) TREATMENT OF NEW STATES.—
19 In the case of a State in which no Medi-
20 care Advantage plan was offered in the
21 previous year, the Administrator shall esti-
22 mate such average. In making such esti-
23 mate, the Administrator may use average
24 risk adjustment factors applied to com-

1 parable States or applied on a national
2 basis.

3 “(B) DETERMINATION OF RISK ADJUSTED
4 BENCHMARK AND RISK-ADJUSTED BID.—For
5 each Medicare Advantage plan offered in a
6 State, the Administrator shall—

7 “(i) adjust the Medicare Advantage
8 area-specific non-drug monthly benchmark
9 amount (as defined in subsection (j)) by
10 the applicable average risk adjustment fac-
11 tor computed under subparagraph (A); and

12 “(ii) adjust the unadjusted Medicare
13 Advantage statutory non-drug monthly bid
14 amount by such applicable average risk ad-
15 justment factor.

16 “(C) DETERMINATION OF AVERAGE PER
17 CAPITA MONTHLY SAVINGS.—The average per
18 capita monthly savings described in this sub-
19 paragraph is equal to the amount (if any) by
20 which—

21 “(i) the risk-adjusted benchmark
22 amount computed under subparagraph
23 (B)(i), exceeds

24 “(ii) the risk-adjusted bid computed
25 under subparagraph (B)(ii).

1 “(D) AUTHORITY TO DETERMINE RISK AD-
2 JUSTMENT FOR AREAS OTHER THAN STATES.—
3 The Administrator may provide for the deter-
4 mination and application of risk adjustment
5 factors under this paragraph on the basis of
6 areas other than States.

7 “(4) BENEFICIARY’S OPTION OF PAYMENT
8 THROUGH WITHHOLDING FROM SOCIAL SECURITY
9 PAYMENT OR USE OF ELECTRONIC FUNDS TRANS-
10 FER MECHANISM.—In accordance with regulations, a
11 Medicare Advantage organization shall permit each
12 enrollee, at the enrollee’s option, to make payment
13 of premiums under this part to the organization in-
14 directly through withholding from benefit payments
15 in the manner provided under section 1840 with re-
16 spect to monthly premiums under section 1839 or
17 through an electronic funds transfer mechanism
18 (such as automatic charges of an account at a finan-
19 cial institution or a credit or debit card account) or
20 otherwise. All premium payments that are withheld
21 under this paragraph that are credited to the Fed-
22 eral Supplementary Medical Insurance Drug Trust
23 Fund shall be paid to the Medicare Advantage orga-
24 nization involved.”.

1 (2) PROVISION OF SINGLE CONSOLIDATED PRE-
2 MIUM.—Section 1854(b) (42 U.S.C. 1395w–24(b)),
3 as amended by paragraph (1), is further amended by
4 adding at the end the following new paragraph:

5 “(5) SINGLE CONSOLIDATED PREMIUM.—In the
6 case of an enrollee in a Medicare Advantage plan
7 who elects under part D to be provided qualified
8 prescription drug coverage through the plan, the Ad-
9 ministrators shall provide a mechanism for the con-
10 solidation of the beneficiary premium amount for
11 non-drug benefits under this part with the premium
12 amount for prescription drug coverage under part D
13 provided through the plan.”.

14 (3) COMPUTATION OF MEDICARE ADVANTAGE
15 AREA-SPECIFIC NON-DRUG BENCHMARK.—Section
16 1853 (42 U.S.C. 1395w–23) is amended by adding
17 at the end the following new subsection:

18 “(j) COMPUTATION OF MEDICARE ADVANTAGE
19 AREA-SPECIFIC NON-DRUG MONTHLY BENCHMARK
20 AMOUNT.—For purposes of this part, the term ‘Medicare
21 Advantage area-specific non-drug monthly benchmark
22 amount’ means, with respect to a Medicare Advantage
23 payment area for a month in a year, an amount equal
24 to $\frac{1}{12}$ of the annual Medicare Advantage capitation rate
25 under section 1853(c)(1) for the area for the year.”.

1 (c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

2 (1) IN GENERAL.—Section 1853(a)(1)(A) (42
3 U.S.C. 1395w-23) is amended by striking “in an
4 amount” and all that follows and inserting the fol-
5 lowing: “in an amount determined as follows:

6 “(i) PAYMENT BEFORE 2006.—For
7 years before 2006, the payment amount
8 shall be equal to $\frac{1}{12}$ of the annual Medi-
9 care Advantage capitation rate (as cal-
10 culated under subsection (c)(1)) with re-
11 spect to that individual for that area, re-
12 duced by the amount of any reduction
13 elected under section 1854(f)(1)(E) and
14 adjusted under clause (iv).

15 “(ii) PAYMENT FOR STATUTORY NON-
16 DRUG BENEFITS BEGINNING WITH 2006.—
17 For years beginning with 2006—

18 “(I) PLANS WITH BIDS BELOW
19 BENCHMARK.—In the case of a plan
20 for which there are average per capita
21 monthly savings described in section
22 1854(b)(3)(C), the payment under
23 this subsection is equal to the
24 unadjusted Medicare Advantage statu-
25 tory non-drug monthly bid amount,

1 adjusted under clause (iv), plus the
2 amount of the monthly rebate com-
3 puted under section 1854(b)(1)(C)(i)
4 for that plan and year.

5 “(II) PLANS WITH BIDS AT OR
6 ABOVE BENCHMARK.—In the case of a
7 plan for which there are no average
8 per capita monthly savings described
9 in section 1854(b)(3)(C), the payment
10 amount under this subsection is equal
11 to the Medicare Advantage area-spe-
12 cific non-drug monthly benchmark
13 amount, adjusted under clause (iv).

14 “(iii) FOR FEDERAL DRUG SUB-
15 SIDIES.—In the case in which an enrollee
16 who elects under part D to be provided
17 qualified prescription drug coverage
18 through the plan, the Medicare Advantage
19 organization offering such plan also is enti-
20 tled—

21 “(I) to direct subsidy payment
22 under section 1860D–8(a)(1);

23 “(II) to reinsurance subsidy pay-
24 ments under section 1860D–8(a)(2);
25 and

1 “(III) to reimbursement for pre-
2 mium and cost-sharing reductions for
3 low-income individuals under section
4 1860D–7(c)(3).

5 “(iv) DEMOGRAPHIC ADJUSTMENT,
6 INCLUDING ADJUSTMENT FOR HEALTH
7 STATUS.—The Administrator shall adjust
8 the payment amount under clause (i), the
9 unadjusted Medicare Advantage statutory
10 non-drug monthly bid amount under clause
11 (ii)(I), and the Medicare Advantage area-
12 specific non-drug monthly benchmark
13 amount under clause (ii)(II) for such risk
14 factors as age, disability status, gender, in-
15 stitutional status, and such other factors
16 as the Administrator determines to be ap-
17 propriate, including adjustment for health
18 status under paragraph (3), so as to en-
19 sure actuarial equivalence. The Adminis-
20 trator may add to, modify, or substitute
21 for such adjustment factors if such
22 changes will improve the determination of
23 actuarial equivalence.”.

24 (d) CONFORMING AMENDMENTS.—

1 (1) PROTECTION AGAINST BENEFICIARY SELEC-
2 TION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w-
3 22(b)(1)(A)) is amended by adding at the end the
4 following: “The Administrator shall not approve a
5 plan of an organization if the Administrator deter-
6 mines that the benefits are designed to substantially
7 discourage enrollment by certain Medicare Advan-
8 tage eligible individuals with the organization.”.

9 (2) CONFORMING AMENDMENT TO PREMIUM
10 TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C.
11 1395w-24(b)(2)) is amended by redesignating sub-
12 paragraph (C) as subparagraph (D) and by striking
13 subparagraphs (A) and (B) and inserting the fol-
14 lowing:

15 “(A) MEDICARE ADVANTAGE MONTHLY
16 BASIC BENEFICIARY PREMIUM.—The term
17 ‘Medicare Advantage monthly basic beneficiary
18 premium’ means, with respect to a Medicare
19 Advantage plan—

20 “(i) described in section
21 1853(a)(1)(A)(ii)(I) (relating to plans pro-
22 viding rebates), zero; or

23 “(ii) described in section
24 1853(a)(1)(A)(ii)(II), the amount (if any)
25 by which the unadjusted Medicare Advan-

1 tage statutory non-drug monthly bid
2 amount exceeds the Medicare Advantage
3 area-specific non-drug monthly benchmark
4 amount.

5 “(B) MEDICARE ADVANTAGE MONTHLY
6 PRESCRIPTION DRUG BENEFICIARY PREMIUM.—

7 The term ‘Medicare Advantage monthly pre-
8 scription drug beneficiary premium’ means,
9 with respect to a Medicare Advantage plan, that
10 portion of the bid amount submitted under
11 clause (i) of subsection (a)(6)(A) for the year
12 that is attributable under such section to the
13 provision of statutory prescription drug bene-
14 fits.

15 “(C) MEDICARE ADVANTAGE MONTHLY
16 SUPPLEMENTAL BENEFICIARY PREMIUM.—The

17 term ‘Medicare Advantage monthly supple-
18 mental beneficiary premium’ means, with re-
19 spect to a Medicare Advantage plan, the portion
20 of the aggregate monthly bid amount submitted
21 under clause (i) of subsection (a)(6)(A) for the
22 year that is attributable under such section to
23 the provision of nonstatutory benefits.”.

1 (3) REQUIREMENT FOR UNIFORM PREMIUM
2 AND BID AMOUNTS.—Section 1854(c) (42 U.S.C.
3 1395w–24(c)) is amended to read as follows:

4 “(c) UNIFORM PREMIUM AND BID AMOUNTS.—The
5 Medicare Advantage monthly bid amount submitted under
6 subsection (a)(6), the Medicare Advantage monthly basic,
7 prescription drug, and supplemental beneficiary pre-
8 miums, and the Medicare Advantage monthly MSA pre-
9 mium charged under subsection (b) of a Medicare Advan-
10 tage organization under this part may not vary among in-
11 dividuals enrolled in the plan.”.

12 (4) PERMITTING BENEFICIARY REBATES.—

13 (A) Section 1851(h)(4)(A) (42 U.S.C.
14 1395w–21(h)(4)(A)) is amended by inserting
15 “except as provided under section
16 1854(b)(1)(C)” after “or otherwise”.

17 (B) Section 1854(d) (42 U.S.C. 1395w–
18 24(d)) is amended by inserting “, except as pro-
19 vided under subsection (b)(1)(C),” after “and
20 may not provide”.

21 (5) OTHER CONFORMING AMENDMENTS RELAT-
22 ING TO BIDS.—Section 1854 (42 U.S.C. 1395w–24)
23 is amended—

1 (A) in the heading of subsection (a), by in-
2 serting “AND BID AMOUNTS” after “PRE-
3 MIUMS”; and

4 (B) in subsection (a)(5)(A), by inserting
5 “paragraphs (2), (3), and (4) of” after “filed
6 under”.

7 (e) ADDITIONAL CONFORMING AMENDMENTS.—

8 (1) ANNUAL DETERMINATION AND ANNOUNCE-
9 MENT OF CERTAIN FACTORS.—Section 1853(b)(1)
10 (42 U.S.C. 1395w-23(b)(1)) is amended by striking
11 “the respective calendar year” and all that follows
12 and inserting the following: “the calendar year con-
13 cerned with respect to each Medicare Advantage
14 payment area, the following:

15 “(A) PRE-COMPETITION INFORMATION.—

16 For years before 2006, the following:

17 “(i) MEDICARE ADVANTAGE CAPITA-
18 TION RATES.—The annual Medicare Ad-
19 vantage capitation rate for each Medicare
20 Advantage payment area for the year.

21 “(ii) ADJUSTMENT FACTORS.—The
22 risk and other factors to be used in adjust-
23 ing such rates under subsection (a)(1)(A)
24 for payments for months in that year.

1 “(B) COMPETITION INFORMATION.—For
2 years beginning with 2006, the following:

3 “(i) BENCHMARK.—The Medicare Ad-
4 vantage area-specific non-drug benchmark
5 under section 1853(j).

6 “(ii) ADJUSTMENT FACTORS.—The
7 adjustment factors applied under section
8 1853(a)(1)(A)(iv) (relating to demographic
9 adjustment), section 1853(a)(1)(B) (relat-
10 ing to adjustment for end-stage renal dis-
11 ease), and section 1853(a)(3) (relating to
12 health status adjustment).”.

13 (2) REPEAL OF PROVISIONS RELATING TO AD-
14 JUSTED COMMUNITY RATE (ACR).—

15 (A) IN GENERAL.—Subsections (e) and (f)
16 of section 1854 (42 U.S.C. 1395w–24) are re-
17 pealed.

18 (B) CONFORMING AMENDMENTS.—(i) Sec-
19 tion 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is
20 amended by striking “, and to reflect” and all
21 that follows and inserting a period.

22 (ii) Section 1852(a)(1) (42 U.S.C. 1395w–
23 22(a)(1)) is amended by striking “title XI” and
24 all that follows and inserting the following:
25 “title XI those items and services (other than

1 hospice care) for which benefits are available
2 under parts A and B to individuals residing in
3 the area served by the plan.”.

4 (iii) Section 1857(d)(1) (42 U.S.C.
5 1395w-27(d)(1)) is amended by striking “,
6 costs, and computation of the adjusted commu-
7 nity rate” and inserting “and costs”.

8 (f) REFERENCES UNDER PART E.—Section 1859 (42
9 U.S.C. 1395w-29) is amended by adding at the end the
10 following new subsection:

11 “(f) APPLICATION UNDER PART E.—In the case of
12 any reference under part E to a requirement or provision
13 of this part in the relation to an EFFS plan or organiza-
14 tion under such part, except as otherwise specified any
15 such requirement or provision shall be applied to such or-
16 ganization or plan in the same manner as such require-
17 ment or provision applies to a Medicare Advantage private
18 fee-for-service plan (and the Medicare Advantage organi-
19 zation that offers such plan) under this part.”.

20 (g) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to payments and premiums for
22 months beginning with January 2006.

1 **CHAPTER 3—ADDITIONAL REFORMS**

2 **SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE AD-**
3 **VANTAGE REPORTING DEADLINES AND AN-**
4 **NUAL, COORDINATED ELECTION PERIOD.**

5 (a) CHANGE IN REPORTING DEADLINE.—Section
6 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by
7 section 532(b)(1) of the Public Health Security and Bio-
8 terrorism Preparedness and Response Act of 2002, is
9 amended by striking “2002, 2003, and 2004 (or July 1
10 of each other year)” and inserting “2002 and each subse-
11 quent year”.

12 (b) DELAY IN ANNUAL, COORDINATED ELECTION
13 PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–
14 21(e)(3)(B)), as amended by section 532(e)(1)(A) of the
15 Public Health Security and Bioterrorism Preparedness
16 and Response Act of 2002, is amended—

17 (1) by striking “and after 2005”; and

18 (2) by striking “, 2004, and 2005” and insert-
19 ing “and any subsequent year”.

20 (c) ANNUAL ANNOUNCEMENT OF PAYMENT
21 RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–
22 23(b)(1)), as amended by section 532(d)(1) of the Public
23 Health Security and Bioterrorism Preparedness and Re-
24 sponse Act of 2002, is amended—

25 (1) by striking “and after 2005”; and

1 (2) by striking “and 2005” and inserting “and
2 each subsequent year”.

3 (d) **REQUIRING PROVISION OF AVAILABLE INFORMA-**
4 **TION COMPARING PLAN OPTIONS.**—The first sentence of
5 section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w-
6 21(d)(2)(A)(ii)) is amended by inserting before the period
7 the following: “to the extent such information is available
8 at the time of preparation of materials for the mailing”.

9 **SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.**

10 (a) **IN GENERAL.**—Section 1856(b)(3) (42 U.S.C.
11 1395w-26(b)(3)) is amended to read as follows:

12 “(3) **RELATION TO STATE LAWS.**—The stand-
13 ards established under this subsection shall super-
14 sede any State law or regulation (other than State
15 licensing laws or State laws relating to plan sol-
16 vency) with respect to Medicare Advantage plans
17 which are offered by Medicare Advantage organiza-
18 tions under this part.”.

19 (b) **EFFECTIVE DATE.**—The amendment made by
20 subsection (a) shall take effect on the date of the enact-
21 ment of this Act.

22 **SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS FOR**
23 **SPECIAL NEEDS BENEFICIARIES.**

24 (a) **TREATMENT AS COORDINATED CARE PLAN.**—
25 Section 1851(a)(2)(A) (42 U.S.C. 1395w-21(a)(2)(A)) is

1 amended by adding at the end the following new sentence:
2 “Specialized Medicare Advantage plans for special needs
3 beneficiaries (as defined in section 1859(b)(4)) may be
4 any type of coordinated care plan.”.

5 (b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR
6 SPECIAL NEEDS BENEFICIARIES DEFINED.—Section
7 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding
8 at the end the following new paragraph:

9 “(4) SPECIALIZED MEDICARE ADVANTAGE
10 PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

11 “(A) IN GENERAL.—The term ‘specialized
12 Medicare Advantage plan for special needs
13 beneficiaries’ means a Medicare Advantage plan
14 that exclusively serves special needs bene-
15 ficiaries (as defined in subparagraph (B)).

16 “(B) SPECIAL NEEDS BENEFICIARY.—The
17 term ‘special needs beneficiary’ means a Medi-
18 care Advantage eligible individual who—

19 “(i) is institutionalized (as defined by
20 the Secretary);

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

23 “(iii) meets such requirements as the
24 Secretary may determine would benefit
25 from enrollment in such a specialized

1 Medicare Advantage plan described in sub-
2 paragraph (A) for individuals with severe
3 or disabling chronic conditions.”.

4 (c) RESTRICTION ON ENROLLMENT PERMITTED.—
5 Section 1859 (42 U.S.C. 1395w–29) is amended by add-
6 ing at the end the following new subsection:

7 “(f) RESTRICTION ON ENROLLMENT FOR SPECIAL-
8 IZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS
9 BENEFICIARIES.—In the case of a specialized Medicare
10 Advantage plan (as defined in subsection (b)(4)), notwith-
11 standing any other provision of this part and in accord-
12 ance with regulations of the Secretary and for periods be-
13 fore January 1, 2007, the plan may restrict the enrollment
14 of individuals under the plan to individuals who are within
15 one or more classes of special needs beneficiaries.”.

16 (d) AUTHORITY TO DESIGNATE OTHER PLANS AS
17 SPECIALIZED MEDICARE ADVANTAGE PLANS.—In pro-
18 mulgating regulations to carry out the last sentence of sec-
19 tion 1851(a)(2)(A) of the Social Security Act (as added
20 by subsection (a)) and section 1859(b)(4) of such Act (as
21 added by subsection (b)), the Secretary may provide (not-
22 withstanding section 1859(b)(4)(A) of such Act) for the
23 offering of specialized Medicare Advantage plans by Medi-
24 care Advantage plans that disproportionately serve special

1 needs beneficiaries who are frail, elderly medicare bene-
2 ficiaries.

3 (e) REPORT TO CONGRESS.—Not later than Decem-
4 ber 31, 2005, the Medicare Benefits Administrator shall
5 submit to Congress a report that assesses the impact of
6 specialized Medicare Advantage plans for special needs
7 beneficiaries on the cost and quality of services provided
8 to enrollees. Such report shall include an assessment of
9 the costs and savings to the medicare program as a result
10 of amendments made by subsections (a), (b), and (c).

11 (f) EFFECTIVE DATES.—

12 (1) IN GENERAL.—The amendments made by
13 subsections (a), (b), and (c) shall take effect upon
14 the date of the enactment of this Act.

15 (2) DEADLINE FOR ISSUANCE OF REQUIRE-
16 MENTS FOR SPECIAL NEEDS BENEFICIARIES; TRAN-
17 SITION.—No later than 6 months after the date of
18 the enactment of this Act, the Secretary shall issue
19 interim final regulations to establish requirements
20 for special needs beneficiaries under section
21 1859(b)(4)(B)(iii) of the Social Security Act, as
22 added by subsection (b).

23 **SEC. 234. MEDICARE MSAS.**

24 (a) EXEMPTION FROM REPORTING ENROLLEE EN-
25 COUNTER DATA.—

1 (1) IN GENERAL.—Section 1852(e)(1) (42
2 U.S.C. 1395w–22(e)(1)) is amended by inserting
3 “(other than MSA plans)” after “plans”.

4 (2) CONFORMING AMENDMENTS.—Section 1852
5 (42 U.S.C. 1395w–22) is amended—

6 (A) in subsection (e)(1)(I), by inserting be-
7 fore the period at the end the following: “if re-
8 quired under such section”; and

9 (B) in subparagraphs (A) and (B) of sub-
10 section (e)(2), by striking “, a non-network
11 MSA plan,” and “, NON-NETWORK MSA
12 PLANS,” each place it appears.

13 (b) MAKING PROGRAM PERMANENT AND ELIMI-
14 NATING CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–
15 21(b)(4)) is amended—

16 (1) in the heading, by striking “ON A DEM-
17 ONSTRATION BASIS”;

18 (2) by striking the first sentence of subpara-
19 graph (A); and

20 (3) by striking the second sentence of subpara-
21 graph (C).

22 (c) APPLYING LIMITATIONS ON BALANCE BILL-
23 ING.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is
24 amended by inserting “or with an organization offering
25 a MSA plan” after “section 1851(a)(2)(A)”.

1 (d) ADDITIONAL AMENDMENT.—Section
2 1851(e)(5)(A) (42 U.S.C. 1395w-21(e)(5)(A)) is amend-
3 ed—

4 (1) by adding “or” at the end of clause (i);

5 (2) by striking “, or” at the end of clause (ii)
6 and inserting a semicolon; and

7 (3) by striking clause (iii).

8 **SEC. 235. EXTENSION OF REASONABLE COST CONTRACTS.**

9 Subparagraph (C) of section 1876(h)(5) (42 U.S.C.
10 1395mm(h)(5)) is amended to read as follows:

11 “(C)(i) Subject to clause (ii), may be extended or re-
12 newed under this subsection indefinitely.

13 “(ii) For any period beginning on or after January
14 1, 2008, a reasonable cost reimbursement contract under
15 this subsection may not be extended or renewed for a serv-
16 ice area insofar as such area, during the entire previous
17 year, was within the service area of 2 or more plans which
18 were coordinated care Medicare Advantage plans under
19 part C or 2 or more enhanced fee-for-service plans under
20 part E and each of which plan for that previous year for
21 the area involved meets the following minimum enrollment
22 requirements:

23 “(I) With respect to any portion of the area in-
24 volved that is within a Metropolitan Statistical Area
25 with a population of more than 250,000 and coun-

1 ties contiguous to such Metropolitan Statistical
2 Area, 5,000 individuals.

3 “(II) With respect to any other portion of such
4 area, 1,500 individuals.”

5 **SEC. 236. EXTENSION OF MUNICIPAL HEALTH SERVICE**
6 **DEMONSTRATION PROJECTS.**

7 Section 9215(a) of the Consolidated Omnibus Budget
8 Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as
9 amended by section 6135 of the Omnibus Budget Rec-
10 onciliation Act of 1989, section 13557 of the Omnibus
11 Budget Reconciliation Act of 1993, section 4017 of BBA,
12 section 534 of BBRA (113 Stat. 1501A–390), and section
13 633 of BIPA, is amended by striking “December 31,
14 2004” and inserting “December 31, 2009”.

15 **SEC. 237. STUDY OF PERFORMANCE-BASED PAYMENT SYS-**
16 **TEMS.**

17 (a) IN GENERAL.—The Secretary shall request the
18 Institute of Medicine of the National Academy of Sciences
19 to—

20 (1) conduct a study that reviews and evaluates
21 public and private sector experiences in establishing
22 performance measures and payment incentives under
23 the medicare program and linking performance to
24 payment; and

1 (2) submit a report to the Secretary and Con-
2 gress, not later than 18 months after the date of the
3 enactment of this Act, regarding such study.

4 (b) STUDY.—The study under subsection (a)(1)
5 shall—

6 (1) include a review and evaluation of incentives
7 that have been or could be used to encourage quality
8 performance, including those aimed at health plans
9 and their enrollees, providers and their patients, and
10 other incentives that encourage quality-based health
11 care purchasing and collaborative efforts to improve
12 performance; and

13 (2) examine how these measures and incentives
14 might be applied in the Medicare Advantage pro-
15 gram, the Enhanced Fee-For-Service (EFTS) pro-
16 gram, and traditional fee-for-service programs.

17 (c) REPORT RECOMMENDATIONS.—The report under
18 subsection (a)(2) shall—

19 (1) include recommendations regarding appro-
20 priate performance measures for use in assessing
21 and paying for quality; and

22 (2) identify options for updating performance
23 measures.

1 **Subtitle C—Application of FEHBP-**
2 **Style Competitive Reforms**

3 **SEC. 241. APPLICATION OF FEHBP-STYLE COMPETITIVE RE-**
4 **FORM BEGINNING IN 2010.**

5 (a) IDENTIFICATION OF COMPETITIVE EFFS RE-
6 GIONS; COMPUTATION OF COMPETITIVE EFFS NON-
7 DRUG BENCHMARKS UNDER EFFS PROGRAM.—

8 (1) IN GENERAL.—Section 1860E–3, as added
9 by section 201(a), is amended by adding at the end
10 the following new subsection:

11 “(e) APPLICATION OF COMPETITION.—

12 “(1) DETERMINATION OF COMPETITIVE EFFS
13 REGIONS.—

14 “(A) IN GENERAL.—For purposes of this
15 part, the term ‘competitive EFFS region’
16 means, for a year beginning with 2010, an
17 EFFS region that the Administrator finds—

18 “(i) there will be offered in the region
19 during the annual, coordinated election pe-
20 riod under section 1851(e)(3)(B) (as ap-
21 plied under section 1860E–1(c)) before the
22 beginning of the year at least 2 EFFS
23 plans (in addition to the fee-for-service
24 program under parts A and B), each of-
25 fered by a different EFFS organization

1 and each of which met the minimum en-
2 rollment requirements of paragraph (1) of
3 section 1857(b) (as applied without regard
4 to paragraph (3) thereof) as of March of
5 the previous year; and

6 “(ii) during March of the previous
7 year at least the percentage specified in
8 subparagraph (C) of the number of EFFE
9 eligible individuals who reside in the region
10 were enrolled in an EFFE plan.

11 “(B) PERCENTAGE SPECIFIED.—

12 “(i) IN GENERAL.—For purposes of
13 subparagraph (A), subject to clause (ii),
14 the percentage specified in this subpara-
15 graph for a year is equal the lesser of 20
16 percent or to the sum of—

17 “(I) the percentage, as estimated
18 by the Administrator, of EFFE eligi-
19 ble individuals in the United States
20 who are enrolled in EFFE plans dur-
21 ing March of the previous year; and

22 “(II) the percentage, as esti-
23 mated by the Administrator, of Medi-
24 care Advantage eligible individuals in
25 the United States who are enrolled in

1 Medicare Advantage plans during
2 March of the previous year.

3 “(ii) EXCEPTION.—In the case of an
4 EFFS region that was a competitive
5 EFFS region for the previous year, the
6 Medicare Benefits Administrator may con-
7 tinue to treat the region as meeting the re-
8 quirement of subparagraph (A)(ii) if the
9 region would meet such requirement but
10 for a de minimis reduction below the per-
11 centage specified in clause (i).

12 “(2) COMPETITIVE EFFS NON-DRUG MONTHLY
13 BENCHMARK AMOUNT.—For purposes of this part,
14 the term ‘competitive EFFS non-drug monthly
15 benchmark amount’ means, with respect to an
16 EFFS region for a month in a year and subject to
17 paragraph (8), the sum of the 2 components de-
18 scribed in paragraph (3) for the region and year.
19 The Administrator shall compute such benchmark
20 amount for each competitive EFFS region before the
21 beginning of each annual, coordinated election pe-
22 riod under section 1851(e)(3)(B) for each year (be-
23 ginning with 2010) in which it is designated as such
24 a region.

1 “(3) 2 COMPONENTS.—For purposes of para-
2 graph (2), the 2 components described in this para-
3 graph for an EFFF region and a year are the fol-
4 lowing:

5 “(A) EFFF COMPONENT.—The product of
6 the following:

7 “(i) WEIGHTED AVERAGE OF PLAN
8 BIDS IN REGION.—The weighted average of
9 the EFFF plan bids for the region and
10 year (as determined under paragraph
11 (4)(A)).

12 “(ii) NON-FFS MARKET SHARE.—1
13 minus the fee-for-service market share per-
14 centage determined under paragraph (5)
15 for the region and the year.

16 “(B) FEE-FOR-SERVICE COMPONENT.—
17 The product of the following:

18 “(i) FEE-FOR-SERVICE REGION-SPE-
19 CIFIC NON-DRUG AMOUNT.—The fee-for-
20 service region-specific non-drug amount (as
21 defined in paragraph (6)) for the region
22 and year.

23 “(ii) FEE-FOR-SERVICE MARKET
24 SHARE.—The fee-for-service market share

1 percentage (determined under paragraph
2 (5)) for the region and the year.

3 “(4) DETERMINATION OF WEIGHTED AVERAGE
4 EFFS PLAN BIDS FOR A REGION.—

5 “(A) IN GENERAL.—For purposes of para-
6 graph (3)(A)(i), the weighted average of EFFS
7 plan bids for an EFFS region and a year is the
8 sum of the following products for EFFS plans
9 described in subparagraph (C) in the region
10 and year:

11 “(i) UNADJUSTED EFFS STATUTORY
12 NON-DRUG MONTHLY BID AMOUNT.—The
13 unadjusted EFFS statutory non-drug
14 monthly bid amount (as defined in sub-
15 section (a)(3)(A)(ii)(I)) for the region and
16 year.

17 “(ii) PLAN’S SHARE OF EFFS ENROLL-
18 MENT IN REGION.—The number of individ-
19 uals described in subparagraph (B), di-
20 vided by the total number of such individ-
21 uals for all EFFS plans described in sub-
22 paragraph (C) for that region and year.

23 “(B) COUNTING OF INDIVIDUALS.—The
24 Administrator shall count, for each EFFS plan
25 described in subparagraph (C) for an EFFS re-

1 region and year, the number of individuals who
2 reside in the region and who were enrolled
3 under such plan under this part during March
4 of the previous year.

5 “(C) EXCLUSION OF PLANS NOT OFFERED
6 IN PREVIOUS YEAR.—For an EFFF region and
7 year, the EFFF plans described in this sub-
8 paragraph are plans that are offered in the re-
9 gion and year and were offered in the region in
10 March of the previous year.

11 “(5) COMPUTATION OF FEE-FOR-SERVICE MAR-
12 KET SHARE PERCENTAGE.—The Administrator shall
13 determine, for a year and an EFFF region, the pro-
14 portion (in this subsection referred to as the ‘fee-for-
15 service market share percentage’) of the EFFF eligi-
16 ble individuals who are residents of the region dur-
17 ing March of the previous year, of such individuals
18 who were not enrolled in an EFFF plan or in a
19 Medicare Advantage plan (or, if greater, such pro-
20 portion determined for individuals nationally).

21 “(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-
22 DRUG AMOUNT.—

23 “(A) IN GENERAL.—For purposes of para-
24 graph (3)(B)(i) and section 1839(h)(2)(A), sub-
25 ject to subparagraph (C), the term ‘fee-for-serv-

1 ice region-specific non-drug amount’ means, for
2 a competitive EFFS region and a year, the ad-
3 justed average per capita cost for the year in-
4 volved, determined under section 1876(a)(4) for
5 such region for services covered under parts A
6 and B for individuals entitled to benefits under
7 part A and enrolled under this part who are not
8 enrolled in an EFFS plan under part E or a
9 Medicare Advantage plan under part C for the
10 year, but adjusted to exclude costs attributable
11 to payments under section 1886(h).

12 “(B) USE OF FULL RISK ADJUSTMENT TO
13 STANDARDIZE FEE-FOR-SERVICE COSTS TO TYP-
14 ICAL BENEFICIARY.—In determining the ad-
15 justed average per capita cost for a region and
16 year under subparagraph (A), such costs shall
17 be adjusted to fully take into account the demo-
18 graphic and health status risk factors estab-
19 lished under subsection (c)(3) so that such per
20 capita costs reflect the average costs for a typ-
21 ical beneficiary residing in the region.

22 “(C) INCLUSION OF COSTS OF VA AND DOD
23 MILITARY FACILITY SERVICES TO MEDICARE-
24 ELIGIBLE BENEFICIARIES.—In determining the
25 adjusted average per capita cost under subpara-

1 graph (A) for a year, such cost shall be ad-
2 justed to include the Administrator's estimate,
3 on a per capita basis, of the amount of addi-
4 tional payments that would have been made in
5 the region involved under this title if individuals
6 entitled to benefits under this title had not re-
7 ceived services from facilities of the Department
8 of Veterans Affairs or the Department of De-
9 fense.

10 “(7) APPLICATION OF COMPETITION.—In the
11 case of an EFFS region that is a competitive EFFS
12 region for a year, for purposes of applying sub-
13 sections (b) and (c)(1) and section 1860E–4(a), any
14 reference to an EFFS region-specific non-drug
15 monthly benchmark amount shall be treated as a
16 reference to the competitive EFFS non-drug month-
17 ly benchmark amount under paragraph (2) for the
18 region and year.

19 “(8) PHASE-IN OF BENCHMARK FOR EACH RE-
20 GION.—

21 “(A) USE OF BLENDED BENCHMARK.—In
22 the case of a region that has not been a com-
23 petitive EFFS region for each of the previous
24 4 years, the competitive EFFS non-drug

1 monthly benchmark amount shall be equal to
2 the sum of the following:

3 “(i) NEW COMPETITIVE COMPO-
4 NENT.—The product of—

5 “(I) the weighted average phase-
6 in proportion for that area and year,
7 as specified in subparagraph (B); and

8 “(II) the competitive EFFS non-
9 drug monthly benchmark amount for
10 the region and year, determined under
11 paragraph (2) without regard to this
12 paragraph.

13 “(ii) OLD COMPETITIVE COMPO-
14 NENT.—The product of—

15 “(I) 1 minus the weighted aver-
16 age phase-in proportion for that re-
17 gion and year; and

18 “(II) the EFFS region-specific
19 non-drug benchmark amount for the
20 region and the year.

21 “(B) COMPUTATION OF WEIGHTED AVER-
22 AGE PHASE-IN PROPORTION.—For purposes of
23 this paragraph, the ‘weighted average phase-in
24 proportion’ for an EFFS region for a year shall
25 be determined as follows:

1 “(i) FIRST YEAR (AND REGION NOT
2 COMPETITIVE REGION IN PREVIOUS
3 YEAR).—If the area was not a competitive
4 EFFS region in the previous year, the
5 weighted average phase-in proportion for
6 the region for the year is equal to $\frac{1}{5}$.

7 “(ii) COMPETITIVE REGION IN PRE-
8 VIOUS YEAR.—If the region was a competi-
9 tive EFFS region in the previous year, the
10 weighted average phase-in proportion for
11 the region for the year is equal to the
12 weighted average phase-in proportion de-
13 termined under this subparagraph for the
14 region for the previous year plus $\frac{1}{5}$, but in
15 no case more than 1.”.

16 (2) CONFORMING AMENDMENTS.—

17 (A) Such section 1860E–3 is further
18 amended—

19 (i) in subsection (b), by adding at the
20 end the following new paragraph:

21 “(4) APPLICATION IN COMPETITIVE RE-
22 GIONS.—For special rules applying this sub-
23 section in competitive EFFS regions, see sub-
24 section (e)(7).”;

1 (ii) in subsection (c)(1), by inserting
 2 “and subsection (e)(7)” after “(as made
 3 applicable under subsection (d))”; and

4 (iii) in subsection (d) , by striking
 5 “and (e)” and inserting “(e), and (k)”.

6 (B) Section 1860E-4(a)(1), as inserted by
 7 section 201(a)(2), is amended by inserting “,
 8 except as provided in section 1860E-3(e)(7)”
 9 after “paragraph (2)”.

10 (b) IDENTIFICATION OF COMPETITIVE MEDICARE
 11 ADVANTAGE AREAS; APPLICATION OF COMPETITIVE
 12 MEDICARE ADVANTAGE NON-DRUG BENCHMARKS
 13 UNDER MEDICARE ADVANTAGE PROGRAM.—

14 (1) IN GENERAL.—Section 1853, as amended
 15 by section 221(b)(3), is amended by adding at the
 16 end the following new subsection:

17 “(k) APPLICATION OF COMPETITION.—

18 “(1) DETERMINATION OF COMPETITIVE MEDI-
 19 CARE ADVANTAGE AREAS.—

20 “(A) IN GENERAL.—For purposes of this
 21 part, the terms ‘competitive Medicare Advan-
 22 tage area’ and ‘CMA area’ mean, for a year be-
 23 ginning with 2010, an area (which is a metro-
 24 politan statistical area or other area with a sub-

1 stantial number of Medicare Advantage enroll-
2 ees) that the Administrator finds—

3 “(i) there will be offered during the
4 annual, coordinated election period under
5 section 1851(e)(3)(B) under this part be-
6 fore the beginning of the year at least 2
7 Medicare Advantage plans (in addition to
8 the fee-for-service program under parts A
9 and B), each offered by a different Medi-
10 care Advantage organization and each of
11 which met the minimum enrollment re-
12 quirements of paragraph (1) of section
13 1857(b) (as applied without regard to
14 paragraph (3) thereof) as of March of the
15 previous year with respect to the area; and

16 “(ii) during March of the previous
17 year at least the percentage specified in
18 subparagraph (B) of the number of Medi-
19 care Advantage eligible individuals who re-
20 side in the area were enrolled in a Medi-
21 care Advantage plan.

22 “(B) PERCENTAGE SPECIFIED.—

23 “(i) IN GENERAL.—For purposes of
24 subparagraph (A), subject to clause (ii),
25 the percentage specified in this subpara-

1 graph for a year is equal the lesser of 20
2 percent or to the sum of—

3 “(I) the percentage, as estimated
4 by the Administrator, of EFFS eligi-
5 ble individuals in the United States
6 who are enrolled in EFFS plans dur-
7 ing March of the previous year; and

8 “(II) the percentage, as esti-
9 mated by the Administrator, of Medi-
10 care Advantage eligible individuals in
11 the United States who are enrolled in
12 Medicare Advantage plans during
13 March of the previous year.

14 “(ii) EXCEPTION.—In the case of an
15 area that was a competitive area for the
16 previous year, the Medicare Benefits Ad-
17 ministrator may continue to treat the area
18 as meeting the requirement of subpara-
19 graph (A)(ii) if the area would meet such
20 requirement but for a de minimis reduction
21 below the percentage specified in clause (i).

22 “(2) COMPETITIVE MEDICARE ADVANTAGE
23 NON-DRUG MONTHLY BENCHMARK AMOUNT.—For
24 purposes of this part, the term ‘competitive Medi-
25 care Advantage non-drug monthly benchmark

1 amount' means, with respect to a competitive Medi-
2 care Advantage area for a month in a year subject
3 to paragraph (8), the sum of the 2 components de-
4 scribed in paragraph (3) for the area and year. The
5 Administrator shall compute such benchmark
6 amount for each competitive Medicare Advantage
7 area before the beginning of each annual, coordi-
8 nated election period under section 1851(e)(3)(B)
9 for each year (beginning with 2010) in which it is
10 designated as such an area.

11 “(3) 2 COMPONENTS.—For purposes of para-
12 graph (2), the 2 components described in this para-
13 graph for a competitive Medicare Advantage area
14 and a year are the following:

15 “(A) MEDICARE ADVANTAGE COMPO-
16 NENT.—The product of the following:

17 “(i) WEIGHTED AVERAGE OF MEDI-
18 CARE ADVANTAGE PLAN BIDS IN AREA.—
19 The weighted average of the plan bids for
20 the area and year (as determined under
21 paragraph (4)(A)).

22 “(ii) NON-FFS MARKET SHARE.—1
23 minus the fee-for-service market share per-
24 centage, determined under paragraph (5)
25 for the area and year.

1 “(B) FEE-FOR-SERVICE COMPONENT.—

2 The product of the following:

3 “(i) FEE-FOR-SERVICE AREA-SPECIFIC
4 NON-DRUG AMOUNT.—The fee-for-service
5 area-specific non-drug amount (as defined
6 in paragraph (6)) for the area and year.

7 “(ii) FEE-FOR-SERVICE MARKET
8 SHARE.—The fee-for-service market share
9 percentage, determined under paragraph
10 (5) for the area and year.

11 “(4) DETERMINATION OF WEIGHTED AVERAGE
12 MEDICARE ADVANTAGE BIDS FOR AN AREA.—

13 “(A) IN GENERAL.—For purposes of para-
14 graph (3)(A)(i), the weighted average of plan
15 bids for an area and a year is the sum of the
16 following products for Medicare Advantage
17 plans described in subparagraph (C) in the area
18 and year:

19 “(i) MONTHLY MEDICARE ADVANTAGE
20 STATUTORY NON-DRUG BID AMOUNT.—The
21 unadjusted Medicare Advantage statutory
22 non-drug monthly bid amount.

23 “(ii) PLAN’S SHARE OF MEDICARE AD-
24 VANTAGE ENROLLMENT IN AREA.—The
25 number of individuals described in sub-

1 paragraph (B), divided by the total num-
2 ber of such individuals for all Medicare Ad-
3 vantage plans described in subparagraph
4 (C) for that area and year.

5 “(B) COUNTING OF INDIVIDUALS.—The
6 Administrator shall count, for each Medicare
7 Advantage plan described in subparagraph (C)
8 for an area and year, the number of individuals
9 who reside in the area and who were enrolled
10 under such plan under this part during March
11 of the previous year.

12 “(C) EXCLUSION OF PLANS NOT OFFERED
13 IN PREVIOUS YEAR.—For an area and year, the
14 Medicare Advantage plans described in this
15 subparagraph are plans described in the first
16 sentence of section 1851(a)(2)(A) that are of-
17 fered in the area and year and were offered in
18 the area in March of the previous year.

19 “(5) COMPUTATION OF FEE-FOR-SERVICE MAR-
20 KET SHARE PERCENTAGE.—The Administrator shall
21 determine, for a year and a competitive Medicare
22 Advantage area, the proportion (in this subsection
23 referred to as the ‘fee-for-service market share per-
24 centage’) of Medicare Advantage eligible individuals
25 residing in the area who during March of the pre-

1 vious year were not enrolled in a Medicare Advan-
2 tage plan or in an EFFE plan (or, if greater, such
3 proportion determined for individuals nationally).

4 “(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-
5 DRUG AMOUNT.—

6 “(A) IN GENERAL.—For purposes of para-
7 graph (3)(B)(i) and section 1839(h)(1)(A), sub-
8 ject to subparagraph (C), the term ‘fee-for-serv-
9 ice area-specific non-drug amount’ means, for a
10 competitive Medicare Advantage area and a
11 year, the adjusted average per capita cost for
12 the year involved, determined under section
13 1876(a)(4) for such area for services covered
14 under parts A and B for individuals entitled to
15 benefits under part A and enrolled under this
16 part who are not enrolled in a Medicare Advan-
17 tage plan under part C or an EFFE plan under
18 part E for the year, but adjusted to exclude
19 costs attributable to payments under section
20 1886(h).

21 “(B) USE OF FULL RISK ADJUSTMENT TO
22 STANDARDIZE FEE-FOR-SERVICE COSTS TO TYP-
23 ICAL BENEFICIARY.—In determining the ad-
24 justed average per capita cost for an area and
25 year under subparagraph (A), such costs shall

1 be adjusted to fully take into account the demo-
2 graphic and health status risk factors estab-
3 lished under subsection (a)(1)(A)(iv) so that
4 such per capita costs reflect the average costs
5 for a typical beneficiary residing in the area.

6 “(C) INCLUSION OF COSTS OF VA AND DOD
7 MILITARY FACILITY SERVICES TO MEDICARE-
8 ELIGIBLE BENEFICIARIES.—In determining the
9 adjusted average per capita cost under subpara-
10 graph (A) for a year, such cost shall be ad-
11 justed to include the Administrator’s estimate,
12 on a per capita basis, of the amount of addi-
13 tional payments that would have been made in
14 the area involved under this title if individuals
15 entitled to benefits under this title had not re-
16 ceived services from facilities of the Department
17 of Veterans Affairs or the Department of De-
18 fense.

19 “(7) APPLICATION OF COMPETITION.—In the
20 case of an area that is a competitive Medicare Ad-
21 vantage area for a year, for purposes of applying
22 subsection (a)(1)(A)(ii) and sections
23 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any ref-
24 erence to a Medicare Advantage area-specific non-
25 drug monthly benchmark amount shall be treated as

1 a reference to the competitive Medicare Advantage
2 non-drug monthly benchmark amount under para-
3 graph (2) for the area and year.

4 “(8) PHASE-IN OF BENCHMARK FOR EACH
5 AREA.—

6 “(A) USE OF BLENDED BENCHMARK.—In
7 the case of an area that has not been a com-
8 petitive Medicare Advantage area for each of
9 the previous 4 years, the competitive Medicare
10 Advantage non-drug monthly benchmark
11 amount shall be equal to the sum of the fol-
12 lowing:

13 “(i) NEW COMPETITIVE COMPO-
14 NENT.—The product of—

15 “(I) the weighted average phase-
16 in proportion for that area and year,
17 as specified in subparagraph (B); and

18 “(II) the competitive Medicare
19 Advantage non-drug monthly bench-
20 mark amount for the area and year,
21 determined under paragraph (2) with-
22 out regard to this paragraph.

23 “(ii) OLD COMPETITIVE COMPO-
24 NENT.—The product of—

1 “(I) 1 minus the weighted aver-
2 age phase-in proportion for that area
3 and year; and

4 “(II) the Medicare Advantage
5 area-wide non-drug benchmark
6 amount for the area and the year.

7 “(B) COMPUTATION OF WEIGHTED AVER-
8 AGE PHASE-IN PROPORTION.—For purposes of
9 this paragraph, the ‘weighted average phase-in
10 proportion’ for a Medicare Advantage payment
11 area for a year shall be determined as follows:

12 “(i) FIRST YEAR (AND AREA NOT
13 COMPETITIVE AREA IN PREVIOUS YEAR).—
14 If the area was not a Medicare Advantage
15 competitive area in the previous year, the
16 weighted average phase-in proportion for
17 the area for the year is equal to $\frac{1}{5}$.

18 “(ii) COMPETITIVE AREA IN PREVIOUS
19 YEAR.—If the area was a competitive
20 Medicare Advantage area in the previous
21 year, the weighted average phase-in pro-
22 portion for the area for the year is equal
23 to the weighted average phase-in propor-
24 tion determined under this subparagraph

1 for the area for the previous year plus $\frac{1}{5}$,
2 but in no case more than 1.

3 “(C) MEDICARE ADVANTAGE AREA-WIDE
4 NON-DRUG BENCHMARK AMOUNT.—For pur-
5 poses of subparagraph (A)(ii)(II), the term
6 ‘Medicare Advantage area-wide non-drug bench-
7 mark amount’ means, for an area and year, the
8 weighted average of the amounts described in
9 section 1853(j) for Medicare Advantage pay-
10 ment area or areas included in the area (based
11 on the number of traditional fee-for-service en-
12 rollees in such payment area or areas) and
13 year.”.

14 (2) APPLICATION.—Section 1854 (42 U.S.C.
15 1395w-24) is amended—

16 (A) in subsection (b)(1)(C)(i), as added by
17 section 221(b)(1)(A), by striking “(i) REQUIRE-
18 MENT.—The” and inserting “(i) REQUIREMENT
19 FOR NON-COMPETITIVE AREAS.—In the case of
20 a Medicare Advantage payment area that is not
21 a competitive Medicare Advantage area des-
22 ignated under section 1853(k)(1), the”;

23 (B) in subsection (b)(1)(C), as so added,
24 by inserting after clause (i) the following new
25 clause:

1 “(ii) REQUIREMENT FOR COMPETITIVE MEDICARE ADVANTAGE AREAS.—In
2 TIVE MEDICARE ADVANTAGE AREAS.—In
3 the case of a Medicare Advantage payment
4 area that is designated as a competitive
5 Medicare Advantage area under section
6 1853(k)(1), if there are average per capita
7 monthly savings described in paragraph
8 (6) for a Medicare Advantage plan and
9 year, the Medicare Advantage plan shall
10 provide to the enrollee a monthly rebate
11 equal to 75 percent of such savings.”; and
12 (C) by adding at the end of subsection (b),
13 as amended by sections 221(b)(1)(B) and
14 221(b)(2), the following new paragraph:

15 “(6) COMPUTATION OF AVERAGE PER CAPITA
16 MONTHLY SAVINGS FOR COMPETITIVE MEDICARE
17 ADVANTAGE AREAS.—For purposes of paragraph
18 (1)(C)(ii), the average per capita monthly savings
19 referred to in such paragraph for a Medicare Advan-
20 tage plan and year shall be computed in the same
21 manner as the average per capita monthly savings is
22 computed under paragraph (3) except that the ref-
23 erence to the Medicare Advantage area-specific non-
24 drug monthly benchmark amount in paragraph
25 (3)(B)(i) (or to the benchmark amount as adjusted

1 under paragraph (3)(C)(i)) is deemed to be a ref-
2 erence to the competitive Medicare Advantage non-
3 drug monthly benchmark amount (or such amount
4 as adjusted in the manner described in paragraph
5 (3)(B)(i)).”.

6 (3) ADDITIONAL CONFORMING AMENDMENTS.—

7 (A) PAYMENT OF PLANS.—Section
8 1853(a)(1)(A)(ii), as amended by section
9 221(c)(1), is amended—

10 (i) in subclauses (I) and (II), by in-
11 sserting “(or, insofar as such payment area
12 is a competitive Medicare Advantage area,
13 described in section 1854(b)(6))” after
14 “section 1854(b)(3)(C)”; and

15 (ii) in subclause (II), by inserting
16 “(or, insofar as such payment area is a
17 competitive Medicare Advantage area, the
18 competitive Medicare Advantage non-drug
19 monthly benchmark amount)” after “Medi-
20 care Advantage area-specific non-drug
21 monthly benchmark amount”; and

22 (B) DISCLOSURE OF INFORMATION.—Sec-
23 tion 1853(b)(1)(B), as amended by section
24 221(e)(1), is amended to read as follows:

1 “(B) COMPETITION INFORMATION.—For
2 years beginning with 2006, the following:

3 “(i) BENCHMARKS.—The Medicare
4 Advantage area-specific non-drug bench-
5 mark under section 1853(j) and, if applica-
6 ble, the competitive Medicare Advantage
7 non-drug benchmark under section
8 1853(k)(2), for the year and competitive
9 Medicare Advantage area involved and the
10 national fee-for-service market share per-
11 centage for the area and year.

12 “(ii) ADJUSTMENT FACTORS.—The
13 adjustment factors applied under section
14 1853(a)(1)(A)(iv) (relating to demographic
15 adjustment), section 1853(a)(1)(B) (relat-
16 ing to adjustment for end-stage renal dis-
17 ease), and section 1853(a)(3) (relating to
18 health status adjustment).

19 “(iii) CERTAIN BENCHMARKS AND
20 AMOUNTS.—In the case of a competitive
21 Medicare Advantage area, the Medicare
22 Advantage area-wide non-drug benchmark
23 amount (as defined in subsection
24 (k)(8)(C)) and the fee-for-service area-spe-

1 cific non-drug amount (as defined in sec-
2 tion 1853(k)(6)) for the area.

3 “(iv) INDIVIDUALS.—The number of
4 individuals counted under subsection
5 (k)(4)(B) and enrolled in each Medicare
6 Advantage plan in the area.”.

7 (C) DEFINITION OF MONTHLY BASIC PRE-
8 MIUM.—Section 1854(b)(2)(A)(ii), as amended
9 by section 221(d)(2), is amended by inserting
10 “(or, in the case of a competitive Medicare Ad-
11 vantage area, the competitive Medicare Advan-
12 tage non-drug monthly benchmark amount or,
13 in applying this paragraph under part E in the
14 case of a competitive EFFE region, the com-
15 petitive EFFE non-drug monthly benchmark
16 amount)” after “benchmark amount”.

17 (c) PREMIUM ADJUSTMENT.—

18 (1) IN GENERAL.—Section 1839 (42 U.S.C.
19 1395r) is amended by adding at the end the fol-
20 lowing new subsection:

21 “(h)(1)(A) In the case of an individual who resides
22 in a competitive Medicare Advantage area under section
23 1853(k)(1) (regardless of whether such area is in a com-
24 petitive EFFE region under section 1860E–3(e)) and who
25 is not enrolled in a Medicare Advantage plan under part

1 C or in an EFFS plan under part E, the monthly premium
2 otherwise applied under this part (determined without re-
3 gard to subsections (b) and (f) or any adjustment under
4 this subsection) shall be adjusted as follows: If the fee-
5 for-service area-specific non-drug amount (as defined in
6 section 1853(k)(6)) for the competitive Medicare Advan-
7 tage area in which the individual resides for a month—

8 “(i) does not exceed the competitive Medicare
9 Advantage non-drug benchmark (as determined
10 under paragraph (2) of section 1853(k), without re-
11 gard to paragraph (8) thereof) for such area, the
12 amount of the premium for the individual for the
13 month shall be reduced by an amount equal to the
14 product of the adjustment factor under subpara-
15 graph (C) and 75 percent of the amount by which
16 such competitive benchmark exceeds such fee-for-
17 service area-specific non-drug amount; or

18 “(ii) exceeds such competitive Medicare Advan-
19 tage non-drug benchmark, the amount of the pre-
20 mium for the individual for the month shall be ad-
21 justed to ensure, subject to subparagraph (B),
22 that—

23 “(I) the sum of the amount of the adjusted
24 premium and the competitive Medicare Advan-

1 tage non-drug benchmark for the area, is equal
2 to

3 “(II) the sum of the unadjusted premium
4 plus amount of the fee-for-service area-specific
5 non-drug amount for the area.

6 “(B) In no case shall the actual amount of an adjust-
7 ment under subparagraph (A)(ii) exceed the product of
8 the adjustment factor under subparagraph (C) and the
9 amount of the adjustment otherwise computed under sub-
10 paragraph (A)(ii) without regard to this subparagraph.

11 “(C) The adjustment factor under this subparagraph
12 for an area for a year is equal to—

13 “(i) the number of consecutive years (in the 5-
14 year period ending with the year involved) in which
15 such area was a competitive Medicare Advantage
16 area; divided by

17 “(ii) 5.

18 “(2)(A) In the case of an individual who resides in
19 an area that is within a competitive EFFE region under
20 section 1860E–3(e) but is not within a competitive Medi-
21 care Advantage area under section 1853(k)(1) and who
22 is not enrolled in a Medicare Advantage plan under part
23 C or in an EFFE plan under part E, the monthly premium
24 otherwise applied under this part (determined without re-
25 gard to subsections (b) and (f) or any adjustment under

1 this subsection) shall be adjusted as follows: If the fee-
2 for-service region-specific non-drug amount (as defined in
3 section 1860E-3(e)(6)) for a region for a month—

4 “(i) does not exceed the competitive EFFS non-
5 drug monthly benchmark amount (as determined
6 under paragraph (2) of section 1860E-3(e), without
7 regard to paragraph (8) thereof) for such region, the
8 amount of the premium for the individual for the
9 month shall be reduced by an amount equal to the
10 product of the adjustment factor under subpara-
11 graph (C) and 75 percent of the amount by which
12 such competitive benchmark amount exceeds such
13 fee-for-service region-specific non-drug benchmark
14 amount; or

15 “(ii) exceeds such competitive EFFS non-drug
16 monthly benchmark amount, the amount of the pre-
17 mium for the individual for the month shall be ad-
18 justed to ensure, subject to subparagraph (B),
19 that—

20 “(I) the sum of the amount of the adjusted
21 premium and the competitive EFFS non-drug
22 monthly benchmark amount for the region, is
23 equal to

1 “(II) the sum of the unadjusted premium
2 plus the amount of the EFFS region-specific
3 non-drug monthly bidfor the region.

4 “(B) In no case shall the actual amount of an adjust-
5 ment under subparagraph (A)(ii) exceed the product of
6 the adjustment factor under subparagraph (C) and the
7 amount of the adjustment otherwise computed under sub-
8 paragraph (A)(ii) without regard to this subparagraph.

9 “(C) The adjustment factor under this subparagraph
10 for an EFFS region for a year is equal to—

11 “(i) the number of consecutive years (in the 5-
12 year period ending with the year involved) in which
13 such region was a competitive EFFS region; divided
14 by

15 “(ii) 5.

16 “(3) Nothing in this subsection shall be construed as
17 preventing a reduction under paragraph (1)(A) or para-
18 graph (2)(A) in the premium otherwise applicable under
19 this part to zero or from requiring the provision of a re-
20 bate to the extent such premium would otherwise be re-
21 quired to be less than zero.

22 “(4) The adjustment in the premium under this sub-
23 section shall be effected in such manner as the Medicare
24 Benefits Administrator determines appropriate.

1 “(5) In order to carry out this subsection (insofar as
2 it is effected through the manner of collection of premiums
3 under 1840(a)), the Medicare Benefits Administrator shall
4 transmit to the Commissioner of Social Security—

5 “(A) at the beginning of each year, the name,
6 social security account number, and the amount of
7 the adjustment (if any) under this subsection for
8 each individual enrolled under this part for each
9 month during the year; and

10 “(B) periodically throughout the year, informa-
11 tion to update the information previously trans-
12 mitted under this paragraph for the year.”.

13 (2) NO CHANGE IN MEDICARE’S DEFINED BEN-
14 EFIT PACKAGE.—Nothing in this part (or the
15 amendments made by this part) shall be construed
16 as changing the entitlement to defined benefits
17 under parts A and B of title XVIII of the Social Se-
18 curity Act.

19 (3) CONFORMING AMENDMENT.—Section
20 1844(e) (42 U.S.C. 1395w(e)) is amended by insert-
21 ing “and without regard to any premium adjustment
22 effected under section 1839(h)” before the period at
23 the end.

24 (d) EFFECTIVE DATE.—The amendments made by
25 this section shall take effect on January 1, 2010.

1 **TITLE III—COMBATTING WASTE,**
2 **FRAUD, AND ABUSE**

3 **SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVI-**
4 **SIONS.**

5 (a) TECHNICAL AMENDMENT CONCERNING SEC-
6 RETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT
7 WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPT-
8 LY.—

9 (1) IN GENERAL.—Section 1862(b)(2) (42
10 U.S.C. 1395y(b)(2)) is amended—

11 (A) in subparagraph (A)(ii), by striking
12 “promptly (as determined in accordance with
13 regulations)”;

14 (B) in subparagraph (B)—

15 (i) by redesignating clauses (i)
16 through (iii) as clauses (ii) through (iv),
17 respectively; and

18 (ii) by inserting before clause (ii), as
19 so redesignated, the following new clause:

20 “(i) AUTHORITY TO MAKE CONDI-
21 TIONAL PAYMENT.—The Secretary may
22 make payment under this title with respect
23 to an item or service if a primary plan de-
24 scribed in subparagraph (A)(ii) has not
25 made or cannot reasonably be expected to

1 make payment with respect to such item or
2 service promptly (as determined in accord-
3 ance with regulations). Any such payment
4 by the Secretary shall be conditioned on
5 reimbursement to the appropriate Trust
6 Fund in accordance with the succeeding
7 provisions of this subsection.”.

8 (2) EFFECTIVE DATE.—The amendments made
9 by paragraph (1) shall be effective as if included in
10 the enactment of title III of the Medicare and Med-
11 icaid Budget Reconciliation Amendments of 1984
12 (Public Law 98-369).

13 (b) CLARIFYING AMENDMENTS TO CONDITIONAL
14 PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.
15 1395y(b)(2)) is further amended—

16 (1) in subparagraph (A), in the matter fol-
17 lowing clause (ii), by inserting the following sentence
18 at the end: “An entity that engages in a business,
19 trade, or profession shall be deemed to have a self-
20 insured plan if it carries its own risk (whether by a
21 failure to obtain insurance, or otherwise) in whole or
22 in part.”;

23 (2) in subparagraph (B)(ii), as redesignated by
24 subsection (a)(2)(B)—

1 (A) by striking the first sentence and in-
2 serting the following: “A primary plan, and an
3 entity that receives payment from a primary
4 plan, shall reimburse the appropriate Trust
5 Fund for any payment made by the Secretary
6 under this title with respect to an item or serv-
7 ice if it is demonstrated that such primary plan
8 has or had a responsibility to make payment
9 with respect to such item or service. A primary
10 plan’s responsibility for such payment may be
11 demonstrated by a judgment, a payment condi-
12 tioned upon the recipient’s compromise, waiver,
13 or release (whether or not there is a determina-
14 tion or admission of liability) of payment for
15 items or services included in a claim against the
16 primary plan or the primary plan’s insured, or
17 by other means.”; and

18 (B) in the final sentence, by striking “on
19 the date such notice or other information is re-
20 ceived” and inserting “on the date notice of, or
21 information related to, a primary plan’s respon-
22 sibility for such payment or other information is
23 received”; and

24 (3) in subparagraph (B)(iii), , as redesignated
25 by subsection (a)(2)(B), by striking the first sen-

1 tence and inserting the following: “In order to re-
2 cover payment made under this title for an item or
3 service, the United States may bring an action
4 against any or all entities that are or were required
5 or responsible (directly, as an insurer or self-insurer,
6 as a third-party administrator, as an employer that
7 sponsors or contributes to a group health plan, or
8 large group health plan, or otherwise) to make pay-
9 ment with respect to the same item or service (or
10 any portion thereof) under a primary plan. The
11 United States may, in accordance with paragraph
12 (3)(A) collect double damages against any such enti-
13 ty. In addition, the United States may recover under
14 this clause from any entity that has received pay-
15 ment from a primary plan or from the proceeds of
16 a primary plan’s payment to any entity.”.

17 (c) CLERICAL AMENDMENTS.—Section 1862(b) (42
18 U.S.C. 1395y(b)) is amended—

19 (1) in paragraph (1)(A), by moving the indenta-
20 tion of clauses (ii) through (v) 2 ems to the left; and

21 (2) in paragraph (3)(A), by striking “such” be-
22 fore “paragraphs”.

1 **SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS**
2 **AND SERVICES.**

3 (a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–
4 3) is amended to read as follows:

5 “COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND
6 SERVICES

7 “SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE
8 ACQUISITION PROGRAMS.—

9 “(1) IMPLEMENTATION OF PROGRAMS.—

10 “(A) IN GENERAL.—The Secretary shall
11 establish and implement programs under which
12 competitive acquisition areas are established
13 throughout the United States for contract
14 award purposes for the furnishing under this
15 part of competitively priced items and services
16 (described in paragraph (2)) for which payment
17 is made under this part. Such areas may differ
18 for different items and services.

19 “(B) PHASED-IN IMPLEMENTATION.—The
20 programs shall be phased-in—

21 “(i) among competitive acquisition
22 areas over a period of not longer than 3
23 years in a manner so that the competition
24 under the programs occurs in—

25 “(I) at least $\frac{1}{3}$ of such areas in
26 2005; and

1 “(II) at least $\frac{2}{3}$ of such areas in
2 2006; and

3 “(ii) among items and services in a
4 manner such that the programs apply to
5 the highest cost and highest volume items
6 and services first.

7 “(C) WAIVER OF CERTAIN PROVISIONS.—
8 In carrying out the programs, the Secretary
9 may waive such provisions of the Federal Ac-
10 quisition Regulation as are necessary for the ef-
11 ficient implementation of this section, other
12 than provisions relating to confidentiality of in-
13 formation and such other provisions as the Sec-
14 retary determines appropriate.

15 “(2) ITEMS AND SERVICES DESCRIBED.—The
16 items and services referred to in paragraph (1) are
17 the following:

18 “(A) DURABLE MEDICAL EQUIPMENT AND
19 MEDICAL SUPPLIES.—Covered items (as defined
20 in section 1834(a)(13)) for which payment is
21 otherwise made under section 1834(a), includ-
22 ing items used in infusion and drugs and sup-
23 plies used in conjunction with durable medical
24 equipment, but excluding class III devices

1 under the Federal Food, Drug, and Cosmetic
2 Act.

3 “(B) OTHER EQUIPMENT AND SUP-
4 PLIES.—Items, equipment, and supplies (as de-
5 scribed in section 1842(s)(2)(D) other than en-
6 teral nutrients).

7 “(C) OFF-THE-SHELF ORTHOTICS.—
8 Orthotics (described in section 1861(s)(9)) for
9 which payment is otherwise made under section
10 1834(h) which require minimal self-adjustment
11 for appropriate use and does not require exper-
12 tise in trimming, bending, molding, assembling,
13 or customizing to fit to the patient.

14 “(3) EXCEPTION AUTHORITY.—In carrying out
15 the programs under this section, the Secretary may
16 exempt—

17 “(A) rural areas and areas with low popu-
18 lation density within urban areas that are not
19 competitive, unless there is a significant na-
20 tional market through mail order for a par-
21 ticular item or service; and

22 “(B) items and services for which the ap-
23 plication of competitive acquisition is not likely
24 to result in significant savings.

1 “(4) SPECIAL RULE FOR CERTAIN RENTED
2 ITEMS OF DURABLE MEDICAL EQUIPMENT.—In the
3 case of a covered item for which payment is made
4 on a rental basis under section 1834(a), the Sec-
5 retary shall establish a process by which rental
6 agreements for the covered items entered into before
7 the application of the competitive acquisition pro-
8 gram under this section for the item may be contin-
9 ued notwithstanding this section. In the case of any
10 such continuation, the supplier involved shall provide
11 for appropriate servicing and replacement, as re-
12 quired under section 1834(a).

13 “(5) PHYSICIAN AUTHORIZATION.—The Sec-
14 retary may establish a process under which a physi-
15 cian may prescribe a particular brand or mode of de-
16 livery of an item or service if the item or service in-
17 volved is clinically more appropriate than other simi-
18 lar items or services.

19 “(6) APPLICATION.—For each competitive ac-
20 quisition area in which the program is implemented
21 under this subsection with respect to items and serv-
22 ices, the payment basis determined under the com-
23 petition conducted under subsection (b) shall be sub-
24 stituted for the payment basis otherwise applied
25 under section 1834(a).

1 “(b) PROGRAM REQUIREMENTS.—

2 “(1) IN GENERAL.—The Secretary shall con-
3 duct a competition among entities supplying items
4 and services described in subsection (a)(2) for each
5 competitive acquisition area in which the program is
6 implemented under subsection (a) with respect to
7 such items and services.

8 “(2) CONDITIONS FOR AWARDING CONTRACT.—

9 “(A) IN GENERAL.—The Secretary may
10 not award a contract to any entity under the
11 competition conducted in an competitive acqui-
12 sition area pursuant to paragraph (1) to fur-
13 nish such items or services unless the Secretary
14 finds all of the following:

15 “(i) The entity meets quality and fi-
16 nancial standards specified by the Sec-
17 retary or developed by the Program Advi-
18 sory and Oversight Committee established
19 under subsection (c).

20 “(ii) The total amounts to be paid
21 under the contract (including costs associ-
22 ated with the administration of the con-
23 tract) are expected to be less than the total
24 amounts that would otherwise be paid.

1 “(iii) Beneficiary access to a choice of
2 multiple suppliers in the area is main-
3 tained.

4 “(iv) Beneficiary liability is limited to
5 20 percent of the applicable contract
6 award price, except in such cases where a
7 supplier has furnished an upgraded item
8 and has executed an advanced beneficiary
9 notice.

10 “(B) DEVELOPMENT OF QUALITY STAND-
11 ARDS FOR DME PRODUCTS.—

12 “(i) IN GENERAL.—The quality stand-
13 ards specified under subparagraph (A)(i)
14 shall not be less than the quality standards
15 that would otherwise apply if this section
16 did not apply and shall include consumer
17 services standards. Not later than July 1,
18 2004, the Secretary shall establish new
19 quality standards for products subject to
20 competitive acquisition under this section.
21 Such standards shall be applied prospec-
22 tively and shall be published on the website
23 of the Department of Health and Human
24 Services.

1 “(ii) CONSULTATION WITH PROGRAM
2 ADVISORY AND OVERSIGHT COMMITTEE.—
3 The Secretary shall consult with the Pro-
4 gram Advisory and Oversight Committee
5 (established under subsection (c)) to review
6 (and advise the Secretary concerning) the
7 quality standards referred to in clause (i).

8 “(iii) CONSTRUCTION.—Nothing in
9 this subparagraph shall be construed as
10 delaying the effective date of the imple-
11 mentation of the competitive acquisition
12 program under this section.

13 “(3) CONTENTS OF CONTRACT.—

14 “(A) IN GENERAL.—A contract entered
15 into with an entity under the competition con-
16 ducted pursuant to paragraph (1) is subject to
17 terms and conditions that the Secretary may
18 specify.

19 “(B) TERM OF CONTRACTS.—The Sec-
20 retary shall recompete contracts under this sec-
21 tion not less often than once every 3 years.

22 “(4) LIMIT ON NUMBER OF CONTRACTORS.—

23 “(A) IN GENERAL.—The Secretary may
24 limit the number of contractors in a competitive
25 acquisition area to the number needed to meet

1 projected demand for items and services covered
2 under the contracts. In awarding contracts, the
3 Secretary shall take into account the ability of
4 bidding entities to furnish items or services in
5 sufficient quantities to meet the anticipated
6 needs of beneficiaries for such items or services
7 in the geographic area covered under the con-
8 tract on a timely basis.

9 “(B) MULTIPLE WINNERS.—The Secretary
10 shall award contracts to multiple entities sub-
11 mitting bids in each area for an item or service.

12 “(5) PAYMENT.—Payment under this part for
13 competitively priced items and services described in
14 subsection (a)(2) shall be based on the bids sub-
15 mitted and accepted under this section for such
16 items and services.

17 “(6) PARTICIPATING CONTRACTORS.—Payment
18 shall not be made for items and services described
19 in subsection (a)(2) furnished by a contractor and
20 for which competition is conducted under this sec-
21 tion unless—

22 “(A) the contractor has submitted a bid
23 for such items and services under this section;
24 and

1 “(B) the Secretary has awarded a contract
2 to the contractor for such items and services
3 under this section.

4 In this section, the term ‘bid’ means a request for
5 a proposal for an item or service that includes the
6 cost of the item or service, and where appropriate,
7 any services that are attendant to the provision of
8 the item or service.

9 “(7) CONSIDERATION IN DETERMINING CAT-
10 EGORIES FOR BIDS.—The Secretary shall consider
11 the similarity of the clinical efficiency and value of
12 specific codes and products, including products that
13 may provide a therapeutic advantage to bene-
14 ficiaries, before delineating the categories and prod-
15 ucts that will be subject to bidding.

