108TH CONGRESS
1ST SESSION

H. R. 1

IN THE HOUSE OF REPRESENTATIVES

JUNE 25, 2003

Mr. HASTERT (for himself, Mr. DELAY, Mr. BLUNT, Ms. PRYCE of Ohio, Mr. THOMAS, Mr. TAUZIN, Mrs. JOHNSON of Connecticut, Mr. BILIRAKIS, Mr. PETERSON of Minnesota, Mrs. CAPITO, Ms. GINNY BROWN-WAITE of Florida, Mr. BRADLEY of New Hampshire, Mr. BURNS, Ms. DUNN, Mr. FLETCHER, Mr. GOSS, Mr. GRAVES, Mr. MCCRERY, Mr. NUNES, Mr. SIMMONS, and Mr. SULLIVAN) introduced the following bill; which was referred to the Committee on _____

A BILL

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, and for other purposes.

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

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

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

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

(c) BIPA; SECRETARY.—In this Act:

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

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

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

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

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

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

"PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

"Sec. 1860D–1. Benefits; eligibility; enrollment; and coverage period.
"Sec. 1860D–2. Requirements for qualified prescription drug coverage.

"Sec. 1860D–3. Beneficiary protections for qualified prescription drug coverage.
"Sec. 1860D–4. Requirements for and contracts with prescription drug plan (PDP) sponsors.
"Sec. 1860D–5. Process for beneficiaries to select qualified prescription drug coverage.
"Sec. 1860D–6. Submission of bids and premiums.
"Sec. 1860D–7. Premium and cost-sharing subsidies for low-income individuals.
"Sec. 1860D–8. Subsidies for all medicare beneficiaries for qualified prescription drug coverage.
"Sec. 1860D–9. Medicare Prescription Drug Trust Fund.
"Sec. 1860D–10. Definitions; application to medicare advantage and EFFS programs; treatment of references to provisions in part C.
Sec. 102. Offering of qualified prescription drug coverage under Medicare Advantage 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 medicare 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.

"Part E—Enhanced Fee-for-Service Program

"Sec. 1860E–1. Offering of enhanced fee-for-service plans throughout the United States.
"Sec. 1860E–2. Offering of enhanced fee-for-service (EFFS) plans.
"Sec. 1860E–3. Submission of bids; beneficiary savings; payment of plans.
"Sec. 1860E–4. Premiums; organizational and financial requirements; establishment of standards; contracts with EFFS organizations.

Subtitle B—Medicare Advantage Program

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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.
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Sec. 702. Establishment of reduced copayment for a home health service episode of care for certain beneficiaries.
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Sec. 801. Establishment of Medicare Benefits Administration.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

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Sec. 903. Compliance with changes in regulations and policies.
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Sec. 911. Increased flexibility in medicare administration.
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Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.
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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.
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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.
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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.
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Subtitle B—Ability of Federal Trade Commission to Enforce Antitrust Laws

Sec. 1111. Definitions.
Sec. 1112. Notification of agreements.
Sec. 1113. Filing deadlines.
Sec. 1114. Disclosure exemption.
Sec. 1115. Enforcement.
Sec. 1116. Rulemaking.

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SUBTITLE C—IMPORTATION OF PRESCRIPTION DRUGS

Sec. 1121. Importation of prescription drugs.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION DRUG BENEFIT.

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

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

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

"PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

"SEC. 1860D–1. BENEFITS; ELIGIBILITY; ENROLLMENT; AND COVERAGE PERIOD.

"(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—Subject to the succeeding provisions of this part, each individual who is entitled to benefits under part A or is enrolled under part B is entitled to obtain qualified prescription drug coverage (described in section 1860D–2(a)) as follows:

"(1) MEDICARE-RELATED PLANS.—

"(A) MEDICARE ADVANTAGE.—If the individual is eligible to enroll in a Medicare Advantage plan that provides qualified prescription

1 drug coverage under section 1851(j), the indi-
2 vidual may enroll in such plan and obtain cov-
3 erage through such plan.
4 "(B) EFFS PLANS.—If the individual is
5 eligible to enroll in an EFFS plan that provides
6 qualified prescription drug coverage under part
7 E under section 1860E–2(d), the individual
8 may enroll in such plan and obtain coverage
9 through such plan.
10 "(C) MA-EFFS PLAN; MA-EFFS RX
11 PLAN.—For purposes of this part, the term
12 'MA-EFFS plan' means a Medicare Advantage
13 plan under part C and an EFFS plan under
14 part E and the term 'MA-EFFS Rx plan'
15 means a MA-EFFS plan insofar as such plan
16 provides qualified prescription drug coverage.
17 "(2) PRESCRIPTION DRUG PLAN.—If the indi-
18 vidual is not enrolled in a MA-EFFS plan, the indi-
19 vidual may enroll under this part in a prescription
20 drug plan (as defined in section 1860D–10(a)(5)).
21 Such individuals shall have a choice of such plans under
22 section 1860D–5(d).
23 "(b) GENERAL ELECTION PROCEDURES.—
24 "(1) IN GENERAL.—An individual eligible to
25 make an election under subsection (a) may elect to

1 enroll in a prescription drug plan under this part, or
2 elect the option of qualified prescription drug cov-
3 erage under a MA-EFFS Rx plan under part C or
4 part E, and to change such election only in such
5 manner and form as may be prescribed by regula-
6 tions of the Administrator of the Medicare Benefits
7 Administration (appointed under section 1809(b))
8 (in this part referred to as the 'Medicare Benefits
9 Administrator') and only during an election period
10 prescribed in or under this subsection.
11 "(2) ELECTION PERIODS.—
12 "(A) IN GENERAL.—Except as provided in
13 this paragraph, the election periods under this
14 subsection shall be the same as the coverage
15 election periods under the Medicare Advantage
16 and EFFS programs under section 1851(e),
17 including—
18 "(i) annual coordinated election peri-
19 ods; and
20 "(ii) special election periods.
21 In applying the last sentence of section
22 1851(e)(4) (relating to discontinuance of an
23 election during the first year of eligibility)
24 under this subparagraph, in the case of an elec-
25 tion described in such section in which the indi-

vidual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug plan under this part at the time of the election of coverage under the original fee-for-service plan.

"(B) INITIAL ELECTION PERIODS.—

"(i) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of October 1, 2005, there shall be an initial election period of 6 months beginning on that date.

"(ii) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

"(C) ADDITIONAL SPECIAL ELECTION PERIODS.—The Administrator shall establish special election periods—

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

"(ii) in cases described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B;

"(iii) in the case of an individual who meets such exceptional conditions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

"(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

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

"(4) ADDITIONAL INFORMATION.—In order to promote the efficient marketing of prescription drug plans and MA-EFFS plans, the Administrator may provide information to the sponsors and organiza-

1 tions offering such plans about individuals eligible to
2 enroll in such plans.
3 "(c) GUARANTEED ISSUE; COMMUNITY RATING; AND
4 NONDISCRIMINATION.—
5 "(1) GUARANTEED ISSUE.—
6 "(A) IN GENERAL.—An eligible individual
7 who is eligible to elect qualified prescription
8 drug coverage under a prescription drug plan or
9 MA-EFFS Rx plan at a time during which elec-
10 tions are accepted under this part with respect
11 to the plan shall not be denied enrollment based
12 on any health status-related factor (described in
13 section 2702(a)(1) of the Public Health Service
14 Act) or any other factor.
15 "(B) MEDICARE ADVANTAGE LIMITATIONS
16 PERMITTED.—The provisions of paragraphs (2)
17 and (3) (other than subparagraph (C)(i), relat-
18 ing to default enrollment) of section 1851(g)
19 (relating to priority and limitation on termi-
20 nation of election) shall apply to PDP sponsors
21 under this subsection.
22 "(2) COMMUNITY-RATED PREMIUM.—
23 "(A) IN GENERAL.—In the case of an indi-
24 vidual who enrolls under a prescription drug
25 plan or in a MA-EFFS Rx plan during the in-

1 dividual's initial enrollment period under this
2 part or maintains (as determined under sub-
3 paragraph (C)) continuous prescription drug
4 coverage since the date the individual first
5 qualifies to elect prescription drug coverage
6 under this part, a PDP sponsor or entity offer-
7 ing a prescription drug plan or MA-EFFS Rx
8 plan and in which the individual is enrolled may
9 not deny, limit, or condition the coverage or
10 provision of covered prescription drug benefits
11 or vary or increase the premium under the plan
12 based on any health status-related factor de-
13 scribed in section 2702(a)(1) of the Public
14 Health Service Act or any other factor.
15 "(B) LATE ENROLLMENT PENALTY.—In
16 the case of an individual who does not maintain
17 such continuous prescription drug coverage (as
18 described in subparagraph (C)), a PDP sponsor
19 or an entity offering a MA-EFFS Rx plan may
20 (notwithstanding any provision in this title) ad-
21 just the premium otherwise applicable with re-
22 spect to qualified prescription drug coverage in
23 a manner that reflects additional actuarial risk
24 involved. Such a risk shall be established
25 through an appropriate actuarial opinion of the

type described in subparagraphs (A) through (C) of section 2103(c)(4). The Administrator shall provide a mechanism for assisting such sponsors and entities in identifying eligible individuals who have (or have not) maintained such continuous prescription drug coverage.

"(C) CONTINUOUS PRESCRIPTION DRUG COVERAGE.—An individual is considered for purposes of this part to be maintaining continuous prescription drug coverage on and after the date the individual first qualifies to elect prescription drug coverage under this part if the individual establishes that as of such date the individual is covered under any of the following prescription drug coverage and before the date that is the last day of the 63-day period that begins on the date of termination of the particular prescription drug coverage involved (regardless of whether the individual subsequently obtains any of the following prescription drug coverage):

"(i) COVERAGE UNDER PRESCRIPTION DRUG PLAN OR MA-EFFS RX PLAN.—Qualified prescription drug coverage under a

1 prescription drug plan or under a MA-
2 EFFS Rx plan.
3 "(ii) MEDICAID PRESCRIPTION DRUG
4 COVERAGE.—Prescription drug coverage
5 under a medicaid plan under title XIX, in-
6 cluding through the Program of All-inclu-
7 sive Care for the Elderly (PACE) under
8 section 1934, or through a demonstration
9 project under part C that demonstrates the
10 application of capitation payment rates for
11 frail elderly medicare beneficiaries through
12 the use of an interdisciplinary team and
13 through the provision of primary care serv-
14 ices to such beneficiaries by means of such
15 a team at the nursing facility involved.
16 "(iii) PRESCRIPTION DRUG COVERAGE
17 UNDER GROUP HEALTH PLAN.—Any out-
18 patient prescription drug coverage under a
19 group health plan, including a health bene-
20 fits plan under the Federal Employees
21 Health Benefit Plan under chapter 89 of
22 title 5, United States Code, and a qualified
23 retiree prescription drug plan as defined in
24 section 1860D–8(f)(1), but only if (subject
25 to subparagraph (E)(ii)) the coverage pro-

1 vides benefits at least equivalent to the
2 benefits under a qualified prescription drug
3 plan.
4 "(iv) PRESCRIPTION DRUG COVERAGE
5 UNDER CERTAIN MEDIGAP POLICIES.—
6 Coverage under a medicare supplemental
7 policy under section 1882 that provides
8 benefits for prescription drugs (whether or
9 not such coverage conforms to the stand-
10 ards for packages of benefits under section
11 1882(p)(1)), but only if the policy was in
12 effect on January 1, 2006, and if (subject
13 to subparagraph (E)(ii)) the coverage pro-
14 vides benefits at least equivalent to the
15 benefits under a qualified prescription drug
16 plan.
17 "(v) STATE PHARMACEUTICAL ASSIST-
18 ANCE PROGRAM.—Coverage of prescription
19 drugs under a State pharmaceutical assist-
20 ance program, but only if (subject to sub-
21 paragraph (E)(ii)) the coverage provides
22 benefits at least equivalent to the benefits
23 under a qualified prescription drug plan.
24 "(vi) VETERANS' COVERAGE OF PRE-
25 SCRIPTION DRUGS.—Coverage of prescrip-

1 tion drugs for veterans under chapter 17
2 of title 38, United States Code, but only if
3 (subject to subparagraph (E)(ii)) the cov-
4 erage provides benefits at least equivalent
5 to the benefits under a qualified prescrip-
6 tion drug plan.

7 "(D) CERTIFICATION.—For purposes of
8 carrying out this paragraph, the certifications
9 of the type described in sections 2701(e) of the
10 Public Health Service Act and in section
11 9801(e) of the Internal Revenue Code shall also
12 include a statement for the period of coverage
13 of whether the individual involved had prescrip-
14 tion drug coverage described in subparagraph
15 (C).

16 "(E) DISCLOSURE.—

17 "(i) IN GENERAL.—Each entity that
18 offers coverage of the type described in
19 clause (iii), (iv), (v), or (vi) of subpara-
20 graph (C) shall provide for disclosure, con-
21 sistent with standards established by the
22 Administrator, of whether such coverage
23 provides benefits at least equivalent to the
24 benefits under a qualified prescription drug
25 plan.

1 "(ii) WAIVER OF LIMITATIONS.—An
2 individual may apply to the Administrator
3 to waive the requirement that coverage of
4 such type provide benefits at least equiva-
5 lent to the benefits under a qualified pre-
6 scription drug plan, if the individual estab-
7 lishes that the individual was not ade-
8 quately informed that such coverage did
9 not provide such level of benefits.
10 "(F) CONSTRUCTION.—Nothing in this
11 section shall be construed as preventing the
12 disenrollment of an individual from a prescrip-
13 tion drug plan or a MA-EFFS Rx plan based
14 on the termination of an election described in
15 section 1851(g)(3), including for non-payment
16 of premiums or for other reasons specified in
17 subsection (d)(3), which takes into account a
18 grace period described in section
19 1851(g)(3)(B)(i).
20 "(3) NONDISCRIMINATION.—A PDP sponsor
21 that offers a prescription drug plan in an area des-
22 ignated under section 1860D–4(b)(5) shall make
23 such plan available to all eligible individuals residing
24 in the area without regard to their health or eco-

1 nomic status or their place of residence within the
2 area.
3 "(d) EFFECTIVE DATE OF ELECTIONS.—
4 "(1) IN GENERAL.—Except as provided in this
5 section, the Administrator shall provide that elec-
6 tions under subsection (b) take effect at the same
7 time as the Administrator provides that similar elec-
8 tions under section 1851(e) take effect under section
9 1851(f).
10 "(2) NO ELECTION EFFECTIVE BEFORE 2006.—
11 In no case shall any election take effect before Janu-
12 ary 1, 2006.
13 "(3) TERMINATION.—The Administrator shall
14 provide for the termination of an election in the case
15 of—
16 "(A) termination of coverage under both
17 part A and part B; and
18 "(B) termination of elections described in
19 section 1851(g)(3) (including failure to pay re-
20 quired premiums).
21 **"SEC. 1860D–2. REQUIREMENTS FOR QUALIFIED PRESCRIP-**
22 **TION DRUG COVERAGE.**
23 "(a) REQUIREMENTS.—

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

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

"(B) ACTUARIALLY EQUIVALENT COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Coverage of covered outpatient drugs which meets the alternative coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if it is approved by the Administrator, as provided under subsection (c).

"(2) PERMITTING ADDITIONAL OUTPATIENT PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered outpatient drugs that exceeds the coverage required under paragraph (1), but any such additional coverage shall be limited to coverage of covered outpatient drugs.

1 "(B) DISAPPROVAL AUTHORITY.—The Ad-
2 ministrator shall review the offering of qualified
3 prescription drug coverage under this part or
4 part C or E. If the Administrator finds, in the
5 case of a qualified prescription drug coverage
6 under a prescription drug plan or a MA-EFFS
7 Rx plan, that the organization or sponsor offer-
8 ing the coverage is engaged in activities in-
9 tended to discourage enrollment of classes of el-
10 igible medicare beneficiaries obtaining coverage
11 through the plan on the basis of their higher
12 likelihood of utilizing prescription drug cov-
13 erage, the Administrator may terminate the
14 contract with the sponsor or organization under
15 this part or part C or E.
16 "(3) APPLICATION OF SECONDARY PAYOR PRO-
17 VISIONS.—The provisions of section 1852(a)(4) shall
18 apply under this part in the same manner as they
19 apply under part C.
20 "(b) STANDARD COVERAGE.—For purposes of this
21 part, the 'standard coverage' is coverage of covered out-
22 patient drugs (as defined in subsection (f)) that meets the
23 following requirements:
24 "(1) DEDUCTIBLE.—The coverage has an an-
25 nual deductible—

1 "(A) for 2006, that is equal to $250; or
2 "(B) for a subsequent year, that is equal
3 to the amount specified under this paragraph
4 for the previous year increased by the percent-
5 age specified in paragraph (5) for the year in-
6 volved.
7 Any amount determined under subparagraph (B)
8 that is not a multiple of $10 shall be rounded to the
9 nearest multiple of $10.
10 "(2) 80:20 BENEFIT STRUCTURE.—
11 "(A) 20 PERCENT COINSURANCE.—The
12 coverage has cost-sharing (for costs above the
13 annual deductible specified in paragraph (1)
14 and up to the initial coverage limit under para-
15 graph (3)) that is—
16 "(i) equal to 20 percent; or
17 "(ii) is actuarially equivalent (using
18 processes established under subsection (e))
19 to an average expected payment of 20 per-
20 cent of such costs.
21 "(B) USE OF TIERS.—Nothing in this part
22 shall be construed as preventing a PDP sponsor
23 from applying tiered copayments, so long as
24 such tiered copayments are consistent with sub-
25 paragraph (A).

1 "(3) INITIAL COVERAGE LIMIT.—Subject to
2 paragraph (4), the coverage has an initial coverage
3 limit on the maximum costs that may be recognized
4 for payment purposes—
5 "(A) for 2006, that is equal to $2,000; or
6 "(B) for a subsequent year, that is equal
7 to the amount specified in this paragraph for
8 the previous year, increased by the annual per-
9 centage increase described in paragraph (5) for
10 the year involved.
11 Any amount determined under subparagraph (B)
12 that is not a multiple of $25 shall be rounded to the
13 nearest multiple of $25.
14 "(4) CATASTROPHIC PROTECTION.—
15 "(A) IN GENERAL.—Notwithstanding para-
16 graph (3), the coverage provides benefits with
17 no cost-sharing after the individual has in-
18 curred costs (as described in subparagraph (C))
19 for covered outpatient drugs in a year equal to
20 the annual out-of-pocket threshold specified in
21 subparagraph (B).
22 "(B) ANNUAL OUT-OF-POCKET THRESH-
23 OLD.—
24 "(i) IN GENERAL.—For purposes of
25 this part, the 'annual out-of-pocket thresh-

old' specified in this subparagraph is equal to $3,500 (subject to adjustment under clause (ii) and subparagraph (D)).

"(ii) INFLATION INCREASE.—For a year after 2006, the dollar amount specified in clause (i) shall be increased by the annual percentage increase described in paragraph (5) for the year involved. Any amount determined under the previous sentence that is not a multiple of $100 shall be rounded to the nearest multiple of $100.

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

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

"(ii) such costs shall be treated as incurred only if they are paid by the individual (or by another individual, such as a family member, on behalf of the indi-

1 vidual), under section 1860D–7, under title
2 XIX, or under a State pharmaceutical as-
3 sistance program and the individual (or
4 other individual) is not reimbursed through
5 insurance or otherwise, a group health
6 plan, or other third-party payment ar-
7 rangement (other than under such title or
8 such program) for such costs.
9 ''(D) ADJUSTMENT OF ANNUAL OUT-OF-
10 POCKET THRESHOLDS.—
11 ''(i) IN GENERAL.—Subject to clause
12 (vii), for each enrollee in a prescription
13 drug plan or in a MA-EFFS Rx plan
14 whose adjusted gross income exceeds the
15 income threshold as defined in clause (ii)
16 for a year, the annual out-of-pocket thresh-
17 old otherwise determined under subpara-
18 graph (B) for such year shall be increased
19 by an amount equal to the percentage
20 specified in clause (iii), multiplied by the
21 lesser of—
22 ''(I) the amount of such excess;
23 or

"(II) the amount by which the income threshold limit exceeds the income threshold.

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

"(ii) INCOME THRESHOLD.—For purposes of clause (i)—

"(I) IN GENERAL.—Subject to subclause (II), the term 'income threshold' means $60,000 and the term 'income threshold limit' means $200,000.

"(II) INCOME INFLATION ADJUSTMENT.—In the case of a year beginning after 2006, each of the dollar amounts in subclause (I) shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment determined under section 1(f)(3) of the Internal Revenue Code of 1986 for such year, determined by substituting 'calendar year 2005' for 'calendar year 1992'.

If any amount increased under the previous sentence is not a multiple of $100, such amount shall be rounded to the nearest multiple of $100.

"(iii) PERCENTAGE.—The percentage specified in this clause for a year is a fraction (expressed as a percentage) equal to—

"(I) the annual out-of-pocket threshold for a year under subparagraph (B) (determined without regard to this subparagraph), divided by

"(II) the income threshold under clause (ii) for that year.

If any percentage determined under the previous sentence that is not a multiple of 1/10th of 1 percentage point, such percentage shall be rounded to the nearest multiple of 1/10th of 1 percentage point.

"(iv) USE OF MOST RECENT RETURN INFORMATION.—For purposes of clause (i) for an enrollee for a year, except as provided in clause (v), the adjusted gross income of an individual shall be based on the most recent information disclosed to the Secretary under section 6109(l)(19) of the

1 Internal Revenue Code of 1986 before the
2 beginning of that year.
3 "(v) INDIVIDUAL ELECTION TO
4 PRESENT MOST RECENT INFORMATION RE-
5 GARDING INCOME.—The Secretary shall
6 provide, in coordination with the Secretary
7 of the Treasury, a procedure under which,
8 for purposes of applying this subparagraph
9 for a calendar year, instead of using the
10 information described in clause (iv), an en-
11 rollee may elect to use more recent infor-
12 mation, including information with respect
13 to a taxable year ending in such calendar
14 year. Such process shall—
15 "(I) require the enrollee to pro-
16 vide the Secretary with a copy of the
17 relevant portion of the more recent re-
18 turn to be used under this clause;
19 "(II) provide for the Medicare
20 Beneficiary Ombudsman (under sec-
21 tion 1810) offering assistance to such
22 enrollees in presenting such informa-
23 tion and the toll-free number under
24 such section being a point of contact

for beneficiaries to inquire as to how to present such information;

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

"(IV) provide for the payment by the Secretary (in a manner specified by the Secretary) to the enrollee of an amount equal to the excess of the benefit payments that would have been payable under the plan if the more recent return information were used, over the benefit payments that were made under the plan.

In the case of a payment under subclause (III) for an enrollee under a prescription drug plan, the PDP sponsor of the plan shall pay to the Secretary the amount so paid, less the applicable reinsurance amount that would have applied under section 1860D–8(c)(1)(B) if such payment had been treated as an allowable cost under such section. Such plan payment

1 shall be deposited in the Treasury to the
2 credit of the Medicare Prescription Drug
3 Account in the Federal Supplementary
4 Medical Insurance Trust Fund (under sec-
5 tion 1841).

6 "(vi) DISSEMINATION OF INFORMA-
7 TION ON PROCESS.—The Secretary shall
8 provide, through the annual medicare
9 handbook under section 1804(a), for a
10 general description of the adjustment of
11 annual out-of-pocket thresholds provided
12 under this subparagraph, including the
13 process for adjustment based upon more
14 recent information and the confidentiality
15 provisions of subparagraph (F), and shall
16 provide for dissemination of a table for
17 each year that sets forth the amount of the
18 adjustment that is made under clause (i)
19 based on the amount of an enrollee's ad-
20 justed gross income.

21 "(vii) ENROLLEE OPT-OUT.—The Sec-
22 retary shall provide a procedure whereby,
23 if an enrollee elects to have the maximum
24 annual out-of-pocket threshold applied
25 under this subparagraph for a year, the

1 Secretary shall not request any informa-
2 tion regarding the enrollee under subpara-
3 graph (E) for that year.
4 "(E) REQUESTING INFORMATION ON EN-
5 ROLLEES.—
6 "(i) IN GENERAL.—The Secretary
7 shall, periodically as required to carry out
8 subparagraph (D), transmit to the Sec-
9 retary of the Treasury a list of the names
10 and TINs of enrollees in prescription drug
11 plans (or in MA-EFFS Rx plans) and re-
12 quest that such Secretary disclose to the
13 Secretary information under subparagraph
14 (A) of section 6103(l)(19) of the Internal
15 Revenue Code of 1986 with respect to
16 those enrollees for a specified taxable year
17 for application in a particular calendar
18 year.
19 "(ii) DISCLOSURE TO PLAN SPON-
20 SORS.—In the case of a specified taxpayer
21 (as defined in section 6103(l)(19)(B) of
22 the Internal Revenue Code of 1986) who is
23 enrolled in a prescription drug plan or in
24 an MA-EFFS Rx plan or an individual
25 who makes an election under subparagraph

1 (D)(vii), the Secretary shall disclose to the
2 entity that offers the plan the annual out-
3 of-pocket threshold applicable to such indi-
4 vidual under subparagraph (D).
5 "(F) MAINTAINING CONFIDENTIALITY OF
6 INFORMATION.—
7 "(i) IN GENERAL.—The amount of
8 any increase in an annual out-of-pocket
9 threshold under subparagraph (D) may not
10 be disclosed by the Secretary except to a
11 PDP sponsor or entity that offers a MA-
12 EFFS Rx plan to the extent necessary to
13 carry out this part.
14 "(ii) CRIMINAL AND CIVIL PENALTIES
15 FOR UNAUTHORIZED DISCLOSURE.—A per-
16 son who makes an unauthorized disclosure
17 of information disclosed under section
18 6103(l)(19) of the Internal Revenue Code
19 of 1986 (including disclosure of any in-
20 crease in an annual out-of-pocket threshold
21 under subparagraph (D)) shall be subject
22 to penalty to the extent provided under—
23 "(I) section 7213 of such Code
24 (relating to criminal penalty for unau-
25 thorized disclosure of information);

1 "(II) section 7213A of such Code
2 (relating to criminal penalty for unau-
3 thorized inspection of returns or re-
4 turn information);
5 "(III) section 7431 of such Code
6 (relating to civil damages for unau-
7 thorized inspection or disclosure of re-
8 turns and return information);
9 "(IV) any other provision of the
10 Internal Revenue Code of 1986; or
11 "(V) any other provision of law.
12 "(iii) APPLICATION OF ADDITIONAL
13 CIVIL MONETARY PENALTY FOR UNAU-
14 THORIZED DISCLOSURES.—In addition to
15 any penalty otherwise provided under law,
16 any person who makes an unauthorized
17 disclosure of such information shall be sub-
18 ject to a civil monetary penalty of not to
19 exceed $10,000 for each such unauthorized
20 disclosure. The provisions of section 1128A
21 (other than subsections (a) and (b)) shall
22 apply to civil money penalties under this
23 subparagraph in the same manner as they
24 apply to a penalty or proceeding under sec-
25 tion 1128A(a).

1 "(G) INFORMATION REGARDING THIRD-
2 PARTY REIMBURSEMENT.—In order to ensure
3 compliance with the requirements of subpara-
4 graph (C)(ii), the Administrator is authorized
5 to establish procedures, in coordination with the
6 Secretary of Treasury and the Secretary of
7 Labor, for determining whether costs for indi-
8 viduals are being reimbursed through insurance
9 or otherwise, a group health plan, or other
10 third-party payment arrangement, and for
11 alerting the sponsors and organization that
12 offer the plans in which such individuals are en-
13 rolled about such reimbursement arrangements.
14 A PDP sponsor or Medicare Advantage or
15 EFFS organization may also periodically ask
16 individuals enrolled in a prescription drug plan
17 or MA-EFFS Rx plan offered by the sponsor or
18 organization whether the individuals have or ex-
19 pect to receive such third-party reimbursement.
20 A material misrepresentation of the information
21 described in the preceding sentence by an indi-
22 vidual (as defined in standards set by the Ad-
23 ministrator and determined through a process
24 established by the Administrator) shall con-

1 stitute grounds for termination of enrollment
2 under section 1860D–1(d)(3).
3 "(5) ANNUAL PERCENTAGE INCREASE.—For
4 purposes of this part, the annual percentage increase
5 specified in this paragraph for a year is equal to the
6 annual percentage increase in average per capita ag-
7 gregate expenditures for covered outpatient drugs in
8 the United States for medicare beneficiaries, as de-
9 termined by the Administrator for the 12-month pe-
10 riod ending in July of the previous year.
11 "(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A
12 prescription drug plan or MA-EFFS Rx plan may provide
13 a different prescription drug benefit design from the
14 standard coverage described in subsection (b) so long as
15 the Administrator determines (based on an actuarial anal-
16 ysis approved by the Administrator) that the following re-
17 quirements are met and the plan applies for, and receives,
18 the approval of the Administrator for such benefit design:
19 "(1) ASSURING AT LEAST ACTUARIALLY EQUIV-
20 ALENT COVERAGE.—
21 "(A) ASSURING EQUIVALENT VALUE OF
22 TOTAL COVERAGE.—The actuarial value of the
23 total coverage (as determined under subsection
24 (e)) is at least equal to the actuarial value (as
25 so determined) of standard coverage.

"(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (e)) exceeds the actuarial value of the subsidy payments under section 1860D–8 with respect to such coverage.