16 “(8) AUTHORITY TO CONTRACT FOR EDU-
17 CATION, MONITORING, OUTREACH AND COMPLAINT
18 SERVICES.—The Secretary may enter into a contract
19 with an appropriate entity to address complaints
20 from beneficiaries who receive items and services
21 from an entity with a contract under this section
22 and to conduct appropriate education of and out-
23 reach to such beneficiaries and monitoring quality of
24 services with respect to the program.

1 “(c) PROGRAM ADVISORY AND OVERSIGHT COM-
2 MITTEE.—

3 “(1) ESTABLISHMENT.—There is established a
4 Program Advisory and Oversight Committee (herein-
5 after in this section referred to as the ‘Committee’).

6 “(2) MEMBERSHIP; TERMS.—The Committee
7 shall consist of such members as the Secretary may
8 appoint who shall serve for such term as the Sec-
9 retary may specify.

10 “(3) DUTIES.—

11 “(A) TECHNICAL ASSISTANCE.—The Com-
12 mittee shall provide advice and technical assist-
13 ance to the Secretary with respect to the fol-
14 lowing functions:

15 “(i) The implementation of the pro-
16 gram under this section.

17 “(ii) The establishment of require-
18 ments for collection of data.

19 “(iii) The development of proposals
20 for efficient interaction among manufac-
21 turers and distributors of the items and
22 services and providers and beneficiaries.

23 “(B) ADDITIONAL DUTIES.—The Com-
24 mittee shall perform such additional functions

1 to assist the Secretary in carrying out this sec-
2 tion as the Secretary may specify.

3 “(4) INAPPLICABILITY OF FACA.—The provi-
4 sions of the Federal Advisory Committee Act (5
5 U.S.C. App.) shall not apply.

6 “(d) ANNUAL REPORTS.—The Secretary shall submit
7 to Congress an annual management report on the pro-
8 grams under this section. Each such report shall include
9 information on savings, reductions in beneficiary cost-
10 sharing, access to and quality of items and services, and
11 beneficiary satisfaction.

12 “(e) DEMONSTRATION PROJECT FOR CLINICAL LAB-
13 ORATORY SERVICES.—

14 “(1) IN GENERAL.—The Secretary shall con-
15 duct a demonstration project on the application of
16 competitive acquisition under this section to clinical
17 diagnostic laboratory tests—

18 “(A) for which payment is otherwise made
19 under section 1833(h) or 1834(d)(1) (relating
20 to colorectal cancer screening tests); and

21 “(B) which are furnished by entities that
22 did not have a face-to-face encounter with the
23 individual.

1 “(2) TERMS AND CONDITIONS.—Such project
2 shall be under the same conditions as are applicable
3 to items and services described in subsection (a)(2).

4 “(3) REPORT.—The Secretary shall submit to
5 Congress—

6 “(A) an initial report on the project not
7 later than December 31, 2005; and

8 “(B) such progress and final reports on
9 the project after such date as the Secretary de-
10 termines appropriate.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) DURABLE MEDICAL EQUIPMENT; ELIMI-
13 NATION OF INHERENT REASONABLENESS AUTHOR-
14 ITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is
15 amended—

16 (A) in paragraph (1)(B), by striking “The
17 payment basis” and inserting “Subject to sub-
18 paragraph (E)(i), the payment basis”;

19 (B) in paragraph (1)(C), by striking “This
20 subsection” and inserting “Subject to subpara-
21 graph (E)(ii), this subsection”;

22 (C) by adding at the end of paragraph (1)
23 the following new subparagraph:

24 “(E) APPLICATION OF COMPETITIVE AC-
25 QUISSION; ELIMINATION OF INHERENT REA-

1 SONABLENESS AUTHORITY.—In the case of cov-
2 ered items and services that are included in a
3 competitive acquisition program in a competi-
4 tive acquisition area under section 1847(a)—

5 “(i) the payment basis under this sub-
6 section for such items and services fur-
7 nished in such area shall be the payment
8 basis determined under such competitive
9 acquisition program; and

10 “(ii) the Secretary may use informa-
11 tion on the payment determined under
12 such competitive acquisition programs to
13 adjust the payment amount otherwise rec-
14 ognized under subparagraph (B)(ii) for an
15 area that is not a competitive acquisition
16 area under section 1847 and in the case of
17 such adjustment, paragraph (10)(B) shall
18 not be applied.”; and

19 (D) in paragraph (10)(B), by inserting “in
20 an area and with respect to covered items and
21 services for which the Secretary does not make
22 a payment amount adjustment under paragraph
23 (1)(E)” after “under this subsection”.

1 (2) OFF-THE-SHELF ORTHOTICS; ELIMINATION
2 OF INHERENT REASONABLENESS AUTHORITY.—Sec-
3 tion 1834(h) (42 U.S.C. 1395m(h)) is amended—

4 (A) in paragraph (1)(B), by striking “and
5 (E)” and inserting “, (E) , and (H)(i)”;

6 (B) in paragraph (1)(D), by striking “This
7 subsection” and inserting “Subject to subpara-
8 graph (H)(ii), this subsection”;

9 (C) by adding at the end of paragraph (1)
10 the following new subparagraph:

11 “(H) APPLICATION OF COMPETITIVE AC-
12 QUISITION TO ORTHOTICS; ELIMINATION OF IN-
13 HERENT REASONABLENESS AUTHORITY.—In
14 the case of orthotics described in paragraph
15 (2)(B) of section 1847(a) that are included in
16 a competitive acquisition program in a competi-
17 tive acquisition area under such section—

18 “(i) the payment basis under this sub-
19 section for such orthotics furnished in such
20 area shall be the payment basis determined
21 under such competitive acquisition pro-
22 gram; and

23 “(ii) the Secretary may use informa-
24 tion on the payment determined under
25 such competitive acquisition programs to

1 adjust the payment amount otherwise rec-
2 ognized under subparagraph (B)(ii) for an
3 area that is not a competitive acquisition
4 area under section 1847, and in the case
5 of such adjustment, paragraphs (8) and
6 (9) of section 1842(b) shall not be ap-
7 plied.”.

8 (c) REPORT ON ACTIVITIES OF SUPPLIERS.—The
9 Secretary shall conduct a study to determine the extent
10 to which (if any) suppliers of covered items of durable
11 medical equipment that are subject to the competitive ac-
12 quisition program under section 1847 of the Social Secu-
13 rity Act, as amended by subsection (a), are soliciting phy-
14 sicians to prescribe certain brands or modes of delivery
15 of covered items based on profitability.

16 (d) GAO STUDY ON SAFE AND EFFECTIVE HOME IN-
17 FUSION AND INHALATION THERAPY; STANDARDS.—

18 (1) STUDY.—The Comptroller General of the
19 United States shall conduct a study of the stand-
20 ards, professional services, and related functions
21 necessary for the provision of safe and effective
22 home infusion therapy and home inhalation therapy.

23 (2) REPORT.—Not later than May 1, 2004, the
24 Comptroller General shall submit to Congress a re-
25 port on the study conducted under paragraph (1).

1 (3) USE OF FINDINGS IN DEVELOPING STAND-
2 ARDS.—In promulgating regulations to carry out
3 section 1847 of the Social Security Act, as amended
4 by subsection (a), the Secretary shall ensure that
5 quality standards developed under subsection
6 (b)(2)(B) of such section reflect the findings of the
7 Comptroller General set forth in the report under
8 paragraph (2).

9 **SEC. 303. COMPETITIVE ACQUISITION OF COVERED OUT-**
10 **PATIENT DRUGS AND BIOLOGICALS.**

11 (a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

12 (1) ADJUSTMENT IN PRACTICE EXPENSE REL-
13 ATIVE VALUE UNITS.—Section 1848(c)(2) (42
14 U.S.C. 1395w-4(e)(2)) is amended—

15 (A) in subparagraph (B)—

16 (i) in clause (ii)(II), by striking “The
17 adjustments” and inserting “Subject to
18 clause (iv), the adjustments”; and

19 (ii) by adding at the end of subpara-
20 graph (B), the following new clause:

21 “(iv) EXCEPTION TO BUDGET NEU-
22 TRALITY.—The additional expenditures at-
23 tributable to clauses (ii) and (iii) of sub-
24 paragraph (H) shall not be taken into ac-

1 count in applying clause (ii)(II) for 2005.”;

2 and

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

5 “(H) ADJUSTMENTS IN PRACTICE EX-
6 PENSE RELATIVE VALUE UNITS FOR 2005.—

7 “(i) IN GENERAL.—As part of the an-
8 nual process of establishing the physician
9 fee schedule under subsection (b) for 2005,
10 the Secretary shall increase the practice
11 expense relative value units for 2005 con-
12 sistent with clauses (ii) and (iii).

13 “(ii) USE OF SUPPLEMENTAL SURVEY
14 DATA.—For 2005 for any specialty that
15 submitted survey data that included ex-
16 penses for the administration of drugs and
17 biologicals for which payment is made
18 under section 1842(o) (or section 1847A),
19 the Secretary shall use such supplemental
20 survey data in carrying out this subpara-
21 graph insofar as they are collected and
22 provided by entities and organizations con-
23 sistent with the criteria established by the
24 Secretary pursuant to section 212(a) of the
25 Medicare, Medicaid, and SCHIP Balanced

1 Budget Refinement Act of 1999 and inso-
2 far as such data are submitted to the Sec-
3 retary by December 31, 2004.

4 “(iii) PROVISIONS FOR APPROPRIATE
5 REPORTING AND BILLING FOR PHYSICIANS’
6 SERVICES ASSOCIATED WITH THE ADMINIS-
7 TRATION OF COVERED OUTPATIENT DRUGS
8 AND BIOLOGICALS.—

9 “(I) EVALUATION OF CODES.—

10 The Secretary shall promptly evaluate
11 existing codes for physicians’ services
12 associated with the administration of
13 covered outpatient drugs and
14 biologicals (as defined in section
15 1847A(a)(2)(A)) to ensure accurate
16 reporting and billing for such services.

17 “(II) USE OF EXISTING PROC-
18 ESSES.—In carrying out subclause (I),
19 the Secretary shall use existing proc-
20 esses for the consideration of coding
21 changes and, to the extent coding
22 changes are made, shall use such
23 processes in establishing relative val-
24 ues for such services.

1 “(III) IMPLEMENTATION.—In
2 carrying out subclause (I), the Sec-
3 retary shall consult with representa-
4 tives of physician specialties affected
5 by the implementation of section
6 1847A or section 1847B, and shall
7 take such steps within the Secretary’s
8 authority to expedite such consider-
9 ations under subclause (II).

10 “(iv) SUBSEQUENT, BUDGET NEU-
11 TRAL ADJUSTMENTS PERMITTED.—Noth-
12 ing in this subparagraph shall be construed
13 as preventing the Secretary from providing
14 for adjustments in practice expense relative
15 value units under (and consistent with)
16 subparagraph (B) for years after 2005.

17 “(v) CONSULTATION.—Before pub-
18 lishing the notice of proposed rulemaking
19 to carry out this subparagraph, the Sec-
20 retary shall consult with the Comptroller
21 General of the United States and with
22 groups representing the physician special-
23 ties involved.

24 “(vi) TREATMENT AS CHANGE IN LAW
25 AND REGULATION IN SUSTAINABLE

1 GROWTH RATE DETERMINATION.—The en-
2 actment of subparagraph (B)(iv) and this
3 subparagraph shall be treated as a change
4 in law for purposes of applying subsection
5 (f)(2)(D).”.

6 (2) PROHIBITION OF ADMINISTRATIVE AND JU-
7 DICIAL REVIEW.—Section 1848(i)(1) (42 U.S.C.
8 1395w-4(i)(1)) is amended—

9 (A) by striking “and” at the end of subpara-
10 graph (D);

11 (B) by striking the period at the end of sub-
12 paragraph (E) and inserting “, and”; and

13 (C) by adding at the end the following new sub-
14 paragraph:

15 “(F) adjustments in practice expense rel-
16 ative value units for 2005 under subsection
17 (e)(2)(H).”.

18 (3) TREATMENT OF OTHER SERVICES CUR-
19 RENTLY IN THE NON-PHYSICIAN WORK POOL.—The
20 Secretary shall make adjustments to the non-physi-
21 cian work pool methodology (as such term is used in
22 the regulations promulgated by the Secretary in the
23 Federal Register as of December 31, 2002) for de-
24 termination of practice expense relative value units
25 under the physician fee schedule described in section

1 1848(e)(2)(C)(ii) of the Social Security Act so that
2 the practice expense relative value units for services
3 determined under such methodology are not affected
4 relative to the practice expense relative value units
5 of other services not determined under such non-
6 physician work pool methodology, as the result of
7 amendments made by paragraph (1).

8 (b) PAYMENT BASED ON COMPETITION.—Title
9 XVIII is amended by inserting after section 1847 (42
10 U.S.C. 1395w-3), as amended by section 302, the fol-
11 lowing new sections:

12 “COMPETITIVE ACQUISITION OF COVERED OUTPATIENT
13 DRUGS AND BIOLOGICALS

14 “SEC. 1847A. (a) IMPLEMENTATION OF COMPETI-
15 TIVE ACQUISITION.—

16 “(1) IMPLEMENTATION OF PROGRAM.—

17 “(A) IN GENERAL.—The Secretary shall
18 establish and implement a competitive acquisi-
19 tion program under which—

20 “(i) competitive acquisition areas are
21 established throughout the United States
22 for contract award purposes for acquisition
23 of and payment for categories of covered
24 outpatient drugs and biologicals (as de-
25 fined in paragraph (2)) under this part;

1 “(ii) each physician is given the op-
2 portunity annually to elect to obtain drugs
3 and biologicals under the program or
4 under section 1847B; and

5 “(iii) each physician who elects to ob-
6 tain drugs and biologicals under the pro-
7 gram makes an annual selection under
8 paragraph (5) of the contractor through
9 which drugs and biologicals within a cat-
10 egory of drugs and biologicals will be ac-
11 quired and delivered to the physician under
12 this part.

13 “(B) IMPLEMENTATION.—The Secretary
14 shall implement the program so that the pro-
15 gram applies to—

16 “(i) the oncology category beginning
17 in 2005; and

18 “(ii) the non-oncology category begin-
19 ning in 2006.

20 This section shall not apply in the case of a
21 physician who elects section 1847B to apply.

22 “(C) WAIVER OF CERTAIN PROVISIONS.—
23 In order to promote competition, efficient serv-
24 ice, and product quality, in carrying out the
25 program the Secretary may waive such provi-

1 sions of the Federal Acquisition Regulation as
2 are necessary for the efficient implementation
3 of this section, other than provisions relating to
4 confidentiality of information and such other
5 provisions as the Secretary determines appro-
6 priate.

7 “(D) EXCLUSION AUTHORITY.—The Sec-
8 retary may exclude covered outpatient drugs
9 and biologicals (including a class of such drugs
10 and biologicals) from the competitive bidding
11 system under this section if the drugs or
12 biologicals (or class) are not appropriate for
13 competitive bidding due to low volume of utili-
14 zation by beneficiaries under this part or a
15 unique mode or method of delivery or similar
16 reasons.

17 “(2) COVERED OUTPATIENT DRUGS AND
18 BIOLOGICALS, CATEGORIES, PROGRAM DEFINED.—
19 For purposes of this section—

20 “(A) COVERED OUTPATIENT DRUGS AND
21 BIOLOGICALS DEFINED.—The term ‘covered
22 outpatient drugs and biologicals’ means drugs
23 and biologicals to which section 1842(o) applies
24 and which are not covered under section 1847
25 (relating to competitive acquisition for items of

1 durable medical equipment). Such term does
2 not include the following:

3 “(i) Blood clotting factors.

4 “(ii) Drugs and biologicals furnished
5 to individuals in connection with the treat-
6 ment of end stage renal disease.

7 “(iii) Radiopharmaceuticals.

8 “(iv) Vaccines.

9 “(B) 2 CATEGORIES.—Each of the fol-
10 lowing shall be a separate category of covered
11 outpatient drugs and biologicals, as identified
12 by the Secretary:

13 “(i) ONCOLOGY CATEGORY.—A cat-
14 egory (in this section referred to as the
15 ‘oncology category’) consisting of those
16 covered outpatient drugs and biologicals
17 that, as determined by the Secretary, are
18 typically primarily billed by oncologists or
19 are otherwise used to treat cancer.

20 “(ii) NON-ONCOLOGY CATEGORIES.—
21 Such numbers of categories (in this section
22 referred to as the ‘non-oncology cat-
23 egories’) consisting of covered outpatient
24 drugs and biologicals not described in
25 clause (i), and appropriate subcategories of

1 such drugs and biologicals as the Secretary
2 may specify.

3 “(C) PROGRAM.—The term ‘program’
4 means the competitive acquisition program
5 under this section.

6 “(D) COMPETITIVE ACQUISITION AREA;
7 AREA.—The terms ‘competitive acquisition area’
8 and ‘area’ mean an appropriate geographic re-
9 gion established by the Secretary under the pro-
10 gram.

11 “(E) CONTRACTOR.—The term ‘contractor’
12 means an entity that has entered into a con-
13 tract with the Secretary under this section.

14 “(3) APPLICATION OF PROGRAM PAYMENT
15 METHODOLOGY.—With respect to covered outpatient
16 drugs and biologicals which are supplied under the
17 program in an area and which are prescribed by a
18 physician who has not elected section 1847B to
19 apply—

20 “(A) the claim for such drugs and
21 biologicals shall be submitted by the contractor
22 that supplied the drugs and biologicals;

23 “(B) collection of amounts of any deduct-
24 ible and coinsurance applicable with respect to
25 such drugs and biologicals shall be the responsi-

1 bility of such contractor and shall not be col-
2 lected unless the drug or biological is adminis-
3 tered to the beneficiary involved; and

4 “(C) the payment under this section (and
5 related coinsurance amounts) for such drugs
6 and biologicals—

7 “(i) shall be made only to such con-
8 tractor;

9 “(ii) shall be conditioned upon the ad-
10 ministration of such drugs and biologicals;
11 and

12 “(iii) shall be based on the average of
13 the bid prices for such drugs and
14 biologicals in the area, as computed under
15 subsection (d).

16 The Secretary shall provide a process for
17 recoupment in the case in which payment is
18 made for drugs and biologicals which were
19 billed at the time of dispensing but which were
20 not actually administered.

21 “(4) CONTRACT REQUIRED.—

22 “(A) IN GENERAL.—Payment may not be
23 made under this part for covered outpatient
24 drugs and biologicals prescribed by a physician
25 who has not elected section 1847B to apply

1 within a category and a competitive acquisition
2 area with respect to which the program applies
3 unless—

4 “(i) the drugs or biologicals are sup-
5 plied by a contractor with a contract under
6 this section for such category of drugs and
7 biologicals and area; and

8 “(ii) the physician has elected such
9 contractor under paragraph (5) for such
10 category and area.

11 “(B) PHYSICIAN CHOICE.—Subparagraph
12 (A) shall not apply for a category of drugs for
13 an area if the physician prescribing the covered
14 outpatient drug in such category and area has
15 elected to apply section 1847B instead of this
16 section.

17 “(5) CONTRACTOR SELECTION PROCESS.—

18 “(A) IN GENERAL.—The Secretary shall
19 provide a process for the selection of a con-
20 tractor, on an annual basis and in such exigent
21 circumstances as the Secretary may provide and
22 with respect to each category of covered out-
23 patient drugs and biologicals for an area, by
24 physicians prescribing such drugs and
25 biologicals in the area of the contractor under

1 this section that will supply the drugs and
2 biologicals within that category and area. Such
3 selection shall also include the election de-
4 scribed in section 1847B(a).

5 “(B) INFORMATION ON CONTRACTORS.—
6 The Secretary shall make available to physi-
7 cians on an ongoing basis, through a directory
8 posted on the Department’s Internet website or
9 otherwise and upon request, a list of the con-
10 tractors under this section in the different com-
11 petitive acquisition areas.

12 “(C) SELECTING PHYSICIAN DEFINED.—
13 For purposes of this section, the term ‘selecting
14 physician’ means, with respect to a contractor
15 and category and competitive acquisition area,
16 a physician who has not elected section 1847B
17 to apply and has selected to apply under this
18 section such contractor for such category and
19 area.

20 “(b) PROGRAM REQUIREMENTS.—

21 “(1) CONTRACT FOR COVERED OUTPATIENT
22 DRUGS AND BIOLOGICALS.—The Secretary shall con-
23 duct a competition among entities for the acquisition
24 of a covered outpatient drug or biological within

1 each HCPCS code within each category for each
2 competitive acquisition area.

3 “(2) CONDITIONS FOR AWARDING CONTRACT.—

4 “(A) IN GENERAL.—The Secretary may
5 not award a contract to any entity under the
6 competition conducted in a competitive acquisi-
7 tion area pursuant to paragraph (1) with re-
8 spect to the acquisition of covered outpatient
9 drugs and biologicals within a category unless
10 the Secretary finds that the entity meets all of
11 the following with respect to the contract period
12 involved:

13 “(i) CAPACITY TO SUPPLY COVERED
14 OUTPATIENT DRUG OR BIOLOGICAL WITHIN
15 CATEGORY.—

16 “(I) IN GENERAL.—The entity
17 has sufficient arrangements to acquire
18 and to deliver covered outpatient
19 drugs and biologicals within such cat-
20 egory in the area specified in the con-
21 tract at the bid price specified in the
22 contract for all physicians that may
23 elect such entity.

24 “(II) SHIPMENT METHODOLOGY.—The entity has arrangements
25

1 in effect for the shipment at least 5
2 days each week of covered outpatient
3 drugs and biologicals under the con-
4 tract and for the timely delivery (in-
5 cluding for emergency situations) of
6 such drugs and biologicals in the area
7 under the contract.

8 “(ii) QUALITY, SERVICE, FINANCIAL
9 PERFORMANCE AND SOLVENCY STAND-
10 ARDS.—The entity meets quality, service,
11 financial performance, and solvency stand-
12 ards specified by the Secretary, includ-
13 ing—

14 “(I) the establishment of proce-
15 dures for the prompt response and
16 resolution of physician and beneficiary
17 complaints and inquiries regarding the
18 shipment of covered outpatient drugs
19 and biologicals; and

20 “(II) a grievance process for the
21 resolution of disputes.

22 “(B) ADDITIONAL CONSIDERATIONS.—The
23 Secretary may refuse to award a contract under
24 this section, and may terminate such a con-
25 tract, with an entity based upon—

1 “(i) the suspension or revocation, by
2 the Federal Government or a State govern-
3 ment, of the entity’s license for the dis-
4 tribution of drugs or biologicals (including
5 controlled substances); or

6 “(ii) the exclusion of the entity under
7 section 1128 from participation under this
8 title.

9 “(C) APPLICATION OF MEDICARE PRO-
10 VIDER OMBUDSMAN.—For provision providing
11 for a program-wide Medicare Provider Ombuds-
12 man to review complaints, see section 1868(b),
13 as added by section 923 of the Medicare Pre-
14 scription Drug and Modernization Act of 2003.

15 “(3) AWARDING MULTIPLE CONTRACTS FOR A
16 CATEGORY AND AREA.—In order to provide a choice
17 of at least 2 contractors in each competitive acquisi-
18 tion area for a category of drugs and biologicals, the
19 Secretary may limit (but not below 2) the number
20 of qualified entities that are awarded such contracts
21 for any category and area. The Secretary shall select
22 among qualified entities based on the following:

23 “(A) The bid prices for covered outpatient
24 drugs and biologicals within the category and
25 area.

1 “(B) Bid price for distribution of such
2 drugs and biologicals.

3 “(C) Ability to ensure product integrity.

4 “(D) Customer service.

5 “(E) Past experience in the distribution of
6 drugs and biologicals, including controlled sub-
7 stances.

8 “(F) Such other factors as the Secretary
9 may specify.

10 “(4) TERMS OF CONTRACTS.—

11 “(A) IN GENERAL.—A contract entered
12 into with an entity under the competition con-
13 ducted pursuant to paragraph (1) is subject to
14 terms and conditions that the Secretary may
15 specify consistent with this section.

16 “(B) PERIOD OF CONTRACTS.—A contract
17 under this section shall be for a term of 2
18 years, but may be terminated by the Secretary
19 or the entity with appropriate, advance notice.

20 “(C) INTEGRITY OF DRUG AND BIOLOGI-
21 CAL DISTRIBUTION SYSTEM.—The Secretary—

22 “(i) shall require that for all drug and
23 biological products distributed by a con-
24 tractor under this section be acquired di-
25 rectly from the manufacturer or from a

1 distributor that has acquired the products
2 directly from the manufacturer; and

3 “(ii) may require, in the case of such
4 products that are particularly susceptible
5 to counterfeit or diversion, that the con-
6 tractor comply with such additional prod-
7 uct integrity safeguards as may be deter-
8 mined to be necessary.

9 “(D) IMPLEMENTATION OF ANTI-COUN-
10 TERFEITING, QUALITY, SAFETY, AND RECORD
11 KEEPING REQUIREMENTS.—The Secretary shall
12 require each contractor to implement (through
13 its officers, agents, representatives, and employ-
14 ees) requirements relating to the storage and
15 handling of covered outpatient drugs and
16 biologicals and for the establishment and main-
17 tenance of distribution records for such drugs
18 and biologicals. A contract under this section
19 may include requirements relating to the fol-
20 lowing:

21 “(i) Secure facilities.

22 “(ii) Safe and appropriate storage of
23 drugs and biologicals.

24 “(iii) Examination of drugs and
25 biologicals received and dispensed.

1 “(iv) Disposition of damaged and out-
2 dated drugs and biologicals.

3 “(v) Record keeping and written poli-
4 cies and procedures.

5 “(vi) Compliance personnel.

6 “(E) COMPLIANCE WITH CODE OF CON-
7 DUCT AND FRAUD AND ABUSE RULES.—Under
8 the contract—

9 “(i) the contractor shall comply with a
10 code of conduct, specified or recognized by
11 the Secretary, that includes standards re-
12 lating to conflicts of interest; and

13 “(ii) the contractor shall comply with
14 all applicable provisions relating to preven-
15 tion of fraud and abuse, including compli-
16 ance with applicable guidelines of the De-
17 partment of Justice and the Inspector
18 General of the Department of Health and
19 Human Services.

20 “(F) DIRECT DELIVERY OF DRUGS AND
21 BIOLOGICALS TO PHYSICIANS.—Under the con-
22 tract the contractor shall only supply covered
23 outpatient drugs and biologicals directly to the
24 selecting physicians and not directly to bene-
25 ficiaries, except under circumstances and set-

1 tings where a beneficiary currently receives a
2 drug or biological in the beneficiary’s home or
3 other non-physician office setting as the Sec-
4 retary may provide. The contractor shall not de-
5 liver drugs and biologicals to a selecting physi-
6 cian except upon receipt of a prescription for
7 such drugs and biologicals, and such necessary
8 data as may be required by the Secretary to
9 carry out this section. This section does not—

10 “(i) require a physician to submit a
11 prescription for each individual treatment;

12 or

13 “(ii) change a physician’s flexibility in
14 terms of writing a prescription for drugs
15 for a single treatment or a course of treat-
16 ment.

17 “(5) PERMITTING ACCESS TO DRUGS AND
18 BIOLOGICALS.—The Secretary shall establish rules
19 under this section under which drugs and biologicals
20 which are acquired through a contractor under this
21 section may be used to resupply inventories of such
22 drugs and biologicals which are administered con-
23 sistent with safe drug practices and with adequate
24 safeguards against fraud and abuse. The previous

1 sentence shall apply if the physicians can dem-
2 onstrate to the Secretary all of the following:

3 “(A) The drugs or biologicals are required
4 immediately.

5 “(B) The physician could not have reason-
6 ably anticipated the immediate requirement for
7 the drugs or biologicals.

8 “(C) The contractor could not deliver to
9 the physician the drugs or biologicals in a time-
10 ly manner.

11 “(D) The drugs or biologicals were admin-
12 istered in an emergency situation.

13 “(6) CONSTRUCTION.—Nothing in this section
14 shall be construed as waiving applicable State re-
15 quirements relating to licensing of pharmacies.

16 “(c) BIDDING PROCESS.—

17 “(1) IN GENERAL.—In awarding a contract for
18 a category of drugs and biologicals in an area under
19 the program, the Secretary shall consider with re-
20 spect to each entity seeking to be awarded a con-
21 tract the prices bid to acquire and supply the cov-
22 ered outpatient drugs and biologicals for that cat-
23 egory and area and the other factors referred to in
24 subsection (b)(3).

1 “(2) PRICES BID.—The prices bid by an entity
2 under paragraph (1) shall be the prices in effect and
3 available for the supply of contracted drugs and
4 biologicals in the area through the entity for the
5 contract period.

6 “(3) REJECTION OF CONTRACT OFFER.—The
7 Secretary shall reject the contract offer of an entity
8 with respect to a category of drugs and biologicals
9 for an area if the Secretary estimates that the prices
10 bid, in the aggregate on average, would exceed 100
11 percent of the average sales price (as determined
12 under section 1847B).

13 “(4) BIDDING ON A NATIONAL OR REGIONAL
14 BASIS.—Nothing in this section shall be construed
15 as precluding a bidder from bidding for contracts in
16 all areas of the United States or as requiring a bid-
17 der to submit a bid for all areas of the United
18 States.

19 “(5) UNIFORMITY OF BIDS WITHIN AREA.—The
20 amount of the bid submitted under a contract offer
21 for any covered outpatient drug or biological for an
22 area shall be the same for that drug or biological for
23 all portions of that area.

24 “(6) CONFIDENTIALITY OF BIDS.—The provi-
25 sions of subparagraph (D) of section 1927(b)(3)

1 shall apply to a bid submitted in a contract offer for
2 a covered outpatient drug or biological under this
3 section in the same manner as it applies to informa-
4 tion disclosed under such section, except that any
5 reference—

6 “(A) in that subparagraph to a ‘manufac-
7 turer or wholesaler’ is deemed a reference to a
8 ‘bidder’ under this section;

9 “(B) in that section to ‘prices charged for
10 drugs’ is deemed a reference to a ‘bid’ sub-
11 mitted under this section; and

12 “(C) in clause (i) of that section to ‘this
13 section’, is deemed a reference to ‘part B of
14 title XVIII’.

15 “(7) INCLUSION OF COSTS.—The bid price sub-
16 mitted in a contract offer for a covered outpatient
17 drug or biological shall—

18 “(A) include all costs related to the deliv-
19 ery of the drug or biological to the selecting
20 physician (or other point of delivery); and

21 “(B) include the costs of dispensing (in-
22 cluding shipping) of such drug or biological and
23 management fees, but shall not include any
24 costs related to the administration of the drug
25 or biological, or wastage, spillage, or spoilage.

1 “(8) PRICE ADJUSTMENTS DURING CONTRACT
2 PERIOD; DISCLOSURE OF COSTS.—Each contract
3 awarded shall provide for—

4 “(A) disclosure to the Secretary the con-
5 tractor’s reasonable, net acquisition costs for
6 periods specified by the Secretary, not more
7 often than quarterly, of the contract; and

8 “(B) appropriate price adjustments over
9 the period of the contract to reflect significant
10 increases or decreases in a contractor’s reason-
11 able, net acquisition costs, as so disclosed.

12 “(d) COMPUTATION OF AVERAGE BID PRICES FOR
13 A CATEGORY AND AREA.—

14 “(1) IN GENERAL.—For each year or other con-
15 tract period for each covered outpatient drug or bio-
16 logical and area with respect to which a competition
17 is conducted under the program, the Secretary shall
18 compute an area average of the bid prices submitted,
19 in contract offers accepted for the category and
20 area, for that year or other contract period.

21 “(2) SPECIAL RULES.—The Secretary shall es-
22 tablish rules regarding the use under this section of
23 the alternative payment amount provided under sec-
24 tion 1847B to the use of a price for specific covered

1 outpatient drugs and biologicals in the following
2 cases:

3 “(A) NEW DRUGS AND BIOLOGICALS.—A
4 covered outpatient drug or biological for which
5 an average bid price has not been previously de-
6 termined.

7 “(B) OTHER CASES.—Such other excep-
8 tional cases as the Secretary may specify in
9 regulations, such as oral drugs under section
10 1861(s)(2)(Q) and immunosuppressives under
11 section 1861(s)(2)(J).

12 “(e) COINSURANCE.—

13 “(1) IN GENERAL.—Coinsurance under this
14 part with respect to a covered outpatient drug or bi-
15 ological for which payment is payable under this sec-
16 tion shall be based on 20 percent of the payment
17 basis under this section.

18 “(2) COLLECTION.—Such coinsurance shall be
19 collected by the contractor that supplies the drug or
20 biological involved and, subject to subsection
21 (a)(3)(B), in the same manner as coinsurance is col-
22 lected for durable medical equipment under this
23 part.

24 “(f) SPECIAL PAYMENT RULES.—

1 “(1) IN GENERAL.—The Secretary may not
2 provide for an adjustment to reimbursement for cov-
3 ered outpatient drugs and biologicals unless adjust-
4 ments to the practice expense payment adjustment
5 are made on the basis of supplemental surveys under
6 section 1848(c)(2)(H)(ii) of the Social Security Act,
7 as added by subsection (a)(1)(B).

8 (2) USE IN EXCLUSION CASES.—If the Sec-
9 retary excludes a drug or biological (or class of
10 drugs or biologicals) under subsection (a)(1)(D), the
11 Secretary may provide for reimbursement to be
12 made under this part for such drugs and biologicals
13 (or class) using the payment methodology under sec-
14 tion 1847B.

15 “(3) COORDINATION RULES.—The provisions of
16 section 1842(h)(3) shall apply to a contractor with
17 respect to covered outpatients drugs and biologicals
18 supplied by that contractor in the same manner as
19 they apply to a participating supplier. In order to
20 administer this section, the Secretary may condition
21 payment under this part to a person for the admin-
22 istration of a drug or biological supplied under this
23 section upon person’s provision of information on
24 such administration.

1 “(4) APPLICATION OF REQUIREMENT FOR AS-
2 SIGNMENT.—For provision requiring assignment of
3 claims for covered outpatient drugs and biologicals,
4 see section 1842(o)(3).

5 “(5) PROTECTION FOR BENEFICIARY IN CASE
6 OF MEDICAL NECESSITY DENIAL.—For protection of
7 beneficiaries against liability in the case of medical
8 necessity determinations, see section
9 1842(b)(3)(B)(ii)(III).

10 “(6) PHYSICIAN ROLE IN APPEALS PROCESS.—
11 The Secretary shall establish a procedure under
12 which a physician who prescribes a drug or biologi-
13 cal for which payment is made under this section
14 has appeal rights that are similar to those provided
15 to a physician who prescribes durable medical equip-
16 ment or a laboratory test.

17 “(g) ADVISORY COMMITTEE.—The Secretary shall
18 establish an advisory committee that includes representa-
19 tives of parties affected by the program under this section,
20 including physicians, specialty pharmacies, distributors,
21 manufacturers, and beneficiaries. The committee shall ad-
22 vise the Secretary on issues relating to the effective imple-
23 mentation of this section.

24 “(h) ANNUAL REPORTS.—The Secretary shall submit
25 to Congress an annual report in each of 2005, 2006, and

1 2007, on the program. Each such report shall include in-
2 formation on savings, reductions in cost-sharing, access to
3 covered outpatient drugs and biologicals, the range of
4 choices of contractors available to providers, and bene-
5 ficiary and provider satisfaction.

6 “OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT

7 METHODOLOGY

8 “SEC. 1847B. (a) IN GENERAL.—

9 “(1) ELECTION.—In connection with the an-
10 nual election made by a physician under section
11 1847A(a)(5), the physician may elect to apply this
12 section to the payment for covered outpatient drugs
13 and biologicals instead of the payment methodology
14 under section 1847A.

15 “(2) IMPLEMENTATION.—This section shall be
16 implemented with respect to categories of covered
17 outpatient drugs and biologicals described in section
18 1847A(a)(2)(B).

19 “(3) COVERED OUTPATIENT DRUGS AND
20 BIOLOGICALS DEFINED.—For purposes of this sec-
21 tion, the term ‘covered outpatient drugs and
22 biologicals’ has the meaning given such term in sec-
23 tion 1847A(a)(2)(A).

24 “(b) COMPUTATION OF PAYMENT AMOUNT.—

25 “(1) IN GENERAL.—If this section applies with
26 respect to a covered outpatient drug or biological,

1 the amount payable for the drug or biological (based
2 on a minimum dosage unit) is, subject to applicable
3 deductible and coinsurance—

4 “(A) in the case of a multiple source drug
5 (as defined in subsection (c)(6)(C)), 100 per-
6 cent (or in the case of covered outpatient drugs
7 and biologicals furnished during 2005 and
8 2006, 112 percent) of the amount determined
9 under paragraph (3); or

10 “(B) in the case of a single source drug
11 (as defined in subsection (c)(6)(D)), 100 per-
12 cent (or in the case of covered outpatient drugs
13 and biologicals furnished during 2005 and
14 2006, 112 percent) of the amount determined
15 under paragraph (4).

16 “(2) SPECIFICATION OF UNIT.—

17 “(A) SPECIFICATION BY MANUFAC-
18 Turer.—The manufacturer of a covered out-
19 patient drug shall specify the unit associated
20 with each National Drug Code as part of the
21 submission of data under section
22 1927(b)(3)(A)(iii).

23 “(B) UNIT DEFINED.—In this section, the
24 term ‘unit’ means, with respect to a covered
25 outpatient drug, the lowest identifiable quantity

1 (such as a capsule or tablet, milligram of mol-
2 ecules, or grams) of the drug that is dispensed,
3 exclusive of any diluent without reference to
4 volume measures pertaining to liquids.

5 “(3) MULTIPLE SOURCE DRUG.—For all drug
6 products included within the same multiple source
7 drug, the amount specified in this paragraph is the
8 volume-weighted average of the average sales prices
9 reported under section 1927(b)(3)(A)(iii) computed
10 as follows:

11 “(A) Compute the sum of the products (for
12 each national drug code assigned to such drug
13 products) of—

14 “(i) the manufacturer’s average sales
15 price (as defined in subsection (c)); and

16 “(ii) the total number of units speci-
17 fied under paragraph (2) sold, as reported
18 under section 1927(b)(3)(A)(iii).

19 “(B) Divide the sum computed under sub-
20 paragraph (A) by the sum of the total number
21 of units under subparagraph (A)(ii) for all na-
22 tional drug codes assigned to such drug prod-
23 ucts.

1 “(4) SINGLE SOURCE DRUG.—The amount
2 specified in this paragraph for a single source drug
3 is the lesser of the following:

4 “(A) MANUFACTURER’S AVERAGE SALES
5 PRICE.—The manufacturer’s average sales price
6 for a national drug code, as computed using the
7 methodology applied under paragraph (3).

8 “(B) WHOLESALE ACQUISITION COST
9 (WAC).—The wholesale acquisition cost (as de-
10 fined in subsection (c)(6)(B)) reported for the
11 single source drug.

12 “(5) BASIS FOR DETERMINATION.—The pay-
13 ment amount shall be determined under this sub-
14 section based on information reported under sub-
15 section (e) and without regard to any special pack-
16 aging, labeling, or identifiers on the dosage form or
17 product or package.

18 “(c) MANUFACTURER’S AVERAGE SALES PRICE.—

19 “(1) IN GENERAL.—For purposes of this sub-
20 section, subject to paragraphs (2) and (3), the man-
21 ufacturer’s ‘average sales price’ means, of a covered
22 outpatient drug for a NDC code for a calendar quar-
23 ter for a manufacturer for a unit—

24 “(A) the manufacturer’s total sales (as de-
25 fined by the Secretary in regulations for pur-

1 poses of section 1927(c)(1)) in the United
2 States for such drug in the calendar quarter;
3 divided by

4 “(B) the total number of such units of
5 such drug sold by the manufacturer in such
6 quarter.

7 “(2) CERTAIN SALES EXEMPTED FROM COM-
8 PUTATION.—In calculating the manufacturer’s aver-
9 age sales price under this subsection, the following
10 sales shall be excluded:

11 “(A) SALES EXEMPT FROM BEST PRICE.—
12 Sales exempt from the inclusion in the deter-
13 mination of ‘best price’ under section
14 1927(c)(1)(C)(i).

15 “(B) SALES AT NOMINAL CHARGE.—Such
16 other sales as the Secretary identifies by regula-
17 tion as sales to an entity that are nominal in
18 price or do not reflect a market price paid by
19 an entity to which payment is made under this
20 section.

21 “(3) SALE PRICE NET OF DISCOUNTS.—In cal-
22 culating the manufacturer’s average sales price
23 under this subsection, such price shall be determined
24 taking into account volume discounts, prompt pay
25 discounts, cash discounts, the free goods that are

1 contingent on any purchase requirement,
2 chargebacks, and rebates (other than rebates under
3 section 1927), that result in a reduction of the cost
4 to the purchaser. A rebate to a payor or other entity
5 that does not take title to a covered outpatient drug
6 shall not be taken into account in determining such
7 price unless the manufacturer has an agreement
8 with the payor or other entity under which the pur-
9 chaser's price for the drug is reduced as a con-
10 sequence of such rebate.

11 “(4) AUTHORITY TO DISREGARD AVERAGE
12 SALES PRICE DURING FIRST QUARTER OF SALES.—
13 In the case of a covered outpatient drug during an
14 initial period (not to exceed a full calendar quarter)
15 in which data on the prices for sales for the drug
16 is not sufficiently available from the manufacturer to
17 compute an average sales price for the drug, the
18 Secretary may determine the amount payable under
19 this section for the drug without considering the
20 manufacturer's average sales price of that manufac-
21 turer for that drug.

22 “(5) FREQUENCY OF DETERMINATIONS.—

23 “(A) IN GENERAL ON A QUARTERLY
24 BASIS.—The manufacturer's average sales
25 price, for a covered outpatient drug of a manu-

1 manufacturer, shall be determined by such manufac-
2 turer under this subsection on a quarterly basis.
3 In making such determination insofar as there
4 is a lag in the reporting of the information on
5 rebates and chargebacks under paragraph (3)
6 so that adequate data are not available on a
7 timely basis, the manufacturer shall apply a
8 methodology established by the Secretary based
9 on a 12-month rolling average for the manufac-
10 turer to estimate costs attributable to rebates
11 and chargebacks.

12 “(B) UPDATES IN RATES.—The payment
13 rates under subsection (b)(1) and (b)(2)(A)
14 shall be updated by the Secretary on a quar-
15 terly basis and shall be applied based upon the
16 manufacturer’s average sales price determined
17 for the most recent calendar quarter.

18 “(C) USE OF CONTRACTORS; IMPLEMENTA-
19 TION.—The Secretary may use a carrier, fiscal
20 intermediary, or other contractor to determine
21 the payment amount under subsection (b). Not-
22 withstanding any other provision of law, the
23 Secretary may implement, by program memo-
24 randum or otherwise, any of the provisions of
25 this section.

1 “(6) DEFINITIONS AND OTHER RULES.—In this
2 section:

3 “(A) MANUFACTURER.—The term ‘manu-
4 facturer’ means, with respect to a covered out-
5 patient drug, the manufacturer (as defined in
6 section 1927(k)(5)) whose national drug code
7 appears on such drug.

8 “(B) WHOLESALE ACQUISITION COST.—
9 The term ‘wholesale acquisition cost’ means,
10 with respect to a covered outpatient drug, the
11 manufacturer’s list price for the drug to whole-
12 salers or direct purchasers in the United States,
13 not including prompt pay or other discounts, re-
14 bates or reductions in price, for the most recent
15 month for which the information is available, as
16 reported in wholesale price guides or other pub-
17 lications of drug pricing data.

18 “(C) MULTIPLE SOURCE DRUG.—The term
19 ‘multiple source drug’ means, for a calendar
20 quarter, a covered outpatient drug for which
21 there are 2 or more drug products which—

22 “(i) are rated as therapeutically equiv-
23 alent (under the Food and Drug Adminis-
24 tration’s most recent publication of ‘Ap-

1 proved Drug Products with Therapeutic
2 Equivalence Evaluations’),

3 “(ii) except as provided in subpara-
4 graph (E), are pharmaceutically equivalent
5 and bioequivalent, as determined under
6 subparagraph (F) and as determined by
7 the Food and Drug Administration, and

8 “(iii) are sold or marketed in the
9 United States during the quarter.

10 “(D) SINGLE SOURCE DRUG.—The term
11 ‘single source drug’ means a covered outpatient
12 drug which is not a multiple source drug and
13 which is produced or distributed under an origi-
14 nal new drug application approved by the Food
15 and Drug Administration, including a drug
16 product marketed by any cross-licensed pro-
17 ducers or distributors operating under the new
18 drug application, or which is a biological.

19 “(E) EXCEPTION FROM PHARMACEUTICAL
20 EQUIVALENCE AND BIOEQUIVALENCE REQUIRE-
21 MENT.—Subparagraph (C)(ii) shall not apply if
22 the Food and Drug Administration changes by
23 regulation the requirement that, for purposes of
24 the publication described in subparagraph
25 (C)(i), in order for drug products to be rated as

1 therapeutically equivalent, they must be phar-
2 maceutically equivalent and bioequivalent, as
3 defined in subparagraph (F).

4 “(F) DETERMINATION OF PHARMA-
5 CEUTICAL EQUIVALENCE AND BIOEQUIVA-
6 LENCE.—For purposes of this paragraph—

7 “(i) drug products are pharmaceuti-
8 cally equivalent if the products contain
9 identical amounts of the same active drug
10 ingredient in the same dosage form and
11 meet compendial or other applicable stand-
12 ards of strength, quality, purity, and iden-
13 tity; and

14 “(ii) drugs are bioequivalent if they do
15 not present a known or potential bio-
16 equivalence problem, or, if they do present
17 such a problem, they are shown to meet an
18 appropriate standard of bioequivalence.

19 “(G) INCLUSION OF VACCINES.—In apply-
20 ing provisions of section 1927 under this sec-
21 tion, ‘other than a vaccine’ is deemed deleted
22 from section 1927(k)(2)(B).

23 “(d) AUTHORITY TO USE ALTERNATIVE PAYMENT
24 IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the
25 case of a public health emergency under section 319 of

1 the Public Health Service Act in which there is a docu-
2 mented inability to access covered outpatient drugs and
3 biologicals, and a concomitant increase in the price, of a
4 drug or biological which is not reflected in the manufac-
5 turer's average sales price for one or more quarters, the
6 Secretary may use the wholesale acquisition cost (or other
7 reasonable measure of drug price) instead of the manufac-
8 turer's average sales price for such quarters and for subse-
9 quent quarters until the price and availability of the drug
10 or biological has stabilized and is substantially reflected
11 in the applicable manufacturer's average sales price.

12 “(e) REPORTS.—

13 “(1) QUARTERLY REPORT ON AVERAGE SALES
14 PRICE.—For requirements for reporting the manu-
15 facturer's average sales price (and, if required to
16 make payment, the manufacturer's wholesale acqui-
17 sition cost) for the covered outpatient drug or bio-
18 logical, see section 1927(b)(3).

19 “(2) ANNUAL REPORT TO CONGRESS.—The
20 Secretary shall submit to the Committees on Energy
21 and Commerce and Ways and Means of the House
22 of Representatives and the Committee on Finance of
23 the Senate an annual report on the operation of this
24 section. Such report shall include information on the
25 following:

1 “(A) Trends in average sales price under
2 subsection (b).

3 “(B) Administrative costs associated with
4 compliance with this section.

5 “(C) Total value of payments made under
6 this section.

7 “(D) Comparison of the average manufac-
8 turer price as applied under section 1927 for a
9 covered outpatient drug or biological with the
10 manufacturer’s average sales price for the drug
11 or biological under this section.

12 “(f) RESTRICTION ON ADMINISTRATIVE AND JUDI-
13 CIAL REVIEW.—There shall be no administrative or judi-
14 cial review under section 1869, section 1878, or otherwise,
15 of determinations of manufacturer’s average sales price
16 under subsection (c).”.

17 (c) CONTINUATION OF PAYMENT METHODOLOGY
18 FOR RADIOPHARMACEUTICALS.—Nothing in the amend-
19 ments made by this section shall be construed as changing
20 the payment methodology under part B of title XVIII of
21 the Social Security Act for radiopharmaceuticals, includ-
22 ing the use by carriers of invoice pricing methodology.

23 (d) CONFORMING AMENDMENTS.—

24 (1) IN GENERAL.—Section 1842(o) (42 U.S.C.
25 1395u(o)) is amended—

1 (A) in paragraph (1), by inserting “, sub-
2 ject to section 1847A and 1847B,” before “the
3 amount payable for the drug or biological”; and

4 (B) by adding at the end of paragraph (2)
5 the following: “This paragraph shall not apply
6 in the case of payment under section 1847A or
7 1847B.”.

8 (2) NO CHANGE IN COVERAGE BASIS.—Section
9 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amend-
10 ed by inserting “(or would have been so included but
11 for the application of section 1847A or 1847B)”
12 after “included in the physicians’ bills”.

13 (3) PAYMENT.—Section 1833(a)(1)(S) (42
14 U.S.C. 1395l(a)(1)(S)) is amended by inserting “(or,
15 if applicable, under section 1847A or 1847B)” after
16 “1842(o)”.

17 (4) CONSOLIDATED REPORTING OF PRICING IN-
18 FORMATION.—Section 1927 (42 U.S.C. 1396r–8) is
19 amended—

20 (A) in subsection (a)(1), by inserting “or
21 under part B of title XVIII” after “section
22 1903(a)”;

23 (B) in subsection (b)(3)(A)—

24 (i) in clause (i), by striking “and” at
25 the end;

1 (ii) in clause (ii), by striking the pe-
2 riod and inserting “; and”; and

3 (iii) by adding at the end the fol-
4 lowing new clause:

5 “(iii) for calendar quarters beginning
6 on or after April 1, 2004, in conjunction
7 with reporting required under clause (i)
8 and by national drug code (NDC)—

9 “(I) the manufacturer’s average
10 sales price (as defined in section
11 1847B(c)) and the total number of
12 units specified under section
13 1847B(b)(2)(A);

14 “(II) if required to make pay-
15 ment under section 1847B, the manu-
16 facturer’s wholesale acquisition cost,
17 as defined in subsection (c)(6) of such
18 section; and

19 “(III) information on those sales
20 that were made at a nominal price or
21 otherwise described in section
22 1847B(c)(2)(B), which information is
23 subject to audit by the Inspector Gen-
24 eral of the Department of Health and
25 Human Services;

1 for a covered outpatient drug or biological
2 for which payment is made under section
3 1847B.”;

4 (C) in subsection (b)(3)(B)—

5 (i) in the heading, by inserting “AND
6 MANUFACTURER’S AVERAGE SALES PRICE”
7 after “PRICE”; and

8 (ii) by inserting “and manufacturer’s
9 average sales prices (including wholesale
10 acquisition cost) if required to make pay-
11 ment” after “manufacturer prices”; and

12 (D) in subsection (b)(3)(D)(i), by inserting
13 “and section 1847B” after “this section”.

14 (e) GAO STUDY.—

15 (1) STUDY.—The Comptroller General of the
16 United States shall conduct a study to assess the
17 impact of the amendments made by this section on
18 the delivery of services, including their impact on—

19 (A) beneficiary access to drugs and
20 biologicals for which payment is made under
21 part B of title XVIII of the Social Security Act;
22 and

23 (B) the site of delivery of such services.

24 (2) REPORT.—Not later than 2 years after the
25 year in which the amendment made by subsection

1 (a)(1) first takes effect, the Comptroller General
2 shall submit to Congress a report on the study con-
3 ducted under paragraph (1).

4 (f) MEDPAC RECOMMENDATIONS ON BLOOD CLOT-
5 TING FACTORS.—The Medicare Payment Advisory Com-
6 mission shall submit to Congress, in its annual report in
7 2004, specific recommendations regarding a payment
8 amount (or amounts) for blood clotting factors and its ad-
9 ministration under the medicare program.

10 (g) ESTABLISHMENT OF PHARMACEUTICAL MANAGE-
11 MENT FEE WHERE DRUGS PROVIDED THROUGH A CON-
12 TRACTOR.—Section 1848(a) (42 U.S.C. 1395w-4(a)) is
13 amended by adding at the end the following new para-
14 graph:

15 “(5) RECOGNITION OF PHARMACEUTICAL MAN-
16 AGEMENT FEE IN CERTAIN CASES.—In establishing
17 the fee schedule under this section, the Secretary
18 shall provide for a separate payment with respect to
19 physicians’ services consisting of the unique adminis-
20 trative and management costs associated with cov-
21 ered drugs and biologicals which are furnished to
22 physicians through a contractor under section
23 1847A (compared with such costs if such drugs and
24 biologicals were acquired directly by such physi-
25 cians).”.

1 (h) STUDY ON CODES FOR NON-ONCOLOGY CODES.—

2 (1) STUDY.—The Secretary shall conduct a
3 study to determine the appropriateness of estab-
4 lishing and implementing separate codes for non-on-
5 cology infusions that are based on the level of com-
6 plexity of the administration and resource consump-
7 tion.

8 (2) REPORT.—Not later than 1 year after the
9 date of the enactment of this Act, the Secretary
10 shall submit a report to Congress on the study. To
11 the extent the Secretary determines it to be appro-
12 priate, the Secretary may implement appropriate
13 changes in the payment methodology for such codes.

14 **SEC. 304. DEMONSTRATION PROJECT FOR USE OF RECOV-**
15 **ERY AUDIT CONTRACTORS.**

16 (a) IN GENERAL.—The Secretary of Health and
17 Human Services shall conduct a demonstration project
18 under this section (in this section referred to as the
19 “project”) to demonstrate the use of recovery audit con-
20 tractors under the Medicare Integrity Program in identi-
21 fying underpayments and overpayments and recouping
22 overpayments under the medicare program for services for
23 which payment is made under part A or part B of title
24 XVIII of the Social Security Act. Under the project—

1 (1) payment may be made to such a contractor
2 on a contingent basis;

3 (2) a percentage of the amount recovered may
4 be retained by the Secretary and shall be available
5 to the program management account of the Centers
6 for Medicare & Medicaid Services; and

7 (3) the Secretary shall examine the efficacy of
8 such use with respect to duplicative payments, accu-
9 racy of coding, and other payment policies in which
10 inaccurate payments arise.

11 (b) SCOPE AND DURATION.—

12 (1) SCOPE.—The project shall cover at least 2
13 States that are among the States with—

14 (A) the highest per capita utilization rates
15 of medicare services, and

16 (B) at least 3 contractors.

17 (2) DURATION.—The project shall last for not
18 longer than 3 years.

19 (c) WAIVER.—The Secretary of Health and Human
20 Services shall waive such provisions of title XVIII of the
21 Social Security Act as may be necessary to provide for
22 payment for services under the project in accordance with
23 subsection (a).

24 (d) QUALIFICATIONS OF CONTRACTORS.—

1 (1) IN GENERAL.—The Secretary shall enter
2 into a recovery audit contract under this section
3 with an entity only if the entity has staff that has
4 the appropriate clinical knowledge of and experience
5 with the payment rules and regulations under the
6 medicare program or the entity has or will contract
7 with another entity that has such knowledgeable and
8 experienced staff.

9 (2) INELIGIBILITY OF CERTAIN CONTRAC-
10 TORS.—The Secretary may not enter into a recovery
11 audit contract under this section with an entity to
12 the extent that the entity is a fiscal intermediary
13 under section 1816 of the Social Security Act (42
14 U.S.C. 1395h), a carrier under section 1842 of such
15 Act (42 U.S.C. 1395u), or a Medicare Administra-
16 tive Contractor under section 1874A of such Act.

17 (3) PREFERENCE FOR ENTITIES WITH DEM-
18 ONSTRATED PROFICIENCY.—In awarding contracts
19 to recovery audit contractors under this section, the
20 Secretary shall give preference to those risk entities
21 that the Secretary determines have demonstrated
22 more than 3 years direct management experience
23 and a proficiency for cost control or recovery audits
24 with private insurers, health care providers, health

1 plans, or under the medicaid program under title
2 XIX of the Social Security Act.

3 (e) CONSTRUCTION RELATING TO CONDUCT OF IN-
4 VESTIGATION OF FRAUD.—A recovery of an overpayment
5 to a provider by a recovery audit contractor shall not be
6 construed to prohibit the Secretary or the Attorney Gen-
7 eral from investigating and prosecuting, if appropriate, al-
8 legations of fraud or abuse arising from such overpay-
9 ment.

10 (f) REPORT.—The Secretary of Health and Human
11 Services shall submit to Congress a report on the project
12 not later than 6 months after the date of its completion.
13 Such reports shall include information on the impact of
14 the project on savings to the medicare program and rec-
15 ommendations on the cost-effectiveness of extending or ex-
16 panding the project.

17 **TITLE IV—RURAL HEALTH CARE**
18 **IMPROVEMENTS**

19 **SEC. 401. ENHANCED DISPROPORTIONATE SHARE HOS-**
20 **PITAL (DSH) TREATMENT FOR RURAL HOS-**
21 **PITALS AND URBAN HOSPITALS WITH FEWER**
22 **THAN 100 BEDS.**

23 (a) DOUBLING THE CAP.—

1 (1) IN GENERAL.—Section 1886(d)(5)(F) (42
2 U.S.C. 1395ww(d)(5)(F)) is amended by adding at
3 the end the following new clause:

4 “(xiv)(I) In the case of discharges in a fiscal year
5 beginning on or after October 1, 2003, subject to sub-
6 clause (II), there shall be substituted for the dispropor-
7 tionate share adjustment percentage otherwise determined
8 under clause (iv) (other than subclause (I)) or under
9 clause (viii), (x), (xi), (xii), or (xiii), the disproportionate
10 share adjustment percentage determined under clause (vii)
11 (relating to large, urban hospitals).

12 “(II) Under subclause (I), the disproportionate share
13 adjustment percentage shall not exceed 10 percent for a
14 hospital that is not classified as a rural referral center
15 under subparagraph (C).”.

16 (2) CONFORMING AMENDMENTS.—Section
17 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is
18 amended—

19 (A) in each of subclauses (II), (III), (IV),
20 (V), and (VI) of clause (iv), by inserting “sub-
21 ject to clause (xiv) and” before “for discharges
22 occurring”;

23 (B) in clause (viii), by striking “The for-
24 mula” and inserting “Subject to clause (xiv),
25 the formula”; and

1 (C) in each of clauses (x), (xi), (xii), and
2 (xiii), by striking “For purposes” and inserting
3 “Subject to clause (xiv), for purposes”.

4 (b) EFFECTIVE DATE.—The amendments made by
5 this section shall apply with respect to discharges occur-
6 ring on or after October 1, 2003.

7 **SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM**
8 **STANDARDIZED AMOUNT IN RURAL AND**
9 **SMALL URBAN AREAS.**

10 (a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C.
11 1395ww(d)(3)(A)) is amended—

12 (1) in clause (iv), by inserting “and ending on
13 or before September 30, 2003,” after “October 1,
14 1995,”; and

15 (2) by redesignating clauses (v) and (vi) as
16 clauses (vii) and (viii), respectively, and inserting
17 after clause (iv) the following new clauses:

18 “(v) For discharges occurring in the fiscal year
19 beginning on October 1, 2003, the average standard-
20 ized amount for hospitals located in areas other than
21 a large urban area shall be equal to the average
22 standardized amount for hospitals located in a large
23 urban area.”.

24 (b) CONFORMING AMENDMENTS.—

1 (1) COMPUTING DRG-SPECIFIC RATES.—Section
2 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is
3 amended—

4 (A) in the heading, by striking “IN DIF-
5 FERENT AREAS”;

6 (B) in the matter preceding clause (i), by
7 striking “, each of”;

8 (C) in clause (i)—

9 (i) in the matter preceding subclause
10 (I), by inserting “for fiscal years before fis-
11 cal year 2004,” before “for hospitals”; and

12 (ii) in subclause (II), by striking
13 “and” after the semicolon at the end;

14 (D) in clause (ii)—

15 (i) in the matter preceding subclause
16 (I), by inserting “for fiscal years before fis-
17 cal year 2004,” before “for hospitals”; and

18 (ii) in subclause (II), by striking the
19 period at the end and inserting “; and”;

20 and

21 (E) by adding at the end the following new
22 clause:

23 “(iii) for a fiscal year beginning after fiscal
24 year 2003, for hospitals located in all areas, to
25 the product of—

1 (2) by adding at the end the following new
2 paragraphs:

3 “(4)(A) The term ‘essential rural hospital’ means a
4 subsection (d) hospital (as defined in section
5 1886(d)(1)(B)) that is located in a rural area (as defined
6 for purposes of section 1886(d)), has more than 25 li-
7 censed acute care inpatient beds, has applied to the Sec-
8 retary for classification as such a hospital, and with re-
9 spect to which the Secretary has determined that the clo-
10 sure of the hospital would significantly diminish the ability
11 of medicare beneficiaries to obtain essential health care
12 services.

13 “(B) The determination under subparagraph (A)
14 shall be based on the following criteria:

15 “(i) HIGH PROPORTION OF MEDICARE BENE-
16 FICIARIES RECEIVING CARE FROM HOSPITAL.—(I) A
17 high percentage of such beneficiaries residing in the
18 area of the hospital who are hospitalized (during the
19 most recent year for which complete data are avail-
20 able) receive basic inpatient medical care at the hos-
21 pital.

22 “(II) For a hospital with more than 200 li-
23 censed beds, a high percentage of such beneficiaries
24 residing in such area who are hospitalized (during

1 such recent year) receive specialized surgical inpa-
2 tient care at the hospital.

3 “(III) Almost all physicians described in section
4 1861(r)(1) in such area have privileges at the hos-
5 pital and provide their inpatient services primarily at
6 the hospital.

7 “(IV) The hospital inpatient score for quality of
8 care is not less than the median hospital score for
9 quality of care for hospitals in the State, as estab-
10 lished under standards of the utilization and quality
11 control peer review organization under part B of
12 title XI or other quality standards recognized by the
13 Secretary.

14 “(ii) SIGNIFICANT ADVERSE IMPACT IN AB-
15 SENCE OF HOSPITAL.—If the hospital were to
16 close—

17 “(I) there would be a significant amount of
18 time needed for residents to reach emergency
19 treatment, resulting in a potential significant
20 harm to beneficiaries with critical illnesses or
21 injuries;

22 “(II) there would be an inability in the
23 community to stabilize emergency cases for
24 transfers to another acute care setting, result-

1 ing in a potential for significant harm to medi-
2 care beneficiaries; and

3 “(III) any other nearby hospital lacks the
4 physical and clinical capacity to take over the
5 hospital’s typical admissions.

6 “(C) In making such determination, the Secretary
7 may also consider the following:

8 “(i) Free-standing ambulatory surgery centers,
9 office-based oncology care, and imaging center serv-
10 ices are insufficient in the hospital’s area to handle
11 the outpatient care of the hospital.

12 “(ii) Beneficiaries in nearby areas would be ad-
13 versely affected if the hospital were to close as the
14 hospital provides specialized knowledge and services
15 to a network of smaller hospitals and critical access
16 hospitals.

17 “(iii) Medicare beneficiaries would have dif-
18 ficulty in accessing care if the hospital were to close
19 as the hospital provides significant subsidies to sup-
20 port ambulatory care in local clinics, including men-
21 tal health clinics and to support post acute care.

22 “(iv) The hospital has a committment to pro-
23 vide graduate medical education in a rural area.

24 A hospital classified as an essential rural hospital may not
25 change such classification and a hospital so classified shall

1 not be treated as a sole community hospital, medicare de-
2 pendent hospital, or rural referral center for purposes of
3 section 1886.”.

4 (b) PAYMENT BASED ON 102 PERCENT OF ALLOWED
5 COSTS.—

6 (1) INPATIENT HOSPITAL SERVICES.—Section
7 1886(d) (42 U.S.C. 1395ww(d)) is amended by add-
8 ing at the end the following:

9 “(11) In the case of a hospital classified as an essen-
10 tial rural hospital under section 1861(mm)(4) for a cost
11 reporting period, the payment under this subsection for
12 inpatient hospital services for discharges occurring during
13 the period shall be based on 102 percent of the reasonable
14 costs for such services. Nothing in this paragraph shall
15 be construed as affecting the application or amount of
16 deductibles or copayments otherwise applicable to such
17 services under part A or as waiving any requirement for
18 billing for such services.”.

19 (2) HOSPITAL OUTPATIENT SERVICES.—Section
20 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by
21 adding at the end the following new subparagraph:

22 “(B) SPECIAL RULE FOR ESSENTIAL
23 RURAL HOSPITALS.—In the case of a hospital
24 classified as an essential rural hospital under
25 section 1861(mm)(4) for a cost reporting pe-

1 riod, the payment under this subsection for cov-
2 ered OPD services during the period shall be
3 based on 102 percent of the reasonable costs
4 for such services. Nothing in this subparagraph
5 shall be construed as affecting the application
6 or amount of deductibles or copayments other-
7 wise applicable to such services under this part
8 or as waiving any requirement for billing for
9 such services.”.

10 (c) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to cost reporting periods beginning
12 on or after October 1, 2004.

13 **SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED IN**
14 **HOSPITAL MARKET BASKET.**

15 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After
16 revising the weights used in the hospital market basket
17 under section 1886(b)(3)(B)(iii) of the Social Security Act
18 (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most cur-
19 rent data available, the Secretary shall establish a fre-
20 quency for revising such weights, including the labor
21 share, in such market basket to reflect the most current
22 data available more frequently than once every 5 years.

23 (b) REPORT.—Not later than October 1, 2004, the
24 Secretary shall submit a report to Congress on the fre-
25 quency established under subsection (a), including an ex-

1 planation of the reasons for, and options considered, in
2 determining such frequency.

3 **SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL**
4 **PROGRAM.**

5 (a) INCREASE IN PAYMENT AMOUNTS.—

6 (1) IN GENERAL.—Sections 1814(l),
7 1834(g)(1), and 1883(a)(3) (42 U.S.C. 1395f(l);
8 1395m(g)(1); 42 U.S.C. 1395tt(a)(3)) are each
9 amended by inserting “equal to 102 percent of” be-
10 fore “the reasonable costs”.

11 (2) EFFECTIVE DATE.—The amendments made
12 by paragraph (1) shall apply to payments for serv-
13 ices furnished during cost reporting periods begin-
14 ning on or after October 1, 2003.

15 (b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY
16 ROOM ON-CALL PROVIDERS.—

17 (1) IN GENERAL.—Section 1834(g)(5) (42
18 U.S.C. 1395m(g)(5)) is amended—

19 (A) in the heading—

20 (i) by inserting “CERTAIN” before
21 “EMERGENCY”; and

22 (ii) by striking “PHYSICIANS” and in-
23 sserting “PROVIDERS”;

24 (B) by striking “emergency room physi-
25 cians who are on-call (as defined by the Sec-

1 retary)” and inserting “physicians, physician
2 assistants, nurse practitioners, and clinical
3 nurse specialists who are on-call (as defined by
4 the Secretary) to provide emergency services”;
5 and

6 (C) by striking “physicians’ services” and
7 inserting “services covered under this title”.

8 (2) EFFECTIVE DATE.—The amendment made
9 by paragraph (1) shall apply with respect to costs
10 incurred for services provided on or after January 1,
11 2004.

12 (c) MODIFICATION OF THE ISOLATION TEST FOR
13 COST-BASED CAH AMBULANCE SERVICES.—

14 (1) IN GENERAL.—Section 1834(l)(8) (42
15 U.S.C. 1395m(l)), as added by section 205(a) of
16 BIPA (114 Stat. 2763A–482), is amended by add-
17 ing at the end the following: “The limitation de-
18 scribed in the matter following subparagraph (B) in
19 the previous sentence shall not apply if the ambu-
20 lance services are furnished by such a provider or
21 supplier of ambulance services who is a first re-
22 sponder to emergencies in accordance with local pro-
23 tocols (as determined by the Secretary).”.

24 (2) EFFECTIVE DATE.—The amendment made
25 by paragraph (1) shall apply to ambulances services

1 furnished on or after the first cost reporting period
2 that begins after the date of the enactment of this
3 Act.

4 (d) REINSTATEMENT OF PERIODIC INTERIM PAY-
5 MENT (PIP).—

6 (1) IN GENERAL.—Section 1815(e)(2) (42
7 U.S.C. 1395g(e)(2)) is amended—

8 (A) in the matter before subparagraph (A),
9 by inserting “, in the cases described in sub-
10 paragraphs (A) through (D)” after “1986”;
11 and

12 (B) by striking “and” at the end of sub-
13 paragraph (C);

14 (C) by adding “and” at the end of sub-
15 paragraph (D); and

16 (D) by inserting after subparagraph (D)
17 the following new subparagraph:

18 “(E) inpatient critical access hospital services;”.

19 (2) DEVELOPMENT OF ALTERNATIVE METHODS
20 OF PERIODIC INTERIM PAYMENTS.—With respect to
21 periodic interim payments to critical access hospitals
22 for inpatient critical access hospital services under
23 section 1815(e)(2)(E) of the Social Security Act, as
24 added by paragraph (1), the Secretary shall develop

1 alternative methods for such payments that are
2 based on expenditures of the hospital.

3 (3) REINSTATEMENT OF PIP.—The amend-
4 ments made by paragraph (1) shall apply to pay-
5 ments made on or after January 1, 2004.

6 (e) CONDITION FOR APPLICATION OF SPECIAL PHY-
7 SICIAN PAYMENT ADJUSTMENT.—

8 (1) IN GENERAL.—Section 1834(g)(2) (42
9 U.S.C. 1395m(g)(2)) is amended by adding after
10 and below subparagraph (B) the following:

11 “The Secretary may not require, as a condition for
12 applying subparagraph (B) with respect to a critical
13 access hospital, that each physician providing profes-
14 sional services in the hospital must assign billing
15 rights with respect to such services, except that such
16 subparagraph shall not apply to those physicians
17 who have not assigned such billing rights.”.

18 (2) EFFECTIVE DATE.—The amendment made
19 by paragraph (1) shall be effective as if included in
20 the enactment of section 403(d) of the Medicare,
21 Medicaid, and SCHIP Balanced Budget Refinement
22 Act of 1999 (113 Stat. 1501A–371).

23 (f) FLEXIBILITY IN BED LIMITATION FOR HOS-
24 PITALS.—Section 1820 (42 U.S.C. 1395i–4) is amended—

1 (1) in subsection (c)(2)(B)(iii), by inserting
2 “subject to paragraph (3)” after “(iii) provides”;

3 (2) by adding at the end of subsection (c) the
4 following new paragraph:

5 “(3) INCREASE IN MAXIMUM NUMBER OF BEDS
6 FOR HOSPITALS WITH STRONG SEASONAL CENSUS
7 FLUCTUATIONS.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (C), in the case of a hospital that dem-
10 onstrates that it meets the standards estab-
11 lished under subparagraph (B) and has not
12 made the election described in subsection
13 (f)(2)(A), the bed limitations otherwise applica-
14 ble under paragraph (2)(B)(iii) and subsection
15 (f) shall be increased by 5 beds.