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

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

1 "(ii) 100 percent minus the cost-shar-
2 ing percentage specified in subsection
3 (b)(2)(A)(i).
4 "(2) CATASTROPHIC PROTECTION.—The cov-
5 erage provides for beneficiaries the catastrophic pro-
6 tection described in subsection (b)(4).
7 "(d) ACCESS TO NEGOTIATED PRICES.—
8 "(1) IN GENERAL.—Under qualified prescrip-
9 tion drug coverage offered by a PDP sponsor or an
10 entity offering a MA-EFFS Rx plan, the sponsor or
11 entity shall provide beneficiaries with access to nego-
12 tiated prices (including applicable discounts) used
13 for payment for covered outpatient drugs, regardless
14 of the fact that no benefits may be payable under
15 the coverage with respect to such drugs because of
16 the application of cost-sharing or an initial coverage
17 limit (described in subsection (b)(3)). Insofar as a
18 State elects to provide medical assistance under title
19 XIX to a beneficiary enrolled under such title and
20 under a prescription drug plan or MA-EFFS Rx
21 plan for a drug based on the prices negotiated by a
22 prescription drug plan or MA-EFFS Rx plan under
23 this part, the requirements of section 1927 shall not
24 apply to such drugs. The prices negotiated by a pre-
25 scription drug plan under this part, by a MA-EFFS

1 Rx plan with respect to covered outpatient drugs, or
2 by a qualified retiree prescription drug plan (as de-
3 fined in section 1860D–8(f)(1)) with respect to such
4 drugs on behalf of individuals entitled to benefits
5 under part A or enrolled under part B, shall (not-
6 withstanding any other provision of law) not be
7 taken into account for the purposes of establishing
8 the best price under section 1927(c)(1)(C).

9 "(2) DISCLOSURE.—The PDP sponsor or entity
10 offering a MA-EFFS Rx plan shall disclose to the
11 Administrator (in a manner specified by the Admin-
12 istrator) the extent to which discounts or rebates or
13 other remuneration or price concessions made avail-
14 able to the sponsor or organization by a manufac-
15 turer are passed through to enrollees through phar-
16 macies and other dispensers or otherwise. The provi-
17 sions of section 1927(b)(3)(D) shall apply to infor-
18 mation disclosed to the Administrator under this
19 paragraph in the same manner as such provisions
20 apply to information disclosed under such section.

21 "(3) AUDITS AND REPORTS.—To protect
22 against fraud and abuse and to ensure proper disclo-
23 sures and accounting under this part, in addition to
24 any protections against fraud and abuse provided
25 under section 1860D–4(b)(3)(C), the Administrator

may periodically audit the financial statements and records of PDP sponsor or entities offering a MA-EFFS Rx plan.

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

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

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

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

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

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

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

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

1 "(2) USE OF OUTSIDE ACTUARIES.—Under the
2 processes under paragraph (1)(A), PDP sponsors
3 and entities offering MA-EFFS Rx plans may use
4 actuarial opinions certified by independent, qualified
5 actuaries to establish actuarial values, but the Ad-
6 ministrator shall determine whether such actuarial
7 values meet the requirements under subsection
8 (c)(1).
9 "(f) COVERED OUTPATIENT DRUGS DEFINED.—
10 "(1) IN GENERAL.—Except as provided in this
11 subsection, for purposes of this part, the term 'cov-
12 ered outpatient drug' means—
13 "(A) a drug that may be dispensed only
14 upon a prescription and that is described in
15 subparagraph (A)(i) or (A)(ii) of section
16 1927(k)(2); or
17 "(B) a biological product described in
18 clauses (i) through (iii) of subparagraph (B) of
19 such section or insulin described in subpara-
20 graph (C) of such section and medical supplies
21 associated with the injection of insulin (as de-
22 fined in regulations of the Secretary),
23 and such term includes a vaccine licensed under sec-
24 tion 351 of the Public Health Service Act and any

1 use of a covered outpatient drug for a medically ac-
2 cepted indication (as defined in section 1927(k)(6)).
3 "(2) EXCLUSIONS.—
4 "(A) IN GENERAL.—Such term does not
5 include drugs or classes of drugs, or their med-
6 ical uses, which may be excluded from coverage
7 or otherwise restricted under section
8 1927(d)(2), other than subparagraph (E) there-
9 of (relating to smoking cessation agents), or
10 under section 1927(d)(3).
11 "(B) AVOIDANCE OF DUPLICATE COV-
12 ERAGE.—A drug prescribed for an individual
13 that would otherwise be a covered outpatient
14 drug under this part shall not be so considered
15 if payment for such drug is available under part
16 A or B for an individual entitled to benefits
17 under part A and enrolled under part B.
18 "(3) APPLICATION OF FORMULARY RESTRIC-
19 TIONS.—A drug prescribed for an individual that
20 would otherwise be a covered outpatient drug under
21 this part shall not be so considered under a plan if
22 the plan excludes the drug under a formulary and
23 such exclusion is not successfully appealed under
24 section 1860D–3(f)(2).

1 "(4) APPLICATION OF GENERAL EXCLUSION
2 PROVISIONS.—A prescription drug plan or MA-
3 EFFS Rx plan may exclude from qualified prescrip-
4 tion drug coverage any covered outpatient drug—
5 "(A) for which payment would not be
6 made if section 1862(a) applied to part D; or
7 "(B) which are not prescribed in accord-
8 ance with the plan or this part.
9 Such exclusions are determinations subject to recon-
10 sideration and appeal pursuant to section 1860D–
11 3(f).

12 **"SEC. 1860D–3. BENEFICIARY PROTECTIONS FOR QUALI-**
13 **FIED PRESCRIPTION DRUG COVERAGE.**

14 "(a) GUARANTEED ISSUE, COMMUNITY-RATED PRE-
15 MIUMS, ACCESS TO NEGOTIATED PRICES, AND NON-
16 DISCRIMINATION.—For provisions requiring guaranteed
17 issue, community-rated premiums, access to negotiated
18 prices, and nondiscrimination, see sections 1860D–
19 1(c)(1), 1860D–1(c)(2), 1860D–2(d), and 1860D–6(b),
20 respectively.
21 "(b) DISSEMINATION OF INFORMATION.—
22 "(1) GENERAL INFORMATION.—A PDP sponsor
23 shall disclose, in a clear, accurate, and standardized
24 form to each enrollee with a prescription drug plan
25 offered by the sponsor under this part at the time

of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

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

"(B) How any formulary used by the sponsor functions, including the drugs included in the formulary.

"(C) Co-payments and deductible requirements, including the identification of the tiered or other co-payment level applicable to each drug (or class of drugs).

"(D) Grievance and appeals procedures.

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

"(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to enroll under a prescription drug plan, the PDP sponsor shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such individual.

1 "(3) RESPONSE TO BENEFICIARY QUESTIONS.—
2 Each PDP sponsor offering a prescription drug plan
3 shall have a mechanism for providing specific infor-
4 mation to enrollees upon request. The sponsor shall
5 make available on a timely basis, through an Inter-
6 net website and in writing upon request, information
7 on specific changes in its formulary.
8 "(4) CLAIMS INFORMATION.—Each PDP spon-
9 sor offering a prescription drug plan must furnish to
10 each enrollee in a form easily understandable to such
11 enrollees an explanation of benefits (in accordance
12 with section 1806(a) or in a comparable manner)
13 and a notice of the benefits in relation to initial cov-
14 erage limit and the annual out-of-pocket threshold
15 applicable to such enrollee for the current year,
16 whenever prescription drug benefits are provided
17 under this part (except that such notice need not be
18 provided more often than monthly).
19 "(c) ACCESS TO COVERED BENEFITS.—
20 "(1) ASSURING PHARMACY ACCESS.—
21 "(A) PARTICIPATION OF ANY WILLING
22 PHARMACY.—A PDP sponsor and an entity of-
23 fering a MA-EFFS Rx plan shall permit the
24 participation of any pharmacy that meets terms
25 and conditions that the plan has established.

1 "(B) DISCOUNTS ALLOWED FOR NETWORK
2 PHARMACIES.—A prescription drug plan and a
3 MA-EFFS Rx plan may, notwithstanding sub-
4 paragraph (A), reduce coinsurance or copay-
5 ments for its enrolled beneficiaries below the
6 level otherwise provided for covered outpatient
7 drugs dispensed through in-network phar-
8 macies, but in no case shall such a reduction re-
9 sult in an increase in payments made by the
10 Administrator under section 1860D–8 to a
11 plan.
12 "(C) CONVENIENT ACCESS FOR NETWORK
13 PHARMACIES.—The PDP sponsor of the pre-
14 scription drug plan and the entity offering a
15 MA-EFFS Rx plan shall secure the participa-
16 tion in its network of a sufficient number of
17 pharmacies that dispense (other than by mail
18 order) drugs directly to patients to ensure con-
19 venient access (consistent with rules of the Ad-
20 ministrator). The Administrator shall establish
21 convenient access rules under this subpara-
22 graph that are no less favorable to enrollees
23 than the rules for convenient access to phar-
24 macies of the Secretary of Defense established
25 as of June 1, 2003, for purposes of the

1 TRICARE Retail Pharmacy (TRRx) program.
2 Such rules shall include adequate emergency ac-
3 cess for enrolled beneficiaries.
4 "(D) LEVEL PLAYING FIELD.—Such a
5 sponsor shall permit enrollees to receive benefits
6 (which may include a 90-day supply of drugs or
7 biologicals) through a community pharmacy,
8 rather than through mail order, with any dif-
9 ferential in charge paid by such enrollees.
10 "(E) NOT REQUIRED TO ACCEPT INSUR-
11 ANCE RISK.—The terms and conditions under
12 subparagraph (A) may not require participating
13 pharmacies to accept insurance risk as a condi-
14 tion of participation.
15 "(2) USE OF STANDARDIZED TECHNOLOGY.—
16 "(A) IN GENERAL.—The PDP sponsor of
17 a prescription drug plan and an entity offering
18 a MA-EFFS Rx plan shall issue (and reissue,
19 as appropriate) such a card (or other tech-
20 nology) that may be used by an enrollee to as-
21 sure access to negotiated prices under section
22 1860D–2(d) for the purchase of prescription
23 drugs for which coverage is not otherwise pro-
24 vided under the plan.
25 "(B) STANDARDS.—

1 "(i) DEVELOPMENT.—The Adminis-
2 trator shall provide for the development or
3 utilization of uniform standards relating to
4 a standardized format for the card or
5 other technology referred to in subpara-
6 graph (A). Such standards shall be com-
7 patible with standards established under
8 part C of title XI.
9 "(ii) APPLICATION OF ADVISORY TASK
10 FORCE.—The advisory task force estab-
11 lished under subsection (d)(3)(B)(ii) shall
12 provide recommendations to the Adminis-
13 trator under such subsection regarding the
14 standards developed under clause (i).
15 "(3) REQUIREMENTS ON DEVELOPMENT AND
16 APPLICATION OF FORMULARIES.—If a PDP sponsor
17 of a prescription drug plan or an entity offering a
18 MA-EFFS Rx plan uses a formulary, the following
19 requirements must be met:
20 "(A) PHARMACY AND THERAPEUTIC (P&T)
21 COMMITTEE.—The sponsor or entity must es-
22 tablish a pharmacy and therapeutic committee
23 that develops and reviews the formulary. Such
24 committee shall include at least one practicing
25 physician and at least one practicing phar-

1 macist independent and free of conflict with re-
2 spect to the committee both with expertise in
3 the care of elderly or disabled persons and a
4 majority of its members shall consist of individ-
5 uals who are practicing physicians or practicing
6 pharmacists (or both).

7 "(B) FORMULARY DEVELOPMENT.—In de-
8 veloping and reviewing the formulary, the com-
9 mittee shall—

10 "(i) base clinical decisions on the
11 strength of scientific evidence and stand-
12 ards of practice, including assessing peer-
13 reviewed medical literature, such as ran-
14 domized clinical trials, pharmacoeconomic
15 studies, outcomes research data, and on
16 such other information as the committee
17 determines to be appropriate; and

18 "(ii) shall take into account whether
19 including in the formulary particular cov-
20 ered outpatient drugs has therapeutic ad-
21 vantages in terms of safety and efficacy.

22 "(C) INCLUSION OF DRUGS IN ALL THERA-
23 PEUTIC CATEGORIES.—The formulary must in-
24 clude drugs within each therapeutic category
25 and class of covered outpatient drugs (although

1 not necessarily for all drugs within such cat-
2 egories and classes). In establishing such class-
3 es, the committee shall take into account the
4 standards published in the United States Phar-
5 macopeia-Drug Information. The committee
6 shall make available to the enrollees under the
7 plan through the Internet or otherwise the
8 bases for the exclusion of coverage of any drug
9 from the formulary.

10 "(D) PROVIDER AND PATIENT EDU-
11 CATION.—The committee shall establish policies
12 and procedures to educate and inform health
13 care providers and enrollees concerning the for-
14 mulary.

15 "(E) NOTICE BEFORE REMOVING DRUG
16 FROM FORMULARY FOR CHANGING PREFERRED
17 OR TIER STATUS OF DRUG.—Any removal of a
18 covered outpatient drug from a formulary and
19 any change in the preferred or tier cost-sharing
20 status of such a drug shall take effect only
21 after appropriate notice is made available to
22 beneficiaries and physicians.

23 "(F) PERIODIC EVALUATION OF PROTO-
24 COLS.—In connection with the formulary, a pre-
25 scription drug plan shall provide for the peri-

odic evaluation and analysis of treatment protocols and procedures.

"(G) GRIEVANCES AND APPEALS RELATING TO APPLICATION OF FORMULARIES.—For provisions relating to grievances and appeals of coverage, see subsections (e) and (f).

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

"(1) IN GENERAL.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall have in place, directly or through appropriate arrangements, with respect to covered outpatient drugs—

"(A) an effective cost and drug utilization management program, including medically appropriate incentives to use generic drugs and therapeutic interchange, when appropriate;

"(B) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including side-effects, and improve medication use, including a medication therapy management program described in paragraph (2) and for years beginning with 2007, an electronic prescription program described in paragraph (3); and

1 "(C) a program to control fraud, abuse,
2 and waste.
3 Nothing in this section shall be construed as impair-
4 ing a PDP sponsor or entity from utilizing cost
5 management tools (including differential payments)
6 under all methods of operation.
7 "(2) MEDICATION THERAPY MANAGEMENT PRO-
8 GRAM.—
9 "(A) IN GENERAL.—A medication therapy
10 management program described in this para-
11 graph is a program of drug therapy manage-
12 ment and medication administration that may
13 be furnished by a pharmacy provider and that
14 is designed to assure, with respect to bene-
15 ficiaries at risk for potential medication prob-
16 lems, such as beneficiaries with complex or
17 chronic diseases (such as diabetes, asthma, hy-
18 pertension, and congestive heart failure) or
19 multiple prescriptions, that covered outpatient
20 drugs under the prescription drug plan are ap-
21 propriately used to optimize therapeutic out-
22 comes through improved medication use and re-
23 duce the risk of adverse events, including ad-
24 verse drug interactions. Such programs may

1 distinguish between services in ambulatory and
2 institutional settings.
3 "(B) ELEMENTS.—Such program may
4 include—
5 "(i) enhanced beneficiary under-
6 standing to promote the appropriate use of
7 medications by beneficiaries and to reduce
8 the risk of potential adverse events associ-
9 ated with medications, through beneficiary
10 education, counseling, case management,
11 disease state management programs, and
12 other appropriate means;
13 "(ii) increased beneficiary adherence
14 with prescription medication regimens
15 through medication refill reminders, special
16 packaging, and other compliance programs
17 and other appropriate means; and
18 "(iii) detection of patterns of overuse
19 and underuse of prescription drugs.
20 "(C) DEVELOPMENT OF PROGRAM IN CO-
21 OPERATION WITH LICENSED PHARMACISTS.—
22 The program shall be developed in cooperation
23 with licensed and practicing pharmacists and
24 physicians.

1 "(D) CONSIDERATIONS IN PHARMACY
2 FEES.—The PDP sponsor of a prescription
3 drug program and an entity offering a MA-
4 EFFS Rx plan shall take into account, in es-
5 tablishing fees for pharmacists and others pro-
6 viding services under the medication therapy
7 management program, the resources and time
8 used in implementing the program. Each such
9 sponsor or entity shall disclose to the Adminis-
10 trator upon request the amount of any such
11 management or dispensing fees and such fees
12 shall be confidential in the same manner as pro-
13 vided under section 1927(b)(3)(D) for informa-
14 tion disclosed under section 1927(b)(3)(A).
15 "(3) ELECTRONIC PRESCRIPTION PROGRAM.—
16 "(A) IN GENERAL.—An electronic prescrip-
17 tion drug program described in this paragraph
18 is a program that includes at least the following
19 components, consistent with uniform standards
20 established under subparagraph (B):
21 "(i) ELECTRONIC TRANSMITTAL OF
22 PRESCRIPTIONS.—Prescriptions must be
23 written and transmitted electronically
24 (other than by facsimile), except in emer-
25 gency cases and other exceptional cir-

1 cumstances recognized by the Adminis-
2 trator.
3 "(ii) PROVISION OF INFORMATION TO
4 PRESCRIBING HEALTH CARE PROFES-
5 SIONAL.—The program provides for the
6 electronic transmittal to the prescribing
7 health care professional of information
8 that includes—
9 "(I) information (to the extent
10 available and feasible) on the drug or
11 drugs being prescribed for that pa-
12 tient and other information relating to
13 the medical history or condition of the
14 patient that may be relevant to the
15 appropriate prescription for that pa-
16 tient;
17 "(II) cost-effective alternatives (if
18 any) for the use of the drug pre-
19 scribed; and
20 "(III) information on the drugs
21 included in the applicable formulary.
22 To the extent feasible, such program shall
23 permit the prescribing health care profes-
24 sional to provide (and be provided) related

1 information on an interactive, real-time
2 basis.
3 ''(B) STANDARDS.—
4 ''(i) DEVELOPMENT.—The Adminis-
5 trator shall provide for the development of
6 uniform standards relating to the elec-
7 tronic prescription drug program described
8 in subparagraph (A). Such standards shall
9 be compatible with standards established
10 under part C of title XI.
11 ''(ii) ADVISORY TASK FORCE.—In de-
12 veloping such standards and the standards
13 described in subsection (c)(2)(B)(i) the Ad-
14 ministrator shall establish a task force that
15 includes representatives of physicians, hos-
16 pitals, pharmacies, beneficiaries, pharmacy
17 benefit managers, individuals with exper-
18 tise in information technology, and phar-
19 macy benefit experts of the Departments
20 of Veterans Affairs and Defense and other
21 appropriate Federal agencies to provide
22 recommendations to the Administrator on
23 such standards, including recommenda-
24 tions relating to the following:

1 "(I) The range of available com-
2 puterized prescribing software and
3 hardware and their costs to develop
4 and implement.
5 "(II) The extent to which such
6 standards and systems reduce medica-
7 tion errors and can be readily imple-
8 mented by physicians, pharmacies,
9 and hospitals.
10 "(III) Efforts to develop uniform
11 standards and a common software
12 platform for the secure electronic
13 communication of medication history,
14 eligibility, benefit, and prescription in-
15 formation.
16 "(IV) Efforts to develop and pro-
17 mote universal connectivity and inter-
18 operability for the secure electronic
19 exchange of such information.
20 "(V) The cost of implementing
21 such systems in the range of hospital
22 and physician office settings and
23 pharmacies, including hardware, soft-
24 ware, and training costs.

1 "(VI) Implementation issues as
2 they relate to part C of title XI, and
3 current Federal and State prescribing
4 laws and regulations and their impact
5 on implementation of computerized
6 prescribing.
7 "(iii) DEADLINES.—
8 "(I) The Administrator shall con-
9 stitute the task force under clause (ii)
10 by not later than April 1, 2004.
11 "(II) Such task force shall sub-
12 mit recommendations to Adminis-
13 trator by not later than January 1,
14 2005.
15 "(III) The Administrator shall
16 provide for the development and pro-
17 mulgation, by not later than January
18 1, 2006, of national standards relat-
19 ing to the electronic prescription drug
20 program described in clause (ii). Such
21 standards shall be issued by a stand-
22 ards organization accredited by the
23 American National Standards Insti-
24 tute (ANSI) and shall be compatible

1 with standards established under part
2 C of title XI.
3 "(4) TREATMENT OF ACCREDITATION.—Section
4 1852(e)(4) (relating to treatment of accreditation)
5 shall apply to prescription drug plans under this
6 part with respect to the following requirements, in
7 the same manner as they apply to plans under part
8 C with respect to the requirements described in a
9 clause of section 1852(e)(4)(B):
10 "(A) Paragraph (1) (including quality as-
11 surance), including medication therapy manage-
12 ment program under paragraph (2).
13 "(B) Subsection (c)(1) (relating to access
14 to covered benefits).
15 "(C) Subsection (g) (relating to confiden-
16 tiality and accuracy of enrollee records).
17 "(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL
18 PRICES FOR EQUIVALENT DRUGS.—Each PDP spon-
19 sor and each entity offering a MA-EFFS Rx plan
20 shall provide that each pharmacy or other dispenser
21 that arranges for the dispensing of a covered out-
22 patient drug shall inform the beneficiary at the time
23 of purchase of the drug of any differential between
24 the price of the prescribed drug to the enrollee and
25 the price of the lowest cost available generic drug

1 covered under the plan that is therapeutically equiv-
2 alent and bioequivalent.
3 "(e) GRIEVANCE MECHANISM, COVERAGE DETER-
4 MINATIONS, AND RECONSIDERATIONS.—
5 "(1) IN GENERAL.—Each PDP sponsor shall
6 provide meaningful procedures for hearing and re-
7 solving grievances between the organization (includ-
8 ing any entity or individual through which the spon-
9 sor provides covered benefits) and enrollees with pre-
10 scription drug plans of the sponsor under this part
11 in accordance with section 1852(f).
12 "(2) APPLICATION OF COVERAGE DETERMINA-
13 TION AND RECONSIDERATION PROVISIONS.—A PDP
14 sponsor shall meet the requirements of paragraphs
15 (1) through (3) of section 1852(g) with respect to
16 covered benefits under the prescription drug plan it
17 offers under this part in the same manner as such
18 requirements apply to an organization with respect
19 to benefits it offers under a plan under part C.
20 "(3) REQUEST FOR REVIEW OF TIERED FOR-
21 MULARY DETERMINATIONS.—In the case of a pre-
22 scription drug plan offered by a PDP sponsor or a
23 MA-EFFS Rx plan that provides for tiered cost-
24 sharing for drugs included within a formulary and
25 provides lower cost-sharing for preferred drugs in-

1 cluded within the formulary, an individual who is en-
2 rolled in the plan may request coverage of a nonpre-
3 ferred drug under the terms applicable for preferred
4 drugs if the prescribing physician determines that
5 the preferred drug for treatment of the same condi-
6 tion either would not be as effective for the indi-
7 vidual or would have adverse effects for the indi-
8 vidual or both.
9 ''(f) APPEALS.—
10 ''(1) IN GENERAL.—Subject to paragraph (2), a
11 PDP sponsor shall meet the requirements of para-
12 graphs (4) and (5) of section 1852(g) with respect
13 to drugs (including a determination related to the
14 application of tiered cost-sharing described in sub-
15 section (e)(3)) in the same manner as such require-
16 ments apply to an organization with respect to bene-
17 fits it offers under a plan under part C.
18 ''(2) FORMULARY DETERMINATIONS.—An indi-
19 vidual who is enrolled in a prescription drug plan of-
20 fered by a PDP sponsor or in a MA-EFFS Rx plan
21 may appeal to obtain coverage for a covered out-
22 patient drug that is not on a formulary of the spon-
23 sor or entity offering the plan if the prescribing phy-
24 sician determines that the formulary drug for treat-
25 ment of the same condition either would not be as

1 effective for the individual or would have adverse ef-
2 fects for the individual or both.
3 "(g) CONFIDENTIALITY AND ACCURACY OF EN-
4 ROLLEE RECORDS.—A PDP sponsor that offers a pre-
5 scription drug plan shall meet the requirements of section
6 1852(h) with respect to enrollees under the plan in the
7 same manner as such requirements apply to an organiza-
8 tion with respect to enrollees under part C. A PDP spon-
9 sor shall be treated as a business associate for purposes
10 of the provisions of subpart E of part 164 of title 45, Code
11 of Federal Regulations, adopted pursuant to the authority
12 of the Secretary under section 264(c) of the Health Insur-
13 ance Portability and Accountability Act of 1996 (42 U.S.
14 C. 1320d-2 note).

15 **"SEC. 1860D–4. REQUIREMENTS FOR AND CONTRACTS WITH**
16 **PRESCRIPTION DRUG PLAN (PDP) SPONSORS.**

17 "(a) GENERAL REQUIREMENTS.—Each PDP sponsor
18 of a prescription drug plan shall meet the following re-
19 quirements:
20 "(1) LICENSURE.—Subject to subsection (c),
21 the sponsor is organized and licensed under State
22 law as a risk-bearing entity eligible to offer health
23 insurance or health benefits coverage in each State
24 in which it offers a prescription drug plan.

1 "(2) ASSUMPTION OF FINANCIAL RISK FOR UN-
2 SUBSIDIZED COVERAGE.—
3 "(A) IN GENERAL.—Subject to subpara-
4 graph (B) and section 1860D–5(d)(2), the enti-
5 ty assumes full financial risk on a prospective
6 basis for qualified prescription drug coverage
7 that it offers under a prescription drug plan
8 and that is not covered under section 1860D–
9 8.
10 "(B) REINSURANCE PERMITTED.—The en-
11 tity may obtain insurance or make other ar-
12 rangements for the cost of coverage provided to
13 any enrollee.
14 "(3) SOLVENCY FOR UNLICENSED SPONSORS.—
15 In the case of a sponsor that is not described in
16 paragraph (1), the sponsor shall meet solvency
17 standards established by the Administrator under
18 subsection (d).
19 "(b) CONTRACT REQUIREMENTS.—
20 "(1) IN GENERAL.—The Administrator shall
21 not permit the election under section 1860D–1 of a
22 prescription drug plan offered by a PDP sponsor
23 under this part, and the sponsor shall not be eligible
24 for payments under section 1860D–7 or 1860D–8,
25 unless the Administrator has entered into a contract

1 under this subsection with the sponsor with respect
2 to the offering of such plan. Such a contract with
3 a sponsor may cover more than one prescription
4 drug plan. Such contract shall provide that the spon-
5 sor agrees to comply with the applicable require-
6 ments and standards of this part and the terms and
7 conditions of payment as provided for in this part.
8 "(2) NEGOTIATION REGARDING TERMS AND
9 CONDITIONS.—The Administrator shall have the
10 same authority to negotiate the terms and conditions
11 of prescription drug plans under this part as the Di-
12 rector of the Office of Personnel Management has
13 with respect to health benefits plans under chapter
14 89 of title 5, United States Code. In negotiating the
15 terms and conditions regarding premiums for which
16 information is submitted under section 1860D–
17 6(a)(2), the Administrator shall take into account
18 the subsidy payments under section 1860D–8.
19 "(3) INCORPORATION OF CERTAIN MEDICARE
20 ADVANTAGE CONTRACT REQUIREMENTS.—The fol-
21 lowing provisions of section 1857 shall apply, subject
22 to subsection (c)(5), to contracts under this section
23 in the same manner as they apply to contracts under
24 section 1857(a):

1 "(A) MINIMUM ENROLLMENT.—Para-
2 graphs (1) and (3) of section 1857(b), except
3 that the requirement of such paragraph (1)
4 shall be waived during the first contract year
5 with respect to an organization in a region.
6 "(B) CONTRACT PERIOD AND EFFECTIVE-
7 NESS.—Paragraphs (1) through (3) and (5) of
8 section 1857(c).
9 "(C) PROTECTIONS AGAINST FRAUD AND
10 BENEFICIARY PROTECTIONS.—Section 1857(d).
11 "(D) ADDITIONAL CONTRACT TERMS.—
12 Section 1857(e); except that in applying section
13 1857(e)(2) under this part—
14 "(i) such section shall be applied sepa-
15 rately to costs relating to this part (from
16 costs under part C and part E);
17 "(ii) in no case shall the amount of
18 the fee established under this subpara-
19 graph for a plan exceed 20 percent of the
20 maximum amount of the fee that may be
21 established under subparagraph (B) of
22 such section; and
23 "(iii) no fees shall be applied under
24 this subparagraph with respect to MA-
25 EFFS Rx plans.

1 "(E) INTERMEDIATE SANCTIONS.—Section
2 1857(g).
3 "(F) PROCEDURES FOR TERMINATION.—
4 Section 1857(h).
5 "(4) RULES OF APPLICATION FOR INTER-
6 MEDIATE SANCTIONS.—In applying paragraph
7 (3)(E)—
8 "(A) the reference in section
9 1857(g)(1)(B) to section 1854 is deemed a ref-
10 erence to this part; and
11 "(B) the reference in section
12 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall
13 not be applied.
14 "(5) SERVICE AREA REQUIREMENT.—For pur-
15 poses of this part, the Administrator shall designate
16 at least 10 areas covering the entire United States
17 and to the extent practicable shall be consistent with
18 EFFS regions established under section 1860E–
19 1(a)(2).
20 "(c) WAIVER OF CERTAIN REQUIREMENTS TO EX-
21 PAND CHOICE.—
22 "(1) IN GENERAL.—In the case of an entity
23 that seeks to offer a prescription drug plan in a
24 State, the Administrator shall waive the requirement
25 of subsection (a)(1) that the entity be licensed in

that State if the Administrator determines, based on the application and other evidence presented to the Administrator, that any of the grounds for approval of the application described in paragraph (2) have been met.

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

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

"(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that an entity is licensed in accordance with subsection (a)(1) does not deem the entity to meet other requirements imposed under this part for a PDP sponsor.