16 “(B) STANDARDS.—The Secretary shall
17 specify standards for determining whether a
18 critical access hospital has sufficiently strong
19 seasonal variations in patient admissions to jus-
20 tify the increase in bed limitation provided
21 under subparagraph (A).”; and

22 (3) in subsection (f)—

23 (A) by inserting “(1)” after “(f)”; and

24 (B) by adding at the end the following new
25 paragraph:

1 “(2)(A) A hospital may elect to treat the reference
2 in paragraph (1) to ‘15 beds’ as a reference to ‘25 beds’,
3 but only if no more than 10 beds in the hospital are at
4 any time used for non-acute care services. A hospital that
5 makes such an election is not eligible for the increase pro-
6 vided under subsection (c)(3)(A).

7 “(B) The limitations in numbers of beds under the
8 first sentence of paragraph (1) are subject to adjustment
9 under subsection (c)(3).”.

10 (4) EFFECTIVE DATE.—The amendments made
11 by this subsection shall apply to designations made
12 before, on, or after January 1, 2004.

13 (g) ADDITIONAL 5-YEAR PERIOD OF FUNDING FOR
14 GRANT PROGRAM.—

15 (1) IN GENERAL.—Section 1820(g) (42 U.S.C.
16 1395i-4(g)) is amended by adding at the end the
17 following new paragraph:

18 “(4) FUNDING.—

19 “(A) IN GENERAL.—Subject to subpara-
20 graph (B), payment for grants made under this
21 subsection during fiscal years 2004 through
22 2008 shall be made from the Federal Hospital
23 Insurance Trust Fund.

24 “(B) ANNUAL AGGREGATE LIMITATION.—

25 In no case may the amount of payment pro-

1 the reference periods (as defined in
2 subclause (II)), effective for cost re-
3 porting periods beginning on or after
4 January 1, 2004, the otherwise appli-
5 cable resident limit shall be reduced
6 by 75 percent of the difference be-
7 tween such limit and the reference
8 resident level specified in subclause
9 (III) (or subclause (IV) if applicable).

10 “(II) REFERENCE PERIODS DE-
11 FINED.—In this clause, the term ‘ref-
12 erence periods’ means, for a hospital,
13 the 3 most recent consecutive cost re-
14 porting periods of the hospital for
15 which cost reports have been settled
16 (or, if not, submitted) on or before
17 September 30, 2002.

18 “(III) REFERENCE RESIDENT
19 LEVEL.—Subject to subclause (IV),
20 the reference resident level specified in
21 this subclause for a hospital is the
22 highest resident level for the hospital
23 during any of the reference periods.

24 “(IV) ADJUSTMENT PROCESS.—
25 Upon the timely request of a hospital,

1 the Secretary shall adjust (subject to
2 audit) the reference resident level for
3 a hospital to be the resident level for
4 the hospital for the cost reporting pe-
5 riod that includes July 1, 2003.

6 “(V) AFFILIATION.—With re-
7 spect to hospitals which are members
8 of the same affiliated group (as de-
9 fined by the Secretary under subpara-
10 graph (H)(ii)), the provisions of this
11 section shall be applied with respect to
12 such an affiliated group by deeming
13 the affiliated group to be a single hos-
14 pital.

15 “(ii) REDISTRIBUTION.—

16 “(I) IN GENERAL.—The Sec-
17 retary is authorized to increase the
18 otherwise applicable resident limits for
19 hospitals by an aggregate number es-
20 timated by the Secretary that does
21 not exceed the aggregate reduction in
22 such limits attributable to clause (i)
23 (without taking into account any ad-
24 justment under subclause (IV) of such
25 clause).

1 “(II) EFFECTIVE DATE.—No in-
2 crease under subclause (I) shall be
3 permitted or taken into account for a
4 hospital for any portion of a cost re-
5 porting period that occurs before July
6 1, 2004, or before the date of the hos-
7 pital’s application for an increase
8 under this clause. No such increase
9 shall be permitted for a hospital un-
10 less the hospital has applied to the
11 Secretary for such increase by Decem-
12 ber 31, 2005.

13 “(III) CONSIDERATIONS IN RE-
14 DISTRIBUTION.—In determining for
15 which hospitals the increase in the
16 otherwise applicable resident limit is
17 provided under subclause (I), the Sec-
18 retary shall take into account the
19 need for such an increase by specialty
20 and location involved, consistent with
21 subclause (IV).

22 “(IV) PRIORITY FOR RURAL AND
23 SMALL URBAN AREAS.—In deter-
24 mining for which hospitals and resi-
25 dency training programs an increase

1 in the otherwise applicable resident
2 limit is provided under subclause (I),
3 the Secretary shall first distribute the
4 increase to programs of hospitals lo-
5 cated in rural areas or in urban areas
6 that are not large urban areas (as de-
7 fined for purposes of subsection (d))
8 on a first-come-first-served basis (as
9 determined by the Secretary) based on
10 a demonstration that the hospital will
11 fill the positions made available under
12 this clause and not to exceed an in-
13 crease of 25 full-time equivalent posi-
14 tions with respect to any hospital.

15 “(V) APPLICATION OF LOCALITY
16 ADJUSTED NATIONAL AVERAGE PER
17 RESIDENT AMOUNT.—With respect to
18 additional residency positions in a
19 hospital attributable to the increase
20 provided under this clause, notwith-
21 standing any other provision of this
22 subsection, the approved FTE resi-
23 dent amount is deemed to be equal to
24 the locality adjusted national average

1 per resident amount computed under
2 subparagraph (E) for that hospital.

3 “(VI) CONSTRUCTION.—Nothing
4 in this clause shall be construed as
5 permitting the redistribution of reduc-
6 tions in residency positions attrib-
7 utable to voluntary reduction pro-
8 grams under paragraph (6) or as af-
9 fecting the ability of a hospital to es-
10 tablish new medical residency training
11 programs under subparagraph (H).

12 “(iii) RESIDENT LEVEL AND LIMIT
13 DEFINED.—In this subparagraph:

14 “(I) RESIDENT LEVEL.—The
15 term ‘resident level’ means, with re-
16 spect to a hospital, the total number
17 of full-time equivalent residents, be-
18 fore the application of weighting fac-
19 tors (as determined under this para-
20 graph), in the fields of allopathic and
21 osteopathic medicine for the hospital.

22 “(II) OTHERWISE APPLICABLE
23 RESIDENT LIMIT.—The term ‘other-
24 wise applicable resident limit’ means,
25 with respect to a hospital, the limit

1 otherwise applicable under subpara-
2 graphs (F)(i) and (H) on the resident
3 level for the hospital determined with-
4 out regard to this subparagraph.”.

5 (b) CONFORMING AMENDMENT TO IME.—Section
6 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is
7 amended by adding at the end the following: “The provi-
8 sions of subparagraph (I) of subsection (h)(4) shall apply
9 with respect to the first sentence of this clause in the same
10 manner as it applies with respect to subparagraph (F) of
11 such subsection.”.

12 (c) REPORT ON EXTENSION OF APPLICATIONS
13 UNDER REDISTRIBUTION PROGRAM.—Not later than July
14 1, 2005, the Secretary shall submit to Congress a report
15 containing recommendations regarding whether to extend
16 the deadline for applications for an increase in resident
17 limits under section 1886(h)(4)(I)(ii)(II) of the Social Se-
18 curity Act (as added by subsection (a)).

19 **SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS PRO-**
20 **VISIONS FOR SMALL RURAL HOSPITALS AND**
21 **SOLE COMMUNITY HOSPITALS UNDER PRO-**
22 **SPECTIVE PAYMENT SYSTEM FOR HOSPITAL**
23 **OUTPATIENT DEPARTMENT SERVICES.**

24 (a) HOLD HARMLESS PROVISIONS.—

1 (1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42
2 U.S.C. 1395l(t)(7)(D)(i)) is amended—

3 (A) in the heading, by striking “SMALL”
4 and inserting “CERTAIN”;

5 (B) by inserting “or a sole community hos-
6 pital (as defined in section 1886(d)(5)(D)(iii))
7 located in a rural area” after “100 beds”; and

8 (C) by striking “2004” and inserting
9 “2006”.

10 (2) EFFECTIVE DATE.—The amendment made
11 by subsection (a)(2) shall apply with respect to pay-
12 ment for OPD services furnished on and after Janu-
13 ary 1, 2004.

14 (b) STUDY; ADJUSTMENT.—

15 (1) STUDY.—The Secretary shall conduct a
16 study to determine if, under the prospective payment
17 system for hospital outpatient department services
18 under section 1833(t) of the Social Security Act (42
19 U.S.C. 1395l(t)), costs incurred by rural providers
20 of services by ambulatory payment classification
21 groups (APCs) exceed those costs incurred by urban
22 providers of services.

23 (2) ADJUSTMENT.—Insofar as the Secretary
24 determines under paragraph (1) that costs incurred
25 by rural providers exceed those costs incurred by

1 urban providers of services, the Secretary shall pro-
2 vide for an appropriate adjustment under such sec-
3 tion 1833(t) to reflect those higher costs by January
4 1, 2005.

5 **SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC**
6 **AND FEDERALLY QUALIFIED HEALTH CEN-**
7 **TER SERVICES FROM THE PROSPECTIVE PAY-**
8 **MENT SYSTEM FOR SKILLED NURSING FA-**
9 **CILITIES.**

10 (a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C.
11 1395yy(e)(2)(A)) is amended—

12 (1) in clause (i)(II), by striking “clauses (ii)
13 and (iii)” and inserting “clauses (ii), (iii), and (iv)”;
14 and

15 (2) by adding at the end the following new
16 clause:

17 “(iv) EXCLUSION OF CERTAIN RURAL
18 HEALTH CLINIC AND FEDERALLY QUALI-
19 FIED HEALTH CENTER SERVICES.—Serv-
20 ices described in this clause are—

21 “(I) rural health clinic services
22 (as defined in paragraph (1) of sec-
23 tion 1861(aa)); and

1 “(II) Federally qualified health
2 center services (as defined in para-
3 graph (3) of such section);
4 that would be described in clause (ii) if
5 such services were not furnished by an in-
6 dividual affiliated with a rural health clinic
7 or a Federally qualified health center.”.

8 (b) EFFECTIVE DATE.—The amendments made by
9 subsection (a) shall apply to services furnished on or after
10 January 1, 2004.

11 **SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTI-**
12 **TIONERS AS ATTENDING PHYSICIANS TO**
13 **SERVE HOSPICE PATIENTS.**

14 (a) IN GENERAL.—Section 1861(dd)(3)(B) (42
15 U.S.C. 1395x(dd)(3)(B)) is amended by inserting “or
16 nurse practitioner (as defined in subsection (aa)(5))” after
17 “the physician (as defined in subsection (r)(1))”.

18 (b) CLARIFICATION OF HOSPICE ROLE OF NURSE
19 PRACTITIONERS.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C.
20 1395f(a)(7)(A)(i)(I)) is amended by inserting “(which for
21 purposes of this subparagraph does not include a nurse
22 practitioner)” after “attending physician (as defined in
23 section 1861(dd)(3)(B))”.

1 **SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN EMER-**
2 **GENCY CAPACITY FOR AMBULANCE SERV-**
3 **ICES IN RURAL AREAS.**

4 Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

5 (1) by redesignating paragraph (8), as added by
6 section 221(a) of BIPA (114 Stat. 2763A–486), as
7 paragraph (9); and

8 (2) by adding at the end the following new
9 paragraph:

10 “(10) ASSISTANCE FOR RURAL PROVIDERS
11 FURNISHING SERVICES IN LOW MEDICARE POPU-
12 LATION DENSITY AREAS.—

13 “(A) IN GENERAL.—In the case of ground
14 ambulance services furnished on or after Janu-
15 ary 1, 2004, for which the transportation origi-
16 nates in a qualified rural area (as defined in
17 subparagraph (B)), the Secretary shall provide
18 for a percent increase in the base rate of the fee
19 schedule for a trip established under this sub-
20 section. In establishing such percent increase,
21 the Secretary shall estimate the average cost
22 per trip for the base rate in the lowest quartile
23 as compared to the average cost for the base
24 rate for such services that is in the highest
25 quartile of all rural county populations.

1 “(B) QUALIFIED RURAL AREA DEFINED.—
2 For purposes of subparagraph (A), the term
3 ‘qualified rural area’ is a rural area (as defined
4 in section 1886(d)(2)(D)) with a population
5 density of medicare beneficiaries residing in the
6 area that is in the lowest quartile of all rural
7 county populations.”.

8 **SEC. 411. TWO-YEAR INCREASE FOR HOME HEALTH SERV-**
9 **ICES FURNISHED IN A RURAL AREA.**

10 (a) IN GENERAL.—In the case of home health serv-
11 ices furnished in a rural area (as defined in section
12 1886(d)(2)(D) of the Social Security Act (42 U.S.C.
13 1395ww(d)(2)(D))) during 2004 and 2005, the Secretary
14 shall increase the payment amount otherwise made under
15 section 1895 of such Act (42 U.S.C. 1395fff) for such
16 services by 5 percent.

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

1 **SEC. 412. PROVIDING SAFE HARBOR FOR CERTAIN COL-**
2 **LABORATIVE EFFORTS THAT BENEFIT MEDI-**
3 **CALLY UNDERSERVED POPULATIONS.**

4 (a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C.
5 1320a–7(b)(3)), as amended by section 101(b)(2), is
6 amended—

7 (1) in subparagraph (F), by striking “and”
8 after the semicolon at the end;

9 (2) in subparagraph (G), by striking the period
10 at the end and inserting “; and”; and

11 (3) by adding at the end the following new sub-
12 paragraph:

13 “(H) any remuneration between a public
14 or nonprofit private health center entity de-
15 scribed under clause (i) or (ii) of section
16 1905(l)(2)(B) and any individual or entity pro-
17 viding goods, items, services, donations or
18 loans, or a combination thereof, to such health
19 center entity pursuant to a contract, lease,
20 grant, loan, or other agreement, if such agree-
21 ment contributes to the ability of the health
22 center entity to maintain or increase the avail-
23 ability, or enhance the quality, of services pro-
24 vided to a medically underserved population
25 served by the health center entity.”.

1 (b) RULEMAKING FOR EXCEPTION FOR HEALTH
2 CENTER ENTITY ARRANGEMENTS.—

3 (1) ESTABLISHMENT.—

4 (A) IN GENERAL.—The Secretary of
5 Health and Human Services (in this subsection
6 referred to as the “Secretary”) shall establish,
7 on an expedited basis, standards relating to the
8 exception described in section 1128B(b)(3)(H)
9 of the Social Security Act, as added by sub-
10 section (a), for health center entity arrange-
11 ments to the antikickback penalties.

12 (B) FACTORS TO CONSIDER.—The Sec-
13 retary shall consider the following factors,
14 among others, in establishing standards relating
15 to the exception for health center entity ar-
16 rangements under subparagraph (A):

17 (i) Whether the arrangement between
18 the health center entity and the other
19 party results in savings of Federal grant
20 funds or increased revenues to the health
21 center entity.

22 (ii) Whether the arrangement between
23 the health center entity and the other
24 party restricts or limits a patient’s freedom
25 of choice.

1 (iii) Whether the arrangement be-
2 tween the health center entity and the
3 other party protects a health care profes-
4 sional's independent medical judgment re-
5 garding medically appropriate treatment.

6 The Secretary may also include other standards
7 and criteria that are consistent with the intent
8 of Congress in enacting the exception estab-
9 lished under this section.

10 (2) INTERIM FINAL EFFECT.—No later than
11 180 days after the date of enactment of this Act, the
12 Secretary shall publish a rule in the Federal Reg-
13 ister consistent with the factors under paragraph
14 (1)(B). Such rule shall be effective and final imme-
15 diately on an interim basis, subject to such change
16 and revision, after public notice and opportunity (for
17 a period of not more than 60 days) for public com-
18 ment, as is consistent with this subsection.

19 **SEC. 413. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN**
20 **PAYMENTS FOR PHYSICIANS' SERVICES.**

21 (a) STUDY.—The Comptroller General of the United
22 States shall conduct a study of differences in payment
23 amounts under the physician fee schedule under section
24 1848 of the Social Security Act (42 U.S.C. 1395w-4) for

1 physicians' services in different geographic areas. Such
2 study shall include—

3 (1) an assessment of the validity of the geo-
4 graphic adjustment factors used for each component
5 of the fee schedule;

6 (2) an evaluation of the measures used for such
7 adjustment, including the frequency of revisions; and

8 (3) an evaluation of the methods used to deter-
9 mine professional liability insurance costs used in
10 computing the malpractice component, including a
11 review of increases in professional liability insurance
12 premiums and variation in such increases by State
13 and physician specialty and methods used to update
14 the geographic cost of practice index and relative
15 weights for the malpractice component.

16 (b) REPORT.—Not later than 1 year after the date
17 of the enactment of this Act, the Comptroller General shall
18 submit to Congress a report on the study conducted under
19 subsection (a). The report shall include recommendations
20 regarding the use of more current data in computing geo-
21 graphic cost of practice indices as well as the use of data
22 directly representative of physicians' costs (rather than
23 proxy measures of such costs).

1 **SEC. 414. TREATMENT OF MISSING COST REPORTING PERI-**
2 **ODS FOR SOLE COMMUNITY HOSPITALS.**

3 (a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C.
4 1395ww(b)(3)(I)) is amended by adding at the end the
5 following new clause:

6 “(iii) In no case shall a hospital be denied treatment
7 as a sole community hospital or payment (on the basis
8 of a target rate as such as a hospital) because data are
9 unavailable for any cost reporting period due to changes
10 in ownership, changes in fiscal intermediaries, or other ex-
11 traordinary circumstances, so long as data for at least one
12 applicable base cost reporting period is available.”.

13 (b) EFFECTIVE DATE.—The amendment made by
14 subsection (a) shall apply to cost reporting periods begin-
15 ning on or after January 1, 2004.

16 **SEC. 415. EXTENSION OF TELEMEDICINE DEMONSTRATION**
17 **PROJECT.**

18 Section 4207 of Balanced Budget Act of 1997 (Pub-
19 lic Law 105–33) is amended—

20 (1) in subsection (a)(4), by striking “4-year”
21 and inserting “8-year”; and

22 (2) in subsection (d)(3), by striking
23 “\$30,000,000” and inserting “\$60,000,000”.

1 **SEC. 416. ADJUSTMENT TO THE MEDICARE INPATIENT HOS-**
2 **PITAL PPS WAGE INDEX TO REVISE THE**
3 **LABOR-RELATED SHARE OF SUCH INDEX.**

4 (a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C.
5 1395ww(d)(3)(E)) is amended—

6 (1) by striking “WAGE LEVELS.—The Sec-
7 retary” and inserting “WAGE LEVELS.—

8 “(i) IN GENERAL.—Except as provided in
9 clause (ii), the Secretary”; and

10 (2) by adding at the end the following new
11 clause:

12 “(ii) ALTERNATIVE PROPORTION TO BE
13 ADJUSTED BEGINNING IN FISCAL YEAR 2004.—

14 “(I) IN GENERAL.—Except as pro-
15 vided in subclause (II), for discharges oc-
16 ccurring on or after October 1, 2003, the
17 Secretary shall substitute the ‘62 percent’
18 for the proportion described in the first
19 sentence of clause (i).

20 “(II) HOLD HARMLESS FOR CERTAIN
21 HOSPITALS.—If the application of sub-
22 clause (I) would result in lower payments
23 to a hospital than would otherwise be
24 made, then this subparagraph shall be ap-
25 plied as if this clause had not been en-
26 acted.”.

1 (b) WAIVING BUDGET NEUTRALITY.—Section
2 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended
3 by subsection (a), is amended by adding at the end of
4 clause (i) the following new sentence: “The Secretary shall
5 apply the previous sentence for any period as if the
6 amendments made by section 402(a) of the Medicare Pre-
7 scription Drug and Modernization Act of 2003 had not
8 been enacted.”.

9 **SEC. 417. MEDICARE INCENTIVE PAYMENT PROGRAM IM-**
10 **PROVEMENTS FOR PHYSICIAN SCARCITY.**

11 (a) ADDITIONAL BONUS PAYMENT FOR CERTAIN
12 PHYSICIAN SCARCITY AREAS.—

13 (1) IN GENERAL.—Section 1833 (42 U.S.C.
14 1395l) is amended by adding at the end the fol-
15 lowing new subsection:

16 “(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCAR-
17 CITY AREAS.—

18 “(1) IN GENERAL.—In the case of physicians’
19 services furnished in a year—

20 “(A) by a primary care physician in a pri-
21 mary care scarcity county (identified under
22 paragraph (4)); or

23 “(B) by a physician who is not a primary
24 care physician in a specialist care scarcity coun-
25 ty (as so identified),

1 in addition to the amount of payment that would
2 otherwise be made for such services under this part,
3 there also shall be paid an amount equal to 5 per-
4 cent of the payment amount for the service under
5 this part.

6 “(2) DETERMINATION OF RATIOS OF PHYSI-
7 CIANS TO MEDICARE BENEFICIARIES IN AREA.—
8 Based upon available data, the Secretary shall peri-
9 odically determine, for each county or equivalent
10 area in the United States, the following:

11 “(A) NUMBER OF PHYSICIANS PRACTICING
12 IN THE AREA.—The number of physicians who
13 furnish physicians’ services in the active prac-
14 tice of medicine or osteopathy in that county or
15 area, other than physicians whose practice is
16 exclusively for the Federal Government, physi-
17 cians who are retired, or physicians who only
18 provide administrative services. Of such num-
19 ber, the number of such physicians who are—

20 “(i) primary care physicians; or

21 “(ii) physicians who are not primary
22 care physicians.

23 “(B) NUMBER OF MEDICARE BENE-
24 FICIARIES RESIDING IN THE AREA.—The num-
25 ber of individuals who are residing in the coun-

1 ty and are entitled to benefits under part A or
2 enrolled under this part, or both.

3 “(C) DETERMINATION OF RATIOS.—

4 “(i) PRIMARY CARE RATIO.—The ratio
5 (in this paragraph referred to as the ‘pri-
6 mary care ratio’) of the number of primary
7 care physicians (determined under sub-
8 paragraph (A)(i)), to number of medicare
9 beneficiaries determined under subpara-
10 graph (B).

11 “(ii) SPECIALIST CARE RATIO.—The
12 ratio (in this paragraph referred to as the
13 ‘specialist care ratio’) of the number of
14 other physicians (determined under sub-
15 paragraph (A)(ii)), to number of medicare
16 beneficiaries determined under subpara-
17 graph (B).

18 “(3) RANKING OF COUNTIES.—The Secretary
19 shall rank each such county or area based separately
20 on its primary care ratio and its specialist care ratio.

21 “(4) IDENTIFICATION OF COUNTIES.—The Sec-
22 retary shall identify—

23 “(A) those counties and areas (in this
24 paragraph referred to as ‘primary care scarcity
25 counties’) with the lowest primary care ratios

1 that represent, if each such county or area were
2 weighted by the number of medicare bene-
3 ficiaries determined under paragraph (2)(B), an
4 aggregate total of 20 percent of the total of the
5 medicare beneficiaries determined under such
6 paragraph; and

7 “(B) those counties and areas (in this sub-
8 section referred to as ‘specialist care scarcity
9 counties’) with the lowest specialist care ratios
10 that represent, if each such county or area were
11 weighted by the number of medicare bene-
12 ficiaries determined under paragraph (2)(B), an
13 aggregate total of 20 percent of the total of the
14 medicare beneficiaries determined under such
15 paragraph.

16 There is no administrative or judicial review respect-
17 ing the identification of a county or area or the as-
18 signment of a specialty of any physician under this
19 paragraph.

20 “(5) RURAL CENSUS TRACKS.—To the extent
21 feasible, the Secretary shall treat a rural census
22 tract of a metropolitan statistical area (as deter-
23 mined under the most recent modification of the
24 Goldsmith Modification, originally published in the
25 Federal Register on February 27, 1992 (57 Fed.

1 Reg. 6725) as an equivalent area for purposes of
2 qualifying as a primary care scarcity county or spe-
3 cialist care scarcity county under this subsection.

4 “(6) PHYSICIAN DEFINED.—For purposes of
5 this paragraph, the term ‘physician’ means a physi-
6 cian described in section 1861(r)(1) and the term
7 ‘primary care physician’ means a physician who is
8 identified in the available data as a general practi-
9 tioner, family practice practitioner, general internist,
10 or obstetrician or gynecologist.

11 “(7) PUBLICATION OF LIST OF COUNTIES.—In
12 carrying out this subsection for a year, the Secretary
13 shall include, as part of the proposed and final rule
14 to implement the physician fee schedule under sec-
15 tion 1848 for the year, a list of all areas which will
16 qualify as a primary care scarcity county or spe-
17 cialist care scarcity county under this subsection for
18 the year involved.”.

19 (2) EFFECTIVE DATE.—The amendments made
20 by subsection (a) shall apply to physicians’ services
21 furnished or after January 1, 2004.

22 (b) IMPROVEMENT TO MEDICARE INCENTIVE PAY-
23 MENT PROGRAM.—

24 (1) IN GENERAL.—Section 1833(m) (42 U.S.C.
25 1395l(m)) is amended—

1 (A) by inserting “(1)” after “(m)”; and

2 (B) by adding at the end the following new
3 paragraphs:

4 “(2) The Secretary shall establish procedures under
5 which the Secretary, and not the physician furnishing the
6 service, is responsible for determining when a payment is
7 required to be made under paragraph (1).

8 “(3) In carrying out paragraph (1) for a year, the
9 Secretary shall include, as part of the proposed and final
10 rule to implement the physician fee schedule under section
11 1848 for the year, a list of all areas which will qualify
12 as a health professional shortage area under paragraph
13 (1) for the year involved.”.

14 (2) EFFECTIVE DATE.—The amendments made
15 by paragraph (1) shall apply to physicians’ services
16 furnished or after January 1, 2004.

17 **SEC. 418. RURAL HOSPICE DEMONSTRATION PROJECT.**

18 (a) IN GENERAL.—The Secretary shall conduct a
19 demonstration project for the delivery of hospice care to
20 medicare beneficiaries in rural areas. Under the project
21 medicare beneficiaries who are unable to receive hospice
22 care in the home for lack of an appropriate caregiver are
23 provided such care in a facility of 20 or fewer beds which
24 offers, within its walls, the full range of services provided

1 by hospice programs under section 1861(dd) of the Social
2 Security Act (42 U.S.C. 1395x(dd)).

3 (b) SCOPE OF PROJECT.—The Secretary shall con-
4 duct the project under this section with respect to no more
5 than 3 hospice programs over a period of not longer than
6 5 years each.

7 (c) COMPLIANCE WITH CONDITIONS.—Under the
8 demonstration project—

9 (1) the hospice program shall comply with oth-
10 erwise applicable requirements, except that it shall
11 not be required to offer services outside of the home
12 or to meet the requirements of section
13 1861(dd)(2)(A)(iii) of the Social Security Act; and

14 (2) payments for hospice care shall be made at
15 the rates otherwise applicable to such care under
16 title XVIII of such Act.

17 The Secretary may require the program to comply with
18 such additional quality assurance standards for its provi-
19 sion of services in its facility as the Secretary deems ap-
20 propriate.

21 (d) REPORT.—Upon completion of the project, the
22 Secretary shall submit a report to Congress on the project
23 and shall include in the report recommendations regarding
24 extension of such project to hospice programs serving
25 rural areas.

1 **TITLE V—PROVISIONS**
2 **RELATING TO PART A**
3 **Subtitle A—Inpatient Hospital**
4 **Services**

5 **SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT**
6 **UPDATES.**

7 Section 1886(b)(3)(B)(i) (42 U.S.C.
8 1395ww(b)(3)(B)(i)) is amended—

9 (1) by striking “and” at the end of subclause
10 (XVIII);

11 (2) by striking subclause (XIX); and

12 (3) by inserting after subclause (XVIII) the fol-
13 lowing new subclauses:

14 “(XIX) for each of fiscal years 2004 through
15 2006, the market basket percentage increase minus
16 0.4 percentage points for hospitals in all areas; and

17 “(XX) for fiscal year 2007 and each subsequent
18 fiscal year, the market basket percentage increase
19 for hospitals in all areas.”.

20 **SEC. 502. RECOGNITION OF NEW MEDICAL TECHNOLOGIES**
21 **UNDER INPATIENT HOSPITAL PPS.**

22 (a) IMPROVING TIMELINESS OF DATA COLLEC-
23 TION.—Section 1886(d)(5)(K) (42 U.S.C.
24 1395ww(d)(5)(K)) is amended by adding at the end the
25 following new clause:

1 “(vii) Under the mechanism under this subpara-
2 graph, the Secretary shall provide for the addition of new
3 diagnosis and procedure codes in April 1 of each year, but
4 the addition of such codes shall not require the Secretary
5 to adjust the payment (or diagnosis-related group classi-
6 fication) under this subsection until the fiscal year that
7 begins after such date.”.

8 (b) ELIGIBILITY STANDARD FOR TECHNOLOGY
9 OUTLIERS.—

10 (1) MINIMUM PERIOD FOR RECOGNITION OF
11 NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi)
12 (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

13 (A) by inserting “(I)” after “(vi)”; and

14 (B) by adding at the end the following new
15 subclause:

16 “(II) Under such criteria, a service or technology
17 shall not be denied treatment as a new service or tech-
18 nology on the basis of the period of time in which the serv-
19 ice or technology has been in use if such period ends before
20 the end of the 2-to-3-year period that begins on the effec-
21 tive date of implementation of a code under ICD–9–CM
22 (or a successor coding methodology) that enables the iden-
23 tification of specific discharges in which the service or
24 technology has been used.”.

1 (2) ADJUSTMENT OF THRESHOLD.—Section
2 1886(d)(5)(K)(ii)(I) (42 U.S.C.
3 1395ww(d)(5)(K)(ii)(I)) is amended by inserting
4 “(applying a threshold specified by the Secretary
5 that is the lesser of 75 percent of the standardized
6 amount (increased to reflect the difference between
7 cost and charges) or 75 percent of one standard de-
8 viation for the diagnosis-related group involved)”
9 after “is inadequate”.

10 (3) CRITERION FOR SUBSTANTIAL IMPROVE-
11 MENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C.
12 1395ww(d)(5)(K)(vi)), as amended by paragraph
13 (1), is further amended by adding at the end the fol-
14 lowing subclause:

15 “(III) The Secretary shall by regulation provide for
16 further clarification of the criteria applied to determine
17 whether a new service or technology represents an advance
18 in medical technology that substantially improves the diag-
19 nosis or treatment of beneficiaries. Under such criteria,
20 in determining whether a new service or technology rep-
21 resents an advance in medical technology that substan-
22 tially improves the diagnosis or treatment of beneficiaries,
23 the Secretary shall deem a service or technology as meet-
24 ing such requirement if the service or technology is a drug
25 or biological that is designated under section 506 of the

1 Federal Food, Drug, and Cosmetic Act, approved under
2 section 314.510 or 601.41 of title 21, Code of Federal
3 Regulations, or designated for priority review when the
4 marketing application for such drug or biological was filed
5 or is a medical device for which an exemption has been
6 granted under section 520(m) of such Act, or for which
7 priority review has been provided under section 515(d)(5)
8 of such Act. Nothing in this subclause shall be construed
9 as effecting the authority of the Secretary to determine
10 whether items and services are medically necessary and
11 appropriate under section 1862(a)(1).”.

12 (4) PROCESS FOR PUBLIC INPUT.—Section
13 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as
14 amended by paragraph (1), is amended—

15 (A) in clause (i), by adding at the end the
16 following: “Such mechanism shall be modified
17 to meet the requirements of clause (viii).”; and

18 (B) by adding at the end the following new
19 clause:

20 “(viii) The mechanism established pursuant to clause
21 (i) shall be adjusted to provide, before publication of a
22 proposed rule, for public input regarding whether a new
23 service or technology not described in the second sentence
24 of clause (vi)(III) represents an advance in medical tech-

1 nology that substantially improves the diagnosis or treat-
2 ment of beneficiaries as follows:

3 “(I) The Secretary shall make public and peri-
4 odically update a list of all the services and tech-
5 nologies for which an application for additional pay-
6 ment under this subparagraph is pending.

7 “(II) The Secretary shall accept comments, rec-
8 ommendations, and data from the public regarding
9 whether the service or technology represents a sub-
10 stantial improvement.

11 “(III) The Secretary shall provide for a meeting
12 at which organizations representing hospitals, physi-
13 cians, medicare beneficiaries, manufacturers, and
14 any other interested party may present comments,
15 recommendations, and data to the clinical staff of
16 the Centers for Medicare & Medicaid Services before
17 publication of a notice of proposed rulemaking re-
18 garding whether service or technology represents a
19 substantial improvement.”.

20 (c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—
21 Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is
22 further amended by adding at the end the following new
23 clause:

24 “(ix) Before establishing any add-on payment under
25 this subparagraph with respect to a new technology, the

1 Secretary shall seek to identify one or more diagnosis-re-
2 lated groups associated with such technology, based on
3 similar clinical or anatomical characteristics and the cost
4 of the technology. Within such groups the Secretary shall
5 assign an eligible new technology into a diagnosis-related
6 group where the average costs of care most closely approx-
7 imate the costs of care of using the new technology. No
8 add-on payment under this subparagraph shall be made
9 with respect to such new technology and this clause shall
10 not affect the application of paragraph (4)(C)(iii).”.

11 (d) IMPROVEMENT IN PAYMENT FOR NEW TECH-
12 NOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C.
13 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after
14 “the estimated average cost of such service or technology”
15 the following: “(based on the marginal rate applied to
16 costs under subparagraph (A))”.

17 (e) ESTABLISHMENT OF NEW FUNDING FOR HOS-
18 PITAL INPATIENT TECHNOLOGY.—

19 (1) IN GENERAL.—Section
20 1886(d)(5)(K)(ii)(III) (42 U.S.C.
21 1395ww(d)(5)(K)(ii)(III)) is amended by striking
22 “subject to paragraph (4)(C)(iii),”.

23 (2) NOT BUDGET NEUTRAL.—There shall be no
24 reduction or other adjustment in payments under
25 section 1886 of the Social Security Act because an

1 additional payment is provided under subsection
2 (d)(5)(K)(ii)(III) of such section.

3 (f) EFFECTIVE DATE.—

4 (1) IN GENERAL.—The Secretary shall imple-
5 ment the amendments made by this section so that
6 they apply to classification for fiscal years beginning
7 with fiscal year 2005.

8 (2) RECONSIDERATIONS OF APPLICATIONS FOR
9 FISCAL YEAR 2004 THAT ARE DENIED.—In the case
10 of an application for a classification of a medical
11 service or technology as a new medical service or
12 technology under section 1886(d)(5)(K) of the Social
13 Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was
14 filed for fiscal year 2004 and that is denied—

15 (A) the Secretary shall automatically re-
16 consider the application as an application for
17 fiscal year 2005 under the amendments made
18 by this section; and

19 (B) the maximum time period otherwise
20 permitted for such classification of the service
21 or technology shall be extended by 12 months.

22 **SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS IN**
23 **PUERTO RICO.**

24 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is
25 amended—

1 (1) in subparagraph (A)—

2 (A) in clause (i), by striking “for dis-
3 charges beginning on or after October 1, 1997,
4 50 percent (and for discharges between October
5 1, 1987, and September 30, 1997, 75 percent)”
6 and inserting “the applicable Puerto Rico per-
7 centage (specified in subparagraph (E))”; and

8 (B) in clause (ii), by striking “for dis-
9 charges beginning in a fiscal year beginning on
10 or after October 1, 1997, 50 percent (and for
11 discharges between October 1, 1987, and Sep-
12 tember 30, 1997, 25 percent)” and inserting
13 “the applicable Federal percentage (specified in
14 subparagraph (E))”; and

15 (2) by adding at the end the following new sub-
16 paragraph:

17 “(E) For purposes of subparagraph (A), for dis-
18 charges occurring—

19 “(i) on or after October 1, 1987, and before Oc-
20 tober 1, 1997, the applicable Puerto Rico percentage
21 is 75 percent and the applicable Federal percentage
22 is 25 percent;

23 “(ii) on or after October 1, 1997, and before
24 October 1, 2003, the applicable Puerto Rico percent-

1 age is 50 percent and the applicable Federal per-
2 centage is 50 percent;

3 “(iii) during fiscal year 2004, the applicable
4 Puerto Rico percentage is 41 percent and the appli-
5 cable Federal percentage is 59 percent;

6 “(iv) during fiscal year 2005, the applicable
7 Puerto Rico percentage is 33 percent and the appli-
8 cable Federal percentage is 67 percent; and

9 “(v) on or after October 1, 2005, the applicable
10 Puerto Rico percentage is 25 percent and the appli-
11 cable Federal percentage is 75 percent.”.

12 **SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICATION**
13 **REFORM .**

14 (a) IN GENERAL.—Section 1886(d) (42 U.S.C.
15 1395ww(d)) is amended by adding at the end the fol-
16 lowing:

17 “(11)(A) In order to recognize commuting patterns
18 among Metropolitan Statistical Areas and between such
19 Areas and rural areas, the Secretary shall establish a proc-
20 ess, upon application of a subsection (d) hospital that es-
21 tablishes that it is a qualifying hospital described in sub-
22 paragraph (B), for an increase of the wage index applied
23 under paragraph (3)(E) for the hospital in the amount
24 computed under subparagraph (D).

1 “(B) A qualifying hospital described in this subpara-
2 graph is a subsection (d) hospital—

3 “(i) the average wages of which exceed the av-
4 erage wages for the area in which the hospital is lo-
5 cated; and

6 “(ii) which has at least 10 percent of its em-
7 ployees who reside in one or more higher wage index
8 areas.

9 “(C) For purposes of this paragraph, the term ‘high-
10 er wage index area’ means, with respect to a hospital, an
11 area with a wage index that exceeds that of the area in
12 which the hospital is located.

13 “(D) The increase in the wage index under subpara-
14 graph (A) for a hospital shall be equal to the percentage
15 of the employees of the hospital that resides in any higher
16 wage index area multiplied by the sum of the products,
17 for each higher wage index area of—

18 “(i) the difference between (I) the wage index
19 for such area, and (II) the wage index of the area
20 in which the hospital is located (before the applica-
21 tion of this paragraph); and

22 “(ii) the number of employees of the hospital
23 that reside in such higher wage index area divided
24 by the total number of such employees that reside in
25 all high wage index areas.

1 “(E) The process under this paragraph shall be based
2 upon the process used by the Medicare Geographic Classi-
3 fication Review Board under paragraph (10) with respect
4 to data submitted by hospitals to the Board on the loca-
5 tion of residence of hospital employees and wages under
6 the applicable schedule established for geographic reclassi-
7 fication.

8 “(F) A reclassification under this paragraph shall be
9 effective for a period of 3 fiscal years, except that the Sec-
10 retary shall establish procedures under which a subsection
11 (d) hospital may elect to terminate such reclassification
12 before the end of such period.

13 “(G) A hospital that is reclassified under this para-
14 graph for a period is not eligible for reclassification under
15 paragraphs (8) or (10) during that period.

16 “(H) Any increase in a wage index under this para-
17 graph for a hospital shall not be taken into account for
18 purposes of—

19 “(i) computing the wage index for the area in
20 which the hospital is located or any other area; or

21 “(ii) applying any budget neutrality adjustment
22 with respect to such index under paragraph
23 (8)(D).”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall first apply to the wage index for dis-
3 charges occurring on or after October 1, 2004.

4 **SEC. 505. MEDPAC REPORT ON SPECIALTY HOSPITALS.**

5 (a) MEDPAC STUDY.—The Medicare Payment Advi-
6 sory Commission shall conduct a study of specialty hos-
7 pitals compared with other similar general acute care hos-
8 pitals under the medicare program. Such study shall ex-
9 amine—

10 (1) whether there are excessive self-referrals;

11 (2) quality of care furnished;

12 (3) the impact of specialty hospitals on such
13 general acute care hospitals; and

14 (4) differences in the scope of services, medicaid
15 utilization, and uncompensated care furnished.

16 (b) REPORT.—Not later than 1 year after the date
17 of the enactment of this Act, the Secretary shall submit
18 to Congress a report on the study conducted under sub-
19 section (a), and shall include any recommendations for
20 legislation or administrative change as the Secretary de-
21 termines appropriate.

1 **Subtitle B—Other Provisions**

2 **SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FA-**
3 **CILITY SERVICES.**

4 (a) ADJUSTMENT TO RUGS FOR AIDS RESI-
5 DENTS.—Paragraph (12) of section 1888(e) (42 U.S.C.
6 1395yy(e)) is amended to read as follows:

7 “(12) ADJUSTMENT FOR RESIDENTS WITH
8 AIDS.—

9 “(A) IN GENERAL.—Subject to subpara-
10 graph (B), in the case of a resident of a skilled
11 nursing facility who is afflicted with acquired
12 immune deficiency syndrome (AIDS), the per
13 diem amount of payment otherwise applicable
14 shall be increased by 128 percent to reflect in-
15 creased costs associated with such residents.

16 “(B) SUNSET.—Subparagraph (A) shall
17 not apply on and after such date as the Sec-
18 retary certifies that there is an appropriate ad-
19 justment in the case mix under paragraph
20 (4)(G)(i) to compensate for the increased costs
21 associated with residents described in such sub-
22 paragraph.”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 paragraph (1) shall apply to services furnished on or after
25 October 1, 2003.

1 **SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERV-**
2 **ICES.**

3 (a) COVERAGE OF HOSPICE CONSULTATION SERV-
4 ICES.—Section 1812(a) (42 U.S.C. 1395d(a)) is amend-
5 ed—

6 (1) by striking “and” at the end of paragraph
7 (3);

8 (2) by striking the period at the end of para-
9 graph (4) and inserting “; and”; and

10 (3) by inserting after paragraph (4) the fol-
11 lowing new paragraph:

12 “(5) for individuals who are terminally ill, have
13 not made an election under subsection (d)(1), and
14 have not previously received services under this
15 paragraph, services that are furnished by a physi-
16 cian who is either the medical director or an em-
17 ployee of a hospice program and that consist of—

18 “(A) an evaluation of the individual’s need
19 for pain and symptom management;

20 “(B) counseling the individual with respect
21 to end-of-life issues and care options; and

22 “(C) advising the individual regarding ad-
23 vanced care planning.”.

24 (b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i))
25 is amended by adding at the end the following new para-
26 graph:

1 “(4) The amount paid to a hospice program with re-
2 spect to the services under section 1812(a)(5) for which
3 payment may be made under this part shall be equal to
4 an amount equivalent to the amount established for an
5 office or other outpatient visit for evaluation and manage-
6 ment associated with presenting problems of moderate se-
7 verity under the fee schedule established under section
8 1848(b), other than the portion of such amount attrib-
9 utable to the practice expense component.”.

10 (c) CONFORMING AMENDMENT.—Section
11 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is
12 amended by inserting before the comma at the end the
13 following: “and services described in section 1812(a)(5)”.

14 (d) EFFECTIVE DATE.—The amendments made by
15 this section shall apply to services provided by a hospice
16 program on or after January 1, 2004.

17 **SEC. 513. CORRECTION OF TRUST FUND HOLDINGS.**

18 (a) IN GENERAL.—Within 120 days after the effec-
19 tive date of this section, the Secretary of the Treasury
20 shall take the actions described in subsection (b) with re-
21 spect to the Federal Hospital Insurance Trust Fund (in
22 this section referred to as the “Trust Fund”) with the goal
23 being that, after the actions are taken, the holdings of the
24 Trust Fund will replicate, to the extent practicable in the
25 judgment of the Secretary of the Treasury, in consultation

1 with the Secretary, the obligations that would have been
2 held by the trust fund if the clerical error had not oc-
3 curred.

4 (b) OBLIGATIONS ISSUED AND REDEEMED.—The
5 Secretary of the Treasury shall—

6 (1) issue to the Trust Fund obligations under
7 chapter 31 of title 31, United States Code, that bear
8 issue dates, interest rates, and maturity dates as the
9 obligations that—

10 (A) would have been issued to the Trust
11 Fund if the clerical error had not occurred; or

12 (B) were issued to the Trust Fund and
13 were redeemed by reason of the clerical error;
14 and

15 (2) redeem from the Trust Fund obligations
16 that would have been redeemed from the Trust
17 Fund if the clerical error had not occurred.

18 (c) APPROPRIATION TO TRUST FUND.—Within 120
19 days after the effective date of this section, there is hereby
20 appropriated to the Trust Fund, out of any money in the
21 Treasury not otherwise appropriated, an amount deter-
22 mined by the Secretary of the Treasury, in consultation
23 with the Secretary of Health and Human Services, to be
24 equal to the interest income lost by the trust fund through
25 the date of credit by reason of the clerical error.

1 (d) CLERICAL ERROR DEFINED.—For purposes of
2 this section, the term “clerical error” means the failure
3 to have transferred the correct amount from the general
4 fund to the Trust Fund, which failure occurred on April
5 15, 2001.

6 **TITLE VI—PROVISIONS**
7 **RELATING TO PART B**
8 **Subtitle A—Physicians’ Services**

9 **SEC. 601. REVISION OF UPDATES FOR PHYSICIANS’ SERV-**
10 **ICES.**

11 (a) UPDATE FOR 2004 AND 2005.—

12 (1) IN GENERAL.—Section 1848(d) (42 U.S.C.
13 1395w-4(d)) is amended by adding at the end the
14 following new paragraph:

15 “(5) UPDATE FOR 2004 AND 2005.—The update
16 to the single conversion factor established in para-
17 graph (1)(C) for each of 2004 and 2005 shall be not
18 less than 1.5 percent.”.

19 (2) CONFORMING AMENDMENT.—Paragraph
20 (4)(B) of such section is amended, in the matter be-
21 fore clause (i), by inserting “and paragraph (5)”
22 after “subparagraph (D)”.

23 (3) NOT TREATED AS CHANGE IN LAW AND
24 REGULATION IN SUSTAINABLE GROWTH RATE DE-
25 TERMINATION.—The amendments made by this sub-

1 section shall not be treated as a change in law for
2 purposes of applying section 1848(f)(2)(D) of the
3 Social Security Act (42 U.S.C. 1395w-4(f)(2)(D)).

4 (b) USE OF 10-YEAR ROLLING AVERAGE IN COM-
5 PUTING GROSS DOMESTIC PRODUCT.—

6 (1) IN GENERAL.—Section 1848(f)(2)(C) (42
7 U.S.C. 1395w-4(f)(2)(C)) is amended—

8 (A) by striking “projected” and inserting
9 “annual average”; and

10 (B) by striking “from the previous applica-
11 ble period to the applicable period involved”
12 and inserting “during the 10-year period ending
13 with the applicable period involved”.

14 (2) EFFECTIVE DATE.—The amendment made
15 by paragraph (1) shall apply to computations of the
16 sustainable growth rate for years beginning with
17 2003.

18 **SEC. 602. STUDIES ON ACCESS TO PHYSICIANS’ SERVICES.**

19 (a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSI-
20 CIANS’ SERVICES.—

21 (1) STUDY.—The Comptroller General of the
22 United States shall conduct a study on access of
23 medicare beneficiaries to physicians’ services under
24 the medicare program. The study shall include—

1 (A) an assessment of the use by bene-
2 ficiaries of such services through an analysis of
3 claims submitted by physicians for such services
4 under part B of the medicare program;

5 (B) an examination of changes in the use
6 by beneficiaries of physicians' services over
7 time;

8 (C) an examination of the extent to which
9 physicians are not accepting new medicare
10 beneficiaries as patients.

11 (2) REPORT.—Not later than 18 months after
12 the date of the enactment of this Act, the Comp-
13 troller General shall submit to Congress a report on
14 the study conducted under paragraph (1). The re-
15 port shall include a determination whether—

16 (A) data from claims submitted by physi-
17 cians under part B of the medicare program in-
18 dicate potential access problems for medicare
19 beneficiaries in certain geographic areas; and

20 (B) access by medicare beneficiaries to
21 physicians' services may have improved, re-
22 mained constant, or deteriorated over time.

23 (b) STUDY AND REPORT ON SUPPLY OF PHYSI-
24 CIANS.—

1 (1) STUDY.—The Secretary shall request the
2 Institute of Medicine of the National Academy of
3 Sciences to conduct a study on the adequacy of the
4 supply of physicians (including specialists) in the
5 United States and the factors that affect such sup-
6 ply.

7 (2) REPORT TO CONGRESS.—Not later than 2
8 years after the date of enactment of this section, the
9 Secretary shall submit to Congress a report on the
10 results of the study described in paragraph (1), in-
11 cluding any recommendations for legislation.

12 (c) GAO STUDY OF MEDICARE PAYMENT FOR INHA-
13 LATION THERAPY.—

14 (1) STUDY.—The Comptroller General of the
15 United States shall conduct a study to examine the
16 adequacy of current reimbursements for inhalation
17 therapy under the medicare program.

18 (2) REPORT.—Not later than May 1, 2004, the
19 Comptroller General shall submit to Congress a re-
20 port on the study conducted under paragraph (1).

21 **SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS’**
22 **SERVICES.**

23 (a) PRACTICE EXPENSE COMPONENT.—Not later
24 than 1 year after the date of the enactment of this Act,
25 the Medicare Payment Advisory Commission shall submit

1 to Congress a report on the effect of refinements to the
2 practice expense component of payments for physicians'
3 services, after the transition to a full resource-based pay-
4 ment system in 2002, under section 1848 of the Social
5 Security Act (42 U.S.C. 1395w-4). Such report shall ex-
6 amine the following matters by physician specialty:

7 (1) The effect of such refinements on payment
8 for physicians' services.

9 (2) The interaction of the practice expense com-
10 ponent with other components of and adjustments to
11 payment for physicians' services under such section.

12 (3) The appropriateness of the amount of com-
13 pensation by reason of such refinements.

14 (4) The effect of such refinements on access to
15 care by medicare beneficiaries to physicians' serv-
16 ices.

17 (5) The effect of such refinements on physician
18 participation under the medicare program.

19 (b) VOLUME OF PHYSICIAN SERVICES.—The Medi-
20 care Payment Advisory Commission shall submit to Con-
21 gress a report on the extent to which increases in the vol-
22 ume of physicians' services under part B of the medicare
23 program are a result of care that improves the health and
24 well-being of medicare beneficiaries. The study shall in-
25 clude the following:

1 (1) An analysis of recent and historic growth in
2 the components that the Secretary includes under
3 the sustainable growth rate (under section 1848(f)
4 of the Social Security Act).

5 (2) An examination of the relative growth of
6 volume in physician services between medicare bene-
7 ficiaries and other populations.

8 (3) An analysis of the degree to which new
9 technology, including coverage determinations of the
10 Centers for Medicare & Medicaid Services, has af-
11 fected the volume of physicians' services.

12 (4) An examination of the impact on volume of
13 demographic changes.

14 (5) An examination of shifts in the site of serv-
15 ice of services that influence the number and inten-
16 sity of services furnished in physicians' offices and
17 the extent to which changes in reimbursement rates
18 to other providers have affected these changes.

19 (6) An evaluation of the extent to which the
20 Centers for Medicare & Medicaid Services takes into
21 account the impact of law and regulations on the
22 sustainable growth rate.

1 **SEC. 604. INCLUSION OF PODIATRISTS AND DENTISTS**
2 **UNDER PRIVATE CONTRACTING AUTHORITY.**

3 Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is
4 amended by striking “section 1861(r)(1)” and inserting
5 “paragraphs (1), (2), and (3) of section 1861(r)”.

6 **SEC. 605. ESTABLISHMENT OF FLOOR ON WORK GEO-**
7 **GRAPHIC ADJUSTMENT.**

8 (a) **MINIMUM INDEX.**—Section 1848(e)(1) (42
9 U.S.C. 1395w-4(e)(1)) is amended by adding at the end
10 the following new subparagraph:

11 “(E) **FLOOR AT 1.0 ON WORK GEOGRAPHIC**
12 **INDEX.**—

13 “(i) **IN GENERAL.**—Subject to clause
14 (ii), after calculating the work geographic
15 index in subparagraph (A)(iii), for pur-
16 poses of payment for services furnished on
17 or after January 1, 2004, and before Jan-
18 uary 1, 2006, the Secretary shall increase
19 the work geographic index to 1.00 for any
20 locality for which such work geographic
21 index is less than 1.00.

22 “(ii) **SECRETARIAL DISCRETION.**—
23 Clause (i) shall have no force or effect in
24 law if the Secretary determines, taking
25 into account the report of the Comptroller
26 General under section 605(b)(2) of the

1 Medicare Prescription Drug and Mod-
2 ernization Act of 2003, that there is no
3 sound economic rationale for the imple-
4 mentation of that clause.”.

5 (b) GAO REPORT.—

6 (1) EVALUATION.—As part of the study on geo-
7 graphic differences in payments for physicians’ serv-
8 ices conducted under section 413, the Comptroller
9 General of the United States shall evaluate the fol-
10 lowing:

11 (A) Whether there is a sound economic
12 basis for the implementation of the adjustment
13 of the work geographic index under section
14 1848(e)(1) of the Social Security Act under
15 subsection (a) in those areas in which the ad-
16 justment applies.

17 (B) The effect of such adjustment on phy-
18 sician location and retention in areas affected
19 by such adjustment, taking into account—

20 (i) differences in recruitment costs
21 and retention rates for physicians, includ-
22 ing specialists, between large urban areas
23 and other areas; and

24 (ii) the mobility of physicians, includ-
25 ing specialists, over the last decade.

1 (C) The appropriateness of establishing a
2 floor of 1.0 for the work geographic index.

3 (2) REPORT.—By not later than September 1,
4 2004, the Comptroller General shall submit to Con-
5 gress and to the Secretary a report on the evaluation
6 conducted under paragraph (1).

7 **Subtitle B—Preventive Services**

8 **SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYS-** 9 **ICAL EXAMINATION.**

10 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
11 1395x(s)(2)) is amended—

12 (1) in subparagraph (U), by striking “and” at
13 the end;

14 (2) in subparagraph (V), by inserting “and” at
15 the end; and

16 (3) by adding at the end the following new sub-
17 paragraph:

18 “(W) an initial preventive physical examination
19 (as defined in subsection (ww));”.

20 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
21 1395x) is amended by adding at the end the following new
22 subsection:

23 “Initial Preventive Physical Examination

24 “(ww) The term ‘initial preventive physical examina-
25 tion’ means physicians’ services consisting of a physical

1 examination with the goal of health promotion and disease
2 detection and includes items and services (excluding clin-
3 ical laboratory tests), as determined by the Secretary, con-
4 sistent with the recommendations of the United States
5 Preventive Services Task Force.”.

6 (c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

7 (1) DEDUCTIBLE.—The first sentence of sec-
8 tion 1833(b) (42 U.S.C. 1395l(b)) is amended—

9 (A) by striking “and” before “(6)”, and

10 (B) by inserting before the period at the
11 end the following: “, and (7) such deductible
12 shall not apply with respect to an initial preven-
13 tive physical examination (as defined in section
14 1861(w))”.

15 (2) COINSURANCE.—Section 1833(a)(1) (42
16 U.S.C. 1395l(a)(1)) is amended—

17 (A) in clause (N), by inserting “(or 100
18 percent in the case of an initial preventive phys-
19 ical examination, as defined in section
20 1861(w))” after “80 percent”; and

21 (B) in clause (O), by inserting “(or 100
22 percent in the case of an initial preventive phys-
23 ical examination, as defined in section
24 1861(w))” after “80 percent”.

1 (d) PAYMENT AS PHYSICIANS' SERVICES.—Section
2 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by in-
3 serting “(2)(W),” after “(2)(S),”.

4 (e) OTHER CONFORMING AMENDMENTS.—Section
5 1862(a) (42 U.S.C. 1395y(a)) is amended—

6 (1) in paragraph (1)—

7 (A) by striking “and” at the end of sub-
8 paragraph (H);

9 (B) by striking the semicolon at the end of
10 subparagraph (I) and inserting “, and”; and

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

13 “(J) in the case of an initial preventive physical
14 examination, which is performed not later than 6
15 months after the date the individual's first coverage
16 period begins under part B;”; and

17 (2) in paragraph (7), by striking “or (H)” and
18 inserting “(H), or (J)”.

19 (f) EFFECTIVE DATE.—The amendments made by
20 this section shall apply to services furnished on or after
21 January 1, 2004, but only for individuals whose coverage
22 period begins on or after such date.

1 **SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD LIPID**
2 **SCREENING.**

3 (a) **COVERAGE.**—Section 1861(s)(2) (42 U.S.C.
4 1395x(s)(2)), as amended by section 611(a), is amended—

5 (1) in subparagraph (V), by striking “and” at
6 the end;

7 (2) in subparagraph (W), by inserting “and” at
8 the end; and

9 (3) by adding at the end the following new sub-
10 paragraph:

11 “(X) cholesterol and other blood lipid
12 screening tests (as defined in subsection
13 (XX));”.

14 (b) **SERVICES DESCRIBED.**—Section 1861 (42 U.S.C.
15 1395x), as amended by section 611(b), is amended by add-
16 ing at the end the following new subsection:

17 “Cholesterol and Other Blood Lipid Screening Test

18 “(xx)(1) The term ‘cholesterol and other blood lipid
19 screening test’ means diagnostic testing of cholesterol and
20 other lipid levels of the blood for the purpose of early de-
21 tection of abnormal cholesterol and other lipid levels.

22 “(2) The Secretary shall establish standards, in con-
23 sultation with appropriate organizations, regarding the
24 frequency and type of cholesterol and other blood lipid
25 screening tests, except that such frequency may not be
26 more often than once every 2 years.”.

1 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
2 1395y(a)(1)), as amended by section 611(e), is amend-
3 ed—

4 (1) by striking “and” at the end of subpara-
5 graph (I);

6 (2) by striking the semicolon at the end of sub-
7 paragraph (J) and inserting “; and”; and

8 (3) by adding at the end the following new sub-
9 paragraph:

10 “(K) in the case of a cholesterol and other
11 blood lipid screening test (as defined in section
12 1861(xx)(1)), which is performed more frequently
13 than is covered under section 1861(xx)(2).”.

14 (d) EFFECTIVE DATE.—The amendments made by
15 this section shall apply to tests furnished on or after Janu-
16 ary 1, 2005.

17 **SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL CAN-**
18 **CER SCREENING TESTS.**

19 (a) IN GENERAL.—The first sentence of section
20 1833(b) (42 U.S.C. 1395l(b)), as amended by section
21 611(e)(1), is amended—

22 (1) by striking “and” before “(7)”; and

23 (2) by inserting before the period at the end the
24 following: “, and (8) such deductible shall not apply

1 with respect to colorectal cancer screening tests (as
2 described in section 1861(pp)(1))”.

3 (b) CONFORMING AMENDMENTS.—Paragraphs
4 (2)(C)(ii) and (3)(C)(ii) of section 1834(d) (42 U.S.C.
5 1395m(d)) are each amended—

6 (1) by striking “DEDUCTIBLE AND” in the
7 heading; and

8 (2) in subclause (I), by striking “deductible or”
9 each place it appears.

10 (c) EFFECTIVE DATE.—The amendment made by
11 this section shall apply to items and services furnished on
12 or after January 1, 2004.

13 **SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
14 **RAPHY SERVICES.**

15 (a) EXCLUSION FROM OPD FEE SCHEDULE.—Sec-
16 tion 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is
17 amended by inserting before the period at the end the fol-
18 lowing: “and does not include screening mammography (as
19 defined in section 1861(jj)) and unilateral and bilateral
20 diagnostic mammography”.

21 (b) EFFECTIVE DATE.—The amendment made by
22 subsection (a) shall apply to mammography performed on
23 or after January 1, 2004.

1 **Subtitle C—Other Services**

2 **SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD)**

3 **PAYMENT REFORM.**

4 (a) PAYMENT FOR DRUGS.—

5 (1) MODIFICATION OF AMBULATORY PAYMENT
6 CLASSIFICATION (APC) GROUPS.—Section 1833(t)
7 (42 U.S.C. 1395l(t)) is amended—

8 (A) by redesignating paragraph (13) as
9 paragraph (14); and

10 (B) by inserting after paragraph (12) the
11 following new paragraph:

12 “(13) DRUG APC PAYMENT RATES.—

13 “(A) IN GENERAL.—With respect to pay-
14 ment for covered OPD services that includes a
15 specified covered outpatient drug (defined in
16 subparagraph (B)), the amount provided for
17 payment for such drug under the payment sys-
18 tem under this subsection for services furnished
19 in—

20 “(i) 2004, 2005, or 2006, shall in no
21 case—

22 “(I) exceed 95 percent of the av-
23 erage wholesale price for the drug; or

24 “(II) be less than the transition
25 percentage (under subparagraph (C))

1 of the average wholesale price for the
2 drug; or

3 “(ii) a subsequent year, shall be equal
4 to the average price for the drug for that
5 area and year established under the com-
6 petitive acquisition program under section
7 1847A as calculated and applied by the
8 Secretary for purposes of this paragraph.

9 “(B) SPECIFIED COVERED OUTPATIENT
10 DRUG DEFINED.—

11 “(i) IN GENERAL.—In this paragraph,
12 the term ‘specified covered outpatient
13 drug’ means, subject to clause (ii), a cov-
14 ered outpatient drug (as defined in
15 1927(k)(2), that is—

16 “(I) a radiopharmaceutical; or

17 “(II) a drug or biological for
18 which payment was made under para-
19 graph (6) (relating to pass-through
20 payments) on or before December 31,
21 2002.

22 “(ii) EXCEPTION.—Such term does
23 not include—

1 “(I) a drug for which payment is
 2 first made on or after January 1,
 3 2003, under paragraph (6); or

4 “(II) a drug for a which a tem-
 5 porary HCPCS code has not been as-
 6 signed.

7 “(C) TRANSITION TOWARDS HISTORICAL
 8 AVERAGE ACQUISITION COST.—The transition
 9 percentage under this subparagraph for drugs
 10 furnished in a year is determined in accordance
 11 with the following table:

The transition percentage for—				
For the year—	Single source drugs are—	Innovator mul- tiple source drugs are—	Generic drugs are—	
2004	83%	81.5%	46%	
2005	77%	75%	46%	
2006	71%	68%	46%	

12 “(D) PAYMENT FOR NEW DRUGS UNTIL
 13 TEMPORARY HCPCS CODE ASSIGNED.—With
 14 respect to payment for covered OPD services
 15 that includes a covered outpatient drug (as de-
 16 fined in 1927(k)) for a which a temporary
 17 HCPCS code has not been assigned, the
 18 amount provided for payment for such drug
 19 under the payment system under this sub-
 20 section shall be equal to 95 percent of the aver-
 21 age wholesale price for the drug.

1 “(E) CLASSES OF DRUGS.—For purposes
2 of this paragraph, each of the following shall be
3 treated as a separate class of drugs:

4 “(i) SOLE SOURCE DRUGS.—A sole
5 source drug which for purposes of this
6 paragraph means a drug or biological that
7 is not a multiple source drug (as defined in
8 subclauses (I) and (II) of section
9 1927(k)(7)(A)(i)) and is not a drug ap-
10 proved under an abbreviated new drug ap-
11 plication under section 355(j) of the Fed-
12 eral Food, Drug, and Cosmetic Act.

13 “(ii) INNOVATOR MULTIPLE SOURCE
14 DRUGS.—Innovator multiple source drugs
15 (as defined in section 1927(k)(7)(A)(ii)).

16 “(iii) NONINNOVATOR MULTIPLE
17 SOURCE DRUGS.—Noninnovator multiple
18 source drugs (as defined in section
19 1927(k)(7)(A)(iii)).

20 “(F) INAPPLICABILITY OF EXPENDITURES
21 IN DETERMINING CONVERSION FACTORS.—Ad-
22 ditional expenditures resulting from this para-
23 graph and paragraph (14)(C) in a year shall
24 not be taken into account in establishing the
25 conversion factor for that year.”.

1 (2) REDUCTION IN THRESHOLD FOR SEPARATE
2 APCS FOR DRUGS.—Section 1833(t)(14), as redesignated by paragraph (1)(A), is amended by adding at
3 the end the following new subparagraph:
4

5 “(B) THRESHOLD FOR ESTABLISHMENT
6 OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs
7 to \$50 per administration.”.

11 (3) EXCLUSION OF SEPARATE DRUG APCS FROM
12 OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by adding at the end the following new subparagraph:
13
14

15 “(E) EXCLUSION OF SEPARATE DRUG
16 APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory procedure codes established separately for drugs.”.

20 (4) PAYMENT FOR PASS THROUGH DRUGS.—
21 Clause (i) of section 1833(t)(6)(D) (42 U.S.C.
22 1395l(t)(6)(D)) is amended by inserting after
23 “under section 1842(o)” the following: “(or if the
24 drug is covered under a competitive acquisition contract under section 1847A for an area, an amount
25

1 determined by the Secretary equal to the average
2 price for the drug for that area and year established
3 under such section as calculated and applied by the
4 Secretary for purposes of this paragraph)”.
5

6 (5) EFFECTIVE DATE.—The amendments made
7 by this subsection shall apply to services furnished
8 on or after January 1, 2004.

9 (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

10 (1) IN GENERAL.—Section 1833(t)(14), as so
11 redesignated and amended by subsection (a)(2), is
12 amended by adding at the end the following new
13 subparagraph:

14 “(C) PAYMENT FOR DEVICES OF
15 BRACHYTHERAPY AT CHARGES ADJUSTED TO
16 COST.—Notwithstanding the preceding provi-
17 sions of this subsection, for a device of
18 brachytherapy furnished on or after January 1,
19 2004, and before January 1, 2007, the payment
20 basis for the device under this subsection shall
21 be equal to the hospital’s charges for each de-
22 vice furnished, adjusted to cost.”.

23 (2) SPECIFICATION OF GROUPS FOR
24 BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42
U.S.C. 1395l(t)(2) is amended—

1 (A) in subparagraph (F), by striking
2 “and” at the end;

3 (B) in subparagraph (G), by striking the
4 period at the end and inserting “; and”; and

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

7 “(H) with respect to devices of
8 brachytherapy, the Secretary shall create addi-
9 tional groups of covered OPD services that clas-
10 sify such devices separately from the other serv-
11 ices (or group of services) paid for under this
12 subsection in a manner reflecting the number,
13 isotope, and radioactive intensity of such de-
14 vices furnished, including separate groups for
15 palladium-103 and iodine-125 devices.”.

16 (3) GAO REPORT.—The Comptroller General of
17 the United States shall conduct a study to determine
18 appropriate payment amounts under section
19 1833(t)(13)(B) of the Social Security Act, as added
20 by paragraph (1), for devices of brachytherapy. Not
21 later than January 1, 2005, the Comptroller General
22 shall submit to Congress and the Secretary a report
23 on the study conducted under this paragraph, and
24 shall include specific recommendations for appro-
25 priate payments for such devices.

1 (c) APPLICATION OF FUNCTIONAL EQUIVALENCE
2 TEST.—

3 (1) IN GENERAL.—Section 1833(t)(6) (42
4 U.S.C. 1395l(t)(6)) is amended by adding at the end
5 the following new subparagraph:

6 “(F) LIMITATION ON APPLICATION OF
7 FUNCTIONAL EQUIVALENCE STANDARD.—The
8 Secretary may not apply a ‘functional equiva-
9 lence’ payment standard (including such stand-
10 ard promulgated on November 1, 2002) or any
11 other similar standard in order to deem a par-
12 ticular product to be functionally equivalent (or
13 a similar standard) unless the Commissioner of
14 Food and Drugs establishes a functional
15 equivalence standard and certifies, under such
16 standards, that the two products are function-
17 ally equivalent. If the Commissioner makes such
18 a certification with respect to two or more prod-
19 ucts, the Secretary may, after complying with
20 applicable rulemaking requirements, implement
21 such standard with respect to such products
22 under this subsection.”.

23 (2) EFFECTIVE DATE.—The amendment made
24 by paragraph (1) shall apply to the application of a
25 functional equivalence standard to a drug or biologi-

1 cal on or after the date of the enactment of this Act,
2 unless such application was being made to such drug
3 or biological prior to June 13, 2003.

4 (d) HOSPITAL ACQUISITION COST STUDY.—

5 (1) IN GENERAL.—The Secretary shall conduct
6 a study on the costs incurred by hospitals in acquir-
7 ing covered outpatient drugs for which payment is
8 made under section 1833(t) of the Social Security
9 Act (42 U.S.C. 1395l(t)).

10 (2) DRUGS COVERED.—The study in paragraph
11 (1) shall not include those drugs for which the ac-
12 quisition costs is less than \$50 per administration.

13 (3) REPRESENTATIVE SAMPLE OF HOS-
14 PITALS.—In conducting the study under paragraph
15 (1), the Secretary shall collect data from a statis-
16 tically valid sample of hospitals with an urban/rural
17 stratification.

18 (4) REPORT.—Not later than January 1, 2006,
19 the Secretary shall submit to Congress a report on
20 the study conducted under paragraph (1), and shall
21 include recommendations with respect to the fol-
22 lowing:

23 (A) Whether the study should be repeated,
24 and if so, how frequently.

1 (B) Whether the study produced useful
2 data on hospital acquisition cost.

3 (C) Whether data produced in the study is
4 appropriate for use in making adjustments to
5 payments for drugs and biologicals under sec-
6 tion 1847A of the Social Security Act.

7 (D) Whether separate estimates can be
8 made of overhead costs, including handling and
9 administering costs for drugs.

10 **SEC. 622. PAYMENT FOR AMBULANCE SERVICES.**

11 (a) PHASE-IN PROVIDING FLOOR USING BLEND OF
12 FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Sec-
13 tion 1834(l) (42 U.S.C. 1395m(l)), as amended by section
14 410(a), is amended—

15 (1) in paragraph (2)(E), by inserting “con-
16 sistent with paragraph (11)” after “in an efficient
17 and fair manner”; and

18 (2) by adding at the end the following new
19 paragraph:

20 “(11) PHASE-IN PROVIDING FLOOR USING
21 BLEND OF FEE SCHEDULE AND REGIONAL FEE
22 SCHEDULES.—In carrying out the phase-in under
23 paragraph (2)(E) for each level of service furnished
24 in a year, the portion of the payment amount that
25 is based on the fee schedule shall be the greater of

1 the amount determined under such fee schedule
2 (without regard to this paragraph) or the following
3 blended rate of the fee schedule under paragraph (1)
4 and of a regional fee schedule for the region in-
5 volved:

6 “(A) For 2004, the blended rate shall be
7 based 20 percent on the fee schedule under
8 paragraph (1) and 80 percent on the regional
9 fee schedule.

10 “(B) For 2005, the blended rate shall be
11 based 40 percent on the fee schedule under
12 paragraph (1) and 60 percent on the regional
13 fee schedule.

14 “(C) For 2006, the blended rate shall be
15 based 60 percent on the fee schedule under
16 paragraph (1) and 40 percent on the regional
17 fee schedule.

18 “(D) For 2007, 2008, and 2009, the
19 blended rate shall be based 80 percent on the
20 fee schedule under paragraph (1) and 20 per-
21 cent on the regional fee schedule.

22 “(E) For 2010 and each succeeding year,
23 the blended rate shall be based 100 percent on
24 the fee schedule under paragraph (1).

1 For purposes of this paragraph, the Secretary shall
2 establish a regional fee schedule for each of the 9
3 Census divisions using the methodology (used in es-
4 tablishing the fee schedule under paragraph (1)) to
5 calculate a regional conversion factor and a regional
6 mileage payment rate and using the same payment
7 adjustments and the same relative value units as
8 used in the fee schedule under such paragraph.”.

9 (b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
10 TRIPS.—Section 1834(l), as amended by subsection (a),
11 is further amended by adding at the end the following new
12 paragraph:

13 “(12) ADJUSTMENT IN PAYMENT FOR CERTAIN
14 LONG TRIPS.—In the case of ground ambulance
15 services furnished on or after January 1, 2004, and
16 before January 1, 2009, regardless of where the
17 transportation originates, the fee schedule estab-
18 lished under this subsection shall provide that, with
19 respect to the payment rate for mileage for a trip
20 above 50 miles the per mile rate otherwise estab-
21 lished shall be increased by $\frac{1}{4}$ of the payment per
22 mile otherwise applicable to such miles.”.

23 (c) GAO REPORT ON COSTS AND ACCESS.—Not later
24 than December 31, 2005, the Comptroller General of the
25 United States shall submit to Congress an initial report

1 on how costs differ among the types of ambulance pro-
2 viders and on access, supply, and quality of ambulance
3 services in those regions and States that have a reduction
4 in payment under the medicare ambulance fee schedule
5 (under section 1834(l) of the Social Security Act, as
6 amended by this section). Not later than December 31,
7 2007, the Comptroller General shall submit to Congress
8 a final report on such access and supply.

9 (d) EFFECTIVE DATE.—The amendments made by
10 this section shall apply to ambulance services furnished
11 on or after January 1, 2004.

12 **SEC. 623. RENAL DIALYSIS SERVICES.**

13 (a) DEMONSTRATION OF ALTERNATIVE DELIVERY
14 MODELS.—

15 (1) USE OF ADVISORY BOARD.—In carrying out
16 the demonstration project relating to improving care
17 for people with end-stage renal disease through al-
18 ternative delivery models (as published in the Fed-
19 eral Register of June 4, 2003), the Secretary shall
20 establish an advisory board comprised of representa-
21 tives described in paragraph (2) to provide advice
22 and recommendations with respect to the establish-
23 ment and operation of such demonstration project.

1 (2) REPRESENTATIVES.—Representatives re-
2 ferred to in paragraph (1) include representatives of
3 the following:

4 (A) Patient organizations.

5 (B) Clinicians.

6 (C) The medicare payment advisory com-
7 mission, established under section 1805 of the
8 Social Security Act (42 U.S.C. 1395b–6).

9 (D) The National Kidney Foundation.

10 (E) The National Institute of Diabetes and
11 Digestive and Kidney Diseases of National In-
12 stitutes of Health.

13 (F) End-stage renal disease networks.

14 (G) Medicare contractors to monitor qual-
15 ity of care.

16 (I) providers of services and renal dialysis
17 facilities furnishing end-stage renal disease
18 services.

19 (J) Economists.

20 (K) Researchers.

21 (b) RESTORING COMPOSITE RATE EXCEPTIONS FOR
22 PEDIATRIC FACILITIES.—

23 (1) IN GENERAL.—Section 422(a)(2) of BIPA
24 is amended—

1 (A) in subparagraph (A), by striking “and
2 (C)” and inserting “, (C), and (D)”;

3 (B) in subparagraph (B), by striking “In
4 the case” and inserting “Subject to subpara-
5 graph (D), in the case”; and

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

8 “(D) INAPPLICABILITY TO PEDIATRIC FA-
9 CILITIES.—Subparagraphs (A) and (B) shall
10 not apply, as of October 1, 2002, to pediatric
11 facilities that do not have an exception rate de-
12 scribed in subparagraph (C) in effect on such
13 date. For purposes of this subparagraph, the
14 term ‘pediatric facility’ means a renal facility at
15 least 50 percent of whose patients are individ-
16 uals under 18 years of age.”.

17 (2) CONFORMING AMENDMENT.—The fourth
18 sentence of section 1881(b)(7) (42 U.S.C.
19 1395rr(b)(7)), as amended by subsection (b), is fur-
20 ther amended by striking “Until” and inserting
21 “Subject to section 422(a)(2) of the Medicare, Med-
22 icaid, and SCHIP Benefits Improvement and Pro-
23 tection Act of 2000, and until”.

24 (c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE
25 FOR SERVICES FURNISHED IN 2004.—Notwithstanding

1 any other provision of law, with respect to payment under
2 part B of title XVIII of the Social Security Act for renal
3 dialysis services furnished in 2004, the composite payment
4 rate otherwise established under section 1881(b)(7) of
5 such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by
6 1.6 percent.

7 **SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS;**
8 **PROVISIONS RELATING TO REPORTS.**

9 (a) 1-YEAR MORATORIUM ON THERAPY CAPS.—Sec-
10 tion 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by
11 striking “and 2002” and inserting “2002, and 2004”.

12 (b) PROMPT SUBMISSION OF OVERDUE REPORTS ON
13 PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY
14 SERVICES.—Not later than December 31, 2003, the Sec-
15 retary shall submit to Congress the reports required under
16 section 4541(d)(2) of the Balanced Budget Act of 1997
17 (relating to alternatives to a single annual dollar cap on
18 outpatient therapy) and under section 221(d) of the Medi-
19 care, Medicaid, and SCHIP Balanced Budget Refinement
20 Act of 1999 (relating to utilization patterns for outpatient
21 therapy).

22 (c) IDENTIFICATION OF CONDITIONS AND DISEASES
23 JUSTIFYING WAIVER OF THERAPY CAP.—

24 (1) STUDY.—The Secretary shall request the
25 Institute of Medicine of the National Academy of

1 Sciences to identify conditions or diseases that
2 should justify conducting an assessment of the need
3 to waive the therapy caps under section 1833(g)(4)
4 of the Social Security Act (42 U.S.C. 1395l(g)(4)).

5 (2) REPORTS TO CONGRESS.—

6 (A) PRELIMINARY REPORT.—Not later
7 than July 1, 2004, the Secretary shall submit
8 to Congress a preliminary report on the condi-
9 tions and diseases identified under paragraph
10 (1).

11 (B) FINAL REPORT.—Not later than Sep-
12 tember 1, 2004, the Secretary shall submit to
13 Congress a final report on such conditions and
14 diseases.

15 (C) RECOMMENDATIONS.—Not later than
16 October 1, 2004, the Secretary shall submit to
17 Congress a recommendation of criteria, with re-
18 spect to such conditions and disease, under
19 which a waiver of the therapy caps would apply.

20 (d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL
21 THERAPIST SERVICES.—

22 (1) STUDY.—The Comptroller General of the
23 United States shall conduct a study on access to
24 physical therapist services in States authorizing such
25 services without a physician referral and in States

1 that require such a physician referral. The study
2 shall—

3 (A) examine the use of and referral pat-
4 terns for physical therapist services for patients
5 age 50 and older in States that authorize such
6 services without a physician referral and in
7 States that require such a physician referral;

8 (B) examine the use of and referral pat-
9 terns for physical therapist services for patients
10 who are medicare beneficiaries;

11 (C) examine the potential effect of prohib-
12 iting a physician from referring patients to
13 physical therapy services owned by the physi-
14 cian and provided in the physician's office;

15 (D) examine the delivery of physical thera-
16 pists' services within the facilities of Depart-
17 ment of Defense; and

18 (E) analyze the potential impact on medi-
19 care beneficiaries and on expenditures under
20 the medicare program of eliminating the need
21 for a physician referral and physician certifi-
22 cation for physical therapist services under the
23 medicare program.

24 (2) REPORT.—The Comptroller General shall
25 submit to Congress a report on the study conducted

1 under paragraph (1) by not later than 1 year after
2 the date of the enactment of this Act.

3 **SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES FUR-**
4 **NISHED IN AMBULATORY SURGICAL CEN-**
5 **TERS.**

6 Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is
7 amended in the last sentence by inserting “and each of
8 fiscal years 2004 through 2008” after “In each of the fis-
9 cal years 1998 through 2002”.

10 **SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS**
11 **UNDER THE FEE SCHEDULE FOR ORTHOTICS**
12 **AND PROSTHETICS.**

13 (a) IN GENERAL.—Section 1833(o) (42 U.S.C.
14 1395l(o)) is amended—

15 (1) in paragraph (1), by striking “no more than
16 the limits established under paragraph (2)” and in-
17 serting “no more than the amount of payment appli-
18 cable under paragraph (2)”; and

19 (2) in paragraph (2), to read as follows:

20 “(2)(A) Except as provided by the Secretary under
21 subparagraphs (B) and (C), the amount of payment under
22 this paragraph for custom molded shoes, extra depth
23 shoes, and inserts shall be the amount determined for such
24 items by the Secretary under section 1834(h).

1 “(B) The Secretary or a carrier may establish pay-
2 ment amounts for shoes and inserts that are lower than
3 the amount established under section 1834(h) if the Sec-
4 retary finds that shoes and inserts of an appropriate qual-
5 ity are readily available at or below the amount established
6 under such section.

7 “(C) In accordance with procedures established by
8 the Secretary, an individual entitled to benefits with re-
9 spect to shoes described in section 1861(s)(12) may sub-
10 stitute modification of such shoes instead of obtaining one
11 (or more, as specified by the Secretary) pair of inserts
12 (other than the original pair of inserts with respect to such
13 shoes). In such case, the Secretary shall substitute, for
14 the payment amount established under section 1834(h),
15 a payment amount that the Secretary estimates will assure
16 that there is no net increase in expenditures under this
17 subsection as a result of this subparagraph.”.

18 (b) CONFORMING AMENDMENTS.—(1) Section
19 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by
20 inserting “(and includes shoes described in section
21 1861(s)(12))” after “in section 1861(s)(9)”.

22 (2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is
23 amended by striking subparagraph (C).

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to items furnished on or after Jan-
3 uary 1, 2004.

4 **SEC. 627. WAIVER OF PART B LATE ENROLLMENT PENALTY**
5 **FOR CERTAIN MILITARY RETIREES; SPECIAL**
6 **ENROLLMENT PERIOD.**

7 (a) WAIVER OF PENALTY.—

8 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.
9 1395r(b)) is amended by adding at the end the fol-
10 lowing new sentence: “No increase in the premium
11 shall be effected for a month in the case of an indi-
12 vidual who is 65 years of age or older, who enrolls
13 under this part during 2001, 2002, 2003, or 2004
14 and who demonstrates to the Secretary before De-
15 cember 31, 2004, that the individual is a covered
16 beneficiary (as defined in section 1072(5) of title 10,
17 United States Code). The Secretary of Health and
18 Human Services shall consult with the Secretary of
19 Defense in identifying individuals described in the
20 previous sentence.”.

21 (2) EFFECTIVE DATE.—The amendment made
22 by paragraph (1) shall apply to premiums for
23 months beginning with January 2004. The Secretary
24 of Health and Human Services shall establish a
25 method for providing rebates of premium penalties

1 paid for months on or after January 2004 for which
2 a penalty does not apply under such amendment but
3 for which a penalty was previously collected.

4 (b) MEDICARE PART B SPECIAL ENROLLMENT PE-
5 RIOD.—

6 (1) IN GENERAL.—In the case of any individual
7 who, as of the date of the enactment of this Act, is
8 65 years of age or older, is eligible to enroll but is
9 not enrolled under part B of title XVIII of the So-
10 cial Security Act, and is a covered beneficiary (as
11 defined in section 1072(5) of title 10, United States
12 Code), the Secretary of Health and Human Services
13 shall provide for a special enrollment period during
14 which the individual may enroll under such part.
15 Such period shall begin as soon as possible after the
16 date of the enactment of this Act and shall end on
17 December 31, 2004.

18 (2) COVERAGE PERIOD.—In the case of an indi-
19 vidual who enrolls during the special enrollment pe-
20 riod provided under paragraph (1), the coverage pe-
21 riod under part B of title XVIII of the Social Secu-
22 rity Act shall begin on the first day of the month
23 following the month in which the individual enrolls.

24 **SEC. 628. PART B DEDUCTIBLE.**

25 Section 1833(b) (42 U.S.C. 1395l(b)) is amended—

1 (1) by striking “1991 and” and inserting
2 “1991,”; and

3 (2) by striking “and subsequent years” and in-
4 serting “and each subsequent year through 2003,
5 and for a subsequent year after 2003 the amount of
6 such deductible for the previous year increased by
7 the annual percentage increase in the monthly actu-
8 arial rate under section 1839(a)(1) ending with such
9 subsequent year (rounded to the nearest \$1)”.

10 **SEC. 629. EXTENSION OF COVERAGE OF INTRAVENOUS IM-**
11 **MUNE GLOBULIN (IVIG) FOR THE TREAT-**
12 **MENT OF PRIMARY IMMUNE DEFICIENCY DIS-**
13 **EASES IN THE HOME.**

14 (a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x),
15 as amended by sections 611(a) and 612(a) is amended—

16 (1) in subsection (s)(2)—

17 (A) by striking “and” at the end of sub-
18 paragraph (W);

19 (B) by adding “and” at the end of sub-
20 paragraph (X); and

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

23 “(Y) intravenous immune globulin for the
24 treatment of primary immune deficiency dis-

1 (1) in subparagraph (W), by striking “and” at
2 the end;

3 (2) in subparagraph (X), by adding “and” at
4 the end; and

5 (3) by adding at the end the following new sub-
6 paragraph:

7 “(Y) diabetes screening tests and services (as
8 defined in subsection (yy));”.

9 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
10 1395x), as amended by sections 611 and 612, is further
11 amended by adding at the end the following new sub-
12 section:

13 “Diabetes Screening Tests and Services

14 “(yy)(1) The term ‘diabetes screening tests’ means
15 diagnostic testing furnished to an individual at risk for
16 diabetes (as defined in paragraph (2)) for the purpose of
17 early detection of diabetes, including—

18 “(A) a fasting plasma glucose test; and

19 “(B) such other tests, and modifications to
20 tests, as the Secretary determines appropriate, in
21 consultation with appropriate organizations.

22 “(2) For purposes of paragraph (1), the term ‘indi-
23 vidual at risk for diabetes’ means an individual who has
24 any, a combination of, or all of the following risk factors
25 for diabetes:

1 “(A) A family history of diabetes.

2 “(B) Overweight defined as a body mass index
3 greater than or equal to 25 kg/m².

4 “(C) Habitual physical inactivity.

5 “(D) Belonging to a high-risk ethnic or racial
6 group.

7 “(E) Previous identification of an elevated im-
8 paired fasting glucose.

9 “(F) Identification of impaired glucose toler-
10 ance.

11 “(G) Hypertension.

12 “(H) Dyslipidemia.

13 “(I) History of gestational diabetes mellitus or
14 delivery of a baby weighing greater than 9 pounds.

15 “(J) Polycystic ovary syndrome.

16 “(3) The Secretary shall establish standards, in con-
17 sultation with appropriate organizations, regarding the
18 frequency of diabetes screening tests, except that such fre-
19 quency may not be more often than twice within the 12-
20 month period following the date of the most recent diabe-
21 tes screening test of that individual.”.

22 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
23 1395y(a)(1)), as amended by sections 611 and 612, is
24 amended—

1 (1) by striking “and” at the end of subpara-
2 graph (J);

3 (2) by striking the semicolon at the end of sub-
4 paragraph (K) and inserting “; and”; and

5 (3) by adding at the end the following new sub-
6 paragraph:

7 “(L) in the case of a diabetes screening tests or
8 service (as defined in section 1861(yy)(1)), which is
9 performed more frequently than is covered under
10 section 1861(yy)(3).”.

11 (d) **EFFECTIVE DATE.**—The amendments made by
12 this section shall apply to tests furnished on or after the
13 date that is 90 days after the date of enactment of this
14 Act.

15 **SEC. 631. DEMONSTRATION PROJECT FOR COVERAGE OF**
16 **CERTAIN PRESCRIPTION DRUGS AND BIO-**
17 **LOGICS.**

18 (a) **DEMONSTRATION PROJECT.**—The Secretary shall
19 conduct a demonstration project under part B of title
20 XVIII of the Social Security Act under which payment is
21 made for drugs or biologics that are prescribed as replace-
22 ments for drugs and biologics described in section
23 1861(s)(2)(A) or 1861(s)(2)(Q) of such Act (42 U.S.C.
24 1395x(s)(2)(A), 1395x(s)(2)(Q))), or both, for which pay-
25 ment is made under such part.

1 (b) DEMONSTRATION PROJECT SITES.—The project
2 established under this section shall be conducted in 3
3 States selected by the Secretary.

4 (c) DURATION.—The Secretary shall conduct the
5 demonstration project for the 2-year period beginning on
6 the date that is 90 days after the date of the enactment
7 of this Act, but in no case may the project extend beyond
8 December 31, 2005.

9 (d) LIMITATION.—Under the demonstration project
10 over the duration of the project, the Secretary may not
11 provide—

12 (1) coverage for more than 10,000 patients;

13 and

14 (2) more than \$100,000,000 in funding.

15 (e) REPORT.—Not later than January 1, 2006, the
16 Secretary shall submit to Congress a report on the project.
17 The report shall include an evaluation of patient access
18 to care and patient outcomes under the project, as well
19 as an analysis of the cost effectiveness of the project, in-
20 cluding an evaluation of the costs savings (if any) to the
21 medicare program attributable to reduced physicians'
22 services and hospital outpatient departments services for
23 administration of the biological.

1 **TITLE VII—PROVISIONS**
2 **RELATING TO PARTS A AND B**
3 **Subtitle A—Home Health Services**

4 **SEC. 701. UPDATE IN HOME HEALTH SERVICES.**

5 (a) CHANGE TO CALENDER YEAR UPDATE.—

6 (1) IN GENERAL.—Section 1895(b) (42 U.S.C.
7 1395fff(b)(3)) is amended—

8 (A) in paragraph (3)(B)(i)—

9 (i) by striking “each fiscal year (be-
10 ginning with fiscal year 2002)” and insert-
11 ing “fiscal year 2002 and for fiscal year
12 2003 and for each subsequent year (begin-
13 ning with 2004)”; and

14 (ii) by inserting “or year” after “the
15 fiscal year”;

16 (B) in paragraph (3)(B)(ii)(II), by striking
17 “any subsequent fiscal year” and inserting
18 “2004 and any subsequent year”;

19 (C) in paragraph (3)(B)(iii), by inserting
20 “or year” after “fiscal year” each place it ap-
21 pears;

22 (D) in paragraph (3)(B)(iv)—

23 (i) by inserting “or year” after “fiscal
24 year” each place it appears; and

1 (ii) by inserting “or years” after “fis-
2 cal years”; and

3 (E) in paragraph (5), by inserting “or
4 year” after “fiscal year”.

5 (2) TRANSITION RULE.—The standard prospec-
6 tive payment amount (or amounts) under section
7 1895(b)(3) of the Social Security Act for the cal-
8 endar quarter beginning on October 1, 2003, shall
9 be such amount (or amounts) for the previous cal-
10 endar quarter.

11 (b) CHANGES IN UPDATES FOR 2004, 2005, AND
12 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C.
13 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B),
14 is amended—

15 (1) by striking “or” at the end of subclause (I);

16 (2) by redesignating subclause (II) as subclause
17 (III);

18 (3) in subclause (III), as so redesignated, by
19 striking “2004” and inserting “2007”; and

20 (4) by inserting after subclause (I) the fol-
21 lowing new subclause:

22 “(II) each of 2004, 2005, and
23 2006 the home health market basket
24 percentage increase minus 0.4 per-
25 centage points; or”.

1 **SEC. 702. ESTABLISHMENT OF REDUCED COPAYMENT FOR**
2 **A HOME HEALTH SERVICE EPISODE OF CARE**
3 **FOR CERTAIN BENEFICIARIES.**

4 (a) PART A.—

5 (1) IN GENERAL.—Section 1813(a) (42 U.S.C.
6 1395e(a)) is amended by adding at the end the fol-
7 lowing new paragraph:

8 “(5)(A)(i) Subject to clause (ii), the amount payable
9 for home health services furnished to the individual under
10 this title for each episode of care beginning in a year (be-
11 ginning with 2004) shall be reduced by a copayment equal
12 to the copayment amount specified in subparagraph
13 (B)(ii) for such year.

14 “(ii) The copayment under clause (i) shall not
15 apply—

16 “(I) in the case of an individual who has been
17 determined to be entitled to medical assistance
18 under section 1902(a)(10)(A) or 1902(a)(10)(C) or
19 to be a qualified medicare beneficiary (as defined in
20 section 1905(p)(1)), a specified low-income medicare
21 beneficiary described in section 1902(a)(10)(E)(iii),
22 or a qualifying individual described in section
23 1902(a)(10)(E)(iv)(I); and

24 “(II) in the case of an episode of care which
25 consists of 4 or fewer visits.

1 “(B)(i) The Secretary shall estimate, before the be-
2 ginning of each year (beginning with 2004), the national
3 average payment under this title per episode for home
4 health services projected for the year involved.

5 “(ii) For each year the copayment amount under this
6 clause is equal to 1.5 percent of the national average pay-
7 ment estimated for the year involved under clause (i). Any
8 amount determined under the preceding sentence which
9 is not a multiple of \$5 shall be rounded to the nearest
10 multiple of \$5.

11 “(iii) There shall be no administrative or judicial re-
12 view under section 1869, 1878, or otherwise of the esti-
13 mation of average payment under clause (i).”.

14 (2) **TIMELY IMPLEMENTATION.**—Unless the
15 Secretary of Health and Human Services otherwise
16 provides on a timely basis, the copayment amount
17 specified under section 1813(a)(5)(B)(ii) of the So-
18 cial Security Act (as added by paragraph (1)) for
19 2004 shall be deemed to be \$40.

20 (b) **CONFORMING PROVISIONS.**—

21 (1) Section 1833(a)(2)(A) (42 U.S.C.
22 1395l(a)(2)(A)) is amended by inserting “less the
23 copayment amount applicable under section
24 1813(a)(5)” after “1895”.

1 (2) Section 1866(a)(2)(A)(i) (42 U.S.C.
2 1395cc(a)(2)(A)(i)) is amended—

3 (A) by striking “or coinsurance” and in-
4 serting “, coinsurance, or copayment”; and

5 (B) by striking “or (a)(4)” and inserting
6 “(a)(4), or (a)(5)”.

7 **SEC. 703. MEDPAC STUDY ON MEDICARE MARGINS OF**
8 **HOME HEALTH AGENCIES.**

9 (a) STUDY.—The Medicare Payment Advisory Com-
10 mission shall conduct a study of payment margins of home
11 health agencies under the home health prospective pay-
12 ment system under section 1895 of the Social Security Act
13 (42 U.S.C. 1395fff). Such study shall examine whether
14 systematic differences in payment margins are related to
15 differences in case mix (as measured by home health re-
16 source groups (HHRGs)) among such agencies. The study
17 shall use the partial or full-year cost reports filed by home
18 health agencies.

19 (b) REPORT.—Not later than 2 years after the date
20 of the enactment of this Act, the Commission shall submit
21 to Congress a report on the study under subsection (a).

22 **SEC. 704. DEMONSTRATION PROJECT TO CLARIFY THE**
23 **DEFINITION OF HOMEBOUND.**

24 (a) DEMONSTRATION PROJECT.—Not later than 180
25 days after the date of the enactment of this Act, the Sec-

1 retary shall conduct a two-year demonstration project
2 under part B of title XVIII of the Social Security Act
3 under which medicare beneficiaries with chronic conditions
4 described in subsection (b) are deemed to be homebound
5 for purposes of receiving home health services under the
6 medicare program.

7 (b) MEDICARE BENEFICIARY DESCRIBED.—For pur-
8 poses of subsection (a), a medicare beneficiary is eligible
9 to be deemed to be homebound, without regard to the pur-
10 pose, frequency, or duration of absences from the home,
11 if—

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

15 (2) the beneficiary requires the individual to re-
16 ceive assistance from another individual with at least
17 3 out of the 5 activities of daily living for the rest
18 of the individual's life;

19 (3) the beneficiary requires skilled nursing serv-
20 ices on a permanent basis and the skilled nursing is
21 more than medication management;

22 (4) either (A) an attendant is needed during
23 the day to monitor and treat the beneficiary's med-
24 ical condition, or (B) the beneficiary needs daily

1 skilled nursing on a permanent basis and the skilled
2 nursing is more than medication management; and

3 (5) the beneficiary requires technological assist-
4 ance or the assistance of another person to leave the
5 home.

6 (c) DEMONSTRATION PROJECT SITES.—The dem-
7 onstration project established under this section shall be
8 conducted in 3 States selected by the Secretary to rep-
9 resent the Northeast, Midwest, and Western regions of the
10 United States.

11 (d) LIMITATION ON NUMBER OF PARTICIPANTS.—
12 The aggregate number of such beneficiaries that may par-
13 ticipate in the project may not exceed 15,000.

14 (e) DATA.—The Secretary shall collect such data on
15 the demonstration project with respect to the provision of
16 home health services to medicare beneficiaries that relates
17 to quality of care, patient outcomes, and additional costs,
18 if any, to the medicare program.

19 (f) REPORT TO CONGRESS.—Not later than 1 year
20 after the date of the completion of the demonstration
21 project under this section, the Secretary shall submit to
22 Congress a report on the project using the data collected
23 under subsection (e) and shall include—

1 (1) an examination of whether the provision of
2 home health services to medicare beneficiaries under
3 the project—

4 (A) adversely effects the provision of home
5 health services under the medicare program; or

6 (B) directly causes an unreasonable in-
7 crease of expenditures under the medicare pro-
8 gram for the provision of such services that is
9 directly attributable to such clarification;

10 (2) the specific data evidencing the amount of
11 any increase in expenditures that is a directly attrib-
12 utable to the demonstration project (expressed both
13 in absolute dollar terms and as a percentage) above
14 expenditures that would otherwise have been in-
15 curred for home health services under the medicare
16 program; and

17 (3) specific recommendations to exempt perma-
18 nently and severely disabled homebound beneficiaries
19 from restrictions on the length, frequency and pur-
20 pose of their absences from the home to qualify for
21 home health services without incurring additional
22 unreasonable costs to the medicare program.

23 (g) WAIVER AUTHORITY.—The Secretary shall waive
24 compliance with the requirements of title XVIII of the So-
25 cial Security Act (42 U.S.C. 1395 et seq.) to such extent

1 and for such period as the Secretary determines is nec-
2 essary to conduct demonstration projects.

3 (h) CONSTRUCTION.—Nothing in this section shall be
4 construed as waiving any applicable civil monetary pen-
5 alty, criminal penalty, or other remedy available to the
6 Secretary under title XI or title XVIII of the Social Secu-
7 rity Act for acts prohibited under such titles, including
8 penalties for false certifications for purposes of receipt of
9 items or services under the medicare program.

10 (i) AUTHORIZATION OF APPROPRIATIONS.—Pay-
11 ments for the costs of carrying out the demonstration
12 project under this section shall be made from the Federal
13 Supplementary Insurance Trust Fund under section 1841
14 of such Act (42 U.S.C. 1395t).

15 (j) DEFINITIONS.—In this section:

16 (1) MEDICARE BENEFICIARY.—The term
17 “medicare beneficiary” means an individual who is
18 enrolled under part B of title XVIII of the Social
19 Security Act.

20 (2) HOME HEALTH SERVICES.—The term
21 “home health services” has the meaning given such
22 term in section 1861(m) of the Social Security Act
23 (42 U.S.C. 1395x(m)).

1 (3) ACTIVITIES OF DAILY LIVING DEFINED.—

2 The term “activities of daily living” means eating,
3 toileting, transferring, bathing, and dressing.

4 (4) SECRETARY.—The term “Secretary” means
5 the Secretary of Health and Human Services.

6 **Subtitle B—Direct Graduate**
7 **Medical Education**

8 **SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH**
9 **COST PROGRAMS.**

10 Section 1886(h)(2)(D)(iv) (42 U.S.C.

11 1395ww(h)(2)(D)(iv)) is amended—

12 (1) in subclause (I)—

13 (A) by inserting “AND 2004 THROUGH
14 2013” after “AND 2002”; and

15 (B) by inserting “or during the period be-
16 ginning with fiscal year 2004 and ending with
17 fiscal year 2013” after “during fiscal year 2001
18 or fiscal year 2002”; and

19 (2) in subclause (II)—

20 (A) by striking “fiscal year 2004, or fiscal
21 year 2005,” and

22 (B) by striking “For a” and inserting
23 “For the”.

1 **Subtitle C—Chronic Care**
2 **Improvement**

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

5 Title XVIII, as amended by section 105(a), is amend-
6 ed by inserting after section 1807 the following new sec-
7 tion:

8 “CHRONIC CARE IMPROVEMENT

9 “SEC. 1808. (a) IN GENERAL.—

10 “(1) IN GENERAL.—The Secretary shall estab-
11 lish a process for providing chronic care improve-
12 ment programs in each CCIA region for medicare
13 beneficiaries who are not enrolled under part C or
14 E and who have certain chronic conditions, such as
15 congestive heart failure, diabetes, chronic obstructive
16 pulmonary disease (COPD), stroke, prostate and
17 colon cancer, hypertension, or other disease as iden-
18 tified by the Secretary as appropriate for chronic
19 care improvement. Such a process shall begin to be
20 implemented no later than 1 year after the date of
21 the enactment of this section.

22 “(2) TERMINOLOGY.—For purposes of this sec-
23 tion:

24 “(A) CCIA REGION.—The term ‘CCIA re-
25 gion’ means a chronic care improvement admin-

1 istrative region delineated under subsection
2 (b)(2).

3 “(B) CHRONIC CARE IMPROVEMENT PRO-
4 GRAM.—The terms ‘chronic care improvement
5 program’ and ‘program’ means such a program
6 provided by a contractor under this section.

7 “(C) CONTRACTOR.—The term ‘contractor’
8 means an entity with a contract to provide a
9 chronic care improvement program in a CCLA
10 region under this section.

11 “(D) INDIVIDUAL PLAN.—The term ‘indi-
12 vidual plan’ means a chronic care improvement
13 plan established under subsection (c)(5) for an
14 individual.

15 “(3) CONSTRUCTION.—Nothing in this section
16 shall be construed as expanding the amount, dura-
17 tion, or scope of benefits under this title.

18 “(b) COMPETITIVE BIDDING PROCESS.—

19 “(1) IN GENERAL.—Under this section the Sec-
20 retary shall award contracts to qualified entities for
21 chronic care improvement programs for each CCLA
22 region under this section through a competitive bid-
23 ding process.

24 “(2) PROCESS.—Under such process—

1 “(A) the Secretary shall delineate the
2 United States into multiple chronic care im-
3 provement administrative regions; and

4 “(B) the Secretary shall select at least 2
5 winning bidders in each CCLA region on the
6 basis of the ability of each bidder to carry out
7 a chronic care improvement program in accord-
8 ance with this section, in order to achieve im-
9 proved health and financial outcomes.

10 “(3) ELIGIBLE CONTRACTOR.—A contractor
11 may be a disease improvement organization, health
12 insurer, provider organization, a group of physicians,
13 or any other legal entity that the Secretary deter-
14 mines appropriate.

15 “(c) CHRONIC CARE IMPROVEMENT PROGRAMS.—

16 “(1) IN GENERAL.—Each contract under this
17 section shall provide for the operation of a chronic
18 care improvement program by a contractor in a
19 CCLA region consistent with this subsection.

20 “(2) IDENTIFICATION OF PROSPECTIVE PRO-
21 GRAM PARTICIPANTS.—Each contractor shall have a
22 method for identifying medicare beneficiaries in the
23 region to whom it will offer services under its pro-
24 gram. The contractor shall identify such bene-
25 ficiaries through claims or other data and other

1 means permitted consistent with applicable disclo-
2 sure provisions.

3 “(3) INITIAL CONTACT BY SECRETARY.—The
4 Secretary shall communicate with each beneficiary
5 identified under paragraph (2) as a prospective par-
6 ticipant in one or more programs concerning partici-
7 pation in a program. Such communication may be
8 made by the Secretary (or on behalf of the Sec-
9 retary) and shall include information on the fol-
10 lowing:

11 “(A) A description of the advantages to
12 the beneficiary in participating in a program.

13 “(B) Notification that the contractor offer-
14 ing a program may contact the beneficiary di-
15 rectly concerning such participation.

16 “(C) Notification that participation in a
17 program is voluntary.

18 “(D) A description of the method for the
19 beneficiary to select the single program in
20 which the beneficiary wishes to participate and
21 for declining to participate and a method for
22 obtaining additional information concerning
23 such participation.

24 “(4) PARTICIPATION.—A medicare beneficiary
25 may participate in only one program under this sec-

1 tion and may terminate participation at any time in
2 a manner specified by the Secretary.

3 “(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT
4 PLANS.—

5 “(A) IN GENERAL.—For each beneficiary
6 participating in a program of a contractor
7 under this section, the contractor shall develop
8 with the beneficiary an individualized, goal-ori-
9 ented chronic care improvement plan.

10 “(B) ELEMENTS OF INDIVIDUAL PLAN.—
11 Each individual plan developed under subpara-
12 graph (A) shall include a single point of contact
13 to coordinate care and the following, as appro-
14 priate:

15 “(i) Self-improvement education for
16 the beneficiary (such as education for dis-
17 ease management through medical nutri-
18 tion therapy) and support education for
19 health care providers, primary caregivers,
20 and family members.

21 “(ii) Coordination of health care serv-
22 ices, such as application of a prescription
23 drug regimen and home health services.

1 “(iii) Collaboration with physicians
2 and other providers to enhance commu-
3 nication of relevant clinical information.

4 “(iv) The use of monitoring tech-
5 nologies that enable patient guidance
6 through the exchange of pertinent clinical
7 information, such as vital signs, sympto-
8 matic information, and health self-assess-
9 ment.

10 “(v) The provision of information
11 about hospice care, pain and palliative
12 care, and end-of-life care.

13 “(C) CONTRACTOR RESPONSIBILITIES.—In
14 establishing and carrying out individual plans
15 under a program, a contractor shall, directly or
16 through subcontractors—

17 “(i) guide participants in managing
18 their health, including all their co-
19 morbidities, and in performing activities as
20 specified under the elements of the plan;

21 “(ii) use decision support tools such
22 as evidence-based practice guidelines or
23 other criteria as determined by the Sec-
24 retary; and

1 “(iii) develop a clinical information
2 database to track and monitor each partic-
3 ipant across settings and to evaluate out-
4 comes.

5 “(6) ADDITIONAL REQUIREMENTS.—The Sec-
6 retary may establish additional requirements for pro-
7 grams and contractors under this section.

8 “(7) ACCREDITATION.—The Secretary may pro-
9 vide that programs that are accredited by qualified
10 organizations may be deemed to meet such require-
11 ments under this section as the Secretary may speci-
12 fy.

13 “(c) CONTRACT TERMS.—

14 “(1) IN GENERAL.—A contract under this sec-
15 tion shall contain such terms and conditions as the
16 Secretary may specify consistent with this section.
17 The Secretary may not enter into a contract with an
18 entity under this section unless the entity meets
19 such clinical, quality improvement, financial, and
20 other requirements as the Secretary deems to be ap-
21 propriate for the population to be served.

22 “(2) USE OF SUBCONTRACTORS PERMITTED.—
23 A contractor may carry out a program directly or
24 through contracts with subcontractors.

1 “(3) BUDGET NEUTRAL PAYMENT CONDI-
2 TION.—In entering into a contract with an entity
3 under this subsection, the Secretary shall establish
4 payment rates that assure that there will be no net
5 aggregate increase in payments under this title over
6 any period of 3 years or longer, as agreed to by the
7 Secretary. Under this section, the Secretary shall as-
8 sure that medicare program outlays plus administra-
9 tive expenses (that would not have been paid under
10 this title without implementation of this section), in-
11 cluding contractor fees, shall not exceed the expendi-
12 tures that would have been incurred under this title
13 for a comparable population in the absence of the
14 program under this section for the 3-year contract
15 period.

16 “(4) AT RISK RELATIONSHIP.—For purposes of
17 section 1128B(b)(3)(F), a contract under this sec-
18 tion shall be treated as a risk-sharing arrangement
19 referred to in such section.

20 “(5) PERFORMANCE STANDARDS.—Payment to
21 contractors under this section shall be subject to the
22 contractor’s meeting of clinical and financial per-
23 formance standards set by the Secretary.

24 “(6) CONTRACTOR OUTCOMES REPORT.—Each
25 contractor offering a program shall monitor and re-

1 port to the Secretary, in a manner specified by the
2 Secretary, the quality of care and efficacy of such
3 program in terms of—

4 “(A) process measures, such as reductions
5 in errors of treatment and rehospitalization
6 rates;

7 “(B) beneficiary and provider satisfaction;

8 “(C) health outcomes; and

9 “(D) financial outcomes.

10 “(7) PHASED IN IMPLEMENTATION.—Nothing
11 in this section shall be construed as preventing the
12 Secretary from phasing in the implementation of
13 programs.

14 “(d) BIENNIAL OUTCOMES REPORTS.—The Sec-
15 retary shall submit to the Congress biennial reports on
16 the implementation of this section. Each such report shall
17 include information on—

18 “(1) the scope of implementation (in terms of
19 both regions and chronic conditions);

20 “(2) program design; and

21 “(3) improvements in health outcomes and fi-
22 nancial efficiencies that result from such implemen-
23 tation.

24 “(e) CLINICAL TRIALS.—The Secretary shall conduct
25 randomized clinical trials, that compare program partici-

1 pants with medicare beneficiaries who are offered, but de-
2 cline, to participate, in order to assess the potential of pro-
3 grams to—

4 “(1) reduce costs under this title; and

5 “(2) improve health outcomes under this title.

6 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
7 are authorized to be appropriated to the Secretary, in ap-
8 propriate part from the Hospital Insurance Trust Fund
9 and the Supplementary Medical Insurance Trust Fund,
10 such sums as may be necessary to provide for contracts
11 with chronic care improvement programs under this sec-
12 tion.

13 “(g) LIMITATION ON FUNDING.—In no case shall the
14 funding under this section exceed \$100,000,000 over a pe-
15 riod of 3 years.”.

16 **SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDI-**
17 **CARE ADVANTAGE AND ENHANCED FEE-FOR-**
18 **SERVICE PROGRAMS.**

19 (a) UNDER MEDICARE ADVANTAGE PROGRAM.—Sec-
20 tion 1852 (42 U.S.C. 1395w–22) is amended—

21 (1) by amending subsection (e) to read as fol-
22 lows:

23 “(e) IMPLEMENTATION OF CHRONIC CARE IMPROVE-
24 MENT PROGRAMS FOR BENEFICIARIES WITH MULTIPLE
25 OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—

1 “(1) IN GENERAL.—Each Medicare Advantage
2 organization with respect to each Medicare Advan-
3 tage plan it offers shall have in effect, for enrollees
4 with multiple or sufficiently severe chronic condi-
5 tions, a chronic care improvement program that is
6 designed to manage the needs of such enrollees and
7 that meets the requirements of this subsection.

8 “(2) ENROLLEE WITH MULTIPLE OR SUFFI-
9 CIENTLY SEVERE CHRONIC CONDITIONS.—For pur-
10 poses of this subsection, the term ‘enrollee with mul-
11 tiple or sufficiently severe chronic conditions’ means,
12 with respect to an enrollee in a Medicare Advantage
13 plan of a Medicare Advantage organization, an en-
14 rollee in the plan who has one or more chronic con-
15 ditions, such as congestive heart failure, diabetes,
16 COPD, stroke, prostate and colon cancer, hyper-
17 tension, or other disease as identified by the organi-
18 zation as appropriate for chronic care improvement.

19 “(3) GENERAL REQUIREMENTS.—

20 “(A) IN GENERAL.—Each chronic care im-
21 provement program under this subsection shall
22 be conducted consistent with this subsection.

23 “(B) IDENTIFICATION OF ENROLLEES.—
24 Each such program shall have a method for
25 monitoring and identifying enrollees with mul-

1 tiple or sufficiently severe chronic conditions
2 that meet the organization’s criteria for partici-
3 pation under the program.

4 “(C) DEVELOPMENT OF PLANS.—For an
5 enrollee identified under subparagraph (B) for
6 participation in a program, the program shall
7 develop, with the enrollee’s consent, an individ-
8 ualized, goal-oriented chronic care improvement
9 plan for chronic care improvement.

10 “(D) ELEMENTS OF PLANS.—Each chronic
11 care improvement plan developed under sub-
12 paragraph (C) shall include a single point of
13 contact to coordinate care and the following, as
14 appropriate:

15 “(i) Self-improvement education for
16 the enrollee (such as education for disease
17 management through medical nutrition
18 therapy) and support education for health
19 care providers, primary caregivers, and
20 family members.

21 “(ii) Coordination of health care serv-
22 ices, such as application of a prescription
23 drug regimen and home health services.

1 “(iii) Collaboration with physicians
2 and other providers to enhance commu-
3 nication of relevant clinical information.

4 “(iv) The use of monitoring tech-
5 nologies that enable patient guidance
6 through the exchange of pertinent clinical
7 information, such as vital signs, sympto-
8 matic information, and health self-assess-
9 ment.

10 “(v) The provision of information
11 about hospice care, pain and palliative
12 care, and end-of-life care.

13 “(E) ORGANIZATION RESPONSIBILITIES.—
14 In establishing and carrying out chronic care
15 improvement plans for participants under this
16 paragraph, a Medicare Advantage organization
17 shall, directly or through subcontractors—

18 “(i) guide participants in managing
19 their health, including all their co-
20 morbidities, and in performing the activi-
21 ties as specified under the elements of the
22 plan;

23 “(ii) use decision support tools such
24 as evidence-based practice guidelines or

1 other criteria as determined by the Sec-
2 retary; and

3 “(iii) develop a clinical information
4 database to track and monitor each partic-
5 ipant across settings and to evaluate out-
6 comes.

7 “(3) ADDITIONAL REQUIREMENTS.—The Sec-
8 retary may establish additional requirements for
9 chronic care improvement programs under this sec-
10 tion.

11 “(4) ACCREDITATION.—The Secretary may pro-
12 vide that chronic care improvement programs that
13 are accredited by qualified organizations may be
14 deemed to meet such requirements under this sub-
15 section as the Secretary may specify.

16 “(5) OUTCOMES REPORT.—Each Medicare Ad-
17 vantage organization with respect to its chronic care
18 improvement program under this subsection shall
19 monitor and report to the Secretary information on
20 the quality of care and efficacy of such program as
21 the Secretary may require.”; and

22 (2) by amending subparagraph (I) of subsection
23 (c)(1) to read as follows:

24 “(I) CHRONIC CARE IMPROVEMENT PRO-
25 GRAM.—A description of the organization’s

1 chronic care improvement program under sub-
2 section (e).”.

3 (b) APPLICATION UNDER ENHANCED FEE-FOR-
4 SERVICE PROGRAM.—Section 1860E–2(c)(3), as inserted
5 by section 201(a), is amended by inserting “, including
6 subsection (e) (relating to implementation of chronic care
7 improvement programs)” after “The provisions of section
8 1852”.

9 (c) EFFECTIVE DATE.—The amendments made by
10 this section shall apply for contract years beginning on
11 or after 1 year after the date of the enactment of this
12 Act.

13 **SEC. 723. INSTITUTE OF MEDICINE REPORT.**

14 (a) STUDY.—

15 (1) IN GENERAL.—The Secretary of Health and
16 Human Services shall contract with the Institute of
17 Medicine of the National Academy of Sciences to
18 conduct a study of the barriers to effective inte-
19 grated care improvement for medicare beneficiaries
20 with multiple or severe chronic conditions across set-
21 tings and over time and to submit a report under
22 subsection (b).

23 (2) SPECIFIC ITEMS.—The study shall examine
24 the statutory and regulatory barriers to coordinating
25 care across settings for medicare beneficiaries in

1 transition from one setting to another (such as be-
2 tween hospital, nursing facility, home health, hos-
3 pice, and home). The study shall specifically identify
4 the following:

5 (A) Clinical, financial, or administrative re-
6 quirements in the medicare program that
7 present barriers to effective, seamless transi-
8 tions across care settings.

9 (B) Policies that impede the establishment
10 of administrative and clinical information sys-
11 tems to track health status, utilization, cost,
12 and quality data across settings.

13 (C) State-level requirements that may
14 present barriers to better care for medicare
15 beneficiaries.

16 (3) CONSULTATION.—The study under this
17 subsection shall be conducted in consultation with
18 experts in the field of chronic care, consumers, and
19 family caregivers, working to integrate care delivery
20 and create more seamless transitions across settings
21 and over time.

22 (b) REPORT.—The report under this subsection shall
23 be submitted to the Secretary and Congress not later than
24 18 months after the date of the enactment of this Act.

1 **SEC. 724. MEDPAC REPORT.**

2 (a) EVALUATION.—shall conduct an evaluation that
 3 includes a description of the status of the implementation
 4 of chronic care improvement programs under section 1808
 5 of the Social Security Act, the quality of health care serv-
 6 ices provided to individuals in such program, the health
 7 status of the participants of such program, and the cost
 8 savings attributed to implementation of such program.

9 (b) REPORT.—Not later than 2 years after the date
 10 of implementation of such chronic care improvement pro-
 11 grams, the Commission shall submit a report on such eval-
 12 uation.

13 **Subtitle D—Other Provisions**

14 **SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT ADVI-**
 15 **SORY COMMISSION (MEDPAC).**

16 (a) EXAMINATION OF BUDGET CONSEQUENCES.—
 17 Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by
 18 adding at the end the following new paragraph:

19 “(8) EXAMINATION OF BUDGET CON-
 20 SEQUENCES.—Before making any recommendations,
 21 the Commission shall examine the budget con-
 22 sequences of such recommendations, directly or
 23 through consultation with appropriate expert enti-
 24 ties.”.

25 (b) CONSIDERATION OF EFFICIENT PROVISION OF
 26 SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–

1 6(b)(2)(B)(i) is amended by inserting “the efficient provi-
2 sion of” after “expenditures for”.

3 (c) APPLICATION OF DISCLOSURE REQUIRE-
4 MENTS.—

5 (1) IN GENERAL.—Section 1805(c)(2)(D) (42
6 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at
7 the end the following: “Members of the Commission
8 shall be treated as employees of the Congress for
9 purposes of applying title I of the Ethics in Govern-
10 ment Act of 1978 (Public Law 95-521).”.

11 (2) EFFECTIVE DATE.—The amendment made
12 by paragraph (1) shall take effect on January 1,
13 2004.

14 (d) ADDITIONAL REPORTS.—

15 (1) DATA NEEDS AND SOURCES.—The Medicare
16 Payment Advisory Commission shall conduct a
17 study, and submit a report to Congress by not later
18 than June 1, 2004, on the need for current data,
19 and sources of current data available, to determine
20 the solvency and financial circumstances of hospitals
21 and other medicare providers of services. The Com-
22 mission shall examine data on uncompensated care,
23 as well as the share of uncompensated care ac-
24 counted for by the expenses for treating illegal
25 aliens.

1 (2) USE OF TAX-RELATED RETURNS.—Using
2 return information provided under Form 990 of the
3 Internal Revenue Service, the Commission shall sub-
4 mit to Congress, by not later than June 1, 2004, a
5 report on the following:

6 (A) Investments, endowments, and fund-
7 raising of hospitals participating under the
8 medicare program and related foundations.

9 (B) Access to capital financing for private
10 and for not-for-profit hospitals.

11 **SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL ADULT**
12 **DAY CARE SERVICES.**

13 (a) ESTABLISHMENT.—Subject to the succeeding
14 provisions of this section, the Secretary of Health and
15 Human Services shall establish a demonstration project
16 (in this section referred to as the “demonstration project”)
17 under which the Secretary shall, as part of a plan of an
18 episode of care for home health services established for
19 a medicare beneficiary, permit a home health agency, di-
20 rectly or under arrangements with a medical adult day
21 care facility, to provide medical adult day care services as
22 a substitute for a portion of home health services that
23 would otherwise be provided in the beneficiary’s home.

24 (b) PAYMENT.—

1 (1) IN GENERAL.—The amount of payment for
2 an episode of care for home health services, a por-
3 tion of which consists of substitute medical adult
4 day care services, under the demonstration project
5 shall be made at a rate equal to 95 percent of the
6 amount that would otherwise apply for such home
7 health services under section 1895 of the Social Se-
8 curity Act (42 u.s.c. 1395fff). In no case may a
9 home health agency, or a medical adult day care fa-
10 cility under arrangements with a home health agen-
11 cy, separately charge a beneficiary for medical adult
12 day care services furnished under the plan of care.

13 (2) BUDGET NEUTRALITY FOR DEMONSTRA-
14 TION PROJECT.—Notwithstanding any other provi-
15 sion of law, the Secretary shall provide for an appro-
16 priate reduction in the aggregate amount of addi-
17 tional payments made under section 1895 of the So-
18 cial Security Act (42 U.S.C. 1395fff) to reflect any
19 increase in amounts expended from the Trust Funds
20 as a result of the demonstration project conducted
21 under this section.

22 (c) DEMONSTRATION PROJECT SITES.—The project
23 established under this section shall be conducted in not
24 more than 5 States selected by the Secretary that license

1 or certify providers of services that furnish medical adult
2 day care services.

3 (d) DURATION.—The Secretary shall conduct the
4 demonstration project for a period of 3 years.

5 (e) VOLUNTARY PARTICIPATION.—Participation of
6 medicare beneficiaries in the demonstration project shall
7 be voluntary. The total number of such beneficiaries that
8 may participate in the project at any given time may not
9 exceed 15,000.

10 (f) PREFERENCE IN SELECTING AGENCIES.—In se-
11 lecting home health agencies to participate under the dem-
12 onstration project, the Secretary shall give preference to
13 those agencies that are currently licensed or certified
14 through common ownership and control to furnish medical
15 adult day care services.

16 (g) WAIVER AUTHORITY.—The Secretary may waive
17 such requirements of title XVIII of the Social Security Act
18 as may be necessary for the purposes of carrying out the
19 demonstration project, other than waiving the requirement
20 that an individual be homebound in order to be eligible
21 for benefits for home health services.

22 (h) EVALUATION AND REPORT.—The Secretary shall
23 conduct an evaluation of the clinical and cost effectiveness
24 of the demonstration project. Not later 30 months after
25 the commencement of the project, the Secretary shall sub-

1 mit to Congress a report on the evaluation, and shall in-
2 clude in the report the following:

3 (1) An analysis of the patient outcomes and
4 costs of furnishing care to the medicare beneficiaries
5 participating in the project as compared to such out-
6 comes and costs to beneficiaries receiving only home
7 health services for the same health conditions.

8 (2) Such recommendations regarding the exten-
9 sion, expansion, or termination of the project as the
10 Secretary determines appropriate.

11 (i) DEFINITIONS.—In this section:

12 (1) HOME HEALTH AGENCY.—The term “home
13 health agency” has the meaning given such term in
14 section 1861(o) of the Social Security Act (42
15 U.S.C. 1395x(o)).

16 (2) MEDICAL ADULT DAY CARE FACILITY.—The
17 term “medical adult day care facility” means a facil-
18 ity that—

19 (A) has been licensed or certified by a
20 State to furnish medical adult day care services
21 in the State for a continuous 2-year period;

22 (B) is engaged in providing skilled nursing
23 services and other therapeutic services directly
24 or under arrangement with a home health agen-
25 cy;

1 (C) meets such standards established by
2 the Secretary to assure quality of care and such
3 other requirements as the Secretary finds nec-
4 essary in the interest of the health and safety
5 of individuals who are furnished services in the
6 facility; and

7 (D) provides medical adult day care serv-
8 ices.

9 (3) MEDICAL ADULT DAY CARE SERVICES.—

10 The term “medical adult day care services” means—

11 (A) home health service items and services
12 described in paragraphs (1) through (7) of sec-
13 tion 1861(m) furnished in a medical adult day
14 care facility;

15 (B) a program of supervised activities fur-
16 nished in a group setting in the facility that—

17 (i) meet such criteria as the Secretary
18 determines appropriate; and

19 (ii) is designed to promote physical
20 and mental health of the individuals; and

21 (C) such other services as the Secretary
22 may specify.

23 (4) MEDICARE BENEFICIARY.—The term
24 “medicare beneficiary” means an individual entitled

1 to benefits under part A of this title, enrolled under
2 part B of this title, or both.

3 **SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL COV-**
4 **ERAGE DETERMINATION PROCESS TO RE-**
5 **SPOND TO CHANGES IN TECHNOLOGY.**

6 (a) NATIONAL AND LOCAL COVERAGE DETERMINA-
7 TION PROCESS.—

8 (1) IN GENERAL.—Section 1862 (42 U.S.C.
9 1395y) is amended—

10 (A) in the third sentence of subsection (a)
11 by inserting “consistent with subsection (k)”
12 after “the Secretary shall ensure”; and

13 (B) by adding at the end the following new
14 subsection:

15 “(k) NATIONAL AND LOCAL COVERAGE DETERMINA-
16 TION PROCESS.—

17 “(1) FACTORS AND EVIDENCE USED IN MAKING
18 NATIONAL COVERAGE DETERMINATIONS.—The Sec-
19 retary shall make available to the public the factors
20 considered in making national coverage determina-
21 tions of whether an item or service is reasonable and
22 necessary. The Secretary shall develop guidance doc-
23 uments to carry out this paragraph in a manner
24 similar to the development of guidance documents

1 under section 701(h) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 371(h)).

3 “(2) TIMEFRAME FOR DECISIONS ON REQUESTS
4 FOR NATIONAL COVERAGE DETERMINATIONS.—In
5 the case of a request for a national coverage deter-
6 mination that—

7 “(A) does not require a technology assess-
8 ment from an outside entity or deliberation
9 from the Medicare Coverage Advisory Com-
10 mittee, the decision on the request shall be
11 made not later than 6 months after the date of
12 the request; or

13 “(B) requires such an assessment or delib-
14 eration and in which a clinical trial is not re-
15 quested, the decision on the request shall be
16 made not later than 9 months after the date of
17 the request.

18 “(3) PROCESS FOR PUBLIC COMMENT IN NA-
19 TIONAL COVERAGE DETERMINATIONS.—At the end
20 of the 6-month period (or 9-month period for re-
21 quests described in paragraph (2)(B)) that begins on
22 the date a request for a national coverage deter-
23 mination is made, the Secretary shall—

24 “(A) make a draft of proposed decision on
25 the request available to the public through the

1 Medicare Internet site of the Department of
2 Health and Human Services or other appro-
3 priate means;

4 “(B) provide a 30-day period for public
5 comment on such draft;

6 “(C) make a final decision on the request
7 within 60 days of the conclusion of the 30-day
8 period referred to under subparagraph (B);

9 “(D) include in such final decision sum-
10 maries of the public comments received and re-
11 sponses thereto;

12 “(E) make available to the public the clin-
13 ical evidence and other data used in making
14 such a decision when the decision differs from
15 the recommendations of the Medicare Coverage
16 Advisory Committee; and

17 “(F) in the case of a decision to grant the
18 coverage determination, assign a temporary or
19 permanent code and implement the coding
20 change.

21 “(4) CONSULTATION WITH OUTSIDE EXPERTS
22 IN CERTAIN NATIONAL COVERAGE DETERMINA-
23 TIONS.—With respect to a request for a national
24 coverage determination for which there is not a re-
25 view by the Medicare Coverage Advisory Committee,

1 the Secretary shall consult with appropriate outside
2 clinical experts.

3 “(5) LOCAL COVERAGE DETERMINATION PROC-
4 ESS.—With respect to local coverage determinations
5 made on or after January 1, 2004—

6 “(A) PLAN TO PROMOTE CONSISTENCY OF
7 COVERAGE DETERMINATIONS.—The Secretary
8 shall develop a plan to evaluate new local cov-
9 erage determinations to determine which deter-
10 minations should be adopted nationally and to
11 what extent greater consistency can be achieved
12 among local coverage determinations.

13 “(B) CONSULTATION.—The Secretary
14 shall require the fiscal intermediaries or car-
15 riers providing services within the same area to
16 consult on all new local coverage determinations
17 within the area.

18 “(C) DISSEMINATION OF INFORMATION.—
19 The Secretary should serve as a center to dis-
20 seminate information on local coverage deter-
21 minations among fiscal intermediaries and car-
22 riers to reduce duplication of effort.

23 “(6) NATIONAL AND LOCAL COVERAGE DETER-
24 MINATION DEFINED.—For purposes of this sub-
25 section, the terms ‘national coverage determination’

1 and ‘local coverage determination’ have the meaning
2 given such terms in paragraphs (1)(B) and (2)(B),
3 respectively, of section 1869(f).”.

4 (2) EFFECTIVE DATE.—The amendments made
5 by paragraph (1) shall apply to national and local
6 coverage determinations as of January 1, 2004.

7 (b) MEDICARE COVERAGE OF ROUTINE COSTS ASSO-
8 CIATED WITH CERTAIN CLINICAL TRIALS.—

9 (1) IN GENERAL.—With respect to the coverage
10 of routine costs of care for beneficiaries participating
11 in a qualifying clinical trial, as set forth on the date
12 of the enactment of this Act in National Coverage
13 Determination 30-1 of the Medicare Coverage Issues
14 Manual, the Secretary shall deem clinical trials con-
15 ducted in accordance with an investigational device
16 exemption approved under section 520(g) of the
17 Federal Food, Drug, and Cosmetic Act (42 U.S.C.
18 360j(g)) to be automatically qualified for such cov-
19 erage.

20 (2) RULE OF CONSTRUCTION.—Nothing in this
21 subsection shall be construed as authorizing or re-
22 quiring the Secretary to modify the regulations set
23 forth on the date of the enactment of this Act at
24 subpart B of part 405 of title 42, Code of Federal
25 Regulations, or subpart A of part 411 of such title,

1 relating to coverage of, and payment for, a medical
2 device that is the subject of an investigational device
3 exemption by the Food and Drug Administration
4 (except as may be necessary to implement paragraph
5 (1)).

6 (3) EFFECTIVE DATE.—This subsection shall
7 apply to clinical trials begun before, on, or after the
8 date of the enactment of this Act and to items and
9 services furnished on or after such date.

10 (c) ISSUANCE OF TEMPORARY NATIONAL CODES.—
11 Not later than January 1, 2004, the Secretary shall imple-
12 ment revised procedures for the issuance of temporary na-
13 tional HCPCS codes under part B of title XVIII of the
14 Social Security Act.

15 **SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY**
16 **SERVICES.**

17 (a) IN GENERAL.—Section 1848(i) (42 U.S.C.
18 1395w-4(i)) is amended by adding at the end the fol-
19 lowing new paragraph:

20 “(4) TREATMENT OF CERTAIN INPATIENT PHY-
21 SICIAN PATHOLOGY SERVICES.—

22 “(A) IN GENERAL.—With respect to serv-
23 ices furnished on or after January 1, 2004, and
24 before January 1, 2009, if an independent lab-
25 oratory furnishes the technical component of a

1 physician pathology service to a fee-for-service
2 medicare beneficiary who is an inpatient or out-
3 patient of a covered hospital, the Secretary
4 shall treat such component as a service for
5 which payment shall be made to the laboratory
6 under this section and not as an inpatient hos-
7 pital service for which payment is made to the
8 hospital under section 1886(d) or as a hospital
9 outpatient service for which payment is made to
10 the hospital under section 1833(t).

11 “(B) DEFINITIONS.—In this paragraph:

12 “(i) COVERED HOSPITAL.—

13 “(I) IN GENERAL.—The term
14 ‘covered hospital’ means, with respect
15 to an inpatient or outpatient, a hos-
16 pital that had an arrangement with
17 an independent laboratory that was in
18 effect as of July 22, 1999, under
19 which a laboratory furnished the tech-
20 nical component of physician pathol-
21 ogy services to fee-for-service medi-
22 care beneficiaries who were hospital
23 inpatients or outpatients, respectively,
24 and submitted claims for payment for
25 such component to a carrier with a

1 contract under section 1842 and not
2 to the hospital.

3 “(II) CHANGE IN OWNERSHIP
4 DOES NOT AFFECT DETERMINA-
5 TION.—A change in ownership with
6 respect to a hospital on or after the
7 date referred to in subclause (I) shall
8 not affect the determination of wheth-
9 er such hospital is a covered hospital
10 for purposes of such subclause.

11 “(ii) FEE-FOR-SERVICE MEDICARE
12 BENEFICIARY.—The term ‘fee-for-service
13 medicare beneficiary’ means an individual
14 who is entitled to benefits under part A, or
15 enrolled under this part, or both, but is not
16 enrolled in any of the following:

17 “(I) A Medicare+Choice plan
18 under part C.

19 “(II) A plan offered by an eligi-
20 ble organization under section 1876.

21 “(III) A program of all-inclusive
22 care for the elderly (PACE) under
23 section 1894.

24 “(IV) A social health mainte-
25 nance organization (SHMO) dem-

1 onstration project established under
2 section 4018(b) of the Omnibus
3 Budget Reconciliation Act of 1987
4 (Public Law 100–203).”.

5 (b) CONFORMING AMENDMENT.—Section 542 of the
6 Medicare, Medicaid, and SCHIP Benefits Improvement
7 and Protection Act of 2000 (114 Stat. 2763A–550), as
8 enacted into law by section 1(a)(6) of Public Law 106–
9 554, is repealed.

10 (c) EFFECTIVE DATES.—The amendments made by
11 this section shall take effect as if included in the enact-
12 ment of the Medicare, Medicaid, and SCHIP Benefits Im-
13 provement and Protection Act of 2000 (Appendix F, 114
14 Stat. 2763A–463), as enacted into law by section 1(a)(6)
15 of Public Law 106–554.

16 **SEC. 735. CLINICAL INVESTIGATION OF MEDICARE PAN-**
17 **CREATIC ISLET CELL TRANSPLANTS.**

18 The Secretary shall authorize payment under title
19 XVIII of the Social Security Act for the routine costs for
20 items and services for medicare beneficiaries received as
21 part of a clinical investigation of pancreatic islet cell trans-
22 plants conducted by the National Institutes of Health.

23 **SEC. 736. DEMONSTRATION PROJECT FOR CONSUMER-DI-**
24 **RECTED CHRONIC OUTPATIENT SERVICES.**

25 (a) ESTABLISHMENT.—

1 (1) IN GENERAL.—Subject to the succeeding
2 provisions of this section, the Secretary shall estab-
3 lish demonstration projects (in this section referred
4 to as “demonstration projects”) under which the
5 Secretary shall evaluate methods that improve the
6 quality of care provided to medicare beneficiaries
7 with chronic conditions and that reduce expenditures
8 that would otherwise be made under the medicare
9 program on behalf of such individuals for such
10 chronic conditions, such methods to include permit-
11 ting those beneficiaries to direct their own health
12 care needs and services.

13 (2) MEDICARE BENEFICIARIES WITH CHRONIC
14 CONDITIONS DEFINED.—In this section, the term
15 “medicare beneficiaries with chronic conditions”
16 means an individual entitled to benefits under part
17 A of title XVIII of the Social Security Act, and en-
18 rolled under part B of such title, but who is not en-
19 rolled under part C of such title who is diagnosed
20 as having one or more chronic conditions (as defined
21 by the Secretary), such as diabetes.

22 (b) DESIGN OF PROJECTS.—

23 (1) IN GENERAL.—In establishing the dem-
24 onstration projects under this section, the Secretary
25 shall evaluate practices employed by group health

1 plans and practices under State plans for medical
2 assistance under the medicaid program under title
3 XIX of the Social Security Act that permit patients
4 to self-direct the provision of personal care services.

5 (2) SCOPE OF SERVICES.—The Secretary shall
6 determine the appropriate scope of personal care
7 services that would apply under the demonstration
8 projects.

9 (c) VOLUNTARY PARTICIPATION.—Participation of
10 medicare beneficiaries in the demonstration projects shall
11 be voluntary.

12 (d) DEMONSTRATION PROJECTS SITES.—Not later
13 than 2 years after the date of the enactment of this Act,
14 the Secretary shall conduct no fewer than 3 demonstration
15 projects established under this section. Of those dem-
16 onstration projects, the Secretary shall conduct at least
17 one in each of the following areas:

18 (1) An urban area.

19 (2) A rural area.

20 (3) An area that the Secretary determines has
21 a medicare population with rate of incidence of dia-
22 betes that significantly exceeds the national average
23 rate of all areas.

24 (e) EVALUATION AND REPORT.—

1 (1) EVALUATIONS.—The Secretary shall con-
2 duct evaluations of the clinical and cost effectiveness
3 of the demonstration projects.

4 (2) REPORTS.—Not later than 2 years after the
5 commencement of the demonstration projects, and
6 biannually thereafter, the Secretary shall submit to
7 Congress a report on the evaluation, and shall in-
8 clude in the report the following:

9 (A) An analysis of the patient outcomes
10 and costs of furnishing care to the medicare
11 beneficiaries participating in the projects as
12 compared to such outcomes and costs to other
13 beneficiaries for the same health conditions.

14 (B) Evaluation of patient satisfaction
15 under the demonstration projects.

16 (C) Such recommendations regarding the
17 extension, expansion, or termination of the
18 projects as the Secretary determines appro-
19 priate.

1 **TITLE VIII—MEDICARE**
2 **BENEFITS ADMINISTRATION**

3 **SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS AD-**
4 **MINISTRATION.**

5 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et
6 seq.), as amended by sections 105 and 721, is amended
7 by inserting after 1808 the following new section:

8 “MEDICARE BENEFITS ADMINISTRATION

9 “SEC. 1809. (a) ESTABLISHMENT.—There is estab-
10 lished within the Department of Health and Human Serv-
11 ices an agency to be known as the Medicare Benefits Ad-
12 ministration.

13 “(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR;
14 CHIEF ACTUARY.—

15 “(1) ADMINISTRATOR.—

16 “(A) IN GENERAL.—The Medicare Bene-
17 fits Administration shall be headed by an ad-
18 ministrator to be known as the ‘Medicare Bene-
19 fits Administrator’ (in this section referred to
20 as the ‘Administrator’) who shall be appointed
21 by the President, by and with the advice and
22 consent of the Senate. The Administrator shall
23 be in direct line of authority to the Secretary.

24 “(B) COMPENSATION.—The Administrator
25 shall be paid at the rate of basic pay payable

1 for level III of the Executive Schedule under
2 section 5314 of title 5, United States Code.

3 “(C) TERM OF OFFICE.—The Adminis-
4 trator shall be appointed for a term of 4 years.
5 In any case in which a successor does not take
6 office at the end of an Administrator’s term of
7 office, that Administrator may continue in of-
8 fice until the entry upon office of such a suc-
9 cessor. An Administrator appointed to a term of
10 office after the commencement of such term
11 may serve under such appointment only for the
12 remainder of such term.

13 “(D) GENERAL AUTHORITY.—The Admin-
14 istrator shall be responsible for the exercise of
15 all powers and the discharge of all duties of the
16 Administration, and shall have authority and
17 control over all personnel and activities thereof.

18 “(E) RULEMAKING AUTHORITY.—The Ad-
19 ministrator may prescribe such rules and regu-
20 lations as the Administrator determines nec-
21 essary or appropriate to carry out the functions
22 of the Administration. The regulations pre-
23 scribed by the Administrator shall be subject to
24 the rulemaking procedures established under
25 section 553 of title 5, United States Code. The

1 Administrator shall provide for the issuance of
2 new regulations to carry out parts C, D, and E.

3 “(F) AUTHORITY TO ESTABLISH ORGANI-
4 ZATIONAL UNITS.—The Administrator may es-
5 tablish, alter, consolidate, or discontinue such
6 organizational units or components within the
7 Administration as the Administrator considers
8 necessary or appropriate, except as specified in
9 this section.

10 “(G) AUTHORITY TO DELEGATE.—The Ad-
11 ministrator may assign duties, and delegate, or
12 authorize successive redelegations of, authority
13 to act and to render decisions, to such officers
14 and employees of the Administration as the Ad-
15 ministrator may find necessary. Within the lim-
16 itations of such delegations, redelegations, or
17 assignments, all official acts and decisions of
18 such officers and employees shall have the same
19 force and effect as though performed or ren-
20 dered by the Administrator.

21 “(2) DEPUTY ADMINISTRATOR.—

22 “(A) IN GENERAL.—There shall be a Dep-
23 uty Administrator of the Medicare Benefits Ad-
24 ministration who shall be appointed by the

1 President, by and with the advice and consent
2 of the Senate.

3 “(B) COMPENSATION.—The Deputy Ad-
4 ministrators shall be paid at the rate of basic
5 pay payable for level IV of the Executive Sched-
6 ule under section 5315 of title 5, United States
7 Code.

8 “(C) TERM OF OFFICE.—The Deputy Ad-
9 ministrators shall be appointed for a term of 4
10 years. In any case in which a successor does not
11 take office at the end of a Deputy Administra-
12 tor’s term of office, such Deputy Administrator
13 may continue in office until the entry upon of-
14 fice of such a successor. A Deputy Adminis-
15 trator appointed to a term of office after the
16 commencement of such term may serve under
17 such appointment only for the remainder of
18 such term.

19 “(D) DUTIES.—The Deputy Administrator
20 shall perform such duties and exercise such
21 powers as the Administrator shall from time to
22 time assign or delegate. The Deputy Adminis-
23 trator shall be Acting Administrator of the Ad-
24 ministration during the absence or disability of
25 the Administrator and, unless the President

1 designates another officer of the Government as
2 Acting Administrator, in the event of a vacancy
3 in the office of the Administrator.

4 “(3) CHIEF ACTUARY.—

5 “(A) IN GENERAL.—There is established in
6 the Administration the position of Chief Actu-
7 ary. The Chief Actuary shall be appointed by,
8 and in direct line of authority to, the Adminis-
9 trator of such Administration. The Chief Actu-
10 ary shall be appointed from among individuals
11 who have demonstrated, by their education and
12 experience, superior expertise in the actuarial
13 sciences. The Chief Actuary may be removed
14 only for cause.