"(5) REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying provi-

1 sions of section 1855(a)(2) under this subsection to
2 prescription drug plans and PDP sponsors—
3 "(A) any reference to a waiver application
4 under section 1855 shall be treated as a ref-
5 erence to a waiver application under paragraph
6 (1); and
7 "(B) any reference to solvency standards
8 shall be treated as a reference to solvency
9 standards established under subsection (d).
10 "(d) SOLVENCY STANDARDS FOR NON-LICENSED
11 SPONSORS.—
12 "(1) ESTABLISHMENT.—The Administrator
13 shall establish, by not later than October 1, 2004,
14 financial solvency and capital adequacy standards
15 that an entity that does not meet the requirements
16 of subsection (a)(1) must meet to qualify as a PDP
17 sponsor under this part.
18 "(2) COMPLIANCE WITH STANDARDS.—Each
19 PDP sponsor that is not licensed by a State under
20 subsection (a)(1) and for which a waiver application
21 has been approved under subsection (c) shall meet
22 solvency and capital adequacy standards established
23 under paragraph (1). The Administrator shall estab-
24 lish certification procedures for such PDP sponsors

with respect to such solvency standards in the manner described in section 1855(c)(2).

"(e) RELATION TO STATE LAWS.—

"(1) IN GENERAL.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency, except as provided in subsection (d)) with respect to prescription drug plans which are offered by PDP sponsors under this part.

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

"SEC. 1860D–5. PROCESS FOR BENEFICIARIES TO SELECT QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) IN GENERAL.—The Administrator shall establish a process for the selection of the prescription drug plan or MA-EFFS Rx plan through which eligible individuals elect qualified prescription drug coverage under this part.

"(b) ELEMENTS.—Such process shall include the following:

1 "(1) Annual, coordinated election periods, in
2 which such individuals can change the qualifying
3 plans through which they obtain coverage, in accord-
4 ance with section 1860D–1(b)(2).
5 "(2) Active dissemination of information to pro-
6 mote an informed selection among qualifying plans
7 based upon price, quality, and other features, in the
8 manner described in (and in coordination with) sec-
9 tion 1851(d), including the provision of annual com-
10 parative information, maintenance of a toll-free hot-
11 line, and the use of non-Federal entities.
12 "(3) Coordination of elections through filing
13 with the entity offering a MA-EFFS Rx plan or a
14 PDP sponsor, in the manner described in (and in co-
15 ordination with) section 1851(c)(2).
16 "(4) Informing each enrollee before the begin-
17 ning of each year of the annual out-of-pocket thresh-
18 old applicable to the enrollee for that year under sec-
19 tion 1860D–2(b)(4) at such time.
20 "(c) MA-EFFS RX ENROLLEE MAY ONLY OBTAIN
21 BENEFITS THROUGH THE PLAN.—An individual who is
22 enrolled under a MA-EFFS Rx plan may only elect to re-
23 ceive qualified prescription drug coverage under this part
24 through such plan.

1 "(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED
2 PRESCRIPTION DRUG COVERAGE.—
3 "(1) CHOICE OF AT LEAST TWO PLANS IN EACH
4 AREA.—
5 "(A) IN GENERAL.—The Administrator
6 shall assure that each individual who is entitled
7 to benefits under part A or enrolled under part
8 B and who is residing in an area in the United
9 States has available, consistent with subpara-
10 graph (B), a choice of enrollment in at least
11 two qualifying plans (as defined in paragraph
12 (5)) in the area in which the individual resides,
13 at least one of which is a prescription drug
14 plan.
15 "(B) REQUIREMENT FOR DIFFERENT
16 PLAN SPONSORS.—The requirement in subpara-
17 graph (A) is not satisfied with respect to an
18 area if only one PDP sponsor or one entity that
19 offers a MA-EFFS Rx plan offers all the quali-
20 fying plans in the area.
21 "(2) GUARANTEEING ACCESS TO COVERAGE.—
22 In order to assure access under paragraph (1) and
23 consistent with paragraph (3), the Administrator
24 may provide partial underwriting of risk for a PDP
25 sponsor to expand the service area under an existing

1 prescription drug plan to adjoining or additional
2 areas or to establish such a plan (including offering
3 such a plan on a regional or nationwide basis), but
4 only so long as (and to the extent) necessary to as-
5 sure the access guaranteed under paragraph (1).
6 "(3) LIMITATION ON AUTHORITY.—In exer-
7 cising authority under this subsection, the
8 Administrator—
9 "(A) shall not provide for the full under-
10 writing of financial risk for any PDP sponsor;
11 and
12 "(B) shall seek to maximize the assump-
13 tion of financial risk by PDP sponsors or enti-
14 ties offering a MA-EFFS Rx plan.
15 "(4) REPORTS.—The Administrator shall, in
16 each annual report to Congress under section
17 1809(f), include information on the exercise of au-
18 thority under this subsection. The Administrator
19 also shall include such recommendations as may be
20 appropriate to minimize the exercise of such author-
21 ity, including minimizing the assumption of financial
22 risk.
23 "(5) QUALIFYING PLAN DEFINED.—For pur-
24 poses of this subsection, the term 'qualifying plan'

means a prescription drug plan or a MA-EFFS Rx plan.

"SEC. 1860D–6. SUBMISSION OF BIDS AND PREMIUMS.

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

"(1) IN GENERAL.—Each PDP sponsor shall submit to the Administrator the information described in paragraph (2) in the same manner as information is submitted by an organization under section 1854(a)(1).

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

"(A) COVERAGE PROVIDED.—Information on the qualified prescription drug coverage to be provided.

"(B) ACTUARIAL VALUE.—Information on the actuarial value of the coverage.

"(C) BID AND PREMIUM.—Information on the bid and the premium for the coverage, including an actuarial certification of—

"(i) the actuarial basis for such bid and premium;

"(ii) the portion of such bid and premium attributable to benefits in excess of standard coverage;

1 "(iii) the reduction in such bid result-
2 ing from the reinsurance subsidy payments
3 provided under section 1860D–8(a)(2);
4 and
5 "(iv) the reduction in such premium
6 resulting from the direct and reinsurance
7 subsidy payments provided under section
8 1860D–8.
9 "(D) ADDITIONAL INFORMATION.—Such
10 other information as the Administrator may re-
11 quire to carry out this part.
12 "(3) REVIEW OF INFORMATION; NEGOTIATION
13 AND APPROVAL OF PREMIUMS.—
14 "(A) IN GENERAL.—Subject to subpara-
15 graph (B), the Administrator shall review the
16 information filed under paragraph (2) for the
17 purpose of conducting negotiations under sec-
18 tion 1860D–4(b)(2) (relating to using OPM-like
19 authority under the FEHBP). The Adminis-
20 trator, using the information provided (includ-
21 ing the actuarial certification under paragraph
22 (2)(C)) shall approve the premium submitted
23 under this subsection only if the premium accu-
24 rately reflects both (i) the actuarial value of the
25 benefits provided, and (ii) the 73 percent aver-

1 age subsidy provided under section 1860D–8
2 for the standard benefit. The Administrator
3 shall apply actuarial principles to approval of a
4 premium under this part in a manner similar to
5 the manner in which those principles are ap-
6 plied in establishing the monthly part B pre-
7 mium under section 1839.
8 "(B) EXCEPTION.—In the case of a plan
9 described in section 1851(a)(2)(C), the provi-
10 sions of subparagraph (A) shall not apply and
11 the provisions of paragraph (5)(B) of section
12 1854(a), prohibiting the review, approval, or
13 disapproval of amounts described in such para-
14 graph, shall apply to the negotiation and rejec-
15 tion of the monthly bid amounts and proportion
16 referred to in subparagraph (A).
17 "(b) UNIFORM BID AND PREMIUM.—
18 "(1) IN GENERAL.—The bid and premium for
19 a prescription drug plan under this section may not
20 vary among enrollees in the plan in the same service
21 area.
22 "(2) CONSTRUCTION.—Nothing in paragraph
23 (1) shall be construed as preventing the imposition
24 of a late enrollment penalty under section 1860D–
25 1(c)(2)(B).

1 "(c) COLLECTION.—
2 "(1) BENEFICIARY'S OPTION OF PAYMENT
3 THROUGH WITHHOLDING FROM SOCIAL SECURITY
4 PAYMENT OR USE OF ELECTRONIC FUNDS TRANS-
5 FER MECHANISM.—In accordance with regulations, a
6 PDP sponsor shall permit each enrollee, at the en-
7 rollee's option, to make payment of premiums under
8 this part to the sponsor through withholding from
9 benefit payments in the manner provided under sec-
10 tion 1840 with respect to monthly premiums under
11 section 1839 or through an electronic funds transfer
12 mechanism (such as automatic charges of an ac-
13 count at a financial institution or a credit or debit
14 card account) or otherwise. All premium payments
15 that are withheld under this paragraph shall be
16 credited to the Medicare Prescription Drug Trust
17 Fund and shall be paid to the PDP sponsor in-
18 volved.
19 "(2) OFFSETTING.—Reductions in premiums
20 for coverage under parts A and B as a result of a
21 selection of a MA-EFFS Rx plan may be used to re-
22 duce the premium otherwise imposed under para-
23 graph (1).
24 "(d) ACCEPTANCE OF REFERENCE PREMIUM
25 AMOUNT AS FULL PREMIUM FOR SUBSIDIZED LOW-IN-

1 COME INDIVIDUALS IF NO STANDARD (OR EQUIVALENT)
2 COVERAGE IN AN AREA.—
3 "(1) IN GENERAL.—If there is no standard pre-
4 scription drug coverage (as defined in paragraph
5 (2)) offered in an area, in the case of an individual
6 who is eligible for a premium subsidy under section
7 1860D–7 and resides in the area, the PDP sponsor
8 of any prescription drug plan offered in the area
9 (and any entity offering a MA-EFFS Rx plan in the
10 area) shall accept the reference premium amount
11 (under paragraph (3)) as payment in full for the
12 premium charge for qualified prescription drug cov-
13 erage.
14 "(2) STANDARD PRESCRIPTION DRUG COV-
15 ERAGE DEFINED.—For purposes of this subsection,
16 the term 'standard prescription drug coverage'
17 means qualified prescription drug coverage that is
18 standard coverage or that has an actuarial value
19 equivalent to the actuarial value for standard cov-
20 erage.
21 "(3) REFERENCE PREMIUM AMOUNT DE-
22 FINED.—For purposes of this subsection, the term
23 'reference premium amount' means, with respect to
24 qualified prescription drug coverage offered under—
25 "(A) a prescription drug plan that—

1 "(i) provides standard coverage (or al-
2 ternative prescription drug coverage the
3 actuarial value is equivalent to that of
4 standard coverage), the plan's PDP pre-
5 mium; or
6 "(ii) provides alternative prescription
7 drug coverage the actuarial value of which
8 is greater than that of standard coverage,
9 the plan's PDP premium multiplied by the
10 ratio of (I) the actuarial value of standard
11 coverage, to (II) the actuarial value of the
12 alternative coverage;
13 "(B) an EFFS plan, the EFFS monthly
14 prescription drug beneficiary premium (as de-
15 fined in section 1860E–4(a)(3)(B)); or
16 "(C) a Medicare Advantage, the Medicare
17 Advantage monthly prescription drug bene-
18 ficiary premium (as defined in section
19 1854(b)(2)(B)).
20 For purposes of subparagraph (A), the term 'PDP
21 premium' means, with respect to a prescription drug
22 plan, the premium amount for enrollment under the
23 plan under this part (determined without regard to
24 any low-income subsidy under section 1860D–7 or

1 any late enrollment penalty under section 1860D–
2 1(c)(2)(B)).

3 **"SEC. 1860D–7. PREMIUM AND COST-SHARING SUBSIDIES**
4 **FOR LOW-INCOME INDIVIDUALS.**

5 "(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS
6 WITH INCOME BELOW 150 PERCENT OF FEDERAL POV-
7 ERTY LEVEL.—

8 "(1) FULL PREMIUM SUBSIDY AND REDUCTION
9 OF COST-SHARING FOR INDIVIDUALS WITH INCOME
10 BELOW 135 PERCENT OF FEDERAL POVERTY
11 LEVEL.—In the case of a subsidy eligible individual
12 (as defined in paragraph (4)) who is determined to
13 have income that does not exceed 135 percent of the
14 Federal poverty level, the individual is entitled under
15 this section—

16 "(A) to an income-related premium subsidy
17 equal to 100 percent of the amount described in
18 subsection (b)(1); and

19 "(B) subject to subsection (c), to the sub-
20 stitution for the beneficiary cost-sharing de-
21 scribed in paragraphs (1) and (2) of section
22 1860D–2(b) (up to the initial coverage limit
23 specified in paragraph (3) of such section) of
24 amounts that do not exceed $2 for a multiple
25 source or generic drug (as described in section

1927(k)(7)(A)) and $5 for a non-preferred drug.

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

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

"(4) DETERMINATION OF ELIGIBILITY.—

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

"(i) is eligible to elect, and has elected, to obtain qualified prescription drug coverage under this part;

"(ii) has income below 150 percent of the Federal poverty line; and

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

"(B) DETERMINATIONS.—The determination of whether an individual residing in a State is a subsidy eligible individual and the amount of such individual's income shall be determined under the State medicaid plan for the State under section 1935(a) or by the Social Security Administration. In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

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

1 "(i) income shall be determined in the
2 manner described in section
3 1905(p)(1)(B); and
4 "(ii) the term 'Federal poverty line'
5 means the official poverty line (as defined
6 by the Office of Management and Budget,
7 and revised annually in accordance with
8 section 673(2) of the Omnibus Budget
9 Reconciliation Act of 1981) applicable to a
10 family of the size involved.
11 "(D) RESOURCE STANDARD APPLIED TO
12 BE BASED ON THREE TIMES SSI RESOURCE
13 STANDARD.—The resource requirement of this
14 subparagraph is that an individual's resources
15 (as determined under section 1613 for purposes
16 of the supplemental security income program)
17 do not exceed—
18 "(i) for 2006 three times the max-
19 imum amount of resources that an indi-
20 vidual may have and obtain benefits under
21 that program; and
22 "(ii) for a subsequent year the re-
23 source limitation established under this
24 clause for the previous year increased by
25 the annual percentage increase in the con-

1 sumer price index (all items; U.S. city av-
2 erage) as of September of such previous
3 year.
4 Any resource limitation established under clause
5 (ii) that is not a multiple of $10 shall be round-
6 ed to the nearest multiple of $10.
7 ''(E) TREATMENT OF TERRITORIAL RESI-
8 DENTS.—In the case of an individual who is not
9 a resident of the 50 States or the District of
10 Columbia, the individual is not eligible to be a
11 subsidy eligible individual but may be eligible
12 for financial assistance with prescription drug
13 expenses under section 1935(e).
14 ''(F) TREATMENT OF CONFORMING
15 MEDIGAP POLICIES.—For purposes of this sec-
16 tion, the term 'qualified prescription drug cov-
17 erage' includes a medicare supplemental policy
18 described in section 1860D–8(b)(4).
19 ''(5) INDEXING DOLLAR AMOUNTS.—
20 ''(A) FOR 2007.—The dollar amounts ap-
21 plied under paragraphs (1)(B) for 2007 shall be
22 the dollar amounts specified in such paragraph
23 increased by the annual percentage increase de-
24 scribed in section 1860D–2(b)(5) for 2007.

1 "(B) FOR SUBSEQUENT YEARS.—The dol-
2 lar amounts applied under paragraph (1)(B) for
3 a year after 2007 shall be the amounts (under
4 this paragraph) applied under paragraph (1)(B)
5 for the preceding year increased by the annual
6 percentage increase described in section
7 1860D–2(b)(5) (relating to growth in medicare
8 prescription drug costs per beneficiary) for the
9 year involved.
10 "(b) PREMIUM SUBSIDY AMOUNT.—
11 "(1) IN GENERAL.—The premium subsidy
12 amount described in this subsection for an individual
13 residing in an area is the benchmark premium
14 amount (as defined in paragraph (2)) for qualified
15 prescription drug coverage offered by the prescrip-
16 tion drug plan or the MA-EFFS Rx plan in which
17 the individual is enrolled.
18 "(2) BENCHMARK PREMIUM AMOUNT DE-
19 FINED.—For purposes of this subsection, the term
20 'benchmark premium amount' means, with respect
21 to qualified prescription drug coverage offered
22 under—
23 "(A) a prescription drug plan that—
24 "(i) provides standard coverage (or al-
25 ternative prescription drug coverage the

1 actuarial value of which is equivalent to
2 that of standard coverage), the premium
3 amount for enrollment under the plan
4 under this part (determined without regard
5 to any subsidy under this section or any
6 late enrollment penalty under section
7 1860D–1(c)(2)(B)); or
8 ''(ii) provides alternative prescription
9 drug coverage the actuarial value of which
10 is greater than that of standard coverage,
11 the premium amount described in clause
12 (i) multiplied by the ratio of (I) the actu-
13 arial value of standard coverage, to (II)
14 the actuarial value of the alternative cov-
15 erage; or
16 ''(B) a MA-EFFS Rx plan, the portion of
17 the premium amount that is attributable to
18 statutory drug benefits (described in section
19 1853(a)(1)(A)(ii)(II)).
20 ''(c) RULES IN APPLYING COST-SHARING SUB-
21 SIDIES.—
22 ''(1) IN GENERAL.—In applying subsection
23 (a)(1)(B), nothing in this part shall be construed as
24 preventing a plan or provider from waiving or reduc-
25 ing the amount of cost-sharing otherwise applicable.

1 "(2) LIMITATION ON CHARGES.—In the case of
2 an individual receiving cost-sharing subsidies under
3 subsection (a)(1)(B), the PDP sponsor or entity of-
4 fering a MA-EFFS Rx plan may not charge more
5 than $5 per prescription.
6 "(3) APPLICATION OF INDEXING RULES.—The
7 provisions of subsection (a)(5) shall apply to the dol-
8 lar amount specified in paragraph (2) in the same
9 manner as they apply to the dollar amounts specified
10 in subsections (a)(1)(B).
11 "(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The
12 Administrator shall provide a process whereby, in the case
13 of an individual who is determined to be a subsidy eligible
14 individual and who is enrolled in prescription drug plan
15 or is enrolled in a MA-EFFS Rx plan—
16 "(1) the Administrator provides for a notifica-
17 tion of the PDP sponsor or the entity offering the
18 MA-EFFS Rx plan involved that the individual is el-
19 igible for a subsidy and the amount of the subsidy
20 under subsection (a);
21 "(2) the sponsor or entity involved reduces the
22 premiums or cost-sharing otherwise imposed by the
23 amount of the applicable subsidy and submits to the
24 Administrator information on the amount of such
25 reduction; and

1 "(3) the Administrator periodically and on a
2 timely basis reimburses the sponsor or entity for the
3 amount of such reductions.
4 The reimbursement under paragraph (3) with respect to
5 cost-sharing subsidies may be computed on a capitated
6 basis, taking into account the actuarial value of the sub-
7 sidies and with appropriate adjustments to reflect dif-
8 ferences in the risks actually involved.
9 "(e) RELATION TO MEDICAID PROGRAM.—
10 "(1) IN GENERAL.—For provisions providing
11 for eligibility determinations, and additional financ-
12 ing, under the medicaid program, see section 1935.
13 "(2) MEDICAID PROVIDING WRAP AROUND BEN-
14 EFITS.—The coverage provided under this part is
15 primary payor to benefits for prescribed drugs pro-
16 vided under the medicaid program under title XIX
17 consistent with section 1935(d)(1).
18 "(3) COORDINATION.—The Administrator shall
19 develop and implement a plan for the coordination
20 of prescription drug benefits under this part with
21 the benefits provided under the medicaid program
22 under title XIX, with particular attention to insur-
23 ing coordination of payments and prevention of
24 fraud and abuse. In developing and implementing
25 such plan, the Administrator shall involve the Sec-

1 retary, the States, the data processing industry,
2 pharmacists, and pharmaceutical manufacturers,
3 and other experts.

4 **"SEC. 1860D–8. SUBSIDIES FOR ALL MEDICARE BENE-**
5 **FICIARIES FOR QUALIFIED PRESCRIPTION**
6 **DRUG COVERAGE.**

7 "(a) SUBSIDY PAYMENT.—In order to reduce pre-
8 mium levels applicable to qualified prescription drug cov-
9 erage for all medicare beneficiaries consistent with an
10 overall subsidy level of 73 percent, to reduce adverse selec-
11 tion among prescription drug plans and MA-EFFS Rx
12 plans, and to promote the participation of PDP sponsors
13 under this part, the Administrator shall provide in accord-
14 ance with this section for payment to a qualifying entity
15 (as defined in subsection (b)) of the following subsidies:

16 "(1) DIRECT SUBSIDY.—In the case of an en-
17 rollee enrolled for a month in a prescription drug
18 plan or a MA-EFFS Rx plan, a direct subsidy equal
19 to 43 percent of the national average monthly bid
20 amount (computed under subsection (g)) for that
21 month.

22 "(2) SUBSIDY THROUGH REINSURANCE.—In
23 the case of an enrollee enrolled for a month in a pre-
24 scription drug plan or a MA-EFFS Rx plan, the re-
25 insurance payment amount (as defined in subsection

1 (c)), which in the aggregate is 30 percent of the
2 total payments made by qualifying entities for stand-
3 ard coverage under the respective plan, for excess
4 costs incurred in providing qualified prescription
5 drug coverage—
6 "(A) for enrollees with a prescription drug
7 plan under this part; and
8 "(B) for enrollees with a MA-EFFS Rx
9 plan.
10 "(3) EMPLOYER AND UNION FLEXIBILITY.—In
11 the case of an individual who is a participant or ben-
12 eficiary in a qualified retiree prescription drug plan
13 (as defined in subsection (f)(1)) and who is not en-
14 rolled in a prescription drug plan or in a MA-EFFS
15 Rx plan, the special subsidy payments under sub-
16 section (f)(3).
17 This section constitutes budget authority in advance of ap-
18 propriations Acts and represents the obligation of the Ad-
19 ministrator to provide for the payment of amounts pro-
20 vided under this section.
21 "(b) QUALIFYING ENTITY DEFINED.—For purposes
22 of this section, the term 'qualifying entity' means any of
23 the following that has entered into an agreement with the
24 Administrator to provide the Administrator with such in-
25 formation as may be required to carry out this section:

1 "(1) A PDP sponsor offering a prescription
2 drug plan under this part.
3 "(2) An entity that offers a MA-EFFS Rx plan.
4 "(3) The sponsor of a qualified retiree prescrip-
5 tion drug plan (as defined in subsection (f)).
6 "(c) REINSURANCE PAYMENT AMOUNT.—
7 "(1) IN GENERAL.—Subject to subsection
8 (d)(1)(B) and paragraph (4), the reinsurance pay-
9 ment amount under this subsection for a qualifying
10 covered individual (as defined in paragraph (5)) for
11 a coverage year (as defined in subsection (h)(2)) is
12 equal to the sum of the following:
13 "(A) REINSURANCE BETWEEN INITIAL RE-
14 INSURANCE THRESHOLD AND THE INITIAL COV-
15 ERAGE LIMIT.—For the portion of the individ-
16 ual's gross covered prescription drug costs (as
17 defined in paragraph (3)) for the year that ex-
18 ceeds the initial reinsurance threshold specified
19 in paragraph (4), but does not exceed the initial
20 coverage limit specified in section 1860D–
21 2(b)(3), an amount equal to 20 percent of the
22 allowable costs (as defined in paragraph (2)) at-
23 tributable to such gross covered prescription
24 drug costs.

1 "(B) REINSURANCE ABOVE ANNUAL OUT-
2 OF-POCKET THRESHOLD.—For the portion of
3 the individual's gross covered prescription drug
4 costs for the year that exceeds the annual out-
5 of-pocket threshold specified in 1860D–
6 2(b)(4)(B), an amount equal to 80 percent of
7 the allowable costs attributable to such gross
8 covered prescription drug costs.
9 "(2) ALLOWABLE COSTS.—For purposes of this
10 section, the term 'allowable costs' means, with re-
11 spect to gross covered prescription drug costs under
12 a plan described in subsection (b) offered by a quali-
13 fying entity, the part of such costs that are actually
14 paid (net of discounts, chargebacks, and average
15 percentage rebates) under the plan, but in no case
16 more than the part of such costs that would have
17 been paid under the plan if the prescription drug
18 coverage under the plan were standard coverage.
19 "(3) GROSS COVERED PRESCRIPTION DRUG
20 COSTS.—For purposes of this section, the term
21 'gross covered prescription drug costs' means, with
22 respect to an enrollee with a qualifying entity under
23 a plan described in subsection (b) during a coverage
24 year, the costs incurred under the plan (including
25 costs attributable to administrative costs) for cov-

1 ered prescription drugs dispensed during the year,
2 including costs relating to the deductible, whether
3 paid by the enrollee or under the plan, regardless of
4 whether the coverage under the plan exceeds stand-
5 ard coverage and regardless of when the payment
6 for such drugs is made.

7 "(4) INITIAL REINSURANCE THRESHOLD.—The
8 initial reinsurance threshold specified in this
9 paragraph—

10 "(A) for 2006, is equal to $1,000; or

11 "(B) for a subsequent year, is equal to the
12 payment threshold specified in this paragraph
13 for the previous year, increased by the annual
14 percentage increase described in section
15 1860D–2(b)(5) for the year involved.

16 Any amount determined under subparagraph (B)
17 that is not a multiple of $10 shall be rounded to the
18 nearest multiple of $10.

19 "(5) QUALIFYING COVERED INDIVIDUAL DE-
20 FINED.—For purposes of this subsection, the term
21 'qualifying covered individual' means an individual
22 who—

23 "(A) is enrolled with a prescription drug
24 plan under this part; or

25 "(B) is enrolled with a MA-EFFS Rx plan.

1 "(d) ADJUSTMENT OF PAYMENTS.—
2 "(1) ADJUSTMENT OF REINSURANCE PAY-
3 MENTS TO ASSURE 30 PERCENT LEVEL OF SUBSIDY
4 THROUGH REINSURANCE.—
5 "(A) ESTIMATION OF PAYMENTS.—The
6 Administrator shall estimate—
7 "(i) the total payments to be made
8 (without regard to this subsection) during
9 a year under subsections (a)(2) and (c);
10 and
11 "(ii) the total payments to be made by
12 qualifying entities for standard coverage
13 under plans described in subsection (b)
14 during the year.
15 "(B) ADJUSTMENT.—The Administrator
16 shall proportionally adjust the payments made
17 under subsections (a)(2) and (c) for a coverage
18 year in such manner so that the total of the
19 payments made under such subsections for the
20 year is equal to 30 percent of the total pay-
21 ments described in subparagraph (A)(ii).
22 "(2) RISK ADJUSTMENT FOR DIRECT SUB-
23 SIDIES.—To the extent the Administrator deter-
24 mines it appropriate to avoid risk selection, the pay-
25 ments made for direct subsidies under subsection

1 (a)(1) are subject to adjustment based upon risk
2 factors specified by the Administrator. Any such risk
3 adjustment shall be designed in a manner as to not
4 result in a change in the aggregate payments made
5 under such subsection.
6 "(e) PAYMENT METHODS.—
7 "(1) IN GENERAL.—Payments under this sec-
8 tion shall be based on such a method as the Admin-
9 istrator determines. The Administrator may estab-
10 lish a payment method by which interim payments
11 of amounts under this section are made during a
12 year based on the Administrator's best estimate of
13 amounts that will be payable after obtaining all of
14 the information.
15 "(2) SOURCE OF PAYMENTS.—Payments under
16 this section shall be made from the Medicare Pre-
17 scription Drug Trust Fund.
18 "(f) RULES RELATING TO QUALIFIED RETIREE PRE-
19 SCRIPTION DRUG PLAN.—
20 "(1) DEFINITION.—For purposes of this sec-
21 tion, the term 'qualified retiree prescription drug
22 plan' means employment-based retiree health cov-
23 erage (as defined in paragraph (4)(A)) if, with re-
24 spect to an individual who is a participant or bene-
25 ficiary under such coverage and is eligible to be en-

1 rolled in a prescription drug plan or a MA-EFFS Rx
2 plan under this part, the following requirements are
3 met:

4 "(A) ACTUARIAL EQUIVALENCE TO STAND-
5 ARD COVERAGE.—The Administrator deter-
6 mines (based on an actuarial analysis approved
7 by the Administrator) that coverage provides at
8 least the same actuarial value as standard cov-
9 erage. Such determination may be made on an
10 annual basis.

11 "(B) AUDITS.—The sponsor (or the ad-
12 ministrator, if designated by the sponsor) and
13 the plan shall maintain, and afford the Admin-
14 istrator access to, such records as the Adminis-
15 trator may require for purposes of audits and
16 other oversight activities necessary to ensure
17 the adequacy of prescription drug coverage and
18 the accuracy of payments made.

19 "(C) PROVISION OF CERTIFICATION OF
20 PRESCRIPTION DRUG COVERAGE.—The sponsor
21 of the plan shall provide for issuance of certifi-
22 cations of the type described in section 1860D–
23 1(c)(2)(D).

24 "(2) LIMITATION ON BENEFIT ELIGIBILITY.—
25 No payment shall be provided under this section

with respect to a participant or beneficiary in a qualified retiree prescription drug plan unless the individual is—

"(A) is covered under the plan; and

"(B) is eligible to obtain qualified prescription drug coverage under section 1860D–1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan).

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

"(A) IN GENERAL.—For purposes of subsection (a), the special subsidy payment amount under this paragraph for a qualifying covered retiree(as defined in paragraph (6)) for a coverage year (as defined in subsection (h)) enrolled in a qualifying entity described in subsection (b)(3) under a qualified retiree prescription drug plan is, for the portion of the individual's gross covered prescription drug costs for the year that exceeds the deductible amount specified in subparagraph (B), an amount equal to, subject to subparagraph (D), 28 percent of the allowable costs attributable to such gross covered prescription drug costs, but only to the

1 extent such costs exceed the deductible under
2 subparagraph (B) and do not exceed the cost
3 limit under such subparagraph in the case of
4 any such individual for the plan year.
5 "(B) DEDUCTIBLE AND COST LIMIT APPLI-
6 CABLE.—Subject to subparagraph (C)—
7 "(i) the deductible under this sub-
8 paragraph is equal to $250 for plan years
9 that end in 2006; and
10 "(ii) the cost limit under this subpara-
11 graph is equal to $5,000 for plan years
12 that end in 2006.
13 "(C) INDEXING.—The deductible and cost
14 limit amounts specified in subparagraphs (B)
15 for a plan year that ends after 2006 shall be
16 adjusted in the same manner as the annual de-
17 ductible under section 1860D–2(b)(1) is annu-
18 ally adjusted under such section.
19 "(4) RELATED DEFINITIONS.—As used in this
20 section:
21 "(A) EMPLOYMENT-BASED RETIREE
22 HEALTH COVERAGE.—The term 'employment-
23 based retiree health coverage' means health in-
24 surance or other coverage of health care costs
25 for individuals eligible to enroll in a prescription

1 drug plan or MA-EFFS Rx plan under this
2 part (or for such individuals and their spouses
3 and dependents) under a group health plan (in-
4 cluding such a plan that is established or main-
5 tained under or pursuant to one or more collec-
6 tive bargaining agreements or that is offered
7 under chapter 89 of title 5, United States
8 Code) based on their status as retired partici-
9 pants in such plan.

10 "(B) QUALIFYING COVERED RETIREE.—
11 The term 'qualifying covered retiree' means an
12 individual who is eligible to obtain qualified pre-
13 scription drug coverage under section 1860D–1
14 but did not elect such coverage under this part
15 (either through a prescription drug plan or
16 through a MA-EFFS Rx plan) but is covered
17 under a qualified retiree prescription drug plan.

18 "(C) SPONSOR.—The term 'sponsor'
19 means a plan sponsor, as defined in section
20 3(16)(B) of the Employee Retirement Income
21 Security Act of 1974.

22 "(5) CONSTRUCTION.—Nothing in this sub-
23 section shall be construed as—

24 "(A) precluding an individual who is cov-
25 ered under employment-based retiree health

1 coverage from enrolling in a prescription drug
2 plan or in a MA-EFFS plan;
3 ''(B) precluding such employment-based
4 retiree health coverage or an employer or other
5 person from paying all or any portion of any
6 premium required for coverage under such a
7 prescription drug plan or MA-EFFS plan on
8 behalf of such an individual; or
9 ''(C) preventing such employment-based
10 retiree health coverage from providing coverage
11 for retirees—
12 ''(i) who are covered under a qualified
13 retiree prescription plan that is better than
14 standard coverage; or
15 ''(ii) who are not covered under a
16 qualified retiree prescription plan but who
17 are enrolled in a prescription drug plan or
18 a MA-EFFS Rx plan, that is supplemental
19 to the benefits provided under such pre-
20 scription drug plan or MA-EFFS Rx plan,
21 except that any such supplemental cov-
22 erage (not including payment of any pre-
23 mium referred to in subparagraph (B))
24 shall be treated as primary coverage to

which section 1862(b)(2)(A)(i) is deemed to apply.

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

"(1) IN GENERAL.—For each year (beginning with 2006) the Administrator shall compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each prescription drug plan and for each MA-EFFS Rx plan (as computed under paragraph (2), but excluding plans described in section 1851(a)(2)(C))) adjusted under paragraph (4) to take into account reinsurance payments.

"(2) BENCHMARK BID AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark bid amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard coverage), the PDP bid; or

"(ii) provides alternative prescription drug coverage the actuarial value of which

is greater than that of standard coverage, the PDP bid multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

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

For purposes of subparagraph (A), the term 'PDP bid' means, with respect to a prescription drug plan, the bid amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or any late enrollment penalty under section 1860D–1(c)(2)(B)).

"(3) WEIGHTED AVERAGE.—

"(A) IN GENERAL.—The monthly national average monthly bid amount computed under paragraph (1) shall be a weighted average, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the previous year.

"(B) SPECIAL RULE FOR 2006.—For purposes of applying this subsection for 2006, the Administrator shall establish procedures for de-

1 termining the weighted average under subpara-
2 graph (A) for 2005.
3 ''(4) ADJUSTMENT TO ADD BACK IN VALUE OF
4 REINSURANCE SUBSIDIES.—The adjustment under
5 this paragraph, to take into account reinsurance
6 payments under subsection (c) making up 30 per-
7 cent of total payments, is such an adjustment as will
8 make the national average monthly bid amount rep-
9 resent represent 100 percent, instead of representing
10 70 percent, of average payments under this part.
11 ''(h) COVERAGE YEAR DEFINED.—For purposes of
12 this section, the term 'coverage year' means a calendar
13 year in which covered outpatient drugs are dispensed if
14 a claim for payment is made under the plan for such
15 drugs, regardless of when the claim is paid.
16 **"SEC. 1860D–9. MEDICARE PRESCRIPTION DRUG TRUST**
17 **FUND.**
18 ''(a) IN GENERAL.—There is created on the books
19 of the Treasury of the United States a trust fund to be
20 known as the 'Medicare Prescription Drug Trust Fund'
21 (in this section referred to as the 'Trust Fund'). The
22 Trust Fund shall consist of such gifts and bequests as
23 may be made as provided in section 201(i)(1), and such
24 amounts as may be deposited in, or appropriated to, such
25 fund as provided in this part. Except as otherwise pro-

1 vided in this section, the provisions of subsections (b)
2 through (i) of section 1841 shall apply to the Trust Fund
3 in the same manner as they apply to the Federal Supple-
4 mentary Medical Insurance Trust Fund under such sec-
5 tion.

6 "(b) PAYMENTS FROM TRUST FUND.—

7 "(1) IN GENERAL.—The Managing Trustee
8 shall pay from time to time from the Trust Fund
9 such amounts as the Administrator certifies are nec-
10 essary to make—

11 "(A) payments under section 1860D–7 (re-
12 lating to low-income subsidy payments);

13 "(B) payments under section 1860D–8 (re-
14 lating to subsidy payments); and

15 "(C) payments with respect to administra-
16 tive expenses under this part in accordance with
17 section 201(g).

18 "(2) TRANSFERS TO MEDICAID ACCOUNT FOR
19 INCREASED ADMINISTRATIVE COSTS.—The Man-
20 aging Trustee shall transfer from time to time from
21 the Trust Fund to the Grants to States for Medicaid
22 account amounts the Administrator certifies are at-
23 tributable to increases in payment resulting from the
24 application of a higher Federal matching percentage
25 under section 1935(b).

1 "(c) DEPOSITS INTO TRUST FUND.—
2 "(1) LOW-INCOME TRANSFER.—There is hereby
3 transferred to the Trust Fund, from amounts appro-
4 priated for Grants to States for Medicaid, amounts
5 equivalent to the aggregate amount of the reductions
6 in payments under section 1903(a)(1) attributable to
7 the application of section 1935(c).
8 "(2) APPROPRIATIONS TO COVER GOVERNMENT
9 CONTRIBUTIONS.—There are authorized to be appro-
10 priated from time to time, out of any moneys in the
11 Treasury not otherwise appropriated, to the Trust
12 Fund, an amount equivalent to the amount of pay-
13 ments made from the Trust Fund under subsection
14 (b), reduced by the amount transferred to the Trust
15 Fund under paragraph (1).
16 "(d) RELATION TO SOLVENCY REQUIREMENTS.—
17 Any provision of law that relates to the solvency of the
18 Trust Fund under this part shall take into account the
19 Trust Fund and amounts receivable by, or payable from,
20 the Trust Fund.
21 **"SEC. 1860D–10. DEFINITIONS; APPLICATION TO MEDICARE**
22 **ADVANTAGE AND EFFS PROGRAMS; TREAT-**
23 **MENT OF REFERENCES TO PROVISIONS IN**
24 **PART C.**
25 "(a) DEFINITIONS.—For purposes of this part:

1 "(1) COVERED OUTPATIENT DRUGS.—The term
2 'covered outpatient drugs' is defined in section
3 1860D–2(f).
4 "(2) INITIAL COVERAGE LIMIT.—The term 'ini-
5 tial coverage limit' means such limit as established
6 under section 1860D–2(b)(3), or, in the case of cov-
7 erage that is not standard coverage, the comparable
8 limit (if any) established under the coverage.
9 "(3) MEDICARE PRESCRIPTION DRUG TRUST
10 FUND.—The term 'Medicare Prescription Drug
11 Trust Fund' means the Trust Fund created under
12 section 1860D–9(a).
13 "(4) PDP SPONSOR.—The term 'PDP sponsor'
14 means an entity that is certified under this part as
15 meeting the requirements and standards of this part
16 for such a sponsor.
17 "(5) PRESCRIPTION DRUG PLAN.—The term
18 'prescription drug plan' means health benefits cov-
19 erage that—
20 "(A) is offered under a policy, contract, or
21 plan by a PDP sponsor pursuant to, and in ac-
22 cordance with, a contract between the Adminis-
23 trator and the sponsor under section 1860D–
24 4(b);

1 "(B) provides qualified prescription drug
2 coverage; and
3 "(C) meets the applicable requirements of
4 the section 1860D–3 for a prescription drug
5 plan.
6 "(6) QUALIFIED PRESCRIPTION DRUG COV-
7 ERAGE.—The term 'qualified prescription drug cov-
8 erage' is defined in section 1860D–2(a).
9 "(7) STANDARD COVERAGE.—The term 'stand-
10 ard coverage' is defined in section 1860D–2(b).
11 "(8) INSURANCE RISK.—The term 'insurance
12 risk' means, with respect to a participating phar-
13 macy, risk of the type commonly assumed only by
14 insurers licensed by a State and does not include
15 payment variations designed to reflect performance-
16 based measures of activities within the control of the
17 pharmacy, such as formulary compliance and generic
18 drug substitution.
19 "(b) OFFER OF QUALIFIED PRESCRIPTION DRUG
20 COVERAGE UNDER MEDICARE ADVANTAGE AND EFFS
21 PROGRAMS.—
22 "(1) AS PART OF MEDICARE ADVANTAGE
23 PLAN.—Medicare Advantage organizations are re-
24 quired to offer Medicare Advantage plans that in-

1 clude qualified prescription drug coverage under part
2 C pursuant to section 1851(j).
3 "(2) AS PART OF EFFS PLAN.—EFFS organi-
4 zations are required to offer EFFS plans that in-
5 clude qualified prescription drug coverage under part
6 E pursuant to section 1860E–2(d).
7 "(c) APPLICATION OF PART C PROVISIONS UNDER
8 THIS PART.—For purposes of applying provisions of part
9 C under this part with respect to a prescription drug plan
10 and a PDP sponsor, unless otherwise provided in this part
11 such provisions shall be applied as if—
12 "(1) any reference to a Medicare Advantage or
13 other plan included a reference to a prescription
14 drug plan;
15 "(2) any reference to a provider-sponsored or-
16 ganization included a reference to a PDP sponsor;
17 "(3) any reference to a contract under section
18 1857 included a reference to a contract under sec-
19 tion 1860D–4(b); and
20 "(4) any reference to part C included a ref-
21 erence to this part.
22 "(d) REPORT ON PHARMACY SERVICES PROVIDED TO
23 LONG-TERM CARE FACILITY PATIENTS.—
24 "(1) REVIEW.—Within 6 months after the date
25 of the enactment of this section, the Secretary shall

1 review the current standards of practice for phar-
2 macy services provided to patients in nursing facili-
3 ties and other long-term care facilities.
4 "(2) EVALUATIONS AND RECOMMENDATIONS.—
5 Specifically in the review under paragraph (1), the
6 Secretary shall—
7 "(A) assess the current standards of prac-
8 tice, clinical services, and other service require-
9 ments generally utilized for pharmacy services
10 in the long-term care setting;
11 "(B) evaluate the impact of those stand-
12 ards with respect to patient safety, reduction of
13 medication errors and quality of care; and
14 "(C) recommend (in the Secretary's report
15 under paragraph (3)) necessary actions and ap-
16 propriate reimbursement to ensure the provision
17 of prescription drugs to medicare beneficiaries
18 residing in nursing facilities and other long-
19 term care facilities in a manner consistent with
20 existing patient safety and quality of care
21 standards under applicable State and Federal
22 laws.
23 "(3) REPORT.—The Secretary shall submit a
24 report to the Congress on the Secretary's findings
25 and recommendations under this subsection, includ-

1 ing a detailed description of the Secretary's plans to
2 implement this part in a manner consistent with ap-
3 plicable State and Federal laws designed to protect
4 the safety and quality of care of patients of nursing
5 facilities and other long-term care facilities.''.
6 (b) ADDITIONAL CONFORMING CHANGES.—
7 (1) CONFORMING REFERENCES TO PREVIOUS
8 PART D.—Any reference in law (in effect before the
9 date of the enactment of this Act) to part D of title
10 XVIII of the Social Security Act is deemed a ref-
11 erence to part F of such title (as in effect after such
12 date).
13 (2) CONFORMING AMENDMENT PERMITTING
14 WAIVER OF COST-SHARING.—Section 1128B(b)(3)
15 (42 U.S.C. 1320a–7b(b)(3)) is amended—
16 (A) by striking ''and'' at the end of sub-
17 paragraph (E);
18 (B) by striking the period at the end of
19 subparagraph (F) and inserting ''; and''; and
20 (C) by adding at the end the following new
21 subparagraph:
22 ''(G) the waiver or reduction of any cost-shar-
23 ing imposed under part D of title XVIII.''.
24 (3) SUBMISSION OF LEGISLATIVE PROPOSAL.—
25 Not later than 6 months after the date of the enact-

1 ment of this Act, the Secretary of Health and
2 Human Services shall submit to the appropriate
3 committees of Congress a legislative proposal pro-
4 viding for such technical and conforming amend-
5 ments in the law as are required by the provisions
6 of this subtitle.

7 (c) STUDY ON TRANSITIONING PART B PRESCRIP-
8 TION DRUG COVERAGE.—Not later than January 1, 2005,
9 the Medicare Benefits Administrator shall submit a report
10 to Congress that makes recommendations regarding meth-
11 ods for providing benefits under part D of title XVIII of
12 the Social Security Act for outpatient prescription drugs
13 for which benefits are provided under part B of such title.

14 **SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION DRUG**
15 **COVERAGE UNDER MEDICARE ADVANTAGE**
16 **AND ENHANCED FEE-FOR-SERVICE (EFFS)**
17 **PROGRAM.**

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

21 "(j) AVAILABILITY OF PRESCRIPTION DRUG BENE-
22 FITS AND SUBSIDIES.—

23 "(1) OFFERING OF QUALIFIED PRESCRIPTION
24 DRUG COVERAGE.—A Medicare Advantage organiza-
25 tion on and after January 1, 2006—

1 "(A) may not offer a Medicare Advantage
2 plan described in section 1851(a)(2)(A) in an
3 area unless either that plan (or another Medi-
4 care Advantage plan offered by the organization
5 in that area) includes qualified prescription
6 drug coverage; and
7 "(B) may not offer the prescription drug
8 coverage (other than that required under parts
9 A and B) to an enrollee under a Medicare Ad-
10 vantage plan, unless such drug coverage is at
11 least qualified prescription drug coverage and
12 unless the requirements of this subsection with
13 respect to such coverage are met.
14 "(2) REQUIREMENT FOR ELECTION OF PART D
15 COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION
16 DRUG COVERAGE.—For purposes of this part, an in-
17 dividual who has not elected qualified prescription
18 drug coverage under section 1860D–1(b) shall be
19 treated as being ineligible to enroll in a Medicare
20 Advantage plan under this part that offers such cov-
21 erage.
22 "(3) COMPLIANCE WITH CERTAIN ADDITIONAL
23 BENEFICIARY PROTECTIONS FOR PRESCRIPTION
24 DRUG COVERAGE.—With respect to the offering of
25 qualified prescription drug coverage by a Medicare

1 Advantage organization under this part on and after
2 January 1, 2006, the organization and plan shall
3 meet the requirements of subsections (a) through (d)
4 of section 1860D–3 in the same manner as they
5 apply to a PDP sponsor and a prescription drug
6 plan under part D and shall submit to the Adminis-
7 trator the information described in section 1860D–
8 6(a)(2). The Administrator shall waive such require-
9 ments to the extent the Administrator determines
10 that such requirements duplicate requirements oth-
11 erwise applicable to the organization or plan under
12 this part.

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

19 ''(5) AVAILABILITY OF DIRECT AND REINSUR-
20 ANCE SUBSIDIES TO REDUCE BIDS AND PRE-
21 MIUMS.—Medicare Advantage organizations are pro-
22 vided direct and reinsurance subsidy payments for
23 providing qualified prescription drug coverage under
24 this part under section 1860D–8.

1 "(6) CONSOLIDATION OF DRUG AND NON-DRUG
2 PREMIUMS.—In the case of a Medicare Advantage
3 plan that includes qualified prescription drug cov-
4 erage, with respect to an enrollee in such plan there
5 shall be a single premium for both drug and non-
6 drug coverage provided under the plan.
7 "(7) TRANSITION IN INITIAL ENROLLMENT PE-
8 RIOD.—Notwithstanding any other provision of this
9 part, the annual, coordinated election period under
10 subsection (e)(3)(B) for 2006 shall be the 6-month
11 period beginning with November 2005.
12 "(8) QUALIFIED PRESCRIPTION DRUG COV-
13 ERAGE; STANDARD COVERAGE.—For purposes of
14 this part, the terms 'qualified prescription drug cov-
15 erage' and 'standard coverage' have the meanings
16 given such terms in section 1860D–2.
17 "(9) SPECIAL RULES FOR PRIVATE FEE-FOR-
18 SERVICE PLANS.— With respect to a Medicare Ad-
19 vantage plan described in section 1851(a)(2)(C) that
20 offers qualified prescription drug coverage—
21 "(A) REQUIREMENTS REGARDING NEGO-
22 TIATED PRICES.—Subsections (a)(1) and (d)(1)
23 of section 1860D–2 shall not be construed to
24 require the plan to negotiate prices or discounts
25 but shall apply to the extent the plan does so.

1 "(B) MODIFICATION OF PHARMACY PAR-
2 TICIPATION REQUIREMENT.—If the plan pro-
3 vides access, without charging additional copay-
4 ments, to all pharmacies without regard to
5 whether they are participating pharmacies in a
6 network, section 1860D-3(c)(1)(A)(iii) shall not
7 apply to the plan.
8 "(C) DRUG UTILIZATION MANAGEMENT
9 PROGRAM NOT REQUIRED.—The requirements
10 of section 1860D-3(d)(1)(A) shall not apply to
11 the plan.
12 "(D) NON-PARTICIPATING PHARMACY DIS-
13 CLOSURE EXCEPTION.—If the plan provides
14 coverage for drugs purchased from all phar-
15 macies, without entering into contracts or
16 agreements with pharmacies to provide drugs to
17 enrollees covered by the plan, section 1860D-
18 3(d)(5) shall not apply to the plan.".
19 (b) APPLICATION TO EFFS PLANS.—Subsection (d)
20 of section 1860E–2, as added by section 201(a), is amend-
21 ed to read as follows:
22 "(d) AVAILABILITY OF PRESCRIPTION DRUG BENE-
23 FITS AND SUBSIDIES.—
24 "(1) OFFERING OF QUALIFIED PRESCRIPTION
25 DRUG COVERAGE.—An EFFS organization—

1 "(A) may not offer an EFFS plan in an
2 area unless either that plan (or another EFFS
3 plan offered by the organization in that area)
4 includes qualified prescription drug coverage;
5 and
6 "(B) may not offer the prescription drug
7 coverage (other than that required under parts
8 A and B) to an enrollee under an EFFS plan,
9 unless such drug coverage is at least qualified
10 prescription drug coverage and unless the re-
11 quirements of this subsection with respect to
12 such coverage are met.
13 "(2) REQUIREMENT FOR ELECTION OF PART D
14 COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION
15 DRUG COVERAGE.—For purposes of this part, an in-
16 dividual who has not elected qualified prescription
17 drug coverage under section 1860D–1(b) shall be
18 treated as being ineligible to enroll in an EFFS plan
19 under this part that offers such coverage.
20 "(3) COMPLIANCE WITH CERTAIN ADDITIONAL
21 BENEFICIARY PROTECTIONS FOR PRESCRIPTION
22 DRUG COVERAGE.—With respect to the offering of
23 qualified prescription drug coverage by an EFFS or-
24 ganization under this part, the organization and
25 plan shall meet the requirements of subsections (a)

1 through (d) of section 1860D–3 in the same manner
2 as they apply to a PDP sponsor and a prescription
3 drug plan under part D and shall submit to the Ad-
4 ministrator the information described in section
5 1860D–6(a)(2). The Administrator shall waive such
6 requirements to the extent the Administrator deter-
7 mines that such requirements duplicate requirements
8 otherwise applicable to the organization or plan
9 under this part.

10 "(4) AVAILABILITY OF PREMIUM AND COST-
11 SHARING SUBSIDIES.—In the case of low-income in-
12 dividuals who are enrolled in an EFFS plan that
13 provides qualified prescription drug coverage, pre-
14 mium and cost-sharing subsidies are provided for
15 such coverage under section 1860D–7.

16 "(5) AVAILABILITY OF DIRECT AND REINSUR-
17 ANCE SUBSIDIES TO REDUCE BIDS AND PRE-
18 MIUMS.—EFFS organizations are provided direct
19 and reinsurance subsidy payments for providing
20 qualified prescription drug coverage under this part
21 under section 1860D–8.

22 "(6) CONSOLIDATION OF DRUG AND NON-DRUG
23 PREMIUMS.—In the case of an EFFS plan that in-
24 cludes qualified prescription drug coverage, with re-
25 spect to an enrollee in such plan there shall be a sin-

gle premium for both drug and non-drug coverage provided under the plan.

"(7) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.".

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

(1) in subsection (a)(1)—

(A) by inserting "(other than qualified prescription drug benefits)" after "benefits";

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

(C) by adding after and below subparagraph (B) the following:

"and may elect qualified prescription drug coverage in accordance with section 1860D–1."; and

(2) in subsection (g)(1), by inserting "and section 1860D–1(c)(2)(B)" after "in this subsection".

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

1 **SEC. 103. MEDICAID AMENDMENTS.**

2 (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-IN-
3 COME SUBSIDIES.—

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

6 (A) by striking ''and'' at the end of para-
7 graph (64);

8 (B) by striking the period at the end of
9 paragraph (65) and inserting ''; and''; and

10 (C) by inserting after paragraph (65) the
11 following new paragraph:

12 ''(66) provide for making eligibility determina-
13 tions under section 1935(a).''.

14 (2) NEW SECTION.—Title XIX is further
15 amended—

16 (A) by redesignating section 1935 as sec-
17 tion 1936; and

18 (B) by inserting after section 1934 the fol-
19 lowing new section:

20 ''SPECIAL PROVISIONS RELATING TO MEDICARE
21 PRESCRIPTION DRUG BENEFIT

22 ''SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGI-
23 BILITY DETERMINATIONS FOR LOW-INCOME SUB-
24 SIDIES.—As a condition of its State plan under this title
25 under section 1902(a)(66) and receipt of any Federal fi-
26 nancial assistance under section 1903(a), a State shall—

1 "(1) make determinations of eligibility for pre-
2 mium and cost-sharing subsidies under (and in ac-
3 cordance with) section 1860D–7;
4 "(2) inform the Administrator of the Medicare
5 Benefits Administration of such determinations in
6 cases in which such eligibility is established; and
7 "(3) otherwise provide such Administrator with
8 such information as may be required to carry out
9 part D of title XVIII (including section 1860D–7).
10 "(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE
11 COSTS.—
12 "(1) IN GENERAL.—The amounts expended by
13 a State in carrying out subsection (a) are, subject to
14 paragraph (2), expenditures reimbursable under the
15 appropriate paragraph of section 1903(a); except
16 that, notwithstanding any other provision of such
17 section, the applicable Federal matching rates with
18 respect to such expenditures under such section shall
19 be increased as follows (but in no case shall the rate
20 as so increased exceed 100 percent):
21 "(A) For expenditures attributable to costs
22 incurred during 2005, the otherwise applicable
23 Federal matching rate shall be increased by 6-
24 ⅔ percent of the percentage otherwise payable
25 (but for this subsection) by the State.

1 "(B)(i) For expenditures attributable to
2 costs incurred during 2006 and each subse-
3 quent year through 2018, the otherwise applica-
4 ble Federal matching rate shall be increased by
5 the applicable percent (as defined in clause (ii))
6 of the percentage otherwise payable (but for
7 this subsection) by the State.
8 "(ii) For purposes of clause (i), the 'appli-
9 cable percent' for—
10 "(I) 2006 is 13-⅓ percent; or
11 "(II) a subsequent year is the applica-
12 ble percent under this clause for the pre-
13 vious year increased by 6-⅔ percentage
14 points.
15 "(C) For expenditures attributable to costs
16 incurred after 2018, the otherwise applicable
17 Federal matching rate shall be increased to 100
18 percent.
19 "(2) COORDINATION.—The State shall provide
20 the Administrator with such information as may be
21 necessary to properly allocate administrative expend-
22 itures described in paragraph (1) that may otherwise
23 be made for similar eligibility determinations.".

1 (b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID
2 RESPONSIBILITY FOR PREMIUM AND COST-SHARING SUB-
3 SIDIES FOR DUALLY ELIGIBLE INDIVIDUALS.—
4 (1) IN GENERAL.—Section 1903(a)(1) (42
5 U.S.C. 1396b(a)(1)) is amended by inserting before
6 the semicolon the following: ", reduced by the
7 amount computed under section 1935(c)(1) for the
8 State and the quarter".
9 (2) AMOUNT DESCRIBED.—Section 1935, as in-
10 serted by subsection (a)(2), is amended by adding at
11 the end the following new subsection:
12 "(c) FEDERAL ASSUMPTION OF MEDICAID PRE-
13 SCRIPTION DRUG COSTS FOR DUALLY-ELIGIBLE BENE-
14 FICIARIES.—
15 "(1) IN GENERAL.—For purposes of section
16 1903(a)(1), for a State that is one of the 50 States
17 or the District of Columbia for a calendar quarter
18 in a year (beginning with 2005) the amount com-
19 puted under this subsection is equal to the product
20 of the following:
21 "(A) MEDICARE SUBSIDIES.—The total
22 amount of payments made in the quarter under
23 section 1860D–7 (relating to premium and
24 cost-sharing prescription drug subsidies for low-
25 income medicare beneficiaries) that are attrib-

1 utable to individuals who are residents of the
2 State and are entitled to benefits with respect
3 to prescribed drugs under the State plan under
4 this title (including such a plan operating under
5 a waiver under section 1115).
6 "(B) STATE MATCHING RATE.—A propor-
7 tion computed by subtracting from 100 percent
8 the Federal medical assistance percentage (as
9 defined in section 1905(b)) applicable to the
10 State and the quarter.
11 "(C) PHASE-OUT PROPORTION.—The
12 phase-out proportion (as defined in paragraph
13 (2)) for the quarter.
14 "(2) PHASE-OUT PROPORTION.—For purposes
15 of paragraph (1)(C), the 'phase-out proportion' for
16 a calendar quarter in—
17 "(A) 2006 is 93-⅓ percent;
18 "(B) a subsequent year before 2021, is the
19 phase-out proportion for calendar quarters in
20 the previous year decreased by 6-⅔ percentage
21 points; or
22 "(C) a year after 2020 is 0 percent.".
23 (c) MEDICAID PROVIDING WRAP-AROUND BENE-
24 FITS.—Section 1935, as so inserted and amended, is fur-

1 ther amended by adding at the end the following new sub-
2 section:
3 "(d) ADDITIONAL PROVISIONS.—
4 "(1) MEDICAID AS SECONDARY PAYOR.—In the
5 case of an individual who is entitled to qualified pre-
6 scription drug coverage under a prescription drug
7 plan under part D of title XVIII (or under a MA-
8 EFFS Rx plan under part C or E of such title) and
9 medical assistance for prescribed drugs under this
10 title, medical assistance shall continue to be provided
11 under this title (other than for copayment amounts
12 specified in section 1860D–7(a)(1)(B), notwith-
13 standing section 1916) for prescribed drugs to the
14 extent payment is not made under the prescription
15 drug plan or MA-EFFS Rx plan selected by the in-
16 dividual.
17 "(2) CONDITION.—A State may require, as a
18 condition for the receipt of medical assistance under
19 this title with respect to prescription drug benefits
20 for an individual eligible to obtain qualified prescrip-
21 tion drug coverage described in paragraph (1), that
22 the individual elect qualified prescription drug cov-
23 erage under section 1860D–1.".
24 (d) TREATMENT OF TERRITORIES.—

1 (1) IN GENERAL.—Section 1935, as so inserted
2 and amended, is further amended—
3 (A) in subsection (a) in the matter pre-
4 ceding paragraph (1), by inserting ''subject to
5 subsection (e)'' after ''section 1903(a)'';
6 (B) in subsection (c)(1), by inserting ''sub-
7 ject to subsection (e)'' after ''1903(a)(1)''; and
8 (C) by adding at the end the following new
9 subsection:
10 ''(e) TREATMENT OF TERRITORIES.—
11 ''(1) IN GENERAL.—In the case of a State,
12 other than the 50 States and the District of
13 Columbia—
14 ''(A) the previous provisions of this section
15 shall not apply to residents of such State; and
16 ''(B) if the State establishes a plan de-
17 scribed in paragraph (2) (for providing medical
18 assistance with respect to the provision of pre-
19 scription drugs to medicare beneficiaries), the
20 amount otherwise determined under section
21 1108(f) (as increased under section 1108(g))
22 for the State shall be increased by the amount
23 specified in paragraph (3).
24 ''(2) PLAN.—The plan described in this para-
25 graph is a plan that—

1 "(A) provides medical assistance with re-
2 spect to the provision of covered outpatient
3 drugs (as defined in section 1860D–2(f)) to
4 low-income medicare beneficiaries; and
5 "(B) assures that additional amounts re-
6 ceived by the State that are attributable to the
7 operation of this subsection are used only for
8 such assistance.
9 "(3) INCREASED AMOUNT.—
10 "(A) IN GENERAL.—The amount specified
11 in this paragraph for a State for a year is equal
12 to the product of—
13 "(i) the aggregate amount specified in
14 subparagraph (B); and
15 "(ii) the amount specified in section
16 1108(g)(1) for that State, divided by the
17 sum of the amounts specified in such sec-
18 tion for all such States.
19 "(B) AGGREGATE AMOUNT.—The aggre-
20 gate amount specified in this subparagraph
21 for—
22 "(i) 2006, is equal to $25,000,000; or
23 "(ii) a subsequent year, is equal to the
24 aggregate amount specified in this sub-
25 paragraph for the previous year increased

by annual percentage increase specified in section 1860D–2(b)(5) for the year involved.