15 “(B) COMPENSATION.—The Chief Actuary
16 shall be compensated at the highest rate of
17 basic pay for the Senior Executive Service
18 under section 5382(b) of title 5, United States
19 Code.

20 “(C) DUTIES.—The Chief Actuary shall
21 exercise such duties as are appropriate for the
22 office of the Chief Actuary and in accordance
23 with professional standards of actuarial inde-
24 pendence.

1 “(4) SECRETARIAL COORDINATION OF PROGRAM
2 ADMINISTRATION.—The Secretary shall ensure ap-
3 propriate coordination between the Administrator
4 and the Administrator of the Centers for Medicare
5 & Medicaid Services in carrying out the programs
6 under this title.

7 “(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

8 “(1) DUTIES.—

9 “(A) GENERAL DUTIES.—The Adminis-
10 trator shall carry out parts C, D, and E, in-
11 cluding—

12 “(i) negotiating, entering into, and en-
13 forcing, contracts with plans for the offer-
14 ing of Medicare Advantage plans under
15 part C and EFFS plans under part E, in-
16 cluding the offering of qualified prescrip-
17 tion drug coverage under such plans; and

18 “(ii) negotiating, entering into, and
19 enforcing, contracts with PDP sponsors for
20 the offering of prescription drug plans
21 under part D.

22 “(B) OTHER DUTIES.—The Administrator
23 shall carry out any duty provided for under
24 part C, part D, or part E, including demonstra-
25 tion projects carried out in part or in whole

1 under such parts, the programs of all-inclusive
2 care for the elderly (PACE program) under sec-
3 tion 1894, the social health maintenance orga-
4 nization (SHMO) demonstration projects (re-
5 ferred to in section 4104(c) of the Balanced
6 Budget Act of 1997), medicare cost contractors
7 under section 1876(h), and through a Medicare
8 Advantage project that demonstrates the appli-
9 cation of capitation payment rates for frail el-
10 derly medicare beneficiaries through the use of
11 a interdisciplinary team and through the provi-
12 sion of primary care services to such bene-
13 ficiaries by means of such a team at the nurs-
14 ing facility involved).

15 “(C) PRESCRIPTION DRUG CARD.—The
16 Administrator shall carry out section 1807 (re-
17 lating to the medicare prescription drug dis-
18 count card endorsement program).

19 “(D) NONINTERFERENCE.—In carrying
20 out its duties with respect to the provision of
21 qualified prescription drug coverage to bene-
22 ficiaries under this title, the Administrator may
23 not—

1 “(i) require a particular formulary or
2 institute a price structure for the reim-
3 bursement of covered outpatient drugs;

4 “(ii) interfere in any way with nego-
5 tiations between PDP sponsors and Medi-
6 care Advantage organizations and EFFS
7 organizations and drug manufacturers,
8 wholesalers, or other suppliers of covered
9 outpatient drugs; and

10 “(iii) otherwise interfere with the
11 competitive nature of providing such cov-
12 erage through such sponsors and organiza-
13 tions.

14 “(E) ANNUAL REPORTS.—Not later March
15 31 of each year, the Administrator shall submit
16 to Congress and the President a report on the
17 administration of parts C, D, and E during the
18 previous fiscal year.

19 “(2) STAFF.—

20 “(A) IN GENERAL.—The Administrator,
21 with the approval of the Secretary, may employ,
22 without regard to chapter 31 of title 5, United
23 States Code, other than sections 3102 through
24 3108, 3110 through 3113, 3136m and 3151,
25 such officers and employees as are necessary to

1 administer the activities to be carried out
2 through the Medicare Benefits Administration.
3 The Administrator shall employ staff with ap-
4 propriate and necessary expertise in negotiating
5 contracts in the private sector.

6 “(B) FLEXIBILITY WITH RESPECT TO COM-
7 PENSATION.—

8 “(i) IN GENERAL.—The staff of the
9 Medicare Benefits Administration shall,
10 subject to clause (ii), be paid without re-
11 gard to the provisions of chapter 51 (other
12 than section 5101) and chapter 53 (other
13 than section 5301) of such title (relating to
14 classification and schedule pay rates).

15 “(ii) MAXIMUM RATE.—In no case
16 may the rate of compensation determined
17 under clause (i) exceed the rate of basic
18 pay payable for level IV of the Executive
19 Schedule under section 5315 of title 5,
20 United States Code.

21 “(C) LIMITATION ON FULL-TIME EQUIVA-
22 LENT STAFFING FOR CURRENT CMS FUNCTIONS
23 BEING TRANSFERRED.—The Administrator may
24 not employ under this paragraph a number of
25 full-time equivalent employees, to carry out

1 functions that were previously conducted by the
2 Centers for Medicare & Medicaid Services and
3 that are conducted by the Administrator by rea-
4 son of this section, that exceeds the number of
5 such full-time equivalent employees authorized
6 to be employed by the Centers for Medicare &
7 Medicaid Services to conduct such functions as
8 of the date of the enactment of this Act.

9 “(3) REDELEGATION OF CERTAIN FUNCTIONS
10 OF THE CENTERS FOR MEDICARE & MEDICAID SERV-
11 ICES.—

12 “(A) IN GENERAL.—The Secretary, the
13 Administrator, and the Administrator of the
14 Centers for Medicare & Medicaid Services shall
15 establish an appropriate transition of responsi-
16 bility in order to redelegate the administration
17 of part C from the Secretary and the Adminis-
18 trator of the Centers for Medicare & Medicaid
19 Services to the Administrator as is appropriate
20 to carry out the purposes of this section.

21 “(B) TRANSFER OF DATA AND INFORMA-
22 TION.—The Secretary shall ensure that the Ad-
23 ministrator of the Centers for Medicare & Med-
24 icaid Services transfers to the Administrator of
25 the Medicare Benefits Administration such in-

1 formation and data in the possession of the Ad-
2 ministrators of the Centers for Medicare & Med-
3 icaid Services as the Administrator of the Medi-
4 care Benefits Administration requires to carry
5 out the duties described in paragraph (1).

6 “(C) CONSTRUCTION.—Insofar as a re-
7 sponsibility of the Secretary or the Adminis-
8 trator of the Centers for Medicare & Medicaid
9 Services is redelegated to the Administrator
10 under this section, any reference to the Sec-
11 retary or the Administrator of the Centers for
12 Medicare & Medicaid Services in this title or
13 title XI with respect to such responsibility is
14 deemed to be a reference to the Administrator.

15 “(d) OFFICE OF BENEFICIARY ASSISTANCE.—

16 “(1) ESTABLISHMENT.—The Secretary shall es-
17 tablish within the Medicare Benefits Administration
18 an Office of Beneficiary Assistance to coordinate
19 functions relating to outreach and education of
20 medicare beneficiaries under this title, including the
21 functions described in paragraph (2). The Office
22 shall be separate operating division within the Ad-
23 ministration.

24 “(2) DISSEMINATION OF INFORMATION ON
25 BENEFITS AND APPEALS RIGHTS.—

1 “(A) DISSEMINATION OF BENEFITS INFOR-
2 MATION.—The Office of Beneficiary Assistance
3 shall disseminate, directly or through contract,
4 to medicare beneficiaries, by mail, by posting on
5 the Internet site of the Medicare Benefits Ad-
6 ministration and through a toll-free telephone
7 number, information with respect to the fol-
8 lowing:

9 “(i) Benefits, and limitations on pay-
10 ment (including cost-sharing, stop-loss pro-
11 visions, and formulary restrictions) under
12 parts C, D, and E.

13 “(ii) Benefits, and limitations on pay-
14 ment under parts A and B, including in-
15 formation on medicare supplemental poli-
16 cies under section 1882.

17 Such information shall be presented in a man-
18 ner so that medicare beneficiaries may compare
19 benefits under parts A, B, D, and medicare
20 supplemental policies with benefits under Medi-
21 care Advantage plans under part C and EFFS
22 plans under part E.

23 “(B) DISSEMINATION OF APPEALS RIGHTS
24 INFORMATION.—The Office of Beneficiary As-
25 sistance shall disseminate to medicare bene-

1 ficiaries in the manner provided under subpara-
2 graph (A) a description of procedural rights (in-
3 cluding grievance and appeals procedures) of
4 beneficiaries under the original medicare fee-
5 for-service program under parts A and B, the
6 Medicare Advantage program under part C, the
7 Voluntary Prescription Drug Benefit Program
8 under part D, and the Enhanced Fee-for-Serv-
9 ice program under part E.

10 “(e) MEDICARE POLICY ADVISORY BOARD.—

11 “(1) ESTABLISHMENT.—There is established
12 within the Medicare Benefits Administration the
13 Medicare Policy Advisory Board (in this section re-
14 ferred to the ‘Board’). The Board shall advise, con-
15 sult with, and make recommendations to the Admin-
16 istrator of the Medicare Benefits Administration
17 with respect to the administration of parts C, D,
18 and E, including the review of payment policies
19 under such parts.

20 “(2) REPORTS.—

21 “(A) IN GENERAL.—With respect to mat-
22 ters of the administration of parts C, D, and E
23 the Board shall submit to Congress and to the
24 Administrator of the Medicare Benefits Admin-
25 istration such reports as the Board determines

1 appropriate. Each such report may contain such
2 recommendations as the Board determines ap-
3 propriate for legislative or administrative
4 changes to improve the administration of such
5 parts, including the topics described in subpara-
6 graph (B). Each such report shall be published
7 in the Federal Register.

8 “(B) TOPICS DESCRIBED.—Reports re-
9 quired under subparagraph (A) may include the
10 following topics:

11 “(i) FOSTERING COMPETITION.—Rec-
12 ommendations or proposals to increase
13 competition under parts C, D, and E for
14 services furnished to medicare bene-
15 ficiaries.

16 “(ii) EDUCATION AND ENROLL-
17 MENT.—Recommendations for the im-
18 provement to efforts to provide medicare
19 beneficiaries information and education on
20 the program under this title, and specifi-
21 cally parts C, D, and E, and the program
22 for enrollment under the title.

23 “(iii) IMPLEMENTATION OF RISK-AD-
24 JUSTMENT.—Evaluation of the implemen-
25 tation under section 1853(a)(3)(C) of the

1 risk adjustment methodology to payment
2 rates under that section to Medicare Ad-
3 vantage organizations offering Medicare
4 Advantage plans (and the corresponding
5 payment provisions under part E) that ac-
6 counts for variations in per capita costs
7 based on health status, geography, and
8 other demographic factors.

9 “(iv) RURAL ACCESS.—Recommendations
10 to improve competition and access to
11 plans under parts C, D, and E in rural
12 areas.

13 “(C) MAINTAINING INDEPENDENCE OF
14 BOARD.—The Board shall directly submit to
15 Congress reports required under subparagraph
16 (A). No officer or agency of the United States
17 may require the Board to submit to any officer
18 or agency of the United States for approval,
19 comments, or review, prior to the submission to
20 Congress of such reports.

21 “(3) DUTY OF ADMINISTRATOR OF MEDICARE
22 BENEFITS ADMINISTRATION.—With respect to any
23 report submitted by the Board under paragraph
24 (2)(A), not later than 90 days after the report is
25 submitted, the Administrator of the Medicare Bene-

1 fits Administration shall submit to Congress and the
2 President an analysis of recommendations made by
3 the Board in such report. Each such analysis shall
4 be published in the Federal Register.

5 “(4) MEMBERSHIP.—

6 “(A) APPOINTMENT.—Subject to the suc-
7 ceeding provisions of this paragraph, the Board
8 shall consist of seven members to be appointed
9 as follows:

10 “(i) Three members shall be ap-
11 pointed by the President.

12 “(ii) Two members shall be appointed
13 by the Speaker of the House of Represent-
14 atives, with the advice of the chairmen and
15 the ranking minority members of the Com-
16 mittees on Ways and Means and on En-
17 ergy and Commerce of the House of Rep-
18 resentatives.

19 “(iii) Two members shall be appointed
20 by the President pro tempore of the Senate
21 with the advice of the chairman and the
22 ranking minority member of the Senate
23 Committee on Finance.

24 “(B) QUALIFICATIONS.—The members
25 shall be chosen on the basis of their integrity,

1 impartiality, and good judgment, and shall be
2 individuals who are, by reason of their edu-
3 cation and experience in health care benefits
4 management, exceptionally qualified to perform
5 the duties of members of the Board.

6 “(C) PROHIBITION ON INCLUSION OF FED-
7 ERAL EMPLOYEES.—No officer or employee of
8 the United States may serve as a member of
9 the Board.

10 “(5) COMPENSATION.—Members of the Board
11 shall receive, for each day (including travel time)
12 they are engaged in the performance of the functions
13 of the board, compensation at rates not to exceed
14 the daily equivalent to the annual rate in effect for
15 level IV of the Executive Schedule under section
16 5315 of title 5, United States Code.

17 “(6) TERMS OF OFFICE.—

18 “(A) IN GENERAL.—The term of office of
19 members of the Board shall be 3 years.

20 “(B) TERMS OF INITIAL APPOINTEES.—As
21 designated by the President at the time of ap-
22 pointment, of the members first appointed—

23 “(i) one shall be appointed for a term
24 of 1 year;

1 “(ii) three shall be appointed for
2 terms of 2 years; and

3 “(iii) three shall be appointed for
4 terms of 3 years.

5 “(C) REAPPOINTMENTS.—Any person ap-
6 pointed as a member of the Board may not
7 serve for more than 8 years.

8 “(D) VACANCY.—Any member appointed
9 to fill a vacancy occurring before the expiration
10 of the term for which the member’s predecessor
11 was appointed shall be appointed only for the
12 remainder of that term. A member may serve
13 after the expiration of that member’s term until
14 a successor has taken office. A vacancy in the
15 Board shall be filled in the manner in which the
16 original appointment was made.

17 “(7) CHAIR.—The Chair of the Board shall be
18 elected by the members. The term of office of the
19 Chair shall be 3 years.

20 “(8) MEETINGS.—The Board shall meet at the
21 call of the Chair, but in no event less than three
22 times during each fiscal year.

23 “(9) DIRECTOR AND STAFF.—

1 “(A) APPOINTMENT OF DIRECTOR.—The
2 Board shall have a Director who shall be ap-
3 pointed by the Chair.

4 “(B) IN GENERAL.—With the approval of
5 the Board, the Director may appoint, without
6 regard to chapter 31 of title 5, United States
7 Code, such additional personnel as the Director
8 considers appropriate.

9 “(C) FLEXIBILITY WITH RESPECT TO COM-
10 PENSATION.—

11 “(i) IN GENERAL.—The Director and
12 staff of the Board shall, subject to clause
13 (ii), be paid without regard to the provi-
14 sions of chapter 51 and chapter 53 of such
15 title (relating to classification and schedule
16 pay rates).

17 “(ii) MAXIMUM RATE.—In no case
18 may the rate of compensation determined
19 under clause (i) exceed the rate of basic
20 pay payable for level IV of the Executive
21 Schedule under section 5315 of title 5,
22 United States Code.

23 “(D) ASSISTANCE FROM THE ADMINIS-
24 TRATOR OF THE MEDICARE BENEFITS ADMINIS-
25 TRATION.—The Administrator of the Medicare

1 Benefits Administration shall make available to
2 the Board such information and other assist-
3 ance as it may require to carry out its func-
4 tions.

5 “(10) CONTRACT AUTHORITY.—The Board may
6 contract with and compensate government and pri-
7 vate agencies or persons to carry out its duties
8 under this subsection, without regard to section
9 3709 of the Revised Statutes (41 U.S.C. 5).

10 “(f) FUNDING.—There is authorized to be appro-
11 priated, in appropriate part from the Federal Hospital In-
12 surance Trust Fund and from the Federal Supplementary
13 Medical Insurance Trust Fund (including the Medicare
14 Prescription Drug Account), such sums as are necessary
15 to carry out this section.”.

16 (b) EFFECTIVE DATE.—

17 (1) IN GENERAL.—The amendment made by
18 subsection (a) shall take effect on the date of the en-
19 actment of this Act.

20 (2) DUTIES WITH RESPECT TO ELIGIBILITY DE-
21 TERMINATIONS AND ENROLLMENT.—The Adminis-
22 trator of the Medicare Benefits Administration shall
23 carry out enrollment under title XVIII of the Social
24 Security Act, make eligibility determinations under

1 such title, and carry out parts C and E of such title
2 for years beginning or after January 1, 2006.

3 (3) TRANSITION.—Before the date the Adminis-
4 trator of the Medicare Benefits Administration is
5 appointed and assumes responsibilities under this
6 section and section 1807 of the Social Security Act,
7 the Secretary of Health and Human Services shall
8 provide for the conduct of any responsibilities of
9 such Administrator that are otherwise provided
10 under law.

11 (c) MISCELLANEOUS ADMINISTRATIVE PROVI-
12 SIONS.—

13 (1) ADMINISTRATOR AS MEMBER OF THE
14 BOARD OF TRUSTEES OF THE MEDICARE TRUST
15 FUNDS.—Section 1817(b) and section 1841(b) (42
16 U.S.C. 1395i(b), 1395t(b)) are each amended by
17 striking “and the Secretary of Health and Human
18 Services, all ex officio,” and inserting “the Secretary
19 of Health and Human Services, and the Adminis-
20 trator of the Medicare Benefits Administration, all
21 ex officio,”.

22 (2) INCREASE IN GRADE TO EXECUTIVE LEVEL
23 III FOR THE ADMINISTRATOR OF THE CENTERS FOR
24 MEDICARE & MEDICAID SERVICES; LEVEL FOR MEDI-
25 CARE BENEFITS ADMINISTRATOR.—

1 (A) IN GENERAL.—Section 5314 of title 5,
 2 United States Code, by adding at the end the
 3 following:

4 “Administrator of the Centers for Medicare &
 5 Medicaid Services.

6 “Administrator of the Medicare Benefits Ad-
 7 ministration.”.

8 (B) CONFORMING AMENDMENT.—Section
 9 5315 of such title is amended by striking “Ad-
 10 ministrator of the Health Care Financing Ad-
 11 ministration.”.

12 (C) EFFECTIVE DATE.—The amendments
 13 made by this paragraph take effect on January
 14 1, 2004.

15 **TITLE IX—REGULATORY REDUC-**
 16 **TION AND CONTRACTING RE-**
 17 **FORM**

18 **Subtitle A—Regulatory Reform**

19 **SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.**

20 (a) CONSTRUCTION.—Nothing in this title shall be
 21 construed—

22 (1) to compromise or affect existing legal rem-
 23 edies for addressing fraud or abuse, whether it be
 24 criminal prosecution, civil enforcement, or adminis-
 25 trative remedies, including under sections 3729

1 through 3733 of title 31, United States Code
2 (known as the False Claims Act); or

3 (2) to prevent or impede the Department of
4 Health and Human Services in any way from its on-
5 going efforts to eliminate waste, fraud, and abuse in
6 the medicare program.

7 Furthermore, the consolidation of medicare administrative
8 contracting set forth in this division does not constitute
9 consolidation of the Federal Hospital Insurance Trust
10 Fund and the Federal Supplementary Medical Insurance
11 Trust Fund or reflect any position on that issue.

12 (b) DEFINITION OF SUPPLIER.—Section 1861 (42
13 U.S.C. 1395x) is amended by inserting after subsection
14 (c) the following new subsection:

15 “Supplier

16 “(d) The term ‘supplier’ means, unless the context
17 otherwise requires, a physician or other practitioner, a fa-
18 cility, or other entity (other than a provider of services)
19 that furnishes items or services under this title.”.

20 **SEC. 902. ISSUANCE OF REGULATIONS.**

21 (a) REGULAR TIMELINE FOR PUBLICATION OF
22 FINAL RULES.—

23 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
24 1395hh(a)) is amended by adding at the end the fol-
25 lowing new paragraph:

1 “(3)(A) The Secretary, in consultation with the Di-
2 rector of the Office of Management and Budget, shall es-
3 tablish and publish a regular timeline for the publication
4 of final regulations based on the previous publication of
5 a proposed regulation or an interim final regulation.

6 “(B) Such timeline may vary among different regula-
7 tions based on differences in the complexity of the regula-
8 tion, the number and scope of comments received, and
9 other relevant factors, but shall not be longer than 3 years
10 except under exceptional circumstances. If the Secretary
11 intends to vary such timeline with respect to the publica-
12 tion of a final regulation, the Secretary shall cause to have
13 published in the Federal Register notice of the different
14 timeline by not later than the timeline previously estab-
15 lished with respect to such regulation. Such notice shall
16 include a brief explanation of the justification for such
17 variation.

18 “(C) In the case of interim final regulations, upon
19 the expiration of the regular timeline established under
20 this paragraph for the publication of a final regulation
21 after opportunity for public comment, the interim final
22 regulation shall not continue in effect unless the Secretary
23 publishes (at the end of the regular timeline and, if appli-
24 cable, at the end of each succeeding 1-year period) a notice
25 of continuation of the regulation that includes an expla-

1 nation of why the regular timeline (and any subsequent
2 1-year extension) was not complied with. If such a notice
3 is published, the regular timeline (or such timeline as pre-
4 viously extended under this paragraph) for publication of
5 the final regulation shall be treated as having been ex-
6 tended for 1 additional year.

7 “(D) The Secretary shall annually submit to Con-
8 gress a report that describes the instances in which the
9 Secretary failed to publish a final regulation within the
10 applicable regular timeline under this paragraph and that
11 provides an explanation for such failures.”.

12 (2) EFFECTIVE DATE.—The amendment made
13 by paragraph (1) shall take effect on the date of the
14 enactment of this Act. The Secretary shall provide
15 for an appropriate transition to take into account
16 the backlog of previously published interim final reg-
17 ulations.

18 (b) LIMITATIONS ON NEW MATTER IN FINAL REGU-
19 LATIONS.—

20 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
21 1395hh(a)), as amended by subsection (a), is
22 amended by adding at the end the following new
23 paragraph:

24 “(4) If the Secretary publishes a final regulation that
25 includes a provision that is not a logical outgrowth of a

1 previously published notice of proposed rulemaking or in-
2 terim final rule, such provision shall be treated as a pro-
3 posed regulation and shall not take effect until there is
4 the further opportunity for public comment and a publica-
5 tion of the provision again as a final regulation.”.

6 (2) EFFECTIVE DATE.—The amendment made
7 by paragraph (1) shall apply to final regulations
8 published on or after the date of the enactment of
9 this Act.

10 **SEC. 903. COMPLIANCE WITH CHANGES IN REGULATIONS**
11 **AND POLICIES.**

12 (a) NO RETROACTIVE APPLICATION OF SUB-
13 STANTIVE CHANGES.—

14 (1) IN GENERAL.—Section 1871 (42 U.S.C.
15 1395hh), as amended by section 902(a), is amended
16 by adding at the end the following new subsection:

17 “(e)(1)(A) A substantive change in regulations, man-
18 ual instructions, interpretative rules, statements of policy,
19 or guidelines of general applicability under this title shall
20 not be applied (by extrapolation or otherwise) retroactively
21 to items and services furnished before the effective date
22 of the change, unless the Secretary determines that—

23 “(i) such retroactive application is necessary to
24 comply with statutory requirements; or

1 “(ii) failure to apply the change retroactively
2 would be contrary to the public interest.”.

3 (2) EFFECTIVE DATE.—The amendment made
4 by paragraph (1) shall apply to substantive changes
5 issued on or after the date of the enactment of this
6 Act.

7 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE
8 CHANGES AFTER NOTICE.—

9 (1) IN GENERAL.—Section 1871(e)(1), as
10 added by subsection (a), is amended by adding at
11 the end the following:

12 “(B)(i) Except as provided in clause (ii), a sub-
13 stantive change referred to in subparagraph (A) shall not
14 become effective before the end of the 30-day period that
15 begins on the date that the Secretary has issued or pub-
16 lished, as the case may be, the substantive change.

17 “(ii) The Secretary may provide for such a sub-
18 stantive change to take effect on a date that precedes the
19 end of the 30-day period under clause (i) if the Secretary
20 finds that waiver of such 30-day period is necessary to
21 comply with statutory requirements or that the application
22 of such 30-day period is contrary to the public interest.
23 If the Secretary provides for an earlier effective date pur-
24 suant to this clause, the Secretary shall include in the
25 issuance or publication of the substantive change a finding

1 described in the first sentence, and a brief statement of
2 the reasons for such finding.

3 “(C) No action shall be taken against a provider of
4 services or supplier with respect to noncompliance with
5 such a substantive change for items and services furnished
6 before the effective date of such a change.”.

7 (2) EFFECTIVE DATE.—The amendment made
8 by paragraph (1) shall apply to compliance actions
9 undertaken on or after the date of the enactment of
10 this Act.

11 (c) RELIANCE ON GUIDANCE.—

12 (1) IN GENERAL.—Section 1871(e), as added
13 by subsection (a), is further amended by adding at
14 the end the following new paragraph:

15 “(2)(A) If—

16 “(i) a provider of services or supplier follows
17 the written guidance (which may be transmitted
18 electronically) provided by the Secretary or by a
19 medicare contractor (as defined in section 1889(g))
20 acting within the scope of the contractor’s contract
21 authority, with respect to the furnishing of items or
22 services and submission of a claim for benefits for
23 such items or services with respect to such provider
24 or supplier;

1 “(ii) the Secretary determines that the provider
2 of services or supplier has accurately presented the
3 circumstances relating to such items, services, and
4 claim to the contractor in writing; and

5 “(iii) the guidance was in error;
6 the provider of services or supplier shall not be subject
7 to any sanction (including any penalty or requirement for
8 repayment of any amount) if the provider of services or
9 supplier reasonably relied on such guidance.

10 “(B) Subparagraph (A) shall not be construed as pre-
11 venting the recoupment or repayment (without any addi-
12 tional penalty) relating to an overpayment insofar as the
13 overpayment was solely the result of a clerical or technical
14 operational error.”.

15 (2) EFFECTIVE DATE.—The amendment made
16 by paragraph (1) shall take effect on the date of the
17 enactment of this Act but shall not apply to any
18 sanction for which notice was provided on or before
19 the date of the enactment of this Act.

20 **SEC. 904. REPORTS AND STUDIES RELATING TO REGU-**
21 **LATORY REFORM.**

22 (a) GAO STUDY ON ADVISORY OPINION AUTHOR-
23 ITY.—

24 (1) STUDY.—The Comptroller General of the
25 United States shall conduct a study to determine the

1 feasibility and appropriateness of establishing in the
2 Secretary authority to provide legally binding advisory
3 opinions on appropriate interpretation and application
4 of regulations to carry out the medicare
5 program under title XVIII of the Social Security
6 Act. Such study shall examine the appropriate time-
7 frame for issuing such advisory opinions, as well as
8 the need for additional staff and funding to provide
9 such opinions.

10 (2) REPORT.—The Comptroller General shall
11 submit to Congress a report on the study conducted
12 under paragraph (1) by not later than one year after
13 the date of the enactment of this Act.

14 (b) REPORT ON LEGAL AND REGULATORY INCON-
15 SISTENCIES.—Section 1871 (42 U.S.C. 1395hh), as
16 amended by section 2(a), is amended by adding at the end
17 the following new subsection:

18 “(f)(1) Not later than 2 years after the date of the
19 enactment of this subsection, and every 2 years thereafter,
20 the Secretary shall submit to Congress a report with re-
21 spect to the administration of this title and areas of incon-
22 sistency or conflict among the various provisions under
23 law and regulation.

24 “(2) In preparing a report under paragraph (1), the
25 Secretary shall collect—

1 “(1) AUTHORITY TO ENTER INTO CON-
2 TRACTS.—The Secretary may enter into contracts
3 with any eligible entity to serve as a medicare ad-
4 ministrative contractor with respect to the perform-
5 ance of any or all of the functions described in para-
6 graph (4) or parts of those functions (or, to the ex-
7 tent provided in a contract, to secure performance
8 thereof by other entities).

9 “(2) ELIGIBILITY OF ENTITIES.—An entity is
10 eligible to enter into a contract with respect to the
11 performance of a particular function described in
12 paragraph (4) only if—

13 “(A) the entity has demonstrated capa-
14 bility to carry out such function;

15 “(B) the entity complies with such conflict
16 of interest standards as are generally applicable
17 to Federal acquisition and procurement;

18 “(C) the entity has sufficient assets to fi-
19 nancially support the performance of such func-
20 tion; and

21 “(D) the entity meets such other require-
22 ments as the Secretary may impose.

23 “(3) MEDICARE ADMINISTRATIVE CONTRACTOR
24 DEFINED.—For purposes of this title and title XI—

1 “(A) IN GENERAL.—The term ‘medicare
2 administrative contractor’ means an agency, or-
3 ganization, or other person with a contract
4 under this section.

5 “(B) APPROPRIATE MEDICARE ADMINIS-
6 TRATIVE CONTRACTOR.—With respect to the
7 performance of a particular function in relation
8 to an individual entitled to benefits under part
9 A or enrolled under part B, or both, a specific
10 provider of services or supplier (or class of such
11 providers of services or suppliers), the ‘appro-
12 priate’ medicare administrative contractor is the
13 medicare administrative contractor that has a
14 contract under this section with respect to the
15 performance of that function in relation to that
16 individual, provider of services or supplier or
17 class of provider of services or supplier.

18 “(4) FUNCTIONS DESCRIBED.—The functions
19 referred to in paragraphs (1) and (2) are payment
20 functions, provider services functions, and functions
21 relating to services furnished to individuals entitled
22 to benefits under part A or enrolled under part B,
23 or both, as follows:

24 “(A) DETERMINATION OF PAYMENT
25 AMOUNTS.—Determining (subject to the provi-

1 sions of section 1878 and to such review by the
2 Secretary as may be provided for by the con-
3 tracts) the amount of the payments required
4 pursuant to this title to be made to providers
5 of services, suppliers and individuals.

6 “(B) MAKING PAYMENTS.—Making pay-
7 ments described in subparagraph (A) (including
8 receipt, disbursement, and accounting for funds
9 in making such payments).

10 “(C) BENEFICIARY EDUCATION AND AS-
11 SISTANCE.—Providing education and outreach
12 to individuals entitled to benefits under part A
13 or enrolled under part B, or both, and pro-
14 viding assistance to those individuals with spe-
15 cific issues, concerns or problems.

16 “(D) PROVIDER CONSULTATIVE SERV-
17 ICES.—Providing consultative services to insti-
18 tutions, agencies, and other persons to enable
19 them to establish and maintain fiscal records
20 necessary for purposes of this title and other-
21 wise to qualify as providers of services or sup-
22 pliers.

23 “(E) COMMUNICATION WITH PRO-
24 VIDERS.—Communicating to providers of serv-
25 ices and suppliers any information or instruc-

1 tions furnished to the medicare administrative
2 contractor by the Secretary, and facilitating
3 communication between such providers and sup-
4 pliers and the Secretary.

5 “(F) PROVIDER EDUCATION AND TECH-
6 NICAL ASSISTANCE.—Performing the functions
7 relating to provider education, training, and
8 technical assistance.

9 “(G) ADDITIONAL FUNCTIONS.—Per-
10 forming such other functions as are necessary
11 to carry out the purposes of this title.

12 “(5) RELATIONSHIP TO MIP CONTRACTS.—

13 “(A) NONDUPLICATION OF DUTIES.—In
14 entering into contracts under this section, the
15 Secretary shall assure that functions of medi-
16 care administrative contractors in carrying out
17 activities under parts A and B do not duplicate
18 activities carried out under the Medicare Integ-
19 rity Program under section 1893. The previous
20 sentence shall not apply with respect to the ac-
21 tivity described in section 1893(b)(5) (relating
22 to prior authorization of certain items of dura-
23 ble medical equipment under section
24 1834(a)(15)).

1 “(B) CONSTRUCTION.—An entity shall not
2 be treated as a medicare administrative con-
3 tractor merely by reason of having entered into
4 a contract with the Secretary under section
5 1893.

6 “(6) APPLICATION OF FEDERAL ACQUISITION
7 REGULATION.—Except to the extent inconsistent
8 with a specific requirement of this title, the Federal
9 Acquisition Regulation applies to contracts under
10 this title.

11 “(b) CONTRACTING REQUIREMENTS.—

12 “(1) USE OF COMPETITIVE PROCEDURES.—

13 “(A) IN GENERAL.—Except as provided in
14 laws with general applicability to Federal acqui-
15 sition and procurement or in subparagraph (B),
16 the Secretary shall use competitive procedures
17 when entering into contracts with medicare ad-
18 ministrative contractors under this section, tak-
19 ing into account performance quality as well as
20 price and other factors.

21 “(B) RENEWAL OF CONTRACTS.—The Sec-
22 retary may renew a contract with a medicare
23 administrative contractor under this section
24 from term to term without regard to section 5
25 of title 41, United States Code, or any other

1 provision of law requiring competition, if the
2 medicare administrative contractor has met or
3 exceeded the performance requirements applica-
4 ble with respect to the contract and contractor,
5 except that the Secretary shall provide for the
6 application of competitive procedures under
7 such a contract not less frequently than once
8 every five years.

9 “(C) TRANSFER OF FUNCTIONS.—The
10 Secretary may transfer functions among medi-
11 care administrative contractors consistent with
12 the provisions of this paragraph. The Secretary
13 shall ensure that performance quality is consid-
14 ered in such transfers. The Secretary shall pro-
15 vide public notice (whether in the Federal Reg-
16 ister or otherwise) of any such transfer (includ-
17 ing a description of the functions so trans-
18 ferred, a description of the providers of services
19 and suppliers affected by such transfer, and
20 contact information for the contractors in-
21 volved).

22 “(D) INCENTIVES FOR QUALITY.—The
23 Secretary shall provide incentives for medicare
24 administrative contractors to provide quality
25 service and to promote efficiency.

1 “(2) COMPLIANCE WITH REQUIREMENTS.—No
2 contract under this section shall be entered into with
3 any medicare administrative contractor unless the
4 Secretary finds that such medicare administrative
5 contractor will perform its obligations under the con-
6 tract efficiently and effectively and will meet such
7 requirements as to financial responsibility, legal au-
8 thority, quality of services provided, and other mat-
9 ters as the Secretary finds pertinent.

10 “(3) PERFORMANCE REQUIREMENTS.—

11 “(A) DEVELOPMENT OF SPECIFIC PER-
12 FORMANCE REQUIREMENTS.—In developing
13 contract performance requirements, the Sec-
14 retary shall develop performance requirements
15 applicable to functions described in subsection
16 (a)(4).

17 “(B) CONSULTATION.—In developing such
18 requirements, the Secretary may consult with
19 providers of services and suppliers, organiza-
20 tions representing individuals entitled to bene-
21 fits under part A or enrolled under part B, or
22 both, and organizations and agencies per-
23 forming functions necessary to carry out the
24 purposes of this section with respect to such
25 performance requirements.

1 “(C) INCLUSION IN CONTRACTS.—All con-
2 tractor performance requirements shall be set
3 forth in the contract between the Secretary and
4 the appropriate medicare administrative con-
5 tractor. Such performance requirements—

6 “(i) shall reflect the performance re-
7 quirements developed under subparagraph
8 (A), but may include additional perform-
9 ance requirements;

10 “(ii) shall be used for evaluating con-
11 tractor performance under the contract;
12 and

13 “(iii) shall be consistent with the writ-
14 ten statement of work provided under the
15 contract.

16 “(4) INFORMATION REQUIREMENTS.—The Sec-
17 retary shall not enter into a contract with a medi-
18 care administrative contractor under this section un-
19 less the contractor agrees—

20 “(A) to furnish to the Secretary such time-
21 ly information and reports as the Secretary may
22 find necessary in performing his functions
23 under this title; and

24 “(B) to maintain such records and afford
25 such access thereto as the Secretary finds nec-

1 essary to assure the correctness and verification
2 of the information and reports under subpara-
3 graph (A) and otherwise to carry out the pur-
4 poses of this title.

5 “(5) SURETY BOND.—A contract with a medi-
6 care administrative contractor under this section
7 may require the medicare administrative contractor,
8 and any of its officers or employees certifying pay-
9 ments or disbursing funds pursuant to the contract,
10 or otherwise participating in carrying out the con-
11 tract, to give surety bond to the United States in
12 such amount as the Secretary may deem appro-
13 priate.

14 “(c) TERMS AND CONDITIONS.—

15 “(1) IN GENERAL.—A contract with any medi-
16 care administrative contractor under this section
17 may contain such terms and conditions as the Sec-
18 retary finds necessary or appropriate and may pro-
19 vide for advances of funds to the medicare adminis-
20 trative contractor for the making of payments by it
21 under subsection (a)(4)(B).

22 “(2) PROHIBITION ON MANDATES FOR CERTAIN
23 DATA COLLECTION.—The Secretary may not require,
24 as a condition of entering into, or renewing, a con-
25 tract under this section, that the medicare adminis-

1 trative contractor match data obtained other than in
2 its activities under this title with data used in the
3 administration of this title for purposes of identi-
4 fying situations in which the provisions of section
5 1862(b) may apply.

6 “(d) LIMITATION ON LIABILITY OF MEDICARE AD-
7 MINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

8 “(1) CERTIFYING OFFICER.—No individual des-
9 ignated pursuant to a contract under this section as
10 a certifying officer shall, in the absence of the reck-
11 less disregard of the individual’s obligations or the
12 intent by that individual to defraud the United
13 States, be liable with respect to any payments cer-
14 tified by the individual under this section.

15 “(2) DISBURSING OFFICER.—No disbursing of-
16 ficer shall, in the absence of the reckless disregard
17 of the officer’s obligations or the intent by that offi-
18 cer to defraud the United States, be liable with re-
19 spect to any payment by such officer under this sec-
20 tion if it was based upon an authorization (which
21 meets the applicable requirements for such internal
22 controls established by the Comptroller General) of
23 a certifying officer designated as provided in para-
24 graph (1) of this subsection.

1 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE
2 CONTRACTOR.—

3 “(A) IN GENERAL.—No medicare administra-
4 tive contractor shall be liable to the United States
5 for a payment by a certifying or disbursing officer
6 unless, in connection with such payment, the medi-
7 care administrative contractor acted with reckless
8 disregard of its obligations under its medicare ad-
9 ministrative contract or with intent to defraud the
10 United States.

11 “(B) RELATIONSHIP TO FALSE CLAIMS ACT.—
12 Nothing in this subsection shall be construed to limit
13 liability for conduct that would constitute a violation
14 of sections 3729 through 3731 of title 31, United
15 States Code (commonly known as the ‘False Claims
16 Act’).

17 “(4) INDEMNIFICATION BY SECRETARY.—

18 “(A) IN GENERAL.—Subject to subpara-
19 graphs (B) and (D), in the case of a medicare
20 administrative contractor (or a person who is a
21 director, officer, or employee of such a con-
22 tractor or who is engaged by the contractor to
23 participate directly in the claims administration
24 process) who is made a party to any judicial or
25 administrative proceeding arising from or relat-

1 ing directly to the claims administration process
2 under this title, the Secretary may, to the ex-
3 tent the Secretary determines to be appropriate
4 and as specified in the contract with the con-
5 tractor, indemnify the contractor and such per-
6 sons.

7 “(B) CONDITIONS.—The Secretary may
8 not provide indemnification under subparagraph
9 (A) insofar as the liability for such costs arises
10 directly from conduct that is determined by the
11 judicial proceeding or by the Secretary to be
12 criminal in nature, fraudulent, or grossly neg-
13 ligent. If indemnification is provided by the Sec-
14 retary with respect to a contractor before a de-
15 termination that such costs arose directly from
16 such conduct, the contractor shall reimburse the
17 Secretary for costs of indemnification.

18 “(C) SCOPE OF INDEMNIFICATION.—In-
19 demnification by the Secretary under subpara-
20 graph (A) may include payment of judgments,
21 settlements (subject to subparagraph (D)),
22 awards, and costs (including reasonable legal
23 expenses).

24 “(D) WRITTEN APPROVAL FOR SETTLE-
25 MENTS.—A contractor or other person de-

1 scribed in subparagraph (A) may not propose to
2 negotiate a settlement or compromise of a pro-
3 ceeding described in such subparagraph without
4 the prior written approval of the Secretary to
5 negotiate such settlement or compromise. Any
6 indemnification under subparagraph (A) with
7 respect to amounts paid under a settlement or
8 compromise of a proceeding described in such
9 subparagraph are conditioned upon prior writ-
10 ten approval by the Secretary of the final settle-
11 ment or compromise.

12 “(E) CONSTRUCTION.—Nothing in this
13 paragraph shall be construed—

14 “(i) to change any common law immu-
15 nity that may be available to a medicare
16 administrative contractor or person de-
17 scribed in subparagraph (A); or

18 “(ii) to permit the payment of costs
19 not otherwise allowable, reasonable, or allo-
20 cable under the Federal Acquisition Regu-
21 lations.”.

22 (2) CONSIDERATION OF INCORPORATION OF
23 CURRENT LAW STANDARDS.—In developing contract
24 performance requirements under section 1874A(b)
25 of the Social Security Act, as inserted by paragraph

1 (1), the Secretary shall consider inclusion of the per-
2 formance standards described in sections 1816(f)(2)
3 of such Act (relating to timely processing of recon-
4 siderations and applications for exemptions) and sec-
5 tion 1842(b)(2)(B) of such Act (relating to timely
6 review of determinations and fair hearing requests),
7 as such sections were in effect before the date of the
8 enactment of this Act.

9 (b) CONFORMING AMENDMENTS TO SECTION 1816
10 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816
11 (42 U.S.C. 1395h) is amended as follows:

12 (1) The heading is amended to read as follows:
13 “PROVISIONS RELATING TO THE ADMINISTRATION OF
14 PART A”.

15 (2) Subsection (a) is amended to read as fol-
16 lows:
17 “(a) The administration of this part shall be con-
18 ducted through contracts with medicare administrative
19 contractors under section 1874A.”.

20 (3) Subsection (b) is repealed.

21 (4) Subsection (c) is amended—

22 (A) by striking paragraph (1); and

23 (B) in each of paragraphs (2)(A) and
24 (3)(A), by striking “agreement under this sec-
25 tion” and inserting “contract under section

1 1874A that provides for making payments
2 under this part”.

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

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

5 (A) by striking “An agreement with an
6 agency or organization under this section” and
7 inserting “A contract with a medicare adminis-
8 trative contractor under section 1874A with re-
9 spect to the administration of this part”; and

10 (B) by striking “such agency or organiza-
11 tion” and inserting “such medicare administra-
12 tive contractor” each place it appears.

13 (7) Subsection (l) is repealed.

14 (c) CONFORMING AMENDMENTS TO SECTION 1842
15 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C.
16 1395u) is amended as follows:

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

18 “PROVISIONS RELATING TO THE ADMINISTRATION OF
19 PART B”.

20 (2) Subsection (a) is amended to read as fol-
21 lows:

22 “(a) The administration of this part shall be con-
23 ducted through contracts with medicare administrative
24 contractors under section 1874A.”.

25 (3) Subsection (b) is amended—

26 (A) by striking paragraph (1);

1 (B) in paragraph (2)—

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

4 (ii) in subparagraph (C), by striking
5 “carriers” and inserting “medicare admin-
6 istrative contractors”; and

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

9 (C) in paragraph (3)—

10 (i) in the matter before subparagraph
11 (A), by striking “Each such contract shall
12 provide that the carrier” and inserting
13 “The Secretary”;

14 (ii) by striking “will” the first place it
15 appears in each of subparagraphs (A), (B),
16 (F), (G), (H), and (L) and inserting
17 “shall”;

18 (iii) in subparagraph (B), in the mat-
19 ter before clause (i), by striking “to the
20 policyholders and subscribers of the car-
21 rier” and inserting “to the policyholders
22 and subscribers of the medicare adminis-
23 trative contractor”;

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

1 (v) in subparagraph (H)—

2 (I) by striking “if it makes deter-
3 minations or payments with respect to
4 physicians’ services,” in the matter
5 preceding clause (i); and

6 (II) by striking “carrier” and in-
7 serting “medicare administrative con-
8 tractor” in clause (i);

9 (vi) by striking subparagraph (I);

10 (vii) in subparagraph (L), by striking
11 the semicolon and inserting a period;

12 (viii) in the first sentence, after sub-
13 paragraph (L), by striking “and shall con-
14 tain” and all that follows through the pe-
15 riod; and

16 (ix) in the seventh sentence, by insert-
17 ing “medicare administrative contractor,”
18 after “carrier,”; and

19 (D) by striking paragraph (5);

20 (E) in paragraph (6)(D)(iv), by striking
21 “carrier” and inserting “medicare administra-
22 tive contractor”; and

23 (F) in paragraph (7), by striking “the car-
24 rier” and inserting “the Secretary” each place
25 it appears.

1 (4) Subsection (c) is amended—

2 (A) by striking paragraph (1);

3 (B) in paragraph (2)(A), by striking “con-
4 tract under this section which provides for the
5 disbursement of funds, as described in sub-
6 section (a)(1)(B),” and inserting “contract
7 under section 1874A that provides for making
8 payments under this part”;

9 (C) in paragraph (3)(A), by striking “sub-
10 section (a)(1)(B)” and inserting “section
11 1874A(a)(3)(B)”;

12 (D) in paragraph (4), in the matter pre-
13 ceding subparagraph (A), by striking “carrier”
14 and inserting “medicare administrative con-
15 tractor”; and

16 (E) by striking paragraphs (5) and (6).

17 (5) Subsections (d), (e), and (f) are repealed.

18 (6) Subsection (g) is amended by striking “car-
19 rier or carriers” and inserting “medicare administra-
20 tive contractor or contractors”.

21 (7) Subsection (h) is amended—

22 (A) in paragraph (2)—

23 (i) by striking “Each carrier having
24 an agreement with the Secretary under

1 subsection (a)” and inserting “The Sec-
2 retary”; and

3 (ii) by striking “Each such carrier”
4 and inserting “The Secretary”;

5 (B) in paragraph (3)(A)—

6 (i) by striking “a carrier having an
7 agreement with the Secretary under sub-
8 section (a)” and inserting “medicare ad-
9 ministrative contractor having a contract
10 under section 1874A that provides for
11 making payments under this part”; and

12 (ii) by striking “such carrier” and in-
13 serting “such contractor”;

14 (C) in paragraph (3)(B)—

15 (i) by striking “a carrier” and insert-
16 ing “a medicare administrative contractor”
17 each place it appears; and

18 (ii) by striking “the carrier” and in-
19 serting “the contractor” each place it ap-
20 pears; and

21 (D) in paragraphs (5)(A) and (5)(B)(iii),
22 by striking “carriers” and inserting “medicare
23 administrative contractors” each place it ap-
24 pears.

25 (8) Subsection (l) is amended—

1 (A) in paragraph (1)(A)(iii), by striking
2 “carrier” and inserting “medicare administra-
3 tive contractor”; and

4 (B) in paragraph (2), by striking “carrier”
5 and inserting “medicare administrative con-
6 tractor”.

7 (9) Subsection (p)(3)(A) is amended by striking
8 “carrier” and inserting “medicare administrative
9 contractor”.

10 (10) Subsection (q)(1)(A) is amended by strik-
11 ing “carrier”.

12 (d) EFFECTIVE DATE; TRANSITION RULE.—

13 (1) EFFECTIVE DATE.—

14 (A) IN GENERAL.—Except as otherwise
15 provided in this subsection, the amendments
16 made by this section shall take effect on Octo-
17 ber 1, 2005, and the Secretary is authorized to
18 take such steps before such date as may be nec-
19 essary to implement such amendments on a
20 timely basis.

21 (B) CONSTRUCTION FOR CURRENT CON-
22 TRACTS.—Such amendments shall not apply to
23 contracts in effect before the date specified
24 under subparagraph (A) that continue to retain
25 the terms and conditions in effect on such date

1 (except as otherwise provided under this Act,
2 other than under this section) until such date
3 as the contract is let out for competitive bid-
4 ding under such amendments.

5 (C) DEADLINE FOR COMPETITIVE BID-
6 DING.—The Secretary shall provide for the let-
7 ting by competitive bidding of all contracts for
8 functions of medicare administrative contrac-
9 tors for annual contract periods that begin on
10 or after October 1, 2010.

11 (D) WAIVER OF PROVIDER NOMINATION
12 PROVISIONS DURING TRANSITION.—During the
13 period beginning on the date of the enactment
14 of this Act and before the date specified under
15 subparagraph (A), the Secretary may enter into
16 new agreements under section 1816 of the So-
17 cial Security Act (42 U.S.C. 1395h) without re-
18 gard to any of the provider nomination provi-
19 sions of such section.

20 (2) GENERAL TRANSITION RULES.—The Sec-
21 retary shall take such steps, consistent with para-
22 graph (1)(B) and (1)(C), as are necessary to provide
23 for an appropriate transition from contracts under
24 section 1816 and section 1842 of the Social Security

1 Act (42 U.S.C. 1395h, 1395u) to contracts under
2 section 1874A, as added by subsection (a)(1).

3 (3) AUTHORIZING CONTINUATION OF MIP
4 FUNCTIONS UNDER CURRENT CONTRACTS AND
5 AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—

6 The provisions contained in the exception in section
7 1893(d)(2) of the Social Security Act (42 U.S.C.
8 1395ddd(d)(2)) shall continue to apply notwith-
9 standing the amendments made by this section, and
10 any reference in such provisions to an agreement or
11 contract shall be deemed to include a contract under
12 section 1874A of such Act, as inserted by subsection
13 (a)(1), that continues the activities referred to in
14 such provisions.

15 (e) REFERENCES.—On and after the effective date
16 provided under subsection (d)(1), any reference to a fiscal
17 intermediary or carrier under title XI or XVIII of the So-
18 cial Security Act (or any regulation, manual instruction,
19 interpretative rule, statement of policy, or guideline issued
20 to carry out such titles) shall be deemed a reference to
21 a medicare administrative contractor (as provided under
22 section 1874A of the Social Security Act).

23 (f) REPORTS ON IMPLEMENTATION.—

24 (1) PLAN FOR IMPLEMENTATION.—By not later
25 than October 1, 2004, the Secretary shall submit a

1 report to Congress and the Comptroller General of
2 the United States that describes the plan for imple-
3 mentation of the amendments made by this section.
4 The Comptroller General shall conduct an evaluation
5 of such plan and shall submit to Congress, not later
6 than 6 months after the date the report is received,
7 a report on such evaluation and shall include in such
8 report such recommendations as the Comptroller
9 General deems appropriate.

10 (2) STATUS OF IMPLEMENTATION.—The Sec-
11 retary shall submit a report to Congress not later
12 than October 1, 2008, that describes the status of
13 implementation of such amendments and that in-
14 cludes a description of the following:

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

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

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

21 (D) A detailed description of how the Sec-
22 retary has modified oversight and management
23 of medicare contractors to adapt to full com-
24 petition.

1 **SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY**
2 **FOR MEDICARE ADMINISTRATIVE CONTRAC-**
3 **TORS.**

4 (a) IN GENERAL.—Section 1874A, as added by sec-
5 tion 911(a)(1), is amended by adding at the end the fol-
6 lowing new subsection:

7 “(e) REQUIREMENTS FOR INFORMATION SECUR-
8 RITY.—

9 “(1) DEVELOPMENT OF INFORMATION SECUR-
10 RITY PROGRAM.—A medicare administrative con-
11 tractor that performs the functions referred to in
12 subparagraphs (A) and (B) of subsection (a)(4) (re-
13 lating to determining and making payments) shall
14 implement a contractor-wide information security
15 program to provide information security for the op-
16 eration and assets of the contractor with respect to
17 such functions under this title. An information secu-
18 rity program under this paragraph shall meet the re-
19 quirements for information security programs im-
20 posed on Federal agencies under paragraphs (1)
21 through (8) of section 3544(b) of title 44, United
22 States Code (other than the requirements under
23 paragraphs (2)(D)(i), (5)(A), and (5)(B) of such
24 section).

25 “(2) INDEPENDENT AUDITS.—

1 “(A) PERFORMANCE OF ANNUAL EVALUA-
2 TIONS.—Each year a medicare administrative
3 contractor that performs the functions referred
4 to in subparagraphs (A) and (B) of subsection
5 (a)(4) (relating to determining and making pay-
6 ments) shall undergo an evaluation of the infor-
7 mation security of the contractor with respect
8 to such functions under this title. The evalua-
9 tion shall—

10 “(i) be performed by an entity that
11 meets such requirements for independence
12 as the Inspector General of the Depart-
13 ment of Health and Human Services may
14 establish; and

15 “(ii) test the effectiveness of informa-
16 tion security control techniques of an ap-
17 propriate subset of the contractor’s infor-
18 mation systems (as defined in section
19 3502(8) of title 44, United States Code)
20 relating to such functions under this title
21 and an assessment of compliance with the
22 requirements of this subsection and related
23 information security policies, procedures,
24 standards and guidelines, including policies
25 and procedures as may be prescribed by

1 the Director of the Office of Management
2 and Budget and applicable information se-
3 curity standards promulgated under sec-
4 tion 11331 of title 40, United States Code.

5 “(B) DEADLINE FOR INITIAL EVALUA-
6 TION.—

7 “(i) NEW CONTRACTORS.—In the case
8 of a medicare administrative contractor
9 covered by this subsection that has not
10 previously performed the functions referred
11 to in subparagraphs (A) and (B) of sub-
12 section (a)(4) (relating to determining and
13 making payments) as a fiscal intermediary
14 or carrier under section 1816 or 1842, the
15 first independent evaluation conducted
16 pursuant subparagraph (A) shall be com-
17 pleted prior to commencing such functions.

18 “(ii) OTHER CONTRACTORS.—In the
19 case of a medicare administrative con-
20 tractor covered by this subsection that is
21 not described in clause (i), the first inde-
22 pendent evaluation conducted pursuant
23 subparagraph (A) shall be completed with-
24 in 1 year after the date the contractor

1 commences functions referred to in clause
2 (i) under this section.

3 “(C) REPORTS ON EVALUATIONS.—

4 “(i) TO THE DEPARTMENT OF
5 HEALTH AND HUMAN SERVICES.—The re-
6 sults of independent evaluations under sub-
7 paragraph (A) shall be submitted promptly
8 to the Inspector General of the Depart-
9 ment of Health and Human Services and
10 to the Secretary.

11 “(ii) TO CONGRESS.—The Inspector
12 General of Department of Health and
13 Human Services shall submit to Congress
14 annual reports on the results of such eval-
15 uations, including assessments of the scope
16 and sufficiency of such evaluations.

17 “(iii) AGENCY REPORTING.—The Sec-
18 retary shall address the results of such
19 evaluations in reports required under sec-
20 tion 3544(c) of title 44, United States
21 Code.”.

22 (b) APPLICATION OF REQUIREMENTS TO FISCAL
23 INTERMEDIARIES AND CARRIERS.—

24 (1) IN GENERAL.—The provisions of section
25 1874A(e)(2) of the Social Security Act (other than

1 subparagraph (B)), as added by subsection (a), shall
2 apply to each fiscal intermediary under section 1816
3 of the Social Security Act (42 U.S.C. 1395h) and
4 each carrier under section 1842 of such Act (42
5 U.S.C. 1395u) in the same manner as they apply to
6 medicare administrative contractors under such pro-
7 visions.

8 (2) DEADLINE FOR INITIAL EVALUATION.—In
9 the case of such a fiscal intermediary or carrier with
10 an agreement or contract under such respective sec-
11 tion in effect as of the date of the enactment of this
12 Act, the first evaluation under section
13 1874A(e)(2)(A) of the Social Security Act (as added
14 by subsection (a)), pursuant to paragraph (1), shall
15 be completed (and a report on the evaluation sub-
16 mitted to the Secretary) by not later than 1 year
17 after such date.

18 **Subtitle C—Education and** 19 **Outreach**

20 **SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSIST-** 21 **ANCE.**

22 (a) COORDINATION OF EDUCATION FUNDING.—

23 (1) IN GENERAL.—Title XVIII is amended by
24 inserting after section 1888 the following new sec-
25 tion:

1 “PROVIDER EDUCATION AND TECHNICAL ASSISTANCE
2 “SEC. 1889. (a) COORDINATION OF EDUCATION
3 FUNDING.—The Secretary shall coordinate the edu-
4 cational activities provided through medicare contractors
5 (as defined in subsection (g), including under section
6 1893) in order to maximize the effectiveness of Federal
7 education efforts for providers of services and suppliers.”.

8 (2) EFFECTIVE DATE.—The amendment made
9 by paragraph (1) shall take effect on the date of the
10 enactment of this Act.

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

17 (b) INCENTIVES TO IMPROVE CONTRACTOR PER-
18 FORMANCE.—

19 (1) IN GENERAL.—Section 1874A, as added by
20 section 911(a)(1) and as amended by section 912(a),
21 is amended by adding at the end the following new
22 subsection:

23 “(f) INCENTIVES TO IMPROVE CONTRACTOR PER-
24 FORMANCE IN PROVIDER EDUCATION AND OUTREACH.—
25 The Secretary shall use specific claims payment error

1 rates or similar methodology of medicare administrative
2 contractors in the processing or reviewing of medicare
3 claims in order to give such contractors an incentive to
4 implement effective education and outreach programs for
5 providers of services and suppliers.”.

6 (2) APPLICATION TO FISCAL INTERMEDIARIES
7 AND CARRIERS.—The provisions of section 1874A(f)
8 of the Social Security Act, as added by paragraph
9 (1), shall apply to each fiscal intermediary under
10 section 1816 of the Social Security Act (42 U.S.C.
11 1395h) and each carrier under section 1842 of such
12 Act (42 U.S.C. 1395u) in the same manner as they
13 apply to medicare administrative contractors under
14 such provisions.

15 (3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the Comptroller General of the United States shall submit to
16 Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of
17 the Social Security Act, as added by paragraph (1),
18 and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

19 (4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later
20 21 22 23 24 25

1 than October 1, 2004, the Secretary shall submit to
2 Congress a report that describes how the Secretary
3 intends to use such methodology in assessing medi-
4 care contractor performance in implementing effec-
5 tive education and outreach programs, including
6 whether to use such methodology as a basis for per-
7 formance bonuses. The report shall include an anal-
8 ysis of the sources of identified errors and potential
9 changes in systems of contractors and rules of the
10 Secretary that could reduce claims error rates.

11 (c) PROVISION OF ACCESS TO AND PROMPT RE-
12 SPONSES FROM MEDICARE ADMINISTRATIVE CONTRAC-
13 TORS.—

14 (1) IN GENERAL.—Section 1874A, as added by
15 section 911(a)(1) and as amended by section 912(a)
16 and subsection (b), is further amended by adding at
17 the end the following new subsection:

18 “(g) COMMUNICATIONS WITH BENEFICIARIES, PRO-
19 VIDERS OF SERVICES AND SUPPLIERS.—

20 “(1) COMMUNICATION STRATEGY.—The Sec-
21 retary shall develop a strategy for communications
22 with individuals entitled to benefits under part A or
23 enrolled under part B, or both, and with providers
24 of services and suppliers under this title.

1 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each
2 medicare administrative contractor shall, for those
3 providers of services and suppliers which submit
4 claims to the contractor for claims processing and
5 for those individuals entitled to benefits under part
6 A or enrolled under part B, or both, with respect to
7 whom claims are submitted for claims processing,
8 provide general written responses (which may be
9 through electronic transmission) in a clear, concise,
10 and accurate manner to inquiries of providers of
11 services, suppliers and individuals entitled to bene-
12 fits under part A or enrolled under part B, or both,
13 concerning the programs under this title within 45
14 business days of the date of receipt of such inquiries.

15 “(3) RESPONSE TO TOLL-FREE LINES.—The
16 Secretary shall ensure that each medicare adminis-
17 trative contractor shall provide, for those providers
18 of services and suppliers which submit claims to the
19 contractor for claims processing and for those indi-
20 viduals entitled to benefits under part A or enrolled
21 under part B, or both, with respect to whom claims
22 are submitted for claims processing, a toll-free tele-
23 phone number at which such individuals, providers
24 of services and suppliers may obtain information re-

1 garding billing, coding, claims, coverage, and other
2 appropriate information under this title.

3 “(4) MONITORING OF CONTRACTOR RE-
4 SPONSES.—

5 “(A) IN GENERAL.—Each medicare admin-
6 istrative contractor shall, consistent with stand-
7 ards developed by the Secretary under subpara-
8 graph (B)—

9 “(i) maintain a system for identifying
10 who provides the information referred to in
11 paragraphs (2) and (3); and

12 “(ii) monitor the accuracy, consist-
13 ency, and timeliness of the information so
14 provided.

15 “(B) DEVELOPMENT OF STANDARDS.—

16 “(i) IN GENERAL.—The Secretary
17 shall establish and make public standards
18 to monitor the accuracy, consistency, and
19 timeliness of the information provided in
20 response to written and telephone inquiries
21 under this subsection. Such standards shall
22 be consistent with the performance require-
23 ments established under subsection (b)(3).

24 “(ii) EVALUATION.—In conducting
25 evaluations of individual medicare adminis-

1 trative contractors, the Secretary shall
2 take into account the results of the moni-
3 toring conducted under subparagraph (A)
4 taking into account as performance re-
5 quirements the standards established
6 under clause (i). The Secretary shall, in
7 consultation with organizations rep-
8 resenting providers of services, suppliers,
9 and individuals entitled to benefits under
10 part A or enrolled under part B, or both,
11 establish standards relating to the accu-
12 racy, consistency, and timeliness of the in-
13 formation so provided.

14 “(C) DIRECT MONITORING.—Nothing in
15 this paragraph shall be construed as preventing
16 the Secretary from directly monitoring the ac-
17 curacy, consistency, and timeliness of the infor-
18 mation so provided.”.

19 (2) EFFECTIVE DATE.—The amendment made
20 by paragraph (1) shall take effect October 1, 2004.

21 (3) APPLICATION TO FISCAL INTERMEDIARIES
22 AND CARRIERS.—The provisions of section 1874A(g)
23 of the Social Security Act, as added by paragraph
24 (1), shall apply to each fiscal intermediary under
25 section 1816 of the Social Security Act (42 U.S.C.

1 1395h) and each carrier under section 1842 of such
2 Act (42 U.S.C. 1395u) in the same manner as they
3 apply to medicare administrative contractors under
4 such provisions.

5 (d) IMPROVED PROVIDER EDUCATION AND TRAIN-
6 ING.—

7 (1) IN GENERAL.—Section 1889, as added by
8 subsection (a), is amended by adding at the end the
9 following new subsections:

10 “(b) ENHANCED EDUCATION AND TRAINING.—

11 “(1) ADDITIONAL RESOURCES.—There are au-
12 thorized to be appropriated to the Secretary (in ap-
13 propriate part from the Federal Hospital Insurance
14 Trust Fund and the Federal Supplementary Medical
15 Insurance Trust Fund) \$25,000,000 for each of fis-
16 cal years 2005 and 2006 and such sums as may be
17 necessary for succeeding fiscal years.

18 “(2) USE.—The funds made available under
19 paragraph (1) shall be used to increase the conduct
20 by medicare contractors of education and training of
21 providers of services and suppliers regarding billing,
22 coding, and other appropriate items and may also be
23 used to improve the accuracy, consistency, and time-
24 liness of contractor responses.

1 “(c) TAILORING EDUCATION AND TRAINING ACTIVI-
2 TIES FOR SMALL PROVIDERS OR SUPPLIERS.—

3 “(1) IN GENERAL.—Insofar as a medicare con-
4 tractor conducts education and training activities, it
5 shall tailor such activities to meet the special needs
6 of small providers of services or suppliers (as defined
7 in paragraph (2)).

8 “(2) SMALL PROVIDER OF SERVICES OR SUP-
9 PLIER.—In this subsection, the term ‘small provider
10 of services or supplier’ means—

11 “(A) a provider of services with fewer than
12 25 full-time-equivalent employees; or

13 “(B) a supplier with fewer than 10 full-
14 time-equivalent employees.”.

15 “(2) EFFECTIVE DATE.—The amendment made
16 by paragraph (1) shall take effect on October 1,
17 2004.

18 “(e) REQUIREMENT TO MAINTAIN INTERNET
19 SITES.—

20 “(1) IN GENERAL.—Section 1889, as added by
21 subsection (a) and as amended by subsection (d), is
22 further amended by adding at the end the following
23 new subsection:

24 “(d) INTERNET SITES; FAQs.—The Secretary, and
25 each medicare contractor insofar as it provides services

1 (including claims processing) for providers of services or
2 suppliers, shall maintain an Internet site which—

3 “(1) provides answers in an easily accessible
4 format to frequently asked questions, and

5 “(2) includes other published materials of the
6 contractor,

7 that relate to providers of services and suppliers under the
8 programs under this title (and title XI insofar as it relates
9 to such programs).”.

10 (2) EFFECTIVE DATE.—The amendment made
11 by paragraph (1) shall take effect on October 1,
12 2004.

13 (f) ADDITIONAL PROVIDER EDUCATION PROVI-
14 SIONS.—

15 (1) IN GENERAL.—Section 1889, as added by
16 subsection (a) and as amended by subsections (d)
17 and (e), is further amended by adding at the end the
18 following new subsections:

19 “(e) ENCOURAGEMENT OF PARTICIPATION IN EDU-
20 CATION PROGRAM ACTIVITIES.—A medicare contractor
21 may not use a record of attendance at (or failure to at-
22 tend) educational activities or other information gathered
23 during an educational program conducted under this sec-
24 tion or otherwise by the Secretary to select or track pro-

1 viders of services or suppliers for the purpose of con-
2 ducting any type of audit or prepayment review.

3 “(f) CONSTRUCTION.—Nothing in this section or sec-
4 tion 1893(g) shall be construed as providing for disclosure
5 by a medicare contractor of information that would com-
6 promise pending law enforcement activities or reveal find-
7 ings of law enforcement-related audits.

8 “(g) DEFINITIONS.—For purposes of this section, the
9 term ‘medicare contractor’ includes the following:

10 “(1) A medicare administrative contractor with
11 a contract under section 1874A, including a fiscal
12 intermediary with a contract under section 1816 and
13 a carrier with a contract under section 1842.

14 “(2) An eligible entity with a contract under
15 section 1893.

16 Such term does not include, with respect to activities of
17 a specific provider of services or supplier an entity that
18 has no authority under this title or title IX with respect
19 to such activities and such provider of services or sup-
20 plier.”.

21 (2) EFFECTIVE DATE.—The amendment made
22 by paragraph (1) shall take effect on the date of the
23 enactment of this Act.

1 **SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE DEM-**
2 **ONSTRATION PROGRAM.**

3 (a) ESTABLISHMENT.—

4 (1) IN GENERAL.—The Secretary shall establish
5 a demonstration program (in this section referred to
6 as the “demonstration program”) under which tech-
7 nical assistance described in paragraph (2) is made
8 available, upon request and on a voluntary basis, to
9 small providers of services or suppliers in order to
10 improve compliance with the applicable requirements
11 of the programs under medicare program under title
12 XVIII of the Social Security Act (including provi-
13 sions of title XI of such Act insofar as they relate
14 to such title and are not administered by the Office
15 of the Inspector General of the Department of
16 Health and Human Services).

17 (2) FORMS OF TECHNICAL ASSISTANCE.—The
18 technical assistance described in this paragraph is—

19 (A) evaluation and recommendations re-
20 garding billing and related systems; and

21 (B) information and assistance regarding
22 policies and procedures under the medicare pro-
23 gram, including coding and reimbursement.

24 (3) SMALL PROVIDERS OF SERVICES OR SUP-
25 PLIERS.—In this section, the term “small providers
26 of services or suppliers” means—

1 (A) a provider of services with fewer than
2 25 full-time-equivalent employees; or

3 (B) a supplier with fewer than 10 full-
4 time-equivalent employees.

5 (b) QUALIFICATION OF CONTRACTORS.—In con-
6 ducting the demonstration program, the Secretary shall
7 enter into contracts with qualified organizations (such as
8 peer review organizations or entities described in section
9 1889(g)(2) of the Social Security Act, as inserted by sec-
10 tion 5(f)(1)) with appropriate expertise with billing sys-
11 tems of the full range of providers of services and sup-
12 pliers to provide the technical assistance. In awarding such
13 contracts, the Secretary shall consider any prior investiga-
14 tions of the entity's work by the Inspector General of De-
15 partment of Health and Human Services or the Comp-
16 troller General of the United States.

17 (c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The
18 technical assistance provided under the demonstration
19 program shall include a direct and in-person examination
20 of billing systems and internal controls of small providers
21 of services or suppliers to determine program compliance
22 and to suggest more efficient or effective means of achiev-
23 ing such compliance.

24 (d) AVOIDANCE OF RECOVERY ACTIONS FOR PROB-
25 LEMS IDENTIFIED AS CORRECTED.—The Secretary shall

1 provide that, absent evidence of fraud and notwith-
2 standing any other provision of law, any errors found in
3 a compliance review for a small provider of services or sup-
4 plier that participates in the demonstration program shall
5 not be subject to recovery action if the technical assistance
6 personnel under the program determine that—

7 (1) the problem that is the subject of the com-
8 pliance review has been corrected to their satisfac-
9 tion within 30 days of the date of the visit by such
10 personnel to the small provider of services or sup-
11 plier; and

12 (2) such problem remains corrected for such pe-
13 riod as is appropriate.

14 The previous sentence applies only to claims filed as part
15 of the demonstration program and lasts only for the dura-
16 tion of such program and only as long as the small pro-
17 vider of services or supplier is a participant in such pro-
18 gram.

19 (e) GAO EVALUATION.—Not later than 2 years after
20 the date of the date the demonstration program is first
21 implemented, the Comptroller General, in consultation
22 with the Inspector General of the Department of Health
23 and Human Services, shall conduct an evaluation of the
24 demonstration program. The evaluation shall include a de-
25 termination of whether claims error rates are reduced for

1 small providers of services or suppliers who participated
2 in the program and the extent of improper payments made
3 as a result of the demonstration program. The Comp-
4 troller General shall submit a report to the Secretary and
5 the Congress on such evaluation and shall include in such
6 report recommendations regarding the continuation or ex-
7 tension of the demonstration program.

8 (f) FINANCIAL PARTICIPATION BY PROVIDERS.—The
9 provision of technical assistance to a small provider of
10 services or supplier under the demonstration program is
11 conditioned upon the small provider of services or supplier
12 paying an amount estimated (and disclosed in advance of
13 a provider's or supplier's participation in the program) to
14 be equal to 25 percent of the cost of the technical assist-
15 ance.

16 (g) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to the Secretary (in ap-
18 propriate part from the Federal Hospital Insurance Trust
19 Fund and the Federal Supplementary Medical Insurance
20 Trust Fund) to carry out the demonstration program—

21 (1) for fiscal year 2005, \$1,000,000, and

22 (2) for fiscal year 2006, \$6,000,000.