"(4) REPORT.—The Administrator shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Administrator deems appropriate.".

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

(e) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(1) by striking "and" at the end of subclause (III);

(2) by striking the period at the end of subclause (IV) and inserting "; and"; and

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

"(V) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by a MA-EFFS Rx plan under part C or

E of such title with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.''.

SEC. 104. MEDIGAP TRANSITION.

(a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

''(v) COVERAGE OF PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, except as provided in paragraph (3) no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under this section on or after January 1, 2006, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs. Nothing in this subsection shall be construed as preventing the policy holder of a medicare supplemental policy issued before Janu-

1 ary 1, 2006, from continuing to receive benefits
2 under such policy on and after such date.
3 ''(2) ISSUANCE OF SUBSTITUTE POLICIES FOR
4 BENEFICIARIES ENROLLED WITH A PLAN UNDER
5 PART D.—
6 ''(A) IN GENERAL.—The issuer of a medi-
7 care supplemental policy—
8 ''(i) may not deny or condition the
9 issuance or effectiveness of a medicare
10 supplemental policy that has a benefit
11 package classified as 'A', 'B', 'C', 'D', 'E',
12 'F', or 'G' (under the standards estab-
13 lished under subsection (p)(2)) and that is
14 offered and is available for issuance to new
15 enrollees by such issuer;
16 ''(ii) may not discriminate in the pric-
17 ing of such policy, because of health sta-
18 tus, claims experience, receipt of health
19 care, or medical condition; and
20 ''(iii) may not impose an exclusion of
21 benefits based on a pre-existing condition
22 under such policy,
23 in the case of an individual described in sub-
24 paragraph (B) who seeks to enroll under the
25 policy not later than 63 days after the date of

1 the termination of enrollment described in such
2 paragraph and who submits evidence of the
3 date of termination or disenrollment along with
4 the application for such medicare supplemental
5 policy.

6 ''(B) INDIVIDUAL COVERED.—An indi-
7 vidual described in this subparagraph is an in-
8 dividual who—

9 ''(i) enrolls in a prescription drug plan
10 under part D; and

11 ''(ii) at the time of such enrollment
12 was enrolled and terminates enrollment in
13 a medicare supplemental policy which has
14 a benefit package classified as 'H', 'I', or
15 'J' under the standards referred to in sub-
16 paragraph (A)(i) or terminates enrollment
17 in a policy to which such standards do not
18 apply but which provides benefits for pre-
19 scription drugs.

20 ''(C) ENFORCEMENT.—The provisions of
21 paragraph (4) of subsection (s) shall apply with
22 respect to the requirements of this paragraph in
23 the same manner as they apply to the require-
24 ments of such subsection.

1 "(3) NEW STANDARDS.—In applying subsection
2 (p)(1)(E) (including permitting the NAIC to revise
3 its model regulations in response to changes in law)
4 with respect to the change in benefits resulting from
5 title I of the Medicare Prescription Drug and Mod-
6 ernization Act of 2003, with respect to policies
7 issued to individuals who are enrolled in a plan
8 under part D, the changes in standards shall only
9 provide for substituting (for the benefit packages de-
10 scribed in paragraph (2)(B)(ii) that included cov-
11 erage for prescription drugs) two benefit packages
12 that may provide for coverage of cost-sharing (other
13 than the prescription drug deductible) with respect
14 to qualified prescription drug coverage under such
15 part. The two benefit packages shall be consistent
16 with the following:
17 "(A) FIRST NEW POLICY.—The policy de-
18 scribed in this subparagraph has the following
19 benefits, notwithstanding any other provision of
20 this section relating to a core benefit package:
21 "(i) Coverage of 50 percent of the
22 cost-sharing otherwise applicable under
23 parts A and B, except coverage of 100 per-
24 cent of any cost-sharing otherwise applica-
25 ble for preventive benefits.

1 "(ii) No coverage of the part B de-
2 ductible.
3 "(iii) Coverage for all hospital coin-
4 surance for long stays (as in the current
5 core benefit package).
6 "(iv) A limitation on annual out-of-
7 pocket expenditures under parts A and B
8 to $4,000 in 2005 (or, in a subsequent
9 year, to such limitation for the previous
10 year increased by an appropriate inflation
11 adjustment specified by the Secretary).
12 "(B) SECOND NEW POLICY.—The policy
13 described in this subparagraph has the same
14 benefits as the policy described in subparagraph
15 (A), except as follows:
16 "(i) Substitute '75 percent' for '50
17 percent' in clause (i) of such subpara-
18 graph.
19 "(ii) Substitute '$2,000' for '$4,000'
20 in clause (iv) of such subparagraph.
21 "(4) CONSTRUCTION.—Any provision in this
22 section or in a medicare supplemental policy relating
23 to guaranteed renewability of coverage shall be
24 deemed to have been met through the offering of
25 other coverage under this subsection.".

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

9 **SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT**
10 **CARD AND ASSISTANCE PROGRAM.**

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

13 ''MEDICARE PRESCRIPTION DRUG DISCOUNT CARD
14 ENDORSEMENT AND ASSISTANCE PROGRAM

15 ''SEC. 1807. (a) ESTABLISHMENT OF PROGRAM.—

16 ''(1) IN GENERAL.—The Secretary shall estab-
17 lish a program—

18 ''(A) to endorse prescription drug discount
19 card programs (each such program referred to
20 as an 'endorsed program') that meet the re-
21 quirements of this section in order to provide
22 access to prescription drug discounts through
23 eligible entities for medicare beneficiaries
24 throughout the United States; and

1 "(B) to provide for prescription drug ac-
2 counts and public contributions into such ac-
3 counts.
4 The Secretary shall make available to medicare
5 beneficiaries information regarding endorsed pro-
6 grams and accounts under this section.
7 "(2) LIMITED PERIOD OF OPERATION.—The
8 Secretary shall begin—
9 "(A) the card endorsement part of the pro-
10 gram under paragraph (1)(A) as soon as pos-
11 sible, but in no case later than 90 days after
12 the date of the enactment of this section; and
13 "(B) the prescription drug account part of
14 the program under paragraph (1)(B) as soon as
15 possible, but in no case later than September
16 2004.
17 "(3) TRANSITION.—The program under this
18 section shall continue through 2005 throughout the
19 United States. The Secretary shall provide for an
20 appropriate transition and termination of such pro-
21 gram on January 1, 2006.
22 "(4) VOLUNTARY NATURE OF PROGRAM.—
23 Nothing in this section shall be construed as requir-
24 ing an eligible beneficiary to enroll in the program
25 under this section.

1 "(b) ELIGIBLE BENEFICIARY; ELIGIBLE ENTITY;
2 PRESCRIPTION DRUG ACCOUNT.—For purposes of this
3 section:
4 "(1) ELIGIBLE BENEFICIARY.—The term 'eligi-
5 ble beneficiary' means an individual who is eligible
6 for benefits under part A or enrolled under part B
7 and who is not enrolled in a Medicare Advantage
8 plan that offers qualified prescription drug coverage.
9 "(2) ELIGIBLE ENTITY.—The term 'eligible en-
10 tity' means any entity that the Secretary determines
11 to be appropriate to provide the benefits under this
12 section, including—
13 "(A) pharmaceutical benefit management
14 companies;
15 "(B) wholesale and retail pharmacy deliv-
16 ery systems;
17 "(C) insurers;
18 "(D) Medicare Advantage organizations;
19 "(E) other entities; or
20 "(F) any combination of the entities de-
21 scribed in subparagraphs (A) through (E).
22 "(3) PRESCRIPTION DRUG ACCOUNT.—The
23 term 'prescription drug account' means, with respect
24 to an eligible beneficiary, an account established for
25 the benefit of that beneficiary under section 1807A.

1 "(c) ENROLLMENT IN ENDORSED PLAN.—
2 "(1) ESTABLISHMENT OF PROCESS.—
3 "(A) IN GENERAL.—The Secretary shall
4 establish a process through which an eligible
5 beneficiary may make an election to enroll
6 under this section with an endorsed program.
7 "(B) REQUIREMENT OF ENROLLMENT.—
8 An eligible beneficiary must enroll under this
9 section for a year in order to be eligible to re-
10 ceive the benefits under this section for that
11 year.
12 "(C) LIMITATION ON ENROLLMENT.—
13 "(i) IN GENERAL.—Except as pro-
14 vided under this subparagraph and under
15 such exceptional circumstances as the Sec-
16 retary may provide, an eligible individual
17 shall have the opportunity to enroll under
18 this section during an initial, general en-
19 rollment period as soon as possible after
20 the date of the enactment of this section
21 and annually thereafter. The Secretary
22 shall specify the form, manner, and timing
23 of such election but shall permit the exer-
24 cise of such election at the time the indi-
25 vidual is eligible to enroll. The annual open

1 enrollment periods shall be coordinated
2 with those provided under the Medicare
3 Advantage program under part C.
4 "(ii) REELECTION AFTER TERMI-
5 NATION OF ENROLLMENT IN A MEDICARE
6 ADVANTAGE PLAN.—In the case of an indi-
7 vidual who is enrolled under this section
8 and who subsequently enrolls in a Medi-
9 care Advantage plan that provides quali-
10 fied prescription drug coverage under part
11 C, the individual shall be given the oppor-
12 tunity to reenroll under this section at the
13 time the individual discontinues the enroll-
14 ment under such part.
15 "(iii) LATE ENROLLMENT.—The Sec-
16 retary shall permit individuals to elect to
17 enroll under this section at times other
18 than as permitted under the previous pro-
19 visions of this paragraph.
20 "(D) TERMINATION OF ENROLLMENT.—
21 An enrollee under this section shall be
22 disenrolled—
23 "(i) upon enrollment in a Medicare
24 Advantage plan under part C that provides
25 qualified prescription drug coverage;

"(ii) upon failure to pay the applicable enrollment fee under subsection (f);

"(iii) upon termination of coverage under part A or part B; or

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

Terminations of enrollment under this subparagraph shall be effective as specified by the Secretary in regulations.

"(2) ENROLLMENT PERIODS.—

"(A) IN GENERAL.—Except as provided under this paragraph, an eligible beneficiary may not enroll in the program under this part during any period after the beneficiary's initial enrollment period under part B (as determined under section 1837).

"(B) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES.—The Secretary shall establish a period, which shall begin on the date on which the Secretary first begins to accept elections for enrollment under this section and shall end not earlier than 3 months later, during which any eligible beneficiary may enroll under this section.

1 "(C) SPECIAL ENROLLMENT PERIOD IN
2 CASE OF TERMINATION OF COVERAGE UNDER A
3 GROUP HEALTH PLAN.—The Secretary shall
4 provide for a special enrollment period under
5 this section in the same manner as is provided
6 under section 1837(i) with respect to part B,
7 except that for purposes of this subparagraph
8 any reference to 'by reason of the individual's
9 (or the individual's spouse's) current employ-
10 ment status' shall be treated as being deleted.
11 "(3) PERIOD OF COVERAGE.—
12 "(A) IN GENERAL.—Except as provided in
13 subparagraph (B) and subject to subparagraph
14 (C), an eligible beneficiary's coverage under the
15 program under this section shall be effective for
16 the period provided under section 1838, as if
17 that section applied to the program under this
18 section.
19 "(B) ENROLLMENT DURING OPEN AND
20 SPECIAL ENROLLMENT.—Subject to subpara-
21 graph (C), an eligible beneficiary who enrolls
22 under the program under this section under
23 subparagraph (B) or (C) of paragraph (2) shall
24 be entitled to the benefits under this section be-

1 ginning on the first day of the month following
2 the month in which such enrollment occurs.
3 "(d) SELECTION OF AN ELIGIBLE ENTITY FOR AC-
4 CESS TO NEGOTIATED PRICES.—
5 "(1) PROCESS.—
6 "(A) IN GENERAL.—The Secretary shall
7 establish a process through which an eligible
8 beneficiary who is enrolled under this section
9 shall select any eligible entity, that has been
10 awarded a contract under this section and
11 serves the State in which the beneficiary re-
12 sides, to provide access to negotiated prices
13 under subsection (i).
14 "(B) RULES.—In establishing the process
15 under subparagraph (A), the Secretary shall
16 use rules similar to the rules for enrollment and
17 disenrollment with a Medicare Advantage plan
18 under section 1851 (including the special elec-
19 tion periods under subsection (e)(4) of such sec-
20 tion), including that—
21 "(i) an individual may not select more
22 than one eligible entity at any time; and
23 "(ii) an individual shall only be per-
24 mitted (except for unusual circumstances)

1 to change the selection of the entity once
2 a year.
3 In carrying out clause (ii), the Secretary may
4 consider a change in residential setting (such as
5 placement in a nursing facility) to be an un-
6 usual circumstance.
7 "(C) DEFAULT SELECTION.—In estab-
8 lishing such process, the Secretary shall provide
9 an equitable method for selecting an eligible en-
10 tity for individuals who enroll under this section
11 and fail to make such a selection.
12 "(2) COMPETITION.—Eligible entities with a
13 contract under this section shall compete for bene-
14 ficiaries on the basis of discounts, formularies, phar-
15 macy networks, and other services provided for
16 under the contract.
17 "(e) PROVIDING ENROLLMENT, SELECTION, AND
18 COVERAGE INFORMATION TO BENEFICIARIES.—
19 "(1) ACTIVITIES.—The Secretary shall provide
20 for activities under this section to broadly dissemi-
21 nate information to eligible beneficiaries (and pro-
22 spective eligible beneficiaries) regarding enrollment
23 under this section, the selection of eligible entities,
24 and the prescription drug coverage made available
25 by eligible entities with a contract under this section.

1 "(2) SPECIAL RULE FOR FIRST ENROLLMENT
2 UNDER THE PROGRAM.—To the extent practicable,
3 the activities described in paragraph (1) shall ensure
4 that eligible beneficiaries are provided with such in-
5 formation at least 60 days prior to the first enroll-
6 ment period described in subsection (c).
7 "(f) ENROLLMENT FEE.—
8 "(1) AMOUNT.—Except as provided in para-
9 graph (3), enrollment under the program under this
10 section is conditioned upon payment of an annual
11 enrollment fee of $30. Such fee for 2004 shall in-
12 clude any portion of 2003 in which the program is
13 implemented under this section.
14 "(2) COLLECTION OF ENROLLMENT FEE.—The
15 annual enrollment fee shall be collected and credited
16 to the Federal Supplementary Medical Insurance
17 Trust Fund in the same manner as the monthly pre-
18 mium determined under section 1839 is collected
19 and credited to such Trust Fund under section
20 1840, except that it shall be collected only 1 time
21 per year.
22 "(3) PAYMENT OF ENROLLMENT FEE BY STATE
23 FOR CERTAIN BENEFICIARIES.—
24 "(A) IN GENERAL.—The Secretary shall
25 establish an arrangement under which a State

may provide for payment of some or all of the enrollment fee for some or all low income enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State and shall not be collected under paragraph (2). In carrying out this paragraph, the Secretary may apply procedures similar to that applied under state agreements under section 1843.

"(B) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State described in subparagraph (A) shall not be treated as State expenditures for purposes of Federal matching payments under titles XIX and XXI insofar as such expenditures are for an enrollment fee under this subsection.

"(4) DISTRIBUTION OF PORTION OF ENROLLMENT FEE.—Of the enrollment fee collected by the Secretary under this subsection with respect to a beneficiary, ⅔ of that fee shall be made available to the eligible entity selected by the eligible beneficiary.

1 "(g) ISSUANCE OF CARD AND COORDINATION.—
2 Each eligible entity shall—
3 "(1) issue, in a uniform standard format
4 specified by the Secretary, to each enrolled ben-
5 eficiary a card and an enrollment number that
6 establishes proof of enrollment and that can be
7 used in a coordinated manner—
8 "(A) to identify the eligible entity selected
9 to provide access to negotiated prices under
10 subsection (i); and
11 "(B) to make deposits to and withdrawals
12 from a prescription drug account under section
13 1807A; and
14 "(2) provide for electronic methods to coordi-
15 nate with the accounts established under section
16 1807A.
17 "(h) ENROLLEE PROTECTIONS.—
18 "(1) GUARANTEED ISSUE AND NONDISCRIMINA-
19 TION.—
20 "(A) GUARANTEED ISSUE.—
21 "(i) IN GENERAL.—An eligible bene-
22 ficiary who is eligible to select an eligible
23 entity under subsection (b) for prescription
24 drug coverage under this section at a time
25 during which selections are accepted under

1 this section with respect to the coverage
2 shall not be denied selection based on any
3 health status-related factor (described in
4 section 2702(a)(1) of the Public Health
5 Service Act) or any other factor and may
6 not be charged any selection or other fee
7 as a condition of such acceptance.
8 ''(ii) MEDICARE ADVANTAGE LIMITA-
9 TIONS PERMITTED.—The provisions of
10 paragraphs (2) and (3) (other than sub-
11 paragraph (C)(i), relating to default enroll-
12 ment) of section 1851(g) (relating to pri-
13 ority and limitation on termination of elec-
14 tion) shall apply to selection of eligible en-
15 tities under this paragraph.
16 ''(B) NONDISCRIMINATION.—An eligible
17 entity offering prescription drug coverage under
18 this section shall not establish a service area in
19 a manner that would discriminate based on
20 health or economic status of potential enrollees.
21 ''(C) COVERAGE OF ALL PORTIONS OF A
22 STATE.—If an eligible entity with a contract
23 under this section serves any part of a State it
24 shall serve the entire State.
25 ''(2) DISSEMINATION OF INFORMATION.—

1 "(A) GENERAL INFORMATION.—An eligible
2 entity with a contract under this section shall
3 disclose, in a clear, accurate, and standardized
4 form to each eligible beneficiary who has se-
5 lected the entity to provide access to negotiated
6 prices under this section at the time of selection
7 and at least annually thereafter, the informa-
8 tion described in section 1852(c)(1) relating to
9 such prescription drug coverage. Such informa-
10 tion includes the following (in a manner de-
11 signed to permit and promote competition
12 among eligible entities):
13 "(i) Summary information regarding
14 negotiated prices (including discounts) for
15 covered outpatient drugs.
16 "(ii) Access to such prices through
17 pharmacy networks.
18 "(iii) How any formulary used by the
19 eligible entity functions.
20 "(B) DISCLOSURE UPON REQUEST OF
21 GENERAL COVERAGE, UTILIZATION, AND GRIEV-
22 ANCE INFORMATION.—Upon request of an eligi-
23 ble beneficiary, the eligible entity shall provide
24 the information described in section 1852(c)(2)

1 (other than subparagraph (D)) to such bene-
2 ficiary.
3 "(C) RESPONSE TO BENEFICIARY QUES-
4 TIONS.—Each eligible entity offering prescrip-
5 tion drug coverage under this section shall have
6 a mechanism (including a toll-free telephone
7 number) for providing upon request specific in-
8 formation (such as negotiated prices, including
9 discounts) to individuals who have selected the
10 entity. The entity shall make available, through
11 an Internet website and in writing upon re-
12 quest, information on specific changes in its
13 formulary.
14 "(D) COORDINATION WITH PRESCRIPTION
15 DRUG ACCOUNT BENEFITS.—Each such eligible
16 entity shall provide for coordination of such in-
17 formation as the Secretary may specify to carry
18 out section 1807A.
19 "(3) ACCESS TO COVERED BENEFITS.—
20 "(A) ENSURING PHARMACY ACCESS.—The
21 provisions of subsection (c)(1) of section
22 1860D–3 (other than payment provisions under
23 section 1860D–8 with respect to sponsors under
24 such subsection) shall apply to an eligible entity

1 under this section in the same manner as they
2 apply to a PDP sponsor under such section.
3 "(B) ACCESS TO NEGOTIATED PRICES FOR
4 PRESCRIPTION DRUGS.—For requirements re-
5 lating to the access of an eligible beneficiary to
6 negotiated prices (including applicable dis-
7 counts), see subsection (i).
8 "(C) REQUIREMENTS ON DEVELOPMENT
9 AND APPLICATION OF FORMULARIES.—Insofar
10 as an eligible entity with a contract under this
11 part uses a formulary, the entity shall comply
12 with the requirements of section 1860D–
13 3(c)(3), insofar as the Secretary determines
14 that such requirements can be implemented on
15 a timely basis.
16 "(4) COST AND UTILIZATION MANAGEMENT;
17 QUALITY ASSURANCE; MEDICATION THERAPY MAN-
18 AGEMENT PROGRAM.—
19 "(A) IN GENERAL.—For purposes of pro-
20 viding access to negotiated benefits under sub-
21 section (i), the eligible entity shall have in place
22 the programs and measure described in section
23 1860D–3(d), including an effective cost and
24 drug utilization management program, quality
25 assurance measures and systems, and a pro-

1 gram to control fraud, abuse, and waste, inso-
2 far as the Secretary determines that such provi-
3 sions can be implemented on a timely basis.
4 "(B) TREATMENT OF ACCREDITATION.—
5 Section 1852(e)(4) (relating to treatment of ac-
6 creditation) shall apply to the requirements for
7 an endorsed program under this section with
8 respect to the following requirements, in the
9 same manner as they apply to Medicare Advan-
10 tage plans under part C with respect to the re-
11 quirements described in a clause of section
12 1852(e)(4)(B):
13 "(i) Paragraph (3)(A) (relating to ac-
14 cess to covered benefits).
15 "(ii) Paragraph (7) (relating to con-
16 fidentiality and accuracy of enrollee
17 records).
18 "(5) GRIEVANCE MECHANISM.—Each eligible
19 entity shall provide meaningful procedures for hear-
20 ing and resolving grievances between the organiza-
21 tion consistent with the requirements of section
22 1860D–3(e) insofar as they relate to PDP sponsors
23 of prescription drug plans.
24 "(6) BENEFICIARY SERVICES.—An eligible enti-
25 ty shall provide for its enrollees pharmaceutical sup-

1 port services, such as education and counseling, and
2 services to prevent adverse drug interactions.
3 "(7) COVERAGE DETERMINATIONS AND RECON-
4 SIDERATIONS.—An eligible entity shall meet the re-
5 quirements of paragraphs (1) through (3) of section
6 1852(g) with respect to covered benefits under the
7 prescription drug coverage it offers under this sec-
8 tion in the same manner as such requirements apply
9 to a Medicare Advantage organization with respect
10 to benefits it offers under a Medicare Advantage
11 plan under part C.
12 "(8) CONFIDENTIALITY AND ACCURACY OF EN-
13 ROLLEE RECORDS.—An eligible entity shall meet the
14 requirements of section 1852(h) with respect to en-
15 rollees under this section in the same manner as
16 such requirements apply to a Medicare Advantage
17 organization with respect to enrollees under part C.
18 The eligible entity shall implement policies and pro-
19 cedures to safeguard the use and disclosure of en-
20 rollees' individually identifiable health information in
21 a manner consistent with the Federal regulations
22 (concerning the privacy of individually identifiable
23 health information) promulgated under section
24 264(c) of the Health Insurance Portability and Ac-
25 countability Act of 1996. The eligible entity shall be

1 treated as a covered entity for purposes of the provi-
2 sions of subpart E of part 164 of title 45, Code of
3 Federal Regulations, adopted pursuant to the au-
4 thority of the Secretary under section 264(c) of the
5 Health Insurance Portability and Accountability Act
6 of 1996 (42 U.S. C. 1320d-2 note).

7 "(9) PERIODIC REPORTS AND OVERSIGHT.—
8 The eligible entity shall submit to the Secretary peri-
9 odic reports on performance, utilization, finances,
10 and such other matters as the Secretary may speci-
11 fy. The Secretary shall provide appropriate oversight
12 to ensure compliance of eligible entities with the re-
13 quirements of this subsection, including verification
14 of the discounts and services provided.

15 "(10) ADDITIONAL BENEFICIARY PROTEC-
16 TIONS.—The eligible entity meets such additional re-
17 quirements as the Secretary identifies to protect and
18 promote the interest of enrollees, including require-
19 ments that ensure that enrollees are not charged
20 more than the lower of the negotiated retail price or
21 the usual and customary price.

22 "(i) BENEFITS UNDER THE PROGRAM THROUGH
23 SAVINGS TO ENROLLEES THROUGH NEGOTIATED
24 PRICES.—

1 "(1) IN GENERAL.—Subject to paragraph (2),
2 each eligible entity with a contract under this section
3 shall provide each eligible beneficiary enrolled with
4 the entity with access to negotiated prices (including
5 applicable discounts). For purposes of this para-
6 graph, the term 'prescription drugs' is not limited to
7 covered outpatient drugs, but does not include any
8 over-the-counter drug that is not a covered out-
9 patient drug. The prices negotiated by an eligible en-
10 tity under this paragraph shall (notwithstanding any
11 other provision of law) not be taken into account for
12 the purposes of establishing the best price under sec-
13 tion 1927(c)(1)(C).
14 "(2) FORMULARY RESTRICTIONS.—Insofar as
15 an eligible entity with a contract under this part
16 uses a formulary, the negotiated prices (including
17 applicable discounts) for prescription drugs shall
18 only be available for drugs included in such for-
19 mulary.
20 "(3) PROHIBITION ON APPLICATION ONLY TO
21 MAIL ORDER.—The negotiated prices under this sub-
22 section shall apply to prescription drugs that are
23 available other than solely through mail order.
24 "(4) PROHIBITION ON CHARGES FOR REQUIRED
25 SERVICES.—An eligible entity (and any pharmacy

1 contracting with such entity for the provision of a
2 discount under this section) may not charge a bene-
3 ficiary any amount for any services required to be
4 provided by the entity under this section.

5 "(5) DISCLOSURE.—The eligible entity offering
6 the endorsed program shall disclose to the Secretary
7 (in a manner specified by the Secretary) the extent
8 to which discounts or rebates or other remuneration
9 or price concessions made available to the entity by
10 a manufacturer are passed through to enrollees
11 through pharmacies and other dispensers or other-
12 wise. The provisions of section 1927(b)(3)(D) shall
13 apply to information disclosed to the Secretary
14 under this paragraph in the same manner as such
15 provisions apply to information disclosed under such
16 section.

17 "(6) PUBLIC DISCLOSURE OF PHARMACEUTICAL
18 PRICES FOR EQUIVALENT DRUGS.—Each eligible en-
19 tity shall provide that each pharmacy or other dis-
20 penser that arranges for the dispensing of a covered
21 outpatient drug in connection with its endorsed pro-
22 gram shall inform the enrollee in that program at
23 the time of purchase of the drug of any differential
24 between the price of the prescribed drug to the en-
25 rollee and the price of the lowest cost available ge-

1 neric drug covered under the program that is thera-
2 peutically equivalent and bioequivalent.
3 "(j) CONTRIBUTION INTO PRESCRIPTION DRUG AC-
4 COUNT.—
5 "(1) IN GENERAL.—In the case of an individual
6 enrolled under this section, the Secretary shall—
7 "(A) establish a prescription drug account
8 for the individual under section 1807A; and
9 "(B) subject to paragraph (5), deposit into
10 such account on a monthly or other periodic
11 basis an amount that, on an annual basis, is
12 equivalent to the annual Federal contribution
13 amount specified in paragraph (2) for the en-
14 rollee involved.
15 "(2) ANNUAL FEDERAL CONTRIBUTION
16 AMOUNT.—Subject to paragraph (3), in the case of
17 an accountholder whose income is—
18 "(A) not more than 135 percent of the
19 poverty line, the annual Federal contribution
20 amount for a year is $800;
21 "(B) more than 135 percent, but not more
22 than 150 percent, of the poverty line, the an-
23 nual Federal contribution amount for a year is
24 $500; or

1 "(C) more than 150 percent of the poverty
2 line, the annual Federal contribution amount
3 for a year is $100.
4 "(3) INCOME ELIGIBILITY DETERMINATIONS.—
5 The determination of whether an individual residing
6 in a State is a eligible for a contribution under para-
7 graph (1) shall be determined under the State med-
8 icaid plan for the State under section 1935(a) or by
9 the Social Security Administration. In the case of a
10 State that does not operate such a medicaid plan
11 (either under title XIX or under a statewide waiver
12 granted under section 1115), such determination
13 shall be made under arrangements made by the Sec-
14 retary. There are authorized to be appropriated to
15 the Social Security Administration such sums as
16 may be necessary for the determination of eligibility
17 under this paragraph.
18 "(4) PARTIAL YEAR.—Insofar as the provisions
19 of this subsection and section 1807A are not imple-
20 mented for all months in 2004, the annual contribu-
21 tion amount under this subsection for 2004 shall be
22 prorated to reflect the portion of that year in which
23 such provisions are in effect.
24 "(5) RESTRICTION ON CONTRIBUTIONS.—There
25 shall only be an annual Federal contribution under

1 paragraph (1) for an individual if the individual is
2 not eligible for coverage of, or assistance for, out-
3 patient prescription drugs under any of the fol-
4 lowing:
5 "(A) A medicaid plan under title XIX (in-
6 cluding under any waiver approved under sec-
7 tion 1115).
8 "(B) Enrollment under a group health
9 plan or health insurance coverage.
10 "(C) Enrollment under a medicare supple-
11 mental insurance policy.
12 "(D) Chapter 55 of title 10, United States
13 Code (relating to medical and dental care for
14 members of the uniformed services).
15 "(E) Chapter 17 of title 38, United States
16 Code (relating to Veterans' medical care).
17 "(F) Enrollment under a plan under chap-
18 ter 89 of title 5, United States Code (relating
19 to the Federal employees' health benefits pro-
20 gram).
21 "(G) The Indian Health Care Improve-
22 ment Act (25 U.S.C. 1601 et seq.).
23 "(6) APPROPRIATION TO COVER NET PROGRAM
24 EXPENDITURES.—There are authorized to be appro-
25 priated from time to time, out of any moneys in the

1 Treasury not otherwise appropriated, to the Federal
2 Supplementary Medical Insurance Trust Fund es-
3 tablished under section 1841, an amount equal to
4 the amount by which the benefits and administrative
5 costs of providing the benefits under this section ex-
6 ceed the sum of the portion of the enrollment fees
7 retained by the Secretary.
8 ''(k) DEFINITIONS.—In this part and section 1807A:
9 ''(1) COVERED OUTPATIENT DRUG.—
10 ''(A) IN GENERAL.—Except as provided in
11 this paragraph, for purposes of this section, the
12 term 'covered outpatient drug' means—
13 ''(i) a drug that may be dispensed
14 only upon a prescription and that is de-
15 scribed in subparagraph (A)(i) or (A)(ii) of
16 section 1927(k)(2); or
17 ''(ii) a biological product described in
18 clauses (i) through (iii) of subparagraph
19 (B) of such section or insulin described in
20 subparagraph (C) of such section and med-
21 ical supplies associated with the injection
22 of insulin (as defined in regulations of the
23 Secretary),
24 and such term includes a vaccine licensed under
25 section 351 of the Public Health Service Act

1 and any use of a covered outpatient drug for a
2 medically accepted indication (as defined in sec-
3 tion 1927(k)(6)).
4 "(B) EXCLUSIONS.—
5 "(i) IN GENERAL.—Such term does
6 not include drugs or classes of drugs, or
7 their medical uses, which may be excluded
8 from coverage or otherwise restricted
9 under section 1927(d)(2), other than sub-
10 paragraph (E) thereof (relating to smoking
11 cessation agents), or under section
12 1927(d)(3).
13 "(ii) AVOIDANCE OF DUPLICATE COV-
14 ERAGE.—A drug prescribed for an indi-
15 vidual that would otherwise be a covered
16 outpatient drug under this section shall
17 not be so considered if payment for such
18 drug is available under part A or B for an
19 individual entitled to benefits under part A
20 and enrolled under part B.
21 "(C) APPLICATION OF FORMULARY RE-
22 STRICTIONS.—A drug prescribed for an indi-
23 vidual that would otherwise be a covered out-
24 patient drug under this section shall not be so
25 considered under an endorsed program if the el-

1 igible entity offering the program excludes the
2 drug under a formulary and a review of such
3 exclusion is not successfully resolved under sub-
4 section (h)(5).
5 "(D) APPLICATION OF GENERAL EXCLU-
6 SION PROVISIONS.—An eligible entity offering
7 an endorsed program may exclude from quali-
8 fied prescription drug coverage any covered out-
9 patient drug—
10 "(i) for which payment would not be
11 made if section 1862(a) applied to part D;
12 or
13 "(ii) which are not prescribed in ac-
14 cordance with the program or this section.
15 Such exclusions are determinations subject to
16 review pursuant to subsection (h)(5).
17 "(2) POVERTY LINE.—The term 'poverty line'
18 means the income official poverty line (as defined by
19 the Office of Management and Budget, and revised
20 annually in accordance with section 673(2) of the
21 Omnibus Budget Reconciliation Act of 1981) appli-
22 cable to a family of the size involved.
23 "(l) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated such sums as may be
25 necessary to carry out this section and section 1807A.

1 "(e) INTERIM, FINAL REGULATORY AUTHORITY.—In
2 order to carry out this section and section 1807A in a
3 timely manner, the Secretary may promulgate regulations
4 that take effect on an interim basis, after notice and pend-
5 ing opportunity for public comment.

6 "PRESCRIPTION DRUG ACCOUNTS

7 "SEC. 1807A. "(a) ESTABLISHMENT OF AC-
8 COUNTS.—

9 "(1) IN GENERAL.—The Secretary shall estab-
10 lish and maintain for each eligible beneficiary who is
11 enrolled under section 1807 at the time of enroll-
12 ment a prescription drug account (in this section
13 and section 1807 referred to as an 'account').

14 "(2) RESERVE ACCOUNTS.—In cases described
15 in subsections (b)(3)(A), (b)(3)(B)(i), and
16 (b)(3)(B)(ii)(I), the Secretary shall establish and
17 maintain for each surviving spouse who is not en-
18 rolled under section 1807 a reserve prescription drug
19 account (in this section referred to as an 'reserve ac-
20 count').

21 "(3) ACCOUNTHOLDER DEFINED.—In this sec-
22 tion and section 1807A, the term 'accountholder'
23 means an individual for whom an account or reserve
24 account has been established under this section.

25 "(4) EXPENDITURES FROM ACCOUNT.—Noth-
26 ing in this section shall be construed as requiring

1 the Federal Government to obligate funds for
2 amounts in any account until such time as a with-
3 drawal from such account is authorized under this
4 section.
5 "(b) USE OF ACCOUNTS.—
6 "(1) APPLICATION OF ACCOUNT.—Except as
7 provided in this subsection, amounts credited to an
8 account shall only be used for the purchase of cov-
9 ered outpatient drugs for the accountholder. Any
10 amounts remaining at the end of a year remain
11 available for expenditures in succeeding years.
12 "(2) ACCOUNT RULES FOR PUBLIC AND PRI-
13 VATE CONTRIBUTIONS.—The Secretary shall estab-
14 lish a ongoing process for the determination of the
15 amount in each account that is attributable to public
16 and private contributions (including spousal rollover
17 contributions) based on the following rules:
18 "(A) TREATMENT OF EXPENDITURES.—
19 Expenditures from the account shall—
20 "(i) first be counted against any pub-
21 lic contribution; and
22 "(ii) next be counted against private
23 contributions.
24 "(B) TREATMENT OF SPOUSAL ROLLOVER
25 CONTRIBUTIONS.—With respect to any spousal

1 rollover contribution, the portions of such con-
2 tribution that were attributable to public and
3 private contributions at the time of its distribu-
4 tion under subsection (b)(3) shall be treated
5 under this paragraph as if it were a direct pub-
6 lic or private contribution, respectively, into the
7 account of the spouse.

8 "(3) DEATH OF ACCOUNTHOLDER.—In the case
9 of the death of an accountholder, the balance in any
10 account (taking into account liabilities accrued be-
11 fore the time of death) shall be distributed as fol-
12 lows:

13 "(A) TREATMENT OF PUBLIC CONTRIBU-
14 TIONS.—If the accountholder is married at the
15 time of death, the amount in the account that
16 is attributable to public contributions shall be
17 credited to the account (if any) of the surviving
18 spouse of the accountholder (or, if the surviving
19 spouse is not an eligible beneficiary, into a re-
20 serve account to be held for when that spouse
21 becomes an eligible beneficiary).

22 "(B) TREATMENT OF PRIVATE CONTRIBU-
23 TIONS.—The amount in the account that is at-
24 tributable to private contributions shall be dis-
25 tributed as follows:

1 "(i) DESIGNATION OF DIS-
2 TRIBUTEE.—If the accountholder has
3 made a designation, in a form and manner
4 specified by the Secretary, for the distribu-
5 tion of some or all of such amount, such
6 amount shall be distributed in accordance
7 with the designation. Such designation
8 may provide for the distribution into an
9 account (including a reserve account) of a
10 surviving spouse.
11 "(ii) ABSENCE OF DESIGNATION.—In-
12 sofar as the accountholder has not made
13 such a designation—
14 "(I) SURVIVING SPOUSE.—If the
15 accountholder was married at the time
16 of death, the remainder shall be cred-
17 ited to an account (including a reserve
18 account) of the accountholder's sur-
19 viving spouse.
20 "(II) NO SURVIVING SPOUSE.—If
21 the accountholder was not so married,
22 the remainder shall be distributed to
23 the estate of the accountholder and
24 distributed as provided by law.

1 "(4) USE OF ACCOUNT FOR PREMIUMS FOR EN-
2 ROLLMENT IN A MEDICARE ADVANTAGE PLAN.—
3 During any period in which an accountholder is en-
4 rolled in a Medicare Advantage plan under part C,
5 the balance in the account may be used and applied
6 only to reimburse the amount of the premium (if
7 any) established for enrollment under the plan.
8 "(5) APPLICATION TO MEDICAID EXPENSES IN
9 CERTAIN CASES.—
10 "(A) IN GENERAL.—Except as provided in
11 this paragraph, an account shall be treated as
12 an asset for purposes of establishing eligibility
13 for medical assistance under title XIX.
14 "(B) APPLICATION TOWARDS
15 SPENDDOWN.—In the case of an accountholder
16 who is applying for such medical assistance and
17 who would, but for the application of subpara-
18 graph (A), be eligible for such assistance—
19 "(i) subparagraph (A) shall not apply;
20 and
21 "(ii) the account shall be available (in
22 accordance with a procedure established by
23 the Secretary) to the State to reimburse
24 the State for any expenditures made under
25 the plan for such medical assistance.

1 "(c) AMOUNTS CREDITED IN ACCOUNT.—The Sec-
2 retary shall credit to a prescription drug account of an
3 eligible beneficiary the following amounts:
4 "(1) PUBLIC CONTRIBUTIONS.—The following
5 contributions (each referred to in this section as a
6 'public contribution'):
7 "(A) FEDERAL CONTRIBUTIONS.—Federal
8 contributions provided under subsection (d).
9 "(B) STATE CONTRIBUTIONS.—Contribu-
10 tions made by a State under subsection (f).
11 "(2) SPOUSAL ROLLOVER CONTRIBUTION.—A
12 distribution from a deceased spouse under sub-
13 section (b)(3) (referred to in this section as a 'spous-
14 al rollover contribution').
15 "(3) PRIVATE CONTRIBUTIONS.—The following
16 contributions (each referred to in this section as a
17 'private contribution'):
18 "(A) EMPLOYER AND INDIVIDUAL CON-
19 TRIBUTIONS.—Contributions made under sub-
20 section (e).
21 "(B) OTHER INDIVIDUAL CONTRIBU-
22 TIONS.—Contributions made by accountholder
23 other than under subsection (e).
24 "(C) CONTRIBUTIONS BY NONPROFIT OR-
25 GANIZATIONS.—Contributions made by a chari-

1 table, not-for-profit organization (that may be a
2 religious organization).
3 Except as provided in this subsection, no amounts may
4 be contributed to, or credited to, a prescription drug ac-
5 count.
6 "(d) FEDERAL CONTRIBUTION.—For Federal con-
7 tributions in the case of accountholders, see section
8 1807(j).
9 "(e) EMPLOYER AND INDIVIDUAL CONTRIBU-
10 TIONS.—
11 "(1) EMPLOYMENT-RELATED CONTRIBUTION.—
12 "(A) IN GENERAL.—In the case of any
13 accountholder who is a beneficiary or partici-
14 pant in a group health plan (including a multi-
15 employer plan), whether as an employee, former
16 employee or otherwise, including as a dependent
17 of an employee or former employee, the plan
18 may make a contribution into the
19 accountholder's account (but not into a reserve
20 account of the accountholder).
21 "(B) LIMITATION.—The total amount that
22 may be contributed under subparagraph (A)
23 under a plan to an account during any year
24 may not exceed $5,000.

1 "(C) CONDITION.—A group health plan
2 may condition a contribution with respect to an
3 accountholder under this paragraph on the
4 accountholder's enrollment under section 1807
5 with an eligible entity that is recognized or ap-
6 proved by that plan.
7 "(2) OTHER INDIVIDUALS.—
8 "(A) IN GENERAL.—Any individual may
9 also contribute to the account of that individual
10 or the account of any other individual under
11 this subsection.
12 "(B) LIMITATION.—The total amount that
13 may be contributed to an account under sub-
14 paragraph (A) during any year may not exceed
15 $5,000, regardless of who makes such contribu-
16 tion.
17 "(3) NO CONTRIBUTION PERMITTED TO RE-
18 SERVE ACCOUNT.—No contribution may be made
19 under this subsection to a reserve account.
20 "(4) FORM AND MANNER OF CONTRIBUTION.—
21 The Secretary shall specify the form and manner of
22 contributions under this subsection.
23 "(f) STATE CONTRIBUTIONS.—

1 ''(1) IN GENERAL.—A State may enter into ar-
2 rangements with the Secretary for the crediting of
3 amounts for accountholders.
4 ''(2) FORM AND MANNER OF CONTRIBUTION.—
5 The Secretary shall specify the form and manner of
6 contributions under this subsection.
7 ''(3) MEDICAID TREATMENT.—Amounts cred-
8 ited under this subsection shall not be treated as
9 medical assistance for purposes of title XIX or child
10 health assistance for purposes of title XXI for indi-
11 viduals who are not qualifying low income enroll-
12 ees.''.
13 (b) EXCLUSION OF COSTS FROM DETERMINATION OF
14 PART B MONTHLY PREMIUM.—Section 1839(g) (42
15 U.S.C. 1395r(g)) is amended—
16 (1) by striking ''attributable to the application
17 of section'' and inserting ''attributable to—
18 ''(1) the application of section'';
19 (2) by striking the period and inserting ''
20 and''; and
21 (3) by adding at the end the following new
22 paragraph:
23 ''(2) the Voluntary Medicare Outpatient Pre-
24 scription Drug Discount and Security Program
25 under sections 1807 and 1807A.''.

(c) STATE ELIGIBILITY DETERMINATIONS.—Section 1935, as added by section 103(a)(2), is amended—

(1) in subsection (a)(1), by inserting "and of eligibility for an annual Federal contribution amount under section 1807A(j)(2)" before the semicolon; and

(2) in subsection (a)(3), by inserting "and sections 1807 and 1807A" after "1860D–7)".

(d) REPORT ON PROGRESS IN IMPLEMENTATION OF PRESCRIPTION DRUG BENEFIT.—Not later than March 1, 2005, the Administrator shall submit a report to Congress on the progress that has been made in implementing the prescription drug benefit under this title. The Administrator shall include in the report specific steps that have been taken, and that need to be taken, to ensure a timely start of the program on January 1, 2006.

SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.

(a) DISCLOSURE.—

(1) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for

1 purposes other than tax administration) is amended
2 by adding at the end the following new paragraph:
3 "(19) DISCLOSURE OF RETURN INFORMATION
4 FOR PURPOSES OF CARRYING OUT MEDICARE CATA-
5 STROPHIC PRESCRIPTION DRUG PROGRAM.—
6 "(A) IN GENERAL.—The Secretary may,
7 upon written request from the Secretary of
8 Health and Human Services under section
9 1860D–2(b)(4)(E)(i) of the Social Security Act,
10 disclose to officers and employees of the De-
11 partment of Health and Human Services with
12 respect to a specified taxpayer for the taxable
13 year specified by the Secretary of Health and
14 Human Services in such request—
15 "(i) the taxpayer identity information
16 with respect to such taxpayer, and
17 "(ii) the adjusted gross income of
18 such taxpayer for the taxable year (or, if
19 less, the income threshold limit specified in
20 section 1860D–2(b)(4)(D)(ii) for the cal-
21 endar year specified by such Secretary in
22 such request).
23 "(B) SPECIFIED TAXPAYER.—For pur-
24 poses of this paragraph, the term 'specified tax-
25 payer' means any taxpayer who—

1 "(i) is identified by the Secretary of
2 Health and Human Services in the request
3 referred to in subparagraph (A), and
4 "(ii) either—
5 "(I) has an adjusted gross in-
6 come for the taxable year referred to
7 in subparagraph (A) in excess of the
8 income threshold specified in section
9 1860D–2(b)(4)(D)(ii) of such Act for
10 the calendar year referred to in such
11 subparagraph, or
12 "(II) is identified by such Sec-
13 retary under subparagraph (A) as
14 being an individual who elected to use
15 more recent information under section
16 1860D–2(b)(4)(D)(v) of such Act.
17 "(C) JOINT RETURNS.—In the case of a
18 joint return, the Secretary shall, for purposes of
19 applying this paragraph, treat each spouse as a
20 separate taxpayer having an adjusted gross in-
21 come equal to one-half of the adjusted gross in-
22 come determined with respect to such return.
23 "(D) RESTRICTION ON USE OF DISCLOSED
24 INFORMATION.—Return information disclosed
25 under subparagraph (A) may be used by offi-

1 cers and employees of the Department of
2 Health and Human Services only for the pur-
3 pose of administering the prescription drug ben-
4 efit under title XVIII of the Social Security
5 Act. Such officers and employees may disclose
6 the annual out-of-pocket threshold which ap-
7 plies to an individual under such part to the en-
8 tity that offers the plan referred to in section
9 1860D–2(b)(4)(E)(ii) of such Act in which such
10 individual is enrolled. Such sponsor may use
11 such information only for purposes of admin-
12 istering such benefit.''.

13 (2) JOINT RETURN PERMITTED IN CASE OF
14 SURVIVING SPOUSES.—Under section 6103(a)(3) of
15 the Internal Revenue Code of 1986, a surviving
16 spouse may file a joint return for the taxable year
17 in which one spouse dies.

18 (b) CONFIDENTIALITY.—Paragraph (3) of section
19 6103(a) of such Code is amended by striking ''or (16)''
20 and inserting ''(16), or (19)''.

21 (c) PROCEDURES AND RECORDKEEPING RELATED
22 TO DISCLOSURES.—Subsection (p)(4) of section 6103 of
23 such Code is amended by striking ''any other person de-
24 scribed in subsection (l)(16) or (17)'' each place it appears

1 and inserting ''any other person described in subsection
2 (l)(16), (17), or (19)''.
3 (d) UNAUTHORIZED DISCLOSURE.—Paragraph (2) of
4 section 7213(a) of such Code is amended by striking ''or
5 (16)'' and inserting ''(16), or (19)''.
6 (e) UNAUTHORIZED INSPECTION.—Subparagraph
7 (B) of section 7213A(a)(1) of such Code is amended by
8 inserting ''or (19)'' after ''subsection (l)(18)''.

9 **SEC. 107. STATE PHARMACEUTICAL ASSISTANCE TRANSI-**
10 **TION COMMISSION.**

11 (a) ESTABLISHMENT.—
12 (1) IN GENERAL.—There is established, as of
13 the first day of the third month beginning after the
14 date of the enactment of this Act, a State Pharma-
15 ceutical Assistance Transition Commission (in this
16 section referred to as the ''Commission'') to develop
17 a proposal for addressing the unique transitional
18 issues facing State pharmaceutical assistance pro-
19 grams, and program participants, due to the imple-
20 mentation of the medicare prescription drug pro-
21 gram under part D of title XVIII of the Social Secu-
22 rity Act.
23 (2) DEFINITIONS.—For purposes of this sec-
24 tion:

1 (A) STATE PHARMACEUTICAL ASSISTANCE
2 PROGRAM DEFINED.—The term ''State pharma-
3 ceutical assistance program'' means a program
4 (other than the medicaid program) operated by
5 a State (or under contract with a State) that
6 provides as of the date of the enactment of this
7 Act assistance to low-income medicare bene-
8 ficiaries for the purchase of prescription drugs.
9 (B) PROGRAM PARTICIPANT.—The term
10 ''program participant'' means a low-income
11 medicare beneficiary who is a participant in a
12 State pharmaceutical assistance program.
13 (b) COMPOSITION.—The Commission shall include
14 the following:
15 (1) A representative of each governor of each
16 State that the Secretary identifies as operating on a
17 statewide basis a State pharmaceutical assistance
18 program that provides for eligibility and benefits
19 that are comparable or more generous than the low-
20 income assistance eligibility and benefits offered
21 under part D of title XVIII of the Social Security
22 Act.
23 (2) Representatives from other States that the
24 Secretary identifies have in operation other State

1 pharmaceutical assistance programs, as appointed by
2 the Secretary.
3 (3) Representatives of organizations that have
4 an inherent interest in program participants or the
5 program itself, as appointed by the Secretary but
6 not to exceed the number of representatives under
7 paragraphs (1) and (2).
8 (4) Representatives of Medicare Advantage or-
9 ganizations and other private health insurance plans,
10 as appointed by the Secretary.
11 (5) The Secretary (or the Secretary's designee)
12 and such other members as the Secretary may speci-
13 fy
14 The Secretary shall designate a member to serve as chair
15 of the Commission and the Commission shall meet at the
16 call of the chair.
17 (c) DEVELOPMENT OF PROPOSAL.—The Commission
18 shall develop the proposal described in subsection (a) in
19 a manner consistent with the following principles:
20 (1) Protection of the interests of program par-
21 ticipants in a manner that is the least disruptive to
22 such participants and that includes a single point of
23 contact for enrollment and processing of benefits.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title.

(3) Principles of medicare modernization provided under title II of this Act.

(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

SEC. 108. ADDITIONAL REQUIREMENTS FOR ANNUAL FINANCIAL REPORT AND OVERSIGHT ON MEDICARE PROGRAM, INCLUDING PRESCRIPTION DRUG SPENDING.

(a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i) is amended by adding at the end the following new subsection:

1 "(l) COMBINED REPORT ON OPERATION AND STATUS
2 OF THE TRUST FUND, THE FEDERAL SUPPLEMENTARY
3 MEDICAL INSURANCE TRUST FUND, AND MEDICARE
4 PRESCRIPTION DRUG TRUST FUND.—
5 "(1) IN GENERAL.—In addition to the duty of
6 the Board of Trustees to report to Congress under
7 subsection (b), on the date the Board submits the
8 report required under subsection (b)(2), the Board
9 shall submit to Congress a report on the operation
10 and status of the Trust Fund, the Federal Supple-
11 mentary Medical Insurance Trust Fund established
12 under section 1841, and the Medicare Prescription
13 Drug Trust Fund under section 1860D–9(a) (in this
14 subsection collectively referred to as the 'Trust
15 Funds'). Such report shall included the following in-
16 formation:
17 "(A) OVERALL SPENDING FROM THE GEN-
18 ERAL FUND OF THE TREASURY.—A statement
19 of total amounts obligated during the preceding
20 fiscal year from the General Revenues of the
21 Treasury to the Trust Funds for payment for
22 benefits covered under this title, stated in terms
23 of the total amount and in terms of the per-
24 centage such amount bears to all other amounts

1 obligated from such General Revenues during
2 such fiscal year.
3 "(B) HISTORICAL OVERVIEW OF SPEND-
4 ING.—From the date of the inception of the
5 program of insurance under this title through
6 the fiscal year involved, a statement of the total
7 amounts referred to in subparagraph (A).
8 "(C) 10-YEAR AND 75-YEAR PROJEC-
9 TIONS.—An estimate of total amounts referred
10 to in subparagraph (A) required to be obligated
11 for payment for benefits covered under this title
12 for each of the 10 fiscal years succeeding the
13 fiscal year involved and for the 75-year period
14 beginning with the succeeding fiscal year.
15 "(D) RELATION TO GDP GROWTH.—A
16 comparison of the rate of growth of the total
17 amounts referred to in subparagraph (A) to the
18 rate of growth in the gross domestic product for
19 the same period.
20 "(2) PUBLICATION.—Each report submitted
21 under paragraph (1) shall be published jointly by the
22 Committee on Ways and Means and the Committee
23 on Energy and Commerce as a public document and
24 shall be made available by such Committees on the
25 Internet.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to fiscal years beginning on or after the date of the enactment of this Act.

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

SEC. 200. MEDICARE MODERNIZATION AND REVITALIZATION.

This title provides for—

(1) establishment of the medicare enhanced fee-for-service (EFFS) program under which medicare beneficiaries are provided access to a range of enhanced fee-for-service (EFFS) plans that may use preferred provider networks to offer an enhanced range of benefits;

(2) establishment of a Medicare Advantage program that offers improved managed care plans with coordinated care; and

(3) competitive bidding, in the style of the Federal Employees Health Benefits program (FEHBP), among enhanced fee-for-service plans and Medicare Advantage plans in order to promote greater efficiency and responsiveness to medicare beneficiaries.

Subtitle A—Medicare Enhanced Fee-for-Service Program

SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM UNDER MEDICARE.

(a) IN GENERAL.—Title XVIII, as amended by section 101(a), is amended—

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

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

"PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

"OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS THROUGHOUT THE UNITED STATES

"SEC. 1860E–1. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—The Administrator shall establish under this part beginning January 1, 2006, an enhanced fee-for-service program under which enhanced fee-for-service plans (as defined in subsection (b)) are offered to EFFS-eligible individuals (as so defined) in EFFS regions throughout the United States.

"(2) EFFS REGIONS.—For purposes of this part the Administrator shall establish EFFS regions throughout the United States by dividing the entire United States into at least 10 such regions. Before

1 establishing such regions, the Administrator shall
2 conduct a market survey and analysis, including an
3 examination of current insurance markets, to deter-
4 mine how the regions should be established. The re-
5 gions shall be established in a manner to take into
6 consideration maximizing full access for all EFFS-
7 eligible individuals, especially those residing in rural
8 areas.
9 ''(b) DEFINITIONS.—For purposes of this part:
10 ''(1) EFFS ORGANIZATION.—The 'EFFS orga-
11 nization' means an entity that the Administrator
12 certifies as meeting the requirements and standards
13 applicable to such organization under this part.
14 ''(2) ENHANCED FEE-FOR-SERVICE PLAN; EFFS
15 PLAN.—The terms 'enhanced fee-for-service plan'
16 and 'EFFS plan' mean health benefits coverage of-
17 fered under a policy, contract, or plan by an EFFS
18 organization pursuant to and in accordance with a
19 contract pursuant to section 1860E–4(c), but only if
20 the plan provides either fee-for-service coverage de-
21 scribed in the following subparagraph (A) or pre-
22 ferred provider coverage described in the following
23 subparagraph (B):
24 ''(A) FEE-FOR-SERVICE COVERAGE.—The
25 plan—

1 "(i) reimburses hospitals, physicians,
2 and other providers at a rate determined
3 by the plan on a fee-for-service basis with-
4 out placing the provider at financial risk;
5 "(ii) does not vary such rates for such
6 a provider based on utilization relating to
7 such provider; and
8 "(iii) does not restrict the selection of
9 providers among those who are lawfully au-
10 thorized to provide the covered services
11 and agree to accept the terms and condi-
12 tions of payment established by the plan.
13 "(B) PREFERRED PROVIDER COVERAGE.—
14 The plan—
15 "(i) has a network of providers that
16 have agreed to a contractually specified re-
17 imbursement for covered benefits with the
18 organization offering the plan; and
19 "(ii) provides for reimbursement for
20 all covered benefits regardless of whether
21 such benefits are provided within such net-
22 work of providers.
23 "(3) EFFS ELIGIBLE INDIVIDUAL.—The term
24 'EFFS eligible individual' means an eligible indi-
25 vidual described in section 1851(a)(3).

1 "(4) EFFS REGION.—The term 'EFFS region'
2 means a region established under subsection (a)(2).
3 "(c) APPLICATION OF CERTAIN ELIGIBILITY, EN-
4 ROLLMENT, ETC. REQUIREMENTS.—The provisions of
5 section 1851 (other than subsection (h)(4)(A)) shall apply
6 to EFFS plans offered by an EFFS organization in an
7 EFFS region, including subsection (g) (relating to guar-
8 anteed issue and renewal).
9 "OFFERING OF ENHANCED FEE-FOR-SERVICE (EFFS)
10 PLANS
11 "SEC. 1860E–2. (a) PLAN REQUIREMENTS.—No
12 EFFS plan may be offered under this part in an EFFS
13 region unless the requirements of this part are met with
14 respect to the plan and EFFS organization offering the
15 plan.
16 "(b) AVAILABLE TO ALL EFFS BENEFICIARIES IN
17 THE ENTIRE REGION.—With respect to an EFFS plan
18 offered in an EFFS region—
19 "(1) IN GENERAL.—The plan must be offered
20 to all EFFS-eligible individuals residing in the re-
21 gion.
22 "(2) ASSURING ACCESS TO SERVICES.—The
23 plan shall comply with the requirements of section
24 1852(d)(4).
25 "(c) BENEFITS.—

1 "(1) IN GENERAL.—Each EFFS plan shall pro-
2 vide to members enrolled in the plan under this part
3 benefits, through providers and other persons that
4 meet the applicable requirements of this title and
5 part A of title XI—
6 "(A) for the items and services described
7 in section 1852(a)(1);
8 "(B) that are uniform for the plan for all
9 EFFS eligible individuals residing in the same
10 EFFS region;
11 "(C) that include a single deductible appli-
12 cable to benefits under parts A and B and in-
13 clude a catastrophic limit on out-of-pocket ex-
14 penditures for such covered benefits; and
15 "(D) that include benefits for prescription
16 drug coverage for each enrollee who elects
17 under part D to be provided qualified prescrip-
18 tion drug coverage through the plan.
19 "(2) DISAPPROVAL AUTHORITY.—The Adminis-
20 trator shall not approve a plan of an EFFS organi-
21 zation if the Administrator determines (pursuant to
22 the last sentence of section 1852(b)(1)(A)) that the
23 benefits are designed to substantially discourage en-
24 rollment by certain EFFS eligible individuals with
25 the organization.