1 **SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDICARE**
2 **BENEFICIARY OMBUDSMAN.**

3 (a) MEDICARE PROVIDER OMBUDSMAN.—Section
4 1868 (42 U.S.C. 1395ee) is amended—

5 (1) by adding at the end of the heading the fol-
6 lowing: “; MEDICARE PROVIDER OMBUDSMAN”;

7 (2) by inserting “PRACTICING PHYSICIANS AD-
8 VISORY COUNCIL.—(1)” after “(a)”;

9 (3) in paragraph (1), as so redesignated under
10 paragraph (2), by striking “in this section” and in-
11 serting “in this subsection”;

12 (4) by redesignating subsections (b) and (c) as
13 paragraphs (2) and (3), respectively; and

14 (5) by adding at the end the following new sub-
15 section:

16 “(b) MEDICARE PROVIDER OMBUDSMAN.—The Sec-
17 retary shall appoint within the Department of Health and
18 Human Services a Medicare Provider Ombudsman. The
19 Ombudsman shall—

20 “(1) provide assistance, on a confidential basis,
21 to providers of services and suppliers with respect to
22 complaints, grievances, and requests for information
23 concerning the programs under this title (including
24 provisions of title XI insofar as they relate to this
25 title and are not administered by the Office of the
26 Inspector General of the Department of Health and

1 Human Services) and in the resolution of unclear or
2 conflicting guidance given by the Secretary and
3 medicare contractors to such providers of services
4 and suppliers regarding such programs and provi-
5 sions and requirements under this title and such
6 provisions; and

7 “(2) submit recommendations to the Secretary
8 for improvement in the administration of this title
9 and such provisions, including—

10 “(A) recommendations to respond to recur-
11 ring patterns of confusion in this title and such
12 provisions (including recommendations regard-
13 ing suspending imposition of sanctions where
14 there is widespread confusion in program ad-
15 ministration), and

16 “(B) recommendations to provide for an
17 appropriate and consistent response (including
18 not providing for audits) in cases of self-identi-
19 fied overpayments by providers of services and
20 suppliers.

21 The Ombudsman shall not serve as an advocate for any
22 increases in payments or new coverage of services, but
23 may identify issues and problems in payment or coverage
24 policies.”.

1 (b) MEDICARE BENEFICIARY OMBUDSMAN.—Title
2 XVIII, as previously amended, is amended by inserting
3 after section 1809 the following new section:

4 “MEDICARE BENEFICIARY OMBUDSMAN

5 “SEC. 1810. (a) IN GENERAL.—The Secretary shall
6 appoint within the Department of Health and Human
7 Services a Medicare Beneficiary Ombudsman who shall
8 have expertise and experience in the fields of health care
9 and education of (and assistance to) individuals entitled
10 to benefits under this title.

11 “(b) DUTIES.—The Medicare Beneficiary Ombuds-
12 man shall—

13 “(1) receive complaints, grievances, and re-
14 quests for information submitted by individuals enti-
15 tled to benefits under part A or enrolled under part
16 B, or both, with respect to any aspect of the medi-
17 care program;

18 “(2) provide assistance with respect to com-
19 plaints, grievances, and requests referred to in para-
20 graph (1), including—

21 “(A) assistance in collecting relevant infor-
22 mation for such individuals, to seek an appeal
23 of a decision or determination made by a fiscal
24 intermediary, carrier, Medicare+Choice organi-
25 zation, or the Secretary;

1 “(B) assistance to such individuals with
2 any problems arising from disenrollment from a
3 Medicare+Choice plan under part C; and

4 “(C) assistance to such individuals in pre-
5 senting information under section 1860D-
6 2(b)(4)(D)(v); and

7 “(3) submit annual reports to Congress and the
8 Secretary that describe the activities of the Office
9 and that include such recommendations for improve-
10 ment in the administration of this title as the Om-
11 budsman determines appropriate.

12 The Ombudsman shall not serve as an advocate for any
13 increases in payments or new coverage of services, but
14 may identify issues and problems in payment or coverage
15 policies.

16 “(c) WORKING WITH HEALTH INSURANCE COUN-
17 SELING PROGRAMS.—To the extent possible, the Ombuds-
18 man shall work with health insurance counseling programs
19 (receiving funding under section 4360 of Omnibus Budget
20 Reconciliation Act of 1990) to facilitate the provision of
21 information to individuals entitled to benefits under part
22 A or enrolled under part B, or both regarding
23 Medicare+Choice plans and changes to those plans. Noth-
24 ing in this subsection shall preclude further collaboration
25 between the Ombudsman and such programs.”.

1 (c) DEADLINE FOR APPOINTMENT.—The Secretary
2 shall appoint the Medicare Provider Ombudsman and the
3 Medicare Beneficiary Ombudsman, under the amendments
4 made by subsections (a) and (b), respectively, by not later
5 than 1 year after the date of the enactment of this Act.

6 (d) FUNDING.—There are authorized to be appro-
7 priated to the Secretary (in appropriate part from the
8 Federal Hospital Insurance Trust Fund and the Federal
9 Supplementary Medical Insurance Trust Fund) to carry
10 out the provisions of subsection (b) of section 1868 of the
11 Social Security Act (relating to the Medicare Provider
12 Ombudsman), as added by subsection (a)(5) and section
13 1807 of such Act (relating to the Medicare Beneficiary
14 Ombudsman), as added by subsection (b), such sums as
15 are necessary for fiscal year 2004 and each succeeding fis-
16 cal year.

17 (e) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-
18 MEDICARE).—

19 (1) PHONE TRIAGE SYSTEM; LISTING IN MEDI-
20 CARE HANDBOOK INSTEAD OF OTHER TOLL-FREE
21 NUMBERS.—Section 1804(b) (42 U.S.C. 1395b-
22 2(b)) is amended by adding at the end the following:
23 “The Secretary shall provide, through the toll-free
24 number 1-800-MEDICARE, for a means by which
25 individuals seeking information about, or assistance

1 with, such programs who phone such toll-free num-
2 ber are transferred (without charge) to appropriate
3 entities for the provision of such information or as-
4 sistance. Such toll-free number shall be the toll-free
5 number listed for general information and assistance
6 in the annual notice under subsection (a) instead of
7 the listing of numbers of individual contractors.”.

8 (2) MONITORING ACCURACY.—

9 (A) STUDY.—The Comptroller General of
10 the United States shall conduct a study to mon-
11 itor the accuracy and consistency of information
12 provided to individuals entitled to benefits
13 under part A or enrolled under part B, or both,
14 through the toll-free number 1-800-MEDI-
15 CARE, including an assessment of whether the
16 information provided is sufficient to answer
17 questions of such individuals. In conducting the
18 study, the Comptroller General shall examine
19 the education and training of the individuals
20 providing information through such number.

21 (B) REPORT.—Not later than 1 year after
22 the date of the enactment of this Act, the
23 Comptroller General shall submit to Congress a
24 report on the study conducted under subpara-
25 graph (A).

1 **SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PRO-**
2 **GRAM.**

3 (a) IN GENERAL.—The Secretary shall establish a
4 demonstration program (in this section referred to as the
5 “demonstration program”) under which medicare special-
6 ists employed by the Department of Health and Human
7 Services provide advice and assistance to individuals enti-
8 tled to benefits under part A of title XVIII of the Social
9 Security Act, or enrolled under part B of such title, or
10 both, regarding the medicare program at the location of
11 existing local offices of the Social Security Administration.

12 (b) LOCATIONS.—

13 (1) IN GENERAL.—The demonstration program
14 shall be conducted in at least 6 offices or areas.
15 Subject to paragraph (2), in selecting such offices
16 and areas, the Secretary shall provide preference for
17 offices with a high volume of visits by individuals re-
18 ferred to in subsection (a).

19 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—
20 The Secretary shall provide for the selection of at
21 least 2 rural areas to participate in the demonstra-
22 tion program. In conducting the demonstration pro-
23 gram in such rural areas, the Secretary shall provide
24 for medicare specialists to travel among local offices
25 in a rural area on a scheduled basis.

1 (c) DURATION.—The demonstration program shall be
2 conducted over a 3-year period.

3 (d) EVALUATION AND REPORT.—

4 (1) EVALUATION.—The Secretary shall provide
5 for an evaluation of the demonstration program.
6 Such evaluation shall include an analysis of—

7 (A) utilization of, and satisfaction of those
8 individuals referred to in subsection (a) with,
9 the assistance provided under the program; and

10 (B) the cost-effectiveness of providing ben-
11 efiary assistance through out-stationing medi-
12 care specialists at local offices of the Social Se-
13 curity Administration.

14 (2) REPORT.—The Secretary shall submit to
15 Congress a report on such evaluation and shall in-
16 clude in such report recommendations regarding the
17 feasibility of permanently out-stationing medicare
18 specialists at local offices of the Social Security Ad-
19 ministration.

20 **SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NO-**
21 **TICES TO BENEFICIARIES ABOUT SKILLED**
22 **NURSING FACILITY BENEFITS.**

23 (a) IN GENERAL.—The Secretary shall provide that
24 in medicare beneficiary notices provided (under section
25 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a))

1 with respect to the provision of post-hospital extended care
2 services under part A of title XVIII of the Social Security
3 Act, there shall be included information on the number
4 of days of coverage of such services remaining under such
5 part for the medicare beneficiary and spell of illness in-
6 volved.

7 (b) EFFECTIVE DATE.—Subsection (a) shall apply to
8 notices provided during calendar quarters beginning more
9 than 6 months after the date of the enactment of this Act.

10 **SEC. 926. INFORMATION ON MEDICARE-CERTIFIED**
11 **SKILLED NURSING FACILITIES IN HOSPITAL**
12 **DISCHARGE PLANS.**

13 (a) AVAILABILITY OF DATA.—The Secretary shall
14 publicly provide information that enables hospital dis-
15 charge planners, medicare beneficiaries, and the public to
16 identify skilled nursing facilities that are participating in
17 the medicare program.

18 (b) INCLUSION OF INFORMATION IN CERTAIN HOS-
19 PITAL DISCHARGE PLANS.—

20 (1) IN GENERAL.—Section 1861(ee)(2)(D) (42
21 U.S.C. 1395x(ee)(2)(D)) is amended—

22 (A) by striking “hospice services” and in-
23 serting “hospice care and post-hospital ex-
24 tended care services”; and

1 (B) by inserting before the period at the
2 end the following: “and, in the case of individ-
3 uals who are likely to need post-hospital ex-
4 tended care services, the availability of such
5 services through facilities that participate in the
6 program under this title and that serve the area
7 in which the patient resides”.

8 (2) EFFECTIVE DATE.—The amendments made
9 by paragraph (1) shall apply to discharge plans
10 made on or after such date as the Secretary shall
11 specify, but not later than 6 months after the date
12 the Secretary provides for availability of information
13 under subsection (a).

14 **Subtitle D—Appeals and Recovery**

15 **SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE**

16 **APPEALS.**

17 (a) TRANSITION PLAN.—

18 (1) IN GENERAL.—Not later than October 1,
19 2004, the Commissioner of Social Security and the
20 Secretary shall develop and transmit to Congress
21 and the Comptroller General of the United States a
22 plan under which the functions of administrative law
23 judges responsible for hearing cases under title
24 XVIII of the Social Security Act (and related provi-
25 sions in title XI of such Act) are transferred from

1 the responsibility of the Commissioner and the So-
2 cial Security Administration to the Secretary and
3 the Department of Health and Human Services.

4 (2) GAO EVALUATION.—The Comptroller Gen-
5 eral of the United States shall evaluate the plan
6 and, not later than the date that is 6 months after
7 the date on which the plan is received by the Comp-
8 troller General, shall submit to Congress a report on
9 such evaluation.

10 (b) TRANSFER OF ADJUDICATION AUTHORITY.—

11 (1) IN GENERAL.—Not earlier than July 1,
12 2005, and not later than October 1, 2005, the Com-
13 missioner of Social Security and the Secretary shall
14 implement the transition plan under subsection (a)
15 and transfer the administrative law judge functions
16 described in such subsection from the Social Secu-
17 rity Administration to the Secretary.

18 (2) ASSURING INDEPENDENCE OF JUDGES.—

19 The Secretary shall assure the independence of ad-
20 ministrative law judges performing the administra-
21 tive law judge functions transferred under para-
22 graph (1) from the Centers for Medicare & Medicaid
23 Services and its contractors. In order to assure such
24 independence, the Secretary shall place such judges
25 in an administrative office that is organizationally

1 and functionally separate from such Centers. Such
2 judges shall report to, and be under the general su-
3 pervision of, the Secretary, but shall not report to,
4 or be subject to supervision by, another other officer
5 of the Department.

6 (3) GEOGRAPHIC DISTRIBUTION.—The Sec-
7 retary shall provide for an appropriate geographic
8 distribution of administrative law judges performing
9 the administrative law judge functions transferred
10 under paragraph (1) throughout the United States
11 to ensure timely access to such judges.

12 (4) HIRING AUTHORITY.—Subject to the
13 amounts provided in advance in appropriations Act,
14 the Secretary shall have authority to hire adminis-
15 trative law judges to hear such cases, giving priority
16 to those judges with prior experience in handling
17 medicare appeals and in a manner consistent with
18 paragraph (3), and to hire support staff for such
19 judges.

20 (5) FINANCING.—Amounts payable under law
21 to the Commissioner for administrative law judges
22 performing the administrative law judge functions
23 transferred under paragraph (1) from the Federal
24 Hospital Insurance Trust Fund and the Federal
25 Supplementary Medical Insurance Trust Fund shall

1 become payable to the Secretary for the functions so
2 transferred.

3 (6) SHARED RESOURCES.—The Secretary shall
4 enter into such arrangements with the Commissioner
5 as may be appropriate with respect to transferred
6 functions of administrative law judges to share office
7 space, support staff, and other resources, with ap-
8 propriate reimbursement from the Trust Funds de-
9 scribed in paragraph (5).

10 (c) INCREASED FINANCIAL SUPPORT.—In addition to
11 any amounts otherwise appropriated, to ensure timely ac-
12 tion on appeals before administrative law judges and the
13 Departmental Appeals Board consistent with section 1869
14 of the Social Security Act (as amended by section 521 of
15 BIPA, 114 Stat. 2763A–534), there are authorized to be
16 appropriated (in appropriate part from the Federal Hos-
17 pital Insurance Trust Fund and the Federal Supple-
18 mentary Medical Insurance Trust Fund) to the Secretary
19 such sums as are necessary for fiscal year 2005 and each
20 subsequent fiscal year to—

21 (1) increase the number of administrative law
22 judges (and their staffs) under subsection (b)(4);

23 (2) improve education and training opportuni-
24 ties for administrative law judges (and their staffs);

25 and

1 (3) increase the staff of the Departmental Ap-
2 peals Board.

3 (d) CONFORMING AMENDMENT.—Section
4 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added
5 by section 522(a) of BIPA (114 Stat. 2763A–543), is
6 amended by striking “of the Social Security Administra-
7 tion”.

8 **SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.**

9 (a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Sec-
10 tion 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA,
11 is amended—

12 (1) in paragraph (1)(A), by inserting “, subject
13 to paragraph (2),” before “to judicial review of the
14 Secretary’s final decision”;

15 (2) in paragraph (1)(F)—

16 (A) by striking clause (ii);

17 (B) by striking “PROCEEDING” and all
18 that follows through “DETERMINATION” and in-
19 serting “DETERMINATIONS AND RECONSIDER-
20 ATIONS”; and

21 (C) by redesignating subclauses (I) and
22 (II) as clauses (i) and (ii) and by moving the
23 indentation of such subclauses (and the matter
24 that follows) 2 ems to the left; and

1 (3) by adding at the end the following new
2 paragraph:

3 “(2) EXPEDITED ACCESS TO JUDICIAL RE-
4 VIEW.—

5 “(A) IN GENERAL.—The Secretary shall
6 establish a process under which a provider of
7 services or supplier that furnishes an item or
8 service or an individual entitled to benefits
9 under part A or enrolled under part B, or both,
10 who has filed an appeal under paragraph (1)
11 may obtain access to judicial review when a re-
12 view panel (described in subparagraph (D)), on
13 its own motion or at the request of the appel-
14 lant, determines that no entity in the adminis-
15 trative appeals process has the authority to de-
16 cide the question of law or regulation relevant
17 to the matters in controversy and that there is
18 no material issue of fact in dispute. The appel-
19 lant may make such request only once with re-
20 spect to a question of law or regulation in a
21 case of an appeal.

22 “(B) PROMPT DETERMINATIONS.—If, after
23 or coincident with appropriately filing a request
24 for an administrative hearing, the appellant re-
25 quests a determination by the appropriate re-

1 view panel that no review panel has the author-
2 ity to decide the question of law or regulations
3 relevant to the matters in controversy and that
4 there is no material issue of fact in dispute and
5 if such request is accompanied by the docu-
6 ments and materials as the appropriate review
7 panel shall require for purposes of making such
8 determination, such review panel shall make a
9 determination on the request in writing within
10 60 days after the date such review panel re-
11 ceives the request and such accompanying docu-
12 ments and materials. Such a determination by
13 such review panel shall be considered a final de-
14 cision and not subject to review by the Sec-
15 retary.

16 “(C) ACCESS TO JUDICIAL REVIEW.—

17 “(i) IN GENERAL.—If the appropriate
18 review panel—

19 “(I) determines that there are no
20 material issues of fact in dispute and
21 that the only issue is one of law or
22 regulation that no review panel has
23 the authority to decide; or

1 “(II) fails to make such deter-
2 mination within the period provided
3 under subparagraph (B);
4 then the appellant may bring a civil action
5 as described in this subparagraph.

6 “(ii) DEADLINE FOR FILING.—Such
7 action shall be filed, in the case described
8 in—

9 “(I) clause (i)(I), within 60 days
10 of date of the determination described
11 in such subparagraph; or

12 “(II) clause (i)(II), within 60
13 days of the end of the period provided
14 under subparagraph (B) for the deter-
15 mination.

16 “(iii) VENUE.—Such action shall be
17 brought in the district court of the United
18 States for the judicial district in which the
19 appellant is located (or, in the case of an
20 action brought jointly by more than one
21 applicant, the judicial district in which the
22 greatest number of applicants are located)
23 or in the district court for the District of
24 Columbia.

1 “(iv) INTEREST ON AMOUNTS IN CON-
2 TROVERSY.—Where a provider of services
3 or supplier seeks judicial review pursuant
4 to this paragraph, the amount in con-
5 troversy shall be subject to annual interest
6 beginning on the first day of the first
7 month beginning after the 60-day period
8 as determined pursuant to clause (ii) and
9 equal to the rate of interest on obligations
10 issued for purchase by the Federal Hos-
11 pital Insurance Trust Fund and by the
12 Federal Supplementary Medical Insurance
13 Trust Fund for the month in which the
14 civil action authorized under this para-
15 graph is commenced, to be awarded by the
16 reviewing court in favor of the prevailing
17 party. No interest awarded pursuant to the
18 preceding sentence shall be deemed income
19 or cost for the purposes of determining re-
20 imbursement due providers of services or
21 suppliers under this Act.

22 “(D) REVIEW PANELS.—For purposes of
23 this subsection, a ‘review panel’ is a panel con-
24 sisting of 3 members (who shall be administra-
25 tive law judges, members of the Departmental

1 Appeals Board, or qualified individuals associ-
2 ated with a qualified independent contractor (as
3 defined in subsection (c)(2)) or with another
4 independent entity) designated by the Secretary
5 for purposes of making determinations under
6 this paragraph.”.

7 (b) APPLICATION TO PROVIDER AGREEMENT DETER-
8 MINATIONS.—Section 1866(h)(1) (42 U.S.C.
9 1395cc(h)(1)) is amended—

10 (1) by inserting “(A)” after “(h)(1)”; and

11 (2) by adding at the end the following new sub-
12 paragraph:

13 “(B) An institution or agency described in subpara-
14 graph (A) that has filed for a hearing under subparagraph
15 (A) shall have expedited access to judicial review under
16 this subparagraph in the same manner as providers of
17 services, suppliers, and individuals entitled to benefits
18 under part A or enrolled under part B, or both, may ob-
19 tain expedited access to judicial review under the process
20 established under section 1869(b)(2). Nothing in this sub-
21 paragraph shall be construed to affect the application of
22 any remedy imposed under section 1819 during the pend-
23 ency of an appeal under this subparagraph.”.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to appeals filed on or after October
3 1, 2004.

4 (d) EXPEDITED REVIEW OF CERTAIN PROVIDER
5 AGREEMENT DETERMINATIONS.—

6 (1) TERMINATION AND CERTAIN OTHER IMME-
7 DIATE REMEDIES.—The Secretary shall develop and
8 implement a process to expedite proceedings under
9 sections 1866(h) of the Social Security Act (42
10 U.S.C. 1395cc(h)) in which the remedy of termi-
11 nation of participation, or a remedy described in
12 clause (i) or (iii) of section 1819(h)(2)(B) of such
13 Act (42 U.S.C. 1395i–3(h)(2)(B)) which is applied
14 on an immediate basis, has been imposed. Under
15 such process priority shall be provided in cases of
16 termination.

17 (2) INCREASED FINANCIAL SUPPORT.—In addi-
18 tion to any amounts otherwise appropriated, to re-
19 duce by 50 percent the average time for administra-
20 tive determinations on appeals under section
21 1866(h) of the Social Security Act (42 U.S.C.
22 1395cc(h)), there are authorized to be appropriated
23 (in appropriate part from the Federal Hospital In-
24 surance Trust Fund and the Federal Supplementary
25 Medical Insurance Trust Fund) to the Secretary

1 such additional sums for fiscal year 2005 and each
2 subsequent fiscal year as may be necessary. The
3 purposes for which such amounts are available in-
4 clude increasing the number of administrative law
5 judges (and their staffs) and the appellate level staff
6 at the Departmental Appeals Board of the Depart-
7 ment of Health and Human Services and educating
8 such judges and staffs on long-term care issues.

9 (e) PROCESS FOR REINSTATEMENT OF APPROVAL OF
10 CERTAIN SNF TRAINING PROGRAMS.—

11 (1) IN GENERAL.—In the case of a termination
12 of approval of a nurse aide training program de-
13 scribed in paragraph (2) of a skilled nursing facility,
14 the Secretary shall develop and implement a process
15 for the reinstatement of approval of such program
16 before the end of the mandatory 2 year disapproval
17 period if the facility and program is certified by the
18 Secretary, in coordination with the applicable State
19 survey and certification agency and after public no-
20 tice, as being in compliance with applicable require-
21 ments and as having remedied any deficiencies in
22 the facility or program that resulted in noncompli-
23 ance.

24 (2) TERMINATION OF APPROVAL DESCRIBED.—

25 A termination of approval of a training program de-

1 scribed in this paragraph is a mandatory 2-year dis-
2 approval provided for under section
3 1819(f)(2)(B)(iii) of the Social Security Act (42
4 U.S.C. 1395i-3(f)(2)(B)(iii)) if the only basis for
5 the mandatory disapproval was the assessment of a
6 civil money penalty of not less than \$5,000.

7 **SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.**

8 (a) **REQUIRING FULL AND EARLY PRESENTATION OF**
9 **EVIDENCE.—**

10 (1) **IN GENERAL.—**Section 1869(b) (42 U.S.C.
11 1395ff(b)), as amended by BIPA and as amended by
12 section 932(a), is further amended by adding at the
13 end the following new paragraph:

14 “(3) **REQUIRING FULL AND EARLY PRESEN-**
15 **TATION OF EVIDENCE BY PROVIDERS.—**A provider
16 of services or supplier may not introduce evidence in
17 any appeal under this section that was not presented
18 at the reconsideration conducted by the qualified
19 independent contractor under subsection (c), unless
20 there is good cause which precluded the introduction
21 of such evidence at or before that reconsideration.”.

22 (2) **EFFECTIVE DATE.—**The amendment made
23 by paragraph (1) shall take effect on October 1,
24 2004.

1 (b) USE OF PATIENTS' MEDICAL RECORDS.—Section
2 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as
3 amended by BIPA, is amended by inserting “(including
4 the medical records of the individual involved)” after
5 “clinical experience”.

6 (c) NOTICE REQUIREMENTS FOR MEDICARE AP-
7 PEALS.—

8 (1) INITIAL DETERMINATIONS AND REDETER-
9 MINATIONS.—Section 1869(a) (42 U.S.C.
10 1395ff(a)), as amended by BIPA, is amended by
11 adding at the end the following new paragraphs:

12 “(4) REQUIREMENTS OF NOTICE OF DETER-
13 MINATIONS.—With respect to an initial determina-
14 tion insofar as it results in a denial of a claim for
15 benefits—

16 “(A) the written notice on the determina-
17 tion shall include—

18 “(i) the reasons for the determination,
19 including whether a local medical review
20 policy or a local coverage determination
21 was used;

22 “(ii) the procedures for obtaining ad-
23 ditional information concerning the deter-
24 mination, including the information de-
25 scribed in subparagraph (B); and

1 “(iii) notification of the right to seek
2 a redetermination or otherwise appeal the
3 determination and instructions on how to
4 initiate such a redetermination under this
5 section; and

6 “(B) the person provided such notice may
7 obtain, upon request, the specific provision of
8 the policy, manual, or regulation used in mak-
9 ing the determination.

10 “(5) REQUIREMENTS OF NOTICE OF REDETER-
11 MINATIONS.—With respect to a redetermination in-
12 sofar as it results in a denial of a claim for bene-
13 fits—

14 “(A) the written notice on the redeter-
15 mination shall include—

16 “(i) the specific reasons for the rede-
17 termination;

18 “(ii) as appropriate, a summary of the
19 clinical or scientific evidence used in mak-
20 ing the redetermination;

21 “(iii) a description of the procedures
22 for obtaining additional information con-
23 cerning the redetermination; and

24 “(iv) notification of the right to ap-
25 peal the redetermination and instructions

1 on how to initiate such an appeal under
2 this section;

3 “(B) such written notice shall be provided
4 in printed form and written in a manner cal-
5 culated to be understood by the individual enti-
6 tled to benefits under part A or enrolled under
7 part B, or both; and

8 “(C) the person provided such notice may
9 obtain, upon request, information on the spe-
10 cific provision of the policy, manual, or regula-
11 tion used in making the redetermination.”.

12 (2) RECONSIDERATIONS.—Section
13 1869(e)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as
14 amended by BIPA, is amended—

15 (A) by inserting “be written in a manner
16 calculated to be understood by the individual
17 entitled to benefits under part A or enrolled
18 under part B, or both, and shall include (to the
19 extent appropriate)” after “in writing, ”; and

20 (B) by inserting “and a notification of the
21 right to appeal such determination and instruc-
22 tions on how to initiate such appeal under this
23 section” after “such decision,”.

24 (3) APPEALS.—Section 1869(d) (42 U.S.C.
25 1395ff(d)), as amended by BIPA, is amended—

1 (A) in the heading, by inserting “; NO-
2 TICE” after “SECRETARY”; and

3 (B) by adding at the end the following new
4 paragraph:

5 “(4) NOTICE.—Notice of the decision of an ad-
6 ministrative law judge shall be in writing in a man-
7 ner calculated to be understood by the individual en-
8 titled to benefits under part A or enrolled under part
9 B, or both, and shall include—

10 “(A) the specific reasons for the deter-
11 mination (including, to the extent appropriate,
12 a summary of the clinical or scientific evidence
13 used in making the determination);

14 “(B) the procedures for obtaining addi-
15 tional information concerning the decision; and

16 “(C) notification of the right to appeal the
17 decision and instructions on how to initiate
18 such an appeal under this section.”.

19 (4) SUBMISSION OF RECORD FOR APPEAL.—
20 Section 1869(c)(3)(J)(i) (42 U.S.C.
21 1395ff(c)(3)(J)(i)) by striking “prepare” and insert-
22 ing “submit” and by striking “with respect to” and
23 all that follows through “and relevant policies”.

24 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

1 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED
2 INDEPENDENT CONTRACTORS.—Section 1869(c)(3)
3 (42 U.S.C. 1395ff(c)(3)), as amended by BIPA, is
4 amended—

5 (A) in subparagraph (A), by striking “suf-
6 ficient training and expertise in medical science
7 and legal matters” and inserting “sufficient
8 medical, legal, and other expertise (including
9 knowledge of the program under this title) and
10 sufficient staffing”; and

11 (B) by adding at the end the following new
12 subparagraph:

13 “(K) INDEPENDENCE REQUIREMENTS.—

14 “(i) IN GENERAL.—Subject to clause
15 (ii), a qualified independent contractor
16 shall not conduct any activities in a case
17 unless the entity—

18 “(I) is not a related party (as de-
19 fined in subsection (g)(5));

20 “(II) does not have a material fa-
21 milial, financial, or professional rela-
22 tionship with such a party in relation
23 to such case; and

24 “(III) does not otherwise have a
25 conflict of interest with such a party.

1 “(ii) EXCEPTION FOR REASONABLE
2 COMPENSATION.—Nothing in clause (i)
3 shall be construed to prohibit receipt by a
4 qualified independent contractor of com-
5 pensation from the Secretary for the con-
6 duct of activities under this section if the
7 compensation is provided consistent with
8 clause (iii).

9 “(iii) LIMITATIONS ON ENTITY COM-
10 PENSATION.—Compensation provided by
11 the Secretary to a qualified independent
12 contractor in connection with reviews
13 under this section shall not be contingent
14 on any decision rendered by the contractor
15 or by any reviewing professional.”.

16 (2) ELIGIBILITY REQUIREMENTS FOR REVIEW-
17 ERS.—Section 1869 (42 U.S.C. 1395ff), as amended
18 by BIPA, is amended—

19 (A) by amending subsection (c)(3)(D) to
20 read as follows:

21 “(D) QUALIFICATIONS FOR REVIEWERS.—
22 The requirements of subsection (g) shall be met
23 (relating to qualifications of reviewing profes-
24 sionals).”; and

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

3 “(g) QUALIFICATIONS OF REVIEWERS.—

4 “(1) IN GENERAL.—In reviewing determina-
5 tions under this section, a qualified independent con-
6 tractor shall assure that—

7 “(A) each individual conducting a review
8 shall meet the qualifications of paragraph (2);

9 “(B) compensation provided by the con-
10 tractor to each such reviewer is consistent with
11 paragraph (3); and

12 “(C) in the case of a review by a panel de-
13 scribed in subsection (c)(3)(B) composed of
14 physicians or other health care professionals
15 (each in this subsection referred to as a ‘review-
16 ing professional’), a reviewing professional
17 meets the qualifications described in paragraph
18 (4) and, where a claim is regarding the fur-
19 nishing of treatment by a physician (allopathic
20 or osteopathic) or the provision of items or
21 services by a physician (allopathic or osteo-
22 pathic), a reviewing professional shall be a phy-
23 sician (allopathic or osteopathic).

24 “(2) INDEPENDENCE.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), each individual conducting a review
3 in a case shall—

4 “(i) not be a related party (as defined
5 in paragraph (5));

6 “(ii) not have a material familial, fi-
7 nancial, or professional relationship with
8 such a party in the case under review; and

9 “(iii) not otherwise have a conflict of
10 interest with such a party.

11 “(B) EXCEPTION.—Nothing in subpara-
12 graph (A) shall be construed to—

13 “(i) prohibit an individual, solely on
14 the basis of a participation agreement with
15 a fiscal intermediary, carrier, or other con-
16 tractor, from serving as a reviewing profes-
17 sional if—

18 “(I) the individual is not involved
19 in the provision of items or services in
20 the case under review;

21 “(II) the fact of such an agree-
22 ment is disclosed to the Secretary and
23 the individual entitled to benefits
24 under part A or enrolled under part

1 B, or both, (or authorized representa-
2 tive) and neither party objects; and

3 “(III) the individual is not an
4 employee of the intermediary, carrier,
5 or contractor and does not provide
6 services exclusively or primarily to or
7 on behalf of such intermediary, car-
8 rier, or contractor;

9 “(ii) prohibit an individual who has
10 staff privileges at the institution where the
11 treatment involved takes place from serv-
12 ing as a reviewer merely on the basis of
13 having such staff privileges if the existence
14 of such privileges is disclosed to the Sec-
15 retary and such individual (or authorized
16 representative), and neither party objects;
17 or

18 “(iii) prohibit receipt of compensation
19 by a reviewing professional from a con-
20 tractor if the compensation is provided
21 consistent with paragraph (3).

22 For purposes of this paragraph, the term ‘par-
23 ticipation agreement’ means an agreement re-
24 lating to the provision of health care services by
25 the individual and does not include the provi-

1 sion of services as a reviewer under this sub-
2 section.

3 “(3) LIMITATIONS ON REVIEWER COMPENSA-
4 TION.—Compensation provided by a qualified inde-
5 pendent contractor to a reviewer in connection with
6 a review under this section shall not be contingent
7 on the decision rendered by the reviewer.

8 “(4) LICENSURE AND EXPERTISE.—Each re-
9 viewing professional shall be—

10 “(A) a physician (allopathic or osteopathic)
11 who is appropriately credentialed or licensed in
12 one or more States to deliver health care serv-
13 ices and has medical expertise in the field of
14 practice that is appropriate for the items or
15 services at issue; or

16 “(B) a health care professional who is le-
17 gally authorized in one or more States (in ac-
18 cordance with State law or the State regulatory
19 mechanism provided by State law) to furnish
20 the health care items or services at issue and
21 has medical expertise in the field of practice
22 that is appropriate for such items or services.

23 “(5) RELATED PARTY DEFINED.—For purposes
24 of this section, the term ‘related party’ means, with
25 respect to a case under this title involving a specific

1 individual entitled to benefits under part A or en-
2 rolled under part B, or both, any of the following:

3 “(A) The Secretary, the medicare adminis-
4 trative contractor involved, or any fiduciary, of-
5 ficer, director, or employee of the Department
6 of Health and Human Services, or of such con-
7 tractor.

8 “(B) The individual (or authorized rep-
9 resentative).

10 “(C) The health care professional that pro-
11 vides the items or services involved in the case.

12 “(D) The institution at which the items or
13 services (or treatment) involved in the case are
14 provided.

15 “(E) The manufacturer of any drug or
16 other item that is included in the items or serv-
17 ices involved in the case.

18 “(F) Any other party determined under
19 any regulations to have a substantial interest in
20 the case involved.”.

21 (3) REDUCING MINIMUM NUMBER OF QUALI-
22 FIED INDEPENDENT CONTRACTORS.—Section
23 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by
24 striking “not fewer than 12 qualified independent
25 contractors under this subsection” and inserting

1 “with a sufficient number of qualified independent
2 contractors (but not fewer than 4 such contractors)
3 to conduct reconsiderations consistent with the time-
4 frames applicable under this subsection”.

5 (4) EFFECTIVE DATE.—The amendments made
6 by paragraphs (1) and (2) shall be effective as if in-
7 cluded in the enactment of the respective provisions
8 of subtitle C of title V of BIPA, (114 Stat. 2763A–
9 534).

10 (5) TRANSITION.—In applying section 1869(g)
11 of the Social Security Act (as added by paragraph
12 (2)), any reference to a medicare administrative con-
13 tractor shall be deemed to include a reference to a
14 fiscal intermediary under section 1816 of the Social
15 Security Act (42 U.S.C. 1395h) and a carrier under
16 section 1842 of such Act (42 U.S.C. 1395u).

17 **SEC. 934. PREPAYMENT REVIEW.**

18 (a) IN GENERAL.—Section 1874A, as added by sec-
19 tion 911(a)(1) and as amended by sections 912(b),
20 921(b)(1), and 921(c)(1), is further amended by adding
21 at the end the following new subsection:

22 “(h) CONDUCT OF PREPAYMENT REVIEW.—

23 “(1) CONDUCT OF RANDOM PREPAYMENT RE-
24 VIEW.—

1 “(A) IN GENERAL.—A medicare adminis-
2 trative contractor may conduct random prepay-
3 ment review only to develop a contractor-wide
4 or program-wide claims payment error rates or
5 under such additional circumstances as may be
6 provided under regulations, developed in con-
7 sultation with providers of services and sup-
8 pliers.

9 “(B) USE OF STANDARD PROTOCOLS
10 WHEN CONDUCTING PREPAYMENT REVIEWS.—
11 When a medicare administrative contractor con-
12 ducts a random prepayment review, the con-
13 tractor may conduct such review only in accord-
14 ance with a standard protocol for random pre-
15 payment audits developed by the Secretary.

16 “(C) CONSTRUCTION.—Nothing in this
17 paragraph shall be construed as preventing the
18 denial of payments for claims actually reviewed
19 under a random prepayment review.

20 “(D) RANDOM PREPAYMENT REVIEW.—
21 For purposes of this subsection, the term ‘ran-
22 dom prepayment review’ means a demand for
23 the production of records or documentation ab-
24 sent cause with respect to a claim.

1 “(2) LIMITATIONS ON NON-RANDOM PREPAY-
2 MENT REVIEW.—

3 “(A) LIMITATIONS ON INITIATION OF NON-
4 RANDOM PREPAYMENT REVIEW.—A medicare
5 administrative contractor may not initiate non-
6 random prepayment review of a provider of
7 services or supplier based on the initial identi-
8 fication by that provider of services or supplier
9 of an improper billing practice unless there is a
10 likelihood of sustained or high level of payment
11 error (as defined in subsection (i)(3)(A)).

12 “(B) TERMINATION OF NON-RANDOM PRE-
13 PAYMENT REVIEW.—The Secretary shall issue
14 regulations relating to the termination, includ-
15 ing termination dates, of non-random prepay-
16 ment review. Such regulations may vary such a
17 termination date based upon the differences in
18 the circumstances triggering prepayment re-
19 view.”.

20 (b) EFFECTIVE DATE.—

21 (1) IN GENERAL.—Except as provided in this
22 subsection, the amendment made by subsection (a)
23 shall take effect 1 year after the date of the enact-
24 ment of this Act.

1 (2) DEADLINE FOR PROMULGATION OF CER-
2 TAIN REGULATIONS.—The Secretary shall first issue
3 regulations under section 1874A(h) of the Social Se-
4 curity Act, as added by subsection (a), by not later
5 than 1 year after the date of the enactment of this
6 Act.

7 (3) APPLICATION OF STANDARD PROTOCOLS
8 FOR RANDOM PREPAYMENT REVIEW.—Section
9 1874A(h)(1)(B) of the Social Security Act, as added
10 by subsection (a), shall apply to random prepayment
11 reviews conducted on or after such date (not later
12 than 1 year after the date of the enactment of this
13 Act) as the Secretary shall specify.

14 (c) APPLICATION TO FISCAL INTERMEDIARIES AND
15 CARRIERS.—The provisions of section 1874A(h) of the So-
16 cial Security Act, as added by subsection (a), shall apply
17 to each fiscal intermediary under section 1816 of the So-
18 cial Security Act (42 U.S.C. 1395h) and each carrier
19 under section 1842 of such Act (42 U.S.C. 1395u) in the
20 same manner as they apply to medicare administrative
21 contractors under such provisions.

22 **SEC. 935. RECOVERY OF OVERPAYMENTS.**

23 (a) IN GENERAL.—Section 1893 (42 U.S.C.
24 1395ddd) is amended by adding at the end the following
25 new subsection:

1 “(f) RECOVERY OF OVERPAYMENTS.—

2 “(1) USE OF REPAYMENT PLANS.—

3 “(A) IN GENERAL.—If the repayment,
4 within 30 days by a provider of services or sup-
5 plier, of an overpayment under this title would
6 constitute a hardship (as defined in subpara-
7 graph (B)), subject to subparagraph (C), upon
8 request of the provider of services or supplier
9 the Secretary shall enter into a plan with the
10 provider of services or supplier for the repay-
11 ment (through offset or otherwise) of such over-
12 payment over a period of at least 6 months but
13 not longer than 3 years (or not longer than 5
14 years in the case of extreme hardship, as deter-
15 mined by the Secretary). Interest shall accrue
16 on the balance through the period of repay-
17 ment. Such plan shall meet terms and condi-
18 tions determined to be appropriate by the Sec-
19 retary.

20 “(B) HARDSHIP.—

21 “(i) IN GENERAL.—For purposes of
22 subparagraph (A), the repayment of an
23 overpayment (or overpayments) within 30
24 days is deemed to constitute a hardship
25 if—

1 “(I) in the case of a provider of
2 services that files cost reports, the ag-
3 gregate amount of the overpayments
4 exceeds 10 percent of the amount paid
5 under this title to the provider of
6 services for the cost reporting period
7 covered by the most recently sub-
8 mitted cost report; or

9 “(II) in the case of another pro-
10 vider of services or supplier, the ag-
11 gregate amount of the overpayments
12 exceeds 10 percent of the amount paid
13 under this title to the provider of
14 services or supplier for the previous
15 calendar year.

16 “(ii) RULE OF APPLICATION.—The
17 Secretary shall establish rules for the ap-
18 plication of this subparagraph in the case
19 of a provider of services or supplier that
20 was not paid under this title during the
21 previous year or was paid under this title
22 only during a portion of that year.

23 “(iii) TREATMENT OF PREVIOUS
24 OVERPAYMENTS.—If a provider of services
25 or supplier has entered into a repayment

1 plan under subparagraph (A) with respect
2 to a specific overpayment amount, such
3 payment amount under the repayment plan
4 shall not be taken into account under
5 clause (i) with respect to subsequent over-
6 payment amounts.

7 “(C) EXCEPTIONS.—Subparagraph (A)
8 shall not apply if—

9 “(i) the Secretary has reason to sus-
10 pect that the provider of services or sup-
11 plier may file for bankruptcy or otherwise
12 cease to do business or discontinue partici-
13 pation in the program under this title; or

14 “(ii) there is an indication of fraud or
15 abuse committed against the program.

16 “(D) IMMEDIATE COLLECTION IF VIOLA-
17 TION OF REPAYMENT PLAN.—If a provider of
18 services or supplier fails to make a payment in
19 accordance with a repayment plan under this
20 paragraph, the Secretary may immediately seek
21 to offset or otherwise recover the total balance
22 outstanding (including applicable interest)
23 under the repayment plan.

24 “(E) RELATION TO NO FAULT PROVI-
25 SION.—Nothing in this paragraph shall be con-

1 strued as affecting the application of section
2 1870(c) (relating to no adjustment in the cases
3 of certain overpayments).

4 “(2) LIMITATION ON RECOUPMENT.—

5 “(A) IN GENERAL.—In the case of a pro-
6 vider of services or supplier that is determined
7 to have received an overpayment under this title
8 and that seeks a reconsideration by a qualified
9 independent contractor on such determination
10 under section 1869(b)(1), the Secretary may
11 not take any action (or authorize any other per-
12 son, including any medicare contractor, as de-
13 fined in subparagraph (C)) to recoup the over-
14 payment until the date the decision on the re-
15 consideration has been rendered. If the provi-
16 sions of section 1869(b)(1) (providing for such
17 a reconsideration by a qualified independent
18 contractor) are not in effect, in applying the
19 previous sentence any reference to such a recon-
20 sideration shall be treated as a reference to a
21 redetermination by the fiscal intermediary or
22 carrier involved.

23 “(B) COLLECTION WITH INTEREST.—Inso-
24 far as the determination on such appeal is
25 against the provider of services or supplier, in-

1 terest on the overpayment shall accrue on and
2 after the date of the original notice of overpay-
3 ment. Insofar as such determination against the
4 provider of services or supplier is later reversed,
5 the Secretary shall provide for repayment of the
6 amount recouped plus interest at the same rate
7 as would apply under the previous sentence for
8 the period in which the amount was recouped.

9 “(C) MEDICARE CONTRACTOR DEFINED.—

10 For purposes of this subsection, the term ‘medi-
11 care contractor’ has the meaning given such
12 term in section 1889(g).

13 “(3) LIMITATION ON USE OF EXTRAPO-
14 LATION.—A medicare contractor may not use ex-
15 trapolation to determine overpayment amounts to be
16 recovered by recoupment, offset, or otherwise un-
17 less—

18 “(A) there is a sustained or high level of
19 payment error (as defined by the Secretary by
20 regulation); or

21 “(B) documented educational intervention
22 has failed to correct the payment error (as de-
23 termined by the Secretary).

24 “(4) PROVISION OF SUPPORTING DOCUMENTA-
25 TION.—In the case of a provider of services or sup-

1 plier with respect to which amounts were previously
2 overpaid, a medicare contractor may request the
3 periodic production of records or supporting docu-
4 mentation for a limited sample of submitted claims
5 to ensure that the previous practice is not con-
6 tinuing.

7 “(5) CONSENT SETTLEMENT REFORMS.—

8 “(A) IN GENERAL.—The Secretary may
9 use a consent settlement (as defined in sub-
10 paragraph (D)) to settle a projected overpay-
11 ment.

12 “(B) OPPORTUNITY TO SUBMIT ADDI-
13 TIONAL INFORMATION BEFORE CONSENT SET-
14 TLEMENT OFFER.—Before offering a provider
15 of services or supplier a consent settlement, the
16 Secretary shall—

17 “(i) communicate to the provider of
18 services or supplier—

19 “(I) that, based on a review of
20 the medical records requested by the
21 Secretary, a preliminary evaluation of
22 those records indicates that there
23 would be an overpayment;

24 “(II) the nature of the problems
25 identified in such evaluation; and

1 “(III) the steps that the provider
2 of services or supplier should take to
3 address the problems; and

4 “(ii) provide for a 45-day period dur-
5 ing which the provider of services or sup-
6 plier may furnish additional information
7 concerning the medical records for the
8 claims that had been reviewed.

9 “(C) CONSENT SETTLEMENT OFFER.—The
10 Secretary shall review any additional informa-
11 tion furnished by the provider of services or
12 supplier under subparagraph (B)(ii). Taking
13 into consideration such information, the Sec-
14 retary shall determine if there still appears to
15 be an overpayment. If so, the Secretary—

16 “(i) shall provide notice of such deter-
17 mination to the provider of services or sup-
18 plier, including an explanation of the rea-
19 son for such determination; and

20 “(ii) in order to resolve the overpay-
21 ment, may offer the provider of services or
22 supplier—

23 “(I) the opportunity for a statis-
24 tically valid random sample; or

25 “(II) a consent settlement.

1 The opportunity provided under clause (ii)(I)
2 does not waive any appeal rights with respect to
3 the alleged overpayment involved.

4 “(D) CONSENT SETTLEMENT DEFINED.—
5 For purposes of this paragraph, the term ‘con-
6 sent settlement’ means an agreement between
7 the Secretary and a provider of services or sup-
8 plier whereby both parties agree to settle a pro-
9 jected overpayment based on less than a statis-
10 tically valid sample of claims and the provider
11 of services or supplier agrees not to appeal the
12 claims involved.

13 “(6) NOTICE OF OVER-UTILIZATION OF
14 CODES.—The Secretary shall establish, in consulta-
15 tion with organizations representing the classes of
16 providers of services and suppliers, a process under
17 which the Secretary provides for notice to classes of
18 providers of services and suppliers served by the con-
19 tractor in cases in which the contractor has identi-
20 fied that particular billing codes may be overutilized
21 by that class of providers of services or suppliers
22 under the programs under this title (or provisions of
23 title XI insofar as they relate to such programs).

24 “(7) PAYMENT AUDITS.—

1 “(A) WRITTEN NOTICE FOR POST-PAY-
2 MENT AUDITS.—Subject to subparagraph (C), if
3 a medicare contractor decides to conduct a
4 post-payment audit of a provider of services or
5 supplier under this title, the contractor shall
6 provide the provider of services or supplier with
7 written notice (which may be in electronic form)
8 of the intent to conduct such an audit.

9 “(B) EXPLANATION OF FINDINGS FOR ALL
10 AUDITS.—Subject to subparagraph (C), if a
11 medicare contractor audits a provider of serv-
12 ices or supplier under this title, the contractor
13 shall—

14 “(i) give the provider of services or
15 supplier a full review and explanation of
16 the findings of the audit in a manner that
17 is understandable to the provider of serv-
18 ices or supplier and permits the develop-
19 ment of an appropriate corrective action
20 plan;

21 “(ii) inform the provider of services or
22 supplier of the appeal rights under this
23 title as well as consent settlement options
24 (which are at the discretion of the Sec-
25 retary);

1 “(iii) give the provider of services or
2 supplier an opportunity to provide addi-
3 tional information to the contractor; and

4 “(iv) take into account information
5 provided, on a timely basis, by the provider
6 of services or supplier under clause (iii).

7 “(C) EXCEPTION.—Subparagraphs (A)
8 and (B) shall not apply if the provision of no-
9 tice or findings would compromise pending law
10 enforcement activities, whether civil or criminal,
11 or reveal findings of law enforcement-related
12 audits.

13 “(8) STANDARD METHODOLOGY FOR PROBE
14 SAMPLING.—The Secretary shall establish a stand-
15 ard methodology for medicare contractors to use in
16 selecting a sample of claims for review in the case
17 of an abnormal billing pattern.”.

18 (b) EFFECTIVE DATES AND DEADLINES.—

19 (1) USE OF REPAYMENT PLANS.—Section
20 1893(f)(1) of the Social Security Act, as added by
21 subsection (a), shall apply to requests for repayment
22 plans made after the date of the enactment of this
23 Act.

24 (2) LIMITATION ON RECOUPMENT.—Section
25 1893(f)(2) of the Social Security Act, as added by

1 subsection (a), shall apply to actions taken after the
2 date of the enactment of this Act.

3 (3) USE OF EXTRAPOLATION.—Section
4 1893(f)(3) of the Social Security Act, as added by
5 subsection (a), shall apply to statistically valid ran-
6 dom samples initiated after the date that is 1 year
7 after the date of the enactment of this Act.

8 (4) PROVISION OF SUPPORTING DOCUMENTA-
9 TION.—Section 1893(f)(4) of the Social Security
10 Act, as added by subsection (a), shall take effect on
11 the date of the enactment of this Act.

12 (5) CONSENT SETTLEMENT.—Section
13 1893(f)(5) of the Social Security Act, as added by
14 subsection (a), shall apply to consent settlements en-
15 tered into after the date of the enactment of this
16 Act.

17 (6) NOTICE OF OVERUTILIZATION.—Not later
18 than 1 year after the date of the enactment of this
19 Act, the Secretary shall first establish the process
20 for notice of overutilization of billing codes under
21 section 1893A(f)(6) of the Social Security Act, as
22 added by subsection (a).

23 (7) PAYMENT AUDITS.—Section 1893A(f)(7) of
24 the Social Security Act, as added by subsection (a),

1 shall apply to audits initiated after the date of the
2 enactment of this Act.

3 (8) STANDARD FOR ABNORMAL BILLING PAT-
4 TERNS.—Not later than 1 year after the date of the
5 enactment of this Act, the Secretary shall first es-
6 tablish a standard methodology for selection of sam-
7 ple claims for abnormal billing patterns under sec-
8 tion 1893(f)(8) of the Social Security Act, as added
9 by subsection (a).

10 **SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF AP-
11 PEAL.**

12 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc)
13 is amended—

14 (1) by adding at the end of the heading the fol-
15 lowing: “; ENROLLMENT PROCESSES”; and

16 (2) by adding at the end the following new sub-
17 section:

18 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF
19 SERVICES AND SUPPLIERS.—

20 “(1) ENROLLMENT PROCESS.—

21 “(A) IN GENERAL.—The Secretary shall
22 establish by regulation a process for the enroll-
23 ment of providers of services and suppliers
24 under this title.

1 “(B) DEADLINES.—The Secretary shall es-
2 tablish by regulation procedures under which
3 there are deadlines for actions on applications
4 for enrollment (and, if applicable, renewal of
5 enrollment). The Secretary shall monitor the
6 performance of medicare administrative con-
7 tractors in meeting the deadlines established
8 under this subparagraph.

9 “(C) CONSULTATION BEFORE CHANGING
10 PROVIDER ENROLLMENT FORMS.—The Sec-
11 retary shall consult with providers of services
12 and suppliers before making changes in the pro-
13 vider enrollment forms required of such pro-
14 viders and suppliers to be eligible to submit
15 claims for which payment may be made under
16 this title.

17 “(2) HEARING RIGHTS IN CASES OF DENIAL OR
18 NON-RENEWAL.—A provider of services or supplier
19 whose application to enroll (or, if applicable, to
20 renew enrollment) under this title is denied may
21 have a hearing and judicial review of such denial
22 under the procedures that apply under subsection
23 (h)(1)(A) to a provider of services that is dissatisfied
24 with a determination by the Secretary.”.

25 (b) EFFECTIVE DATES.—

1 (1) ENROLLMENT PROCESS.—The Secretary
2 shall provide for the establishment of the enrollment
3 process under section 1866(j)(1) of the Social Secu-
4 rity Act, as added by subsection (a)(2), within 6
5 months after the date of the enactment of this Act.

6 (2) CONSULTATION.—Section 1866(j)(1)(C) of
7 the Social Security Act, as added by subsection
8 (a)(2), shall apply with respect to changes in pro-
9 vider enrollment forms made on or after January 1,
10 2004.

11 (3) HEARING RIGHTS.—Section 1866(j)(2) of
12 the Social Security Act, as added by subsection
13 (a)(2), shall apply to denials occurring on or after
14 such date (not later than 1 year after the date of
15 the enactment of this Act) as the Secretary specifies.

16 **SEC. 937. PROCESS FOR CORRECTION OF MINOR ERRORS**
17 **AND OMISSIONS WITHOUT PURSUING AP-**
18 **PEALS PROCESS.**

19 (a) CLAIMS.—The Secretary shall develop, in con-
20 sultation with appropriate medicare contractors (as de-
21 fined in section 1889(g) of the Social Security Act, as in-
22 serted by section 301(a)(1)) and representatives of pro-
23 viders of services and suppliers, a process whereby, in the
24 case of minor errors or omissions (as defined by the Sec-
25 retary) that are detected in the submission of claims under

1 the programs under title XVIII of such Act, a provider
2 of services or supplier is given an opportunity to correct
3 such an error or omission without the need to initiate an
4 appeal. Such process shall include the ability to resubmit
5 corrected claims.

6 (b) PERMITTING USE OF CORRECTED AND SUPPLE-
7 MENTARY DATA.—

8 (1) IN GENERAL.—Section 1886(d)(10)(D)(vi)
9 (42 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by
10 adding after subclause (II) at the end the following:
11 “Notwithstanding subclause (I), a hospital may submit,
12 and the Secretary may accept upon verification, data that
13 corrects or supplements the data described in such sub-
14 clause without regard to whether the corrected or supple-
15 mentary data relate to a cost report that has been set-
16 tled.”.

17 (2) EFFECTIVE DATE.—The amendment made
18 by paragraph (1) shall apply to fiscal years begin-
19 ning with fiscal year 2004.

20 (3) SUBMITTAL AND RESUBMITTAL OF APPLI-
21 CATIONS PERMITTED FOR FISCAL YEAR 2004.—

22 (A) IN GENERAL.—Notwithstanding any
23 other provision of law, a hospital may submit
24 (or resubmit) an application for a change de-
25 scribed in section 1886(d)(10)(C)(i)(II) of the

1 Social Security Act for fiscal year 2004 if the
2 hospital demonstrates on a timely basis to the
3 satisfaction of the Secretary that the use of cor-
4 rected or supplementary data under the amend-
5 ment made by paragraph (1) would materially
6 affect the approval of such an application.

7 (B) APPLICATION OF BUDGET NEU-
8 TRALITY.—If one or more hospital’s applica-
9 tions are approved as a result of paragraph (1)
10 and subparagraph (A) for fiscal year 2004, the
11 Secretary shall make a proportional adjustment
12 in the standardized amounts determined under
13 section 1886(d)(3) of the Social Security Act
14 (42 U.S.C. 1395ww(d)(3)) for fiscal year 2004
15 to assure that approval of such applications
16 does not result in aggregate payments under
17 section 1886(d) of such Act that are greater or
18 less than those that would otherwise be made if
19 paragraph (1) and subparagraph (A) did not
20 apply.

21 **SEC. 938. PRIOR DETERMINATION PROCESS FOR CERTAIN**
22 **ITEMS AND SERVICES; ADVANCE BENE-**
23 **FICIARY NOTICES.**

24 (a) IN GENERAL.—Section 1869 (42 U.S.C.
25 1395ff(b)), as amended by sections 521 and 522 of BIPA

1 and section 933(d)(2)(B), is further amended by adding
2 at the end the following new subsection:

3 “(h) PRIOR DETERMINATION PROCESS FOR CERTAIN
4 ITEMS AND SERVICES.—

5 “(1) ESTABLISHMENT OF PROCESS.—

6 “(A) IN GENERAL.—With respect to a
7 medicare administrative contractor that has a
8 contract under section 1874A that provides for
9 making payments under this title with respect
10 to eligible items and services described in sub-
11 paragraph (C), the Secretary shall establish a
12 prior determination process that meets the re-
13 quirements of this subsection and that shall be
14 applied by such contractor in the case of eligible
15 requesters.

16 “(B) ELIGIBLE REQUESTER.—For pur-
17 poses of this subsection, each of the following
18 shall be an eligible requester:

19 “(i) A physician, but only with respect
20 to eligible items and services for which the
21 physician may be paid directly.

22 “(ii) An individual entitled to benefits
23 under this title, but only with respect to an
24 item or service for which the individual re-
25 ceives, from the physician who may be paid

1 directly for the item or service, an advance
2 beneficiary notice under section 1879(a)
3 that payment may not be made (or may no
4 longer be made) for the item or service
5 under this title.

6 “(C) ELIGIBLE ITEMS AND SERVICES.—
7 For purposes of this subsection and subject to
8 paragraph (2), eligible items and services are
9 items and services which are physicians’ serv-
10 ices (as defined in paragraph (4)(A) of section
11 1848(f) for purposes of calculating the sustain-
12 able growth rate under such section).

13 “(2) SECRETARIAL FLEXIBILITY.—The Sec-
14 retary shall establish by regulation reasonable limits
15 on the categories of eligible items and services for
16 which a prior determination of coverage may be re-
17 quested under this subsection. In establishing such
18 limits, the Secretary may consider the dollar amount
19 involved with respect to the item or service, adminis-
20 trative costs and burdens, and other relevant factors.

21 “(3) REQUEST FOR PRIOR DETERMINATION.—

22 “(A) IN GENERAL.—Subject to paragraph
23 (2), under the process established under this
24 subsection an eligible requester may submit to
25 the contractor a request for a determination,

1 before the furnishing of an eligible item or serv-
2 ice involved as to whether the item or service is
3 covered under this title consistent with the ap-
4 plicable requirements of section 1862(a)(1)(A)
5 (relating to medical necessity).

6 “(B) ACCOMPANYING DOCUMENTATION.—

7 The Secretary may require that the request be
8 accompanied by a description of the item or
9 service, supporting documentation relating to
10 the medical necessity for the item or service,
11 and any other appropriate documentation. In
12 the case of a request submitted by an eligible
13 requester who is described in paragraph
14 (1)(B)(ii), the Secretary may require that the
15 request also be accompanied by a copy of the
16 advance beneficiary notice involved.

17 “(4) RESPONSE TO REQUEST.—

18 “(A) IN GENERAL.—Under such process,
19 the contractor shall provide the eligible re-
20 quester with written notice of a determination
21 as to whether—

22 “(i) the item or service is so covered;

23 “(ii) the item or service is not so cov-
24 ered; or

1 “(iii) the contractor lacks sufficient
2 information to make a coverage determina-
3 tion.

4 If the contractor makes the determination de-
5 scribed in clause (iii), the contractor shall in-
6 clude in the notice a description of the addi-
7 tional information required to make the cov-
8 erage determination.

9 “(B) DEADLINE TO RESPOND.—Such no-
10 tice shall be provided within the same time pe-
11 riod as the time period applicable to the con-
12 tractor providing notice of initial determinations
13 on a claim for benefits under subsection
14 (a)(2)(A).

15 “(C) INFORMING BENEFICIARY IN CASE OF
16 PHYSICIAN REQUEST.—In the case of a request
17 in which an eligible requester is not the indi-
18 vidual described in paragraph (1)(B)(ii), the
19 process shall provide that the individual to
20 whom the item or service is proposed to be fur-
21 nished shall be informed of any determination
22 described in clause (ii) (relating to a determina-
23 tion of non-coverage) and the right (referred to
24 in paragraph (6)(B)) to obtain the item or serv-

1 ice and have a claim submitted for the item or
2 service.

3 “(5) EFFECT OF DETERMINATIONS.—

4 “(A) BINDING NATURE OF POSITIVE DE-
5 TERMINATION.—If the contractor makes the de-
6 termination described in paragraph (4)(A)(i),
7 such determination shall be binding on the con-
8 tractor in the absence of fraud or evidence of
9 misrepresentation of facts presented to the con-
10 tractor.

11 “(B) NOTICE AND RIGHT TO REDETER-
12 MINATION IN CASE OF A DENIAL.—

13 “(i) IN GENERAL.—If the contractor
14 makes the determination described in para-
15 graph (4)(A)(ii)—

16 “(I) the eligible requester has the
17 right to a redetermination by the con-
18 tractor on the determination that the
19 item or service is not so covered; and

20 “(II) the contractor shall include
21 in notice under paragraph (4)(A) a
22 brief explanation of the basis for the
23 determination, including on what na-
24 tional or local coverage or noncov-
25 erage determination (if any) the de-

1 termination is based, and the right to
2 such a redetermination.

3 “(ii) DEADLINE FOR REDETERMINA-
4 TIONS.—The contractor shall complete and
5 provide notice of such redetermination
6 within the same time period as the time
7 period applicable to the contractor pro-
8 viding notice of redeterminations relating
9 to a claim for benefits under subsection
10 (a)(3)(C)(ii).

11 “(6) LIMITATION ON FURTHER REVIEW.—

12 “(A) IN GENERAL.—Contractor determina-
13 tions described in paragraph (4)(A)(ii) or
14 (4)(A)(iii) (and redeterminations made under
15 paragraph (5)(B)), relating to pre-service
16 claims are not subject to further administrative
17 appeal or judicial review under this section or
18 otherwise.

19 “(B) DECISION NOT TO SEEK PRIOR DE-
20 TERMINATION OR NEGATIVE DETERMINATION
21 DOES NOT IMPACT RIGHT TO OBTAIN SERVICES,
22 SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—
23 Nothing in this subsection shall be construed as
24 affecting the right of an individual who—

1 “(i) decides not to seek a prior deter-
2 mination under this subsection with re-
3 spect to items or services; or

4 “(ii) seeks such a determination and
5 has received a determination described in
6 paragraph (4)(A)(ii),

7 from receiving (and submitting a claim for)
8 such items services and from obtaining adminis-
9 trative or judicial review respecting such claim
10 under the other applicable provisions of this
11 section. Failure to seek a prior determination
12 under this subsection with respect to items and
13 services shall not be taken into account in such
14 administrative or judicial review.

15 “(C) NO PRIOR DETERMINATION AFTER
16 RECEIPT OF SERVICES.—Once an individual is
17 provided items and services, there shall be no
18 prior determination under this subsection with
19 respect to such items or services.”.

20 (b) EFFECTIVE DATE; TRANSITION.—

21 (1) EFFECTIVE DATE.—The Secretary shall es-
22 tablish the prior determination process under the
23 amendment made by subsection (a) in such a man-
24 ner as to provide for the acceptance of requests for
25 determinations under such process filed not later

1 than 18 months after the date of the enactment of
2 this Act.

3 (2) TRANSITION.—During the period in which
4 the amendment made by subsection (a) has become
5 effective but contracts are not provided under sec-
6 tion 1874A of the Social Security Act with medicare
7 administrative contractors, any reference in section
8 1869(g) of such Act (as added by such amendment)
9 to such a contractor is deemed a reference to a fiscal
10 intermediary or carrier with an agreement under
11 section 1816, or contract under section 1842, re-
12 spectively, of such Act.

13 (3) LIMITATION ON APPLICATION TO SGR.—For
14 purposes of applying section 1848(f)(2)(D) of the
15 Social Security Act (42 U.S.C. 1395w-4(f)(2)(D)),
16 the amendment made by subsection (a) shall not be
17 considered to be a change in law or regulation.

18 (c) PROVISIONS RELATING TO ADVANCE BENE-
19 FICIARY NOTICES; REPORT ON PRIOR DETERMINATION
20 PROCESS.—

21 (1) DATA COLLECTION.—The Secretary shall
22 establish a process for the collection of information
23 on the instances in which an advance beneficiary no-
24 tice (as defined in paragraph (5)) has been provided
25 and on instances in which a beneficiary indicates on

1 such a notice that the beneficiary does not intend to
2 seek to have the item or service that is the subject
3 of the notice furnished.

4 (2) OUTREACH AND EDUCATION.—The Sec-
5 retary shall establish a program of outreach and
6 education for beneficiaries and providers of services
7 and other persons on the appropriate use of advance
8 beneficiary notices and coverage policies under the
9 medicare program.

10 (3) GAO REPORT REPORT ON USE OF ADVANCE
11 BENEFICIARY NOTICES.—Not later than 18 months
12 after the date on which section 1869(g) of the Social
13 Security Act (as added by subsection (a)) takes ef-
14 fect, the Comptroller General of the United States
15 shall submit to Congress a report on the use of ad-
16 vance beneficiary notices under title XVIII of such
17 Act. Such report shall include information con-
18 cerning the providers of services and other persons
19 that have provided such notices and the response of
20 beneficiaries to such notices.

21 (4) GAO REPORT ON USE OF PRIOR DETER-
22 MINATION PROCESS.—Not later than 18 months
23 after the date on which section 1869(g) of the Social
24 Security Act (as added by subsection (a)) takes ef-
25 fect, the Comptroller General of the United States

1 shall submit to Congress a report on the use of the
2 prior determination process under such section. Such
3 report shall include—

4 (A) information concerning the types of
5 procedures for which a prior determination has
6 been sought, determinations made under the
7 process, and changes in receipt of services re-
8 sulting from the application of such process;
9 and

10 (B) an evaluation of whether the process
11 was useful for physicians (and other suppliers)
12 and beneficiaries, whether it was timely, and
13 whether the amount of information required
14 was burdensome to physicians and beneficiaries.

15 (5) ADVANCE BENEFICIARY NOTICE DE-
16 FINED.—In this subsection, the term “advance bene-
17 ficiary notice” means a written notice provided
18 under section 1879(a) of the Social Security Act (42
19 U.S.C. 1395pp(a)) to an individual entitled to bene-
20 fits under part A or B of title XVIII of such Act
21 before items or services are furnished under such
22 part in cases where a provider of services or other
23 person that would furnish the item or service be-
24 lieves that payment will not be made for some or all
25 of such items or services under such title.

1 **Subtitle V—Miscellaneous**
2 **Provisions**

3 **SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION**
4 **AND MANAGEMENT (E & M) DOCUMENTATION**
5 **GUIDELINES.**

6 (a) IN GENERAL.—The Secretary may not implement
7 any new documentation guidelines for, or clinical examples
8 of, evaluation and management physician services under
9 the title XVIII of the Social Security Act on or after the
10 date of the enactment of this Act unless the Secretary—

11 (1) has developed the guidelines in collaboration
12 with practicing physicians (including both generalists
13 and specialists) and provided for an assessment of
14 the proposed guidelines by the physician community;

15 (2) has established a plan that contains specific
16 goals, including a schedule, for improving the use of
17 such guidelines;

18 (3) has conducted appropriate and representa-
19 tive pilot projects under subsection (b) to test modi-
20 fications to the evaluation and management docu-
21 mentation guidelines;

22 (4) finds that the objectives described in sub-
23 section (c) will be met in the implementation of such
24 guidelines; and

1 (5) has established, and is implementing, a pro-
2 gram to educate physicians on the use of such guide-
3 lines and that includes appropriate outreach.

4 The Secretary shall make changes to the manner in which
5 existing evaluation and management documentation guide-
6 lines are implemented to reduce paperwork burdens on
7 physicians.

8 (b) PILOT PROJECTS TO TEST EVALUATION AND
9 MANAGEMENT DOCUMENTATION GUIDELINES.—

10 (1) IN GENERAL.—The Secretary shall conduct
11 under this subsection appropriate and representative
12 pilot projects to test new evaluation and manage-
13 ment documentation guidelines referred to in sub-
14 section (a).

15 (2) LENGTH AND CONSULTATION.—Each pilot
16 project under this subsection shall—

17 (A) be voluntary;

18 (B) be of sufficient length as determined
19 by the Secretary to allow for preparatory physi-
20 cian and medicare contractor education, anal-
21 ysis, and use and assessment of potential eval-
22 uation and management guidelines; and

23 (C) be conducted, in development and
24 throughout the planning and operational stages
25 of the project, in consultation with practicing

1 physicians (including both generalists and spe-
2 cialists).

3 (3) RANGE OF PILOT PROJECTS.—Of the pilot
4 projects conducted under this subsection—

5 (A) at least one shall focus on a peer re-
6 view method by physicians (not employed by a
7 medicare contractor) which evaluates medical
8 record information for claims submitted by phy-
9 sicians identified as statistical outliers relative
10 to definitions published in the Current Proce-
11 dures Terminology (CPT) code book of the
12 American Medical Association;

13 (B) at least one shall focus on an alter-
14 native method to detailed guidelines based on
15 physician documentation of face to face encoun-
16 ter time with a patient;

17 (C) at least one shall be conducted for
18 services furnished in a rural area and at least
19 one for services furnished outside such an area;
20 and

21 (D) at least one shall be conducted in a
22 setting where physicians bill under physicians'
23 services in teaching settings and at least one
24 shall be conducted in a setting other than a
25 teaching setting.

1 (4) BANNING OF TARGETING OF PILOT
2 PROJECT PARTICIPANTS.—Data collected under this
3 subsection shall not be used as the basis for overpay-
4 ment demands or post-payment audits. Such limita-
5 tion applies only to claims filed as part of the pilot
6 project and lasts only for the duration of the pilot
7 project and only as long as the provider is a partici-
8 pant in the pilot project.

9 (5) STUDY OF IMPACT.—Each pilot project
10 shall examine the effect of the new evaluation and
11 management documentation guidelines on—

12 (A) different types of physician practices,
13 including those with fewer than 10 full-time-
14 equivalent employees (including physicians);
15 and

16 (B) the costs of physician compliance, in-
17 cluding education, implementation, auditing,
18 and monitoring.

19 (6) PERIODIC REPORTS.—The Secretary shall
20 submit to Congress periodic reports on the pilot
21 projects under this subsection.

22 (c) OBJECTIVES FOR EVALUATION AND MANAGE-
23 MENT GUIDELINES.—The objectives for modified evalua-
24 tion and management documentation guidelines developed
25 by the Secretary shall be to—

1 (1) identify clinically relevant documentation
2 needed to code accurately and assess coding levels
3 accurately;

4 (2) decrease the level of non-clinically pertinent
5 and burdensome documentation time and content in
6 the physician's medical record;

7 (3) increase accuracy by reviewers; and

8 (4) educate both physicians and reviewers.

9 (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF
10 DOCUMENTATION FOR PHYSICIAN CLAIMS.—

11 (1) STUDY.—The Secretary shall carry out a
12 study of the matters described in paragraph (2).