1 "(d) OUTPATIENT PRESCRIPTION DRUG COV-
2 ERAGE.—For rules concerning the offering of prescription
3 drug coverage under EFFS plans, see the amendment
4 made by section 102(b) of the Medicare Prescription Drug
5 and Modernization Act of 2003.

6 "(e) OTHER ADDITIONAL PROVISIONS.—The provi-
7 sions of section 1852 (other than subsection (a)(1)) shall
8 apply under this part to EFFS plans. For the application
9 of chronic care improvement provisions, see the amend-
10 ment made by section 722(b).

11 "SUBMISSION OF BIDS; BENEFICIARY SAVINGS; PAYMENT
12 OF PLANS

13 "SEC. 1860E–3. (a) SUBMISSION OF BIDS.—

14 "(1) REQUIREMENT.—

15 "(A) EFFS MONTHLY BID AMOUNT.—For
16 each year (beginning with 2006), an EFFS or-
17 ganization shall submit to the Administrator an
18 EFFS monthly bid amount for each EFFS
19 plan offered in each region. Each such bid is re-
20 ferred to in this section as the 'EFFS monthly
21 bid amount'.

22 "(B) FORM.—Such bid amounts shall be
23 submitted for each such plan and region in a
24 form and manner and time specified by the Ad-
25 ministrator, and shall include information de-
26 scribed in paragraph (3)(A).

1 "(2) UNIFORM BID AMOUNTS.—Each EFFS
2 monthly bid amount submitted under paragraph (1)
3 by an EFFS organization under this part for an
4 EFFS plan in an EFFS region may not vary among
5 EFFS eligible individuals residing in the EFFS re-
6 gion involved.
7 "(3) SUBMISSION OF BID AMOUNT INFORMA-
8 TION BY EFFS ORGANIZATIONS.—
9 "(A) INFORMATION TO BE SUBMITTED.—
10 The information described in this subparagraph
11 is as follows:
12 "(i) The EFFS monthly bid amount
13 for provision of all items and services
14 under this part, which amount shall be
15 based on average costs for a typical bene-
16 ficiary residing in the region, and the actu-
17 arial basis for determining such amount.
18 "(ii) The proportions of such bid
19 amount that are attributable to—
20 "(I) the provision of statutory
21 non-drug benefits (such portion re-
22 ferred to in this part as the
23 'unadjusted EFFS statutory non-drug
24 monthly bid amount');

1 "(II) the provision of statutory
2 prescription drug benefits; and
3 "(III) the provision of non-statu-
4 tory benefits;
5 and the actuarial basis for determining
6 such proportions.
7 "(iii) Such additional information as
8 the Administrator may require to verify
9 the actuarial bases described in clauses (i)
10 and (ii).
11 "(B) STATUTORY BENEFITS DEFINED.—
12 For purposes of this part:
13 "(i) The term 'statutory non-drug
14 benefits' means benefits under section
15 1852(a)(1).
16 "(ii) The term 'statutory prescription
17 drug benefits' means benefits under part
18 D.
19 "(iii) The term 'statutory benefits'
20 means statutory prescription drug benefits
21 and statutory non-drug benefits.
22 "(C) ACCEPTANCE AND NEGOTIATION OF
23 BID AMOUNTS.—The Administrator has the au-
24 thority to negotiate regarding monthly bid
25 amounts submitted under subparagraph (A)

1 (and the proportion described in subparagraph
2 (A)(ii)), and for such purpose, the Adminis-
3 trator has negotiation authority that the Direc-
4 tor of the Office of Personnel Management has
5 with respect to health benefits plans under
6 chapter 89 of title 5, United States Code. The
7 Administrator may reject such a bid amount or
8 proportion if the Administrator determines that
9 such amount or proportion is not supported by
10 the actuarial bases provided under subpara-
11 graph (A).
12 "(D) CONTRACT AUTHORITY.—The Ad-
13 ministrator may, taking into account the
14 unadjusted EFFS statutory non-drug monthly
15 bid amounts accepted under subparagraph (C),
16 enter into contracts for the offering of EFFS
17 plans by up to 3 EFFS organizations in any re-
18 gion.
19 "(b) PROVISION OF BENEFICIARY SAVINGS FOR CER-
20 TAIN PLANS.—
21 "(1) BENEFICIARY REBATE RULE.—
22 "(A) REQUIREMENT.—The EFFS plan
23 shall provide to the enrollee a monthly rebate
24 equal to 75 percent of the average per capita

1 savings (if any) described in paragraph (2) ap-
2 plicable to the plan and year involved.
3 "(B) FORM OF REBATE.—A rebate re-
4 quired under this paragraph shall be provided—
5 "(i) through the crediting of the
6 amount of the rebate towards the EFFS
7 monthly prescription drug beneficiary pre-
8 mium (as defined in section 1860E–
9 4(a)(3)(B)) and the EFFS monthly sup-
10 plemental beneficiary premium (as defined
11 in section 1860E–4(a)(3)(C));
12 "(ii) through a direct monthly pay-
13 ment (through electronic funds transfer or
14 otherwise); or
15 "(iii) through other means approved
16 by the Medicare Benefits Administrator,
17 or any combination thereof.
18 "(2) COMPUTATION OF AVERAGE PER CAPITA
19 MONTHLY SAVINGS.—For purposes of paragraph
20 (1)(A), the average per capita monthly savings re-
21 ferred to in such paragraph for an EFFS plan and
22 year is computed as follows:
23 "(A) DETERMINATION OF REGION-WIDE
24 AVERAGE RISK ADJUSTMENT.—

1 "(i) IN GENERAL.—The Medicare
2 Benefits Administrator shall determine, at
3 the same time rates are promulgated under
4 section 1853(b)(1) (beginning with 2006),
5 for each EFFS region the average of the
6 risk adjustment factors described in sub-
7 section (c)(3) to be applied to enrollees
8 under this part in that region. In the case
9 of an EFFS region in which an EFFS
10 plan was offered in the previous year, the
11 Administrator may compute such average
12 based upon risk adjustment factors applied
13 under subsection (c)(3) in that region in a
14 previous year.
15 "(ii) TREATMENT OF NEW RE-
16 GIONS.—In the case of a region in which
17 no EFFS plan was offered in the previous
18 year, the Administrator shall estimate such
19 average. In making such estimate, the Ad-
20 ministrator may use average risk adjust-
21 ment factors applied to comparable EFFS
22 regions or applied on a national basis.
23 "(B) DETERMINATION OF RISK ADJUSTED
24 BENCHMARK AND RISK-ADJUSTED BID.—For

1 each EFFS plan offered in an EFFS region,
2 the Administrator shall—
3 "(i) adjust the EFFS region-specific
4 non-drug monthly benchmark amount (as
5 defined in paragraph (3)) by the applicable
6 average risk adjustment factor computed
7 under subparagraph (A); and
8 "(ii) adjust the unadjusted EFFS
9 statutory non-drug monthly bid amount by
10 such applicable average risk adjustment
11 factor.
12 "(C) DETERMINATION OF AVERAGE PER
13 CAPITA MONTHLY SAVINGS.—The average per
14 capita monthly savings described in this sub-
15 paragraph is equal to the amount (if any) by
16 which—
17 "(i) the risk-adjusted benchmark
18 amount computed under subparagraph
19 (B)(i), exceeds
20 "(ii) the risk-adjusted bid computed
21 under subparagraph (B)(ii).
22 "(3) COMPUTATION OF EFFS REGION-SPECIFIC
23 NON-DRUG MONTHLY BENCHMARK AMOUNT.—For
24 purposes of this part, the term 'EFFS region-spe-
25 cific non-drug monthly benchmark amount' means,

with respect to an EFFS region for a month in a year, an amount equal to 1/12 of the average (weighted by number of EFFS eligible individuals in each payment area described in section 1853(d)) of the annual capitation rate as calculated under section 1853(c)(1) for that area.

"(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

"(1) NON-DRUG BENEFITS.—Under a contract under section 1860E–4(c) and subject to section 1853(g) (as made applicable under subsection (d)), the Administrator shall make monthly payments under this subsection in advance to each EFFS organization, with respect to coverage of an individual under this part in an EFFS region for a month, in an amount determined as follows:

"(A) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in subsection (b)(2)(C), the payment under this subsection is equal to the unadjusted EFFS statutory non-drug monthly bid amount, adjusted under paragraphs (3) and (4), plus the amount of the monthly rebate computed under subsection (b)(1)(A) for that plan and year.

1 "(B) PLANS WITH BIDS AT OR ABOVE
2 BENCHMARK.—In the case of a plan for which
3 there are no average per capita monthly savings
4 described in subsection (b)(2)(C), the payment
5 amount under this subsection is equal to the
6 EFFS region-specific non-drug monthly bench-
7 mark amount, adjusted under paragraphs (3)
8 and (4).
9 "(2) FOR FEDERAL DRUG SUBSIDIES.—In the
10 case in which an enrollee who elects under part D
11 to be provided qualified prescription drug coverage
12 through the plan, the EFFS organization offering
13 such plan also is entitled—
14 "(A) to direct subsidy payment under sec-
15 tion 1860D–8(a)(1);
16 "(B) to reinsurance subsidy payments
17 under section 1860D–8(a)(2); and
18 "(C) to reimbursement for premium and
19 cost-sharing reductions for low-income individ-
20 uals under section 1860D–7(c)(3).
21 "(3) DEMOGRAPHIC RISK ADJUSTMENT, IN-
22 CLUDING ADJUSTMENT FOR HEALTH STATUS.—The
23 Administrator shall adjust under paragraph (1)(A)
24 the unadjusted EFFS statutory non-drug monthly
25 bid amount and under paragraph (1)(B) the EFFS

1 region-specific non-drug monthly benchmark amount
2 for such risk factors as age, disability status, gen-
3 der, institutional status, and such other factors as
4 the Administrator determines to be appropriate, in-
5 cluding adjustment for health status under section
6 1853(a)(3) (as applied under subsection (d)), so as
7 to ensure actuarial equivalence. The Administrator
8 may add to, modify, or substitute for such adjust-
9 ment factors if such changes will improve the deter-
10 mination of actuarial equivalence.

11 "(4) ADJUSTMENT FOR INTRA-REGIONAL GEO-
12 GRAPHIC VARIATIONS.—The Administrator shall also
13 adjust such amounts in a manner to take into ac-
14 count variations in payments rates under part C
15 among the different payment areas under such part
16 included in each EFFS region.

17 "(d) APPLICATION OF ADDITIONAL PAYMENT
18 RULES.—The provisions of section 1853 (other than sub-
19 sections (a)(1)(A), (d), and (e)) shall apply to an EFFS
20 plan under this part, except as otherwise provided in this
21 section.

22 "PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIRE-
23 MENTS; ESTABLISHMENT OF STANDARDS; CON-
24 TRACTS WITH EFFS ORGANIZATIONS

25 "SEC. 1860E–4. (a) PREMIUMS.—

1 "(1) IN GENERAL.—The provisions of section
2 1854 (other than subsections (a)(6)(C) and (h)), in-
3 cluding subsection (b)(5) relating to the consolida-
4 tion of drug and non-drug beneficiary premiums and
5 subsection (c) relating to uniform bids and pre-
6 miums, shall apply to an EFFS plan under this
7 part, subject to paragraph (2).
8 "(2) CROSS-WALK.—In applying paragraph (1),
9 any reference in section 1854(b)(1)(A) or 1854(d)
10 to—
11 "(A) a Medicare Advantage monthly basic
12 beneficiary premium is deemed a reference to
13 the EFFS monthly basic beneficiary premium
14 (as defined in paragraph (3)(A));
15 "(B) a Medicare Advantage monthly pre-
16 scription drug beneficiary premium is deemed a
17 reference to the EFFS monthly prescription
18 drug beneficiary premium (as defined in para-
19 graph (3)(B)); and
20 "(C) a Medicare Advantage monthly sup-
21 plemental beneficiary premium is deemed a ref-
22 erence to the EFFS monthly supplemental ben-
23 eficiary premium (as defined in paragraph
24 (3)(C)).
25 "(3) DEFINITIONS.—For purposes of this part:

1 "(A) EFFS MONTHLY BASIC BENEFICIARY
2 PREMIUM.—The term 'EFFS monthly basic
3 beneficiary premium' means, with respect to an
4 EFFS plan—
5 "(i) described in section 1860E–
6 3(c)(1)(A) (relating to plans providing re-
7 bates), zero; or
8 "(ii) described in section 1860E–
9 3(c)(1)(B), the amount (if any) by which
10 the unadjusted EFFS statutory non-drug
11 monthly bid amount exceeds the EFFS re-
12 gion-specific non-drug monthly benchmark
13 amount (as defined in section 1860E–
14 3(b)(3)).
15 "(B) EFFS MONTHLY PRESCRIPTION
16 DRUG BENEFICIARY PREMIUM.—The term
17 'EFFS monthly prescription drug beneficiary
18 premium' means, with respect to an EFFS
19 plan, the portion of the aggregate monthly bid
20 amount submitted under clause (i) of section
21 1860E–3(a)(3)(A) for the year that is attrib-
22 utable under such section to the provision of
23 statutory prescription drug benefits.
24 "(C) EFFS MONTHLY SUPPLEMENTAL
25 BENEFICIARY PREMIUM.—The term 'EFFS

1 monthly supplemental beneficiary premium'
2 means, with respect to an EFFS plan, the por-
3 tion of the aggregate monthly bid amount sub-
4 mitted under clause (i) of section 1860E–
5 3(a)(3)(A) for the year that is attributable
6 under such section to the provision of nonstatu-
7 tory benefits.

8 ''(b) ORGANIZATIONAL AND FINANCIAL REQUIRE-
9 MENTS.—The provisions of section 1855 shall apply to an
10 EFFS plan offered by an EFFS organization under this
11 part.

12 ''(c) STANDARDS.—The provisions of paragraphs (1),
13 (3), and (4) of section 1856(b) shall apply to an EFFS
14 plan offered by an EFFS organization under this part.

15 ''(d) CONTRACTS WITH EFFS ORGANIZATIONS.—
16 The provisions of section 1857 shall apply to an EFFS
17 plan offered by an EFFS organization under this part,
18 except that any reference in such section to part C is
19 deemed a reference to this part.''.

20 (b) APPLICATION OF MEDIGAP PROVISIONS TO
21 EFFS PLANS.—Section 1882 of the Social Security Act
22 (42 U.S.C. 1395ss) shall be administered as if any ref-
23 erence to a Medicare+Choice organization offering a
24 Medicare+Choice plan under part C of title XVIII of such
25 Act were a reference both to a Medicare Advantage orga-

1 nization offering a Medicare Advantage plan under such
2 part and an EFFS organization offering an EFFS plan
3 under part E of such title.

4 Subtitle B—Medicare Advantage 5 Program

6 CHAPTER 1—IMPLEMENTATION OF 7 PROGRAM

8 SEC. 211. IMPLEMENTATION OF MEDICARE ADVANTAGE 9 PROGRAM.

10 (a) IN GENERAL.—There is hereby established the
11 Medicare Advantage program. The Medicare Advantage
12 program shall consist of the program under part C of title
13 XVIII of the Social Security Act, as amended by this title.
14 (b) REFERENCES.—Any reference to the program
15 under part C of title XVIII of the Social Security Act shall
16 be deemed a reference to the Medicare Advantage program
17 and, with respect to such part, any reference to
18 ''Medicare+Choice'' is deemed a reference to ''Medicare
19 Advantage''.

20 SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.

21 (a) EQUALIZING PAYMENTS WITH FEE-FOR-SERV-
22 ICE.—
23 (1) IN GENERAL.—Section 1853(c)(1) (42
24 U.S.C. 1395w–23(c)(1)) is amended by adding at
25 the end the following:

1 "(D) BASED ON 100 PERCENT OF FEE-
2 FOR-SERVICE COSTS.—
3 "(i) IN GENERAL.—For 2004, the ad-
4 justed average per capita cost for the year
5 involved, determined under section
6 1876(a)(4) for the Medicare Advantage
7 payment area for services covered under
8 parts A and B for individuals entitled to
9 benefits under part A and enrolled under
10 part B who are not enrolled in a Medicare
11 Advantage under this part for the year,
12 but adjusted to exclude costs attributable
13 to payments under section 1886(h).
14 "(ii) INCLUSION OF COSTS OF VA AND
15 DOD MILITARY FACILITY SERVICES TO
16 MEDICARE-ELIGIBLE BENEFICIARIES.—In
17 determining the adjusted average per cap-
18 ita cost under clause (i) for a year, such
19 cost shall be adjusted to include the Sec-
20 retary's estimate, on a per capita basis, of
21 the amount of additional payments that
22 would have been made in the area involved
23 under this title if individuals entitled to
24 benefits under this title had not received
25 services from facilities of the Department

of Veterans Affairs or the Department of Defense.''.

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking ''or (C)'' and inserting ''(C), or (D)''.

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

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

(2) in paragraph (5), by inserting ''(other than 2004)'' after ''for each year''.

(c) INCREASING MINIMUM PERCENTAGE INCREASE TO NATIONAL GROWTH RATE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended—

(A) in subparagraph (A), by striking ''The sum'' and inserting ''For a year before 2005, the sum'';

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

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

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

"(v) For 2004 and each succeeding year, the greater of—

"(I) 102 percent of the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year; or

"(II) the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year increased by the national per capita Medicare Advantage growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before 2004.".

(2) CONFORMING AMENDMENT.—Section 1853(c)(6)(C) (42 U.S.C. 1395w–23(c)(6)(C)) is amended by inserting before the period at the end the following: ", except that for purposes of para-

1 graph (1)(C)(v)(II), no such adjustment shall be
2 made for a year before 2004''.
3 (d) INCLUSION OF COSTS OF DOD AND VA MILI-
4 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
5 BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE
6 PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C.
7 1395w–23(c)(3)) is amended—
8 (1) in subparagraph (A), by striking ''subpara-
9 graph (B)'' and inserting ''subparagraphs (B) and
10 (E)'', and
11 (2) by adding at the end the following new sub-
12 paragraph:
13 ''(E) INCLUSION OF COSTS OF DOD AND
14 VA MILITARY FACILITY SERVICES TO MEDICARE-
15 ELIGIBLE BENEFICIARIES.—In determining the
16 area-specific Medicare+Choice capitation rate
17 under subparagraph (A) for a year (beginning
18 with 2004), the annual per capita rate of pay-
19 ment for 1997 determined under section
20 1876(a)(1)(C) shall be adjusted to include in
21 the rate the Secretary's estimate, on a per cap-
22 ita basis, of the amount of additional payments
23 that would have been made in the area involved
24 under this title if individuals entitled to benefits
25 under this title had not received services from

1 facilities of the Department of Defense or the
2 Department of Veterans Affairs.''.
3 (e) EXTENDING SPECIAL RULE FOR CERTAIN INPA-
4 TIENT HOSPITAL STAYS TO REHABILITATION HOS-
5 PITALS.—
6 (1) IN GENERAL.—Section 1853(g) (42 U.S.C.
7 1395w–23(g)) is amended—
8 (A) by inserting ''or from a rehabilitation
9 facility (as defined in section 1886(j)(1)(A))''
10 after ''1886(d)(1)(B))''; and
11 (B) in paragraph (2)(B), by inserting ''or
12 section 1886(j), as the case may be,'' after
13 ''1886(d)''.
14 (2) EFFECTIVE DATE.—The amendments made
15 by paragraph (1) shall apply to contract years begin-
16 ning on or after January 1, 2004.
17 (f) MEDPAC STUDY OF AAPCC.—
18 (1) STUDY.—The Medicare Payment Advisory
19 Commission shall conduct a study that assesses the
20 method used for determining the adjusted average
21 per capita cost (AAPCC) under section 1876(a)(4)
22 of the Social Security Act (42 U.S.C.
23 1395mm(a)(4)) as applied under section
24 1853(c)(1)(A) of such Act (as amended by sub-

1 section (a)). Such study shall include an examination
2 of—
3 (A) the bases for variation in such costs
4 between different areas, including differences in
5 input prices, utilization, and practice patterns;
6 (B) the appropriate geographic area for
7 payment under the Medicare Advantage pro-
8 gram under part C of title XVIII of such Act;
9 and
10 (C) the accuracy of risk adjustment meth-
11 ods in reflecting differences in costs of pro-
12 viding care to different groups of beneficiaries
13 served under such program.
14 (2) REPORT.—Not later than 18 months after
15 the date of the enactment of this Act, the Commis-
16 sion shall submit to Congress a report on the study
17 conducted under paragraph (1).
18 (g) REPORT ON IMPACT OF INCREASED FINANCIAL
19 ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not
20 later than July 1, 2006, the Medicare Benefits Adminis-
21 trator shall submit to Congress a report that describes the
22 impact of additional financing provided under this Act and
23 other Acts (including the Medicare, Medicaid, and SCHIP
24 Balanced Budget Refinement Act of 1999 and BIPA) on
25 the availability of Medicare Advantage plans in different

areas and its impact on lowering premiums and increasing benefits under such plans.

(h) ANNOUNCEMENT OF REVISED MEDICARE ADVANTAGE PAYMENT RATES.—Within 6 weeks after the date of the enactment of this Act, the Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties) Medicare Advantage capitation rates under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for 2004, revised in accordance with the provisions of this section.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

SEC. 221. COMPETITION PROGRAM BEGINNING IN 2006.

(a) SUBMISSION OF EFFS-LIKE BIDDING INFORMATION BEGINNING IN 2006.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(1) by amending the section heading to read as follows:

"PREMIUMS AND BID AMOUNT";

(2) in subsection (a)(1)(A)—

(A) by striking "(A)" and inserting "(A)(i) if the following year is before 2006,"; and

(B) by inserting before the semicolon at the end the following: "or (ii) if the following year is 2006 or later, the information described

in paragraph (3) or (6)(A) for the type of plan involved''; and

(3) by adding at the end of subsection (a) the following:

''(6) SUBMISSION OF BID AMOUNTS BY MEDICARE ADVANTAGE ORGANIZATIONS.—

''(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

''(i) The monthly aggregate bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the area, and the actuarial basis for determining such amount.

''(ii) The proportions of such bid amount that are attributable to—

''(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted Medicare Advantage statutory non-drug monthly bid amount');

''(II) the provision of statutory prescription drug benefits; and

1 "(III) the provision of non-statu-
2 tory benefits;
3 and the actuarial basis for determining
4 such proportions.
5 "(iii) Such additional information as
6 the Administrator may require to verify
7 the actuarial bases described in clauses (i)
8 and (ii).
9 "(B) STATUTORY BENEFITS DEFINED.—
10 For purposes of this part:
11 "(i) The term 'statutory non-drug
12 benefits' means benefits under section
13 1852(a)(1).
14 "(ii) The term 'statutory prescription
15 drug benefits' means benefits under part
16 D.
17 "(iii) The term 'statutory benefits'
18 means statutory prescription drug benefits
19 and statutory non-drug benefits.
20 "(C) ACCEPTANCE AND NEGOTIATION OF
21 BID AMOUNTS.—
22 "(i) IN GENERAL.—Subject to clause
23 (ii)—
24 "(I) the Administrator has the
25 authority to negotiate regarding

1 monthly bid amounts submitted under
2 subparagraph (A) (and the proportion
3 described in subparagraph (A)(ii)),
4 and for such purpose and subject to
5 such clause, the Administrator has ne-
6 gotiation authority that the Director
7 of the Office of Personnel Manage-
8 ment has with respect to health bene-
9 fits plans under chapter 89 of title 5,
10 United States Code; and
11 ''(II) the Administrator may re-
12 ject such a bid amount or proportion
13 if the Administrator determines that
14 such amount or proportion is not sup-
15 ported by the actuarial bases provided
16 under subparagraph (A).
17 ''(ii) EXCEPTION.—In the case of a
18 plan described in section 1851(a)(2)(C),
19 the provisions of clause (i) shall not apply
20 and the provisions of paragraph (5)(B),
21 prohibiting the review, approval, or dis-
22 approval of amounts described in such
23 paragraph, shall apply to the negotiation
24 and rejection of the monthly bid amounts

1 and proportion referred to in subparagraph
2 (A).''.
3 (b) PROVIDING FOR BENEFICIARY SAVINGS FOR
4 CERTAIN PLANS.—
5 (1) IN GENERAL.—Section 1854(b) (42 U.S.C.
6 1395w–24(b)) is amended—
7 (A) by adding at the end of paragraph (1)
8 the following new subparagraph:
9 ''(C) BENEFICIARY REBATE RULE.—
10 ''(i) REQUIREMENT.—The Medicare
11 Advantage plan shall provide to the en-
12 rollee a monthly rebate equal to 75 percent
13 of the average per capita savings (if any)
14 described in paragraph (3) applicable to
15 the plan and year involved.
16 ''(iii) FORM OF REBATE.—A rebate
17 required under this subparagraph shall be
18 provided—
19 ''(I) through the crediting of the
20 amount of the rebate towards the
21 Medicare Advantage monthly supple-
22 mentary beneficiary premium or the
23 premium imposed for prescription
24 drug coverage under part D;

1 "(II) through a direct monthly
2 payment (through electronic funds
3 transfer or otherwise); or
4 "(III) through other means ap-
5 proved by the Medicare Benefits Ad-
6 ministrator,
7 or any combination thereof."; and
8 (B) by adding at the end the following new
9 paragraphs:
10 "(3) COMPUTATION OF AVERAGE PER CAPITA
11 MONTHLY SAVINGS.—For purposes of paragraph
12 (1)(C)(i), the average per capita monthly savings re-
13 ferred to in such paragraph for a Medicare Advan-
14 tage plan and year is computed as follows:
15 "(A) DETERMINATION OF STATE-WIDE AV-
16 ERAGE RISK ADJUSTMENT.—
17 "(i) IN GENERAL.—The Medicare
18 Benefits Administrator shall determine, at
19 the same time rates are promulgated under
20 section 1853(b)(1) (beginning with 2006),
21 for each State the average of the risk ad-
22 justment factors to be applied under sec-
23 tion 1853(a)(1)(A) to payment for enroll-
24 ees in that State. In the case of a State in
25 which a Medicare Advantage plan was of-

1 fered in the previous year, the Adminis-
2 trator may compute such average based
3 upon risk adjustment factors applied in
4 that State in a previous year.
5 "(ii) TREATMENT OF NEW STATES.—
6 In the case of a State in which no Medi-
7 care Advantage plan was offered in the
8 previous year, the Administrator shall esti-
9 mate such average. In making such esti-
10 mate, the Administrator may use average
11 risk adjustment factors applied to com-
12 parable States or applied on a national
13 basis.
14 "(B) DETERMINATION OF RISK ADJUSTED
15 BENCHMARK AND RISK-ADJUSTED BID.—For
16 each Medicare Advantage plan offered in a
17 State, the Administrator shall—
18 "(i) adjust the Medicare Advantage
19 area-specific non-drug monthly benchmark
20 amount (as defined in subsection (j)) by
21 the applicable average risk adjustment fac-
22 tor computed under subparagraph (A); and
23 "(ii) adjust the unadjusted Medicare
24 Advantage statutory non-drug monthly bid

1 amount by such applicable average risk ad-
2 justment factor.
3 "(C) DETERMINATION OF AVERAGE PER
4 CAPITA MONTHLY SAVINGS.—The average per
5 capita monthly savings described in this sub-
6 paragraph is equal to the amount (if any) by
7 which—
8 "(i) the risk-adjusted benchmark
9 amount computed under subparagraph
10 (B)(i), exceeds
11 "(ii) the risk-adjusted bid computed
12 under subparagraph (B)(ii).
13 "(D) AUTHORITY TO DETERMINE RISK AD-
14 JUSTMENT FOR AREAS OTHER THAN STATES.—
15 The Administrator may provide for the deter-
16 mination and application of risk adjustment
17 factors under this paragraph on the basis of
18 areas other than States.
19 "(4) BENEFICIARY'S OPTION OF PAYMENT
20 THROUGH WITHHOLDING FROM SOCIAL SECURITY
21 PAYMENT OR USE OF ELECTRONIC FUNDS TRANS-
22 FER MECHANISM.—In accordance with regulations, a
23 Medicare Advantage organization shall permit each
24 enrollee, at the enrollee's option, to make payment
25 of premiums under this part to the organization in-

1 directly through withholding from benefit payments
2 in the manner provided under section 1840 with re-
3 spect to monthly premiums under section 1839 or
4 through an electronic funds transfer mechanism
5 (such as automatic charges of an account at a finan-
6 cial institution or a credit or debit card account) or
7 otherwise. All premium payments that are withheld
8 under this paragraph that are credited to the Fed-
9 eral Supplementary Medical Insurance Drug Trust
10 Fund shall be paid to the Medicare Advantage orga-
11 nization involved.''.

12 (2) PROVISION OF SINGLE CONSOLIDATED PRE-
13 MIUM.—Section 1854(b) (42 U.S.C. 1395w–24(b)),
14 as amended by paragraph (1), is further amended by
15 adding at the end the following new paragraph:

16 ''(5) SINGLE CONSOLIDATED PREMIUM.—In the
17 case of an enrollee in a Medicare Advantage plan
18 who elects under part D to be provided qualified
19 prescription drug coverage through the plan, the Ad-
20 ministrator shall provide a mechanism for the con-
21 solidation of the beneficiary premium amount for
22 non-drug benefits under this part with the premium
23 amount for prescription drug coverage under part D
24 provided through the plan.''.

(3) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w–23) is amended by adding at the end the following new subsection:

"(j) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'Medicare Advantage area-specific non-drug monthly benchmark amount' means, with respect to a Medicare Advantage payment area for a month in a year, an amount equal to 1/12 of the annual Medicare Advantage capitation rate under section 1853(c)(1) for the area for the year.".