13 (2) MATTERS DESCRIBED.—The matters re-
14 ferred to in paragraph (1) are—

15 (A) the development of a simpler, alter-
16 native system of requirements for documenta-
17 tion accompanying claims for evaluation and
18 management physician services for which pay-
19 ment is made under title XVIII of the Social
20 Security Act; and

21 (B) consideration of systems other than
22 current coding and documentation requirements
23 for payment for such physician services.

24 (3) CONSULTATION WITH PRACTICING PHYSI-
25 CIANS.—In designing and carrying out the study

1 under paragraph (1), the Secretary shall consult
2 with practicing physicians, including physicians who
3 are part of group practices and including both gen-
4 eralists and specialists.

5 (4) APPLICATION OF HIPAA UNIFORM CODING
6 REQUIREMENTS.—In developing an alternative sys-
7 tem under paragraph (2), the Secretary shall con-
8 sider requirements of administrative simplification
9 under part C of title XI of the Social Security Act.

10 (5) REPORT TO CONGRESS.—(A) Not later than
11 October 1, 2005, the Secretary shall submit to Con-
12 gress a report on the results of the study conducted
13 under paragraph (1).

14 (B) The Medicare Payment Advisory Commis-
15 sion shall conduct an analysis of the results of the
16 study included in the report under subparagraph (A)
17 and shall submit a report on such analysis to Con-
18 gress.

19 (e) STUDY ON APPROPRIATE CODING OF CERTAIN
20 EXTENDED OFFICE VISITS.—The Secretary shall conduct
21 a study of the appropriateness of coding in cases of ex-
22 tended office visits in which there is no diagnosis made.
23 Not later than October 1, 2005, the Secretary shall submit
24 a report to Congress on such study and shall include rec-
25 ommendations on how to code appropriately for such visits

1 in a manner that takes into account the amount of time
2 the physician spent with the patient.

3 (f) DEFINITIONS.—In this section—

4 (1) the term “rural area” has the meaning
5 given that term in section 1886(d)(2)(D) of the So-
6 cial Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

7 (2) the term “teaching settings” are those set-
8 tings described in section 415.150 of title 42, Code
9 of Federal Regulations.

10 **SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY**
11 **AND COVERAGE.**

12 (a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—
13 Section 1868 (42 U.S.C. 1395ee), as amended by section
14 921(a), is amended by adding at the end the following new
15 subsection:

16 “(c) COUNCIL FOR TECHNOLOGY AND INNOVA-
17 TION.—

18 “(1) ESTABLISHMENT.—The Secretary shall es-
19 tablish a Council for Technology and Innovation
20 within the Centers for Medicare & Medicaid Services
21 (in this section referred to as ‘CMS’).

22 “(2) COMPOSITION.—The Council shall be com-
23 posed of senior CMS staff and clinicians and shall
24 be chaired by the Executive Coordinator for Tech-

1 nology and Innovation (appointed or designated
2 under paragraph (4)).

3 “(3) DUTIES.—The Council shall coordinate the
4 activities of coverage, coding, and payment processes
5 under this title with respect to new technologies and
6 procedures, including new drug therapies, and shall
7 coordinate the exchange of information on new tech-
8 nologies between CMS and other entities that make
9 similar decisions.

10 “(4) EXECUTIVE COORDINATOR FOR TECH-
11 NOLOGY AND INNOVATION.—The Secretary shall ap-
12 point (or designate) a noncareer appointee (as de-
13 fined in section 3132(a)(7) of title 5, United States
14 Code) who shall serve as the Executive Coordinator
15 for Technology and Innovation. Such executive coor-
16 dinator shall report to the Administrator of CMS,
17 shall chair the Council, shall oversee the execution of
18 its duties, and shall serve as a single point of con-
19 tact for outside groups and entities regarding the
20 coverage, coding, and payment processes under this
21 title.”.

22 (b) METHODS FOR DETERMINING PAYMENT BASIS
23 FOR NEW LAB TESTS.—Section 1833(h) (42 U.S.C.
24 1395l(h)) is amended by adding at the end the following:

1 “(8)(A) The Secretary shall establish by regulation
2 procedures for determining the basis for, and amount of,
3 payment under this subsection for any clinical diagnostic
4 laboratory test with respect to which a new or substan-
5 tially revised HCPCS code is assigned on or after January
6 1, 2005 (in this paragraph referred to as ‘new tests’).

7 “(B) Determinations under subparagraph (A) shall
8 be made only after the Secretary—

9 “(i) makes available to the public (through an
10 Internet site and other appropriate mechanisms) a
11 list that includes any such test for which establish-
12 ment of a payment amount under this subsection is
13 being considered for a year;

14 “(ii) on the same day such list is made avail-
15 able, causes to have published in the Federal Reg-
16 ister notice of a meeting to receive comments and
17 recommendations (and data on which recommenda-
18 tions are based) from the public on the appropriate
19 basis under this subsection for establishing payment
20 amounts for the tests on such list;

21 “(iii) not less than 30 days after publication of
22 such notice convenes a meeting, that includes rep-
23 resentatives of officials of the Centers for Medicare
24 & Medicaid Services involved in determining pay-
25 ment amounts, to receive such comments and rec-

1 ommendations (and data on which the recommenda-
2 tions are based);

3 “(iv) taking into account the comments and rec-
4 ommendations (and accompanying data) received at
5 such meeting, develops and makes available to the
6 public (through an Internet site and other appro-
7 priate mechanisms) a list of proposed determinations
8 with respect to the appropriate basis for establishing
9 a payment amount under this subsection for each
10 such code, together with an explanation of the rea-
11 sons for each such determination, the data on which
12 the determinations are based, and a request for pub-
13 lic written comments on the proposed determination;
14 and

15 “(v) taking into account the comments received
16 during the public comment period, develops and
17 makes available to the public (through an Internet
18 site and other appropriate mechanisms) a list of
19 final determinations of the payment amounts for
20 such tests under this subsection, together with the
21 rationale for each such determination, the data on
22 which the determinations are based, and responses
23 to comments and suggestions received from the pub-
24 lic.

1 “(C) Under the procedures established pursuant to
2 subparagraph (A), the Secretary shall—

3 “(i) set forth the criteria for making determina-
4 tions under subparagraph (A); and

5 “(ii) make available to the public the data
6 (other than proprietary data) considered in making
7 such determinations.

8 “(D) The Secretary may convene such further public
9 meetings to receive public comments on payment amounts
10 for new tests under this subsection as the Secretary deems
11 appropriate.

12 “(E) For purposes of this paragraph:

13 “(i) The term ‘HCPCS’ refers to the Health
14 Care Procedure Coding System.

15 “(ii) A code shall be considered to be ‘substan-
16 tially revised’ if there is a substantive change to the
17 definition of the test or procedure to which the code
18 applies (such as a new analyte or a new methodology
19 for measuring an existing analyte-specific test).”.

20 (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL
21 DATA COLLECTION FOR USE IN THE MEDICARE INPA-
22 TIENT PAYMENT SYSTEM.—

23 (1) STUDY.—The Comptroller General of the
24 United States shall conduct a study that analyzes
25 which external data can be collected in a shorter

1 time frame by the Centers for Medicare & Medicaid
2 Services for use in computing payments for inpatient
3 hospital services. The study may include an evalua-
4 tion of the feasibility and appropriateness of using
5 of quarterly samples or special surveys or any other
6 methods. The study shall include an analysis of
7 whether other executive agencies, such as the Bu-
8 reau of Labor Statistics in the Department of Com-
9 merce, are best suited to collect this information.

10 (2) REPORT.—By not later than October 1,
11 2004, the Comptroller General shall submit a report
12 to Congress on the study under paragraph (1).

13 (d) PROCESS FOR ADOPTION OF ICD CODES AS
14 DATA STANDARD.—Section 1172(f) (42 U.S.C. 1320d-
15 1(f)) is amended by inserting after the first sentence the
16 following: “Notwithstanding the first sentence of this sub-
17 section, if the National Committee on Vital and Health
18 Statistics has not made a recommendation to the Sec-
19 retary, within 1 year after the date of the enactment of
20 this sentence, with respect to the adoption of the Inter-
21 national Classification of Diseases, 10th Revision, Proce-
22 dure Coding System (‘ICD–10–PCS’) and the Inter-
23 national Classification of Diseases, 10th Revision, Clinical
24 Modification (‘ICD–10–CM’) as a standard under this

1 part, then the Secretary may adopt ICD–10–PCS and
2 ICD–10–CM as such a standard.”.

3 **SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN SERV-**
4 **ICES UNDER MEDICARE SECONDARY PAYOR**
5 **(MSP) PROVISIONS.**

6 (a) IN GENERAL.—The Secretary shall not require
7 a hospital (including a critical access hospital) to ask ques-
8 tions (or obtain information) relating to the application
9 of section 1862(b) of the Social Security Act (relating to
10 medicare secondary payor provisions) in the case of ref-
11 erence laboratory services described in subsection (b), if
12 the Secretary does not impose such requirement in the
13 case of such services furnished by an independent labora-
14 tory.

15 (b) REFERENCE LABORATORY SERVICES DE-
16 SCRIBED.—Reference laboratory services described in this
17 subsection are clinical laboratory diagnostic tests (or the
18 interpretation of such tests, or both) furnished without a
19 face-to-face encounter between the individual entitled to
20 benefits under part A or enrolled under part B, or both,
21 and the hospital involved and in which the hospital sub-
22 mits a claim only for such test or interpretation.

23 **SEC. 944. EMTALA IMPROVEMENTS.**

24 (a) PAYMENT FOR EMTALA-MANDATED SCREEN-
25 ING AND STABILIZATION SERVICES.—

1 (1) IN GENERAL.—Section 1862 (42 U.S.C.
2 1395y) is amended by inserting after subsection (c)
3 the following new subsection:

4 “(d) For purposes of subsection (a)(1)(A), in the case
5 of any item or service that is required to be provided pur-
6 suant to section 1867 to an individual who is entitled to
7 benefits under this title, determinations as to whether the
8 item or service is reasonable and necessary shall be made
9 on the basis of the information available to the treating
10 physician or practitioner (including the patient’s pre-
11 senting symptoms or complaint) at the time the item or
12 service was ordered or furnished by the physician or prac-
13 titioner (and not on the patient’s principal diagnosis).
14 When making such determinations with respect to such
15 an item or service, the Secretary shall not consider the
16 frequency with which the item or service was provided to
17 the patient before or after the time of the admission or
18 visit.”.

19 (2) EFFECTIVE DATE.—The amendment made
20 by paragraph (1) shall apply to items and services
21 furnished on or after January 1, 2004.

22 (b) NOTIFICATION OF PROVIDERS WHEN EMTALA
23 INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42
24 U.S.C. 1395dd(d)) is amended by adding at the end the
25 following new paragraph:

1 “(4) NOTICE UPON CLOSING AN INVESTIGA-
2 TION.—The Secretary shall establish a procedure to
3 notify hospitals and physicians when an investigation
4 under this section is closed.”.

5 (c) PRIOR REVIEW BY PEER REVIEW ORGANIZA-
6 TIONS IN EMTALA CASES INVOLVING TERMINATION OF
7 PARTICIPATION.—

8 (1) IN GENERAL.—Section 1867(d)(3) (42
9 U.S.C. 1395dd(d)(3)) is amended—

10 (A) in the first sentence, by inserting “or
11 in terminating a hospital’s participation under
12 this title” after “in imposing sanctions under
13 paragraph (1)”; and

14 (B) by adding at the end the following new
15 sentences: “Except in the case in which a delay
16 would jeopardize the health or safety of individ-
17 uals, the Secretary shall also request such a re-
18 view before making a compliance determination
19 as part of the process of terminating a hos-
20 pital’s participation under this title for viola-
21 tions related to the appropriateness of a med-
22 ical screening examination, stabilizing treat-
23 ment, or an appropriate transfer as required by
24 this section, and shall provide a period of 5
25 days for such review. The Secretary shall pro-

1 vide a copy of the organization’s report to the
2 hospital or physician consistent with confiden-
3 tiality requirements imposed on the organiza-
4 tion under such part B.”.

5 (2) EFFECTIVE DATE.—The amendments made
6 by paragraph (1) shall apply to terminations of par-
7 ticipation initiated on or after the date of the enact-
8 ment of this Act.

9 (d) MODIFICATION OF REQUIRMENT FOR MEDICAL
10 SCREENING EXAMINATIONS FOR PATIENTS NOT RE-
11 QUESTING EMERGENCY DEPARTMENT SERVICES.—

12 (1) IN GENERAL.—Section 1867(a) (42 U.S.C.
13 1395dd(a)) is amended—

14 (A) by designating all that follows “(a)
15 MEDICAL SCREENING REQUIREMENT.—” as
16 paragraph (1) with the heading “IN GEN-
17 ERAL.—”;

18 (B) by aligning such paragraph with the
19 paragraph added by paragraph (3); and

20 (C) by adding at the end the following new
21 paragraph:

22 “(2) EXCEPTION FOR CERTAIN CASES.—The re-
23 quirement for an appropriate medical screening ex-
24 amination under paragraph (1) shall not apply in
25 the case of an individual who comes to the emer-

1 agency department and neither the individual, nor an-
2 other person on the individual's behalf, requests ex-
3 amination or treatment for an emergency medical
4 condition (such as a request solely for preventive
5 services, such as blood pressure screening or non-
6 emergency laboratory and diagnostic tests).”.

7 (2) EFFECTIVE DATE.—The amendments made
8 by paragraph (1) shall apply to terminations of par-
9 ticipation initiated on or after the date of the enact-
10 ment of this Act.

11 **SEC. 945. EMERGENCY MEDICAL TREATMENT AND ACTIVE**
12 **LABOR ACT (EMTALA) TECHNICAL ADVISORY**
13 **GROUP.**

14 (a) ESTABLISHMENT.—The Secretary shall establish
15 a Technical Advisory Group (in this section referred to
16 as the “Advisory Group”) to review issues related to the
17 Emergency Medical Treatment and Labor Act
18 (EMTALA) and its implementation. In this section, the
19 term “EMTALA” refers to the provisions of section 1867
20 of the Social Security Act (42 U.S.C. 1395dd).

21 (b) MEMBERSHIP.—The Advisory Group shall be
22 composed of 19 members, including the Administrator of
23 the Centers for Medicare & Medicaid Services and the In-
24 spector General of the Department of Health and Human
25 Services and of which—

1 (1) 4 shall be representatives of hospitals, in-
2 cluding at least one public hospital, that have experi-
3 ence with the application of EMTALA and at least
4 2 of which have not been cited for EMTALA viola-
5 tions;

6 (2) 7 shall be practicing physicians drawn from
7 the fields of emergency medicine, cardiology or
8 cardiothoracic surgery, orthopedic surgery, neuro-
9 surgery, pediatrics or a pediatric subspecialty, ob-
10 stetrics-gynecology, and psychiatry, with not more
11 than one physician from any particular field;

12 (3) 2 shall represent patients;

13 (4) 2 shall be staff involved in EMTALA inves-
14 tigations from different regional offices of the Cen-
15 ters for Medicare & Medicaid Services; and

16 (5) 1 shall be from a State survey office in-
17 volved in EMTALA investigations and 1 shall be
18 from a peer review organization, both of whom shall
19 be from areas other than the regions represented
20 under paragraph (4).

21 In selecting members described in paragraphs (1) through
22 (3), the Secretary shall consider qualified individuals nom-
23 inated by organizations representing providers and pa-
24 tients.

1 (c) GENERAL RESPONSIBILITIES.—The Advisory
2 Group—

3 (1) shall review EMTALA regulations;

4 (2) may provide advice and recommendations to
5 the Secretary with respect to those regulations and
6 their application to hospitals and physicians;

7 (3) shall solicit comments and recommendations
8 from hospitals, physicians, and the public regarding
9 the implementation of such regulations; and

10 (4) may disseminate information on the applica-
11 tion of such regulations to hospitals, physicians, and
12 the public.

13 (d) ADMINISTRATIVE MATTERS.—

14 (1) CHAIRPERSON.—The members of the Advi-
15 sory Group shall elect a member to serve as chair-
16 person of the Advisory Group for the life of the Ad-
17 visory Group.

18 (2) MEETINGS.—The Advisory Group shall first
19 meet at the direction of the Secretary. The Advisory
20 Group shall then meet twice per year and at such
21 other times as the Advisory Group may provide.

22 (e) TERMINATION.—The Advisory Group shall termi-
23 nate 30 months after the date of its first meeting.

24 (f) WAIVER OF ADMINISTRATIVE LIMITATION.—The
25 Secretary shall establish the Advisory Group notwith-

1 standing any limitation that may apply to the number of
2 advisory committees that may be established (within the
3 Department of Health and Human Services or otherwise).

4 **SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO PRO-**
5 **VIDE CORE HOSPICE SERVICES IN CERTAIN**
6 **CIRCUMSTANCES.**

7 (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.
8 1395x(dd)(5)) is amended by adding at the end the fol-
9 lowing:

10 “(D) In extraordinary, exigent, or other non-routine
11 circumstances, such as unanticipated periods of high pa-
12 tient loads, staffing shortages due to illness or other
13 events, or temporary travel of a patient outside a hospice
14 program’s service area, a hospice program may enter into
15 arrangements with another hospice program for the provi-
16 sion by that other program of services described in para-
17 graph (2)(A)(ii)(I). The provisions of paragraph
18 (2)(A)(ii)(II) shall apply with respect to the services pro-
19 vided under such arrangements.

20 “(E) A hospice program may provide services de-
21 scribed in paragraph (1)(A) other than directly by the pro-
22 gram if the services are highly specialized services of a
23 registered professional nurse and are provided non-rou-
24 tinely and so infrequently so that the provision of such

1 services directly would be impracticable and prohibitively
2 expensive.”.

3 (b) CONFORMING PAYMENT PROVISION.—Section
4 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the
5 end the following new paragraph:

6 “(4) In the case of hospice care provided by a hospice
7 program under arrangements under section
8 1861(dd)(5)(D) made by another hospice program, the
9 hospice program that made the arrangements shall bill
10 and be paid for the hospice care.”.

11 (c) EFFECTIVE DATE.—The amendments made by
12 this section shall apply to hospice care provided on or after
13 the date of the enactment of this Act.

14 **SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHO-**
15 **GENS STANDARD TO CERTAIN HOSPITALS.**

16 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc)
17 is amended—

18 (1) in subsection (a)(1)—

19 (A) in subparagraph (R), by striking
20 “and” at the end;

21 (B) in subparagraph (S), by striking the
22 period at the end and inserting “, and”; and

23 (C) by inserting after subparagraph (S)
24 the following new subparagraph:

1 “(T) in the case of hospitals that are not other-
2 wise subject to the Occupational Safety and Health
3 Act of 1970, to comply with the Bloodborne Patho-
4 gens standard under section 1910.1030 of title 29 of
5 the Code of Federal Regulations (or as subsequently
6 redesignated).”; and

7 (2) by adding at the end of subsection (b) the
8 following new paragraph:

9 “(4)(A) A hospital that fails to comply with the re-
10 quirement of subsection (a)(1)(T) (relating to the
11 Bloodborne Pathogens standard) is subject to a civil
12 money penalty in an amount described in subparagraph
13 (B), but is not subject to termination of an agreement
14 under this section.

15 “(B) The amount referred to in subparagraph (A) is
16 an amount that is similar to the amount of civil penalties
17 that may be imposed under section 17 of the Occupational
18 Safety and Health Act of 1970 for a violation of the
19 Bloodborne Pathogens standard referred to in subsection
20 (a)(1)(T) by a hospital that is subject to the provisions
21 of such Act.

22 “(C) A civil money penalty under this paragraph shall
23 be imposed and collected in the same manner as civil
24 money penalties under subsection (a) of section 1128A are
25 imposed and collected under that section.”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 this subsection (a) shall apply to hospitals as of July 1,
3 2004.

4 **SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND**
5 **CORRECTIONS.**

6 (a) TECHNICAL AMENDMENTS RELATING TO ADVI-
7 SORY COMMITTEE UNDER BIPA SECTION 522.—(1) Sub-
8 section (i) of section 1114 (42 U.S.C. 1314)—

9 (A) is transferred to section 1862 and added at
10 the end of such section; and

11 (B) is redesignated as subsection (j).

12 (2) Section 1862 (42 U.S.C. 1395y) is amended—

13 (A) in the last sentence of subsection (a), by
14 striking “established under section 1114(f)”; and

15 (B) in subsection (j), as so transferred and re-
16 designated—

17 (i) by striking “under subsection (f)”; and

18 (ii) by striking “section 1862(a)(1)” and
19 inserting “subsection (a)(1)”.

20 (b) TERMINOLOGY CORRECTIONS.—(1) Section
21 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as
22 amended by section 521 of BIPA, is amended—

23 (A) in subclause (III), by striking “policy” and
24 inserting “determination”; and

1 (B) in subclause (IV), by striking “medical re-
2 view policies” and inserting “coverage determina-
3 tions”.

4 (2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-
5 22(a)(2)(C)) is amended by striking “policy” and “POL-
6 ICY” and inserting “determination” each place it appears
7 and “DETERMINATION”, respectively.

8 (c) REFERENCE CORRECTIONS.—Section 1869(f)(4)
9 (42 U.S.C. 1395ff(f)(4)), as added by section 522 of
10 BIPA, is amended—

11 (1) in subparagraph (A)(iv), by striking “sub-
12 clause (I), (II), or (III)” and inserting “clause (i),
13 (ii), or (iii)”;

14 (2) in subparagraph (B), by striking “clause
15 (i)(IV)” and “clause (i)(III)” and inserting “sub-
16 paragraph (A)(iv)” and “subparagraph (A)(iii)”, re-
17 spectively; and

18 (3) in subparagraph (C), by striking “clause
19 (i)”, “subclause (IV)” and “subparagraph (A)” and
20 inserting “subparagraph (A)”, “clause (iv)” and
21 “paragraph (1)(A)”, respectively each place it ap-
22 pears.

23 (d) OTHER CORRECTIONS.—Effective as if included
24 in the enactment of section 521(c) of BIPA, section

1 1154(e) (42 U.S.C. 1320c-3(e)) is amended by striking
2 paragraph (5).

3 (e) EFFECTIVE DATE.—Except as otherwise pro-
4 vided, the amendments made by this section shall be effec-
5 tive as if included in the enactment of BIPA.

6 **SEC. 949. CONFORMING AUTHORITY TO WAIVE A PROGRAM**

7 **EXCLUSION.**

8 The first sentence of section 1128(c)(3)(B) (42
9 U.S.C. 1320a-7(c)(3)(B)) is amended to read as follows:
10 “Subject to subparagraph (G), in the case of an exclusion
11 under subsection (a), the minimum period of exclusion
12 shall be not less than five years, except that, upon the
13 request of the administrator of a Federal health care pro-
14 gram (as defined in section 1128B(f)) who determines
15 that the exclusion would impose a hardship on individuals
16 entitled to benefits under part A of title XVIII or enrolled
17 under part B of such title, or both, the Secretary may
18 waive the exclusion under subsection (a)(1), (a)(3), or
19 (a)(4) with respect to that program in the case of an indi-
20 vidual or entity that is the sole community physician or
21 sole source of essential specialized services in a commu-
22 nity.”.

1 **SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.**

2 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y)
3 is amended by adding after subsection (g) the following
4 new subsection:

5 “(h)(1) Subject to paragraph (2), a group health plan
6 (as defined in subsection (a)(1)(A)(v)) providing supple-
7 mental or secondary coverage to individuals also entitled
8 to services under this title shall not require a medicare
9 claims determination under this title for dental benefits
10 specifically excluded under subsection (a)(12) as a condi-
11 tion of making a claims determination for such benefits
12 under the group health plan.

13 “(2) A group health plan may require a claims deter-
14 mination under this title in cases involving or appearing
15 to involve inpatient dental hospital services or dental serv-
16 ices expressly covered under this title pursuant to actions
17 taken by the Secretary.”.

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) shall take effect on the date that is 60 days
20 after the date of the enactment of this Act.

21 **SEC. 951. FURNISHING HOSPITALS WITH INFORMATION TO**
22 **COMPUTE DSH FORMULA.**

23 Beginning not later than 1 year after the date of the
24 enactment of this Act, the Secretary shall arrange to fur-
25 nish to subsection (d) hospitals (as defined in section
26 1886(d)(1)(B) of the Social Security Act, 42 U.S.C.

1 1395ww(d)(1)(B)) the data necessary for such hospitals
2 to compute the number of patient days used in computing
3 the disproportionate patient percentage under such section
4 for that hospital for the current cost reporting year. Such
5 data shall also be furnished to other hospitals which would
6 qualify for additional payments under part A of title
7 XVIII of the Social Security Act on the basis of such data.

8 **SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.**

9 (a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C.
10 1395u(b)(6)(A)) is amended by striking “or (ii) (where
11 the service was provided in a hospital, critical access hos-
12 pital, clinic, or other facility) to the facility in which the
13 service was provided if there is a contractual arrangement
14 between such physician or other person and such facility
15 under which such facility submits the bill for such serv-
16 ice,” and inserting “or (ii) where the service was provided
17 under a contractual arrangement between such physician
18 or other person and an entity (as defined by the Sec-
19 retary), to the entity if, under the contractual arrange-
20 ment, the entity submits the bill for the service and the
21 contractual arrangement meets such other program integ-
22 rity and other safeguards as the Secretary may determine
23 to be appropriate.”.

24 (b) CONFORMING AMENDMENT.—The second sen-
25 tence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is

1 amended by striking “except to an employer or facility”
2 and inserting “except to an employer, entity, or other per-
3 son”.

4 (c) EFFECTIVE DATE.—The amendments made by
5 section shall apply to payments made on or after the date
6 of the enactment of this Act.

7 **SEC. 953. OTHER PROVISIONS.**

8 (a) GAO REPORTS ON THE PHYSICIAN COMPENSA-
9 TION.—

10 (1) SUSTAINABLE GROWTH RATE AND UP-
11 DATES.—Not later than 6 months after the date of
12 the enactment of this Act, the Comptroller General
13 of the United States shall submit to Congress a re-
14 port on the appropriateness of the updates in the
15 conversion factor under subsection (d)(3) of section
16 1848 of the Social Security Act (42 U.S.C. 1395w-
17 4), including the appropriateness of the sustainable
18 growth rate formula under subsection (f) of such
19 section for 2002 and succeeding years. Such report
20 shall examine the stability and predictability of such
21 updates and rate and alternatives for the use of such
22 rate in the updates.

23 (2) PHYSICIAN COMPENSATION GENERALLY.—
24 Not later than 12 months after the date of the en-
25 actment of this Act, the Comptroller General shall

1 submit to Congress a report on all aspects of physi-
2 cian compensation for services furnished under title
3 XVIII of the Social Security Act, and how those as-
4 pects interact and the effect on appropriate com-
5 pensation for physician services. Such report shall
6 review alternatives for the physician fee schedule
7 under section 1848 of such title (42 U.S.C. 1395w-
8 4).

9 (b) ANNUAL PUBLICATION OF LIST OF NATIONAL
10 COVERAGE DETERMINATIONS.—The Secretary shall pro-
11 vide, in an appropriate annual publication available to the
12 public, a list of national coverage determinations made
13 under title XVIII of the Social Security Act in the pre-
14 vious year and information on how to get more informa-
15 tion with respect to such determinations.

16 (c) GAO REPORT ON FLEXIBILITY IN APPLYING
17 HOME HEALTH CONDITIONS OF PARTICIPATION TO PA-
18 TIENTS WHO ARE NOT MEDICARE BENEFICIARIES.—Not
19 later than 6 months after the date of the enactment of
20 this Act, the Comptroller General of the United States
21 shall submit to Congress a report on the implications if
22 there were flexibility in the application of the medicare
23 conditions of participation for home health agencies with
24 respect to groups or types of patients who are not medi-
25 care beneficiaries. The report shall include an analysis of

1 the potential impact of such flexible application on clinical
2 operations and the recipients of such services and an anal-
3 ysis of methods for monitoring the quality of care provided
4 to such recipients.

5 (d) **OIG REPORT ON NOTICES RELATING TO USE OF**
6 **HOSPITAL LIFETIME RESERVE DAYS.**—Not later than 1
7 year after the date of the enactment of this Act, the In-
8 spector General of the Department of Health and Human
9 Services shall submit a report to Congress on—

10 (1) the extent to which hospitals provide notice
11 to medicare beneficiaries in accordance with applica-
12 ble requirements before they use the 60 lifetime re-
13 serve days described in section 1812(a)(1) of the So-
14 cial Security Act (42 U.S.C. 1395d(a)(1)); and

15 (2) the appropriateness and feasibility of hos-
16 pitals providing a notice to such beneficiaries before
17 they completely exhaust such lifetime reserve days.

18 **SEC. 954. TEMPORARY SUSPENSION OF OASIS REQUIRE-**
19 **MENT FOR COLLECTION OF DATA ON NON-**
20 **MEDICARE AND NON-MEDICAID PATIENTS.**

21 (a) **IN GENERAL.**—During the period described in
22 subsection (b), the Secretary may not require, under sec-
23 tion 4602(e) of the Balanced Budget Act of 1997 or other-
24 wise under OASIS, a home health agency to gather or sub-
25 mit information that relates to an individual who is not

1 eligible for benefits under either title XVIII or title XIX
2 of the Social Security Act (such information in this section
3 referred to as “non-medicare/medicaid OASIS informa-
4 tion”).

5 (b) PERIOD OF SUSPENSION.—The period described
6 in this subsection—

7 (1) begins on the date of the enactment of this
8 Act; and

9 (2) ends on the last day of the 2nd month be-
10 ginning after the date as of which the Secretary has
11 published final regulations regarding the collection
12 and use by the Centers for Medicare & Medicaid
13 Services of non-medicare/medicaid OASIS informa-
14 tion following the submission of the report required
15 under subsection (c).

16 (c) REPORT.—

17 (1) STUDY.—The Secretary shall conduct a
18 study on how non-medicare/medicaid OASIS infor-
19 mation is and can be used by large home health
20 agencies. Such study shall examine—

21 (A) whether there are unique benefits from
22 the analysis of such information that cannot be
23 derived from other information available to, or
24 collected by, such agencies; and

1 (B) the value of collecting such informa-
2 tion by small home health agencies compared to
3 the administrative burden related to such collec-
4 tion.

5 In conducting the study the Secretary shall obtain
6 recommendations from quality assessment experts in
7 the use of such information and the necessity of
8 small, as well as large, home health agencies col-
9 lecting such information.

10 (2) REPORT.—The Secretary shall submit to
11 Congress a report on the study conducted under
12 paragraph (1) by not later than 18 months after the
13 date of the enactment of this Act.

14 (d) CONSTRUCTION.—Nothing in this section shall be
15 construed as preventing home health agencies from col-
16 lecting non-medicare/medicaid OASIS information for
17 their own use.

18 **TITLE X—MEDICAID**

19 **SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOS-** 20 **PITAL (DSH) PAYMENTS.**

21 Section 1923(f)(3) (42 U.S.C. 1396r-4(f)(3)) is
22 amended—

23 (1) in subparagraph (A), by striking “subpara-
24 graph (B)” and inserting “subparagraphs (B) and
25 (C)”; and

1 (2) by adding at the end the following new sub-
2 paragraphs:

3 “(C) SPECIAL, TEMPORARY INCREASE IN
4 ALLOTMENTS ON A ONE-TIME, NON-CUMU-
5 LATIVE BASIS.—The DSH allotment for any
6 State—

7 “(i) for fiscal year 2004 is equal to
8 120 percent of the DSH allotment for the
9 State for fiscal year 2003 under this para-
10 graph, notwithstanding subparagraph (B);
11 and

12 “(ii) for each succeeding fiscal year is
13 equal to the DSH allotment for the State
14 for fiscal year 2004 or, in the case of fiscal
15 years beginning with the fiscal year speci-
16 fied in subparagraph (D) for that State,
17 the percentage change in the consumer
18 price index for all urban consumers (all
19 items; U.S. city average), for the previous
20 fiscal year.

21 “(D) FISCAL YEAR SPECIFIED.—For pur-
22 poses of subparagraph (C)(ii), the fiscal year
23 specified in this subparagraph for a State is the
24 first fiscal year for which the Secretary esti-
25 mates that the DSH allotment for that State

1 will equal (or no longer exceed) the DSH allot-
2 ment for that State under the law as in effect
3 before the date of the enactment of this sub-
4 paragraph.”.

5 **SEC. 1002. CLARIFICATION OF INCLUSION OF INPATIENT**
6 **DRUG PRICES CHARGED TO CERTAIN PUBLIC**
7 **HOSPITALS IN THE BEST PRICE EXEMPTIONS**
8 **FOR THE MEDICAID DRUG REBATE PRO-**
9 **GRAM.**

10 (a) **IN GENERAL.**—Section 1927(c)(1)(C)(i)(I) (42
11 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is amended by inserting
12 before the semicolon the following: “(including inpatient
13 prices charged to hospitals described in section
14 340B(a)(4)(L) of the Public Health Service Act)”.

15 (b) **ANTI-DIVERSION PROTECTION.**—Section
16 1927(c)(1)(C) (42 U.S.C. 1396r–8(c)(1)(C)) is amended
17 by adding at the end the following:

18 “(iii) **APPLICATION OF AUDITING AND**
19 **RECORDKEEPING REQUIREMENTS.**—With
20 respect to a covered entity described in
21 section 340B(a)(4)(L) of the Public Health
22 Service Act, any drug purchased for inpa-
23 tient use shall be subject to the auditing
24 and recordkeeping requirements described

1 in section 340B(a)(5)(C) of the Public
2 Health Service Act.”.

3 **TITLE XI—ACCESS TO AFFORD-**
4 **ABLE PHARMACEUTICALS**
5 **Subtitle A—Access to Affordable**
6 **Pharmaceuticals**

7 **SEC. 1101. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

8 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
9 tion 505(j) of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 355(j)) is amended—

11 (1) in paragraph (2)—

12 (A) by striking subparagraph (B) and in-
13 serting the following:

14 “(B) NOTICE OF OPINION THAT PATENT IS INVALID
15 OR WILL NOT BE INFRINGED.—

16 “(i) AGREEMENT TO GIVE NOTICE.—An appli-
17 cant that makes a certification described in subpara-
18 graph (A)(vii)(IV) shall include in the application a
19 statement that the applicant will give notice as re-
20 quired by this subparagraph.

21 “(ii) TIMING OF NOTICE.—An applicant that
22 makes a certification described in subparagraph
23 (A)(vii)(IV) shall give notice as required under this
24 subparagraph—

1 “(I) if the certification is in the applica-
2 tion, not later than 20 days after the date of
3 the postmark on the notice with which the Sec-
4 retary informs the applicant that the applica-
5 tion has been filed; or

6 “(II) if the certification is in an amend-
7 ment or supplement to the application, at the
8 time at which the applicant submits the amend-
9 ment or supplement, regardless of whether the
10 applicant has already given notice with respect
11 to another such certification contained in the
12 application or in an amendment or supplement
13 to the application.

14 “(iii) RECIPIENTS OF NOTICE.—An applicant
15 required under this subparagraph to give notice shall
16 give notice to—

17 “(I) each owner of the patent that is the
18 subject of the certification (or a representative
19 of the owner designated to receive such a no-
20 tice); and

21 “(II) the holder of the approved applica-
22 tion under subsection (b) for the drug that is
23 claimed by the patent or a use of which is
24 claimed by the patent (or a representative of
25 the holder designated to receive such a notice).

1 “(iv) CONTENTS OF NOTICE.—A notice required
2 under this subparagraph shall—

3 “(I) state that an application that contains
4 data from bioavailability or bioequivalence stud-
5 ies has been submitted under this subsection for
6 the drug with respect to which the certification
7 is made to obtain approval to engage in the
8 commercial manufacture, use, or sale of the
9 drug before the expiration of the patent re-
10 ferred to in the certification; and

11 “(II) include a detailed statement of the
12 factual and legal basis of the opinion of the ap-
13 plicant that the patent is invalid or will not be
14 infringed.”; and

15 (B) by adding at the end the following sub-
16 paragraph:

17 “(D)(i) An applicant may not amend or supplement
18 an application to seek approval of a drug referring to a
19 different listed drug from the listed drug identified in the
20 application as submitted to the Secretary.

21 “(ii) With respect to the drug for which an applica-
22 tion is submitted, nothing in this subsection prohibits an
23 applicant from amending or supplementing the application
24 to seek approval of a different strength.”; and

25 (2) in paragraph (5)—

1 (A) in subparagraph (B)—

2 (i) by striking “under the following”
3 and inserting “by applying the following to
4 each certification made under paragraph
5 (2)(A)(vii)”;

6 (ii) in clause (iii)—

7 (I) in the first sentence, by strik-
8 ing “unless” and all that follows and
9 inserting “unless, before the expira-
10 tion of 45 days after the date on
11 which the notice described in para-
12 graph (2)(B) is received, an action is
13 brought for infringement of the patent
14 that is the subject of the certification
15 and for which information was sub-
16 mitted to the Secretary under sub-
17 section (b)(1) or (c)(2) before the date
18 on which the application (excluding an
19 amendment or supplement to the ap-
20 plication), which the Secretary later
21 determines to be substantially com-
22 plete, was submitted.”;

23 (II) in the second sentence—

24 (aa) by striking subclause

25 (I) and inserting the following:

1 “(I) if before the expiration of such period
2 the district court decides that the patent is in-
3 valid or not infringed (including any substantive
4 determination that there is no cause of action
5 for patent infringement or invalidity), the ap-
6 proval shall be made effective on—

7 “(aa) the date on which the court en-
8 ters judgment reflecting the decision; or

9 “(bb) the date of a settlement order
10 or consent decree signed and entered by
11 the court stating that the patent that is
12 the subject of the certification is invalid or
13 not infringed;”;

14 (bb) by striking subclause

15 (II) and inserting the following:

16 “(II) if before the expiration of such period
17 the district court decides that the patent has
18 been infringed—

19 “(aa) if the judgment of the district
20 court is appealed, the approval shall be
21 made effective on—

22 “(AA) the date on which the
23 court of appeals decides that the pat-
24 ent is invalid or not infringed (includ-
25 ing any substantive determination

1 that there is no cause of action for
2 patent infringement or invalidity); or

3 “(BB) the date of a settlement
4 order or consent decree signed and
5 entered by the court of appeals stat-
6 ing that the patent that is the subject
7 of the certification is invalid or not in-
8 fringed; or

9 “(bb) if the judgment of the district
10 court is not appealed or is affirmed, the
11 approval shall be made effective on the
12 date specified by the district court in a
13 court order under section 271(e)(4)(A) of
14 title 35, United States Code;”;

15 (cc) in subclause (III), by
16 striking “on the date of such
17 court decision.” and inserting “as
18 provided in subclause (I); or”;

19 (dd) by inserting after sub-
20 clause (III) the following:

21 “(IV) if before the expiration of such pe-
22 riod the court grants a preliminary injunction
23 prohibiting the applicant from engaging in the
24 commercial manufacture or sale of the drug
25 until the court decides the issues of patent va-

1 lidity and infringement and if the court decides
2 that such patent has been infringed, the ap-
3 proval shall be made effective as provided in
4 subclause (II).”; and

5 (ee) in the matter after and
6 below subclause (IV) (as added
7 by item (dd)), by striking “Until
8 the expiration” and all that fol-
9 lows;

10 (B) by redesignating subparagraphs (C)
11 and (D) as subparagraphs (E) and (F), respec-
12 tively; and

13 (C) by inserting after subparagraph (B)
14 the following:

15 “(C) CIVIL ACTION TO OBTAIN PATENT
16 CERTAINTY.—

17 “(i) DECLARATORY JUDGMENT AB-
18 SENT INFRINGEMENT ACTION.—

19 “(I) IN GENERAL.—No action
20 may be brought under section 2201 of
21 title 28, United States Code, by an
22 applicant under paragraph (2) for a
23 declaratory judgment with respect to
24 a patent which is the subject of the
25 certification referred to in subpara-

1 graph (B)(iii) unless the forty-five day
2 period referred to in such subpara-
3 graph has expired, and unless, if the
4 notice provided under paragraph
5 (2)(B) relates to noninfringement, the
6 notice was accompanied by a docu-
7 ment described in subclause (II). Any
8 such action shall be brought in the ju-
9 dicial district where the defendant has
10 its principal place of business or a
11 regular and established place of busi-
12 ness.

13 “(II) RIGHT OF CONFIDENTIAL
14 ACCESS TO APPLICATION.—For pur-
15 poses of subclause (I), the document
16 described in this subclause is a docu-
17 ment providing a right of confidential
18 access to the application of the appli-
19 cant under paragraph (2) for the pur-
20 pose of determining whether an action
21 referred to in subparagraph (B)(iii)
22 should be brought. The document pro-
23 viding the right of confidential access
24 shall contain such restrictions as to
25 persons entitled to access, and on the

1 use and disposition of any information
2 accessed, as would apply had a protec-
3 tive order been entered for the pur-
4 pose of protecting trade secrets and
5 other confidential business informa-
6 tion. Any person provided a right of
7 confidential access shall review the ap-
8 plication for the sole and limited pur-
9 pose of evaluating possible infringe-
10 ment of the patent that is the subject
11 of the certification under paragraph
12 (2)(A)(vii)(IV) and for no other pur-
13 pose, and may not disclose informa-
14 tion of no relevance to any issue of
15 patent infringement to any person
16 other than a person provided a right
17 of confidential access. Further, the
18 application may be redacted by the
19 applicant to remove any information
20 of no relevance to any issue of patent
21 infringement.

22 “(ii) COUNTERCLAIM TO INFRINGE-
23 MENT ACTION.—

24 “(I) IN GENERAL.—If an owner
25 of the patent or the holder of the ap-

1 proved application under subsection
2 (b) for the drug that is claimed by the
3 patent or a use of which is claimed by
4 the patent brings a patent infringe-
5 ment action against the applicant, the
6 applicant may assert a counterclaim
7 seeking an order requiring the holder
8 to correct or delete the patent infor-
9 mation submitted by the holder under
10 subsection (b) or (c) on the ground
11 that the patent does not claim ei-
12 ther—

13 “(aa) the drug for which the
14 application was approved; or

15 “(bb) an approved method
16 of using the drug.

17 “(II) NO INDEPENDENT CAUSE
18 OF ACTION.—Subclause (I) does not
19 authorize the assertion of a claim de-
20 scribed in subclause (I) in any civil
21 action or proceeding other than a
22 counterclaim described in subclause
23 (I).

24 “(iii) NO DAMAGES.—An applicant
25 shall not be entitled to damages in a civil

1 action under subparagraph (i) or a coun-
2 terclaim under subparagraph (ii).”.

3 (b) APPLICATIONS GENERALLY.—Section 505 of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
5 is amended—

6 (1) in subsection (b)—

7 (A) by striking paragraph (3) and insert-
8 ing the following:

9 “(3) NOTICE OF OPINION THAT PATENT IS INVALID
10 OR WILL NOT BE INFRINGED.—

11 “(A) AGREEMENT TO GIVE NOTICE.—An appli-
12 cant that makes a certification described in para-
13 graph (2)(A)(iv) shall include in the application a
14 statement that the applicant will give notice as re-
15 quired by this paragraph.

16 “(B) TIMING OF NOTICE.—An applicant that
17 makes a certification described in paragraph
18 (2)(A)(iv) shall give notice as required under this
19 paragraph—

20 “(i) if the certification is in the applica-
21 tion, not later than 20 days after the date of
22 the postmark on the notice with which the Sec-
23 retary informs the applicant that the applica-
24 tion has been filed; or

1 “(ii) if the certification is in an amend-
2 ment or supplement to the application, at the
3 time at which the applicant submits the amend-
4 ment or supplement, regardless of whether the
5 applicant has already given notice with respect
6 to another such certification contained in the
7 application or in an amendment or supplement
8 to the application.

9 “(C) RECIPIENTS OF NOTICE.—An applicant
10 required under this paragraph to give notice shall
11 give notice to—

12 “(i) each owner of the patent that is the
13 subject of the certification (or a representative
14 of the owner designated to receive such a no-
15 tice); and

16 “(ii) the holder of the approved application
17 under this subsection for the drug that is
18 claimed by the patent or a use of which is
19 claimed by the patent (or a representative of
20 the holder designated to receive such a notice).

21 “(D) CONTENTS OF NOTICE.—A notice re-
22 quired under this paragraph shall—

23 “(i) state that an application that contains
24 data from bioavailability or bioequivalence stud-
25 ies has been submitted under this subsection for

1 the drug with respect to which the certification
2 is made to obtain approval to engage in the
3 commercial manufacture, use, or sale of the
4 drug before the expiration of the patent re-
5 ferred to in the certification; and

6 “(ii) include a detailed statement of the
7 factual and legal basis of the opinion of the ap-
8 plicant that the patent is invalid or will not be
9 infringed.”; and

10 (B)(i) by redesignating paragraph (4) as
11 paragraph (5); and

12 (ii) by inserting after paragraph (3) the
13 following paragraph:

14 “(4)(A) An applicant may not amend or supplement
15 an application referred to in paragraph (2) to seek ap-
16 proval of a drug that is a different drug than the drug
17 identified in the application as submitted to the Secretary.

18 “(B) With respect to the drug for which such an ap-
19 plication is submitted, nothing in this subsection or sub-
20 section (c)(3) prohibits an applicant from amending or
21 supplementing the application to seek approval of a dif-
22 ferent strength.”; and

23 (2) in subsection (c)(3)—

24 (A) in the first sentence, by striking

25 “under the following” and inserting “by apply-

1 ing the following to each certification made
2 under subsection (b)(2)(A)(iv)”;

3 (B) in subparagraph (C)—

4 (i) in the first sentence, by striking
5 “unless” and all that follows and inserting
6 “unless, before the expiration of 45 days
7 after the date on which the notice de-
8 scribed in subsection (b)(3) is received, an
9 action is brought for infringement of the
10 patent that is the subject of the certifi-
11 cation and for which information was sub-
12 mitted to the Secretary under paragraph
13 (2) or subsection (b)(1) before the date on
14 which the application (excluding an amend-
15 ment or supplement to the application) was
16 submitted.”;

17 (ii) in the second sentence—

18 (I) by striking “paragraph
19 (3)(B)” and inserting “subsection
20 (b)(3)”;

21 (II) by striking clause (i) and in-
22 serting the following:

23 “(i) if before the expiration of such period
24 the district court decides that the patent is in-
25 valid or not infringed (including any substantive

1 determination that there is no cause of action
2 for patent infringement or invalidity), the ap-
3 proval shall be made effective on—

4 “(I) the date on which the court en-
5 ters judgment reflecting the decision; or

6 “(II) the date of a settlement order or
7 consent decree signed and entered by the
8 court stating that the patent that is the
9 subject of the certification is invalid or not
10 infringed;”;

11 (III) by striking clause (ii) and
12 inserting the following:

13 “(ii) if before the expiration of such period
14 the district court decides that the patent has
15 been infringed—

16 “(I) if the judgment of the district
17 court is appealed, the approval shall be
18 made effective on—

19 “(aa) the date on which the court
20 of appeals decides that the patent is
21 invalid or not infringed (including any
22 substantive determination that there
23 is no cause of action for patent in-
24 fringement or invalidity); or

1 “(bb) the date of a settlement
2 order or consent decree signed and
3 entered by the court of appeals stat-
4 ing that the patent that is the subject
5 of the certification is invalid or not in-
6 fringed; or

7 “(II) if the judgment of the district
8 court is not appealed or is affirmed, the
9 approval shall be made effective on the
10 date specified by the district court in a
11 court order under section 271(e)(4)(A) of
12 title 35, United States Code;”;

13 (IV) in clause (iii), by striking
14 “on the date of such court decision.”
15 and inserting “as provided in clause
16 (i); or”;

17 (V) by inserting after clause (iii),
18 the following:

19 “(iv) if before the expiration of such period
20 the court grants a preliminary injunction pro-
21 hibiting the applicant from engaging in the
22 commercial manufacture or sale of the drug
23 until the court decides the issues of patent va-
24 lidity and infringement and if the court decides
25 that such patent has been infringed, the ap-

1 proval shall be made effective as provided in
2 clause (ii).”; and

3 (VI) in the matter after and
4 below clause (iv) (as added by sub-
5 clause (V)), by striking “Until the ex-
6 piration” and all that follows; and

7 (iii) in the third sentence, by striking
8 “paragraph (3)(B)” and inserting “sub-
9 section (b)(3)”; and

10 (C) by redesignating subparagraph (D) as
11 subparagraph (E); and

12 (D) by inserting after subparagraph (C)
13 the following:

14 “(D) CIVIL ACTION TO OBTAIN PATENT
15 CERTAINTY.—

16 “(i) DECLARATORY JUDGMENT AB-
17 SENT INFRINGEMENT ACTION.—

18 “(I) IN GENERAL.—No action
19 may be brought under section 2201 of
20 title 28, United States Code, by an
21 applicant referred to in subsection
22 (b)(2) for a declaratory judgment with
23 respect to a patent which is the sub-
24 ject of the certification referred to in
25 subparagraph (C) unless the forty-five

1 day period referred to in such sub-
2 paragraph has expired, and unless, if
3 the notice the applicant provided
4 under subsection (b)(3) relates to
5 noninfringement, the notice was ac-
6 companied by a document described in
7 subclause (II). Any such action shall
8 be brought in the judicial district
9 where the defendant has its principal
10 place of business or a regular and es-
11 tablished place of business.

12 “(II) RIGHT OF CONFIDENTIAL
13 ACCESS TO APPLICATION.—For pur-
14 poses of subclause (I), the document
15 described in this subclause is a docu-
16 ment providing a right of confidential
17 access to the application of the appli-
18 cant referred to in subsection (b)(2)
19 for the purpose of determining wheth-
20 er an action referred to in subpara-
21 graph (C) should be brought. The
22 document providing the right of con-
23 fidential access shall contain such re-
24 strictions as to persons entitled to ac-
25 cess, and on the use and disposition of

1 any information accessed, as would
2 apply had a protective order been en-
3 tered for the purpose of protecting
4 trade secrets and other confidential
5 business information. Any person pro-
6 vided a right of confidential access
7 shall review the application for the
8 sole and limited purpose of evaluating
9 possible infringement of the patent
10 that is the subject of the certification
11 under subsection (b)(2)(A)(iv) and for
12 no other purpose, and may not dis-
13 close information of no relevance to
14 any issue of patent infringement to
15 any person other than a person pro-
16 vided a right of confidential access.
17 Further, the application may be re-
18 dacted by the applicant to remove any
19 information of no relevance to any
20 issue of patent infringement.

21 “(ii) COUNTERCLAIM TO INFRINGE-
22 MENT ACTION.—

23 “(I) IN GENERAL.—If an owner
24 of the patent or the holder of the ap-
25 proved application under subsection

1 (b) for the drug that is claimed by the
2 patent or a use of which is claimed by
3 the patent brings a patent infringe-
4 ment action against the applicant, the
5 applicant may assert a counterclaim
6 seeking an order requiring the holder
7 to correct or delete the patent infor-
8 mation submitted by the holder under
9 subsection (b) or this subsection on
10 the ground that the patent does not
11 claim either—

12 “(aa) the drug for which the
13 application was approved; or

14 “(bb) an approved method
15 of using the drug.

16 “(II) NO INDEPENDENT CAUSE
17 OF ACTION.—Subclause (I) does not
18 authorize the assertion of a claim de-
19 scribed in subclause (I) in any civil
20 action or proceeding other than a
21 counterclaim described in subclause
22 (I).

23 “(iii) NO DAMAGES.—An applicant
24 shall not be entitled to damages in a civil

1 action under clause (i) or a counterclaim
2 under clause (ii).”.

3 (c) APPLICABILITY.—

4 (1) IN GENERAL.—Except as provided in para-
5 graphs (2) and (3), the amendments made by sub-
6 sections (a), (b), and (c) apply to any proceeding
7 under section 505 of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 355) that is pending on or
9 after the date of enactment of this Act regardless of
10 the date on which the proceeding was commenced or
11 is commenced.

12 (2) NOTICE OF OPINION THAT PATENT IS IN-
13 VALID OR WILL NOT BE INFRINGED.—The amend-
14 ments made by subsections (a)(1) and (b)(1) apply
15 with respect to any certification under subsection
16 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 355) after the date of enactment of this Act
19 in an application filed under subsection (b)(2) or (j)
20 of that section or in an amendment or supplement
21 to an application filed under subsection (b)(2) or (j)
22 of that section.

23 (3) EFFECTIVE DATE OF APPROVAL.—The
24 amendments made by subsections (a)(2)(A)(ii)(I)
25 and (b)(2)(B)(i) apply with respect to any patent in-

1 formation submitted under subsection (b)(1) or
2 (c)(2) of section 505 of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355) made after the date
4 of enactment of this Act.

5 **SEC. 1102. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

6 (a) IN GENERAL.—Section 505(j)(5) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as
8 amended by section 1101) is amended—

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

11 “(iv) 180-DAY EXCLUSIVITY PERIOD.—

12 “(I) DEFINITIONS.—In this paragraph:

13 “(aa) 180-DAY EXCLUSIVITY PE-
14 RIOD.—The term ‘180-day exclusivity pe-
15 riod’ means the 180-day period ending on
16 the day before the date on which an appli-
17 cation submitted by an applicant other
18 than a first applicant could become effec-
19 tive under this clause.

20 “(bb) FIRST APPLICANT.—As used in
21 this subsection, the term ‘first applicant’
22 means an applicant that, on the first day
23 on which a substantially complete applica-
24 tion containing a certification described in
25 paragraph (2)(A)(vii)(IV) is submitted for

1 approval of a drug, submits a substantially
2 complete application containing a certifi-
3 cation described in paragraph
4 (2)(A)(vii)(IV) for the drug.

5 “(cc) SUBSTANTIALLY COMPLETE AP-
6 PPLICATION.—As used in this subsection,
7 the term ‘substantially complete applica-
8 tion’ means an application under this sub-
9 section that on its face is sufficiently com-
10 plete to permit a substantive review and
11 contains all the information required by
12 paragraph (2)(A).

13 “(dd) TENTATIVE APPROVAL.—

14 “(AA) IN GENERAL.—The term
15 ‘tentative approval’ means notification
16 to an applicant by the Secretary that
17 an application under this subsection
18 meets the requirements of paragraph
19 (2)(A), but cannot receive effective
20 approval because the application does
21 not meet the requirements of this sub-
22 paragraph, there is a period of exclu-
23 sivity for the listed drug under sub-
24 paragraph (E) or section 505A, or

1 there is a 7-year period of exclusivity
2 for the listed drug under section 527.

3 “(BB) LIMITATION.—A drug
4 that is granted tentative approval by
5 the Secretary is not an approved drug
6 and shall not have an effective ap-
7 proval until the Secretary issues an
8 approval after any necessary addi-
9 tional review of the application.

10 “(II) EFFECTIVENESS OF APPLICATION.—

11 Subject to subparagraph (D), if the application
12 contains a certification described in paragraph
13 (2)(A)(vii)(IV) and is for a drug for which a
14 first applicant has submitted an application
15 containing such a certification, the application
16 shall be made effective on the date that is 180
17 days after the date of the first commercial mar-
18 keting of the drug (including the commercial
19 marketing of the listed drug) by any first appli-
20 cant.”; and

21 (2) by inserting after subparagraph (C) the fol-
22 lowing:

23 “(D) FORFEITURE OF 180-DAY EXCLU-
24 SIVITY PERIOD.—

1 “(i) DEFINITION OF FORFEITURE
2 EVENT.—In this subparagraph, the term
3 ‘forfeiture event’, with respect to an appli-
4 cation under this subsection, means the oc-
5 currence of any of the following:

6 “(I) FAILURE TO MARKET.—The
7 first applicant fails to market the
8 drug by the later of—

9 “(aa) the earlier of the date
10 that is—

11 “(AA) 75 days after the
12 date on which the approval
13 of the application of the first
14 applicant is made effective
15 under subparagraph (B)(iii);
16 or

17 “(BB) 30 months after
18 the date of submission of
19 the application of the first
20 applicant; or

21 “(bb) with respect to the
22 first applicant or any other appli-
23 cant (which other applicant has
24 received tentative approval), the
25 date that is 75 days after the

1 date as of which, as to each of
2 the patents with respect to which
3 the first applicant submitted a
4 certification qualifying the first
5 applicant for the 180-day exclu-
6 sivity period under subparagraph
7 (B)(iv), at least 1 of the fol-
8 lowing has occurred:

9 “(AA) In an infringe-
10 ment action brought against
11 that applicant with respect
12 to the patent or in a declar-
13 atory judgment action
14 brought by that applicant
15 with respect to the patent, a
16 court enters a final decision
17 from which no appeal (other
18 than a petition to the Su-
19 preme Court for a writ of
20 certiorari) has been or can
21 be taken that the patent is
22 invalid or not infringed.

23 “(BB) In an infringe-
24 ment action or a declaratory
25 judgment action described in

1 subitem (AA), a court signs
2 a settlement order or con-
3 sent decree that enters a
4 final judgment that includes
5 a finding that the patent is
6 invalid or not infringed.

7 “(CC) The patent ex-
8 pires.

9 “(DD) The patent is
10 withdrawn by the holder of
11 the application approved
12 under subsection (b).

13 “(II) WITHDRAWAL OF APPLICA-
14 TION.—The first applicant withdraws
15 the application or the Secretary con-
16 siders the application to have been
17 withdrawn as a result of a determina-
18 tion by the Secretary that the applica-
19 tion does not meet the requirements
20 for approval under paragraph (4).

21 “(III) AMENDMENT OF CERTIFI-
22 CATION.—The first applicant amends
23 or withdraws the certification for all
24 of the patents with respect to which
25 that applicant submitted a certifi-

1 cation qualifying the applicant for the
2 180-day exclusivity period.

3 “(IV) FAILURE TO OBTAIN TEN-
4 TATIVE APPROVAL.—The first appli-
5 cant fails to obtain tentative approval
6 of the application within 30 months
7 after the date on which the applica-
8 tion is filed, unless the failure is
9 caused by a change in or a review of
10 the requirements for approval of the
11 application imposed after the date on
12 which the application is filed.

13 “(V) AGREEMENT WITH AN-
14 OTHER APPLICANT, THE LISTED DRUG
15 APPLICATION HOLDER, OR A PATENT
16 OWNER.—The first applicant enters
17 into an agreement with another appli-
18 cant under this subsection for the
19 drug, the holder of the application for
20 the listed drug, or an owner of the
21 patent that is the subject of the cer-
22 tification under paragraph
23 (2)(A)(vii)(IV), the Federal Trade
24 Commission or the Attorney General
25 files a complaint, and there is a final

1 decision of the Federal Trade Com-
2 mission or the court with regard to
3 the complaint from which no appeal
4 (other than a petition to the Supreme
5 Court for a writ of certiorari) has
6 been or can be taken that the agree-
7 ment has violated the antitrust laws
8 (as defined in section 1 of the Clayton
9 Act (15 U.S.C. 12), except that the
10 term includes section 5 of the Federal
11 Trade Commission Act (15 U.S.C. 45)
12 to the extent that that section applies
13 to unfair methods of competition).

14 “(VI) EXPIRATION OF ALL PAT-
15 ENTS.—All of the patents as to which
16 the applicant submitted a certification
17 qualifying it for the 180-day exclu-
18 sivity period have expired.

19 “(ii) FORFEITURE.—The 180-day ex-
20 clusivity period described in subparagraph
21 (B)(iv) shall be forfeited by a first appli-
22 cant if a forfeiture event occurs with re-
23 spect to that first applicant.

1 “(iii) SUBSEQUENT APPLICANT.—If
2 all first applicants forfeit the 180-day ex-
3 clusivity period under clause (ii)—

4 “(I) approval of any application
5 containing a certification described in
6 paragraph (2)(A)(vii)(IV) shall be
7 made effective in accordance with sub-
8 paragraph (B)(iii); and

9 “(II) no applicant shall be eligi-
10 ble for a 180-day exclusivity period.”.

11 (b) EFFECTIVE DATE.—

12 (1) IN GENERAL.—Except as provided in para-
13 graph (2), the amendment made by subsection (a)
14 shall be effective only with respect to an application
15 filed under section 505(j) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the
17 date of enactment of this Act for a listed drug for
18 which no certification under section
19 505(j)(2)(A)(vii)(IV) of that Act was made before
20 the date of enactment of this Act.

21 (2) COLLUSIVE AGREEMENTS.—If a forfeiture
22 event described in section 505(j)(5)(D)(i)(V) of that
23 Act occurs in the case of an applicant, the applicant
24 shall forfeit the 180-day period under section
25 505(j)(5)(B)(iv) of that Act without regard to when

1 the first certification under section
2 505(j)(2)(A)(vii)(IV) of that Act for the listed drug
3 was made.

4 (3) DECISION OF A COURT WHEN THE 180-DAY
5 EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.—
6 With respect to an application filed before, on, or
7 after the date of enactment of this Act for a listed
8 drug for which a certification under section
9 505(j)(2)(A)(vii)(IV) of that Act was made before
10 the date of enactment of this Act and for which nei-
11 ther of the events described in subclause (I) or (II)
12 of section 505(j)(5)(B)(iv) of that Act (as in effect
13 on the day before the date of enactment of this Act)
14 has occurred on or before the date of enactment of
15 this Act, the term “decision of a court” as used in
16 clause (iv) of section 505(j)(5)(B) of that Act means
17 a final decision of a court from which no appeal
18 (other than a petition to the Supreme Court for a
19 writ of certiorari) has been or can be taken.

20 **SEC. 1103. BIOAVAILABILITY AND BIOEQUIVALENCE.**

21 (a) IN GENERAL.—Section 505(j)(8) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is
23 amended—

24 (1) by striking subparagraph (A) and inserting
25 the following:

1 “(A)(i) The term ‘bioavailability’ means the
2 rate and extent to which the active ingredient or
3 therapeutic ingredient is absorbed from a drug and
4 becomes available at the site of drug action.

5 “(ii) For a drug that is not intended to be ab-
6 sorbed into the bloodstream, the Secretary may as-
7 sess bioavailability by scientifically valid measure-
8 ments intended to reflect the rate and extent to
9 which the active ingredient or therapeutic ingredient
10 becomes available at the site of drug action.”; and

11 (2) by adding at the end the following:

12 “(C) For a drug that is not intended to be ab-
13 sorbed into the bloodstream, the Secretary may es-
14 tablish alternative, scientifically valid methods to
15 show bioequivalence if the alternative methods are
16 expected to detect a significant difference between
17 the drug and the listed drug in safety and thera-
18 peutic effect.”.

19 (b) EFFECT OF AMENDMENT.—The amendment
20 made by subsection (a) does not alter the standards for
21 approval of drugs under section 505(j) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

23 **SEC. 1104. CONFORMING AMENDMENTS.**

24 Section 505A of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 355a) is amended—

1 (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i),
2 by striking “(j)(5)(D)(ii)” each place it appears and
3 inserting “(j)(5)(F)(ii)”;

4 (2) in subsections (b)(1)(A)(ii) and
5 (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it
6 appears and inserting “(j)(5)(F)”;

7 (3) in subsections (e) and (l), by striking
8 “505(j)(5)(D)” each place it appears and inserting
9 “505(j)(5)(F)”.

10 **Subtitle B—Federal Trade** 11 **Commission Review**

12 **SEC. 1111. DEFINITIONS.**

13 In this subtitle:

14 (1) ANDA.—The term “ANDA” means an ab-
15 breviated drug application, as defined under section
16 201(aa) of the Federal Food, Drug, and Cosmetic
17 Act.

18 (2) BRAND NAME DRUG.—The term “brand
19 name drug” means a drug for which an application
20 is approved under section 505(c) of the Federal
21 Food, Drug, and Cosmetic Act, including an applica-
22 tion referred to in section 505(b)(2) of such Act.

23 (3) BRAND NAME DRUG COMPANY.—The term
24 “brand name drug company” means the party that
25 holds the approved application referred to in para-

1 graph (2) for a brand name drug that is a listed
2 drug in an ANDA, or a party that is the owner of
3 a patent for which information is submitted for such
4 drug under subsection (b) or (c) of section 505 of
5 the Federal Food, Drug, and Cosmetic Act.

6 (4) COMMISSION.—The term “Commission”
7 means the Federal Trade Commission.

8 (5) GENERIC DRUG.—The term “generic drug”
9 means a drug for which an application under section
10 505(j) of the Federal Food, Drug, and Cosmetic Act
11 is approved.

12 (6) GENERIC DRUG APPLICANT.—The term
13 “generic drug applicant” means a person who has
14 filed or received approval for an ANDA under sec-
15 tion 505(j) of the Federal Food, Drug, and Cosmetic
16 Act.

17 (7) LISTED DRUG.—The term “listed drug”
18 means a brand name drug that is listed under sec-
19 tion 505(j)(7) of the Federal Food, Drug, and Cos-
20 metic Act.

21 **SEC. 1112. NOTIFICATION OF AGREEMENTS.**

22 (a) AGREEMENT WITH BRAND NAME DRUG COM-
23 PANY.—

24 (1) REQUIREMENT.—A generic drug applicant
25 that has submitted an ANDA containing a certifi-

1 cation under section 505(j)(2)(A)(vii)(IV) of the
2 Federal Food, Drug, and Cosmetic Act and a brand
3 name drug company that enter into an agreement
4 described in paragraph (2) shall each file the agree-
5 ment in accordance with subsection (c). The agree-
6 ment shall be filed prior to the date of the first com-
7 mercial marketing of the generic drug that is the
8 subject of the ANDA.

9 (2) SUBJECT MATTER OF AGREEMENT.—An
10 agreement described in this paragraph between a ge-
11 neric drug applicant and a brand name drug com-
12 pany is an agreement regarding—

13 (A) the manufacture, marketing or sale of
14 the brand name drug that is the listed drug in
15 the ANDA involved;

16 (B) the manufacture, marketing, or sale of
17 the generic drug for which the ANDA was sub-
18 mitted; or

19 (C) the 180-day period referred to in sec-
20 tion 505(j)(5)(B)(iv) of the Federal Food,
21 Drug, and Cosmetic Act as it applies to such
22 ANDA or to any other ANDA based on the
23 same brand name drug.

24 (b) AGREEMENT WITH ANOTHER GENERIC DRUG
25 APPLICANT.—

1 (1) REQUIREMENT.—A generic drug applicant
2 that has submitted an ANDA containing a certifi-
3 cation under section 505(j)(2)(A)(vii)(IV) of the
4 Federal Food, Drug, and Cosmetic Act with respect
5 to a listed drug and another generic drug applicant
6 that has submitted an ANDA containing such a cer-
7 tification for the same listed drug shall each file the
8 agreement in accordance with subsection (c). The
9 agreement shall be filed prior to the date of the first
10 commercial marketing of either of the generic drugs
11 for which such ANDAs were submitted.

12 (2) SUBJECT MATTER OF AGREEMENT.—An
13 agreement described in this paragraph between two
14 generic drug applicants is an agreement regarding
15 the 180-day period referred to in section
16 505(j)(5)(B)(iv) of the Federal Food, Drug, and
17 Cosmetic Act as it applies to the ANDAs with which
18 the agreement is concerned.

19 (c) FILING.—

20 (1) AGREEMENT.—The parties that are re-
21 quired in subsection (a) or (b) to file an agreement
22 in accordance with this subsection shall file with the
23 Commission the text of any such agreement, except
24 that such parties are not required to file an agree-
25 ment that solely concerns—

1 (A) purchase orders for raw material sup-
2 plies;

3 (B) equipment and facility contracts;

4 (C) employment or consulting contracts; or

5 (D) packaging and labeling contracts.

6 (2) OTHER AGREEMENTS.—The parties that
7 are required in subsection (a) or (b) to file an agree-
8 ment in accordance with this subsection shall file
9 with the Commission the text of any agreements be-
10 tween the parties that are not described in such sub-
11 sections and are contingent upon, provide a contin-
12 gent condition for, or are otherwise related to an
13 agreement that is required in subsection (a) or (b)
14 to be filed in accordance with this subsection.

15 (3) DESCRIPTION.—In the event that any
16 agreement required in subsection (a) or (b) to be
17 filed in accordance with this subsection has not been
18 reduced to text, each of the parties involved shall file
19 written descriptions of such agreement that are suf-
20 ficient to disclose all the terms and conditions of the
21 agreement.

22 **SEC. 1113. FILING DEADLINES.**

23 Any filing required under section 1112 shall be filed
24 with the Commission not later than 10 business days after
25 the date the agreements are executed.

1 **SEC. 1114. DISCLOSURE EXEMPTION.**

2 Any information or documentary material filed with
3 the Commission pursuant to this subtitle shall be exempt
4 from disclosure under section 552 of title 5, United States
5 Code, and no such information or documentary material
6 may be made public, except as may be relevant to any
7 administrative or judicial action or proceeding. Nothing in
8 this section is intended to prevent disclosure to either body
9 of Congress or to any duly authorized committee or sub-
10 committee of the Congress.

11 **SEC. 1115. ENFORCEMENT.**

12 (a) CIVIL PENALTY.—Any brand name drug com-
13 pany or generic drug applicant which fails to comply with
14 any provision of this subtitle shall be liable for a civil pen-
15 alty of not more than \$11,000, for each day during which
16 such entity is in violation of this subtitle. Such penalty
17 may be recovered in a civil action brought by the United
18 States, or brought by the Commission in accordance with
19 the procedures established in section 16(a)(1) of the Fed-
20 eral Trade Commission Act (15 U.S.C. 56(a)).

21 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any
22 brand name drug company or generic drug applicant fails
23 to comply with any provision of this subtitle, the United
24 States district court may order compliance, and may grant
25 such other equitable relief as the court in its discretion

1 determines necessary or appropriate, upon application of
2 the Commission.

3 **SEC. 1116. RULEMAKING.**

4 The Commission, by rule in accordance with section
5 553 of title 5, United States Code, consistent with the pur-
6 poses of this subtitle—

7 (1) may define the terms used in this subtitle;

8 (2) may exempt classes of persons or agree-
9 ments from the requirements of this subtitle; and

10 (3) may prescribe such other rules as may be
11 necessary and appropriate to carry out the purposes
12 of this subtitle.

13 **SEC. 1117. SAVINGS CLAUSE.**

14 Any action taken by the Commission, or any failure
15 of the Commission to take action, under this subtitle shall
16 not at any time bar any proceeding or any action with
17 respect to any agreement between a brand name drug
18 company and a generic drug applicant, or any agreement
19 between generic drug applicants, under any other provi-
20 sion of law, nor shall any filing under this subtitle con-
21 stitute or create a presumption of any violation of any
22 competition laws.

23 **SEC. 1118. EFFECTIVE DATE.**

24 This subtitle shall—

1 (1) take effect 30 days after the date of enact-
2 ment of this Act; and

3 (2) shall apply to agreements described in sec-
4 tion 1112 that are entered into 30 days after the
5 date of enactment of this Act.

6 **Subtitle C—Importation of**
7 **Prescription Drugs**

8 **SEC. 1121. IMPORTATION OF PRESCRIPTION DRUGS.**

9 (a) IN GENERAL.—Chapter VIII of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
11 is amended by striking section 804 and inserting the fol-
12 lowing:

13 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

14 **“(a) DEFINITIONS.—**In this section:

15 **“(1) IMPORTER.—**The term ‘importer’ means a
16 pharmacist or wholesaler.

17 **“(2) PHARMACIST.—**The term ‘pharmacist’
18 means a person licensed by a State to practice phar-
19 macy, including the dispensing and selling of pre-
20 scription drugs.

21 **“(3) PRESCRIPTION DRUG.—**The term ‘pre-
22 scription drug’ means a drug subject to section
23 503(b), other than—

1 “(A) a controlled substance (as defined in
2 section 102 of the Controlled Substances Act
3 (21 U.S.C. 802));

4 “(B) a biological product (as defined in
5 section 351 of the Public Health Service Act
6 (42 U.S.C. 262));

7 “(C) an infused drug (including a peri-
8 toneal dialysis solution);

9 “(D) an intravenously injected drug;

10 “(E) a drug that is inhaled during surgery;

11 or

12 “(F) a drug which is a parenteral drug,
13 the importation of which pursuant to subsection
14 (b) is determined by the Secretary to pose a
15 threat to the public health, in which case sec-
16 tion 801(d)(1) shall continue to apply.

17 “(4) QUALIFYING LABORATORY.—The term
18 ‘qualifying laboratory’ means a laboratory in the
19 United States that has been approved by the Sec-
20 retary for the purposes of this section.

21 “(5) WHOLESALER.—

22 “(A) IN GENERAL.—The term ‘wholesaler’
23 means a person licensed as a wholesaler or dis-
24 tributor of prescription drugs in the United
25 States under section 503(e)(2)(A).

1 “(B) EXCLUSION.—The term ‘wholesaler’
2 does not include a person authorized to import
3 drugs under section 801(d)(1).

4 “(b) REGULATIONS.—The Secretary shall promul-
5 gate regulations permitting pharmacists and wholesalers
6 to import prescription drugs from Canada into the United
7 States.

8 “(c) LIMITATION.—The regulations under subsection
9 (b) shall—

10 “(1) require that each prescription drug im-
11 ported under the regulations complies with section
12 505 (including with respect to being safe and effec-
13 tive for the intended use of the prescription drug),
14 with sections 501 and 502, and with all other appli-
15 cable requirements of this Act;

16 “(2) require that an importer of a prescription
17 drug under the regulations comply with subsections
18 (d)(1) and (e);

19 “(3) require that any prescription drug from
20 Canada imported by a domestic pharmacist or
21 wholesaler under this section be contained in pack-
22 aging which the Secretary has determined to be rea-
23 sonably certain to be tamper-resistant and not capa-
24 ble of counterfeiting;

1 “(4) require that all prescription drugs from
2 Canada imported by a domestic pharmacist or a
3 wholesaler under this section contain a statement
4 designed to inform the end-user of such drug that
5 such drug has been imported from a foreign seller
6 other than a manufacturer;

7 “(5) require that only prescription drugs which
8 have not left the possession of the first Canadian re-
9 cipient of such prescription drugs after receipt from
10 the manufacturer of such prescription drugs be eligi-
11 ble for importation into the United States under this
12 section;

13 “(6) require, if determined appropriate by the
14 Secretary, that all prescription drugs imported from
15 Canada under this section by domestic pharmacists
16 and wholesalers enter the United States through
17 ports of entry designated by the Secretary for pur-
18 poses of this section;

19 “(7) contain any additional provisions deter-
20 mined by the Secretary to be appropriate to protect
21 the public health; and

22 “(8) contain any additional provisions deter-
23 mined by the Secretary to be appropriate to facili-
24 tate the importation of prescription drugs that do
25 not jeopardize the public health.

1 “(d) INFORMATION AND RECORDS.—

2 “(1) IN GENERAL.—The regulations under sub-
3 section (b) shall require an importer of a prescrip-
4 tion drug under subsection (b) to submit to the Sec-
5 retary the following information and documentation:

6 “(A) The name and quantity of the active
7 ingredient of the prescription drug.

8 “(B) A description of the dosage form of
9 the prescription drug.

10 “(C) The date on which the prescription
11 drug is shipped.

12 “(D) The quantity of the prescription drug
13 that is shipped.

14 “(E) The point of origin and destination of
15 the prescription drug.

16 “(F) The price paid and the price charged
17 by the importer for the prescription drug.

18 “(G) Documentation from the foreign sell-
19 er specifying—

20 “(i) the original source of the pre-
21 scription drug; and

22 “(ii) the quantity of each lot of the
23 prescription drug originally received by the
24 seller from that source.

1 “(H) The lot or control number assigned
2 to the prescription drug by the manufacturer of
3 the prescription drug.

4 “(I) The name, address, telephone number,
5 and professional license number (if any) of the
6 importer.

7 “(J)(i) Documentation demonstrating that
8 the prescription drug was received by the recipi-
9 ent from the manufacturer and subsequently
10 shipped by the first foreign recipient to the im-
11 porter.

12 “(ii) Documentation of the quantity of
13 each lot of the prescription drug received by the
14 first foreign recipient demonstrating that the
15 quantity being imported into the United States
16 is not more than the quantity that was received
17 by the first foreign recipient.

18 “(iii) In the case of an initial imported
19 shipment, documentation demonstrating that
20 each batch of the prescription drug in the ship-
21 ment was statistically sampled and tested for
22 authenticity and degradation.

23 “(K) Certification from the importer or
24 manufacturer of the prescription drug that the
25 prescription drug—

1 “(i) is approved for marketing in the
2 United States and is not adulterated or
3 misbranded; and

4 “(ii) meets all labeling requirements
5 under this Act.

6 “(L) Laboratory records, including com-
7 plete data derived from all tests necessary to
8 ensure that the prescription drug is in compli-
9 ance with established specifications and stand-
10 ards.

11 “(M) Documentation demonstrating that
12 the testing required by subparagraphs (J) and
13 (L) was conducted at a qualifying laboratory.

14 “(N) Any other information that the Sec-
15 retary determines is necessary to ensure the
16 protection of the public health.

17 “(2) MAINTENANCE BY THE SECRETARY.—The
18 Secretary shall maintain information and docu-
19 mentation submitted under paragraph (1) for such
20 period of time as the Secretary determines to be nec-
21 essary.

22 “(e) TESTING.—The regulations under subsection (b)
23 shall require—

24 “(1) that testing described in subparagraphs
25 (J) and (L) of subsection (d)(1) be conducted by the

1 importer or by the manufacturer of the prescription
2 drug at a qualified laboratory;

3 “(2) if the tests are conducted by the im-
4 porter—

5 “(A) that information needed to—

6 “(i) authenticate the prescription drug
7 being tested; and

8 “(ii) confirm that the labeling of the
9 prescription drug complies with labeling re-
10 quirements under this Act;

11 be supplied by the manufacturer of the pre-
12 scription drug to the pharmacist or wholesaler;
13 and

14 “(B) that the information supplied under
15 subparagraph (A) be kept in strict confidence
16 and used only for purposes of testing under this
17 section; and

18 “(3) may include such additional provisions as
19 the Secretary determines to be appropriate to pro-
20 vide for the protection of trade secrets and commer-
21 cial or financial information that is privileged or
22 confidential.

23 “(f) REGISTRATION OF FOREIGN SELLERS.—Any es-
24 tablishment within Canada engaged in the distribution of
25 a prescription drug that is imported or offered for impor-

1 tation into the United States shall register with the Sec-
2 retary the name and place of business of the establishment
3 and the name of the United States agent for the establish-
4 ment.

5 “(g) SUSPENSION OF IMPORTATION.—The Secretary
6 shall require that importations of a specific prescription
7 drug or importations by a specific importer under sub-
8 section (b) be immediately suspended on discovery of a
9 pattern of importation of that specific prescription drug
10 or by that specific importer of drugs that are counterfeit
11 or in violation of any requirement under this section, until
12 an investigation is completed and the Secretary deter-
13 mines that the public is adequately protected from coun-
14 terfeit and violative prescription drugs being imported
15 under subsection (b).

16 “(h) APPROVED LABELING.—The manufacturer of a
17 prescription drug shall provide an importer written au-
18 thorization for the importer to use, at no cost, the ap-
19 proved labeling for the prescription drug.

20 “(i) CHARITABLE CONTRIBUTIONS.—Notwith-
21 standing any other provision of this section, section
22 801(d)(1) continues to apply to a prescription drug that
23 is donated or otherwise supplied at no charge by the man-
24 ufacturer of the drug to a charitable or humanitarian or-

1 ganization (including the United Nations and affiliates)
2 or to a government of a foreign country.

3 “(j) WAIVER AUTHORITY FOR IMPORTATION BY IN-
4 DIVIDUALS.—The Secretary may, for drugs being im-
5 ported from a licensed Canadian pharmacy, grant to indi-
6 viduals, by regulation or on a case-by-case basis, a waiver
7 of the prohibition of importation of a prescription drug
8 or device or class of prescription drugs or devices, under
9 such conditions as the Secretary determines to be appro-
10 priate. Such conditions shall include conditions that such
11 drug or device be—

12 “(1) in the possession of an individual when the
13 individual enters the United States;

14 “(2) imported by such individual from a li-
15 censed pharmacy for personal use by the individual,
16 not for resale, in quantities that do not exceed a 90-
17 day supply, which individual will use the drug or de-
18 vice (or for a family member of such individual);

19 “(3) accompanied by a copy of a valid prescrip-
20 tion;

21 “(4) imported from Canada, from a seller reg-
22 istered with the Secretary;

23 “(5) a prescription drug approved by the Sec-
24 retary under chapter V that is not adulterated or
25 misbranded;

1 “(6) in the form of a final finished dosage that
2 was manufactured in an establishment registered
3 under section 510; and

4 “(7) imported under such other conditions as
5 the Secretary determines to be necessary to ensure
6 public safety.

7 “(k) STUDIES; REPORTS.—

8 “(1) BY THE INSTITUTE OF MEDICINE OF THE
9 NATIONAL ACADEMY OF SCIENCES.—

10 “(A) STUDY.—

11 “(i) IN GENERAL.—The Secretary
12 shall request that the Institute of Medicine
13 of the National Academy of Sciences con-
14 duct a study of—

15 “(I) importations of prescription
16 drugs made under the regulations
17 under subsection (b); and

18 “(II) information and docu-
19 mentation submitted under subsection
20 (d).

21 “(ii) REQUIREMENTS.—In conducting
22 the study, the Institute of Medicine shall—

23 “(I) evaluate the compliance of
24 importers with the regulations under
25 subsection (b);

1 “(II) compare the number of
2 shipments under the regulations
3 under subsection (b) during the study
4 period that are determined to be
5 counterfeit, misbranded, or adulter-
6 ated, and compare that number with
7 the number of shipments made during
8 the study period within the United
9 States that are determined to be
10 counterfeit, misbranded, or adulter-
11 ated; and

12 “(III) consult with the Secretary
13 to evaluate the effect of importations
14 under the regulations under sub-
15 section (b) on trade and patent rights
16 under Federal law.

17 “(B) REPORT.—Not later than 2 years
18 after the effective date of the regulations under
19 subsection (b), the Institute of Medicine shall
20 submit to Congress a report describing the find-
21 ings of the study under subparagraph (A).

22 “(2) BY THE COMPTROLLER GENERAL.—

23 “(A) STUDY.—The Comptroller General of
24 the United States shall conduct a study to de-

1 termine the effect of this section on the price of
2 prescription drugs sold to consumers at retail.

3 “(B) REPORT.—Not later than 18 months
4 after the effective date of the regulations under
5 subsection (b), the Comptroller General of the
6 United States shall submit to Congress a report
7 describing the findings of the study under sub-
8 paragraph (A).

9 “(l) CONSTRUCTION.—Nothing in this section limits
10 the authority of the Secretary relating to the importation
11 of prescription drugs, other than with respect to section
12 801(d)(1) as provided in this section.

13 “(m) AUTHORIZATION OF APPROPRIATIONS.—There
14 are authorized to be appropriated such sums as are nec-
15 essary to carry out this section.

16 “(n) CONDITIONS.—This section shall become effec-
17 tive only if the Secretary demonstrates to the Congress
18 that the implementation of this section will—

19 “(1) pose no additional risk to the public’s
20 health and safety; and

21 “(2) result in a significant reduction in the cost
22 of prescription drugs to the American consumer.”.

23 (b) CONFORMING AMENDMENTS.—The Federal
24 Food, Drug, and Cosmetic Act is amended—

1 (1) in section 301(aa) (21 U.S.C. 331(aa)), by
2 striking “covered product in violation of section
3 804” and inserting “prescription drug in violation of
4 section 804”; and

5 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6),
6 by striking “covered product pursuant to section
7 804(a)” and inserting “prescription drug under sec-
8 tion 804(b)”.

9 **DIVISION B—HEALTH SAVINGS**
10 **AND AFFORDABILITY ACT OF**
11 **2003**

12 **TITLE XII—HEALTH SAVINGS SE-**
13 **CURITY ACCOUNTS AND**
14 **HEALTH SAVINGS ACCOUNTS**

15 **SEC. 1201. SHORT TITLE.**

16 This division may be cited as the “Health Savings
17 and Affordability Act of 2003”.

18 **SEC. 1202. HEALTH SAVINGS SECURITY ACCOUNTS AND**
19 **HEALTH SAVINGS ACCOUNTS.**

20 (a) IN GENERAL.—Part VII of subchapter B of chap-
21 ter 1 of the Internal Revenue Code of 1986 (relating to
22 additional itemized deductions for individuals) is amended
23 by redesignating section 223 as section 225 and by insert-
24 ing after section 222 the following new sections:

1 **“SEC. 223. HEALTH SAVINGS SECURITY ACCOUNTS.**

2 “(a) DEDUCTION ALLOWED.—In the case of an indi-
3 vidual who is an eligible individual for any month during
4 the taxable year, there shall be allowed as a deduction for
5 the taxable year an amount equal to the aggregate amount
6 paid in cash during such taxable year by such individual
7 to a health savings security account of such individual.

8 “(b) LIMITATIONS.—

9 “(1) IN GENERAL.—The amount allowable as a
10 deduction under subsection (a) to an individual for
11 the taxable year shall not exceed the sum of the
12 monthly limitations for months during such taxable
13 year that the individual is an eligible individual.

14 “(2) MONTHLY LIMITATION.—The monthly lim-
15 itation for any month is $\frac{1}{12}$ of—

16 “(A) \$2,000, in the case of an eligible indi-
17 vidual who—

18 “(i) has self-only coverage under a
19 minimum deductible plan as of the first
20 day of such month, or

21 “(ii) is uninsured as of the first day
22 of such month and is not described in sub-
23 paragraph (B)(ii) with respect to the tax-
24 able year which includes such month,

25 “(B) \$4,000, in the case of an eligible indi-
26 vidual who—

1 “(i) has family coverage under a min-
2 imum deductible plan as of the first day of
3 such month, or

4 “(ii) is uninsured as of the first day
5 of such month and, with respect to the tax-
6 able year which includes such month—

7 “(I) is entitled to a deduction for
8 a dependent under section 151(e) (or
9 would be so entitled but for paragraph
10 (2) or (4) of section 152(e)), or

11 “(II) files a joint return, and

12 “(C) zero in any other case.

13 “(3) ADDITIONAL CONTRIBUTIONS FOR INDI-
14 VIDUALS 55 OR OLDER.—

15 “(A) IN GENERAL.—In the case of an indi-
16 vidual who has attained the age of 55 before
17 the close of the taxable year, paragraph (2)
18 shall be applied by increasing the \$2,000
19 amount in paragraph (2)(A) and the \$4,000
20 amount in paragraph (2)(B) by the additional
21 contribution amount.

22 “(B) ADDITIONAL CONTRIBUTION
23 AMOUNT.—For purposes of this section, the ad-
24 ditional contribution amount is the amount de-
25 termined in accordance with the following table:

“For taxable years beginning in:	The additional contribution amount is:
2004	\$500
2005	\$600
2006	\$700
2007	\$800
2008	\$900
2009 and thereafter	\$1,000.

1 “(4) LIMITATION BASED ON ADJUSTED GROSS
2 INCOME.—

3 “(A) SELF-ONLY COVERAGE.—The dollar
4 amount in paragraph (2)(A) (as increased
5 under paragraph (3)) shall be reduced (but not
6 below zero) by an amount which bears the same
7 ratio to such dollar amount as—

8 “(i) the amount (if any) by which the
9 taxpayer’s adjusted gross income for such
10 taxable year exceeds \$75,000 (\$150,000 in
11 the case of a joint return), bears to

12 “(ii) \$10,000 (\$20,000 in the case of
13 a joint return).

14 “(B) FAMILY COVERAGE.—The dollar
15 amount in paragraph (2)(B) (as increased
16 under paragraph (3)) shall be reduced (but not
17 below zero) by an amount which bears the same
18 ratio to such dollar amount as—

19 “(i) the amount (if any) by which the
20 taxpayer’s adjusted gross income for such
21 taxable year exceeds \$150,000, bears to

1 “(ii) \$20,000.

2 “(C) NO REDUCTION BELOW \$200 UNTIL
3 COMPLETE PHASE-OUT.—No dollar amount
4 shall be reduced below \$200 under subpara-
5 graph (A) or (B) unless (without regard to this
6 subparagraph) such limitation is reduced to
7 zero.

8 “(D) ROUNDING.—Any amount deter-
9 mined under this paragraph which is not a mul-
10 tiple of \$10 shall be rounded to the next lowest
11 \$10.

12 “(E) ADJUSTED GROSS INCOME.—For pur-
13 poses of this paragraph, adjusted gross income
14 shall be determined—

15 “(i) without regard to this section or
16 section 911, and

17 “(ii) after application of sections 86,
18 135, 137, 219, 221, 222, and 469.

19 “(5) COORDINATION WITH OTHER CONTRIBU-
20 TIONS.—The limitation which would (but for this
21 paragraph) apply under this subsection to the tax-
22 payer for any taxable year shall be reduced (but not
23 below zero) by the sum of—

1 “(A) the aggregate amount paid during
2 such taxable year to Archer MSAs of such indi-
3 vidual,

4 “(B) the aggregate amount paid during
5 such taxable year to health savings accounts of
6 such individual, and

7 “(C) the aggregate amount paid during
8 such taxable year to health savings security ac-
9 counts of such individual by persons other than
10 such individual.

11 “(6) SPECIAL RULES FOR MARRIED INDIVID-
12 UALS, DEPENDENTS, AND MEDICARE ELIGIBLE INDI-
13 VIDUALS.—Rules similar to the rules of paragraphs
14 (3), (6), and (7) of section 220(b) shall apply for
15 purposes of this section.

16 “(c) DEFINITIONS.—For purposes of this section—

17 “(1) ELIGIBLE INDIVIDUAL.—

18 “(A) IN GENERAL.—The term ‘eligible in-
19 dividual’ means, with respect to any month, any
20 individual unless such individual is covered, as
21 of the first day of such month, under any
22 health plan which is not a minimum deductible
23 plan.

1 “(B) CERTAIN COVERAGE DIS-
2 REGARDED.—Subparagraph (A) shall be ap-
3 plied without regard to—

4 “(i) coverage for any benefit provided
5 by permitted insurance, and

6 “(ii) coverage (whether through insur-
7 ance or otherwise) for accidents, disability,
8 dental care, vision care, or long-term care.

9 “(2) MINIMUM DEDUCTIBLE PLAN.—

10 “(A) IN GENERAL.—The term ‘minimum
11 deductible plan’ means a health plan—

12 “(i) in the case of self-only coverage,
13 which has an annual deductible which is
14 not less than \$500, and

15 “(ii) in the case of family coverage,
16 which has an annual deductible which is
17 not less than twice the dollar amount in
18 clause (i) (as increased under subpara-
19 graph (B)).

20 “(B) COST-OF-LIVING ADJUSTMENT FOR
21 ANNUAL DEDUCTIBLES.—

22 “(i) IN GENERAL.—In the case of any
23 taxable year beginning in a calendar year
24 after 2004, the \$500 amount in subpara-

1 graph (A)(i) shall be increased by an
2 amount equal to—

3 “(I) such dollar amount, multi-
4 plied by

5 “(II) the cost-of-living adjust-
6 ment determined under section 1(f)(3)
7 for the calendar year in which such
8 taxable year begins by substituting
9 ‘calendar year 2003’ for ‘calendar
10 year 1992’ in subparagraph (B) there-
11 of.

12 “(ii) ROUNDING.—If any increase
13 under clause (i) is not a multiple of \$50,
14 such increase shall be rounded to the near-
15 est multiple of \$50.

16 “(C) SPECIAL RULES.—

17 “(i) EXCLUSION OF CERTAIN
18 PLANS.—Such term does not include a
19 health plan if substantially all of its cov-
20 erage is coverage described in paragraph
21 (1)(B).

22 “(ii) SAFE HARBOR FOR ABSENCE OF
23 PREVENTIVE CARE DEDUCTIBLE.—A plan
24 shall not fail to be treated as a minimum

1 deductible plan by reason of failing to have
2 a deductible for preventive care.

3 “(3) UNINSURED.—An individual shall be treat-
4 ed as uninsured if such individual is not covered by
5 insurance which constitutes medical care. The pre-
6 ceding sentence shall be applied without regard to
7 the coverage described in paragraph (1)(B).

8 “(4) PERMITTED INSURANCE.—The term ‘per-
9 mitted insurance’ has the meaning given such term
10 in section 220(c)(3).

11 “(5) FAMILY COVERAGE.—The term ‘family
12 coverage’ has the meaning given such term in sec-
13 tion 220(c)(5).

14 “(6) ARCHER MSA.—The term ‘Archer MSA’
15 has the meaning given such term in section 220(d).

16 “(7) HEALTH SAVINGS ACCOUNT.—The term
17 ‘health savings account’ has the meaning given such
18 term in section 224(d).

19 “(d) HEALTH SAVINGS SECURITY ACCOUNT.—For
20 purposes of this section—

21 “(1) IN GENERAL.—The term ‘health savings
22 security account’ means a trust created or organized
23 in the United States as a health savings security ac-
24 count exclusively for the purpose of paying the quali-
25 fied medical expenses of the account beneficiary, but

1 only if the written governing instrument creating the
2 trust meets the following requirements:

3 “(A) Except in the case of a rollover con-
4 tribution from an Archer MSA, or a health sav-
5 ings security account, which is not includible in
6 gross income, no contribution will be accepted—

7 “(i) unless it is in cash and is contrib-
8 uted by—

9 “(I) the account beneficiary,

10 “(II) a member of the family of
11 the account beneficiary, or

12 “(III) an employer of the account
13 beneficiary, and

14 “(ii) to the extent such contribution,
15 when added to previous contributions to
16 the trust for the calendar year, exceeds the
17 highest annual limitation which could
18 apply to an individual under subsection (b)
19 for a taxable year beginning in such cal-
20 endar year.

21 “(B) The trustee is a bank (as defined in
22 section 408(n)), an insurance company (as de-
23 fined in section 816), or another person who
24 demonstrates to the satisfaction of the Sec-
25 retary that the manner in which such person

1 will administer the trust will be consistent with
2 the requirements of this section.

3 “(C) No part of the trust assets will be in-
4 vested in life insurance contracts.

5 “(D) The assets of the trust will not be
6 commingled with other property except in a
7 common trust fund or common investment
8 fund.

9 “(E) The interest of an individual in the
10 balance in his account is nonforfeitable.

11 “(2) MEMBER OF THE FAMILY.—The term
12 ‘member of the family’ has the meaning given such
13 term in section 2032A(e)(2).

14 “(3) QUALIFIED MEDICAL EXPENSES.—The
15 term ‘qualified medical expenses’ has the meaning
16 given such term in section 220(d)(2), except that—

17 “(A) subparagraph (B)(i) thereof shall not
18 apply to—

19 “(i) insurance which constitutes a
20 minimum deductible plan if no portion of
21 the cost of such insurance is paid by an
22 employer or former employer of the ac-
23 count beneficiary or the spouse of such
24 beneficiary, and

1 “(ii) any health insurance (other than
2 health insurance substantially all of its
3 coverage is coverage described in sub-
4 section (c)(1)(B)) if the account bene-
5 ficiary has attained age 65, and

6 “(B) subparagraph (C) thereof shall not
7 apply for purposes of this section.

8 “(4) ACCOUNT BENEFICIARY.—The term ‘ac-
9 count beneficiary’ means the individual on whose be-
10 half the health savings security account was estab-
11 lished.

12 “(5) CERTAIN RULES TO APPLY.—Rules similar
13 to the following rules shall apply for purposes of this
14 section:

15 “(A) Section 219(d)(2) (relating to no de-
16 duction for rollovers).

17 “(B) Section 219(f)(3) (relating to time
18 when contributions deemed made).

19 “(C) Except as provided in section 106(d),
20 section 219(f)(5) (relating to employer pay-
21 ments).

22 “(D) Section 408(g) (relating to commu-
23 nity property laws).

24 “(E) Section 408(h) (relating to custodial
25 accounts).

1 “(6) CONTRIBUTIONS FROM FLEXIBLE SPEND-
2 ING ACCOUNTS TREATED AS MADE BY THE EM-
3 PLOYER.—Any contribution from a flexible spending
4 account to a health savings security account which
5 is not includible in the gross income of the employee
6 by reason of section 125(h) shall be treated as a
7 contribution made by the employer for purposes of
8 this section.

9 “(e) TAX TREATMENT OF ACCOUNTS.—

10 “(1) IN GENERAL.—A health savings security
11 account is exempt from taxation under this subtitle
12 unless such account has ceased to be a health sav-
13 ings security account. Notwithstanding the preceding
14 sentence, any such account is subject to the taxes
15 imposed by section 511 (relating to imposition of tax
16 on unrelated business income of charitable, etc. or-
17 ganizations).

18 “(2) ACCOUNT TERMINATIONS.—Rules similar
19 to the rules of paragraphs (2) and (4) of section
20 408(e) shall apply to health savings security ac-
21 counts, and any amount treated as distributed under
22 such similar rules shall be treated as not used to pay
23 qualified medical expenses.

24 “(f) TAX TREATMENT OF DISTRIBUTIONS.—

1 “(1) AMOUNTS USED FOR QUALIFIED MEDICAL
2 EXPENSES.—Any amount paid or distributed out of
3 a health savings security account which is used ex-
4 clusively to pay qualified medical expenses of any ac-
5 count beneficiary shall not be includible in gross in-
6 come.

7 “(2) INCLUSION OF AMOUNTS NOT USED FOR
8 QUALIFIED MEDICAL EXPENSES.—

9 “(A) IN GENERAL.—Any amount paid or
10 distributed out of a health savings security ac-
11 count which is not used exclusively to pay the
12 qualified medical expenses of the account bene-
13 ficiary shall be included in the gross income of
14 such beneficiary in the manner provided under
15 section 72.

16 “(B) SPECIAL RULES FOR APPLYING SEC-
17 TION 72.—For purposes of applying section 72
18 to any amount described in subparagraph (A)—

19 “(i) all health savings security ac-
20 counts shall be treated as 1 contract,

21 “(ii) all distributions during any tax-
22 able year shall be treated as 1 distribution,

23 “(iii) the value of the contract, income
24 on the contract, and investment in the con-
25 tract shall be computed as of the close of

1 the calendar year in which the taxable year
2 begins, and

3 “(iv) such distributions shall be treat-
4 ed as made from contributions from mem-
5 bers of the family of the account bene-
6 ficiary to the extent that such distribution,
7 when added to all previous distributions
8 from the health savings security account
9 taken into account under this clause, do
10 not exceed the aggregate contributions
11 from members of such family.

12 “(3) EXCESS CONTRIBUTIONS RETURNED BE-
13 FORE DUE DATE OF RETURN.—

14 “(A) IN GENERAL.—If any excess con-
15 tribution is contributed for a taxable year to
16 any health savings security account of an indi-
17 vidual, paragraph (2) shall not apply to dis-
18 tributions from the health savings security ac-
19 counts of such individual (to the extent such
20 distributions do not exceed the aggregate excess
21 contributions to all such accounts of such indi-
22 vidual for such year) if—

23 “(i) such distribution is made on or
24 before the last day prescribed by law (in-
25 cluding extensions of time) for filing the

1 account beneficiary's return for such tax-
2 able year,

3 “(ii) no deduction is allowed under
4 this section with respect to such contribu-
5 tion,

6 “(iii) such distribution is accompanied
7 by the amount of net income attributable
8 to such excess contribution, and

9 “(iv) such distribution satisfies the re-
10 quirements of subparagraph (B).

11 “(B) RULES RELATED TO ORDERING.—

12 “(i) DISTRIBUTIONS LIMITED TO CON-
13 TRIBUTIONS.—Subparagraph (A) shall
14 apply to distributions to a person only to
15 the extent of the contributions of such per-
16 son to such accounts during such taxable
17 year.

18 “(ii) CLASSES OF CONTRIBUTORS.—
19 Subparagraph (A) shall apply only to dis-
20 tributions of such contributions which are
21 made in the following order:

22 “(I) first, to members of the fam-
23 ily of the account beneficiary,

24 “(II) second, to the account ben-
25 eficiary,

1 “(III) third, to employers of the
2 account beneficiary with respect to
3 contributions under section 125(h),
4 and

5 “(IV) fourth, to employers of the
6 account beneficiary with respect to
7 contributions under section 106(d).

8 “(iii) LAST-IN FIRST-OUT.—If dis-
9 tributions could be made to more than one
10 person under any subclause of clause (ii),
11 subparagraph (A) shall not apply to any
12 such distribution unless such distribution
13 is of the most recent excess contribution
14 which has not been distributed to the con-
15 tributor.

16 “(C) TREATMENT OF NET INCOME.—Any
17 net income described in subparagraph (A)(iii)
18 shall be included in the gross income of the per-
19 son receiving the distribution for the taxable
20 year in which received.

21 “(D) EXCESS CONTRIBUTION.—For pur-
22 poses of subparagraph (A), the term ‘excess
23 contribution’ means any contribution (other
24 than a rollover contribution from another health
25 savings security account, or from an Archer

1 MSA, which is not includible in gross income)
2 to the extent such contribution results in the
3 aggregate contributions to health savings secu-
4 rity accounts of the account beneficiary for the
5 taxable year to be in excess of the limitation
6 under subsection (b) (determined without re-
7 gard to paragraph (5)(C) thereof) which applies
8 to such beneficiary for such year.

9 “(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT
10 USED FOR QUALIFIED MEDICAL EXPENSES.—

11 “(A) IN GENERAL.—The tax imposed by
12 this chapter on the account beneficiary for any
13 taxable year in which there is a payment or dis-
14 tribution from a health savings security account
15 of such beneficiary which is includible in gross
16 income under paragraph (2) shall be increased
17 by 15 percent of the amount which is so includ-
18 ible.

19 “(B) EXCEPTION FOR DISABILITY OR
20 DEATH.—Subparagraph (A) shall not apply if
21 the payment or distribution is made after the
22 account beneficiary becomes disabled within the
23 meaning of section 72(m)(7) or dies.

24 “(C) EXCEPTION FOR DISTRIBUTIONS
25 AFTER MEDICARE ELIGIBILITY.—Subparagraph

1 (A) shall not apply to any payment or distribu-
2 tion after the date on which the account bene-
3 ficiary attains the age specified in section 1811
4 of the Social Security Act.

5 “(5) ROLLOVER CONTRIBUTION.—

6 “(A) IN GENERAL.—Paragraph (2) shall
7 not apply to any amount paid or distributed
8 from a health savings security account to the
9 account beneficiary to the extent the amount
10 received is paid into a health savings security
11 account, or a health savings account, for the
12 benefit of such beneficiary not later than the
13 60th day after the day on which the beneficiary
14 receives the payment or distribution.

15 “(B) LIMITATION.—This paragraph shall
16 not apply to any amount described in subpara-
17 graph (A) received by an individual from a
18 health savings security account if, at any time
19 during the 1-year period ending on the day of
20 such receipt, such individual received any other
21 amount described in subparagraph (A) from a
22 health savings security account which was not
23 includible in the individual’s gross income be-
24 cause of the application of this paragraph.

1 “(6) SPECIAL RULES.—Rules similar to the
2 rules of paragraphs (6), (7), and (8) of section
3 220(f) shall apply for purposes of this section.

4 “(g) REPORTS.—The Secretary may require the
5 trustee of a health savings security account to make such
6 reports regarding such account to the Secretary and to
7 the account beneficiary with respect to contributions, dis-
8 tributions, and such other matters as the Secretary deter-
9 mines appropriate. The reports required by this subsection
10 shall be filed at such time and in such manner and fur-
11 nished to such individuals at such time and in such man-
12 ner as may be required by the Secretary.

13 “(h) REGULATIONS.—The Secretary may issue regu-
14 lations to carry out the purposes of this section, including
15 regulations regarding the proper treatment of distribu-
16 tions described in subsection (f)(3) and nondeductible con-
17 tributions by members of the family of the account bene-
18 ficiary.

19 **“SEC. 224. HEALTH SAVINGS ACCOUNTS.**

20 “(a) DEDUCTION ALLOWED.—In the case of an indi-
21 vidual who is an eligible individual for any month during
22 the taxable year, there shall be allowed as a deduction for
23 the taxable year an amount equal to the aggregate amount
24 paid in cash during such taxable year by such individual
25 to a health savings account of such individual.

1 “(b) LIMITATIONS.—

2 “(1) IN GENERAL.—The amount allowable as a
3 deduction under subsection (a) to an individual for
4 the taxable year shall not exceed the sum of the
5 monthly limitations for months during such taxable
6 year that the individual is an eligible individual.

7 “(2) MONTHLY LIMITATION.—The monthly lim-
8 itation for any month is the amount equal to $\frac{1}{12}$ of
9 the annual deductible (as of the first day of such
10 month) of the individual’s coverage under the high
11 deductible health plan.

12 “(3) COORDINATION WITH OTHER CONTRIBU-
13 TIONS.—The limitation which would (but for this
14 paragraph) apply under this subsection to the tax-
15 payer for any taxable year shall be reduced (but not
16 below zero) by the sum of—

17 “(A) the aggregate amount paid during
18 such taxable year to Archer MSAs of such indi-
19 vidual,

20 “(B) the aggregate amount paid during
21 such taxable year to health savings security ac-
22 counts of such individual, and

23 “(C) the aggregate amount paid during
24 such taxable year to health savings accounts of

1 such individual by persons other than such indi-
2 vidual.

3 “(4) SPECIAL RULES FOR MARRIED INDIVID-
4 UALS, DEPENDENTS, AND MEDICARE ELIGIBLE INDI-
5 VIDUALS.—Rules similar to the rules of paragraphs
6 (3), (6), and (7) of section 220(b) shall apply for
7 purposes of this section.

8 “(c) DEFINITIONS.—For purposes of this section—

9 “(1) ELIGIBLE INDIVIDUAL.—

10 “(A) IN GENERAL.—The term ‘eligible in-
11 dividual’ means, with respect to any month, any
12 individual if—

13 “(i) such individual is covered under a
14 high deductible health plan as of the 1st
15 day of such month, and

16 “(ii) such individual is not, while cov-
17 ered under a high deductible health plan,
18 covered under any health plan—

19 “(I) which is not a high deduct-
20 ible health plan, and

21 “(II) which provides coverage for
22 any benefit which is covered under the
23 high deductible health plan.

1 “(B) CERTAIN COVERAGE DIS-
2 REGARDED.—Subparagraph (A)(ii) shall be ap-
3 plied without regard to—

4 “(i) coverage for any benefit provided
5 by permitted insurance, and

6 “(ii) coverage (whether through insur-
7 ance or otherwise) for accidents, disability,
8 dental care, vision care, or long-term care.

9 “(2) HIGH DEDUCTIBLE HEALTH PLAN.—

10 “(A) IN GENERAL.—The term ‘high de-
11 ductible health plan’ means a health plan—

12 “(i) in the case of self-only coverage,
13 which has an annual deductible which is
14 not less than \$1,000 and not more than
15 \$2,250,

16 “(ii) in the case of family coverage,
17 which has an annual deductible which is
18 not less than \$2,000 and not more than
19 \$4,500, and

20 “(iii) the annual out-of-pocket ex-
21 penses required to be paid under the plan
22 (other than for premiums) for covered ben-
23 efits does not exceed—

24 “(I) \$3,000 for self-only cov-
25 erage, and

1 “(II) \$5,500 for family coverage.

2 “(B) COST-OF-LIVING ADJUSTMENT.—

3 “(i) IN GENERAL.—In the case of any
4 taxable year beginning in a calendar year
5 after 1998, each dollar amount in subpara-
6 graph (A) shall be increased by an amount
7 equal to—

8 “(I) such dollar amount, multi-
9 plied by

10 “(II) the cost-of-living adjust-
11 ment determined under section 1(f)(3)
12 for the calendar year in which such
13 taxable year begins by substituting
14 ‘calendar year 1997’ for ‘calendar
15 year 1992’ in subparagraph (B) there-
16 of.

17 “(ii) SPECIAL RULES.—In the case of
18 the \$1,000 amount in subparagraph (A)(i)
19 and the \$2,000 amount in subparagraph
20 (A)(ii), subclause (i)(II) shall be applied by
21 substituting ‘calendar year 2002’ for ‘cal-
22 endar year 1997’.

23 “(iii) ROUNDING.—If any increase
24 under clause (i) or (ii) is not a multiple of

1 \$50, such increase shall be rounded to the
2 nearest multiple of \$50.

3 “(C) SPECIAL RULES.—

4 “(i) EXCLUSION OF CERTAIN
5 PLANS.—Such term does not include a
6 health plan if substantially all of its cov-
7 erage is coverage described in paragraph
8 (1)(B).

9 “(ii) SAFE HARBOR FOR ABSENCE OF
10 PREVENTIVE CARE DEDUCTIBLE.— A plan
11 shall not fail to be treated as a high de-
12 ductible health plan by reason of failing to
13 have a deductible for preventive care.

14 “(D) TREATMENT OF NETWORK SERV-
15 ICES.—

16 “(i) IN GENERAL.—In the case of a
17 health plan which is a preferred provider
18 organization plan and which would (with-
19 out regard to services provided outside
20 such organization’s network of providers
21 described in clause (iii)(I)) be a high de-
22 ductible health plan, such plan shall not
23 fail to be a high deductible health plan be-
24 cause—

1 “(I) the annual deductible for
2 services provided outside such network
3 exceeds the applicable maximum dol-
4 lar amount in clause (i) or (ii) of sub-
5 paragraph (A), or

6 “(II) the annual out-of-pocket ex-
7 penses required to be paid for services
8 provided outside such network exceeds
9 the applicable dollar amount in sub-
10 paragraph (A)(iii).

11 “(ii) ANNUAL DEDUCTIBLE.—The an-
12 nual deductible taken into account under
13 subsection (b)(2) with respect to a plan
14 which is a high deductible health plan by
15 reason of clause (i) shall be the annual de-
16 ductible for services provided within such
17 network.

18 “(iii) PREFERRED PROVIDER ORGANI-
19 ZATION PLAN DEFINED.—In this subpara-
20 graph, the term ‘preferred provider organi-
21 zation plan’ means a health plan that—

22 “(I) has a network of providers
23 that have agreed to a contractually
24 specified reimbursement for covered

1 benefits with the organization offering
2 the plan,

3 “(II) provides for reimbursement
4 for all covered benefits regardless of
5 whether such benefits are provided
6 within such network of providers, and

7 “(III) is offered by an organiza-
8 tion that is not licensed or organized
9 under State law as a health mainte-
10 nance organization.

11 “(3) PERMITTED INSURANCE.—The term ‘per-
12 mitted insurance’ has the meaning given such term
13 in section 220(c)(3).

14 “(4) FAMILY COVERAGE.—The term ‘family
15 coverage’ has the meaning given such term in sec-
16 tion 220(c)(5).

17 “(5) ARCHER MSA.—The term ‘Archer MSA’
18 has the meaning given such term in section 220(d).

19 “(6) HEALTH SAVINGS SECURITY ACCOUNT.—
20 The term ‘health savings security account’ has the
21 meaning given such term in section 223(d).

22 “(d) HEALTH SAVINGS ACCOUNT.—For purposes of
23 this section—

24 “(1) IN GENERAL.—The term ‘health savings
25 account’ means a trust created or organized in the

1 United States as a health savings account exclusively
2 for the purpose of paying the qualified medical ex-
3 penses of the account beneficiary, but only if the
4 written governing instrument creating the trust
5 meets the following requirements:

6 “(A) Except in the case of a rollover con-
7 tribution from an Archer MSA, a health savings
8 security account, or a health savings account,
9 which is not includible in gross income, no con-
10 tribution will be accepted—

11 “(i) unless it is in cash and is contrib-
12 uted by—

13 “(I) the account beneficiary, or

14 “(II) an employer of the account
15 beneficiary, and

16 “(ii) to the extent such contribution,
17 when added to previous contributions to
18 the trust for the calendar year, exceeds the
19 highest annual limitation which could
20 apply to an individual under subsection (b)
21 for a taxable year beginning in such cal-
22 endar year.

23 “(B) The trustee is a bank (as defined in
24 section 408(n)), an insurance company (as de-
25 fined in section 816), or another person who

1 demonstrates to the satisfaction of the Sec-
2 retary that the manner in which such person
3 will administer the trust will be consistent with
4 the requirements of this section.

5 “(C) No part of the trust assets will be in-
6 vested in life insurance contracts.

7 “(D) The assets of the trust will not be
8 commingled with other property except in a
9 common trust fund or common investment
10 fund.

11 “(E) The interest of an individual in the
12 balance in his account is nonforfeitable.

13 “(2) QUALIFIED MEDICAL EXPENSES.—The
14 term ‘qualified medical expenses’ has the meaning
15 given such term in section 220(d)(2).

16 “(3) ACCOUNT BENEFICIARY.—The term ‘ac-
17 count beneficiary’ means the individual on whose be-
18 half the health savings account was established.

19 “(4) CERTAIN RULES TO APPLY.—Rules similar
20 to the following rules shall apply for purposes of this
21 section:

22 “(A) Section 219(d)(2) (relating to no de-
23 duction for rollovers).

24 “(B) Section 219(f)(3) (relating to time
25 when contributions deemed made).

1 “(C) Except as provided in section 106(d),
2 section 219(f)(5) (relating to employer pay-
3 ments).

4 “(D) Section 408(g) (relating to commu-
5 nity property laws).

6 “(E) Section 408(h) (relating to custodial
7 accounts).

8 “(6) CONTRIBUTIONS FROM FLEXIBLE SPEND-
9 ING ACCOUNTS TREATED AS MADE BY THE EM-
10 PLOYER.—Any contribution from a flexible spending
11 account to a health savings account which is not in-
12 cludible in the gross income of the employee by rea-
13 son of section 125(h) shall be treated as a contribu-
14 tion made by the employer for purposes of this sec-
15 tion.

16 “(e) TAX TREATMENT OF ACCOUNTS.—

17 “(1) IN GENERAL.—A health savings account is
18 exempt from taxation under this subtitle unless such
19 account has ceased to be a health savings account.
20 Notwithstanding the preceding sentence, any such
21 account is subject to the taxes imposed by section
22 511 (relating to imposition of tax on unrelated busi-
23 ness income of charitable, etc. organizations).

24 “(2) ACCOUNT TERMINATIONS.—Rules similar
25 to the rules of paragraphs (2) and (4) of section

1 408(e) shall apply to health savings accounts, and
2 any amount treated as distributed under such rules
3 shall be treated as not used to pay qualified medical
4 expenses.

5 “(f) TAX TREATMENT OF DISTRIBUTIONS.—

6 “(1) AMOUNTS USED FOR QUALIFIED MEDICAL
7 EXPENSES.—Any amount paid or distributed out of
8 a health savings account which is used exclusively to
9 pay qualified medical expenses of any account bene-
10 ficiary shall not be includible in gross income.

11 “(2) INCLUSION OF AMOUNTS NOT USED FOR
12 QUALIFIED MEDICAL EXPENSES.—Any amount paid
13 or distributed out of a health savings account which
14 is not used exclusively to pay the qualified medical
15 expenses of the account beneficiary shall be included
16 in the gross income of such beneficiary.

17 “(3) EXCESS CONTRIBUTIONS RETURNED BE-
18 FORE DUE DATE OF RETURN.—

19 “(A) IN GENERAL.—If any excess con-
20 tribution is contributed for a taxable year to
21 any health savings account of an individual,
22 paragraph (2) shall not apply to distributions
23 from the health savings accounts of such indi-
24 vidual (to the extent such distributions do not
25 exceed the aggregate excess contributions to all

1 such accounts of such individual for such year)
2 if—

3 “(i) such distribution is made on or
4 before the last day prescribed by law (in-
5 cluding extensions of time) for filing the
6 account beneficiary’s return for such tax-
7 able year,

8 “(ii) no deduction is allowed under
9 this section with respect to such contribu-
10 tion,

11 “(iii) such distribution is accompanied
12 by the amount of net income attributable
13 to such excess contribution, and

14 “(iv) such distribution satisfies the re-
15 quirements of subparagraph (B).

16 “(B) RULES RELATED TO ORDERING.—

17 “(i) DISTRIBUTIONS LIMITED TO CON-
18 TRIBUTIONS.—Subparagraph (A) shall
19 apply to distributions to a person only to
20 the extent of the contributions of such per-
21 son to such accounts during such taxable
22 year.

23 “(ii) CLASSES OF CONTRIBUTORS.—
24 Subparagraph (A) shall apply only to dis-

1 tributions of such contributions which are
2 made in the following order:

3 “(I) first, to the account bene-
4 ficiary,

5 “(II) second, to employers of the
6 account beneficiary with respect to
7 contributions under section 125(h),
8 and

9 “(III) third, to employers of the
10 account beneficiary with respect to
11 contributions under section 106(d).

12 “(iii) LAST-IN FIRST-OUT.—If dis-
13 tributions could be made to more than one
14 person under any subclause of clause (ii),
15 subparagraph (A) shall not apply to any
16 such distribution unless such distribution
17 is of the most recent excess contribution
18 which has not been distributed to the con-
19 tributor.

20 “(C) TREATMENT OF NET INCOME.—Any
21 net income described in subparagraph (A)(iii)
22 shall be included in the gross income of the per-
23 son receiving the distribution for the taxable
24 year in which received.

1 “(D) EXCESS CONTRIBUTION.—For pur-
2 poses of subparagraph (A), the term ‘excess
3 contribution’ means any contribution (other
4 than a rollover contribution from another health
5 savings account, from a health savings security
6 account, or from an Archer MSA, which is not
7 includible in gross income) to the extent such
8 contribution results in the aggregate contribu-
9 tions to health savings accounts of the account
10 beneficiary for the taxable year to be in excess
11 of the limitation under subsection (b) (deter-
12 mined without regard to paragraph (3)(C)
13 thereof) which applies to such beneficiary for
14 such year.

15 “(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT
16 USED FOR QUALIFIED MEDICAL EXPENSES.—

17 “(A) IN GENERAL.—The tax imposed by
18 this chapter on the account beneficiary for any
19 taxable year in which there is a payment or dis-
20 tribution from a health savings account of such
21 beneficiary which is includible in gross income
22 under paragraph (2) shall be increased by 15
23 percent of the amount which is so includible.

24 “(B) EXCEPTION FOR DISABILITY OR
25 DEATH.—Subparagraph (A) shall not apply if

1 the payment or distribution is made after the
2 account beneficiary becomes disabled within the
3 meaning of section 72(m)(7) or dies.

4 “(C) EXCEPTION FOR DISTRIBUTIONS
5 AFTER MEDICARE ELIGIBILITY.—Subparagraph
6 (A) shall not apply to any payment or distribu-
7 tion after the date on which the account bene-
8 ficiary attains the age specified in section 1811
9 of the Social Security Act.

10 “(5) ROLLOVER CONTRIBUTION.—

11 “(A) IN GENERAL.—Paragraph (2) shall
12 not apply to any amount paid or distributed
13 from a health savings account to the account
14 beneficiary to the extent the amount received is
15 paid into a health savings account for the ben-
16 efit of such beneficiary not later than the 60th
17 day after the day on which the beneficiary re-
18 ceives the payment or distribution.

19 “(B) LIMITATION.—This paragraph shall
20 not apply to any amount described in subpara-
21 graph (A) received by an individual from a
22 health savings account if, at any time during
23 the 1-year period ending on the day of such re-
24 ceipt, such individual received any other amount
25 described in subparagraph (A) from a health

1 savings account which was not includible in the
2 individual's gross income because of the appli-
3 cation of this paragraph.

4 “(6) SPECIAL RULES.—Rules similar to the
5 rules of paragraphs (6), (7), and (8) of section
6 220(f) shall apply for purposes of this section.

7 “(g) REPORTS.—The Secretary may require the
8 trustee of a health savings account to make such reports
9 regarding such account to the Secretary and to the ac-
10 count beneficiary with respect to contributions, distribu-
11 tions, and such other matters as the Secretary determines
12 appropriate. The reports required by this subsection shall
13 be filed at such time and in such manner and furnished
14 to such individuals at such time and in such manner as
15 may be required by the Secretary.”.

16 (b) DEDUCTION ALLOWED WHETHER OR NOT INDI-
17 VIDUAL ITEMIZES OTHER DEDUCTIONS.—Subsection (a)
18 of section 62 of such Code is amended by inserting after
19 paragraph (18) the following new paragraphs:

20 “(19) HEALTH SAVINGS SECURITY AC-
21 COUNTS.—The deduction allowed by section 223.

22 “(20) HEALTH SAVINGS ACCOUNTS.—The de-
23 duction allowed by section 224.”.

24 (c) COORDINATION WITH ARCHER MSAs.—

1 (1) ROLLOVERS FROM ARCHER MSAS PER-
2 MITTED.—Subparagraph (A) of section 220(f)(5) of
3 such Code (relating to rollover contribution) is
4 amended by inserting “, a health savings security
5 account (as defined in section 223(d)), or a health
6 savings account (as defined in section 224(d)),”
7 after “paid into an Archer MSA”.

8 (2) REDUCTION IN ARCHER MSA LIMITATION
9 FOR CONTRIBUTIONS TO HEALTH SAVINGS SECURITY
10 ACCOUNTS AND HEALTH SAVINGS ACCOUNTS.—Sub-
11 section (b) of section 220 of such Code (relating to
12 limitations) is amended by adding at the end the fol-
13 lowing new paragraph:

14 “(8) COORDINATION WITH HEALTH SAVINGS
15 SECURITY ACCOUNTS AND HEALTH SAVINGS AC-
16 COUNTS.—The limitation which would (but for this
17 paragraph) apply under this subsection to the tax-
18 payer for any taxable year shall be reduced (but not
19 below zero) by the sum of—

20 “(A) the aggregate amount paid during
21 such taxable year to health savings security ac-
22 counts of such individual, and

23 “(B) the aggregate amount paid during
24 such taxable year to health savings accounts of
25 such individual.”.

1 (d) EXCLUSIONS FOR EMPLOYER CONTRIBUTIONS TO
2 HEALTH SAVINGS SECURITY ACCOUNTS AND HEALTH
3 SAVINGS ACCOUNTS.—

4 (1) EXCLUSION FROM INCOME TAX.—Section
5 106 of such Code (relating to contributions by em-
6 ployer to accident and health plans) is amended by
7 adding at the end the following new subsections:

8 “(d) CONTRIBUTIONS TO HEALTH SAVINGS SECUR-
9 RITY ACCOUNTS.—

10 “(1) IN GENERAL.—In the case of an employee
11 who is an eligible individual, amounts contributed by
12 such employee’s employer to any health savings se-
13 curity account of such employee shall be treated as
14 employer-provided coverage for medical expenses
15 under an accident or health plan to the extent such
16 amounts do not exceed the limitation under section
17 223(b) (determined without regard to this sub-
18 section) which is applicable to such employee for
19 such taxable year.

20 “(2) SPECIAL RULES.—Rules similar to the
21 rules of paragraphs (2), (3), (4), and (5) of sub-
22 section (b) shall apply for purposes of this sub-
23 section.

24 “(3) DEFINITIONS.—For purposes of this sub-
25 section, the terms ‘eligible individual’ and ‘health

1 savings security account' have the respective mean-
2 ings given to such terms by section 223.

3 “(4) CROSS REFERENCE.—

“**For penalty on failure by employer to make com-
parable contributions to the health savings security
accounts of comparable employees, see section
4980G.**

4 “(e) CONTRIBUTIONS TO HEALTH SAVINGS AC-
5 COUNTS.—

6 “(1) IN GENERAL.—In the case of an employee
7 who is an eligible individual, amounts contributed by
8 such employee's employer to any health savings ac-
9 count of such employee shall be treated as employer-
10 provided coverage for medical expenses under an ac-
11 cident or health plan to the extent such amounts do
12 not exceed the limitation under section 224(b) (de-
13 termined without regard to this subsection) which is
14 applicable to such employee for such taxable year.

15 “(2) SPECIAL RULES.—Rules similar to the
16 rules of paragraphs (2), (3), (4), and (5) of sub-
17 section (b) shall apply for purposes of this sub-
18 section.

19 “(3) DEFINITIONS.—For purposes of this sub-
20 section, the terms ‘eligible individual’ and ‘health
21 savings account’ have the respective meanings given
22 to such terms by section 224.

1 “(4) CROSS REFERENCE.—

“For penalty on failure by employer to make comparable contributions to the health savings accounts of comparable employees, see section 4980G.”.

2 (2) EXCLUSION FROM EMPLOYMENT TAXES.—

3 (A) RAILROAD RETIREMENT TAX.—Sub-
4 section (e) of section 3231 of such Code is
5 amended by adding at the end the following
6 new paragraph:

7 “(11) HEALTH SAVINGS SECURITY ACCOUNT
8 AND HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—
9 The term ‘compensation’ shall not include any pay-
10 ment made to or for the benefit of an employee if
11 at the time of such payment it is reasonable to be-
12 lieve that the employee will be able to exclude such
13 payment from income under subsection (d) or (e) of
14 section 106.”.

15 (B) UNEMPLOYMENT TAX.—Subsection (b)
16 of section 3306 of such Code is amended by
17 striking “or” at the end of paragraph (16), by
18 striking the period at the end of paragraph (17)
19 and inserting “; or”, and by inserting after
20 paragraph (17) the following new paragraph:

21 “(18) any payment made to or for the benefit
22 of an employee if at the time of such payment it is
23 reasonable to believe that the employee will be able

1 to exclude such payment from income under sub-
2 section (d) or (e) of section 106.”.

3 (C) WITHHOLDING TAX.—Subsection (a)
4 of section 3401 of such Code is amended by
5 striking “or” at the end of paragraph (20), by
6 striking the period at the end of paragraph (21)
7 and inserting “; or”, and by inserting after
8 paragraph (21) the following new paragraph:

9 “(22) any payment made to or for the benefit
10 of an employee if at the time of such payment it is
11 reasonable to believe that the employee will be able
12 to exclude such payment from income under sub-
13 section (d) or (e) of section 106.”.

14 (3) EMPLOYER CONTRIBUTIONS REQUIRED TO
15 BE SHOWN ON W-2.—Subsection (a) of section 6051
16 of such Code is amended by striking “and” at the
17 end of paragraph (10), by striking the period at the
18 end of paragraph (11) and inserting a comma, and
19 by inserting after paragraph (11) the following new
20 paragraphs:

21 “(12) the amount contributed to any health
22 savings security account (as defined in section
23 223(d)) of such employee or such employee’s spouse,
24 and

1 “(13) the amount contributed to any health
2 savings account (as defined in section 224(d)) of
3 such employee or such employee’s spouse.”.

4 (4) PENALTY FOR FAILURE OF EMPLOYER TO
5 MAKE COMPARABLE HEALTH SAVINGS ACCOUNT
6 CONTRIBUTIONS.—

7 (A) IN GENERAL.—Chapter 43 of such
8 Code is amended by adding after section 4980F
9 the following new section:

10 **“SEC. 4980G. FAILURE OF EMPLOYER TO MAKE COM-**
11 **PARABLE HEALTH SAVINGS ACCOUNT CON-**
12 **TRIBUTIONS.**

13 “(a) GENERAL RULE.—In the case of an employer
14 who makes a contribution to the health savings security
15 account or the health savings account of any employee
16 during a calendar year, there is hereby imposed a tax on
17 the failure of such employer to meet the requirements of
18 subsection (b) for such calendar year.

19 “(b) RULES AND REQUIREMENTS.—Rules and re-
20 quirements similar to the rules and requirements of sec-
21 tion 4980E shall apply for purposes of this section.

22 “(c) REGULATIONS.—The Secretary shall issue regu-
23 lations to carry out the purposes of this section, including
24 regulations providing special rules for employers who

1 make contributions to more than one of the following types
2 of accounts during the calendar year:

3 “(1) An Archer MSA.

4 “(2) A health savings security account.

5 “(3) A health savings account.”.

6 (B) CLERICAL AMENDMENT.—The table of
7 sections for chapter 43 of such Code is amend-
8 ed by adding after the item relating to section
9 4980F the following new item:

“Sec. 4980G. Failure of employer to make comparable health savings account contributions.”.

10 (e) TAX ON EXCESS CONTRIBUTIONS.—Section 4973
11 of such Code (relating to tax on excess contributions to
12 certain tax-favored accounts and annuities) is amended—

13 (1) by striking “or” at the end of paragraph
14 (3) of subsection (a),

15 (2) by inserting after paragraph (4) of sub-
16 section (a) the following new paragraphs:

17 “(5) a health savings security account (within
18 the meaning of section 223(d)), or

19 “(6) a health savings account (within the mean-
20 ing of section 224(d))”, and

21 (4) by adding at the end the following new sub-
22 sections:

23 “(g) EXCESS CONTRIBUTIONS TO HEALTH SAVINGS
24 SECURITY ACCOUNTS.—For purposes of this section, in

1 the case of health savings security accounts (within the
2 meaning of section 223(d)), the term ‘excess contribu-
3 tions’ means the sum of—

4 “(1) the aggregate amount contributed for the
5 taxable year to the accounts (other than a rollover
6 contribution from another health savings security ac-
7 count, or from an Archer MSA, which is not includ-
8 ible in gross income) which is in excess of the limita-
9 tion under section 223(b) (determined without re-
10 gard to paragraph (5)(C) thereof), and

11 “(2) the amount determined under this sub-
12 section for the preceding taxable year, reduced by
13 the sum of—

14 “(A) the distributions out of the accounts
15 which were included in gross income under sec-
16 tion 223(f)(2), and

17 “(B) the excess (if any) of—

18 “(i) the sum of limitations described
19 in paragraph (1), over

20 “(ii) the amount contributed to the
21 accounts for the taxable year.

22 For purposes of this subsection, any contribution which
23 is distributed out of the health savings security account
24 in a distribution to which section 223(f)(3) applies shall
25 be treated as an amount not contributed.

1 “(h) EXCESS CONTRIBUTIONS TO HEALTH SAVINGS
2 ACCOUNTS.—For purposes of this section, in the case of
3 health savings accounts (within the meaning of section
4 224(d)), the term ‘excess contributions’ means the sum
5 of—

6 “(1) the aggregate amount contributed for the
7 taxable year to the accounts (other than a rollover
8 contribution from another health savings account, a
9 health savings security account, or from an Archer
10 MSA, which is not includible in gross income) which
11 is in excess of the limitation under section 224(b)
12 (determined without regard to paragraph (3)(C)
13 thereof), and

14 “(2) the amount determined under this sub-
15 section for the preceding taxable year, reduced by
16 the sum of—

17 “(A) the distributions out of the accounts
18 which were included in gross income under sec-
19 tion 224(f)(2), and

20 “(B) the excess (if any) of—

21 “(i) the sum of limitations described
22 in paragraph (1), over

23 “(ii) the amount contributed to the
24 accounts for the taxable year.

1 For purposes of this subsection, any contribution which
2 is distributed out of the health savings account in a dis-
3 tribution to which section 224(f)(3) applies shall be treat-
4 ed as an amount not contributed.”.

5 (f) TAX ON PROHIBITED TRANSACTIONS.—

6 (1) Section 4975 of such Code (relating to tax
7 on prohibited transactions) is amended by adding at
8 the end of subsection (c) the following new para-
9 graphs:

10 “(6) SPECIAL RULE FOR HEALTH SAVINGS SE-
11 CURITY ACCOUNTS.—An individual for whose benefit
12 a health savings security account (within the mean-
13 ing of section 223(d)) is established shall be exempt
14 from the tax imposed by this section with respect to
15 any transaction concerning such account (which
16 would otherwise be taxable under this section) if,
17 with respect to such transaction, the account ceases
18 to be a health savings security account by reason of
19 the application of section 223(e)(2) to such account.

20 “(7) SPECIAL RULE FOR HEALTH SAVINGS AC-
21 COUNTS.—An individual for whose benefit a health
22 savings account (within the meaning of section
23 224(d)) is established shall be exempt from the tax
24 imposed by this section with respect to any trans-
25 action concerning such account (which would other-

1 wise be taxable under this section) if, with respect
2 to such transaction, the account ceases to be a
3 health savings account by reason of the application
4 of section 224(e)(2) to such account.”.

5 (2) Paragraph (1) of section 4975(e) of such
6 Code is amended by redesignating subparagraphs
7 (E) and (F) as subparagraphs (G) and (H), respec-
8 tively, and by inserting after subparagraph (D) the
9 following new subparagraphs:

10 “(E) a health savings security account de-
11 scribed in section 223(d),

12 “(F) a health savings account described in
13 section 224(d),”.

14 (g) FAILURE TO PROVIDE REPORTS ON HEALTH
15 SAVINGS ACCOUNTS.—Paragraph (2) of section 6693(a)
16 of such Code (relating to reports) is amended by redesi-
17 gnating subparagraphs (C) and (D) as subparagraphs (E)
18 and (F), respectively, and by inserting after subparagraph
19 (B) the following new subparagraphs:

20 “(C) section 223(g) (relating to health sav-
21 ings security accounts),

22 “(D) section 224(g) (relating to health
23 savings accounts),”.

24 (h) EXCEPTION FROM CAPITALIZATION OF POLICY
25 ACQUISITION EXPENSES.—Subparagraph (B) of section

1 848(e)(1) of such Code (defining specified insurance con-
2 tract) is amended by striking “and” at the end of clause
3 (iii), by striking the period at the end of clause (iv) and
4 inserting a comma, and by adding at the end the following
5 new clauses:

6 “(v) any contract which is a health
7 savings security account (as defined in sec-
8 tion 223(d)), and”.

9 “(vi) any contract which is a health
10 savings account (as defined in section
11 224(d)).”.

12 (i) HEALTH SAVINGS SECURITY ACCOUNTS AND
13 HEALTH SAVINGS ACCOUNTS MAY BE OFFERED UNDER
14 CAFETERIA PLANS.—Paragraph (2) of section 125(d) (re-
15 lating to cafeteria plan defined) is amended by adding at
16 the end the following new subparagraph:

17 “(D) EXCEPTION FOR HEALTH SAVINGS
18 ACCOUNTS.—Subparagraph (A) shall not apply
19 to a plan to the extent of amounts which a cov-
20 ered employee may elect to have the employer
21 pay as contributions to a health savings secu-
22 rity account, or a health savings account, estab-
23 lished on behalf of the employee.”.

24 (j) INFORMATION REPORTING BY PROVIDERS OF
25 HEALTH INSURANCE.—Subpart B of part III of sub-

1 chapter A of chapter 61 of such Code is amended by add-
2 ing at the end the following new section:

3 **“SEC. 6050U. RETURNS RELATING TO PROVIDERS OF**
4 **HEALTH INSURANCE.**

5 “(a) REQUIREMENT OF REPORTING.—Under regula-
6 tions prescribed by the Secretary, every person who pro-
7 vides any individual with coverage under a plan which con-
8 stitutes medical care shall, at such time as the Secretary
9 may prescribe, make the return described in subsection (b)
10 with respect to such individual.

11 “(b) FORM AND MANNER OF RETURNS.—A return
12 is described in this subsection if such return—

13 “(1) is in such form as the Secretary may pre-
14 scribe, and

15 “(2) contains such information as the Secretary
16 prescribes.

17 “(c) STATEMENTS TO BE FURNISHED TO INDIVID-
18 UALS WITH RESPECT TO WHOM INFORMATION IS RE-
19 QUIRED.—Every person required to make a return under
20 subsection (a) shall furnish to each individual whose name
21 is required to be set forth in such return a written state-
22 ment showing—

23 “(1) the name and address of the person re-
24 quired to make such return and the phone number
25 of the information contact for such person, and

1 “(2) the information required to be shown on
2 the return with respect to such individual.

3 The written statement required under the preceding sen-
4 tence shall be furnished on or before January 31 of the
5 year following the calendar year for which the return
6 under subsection (a) is required to be made.”.

7 (k) CONFORMING AMENDMENTS.—

8 (1) The table of sections for part VII of sub-
9 chapter B of chapter 1 of such Code is amended by
10 striking the last item and inserting the following:

“Sec. 223. Health savings security accounts.

“Sec. 224. Health savings accounts.

“Sec. 225. Cross reference.”.

11 (2)(A) Sections 86(b)(2)(A), 135(c)(4)(A),
12 137(b)(3)(A), 219(g)(3)(A)(ii), and 221(b)(2)(C)(i)
13 are each amended by inserting “223,” after “222,”.

14 (B) Section 222(b)(2)(C)(i) is amended by in-
15 serting “223,” before “911”.

16 (C) Section 469(i)(3)(F)(iii) is amended by
17 striking “and 222” and inserting “222, and 223”.

18 (l) EFFECTIVE DATE.—The amendments made by
19 this section shall apply to taxable years beginning after
20 December 31, 2003.

1 **SEC. 1203. DISPOSITION OF UNUSED HEALTH BENEFITS IN**
2 **CAFETERIA PLANS AND FLEXIBLE SPENDING**
3 **ARRANGEMENTS.**

4 (a) IN GENERAL.—Section 125 of the Internal Rev-
5 enue Code of 1986 (relating to cafeteria plans) is amended
6 by redesignating subsections (h) and (i) as subsections (i)
7 and (j), respectively, and by inserting after subsection (g)
8 the following:

9 “(h) CONTRIBUTIONS OF CERTAIN UNUSED HEALTH
10 BENEFITS.—

11 “(1) IN GENERAL.—For purposes of this title,
12 a plan or other arrangement shall not fail to be
13 treated as a cafeteria plan solely because qualified
14 benefits under such plan include a health flexible
15 spending arrangement under which not more than
16 \$500 of unused health benefits may be—

17 “(A) carried forward to the succeeding
18 plan year of such health flexible spending ar-
19 rangement,

20 “(B) to the extent permitted by sections
21 223 and 224, contributed on behalf of the em-
22 ployee to a health savings security account (as
23 defined in section 223(d)), or a health savings
24 account (as defined in section 224(d)), main-
25 tained for the benefit of such employee, or

1 “(C) contributed to a qualified retirement
2 plan (as defined in section 4974(e)), or an eligi-
3 ble deferred compensation plan (as defined in
4 section 457(b)) of an eligible employer de-
5 scribed in section 457(e)(1)(A), but only to the
6 extent such amount would not be allowed as a
7 deduction under—

8 “(i) section 223 if made directly by
9 the employee to a health savings security
10 account of the employee (determined with-
11 out regard to any other contributions made
12 by the employee), and

13 “(ii) section 224 if made directly by
14 the employee to a health savings account
15 of the employee (determined without re-
16 gard to any other contributions made by
17 the employee).

18 “(2) SPECIAL RULES FOR TREATMENT OF CON-
19 TRIBUTIONS TO RETIREMENT PLANS.—For purposes
20 of this title, contributions under paragraph (1)(C)—

21 “(A) shall be treated as elective deferrals
22 (as defined in section 402(g)(3)) in the case of
23 contributions to a qualified cash or deferred ar-
24 rangement (as defined in section 401(k)) or to
25 an annuity contract described in section 403(b),

1 “(B) shall be treated as employer contribu-
2 tions to which the employee has a nonforfeitable
3 right in the case of a plan (other than a plan
4 described in subparagraph (A)) which is de-
5 scribed in section 401(a) which includes a trust
6 exempt from tax under section 501(a),

7 “(C) shall be treated as deferred com-
8 pensation in the case of contributions to an eli-
9 gible deferred compensation plan (as defined in
10 section 457(b)), and

11 “(D) shall be treated in the manner des-
12 ignated for purposes of section 408 or 408A in
13 the case of contributions to an individual retire-
14 ment plan.

15 “(3) HEALTH FLEXIBLE SPENDING ARRANGE-
16 MENT.—For purposes of this subsection, the term
17 ‘health flexible spending arrangement’ means a flexi-
18 ble spending arrangement (as defined in section
19 106(c)) that is a qualified benefit and only permits
20 reimbursement for expenses for medical care (as de-
21 fined in section 213(d)(1) (without regard to sub-
22 paragraphs (C) and (D) thereof).

23 “(4) UNUSED HEALTH BENEFITS.—For pur-
24 poses of this subsection, with respect to an em-

1 ployee, the term ‘unused health benefits’ means the
2 excess of—

3 “(A) the maximum amount of reimburse-
4 ment allowable to the employee during a plan
5 year under a health flexible spending arrange-
6 ment, taking into account any election by the
7 employee, over

8 “(B) the actual amount of reimbursement
9 during such year under such arrangement.”.

10 (b) EFFECTIVE DATE.—The amendment made by
11 subsection (a) shall apply to taxable years beginning after
12 December 31, 2003.

13 **SEC. 1204. EXCEPTION TO INFORMATION REPORTING RE-**
14 **QUIREMENTS RELATED TO CERTAIN HEALTH**
15 **ARRANGEMENTS.**

16 (a) IN GENERAL.—Section 6041 (relating to infor-
17 mation at source) is amended by adding at the end the
18 following new subsection:

19 “(f) SECTION DOES NOT APPLY TO CERTAIN
20 HEALTH ARRANGEMENTS.—This section shall not apply
21 to any payment for medical care (as defined in section
22 213(d)) made under—

23 “(1) a flexible spending arrangement (as de-
24 fined in section 106(c)(2)), or

1 “(2) a health reimbursement arrangement
2 which is treated as employer-provided coverage
3 under an accident or health plan for purposes of sec-
4 tion 106.”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 this section shall apply to payments made after December
7 31, 2002.

 Passed the House of Representatives June 27 (legis-
 lative day, June 26), 2003.

Attest:

Clerk.