(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C. 1395w–23) is amended by striking "in an amount" and all that follows and inserting the following: "in an amount determined as follows:

"(i) PAYMENT BEFORE 2006.—For years before 2006, the payment amount shall be equal to 1/12 of the annual Medicare Advantage capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, reduced by the amount of any reduction

1 elected under section 1854(f)(1)(E) and
2 adjusted under clause (iv).
3 "(ii) PAYMENT FOR STATUTORY NON-
4 DRUG BENEFITS BEGINNING WITH 2006.—
5 For years beginning with 2006—
6 "(I) PLANS WITH BIDS BELOW
7 BENCHMARK.—In the case of a plan
8 for which there are average per capita
9 monthly savings described in section
10 1854(b)(3)(C), the payment under
11 this subsection is equal to the
12 unadjusted Medicare Advantage statu-
13 tory non-drug monthly bid amount,
14 adjusted under clause (iv), plus the
15 amount of the monthly rebate com-
16 puted under section 1854(b)(1)(C)(i)
17 for that plan and year.
18 "(II) PLANS WITH BIDS AT OR
19 ABOVE BENCHMARK.—In the case of a
20 plan for which there are no average
21 per capita monthly savings described
22 in section 1854(b)(3)(C), the payment
23 amount under this subsection is equal
24 to the Medicare Advantage area-spe-

1 cific non-drug monthly benchmark
2 amount, adjusted under clause (iv).
3 "(iii) FOR FEDERAL DRUG SUB-
4 SIDIES.—In the case in which an enrollee
5 who elects under part D to be provided
6 qualified prescription drug coverage
7 through the plan, the Medicare Advantage
8 organization offering such plan also is
9 entitled—
10 "(I) to direct subsidy payment
11 under section 1860D–8(a)(1);
12 "(II) to reinsurance subsidy pay-
13 ments under section 1860D–8(a)(2);
14 and
15 "(III) to reimbursement for pre-
16 mium and cost-sharing reductions for
17 low-income individuals under section
18 1860D–7(c)(3).
19 "(iv) DEMOGRAPHIC ADJUSTMENT,
20 INCLUDING ADJUSTMENT FOR HEALTH
21 STATUS.—The Administrator shall adjust
22 the payment amount under clause (i), the
23 unadjusted Medicare Advantage statutory
24 non-drug monthly bid amount under clause
25 (ii)(I), and the Medicare Advantage area-

specific non-drug monthly benchmark amount under clause (ii)(II) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.''.

(d) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: ''The Administrator shall not approve a plan of an organization if the Administrator determines that the benefits are designed to substantially discourage enrollment by certain Medicare Advantage eligible individuals with the organization.''.

(2) CONFORMING AMENDMENT TO PREMIUM TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) is amended by redesignating subparagraph (C) as subparagraph (D) and by striking

1 subparagraphs (A) and (B) and inserting the fol-
2 lowing:
3 "(A) MEDICARE ADVANTAGE MONTHLY
4 BASIC BENEFICIARY PREMIUM.—The term
5 'Medicare Advantage monthly basic beneficiary
6 premium' means, with respect to a Medicare
7 Advantage plan—
8 "(i) described in section
9 1853(a)(1)(A)(ii)(I) (relating to plans pro-
10 viding rebates), zero; or
11 "(ii) described in section
12 1853(a)(1)(A)(ii)(II), the amount (if any)
13 by which the unadjusted Medicare Advan-
14 tage statutory non-drug monthly bid
15 amount exceeds the Medicare Advantage
16 area-specific non-drug monthly benchmark
17 amount.
18 "(B) MEDICARE ADVANTAGE MONTHLY
19 PRESCRIPTION DRUG BENEFICIARY PREMIUM.—
20 The term 'Medicare Advantage monthly pre-
21 scription drug beneficiary premium' means,
22 with respect to a Medicare Advantage plan, that
23 portion of the bid amount submitted under
24 clause (i) of subsection (a)(6)(A) for the year
25 that is attributable under such section to the

1 provision of statutory prescription drug bene-
2 fits.
3 "(C) MEDICARE ADVANTAGE MONTHLY
4 SUPPLEMENTAL BENEFICIARY PREMIUM.—The
5 term 'Medicare Advantage monthly supple-
6 mental beneficiary premium' means, with re-
7 spect to a Medicare Advantage plan, the portion
8 of the aggregate monthly bid amount submitted
9 under clause (i) of subsection (a)(6)(A) for the
10 year that is attributable under such section to
11 the provision of nonstatutory benefits.".
12 (3) REQUIREMENT FOR UNIFORM PREMIUM
13 AND BID AMOUNTS.—Section 1854(c) (42 U.S.C.
14 1395w–24(c)) is amended to read as follows:
15 "(c) UNIFORM PREMIUM AND BID AMOUNTS.—The
16 Medicare Advantage monthly bid amount submitted under
17 subsection (a)(6), the Medicare Advantage monthly basic,
18 prescription drug, and supplemental beneficiary pre-
19 miums, and the Medicare Advantage monthly MSA pre-
20 mium charged under subsection (b) of a Medicare Advan-
21 tage organization under this part may not vary among in-
22 dividuals enrolled in the plan.".
23 (4) PERMITTING BENEFICIARY REBATES.—
24 (A) Section 1851(h)(4)(A) (42 U.S.C.
25 1395w–21(h)(4)(A)) is amended by inserting

"except as provided under section 1854(b)(1)(C)" after "or otherwise".

(B) Section 1854(d) (42 U.S.C. 1395w–24(d)) is amended by inserting ", except as provided under subsection (b)(1)(C)," after "and may not provide".

(5) OTHER CONFORMING AMENDMENTS RELATING TO BIDS.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) in the heading of subsection (a), by inserting "AND BID AMOUNTS" after "PREMIUMS"; and

(B) in subsection (a)(5)(A), by inserting "paragraphs (2), (3), and (4) of" after "filed under".

(e) ADDITIONAL CONFORMING AMENDMENTS.—

(1) ANNUAL DETERMINATION AND ANNOUNCEMENT OF CERTAIN FACTORS.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)) is amended by striking "the respective calendar year" and all that follows and inserting the following: "the calendar year concerned with respect to each Medicare Advantage payment area, the following:

"(A) PRE-COMPETITION INFORMATION.—For years before 2006, the following:

1 "(i) MEDICARE ADVANTAGE CAPITA-
2 TION RATES.—The annual Medicare Ad-
3 vantage capitation rate for each Medicare
4 Advantage payment area for the year.
5 "(ii) ADJUSTMENT FACTORS.—The
6 risk and other factors to be used in adjust-
7 ing such rates under subsection (a)(1)(A)
8 for payments for months in that year.
9 "(B) COMPETITION INFORMATION.—For
10 years beginning with 2006, the following:
11 "(i) BENCHMARK.—The Medicare Ad-
12 vantage area-specific non-drug benchmark
13 under section 1853(j).
14 "(ii) ADJUSTMENT FACTORS.—The
15 adjustment factors applied under section
16 1853(a)(1)(A)(iv) (relating to demographic
17 adjustment), section 1853(a)(1)(B) (relat-
18 ing to adjustment for end-stage renal dis-
19 ease), and section 1853(a)(3) (relating to
20 health status adjustment).".
21 (2) REPEAL OF PROVISIONS RELATING TO AD-
22 JUSTED COMMUNITY RATE (ACR).—
23 (A) IN GENERAL.—Subsections (e) and (f)
24 of section 1854 (42 U.S.C. 1395w–24) are re-
25 pealed.

(B) CONFORMING AMENDMENTS.—(i) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking ", and to reflect" and all that follows and inserting a period.

(ii) Section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)) is amended by striking "title XI" and all that follows and inserting the following: "title XI those items and services (other than hospice care) for which benefits are available under parts A and B to individuals residing in the area served by the plan.".

(iii) Section 1857(d)(1) (42 U.S.C. 1395w–27(d)(1)) is amended by striking ", costs, and computation of the adjusted community rate" and inserting "and costs".

(f) REFERENCES UNDER PART E.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

"(f) APPLICATION UNDER PART E.—In the case of any reference under part E to a requirement or provision of this part in the relation to an EFFS plan or organization under such part, except as otherwise specified any such requirement or provision shall be applied to such organization or plan in the same manner as such requirement or provision applies to a Medicare Advantage private

1 fee-for-service plan (and the Medicare Advantage organi-
2 zation that offers such plan) under this part.''.
3 (g) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to payments and premiums for
5 months beginning with January 2006.

6 CHAPTER 3—ADDITIONAL REFORMS

7 SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE AD-
8 VANTAGE REPORTING DEADLINES AND AN-
9 NUAL, COORDINATED ELECTION PERIOD.

10 (a) CHANGE IN REPORTING DEADLINE.—Section
11 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by
12 section 532(b)(1) of the Public Health Security and Bio-
13 terrorism Preparedness and Response Act of 2002, is
14 amended by striking ''2002, 2003, and 2004 (or July 1
15 of each other year)'' and inserting ''2002 and each subse-
16 quent year''.
17 (b) DELAY IN ANNUAL, COORDINATED ELECTION
18 PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–
19 21(e)(3)(B)), as amended by section 532(c)(1)(A) of the
20 Public Health Security and Bioterrorism Preparedness
21 and Response Act of 2002, is amended—
22 (1) by striking ''and after 2005''; and
23 (2) by striking '', 2004, and 2005'' and insert-
24 ing ''and any subsequent year''.

1 (c) ANNUAL ANNOUNCEMENT OF PAYMENT
2 RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–
3 23(b)(1)), as amended by section 532(d)(1) of the Public
4 Health Security and Bioterrorism Preparedness and Re-
5 sponse Act of 2002, is amended—
6 (1) by striking ''and after 2005''; and
7 (2) by striking ''and 2005'' and inserting ''and
8 each subsequent year''.
9 (d) REQUIRING PROVISION OF AVAILABLE INFORMA-
10 TION COMPARING PLAN OPTIONS.—The first sentence of
11 section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w–
12 21(d)(2)(A)(ii)) is amended by inserting before the period
13 the following: ''to the extent such information is available
14 at the time of preparation of materials for the mailing''.
15 **SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.**
16 (a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C.
17 1395w–26(b)(3)) is amended to read as follows:
18 ''(3) RELATION TO STATE LAWS.—The stand-
19 ards established under this subsection shall super-
20 sede any State law or regulation (other than State
21 licensing laws or State laws relating to plan sol-
22 vency) with respect to Medicare Advantage plans
23 which are offered by Medicare Advantage organiza-
24 tions under this part.''.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall take effect on the date of the enact-
3 ment of this Act.

4 **SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS FOR**
5 **SPECIAL NEEDS BENEFICIARIES.**

6 (a) TREATMENT AS COORDINATED CARE PLAN.—
7 Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is
8 amended by adding at the end the following new sentence:
9 ''Specialized Medicare Advantage plans for special needs
10 beneficiaries (as defined in section 1859(b)(4)) may be
11 any type of coordinated care plan.''.

12 (b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR
13 SPECIAL NEEDS BENEFICIARIES DEFINED.—Section
14 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding
15 at the end the following new paragraph:

16 ''(4) SPECIALIZED MEDICARE ADVANTAGE
17 PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

18 ''(A) IN GENERAL.—The term 'specialized
19 Medicare Advantage plan for special needs
20 beneficiaries' means a Medicare Advantage plan
21 that exclusively serves special needs bene-
22 ficiaries (as defined in subparagraph (B)).

23 ''(B) SPECIAL NEEDS BENEFICIARY.—The
24 term 'special needs beneficiary' means a Medi-
25 care Advantage eligible individual who—

1 "(i) is institutionalized (as defined by
2 the Secretary);
3 "(ii) is entitled to medical assistance
4 under a State plan under title XIX; or
5 "(iii) meets such requirements as the
6 Secretary may determine would benefit
7 from enrollment in such a specialized
8 Medicare Advantage plan described in sub-
9 paragraph (A) for individuals with severe
10 or disabling chronic conditions.".
11 (c) RESTRICTION ON ENROLLMENT PERMITTED.—
12 Section 1859 (42 U.S.C. 1395w–29) is amended by add-
13 ing at the end the following new subsection:
14 "(f) RESTRICTION ON ENROLLMENT FOR SPECIAL-
15 IZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS
16 BENEFICIARIES.—In the case of a specialized Medicare
17 Advantage plan (as defined in subsection (b)(4)), notwith-
18 standing any other provision of this part and in accord-
19 ance with regulations of the Secretary and for periods be-
20 fore January 1, 2007, the plan may restrict the enrollment
21 of individuals under the plan to individuals who are within
22 one or more classes of special needs beneficiaries.".
23 (d) AUTHORITY TO DESIGNATE OTHER PLANS AS
24 SPECIALIZED MEDICARE ADVANTAGE PLANS.—In pro-
25 mulgating regulations to carry out the last sentence of sec-

1 tion 1851(a)(2)(A) of the Social Security Act (as added
2 by subsection (a)) and section 1859(b)(4) of such Act (as
3 added by subsection (b)), the Secretary may provide (not-
4 withstanding section 1859(b)(4)(A) of such Act) for the
5 offering of specialized Medicare Advantage plans by Medi-
6 care Advantage plans that disproportionately serve special
7 needs beneficiaries who are frail, elderly medicare bene-
8 ficiaries.

9 (e) REPORT TO CONGRESS.—Not later than Decem-
10 ber 31, 2005, the Medicare Benefits Administrator shall
11 submit to Congress a report that assesses the impact of
12 specialized Medicare Advantage plans for special needs
13 beneficiaries on the cost and quality of services provided
14 to enrollees. Such report shall include an assessment of
15 the costs and savings to the medicare program as a result
16 of amendments made by subsections (a), (b), and (c).

17 (f) EFFECTIVE DATES.—

18 (1) IN GENERAL.—The amendments made by
19 subsections (a), (b), and (c) shall take effect upon
20 the date of the enactment of this Act.

21 (2) DEADLINE FOR ISSUANCE OF REQUIRE-
22 MENTS FOR SPECIAL NEEDS BENEFICIARIES; TRAN-
23 SITION.—No later than 6 months after the date of
24 the enactment of this Act, the Secretary shall issue
25 interim final regulations to establish requirements

for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 234. MEDICARE MSAS.

(a) EXEMPTION FROM REPORTING ENROLLEE ENCOUNTER DATA.—

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w–22(e)(1)) is amended by inserting ''(other than MSA plans)'' after ''plans''.

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: ''if required under such section''; and

(B) in subparagraphs (A) and (B) of subsection (e)(2), by striking '', a non-network MSA plan,'' and '', NON-NETWORK MSA PLANS,'' each place it appears.

(b) MAKING PROGRAM PERMANENT AND ELIMINATING CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is amended—

(1) in the heading, by striking ''ON A DEMONSTRATION BASIS'';

(2) by striking the first sentence of subparagraph (A); and

1 (3) by striking the second sentence of subpara-
2 graph (C).
3 (c) APPLYING LIMITATIONS ON BALANCE BILL-
4 ING.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is
5 amended by inserting ''or with an organization offering
6 a MSA plan'' after ''section 1851(a)(2)(A)''.
7 (d) ADDITIONAL AMENDMENT.—Section
8 1851(e)(5)(A) (42 U.S.C. 1395w–21(e)(5)(A)) is
9 amended—
10 (1) by adding ''or'' at the end of clause (i);
11 (2) by striking '', or'' at the end of clause (ii)
12 and inserting a semicolon; and
13 (3) by striking clause (iii).
14 **SEC. 235. EXTENSION OF REASONABLE COST CONTRACTS.**
15 Subparagraph (C) of section 1876(h)(5) (42 U.S.C.
16 1395mm(h)(5)) is amended to read as follows:
17 ''(C)(i) Subject to clause (ii), may be extended or re-
18 newed under this subsection indefinitely.
19 ''(ii) For any period beginning on or after January
20 1, 2008, a reasonable cost reimbursement contract under
21 this subsection may not be extended or renewed for a serv-
22 ice area insofar as such area, during the entire previous
23 year, was within the service area of 2 or more plans which
24 were coordinated care Medicare Advantage plans under
25 part C or 2 or more enhanced fee-for-service plans under

1 part E and each of which plan for that previous year for
2 the area involved meets the following minimum enrollment
3 requirements:

4 "(I) With respect to any portion of the area in-
5 volved that is within a Metropolitan Statistical Area
6 with a population of more than 250,000 and coun-
7 ties contiguous to such Metropolitan Statistical
8 Area, 5,000 individuals.

9 "(II) With respect to any other portion of such
10 area, 1,500 individuals.".

11 **SEC. 236. EXTENSION OF MUNICIPAL HEALTH SERVICE**
12 **DEMONSTRATION PROJECTS.**

13 Section 9215(a) of the Consolidated Omnibus Budget
14 Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as
15 amended by section 6135 of the Omnibus Budget Rec-
16 onciliation Act of 1989, section 13557 of the Omnibus
17 Budget Reconciliation Act of 1993, section 4017 of BBA,
18 section 534 of BBRA (113 Stat. 1501A–390), and section
19 633 of BIPA, is amended by striking "December 31,
20 2004" and inserting "December 31, 2009".

21 **SEC. 237. STUDY OF PERFORMANCE-BASED PAYMENT SYS-**
22 **TEMS.**

23 (a) IN GENERAL.—The Secretary shall request the
24 Institute of Medicine of the National Academy of Sciences
25 to—

1 (1) conduct a study that reviews and evaluates
2 public and private sector experiences in establishing
3 performance measures and payment incentives under
4 the medicare program and linking performance to
5 payment; and
6 (2) submit a report to the Secretary and Con-
7 gress, not later than 18 months after the date of the
8 enactment of this Act, regarding such study.
9 (b) STUDY.—The study under subsection (a)(1)
10 shall—
11 (1) include a review and evaluation of incentives
12 that have been or could be used to encourage quality
13 performance, including those aimed at health plans
14 and their enrollees, providers and their patients, and
15 other incentives that encourage quality-based health
16 care purchasing and collaborative efforts to improve
17 performance; and
18 (2) examine how these measures and incentives
19 might be applied in the Medicare Advantage pro-
20 gram, the Enhanced Fee-For-Service (EFFS) pro-
21 gram, and traditional fee-for-service programs.
22 (c) REPORT RECOMMENDATIONS.—The report under
23 subsection (a)(2) shall—

(1) include recommendations regarding appropriate performance measures for use in assessing and paying for quality; and

(2) identify options for updating performance measures.

Subtitle C—Application of FEHBP-Style Competitive Reforms

SEC. 241. APPLICATION OF FEHBP-STYLE COMPETITIVE REFORM BEGINNING IN 2010.

(a) IDENTIFICATION OF COMPETITIVE EFFS REGIONS; COMPUTATION OF COMPETITIVE EFFS NON-DRUG BENCHMARKS UNDER EFFS PROGRAM.—

(1) IN GENERAL.—Section 1860E–3, as added by section 201(a), is amended by adding at the end the following new subsection:

''(e) APPLICATION OF COMPETITION.—

''(1) DETERMINATION OF COMPETITIVE EFFS REGIONS.—

''(A) IN GENERAL.—For purposes of this part, the term 'competitive EFFS region' means, for a year beginning with 2010, an EFFS region that the Administrator finds—

''(i) there will be offered in the region during the annual, coordinated election period under section 1851(e)(3)(B) (as ap-

1 plied under section 1860E–1(c)) before the
2 beginning of the year at least 2 EFFS
3 plans (in addition to the fee-for-service
4 program under parts A and B), each of-
5 fered by a different EFFS organization
6 and each of which met the minimum en-
7 rollment requirements of paragraph (1) of
8 section 1857(b) (as applied without regard
9 to paragraph (3) thereof) as of March of
10 the previous year; and
11 ''(ii) during March of the previous
12 year at least the percentage specified in
13 subparagraph (C) of the number of EFFS
14 eligible individuals who reside in the region
15 were enrolled in an EFFS plan.
16 ''(B) PERCENTAGE SPECIFIED.—
17 ''(i) IN GENERAL.—For purposes of
18 subparagraph (A), subject to clause (ii),
19 the percentage specified in this subpara-
20 graph for a year is equal the lesser of 20
21 percent or to the sum of—
22 ''(I) the percentage, as estimated
23 by the Administrator, of EFFS eligi-
24 ble individuals in the United States

1 who are enrolled in EFFS plans dur-
2 ing March of the previous year; and
3 ''(II) the percentage, as esti-
4 mated by the Administrator, of Medi-
5 care Advantage eligible individuals in
6 the United States who are enrolled in
7 Medicare Advantage plans during
8 March of the previous year.
9 ''(ii) EXCEPTION.—In the case of an
10 EFFS region that was a competitive
11 EFFS region for the previous year, the
12 Medicare Benefits Administrator may con-
13 tinue to treat the region as meeting the re-
14 quirement of subparagraph (A)(ii) if the
15 region would meet such requirement but
16 for a de minimis reduction below the per-
17 centage specified in clause (i).
18 ''(2) COMPETITIVE EFFS NON-DRUG MONTHLY
19 BENCHMARK AMOUNT.—For purposes of this part,
20 the term 'competitive EFFS non-drug monthly
21 benchmark amount' means, with respect to an
22 EFFS region for a month in a year and subject to
23 paragraph (8), the sum of the 2 components de-
24 scribed in paragraph (3) for the region and year.
25 The Administrator shall compute such benchmark

1 amount for each competitive EFFS region before the
2 beginning of each annual, coordinated election pe-
3 riod under section 1851(e)(3)(B) for each year (be-
4 ginning with 2010) in which it is designated as such
5 a region.

6 "(3) 2 COMPONENTS.—For purposes of para-
7 graph (2), the 2 components described in this para-
8 graph for an EFFS region and a year are the fol-
9 lowing:

10 "(A) EFFS COMPONENT.—The product of
11 the following:

12 "(i) WEIGHTED AVERAGE OF PLAN
13 BIDS IN REGION.—The weighted average of
14 the EFFS plan bids for the region and
15 year (as determined under paragraph
16 (4)(A)).

17 "(ii) NON-FFS MARKET SHARE.—1
18 minus the fee-for-service market share per-
19 centage determined under paragraph (5)
20 for the region and the year.

21 "(B) FEE-FOR-SERVICE COMPONENT.—
22 The product of the following:

23 "(i) FEE-FOR-SERVICE REGION-SPE-
24 CIFIC NON-DRUG AMOUNT.—The fee-for-
25 service region-specific non-drug amount (as

1 defined in paragraph (6)) for the region
2 and year.
3 "(ii) FEE-FOR-SERVICE MARKET
4 SHARE.—The fee-for-service market share
5 percentage (determined under paragraph
6 (5)) for the region and the year.
7 "(4) DETERMINATION OF WEIGHTED AVERAGE
8 EFFS PLAN BIDS FOR A REGION.—
9 "(A) IN GENERAL.—For purposes of para-
10 graph (3)(A)(i), the weighted average of EFFS
11 plan bids for an EFFS region and a year is the
12 sum of the following products for EFFS plans
13 described in subparagraph (C) in the region
14 and year:
15 "(i) UNADJUSTED EFFS STATUTORY
16 NON-DRUG MONTHLY BID AMOUNT.—The
17 unadjusted EFFS statutory non-drug
18 monthly bid amount (as defined in sub-
19 section (a)(3)(A)(ii)(I)) for the region and
20 year.
21 "(ii) PLAN'S SHARE OF EFFS ENROLL-
22 MENT IN REGION.—The number of individ-
23 uals described in subparagraph (B), di-
24 vided by the total number of such individ-

1 uals for all EFFS plans described in sub-
2 paragraph (C) for that region and year.
3 "(B) COUNTING OF INDIVIDUALS.—The
4 Administrator shall count, for each EFFS plan
5 described in subparagraph (C) for an EFFS re-
6 gion and year, the number of individuals who
7 reside in the region and who were enrolled
8 under such plan under this part during March
9 of the previous year.
10 "(C) EXCLUSION OF PLANS NOT OFFERED
11 IN PREVIOUS YEAR.—For an EFFS region and
12 year, the EFFS plans described in this sub-
13 paragraph are plans that are offered in the re-
14 gion and year and were offered in the region in
15 March of the previous year.
16 "(5) COMPUTATION OF FEE-FOR-SERVICE MAR-
17 KET SHARE PERCENTAGE.—The Administrator shall
18 determine, for a year and an EFFS region, the pro-
19 portion (in this subsection referred to as the 'fee-for-
20 service market share percentage') of the EFFS eligi-
21 ble individuals who are residents of the region dur-
22 ing March of the previous year, of such individuals
23 who were not enrolled in an EFFS plan or in a
24 Medicare Advantage plan (or, if greater, such pro-
25 portion determined for individuals nationally).

1 "(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-
2 DRUG AMOUNT.—
3 "(A) IN GENERAL.—For purposes of para-
4 graph (3)(B)(i) and section 1839(h)(2)(A), sub-
5 ject to subparagraph (C), the term 'fee-for-serv-
6 ice region-specific non-drug amount' means, for
7 a competitive EFFS region and a year, the ad-
8 justed average per capita cost for the year in-
9 volved, determined under section 1876(a)(4) for
10 such region for services covered under parts A
11 and B for individuals entitled to benefits under
12 part A and enrolled under this part who are not
13 enrolled in an EFFS plan under part E or a
14 Medicare Advantage plan under part C for the
15 year, but adjusted to exclude costs attributable
16 to payments under section 1886(h).
17 "(B) USE OF FULL RISK ADJUSTMENT TO
18 STANDARDIZE FEE-FOR-SERVICE COSTS TO TYP-
19 ICAL BENEFICIARY.—In determining the ad-
20 justed average per capita cost for a region and
21 year under subparagraph (A), such costs shall
22 be adjusted to fully take into account the demo-
23 graphic and health status risk factors estab-
24 lished under subsection (c)(3) so that such per

capita costs reflect the average costs for a typical beneficiary residing in the region.

"(C) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the region involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

"(7) APPLICATION OF COMPETITION.—In the case of an EFFS region that is a competitive EFFS region for a year, for purposes of applying subsections (b) and (c)(1) and section 1860E–4(a), any reference to an EFFS region-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive EFFS non-drug monthly benchmark amount under paragraph (2) for the region and year.

1 "(8) PHASE-IN OF BENCHMARK FOR EACH RE-
2 GION.—
3 "(A) USE OF BLENDED BENCHMARK.—In
4 the case of a region that has not been a com-
5 petitive EFFS region for each of the previous
6 4 years, the competitive EFFS non-drug
7 monthly benchmark amount shall be equal to
8 the sum of the following:
9 "(i) NEW COMPETITIVE COMPO-
10 NENT.—The product of—
11 "(I) the weighted average phase-
12 in proportion for that area and year,
13 as specified in subparagraph (B); and
14 "(II) the competitive EFFS non-
15 drug monthly benchmark amount for
16 the region and year, determined under
17 paragraph (2) without regard to this
18 paragraph.
19 "(ii) OLD COMPETITIVE COMPO-
20 NENT.—The product of—
21 "(I) 1 minus the weighted aver-
22 age phase-in proportion for that re-
23 gion and year; and

"(II) the EFFS region-specific non-drug benchmark amount for the region and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for an EFFS region for a year shall be determined as follows:

"(i) FIRST YEAR (AND REGION NOT COMPETITIVE REGION IN PREVIOUS YEAR).—If the area was not a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to ⅕.

"(ii) COMPETITIVE REGION IN PREVIOUS YEAR.—If the region was a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to the weighted average phase-in proportion determined under this subparagraph for the region for the previous year plus ⅕, but in no case more than 1.".

(2) CONFORMING AMENDMENTS.—

(A) Such section 1860E–3 is further amended—

(i) in subsection (b), by adding at the end the following new paragraph:

"(4) APPLICATION IN COMPETITIVE REGIONS.—For special rules applying this subsection in competitive EFFS regions, see subsection (e)(7).";

(ii) in subsection (c)(1), by inserting "and subsection (e)(7)" after "(as made applicable under subsection (d))"; and

(iii) in subsection (d) , by striking "and (e)" and inserting "(e), and (k) ".

(B) Section 1860E–4(a)(1), as inserted by section 201(a)(2), is amended by inserting ", except as provided in section 1860E–3(e)(7)" after "paragraph (2)".

(b) IDENTIFICATION OF COMPETITIVE MEDICARE ADVANTAGE AREAS; APPLICATION OF COMPETITIVE MEDICARE ADVANTAGE NON-DRUG BENCHMARKS UNDER MEDICARE ADVANTAGE PROGRAM.—

(1) IN GENERAL.—Section 1853, as amended by section 221(b)(3), is amended by adding at the end the following new subsection:

"(k) APPLICATION OF COMPETITION.—

1 "(1) DETERMINATION OF COMPETITIVE MEDI-
2 CARE ADVANTAGE AREAS.—
3 "(A) IN GENERAL.—For purposes of this
4 part, the terms 'competitive Medicare Advan-
5 tage area' and 'CMA area' mean, for a year be-
6 ginning with 2010, an area (which is a metro-
7 politan statistical area or other area with a sub-
8 stantial number of Medicare Advantage enroll-
9 ees) that the Administrator finds—
10 "(i) there will be offered during the
11 annual, coordinated election period under
12 section 1851(e)(3)(B) under this part be-
13 fore the beginning of the year at least 2
14 Medicare Advantage plans (in addition to
15 the fee-for-service program under parts A
16 and B), each offered by a different Medi-
17 care Advantage organization and each of
18 which met the minimum enrollment re-
19 quirements of paragraph (1) of section
20 1857(b) (as applied without regard to
21 paragraph (3) thereof) as of March of the
22 previous year with respect to the area; and
23 "(ii) during March of the previous
24 year at least the percentage specified in
25 subparagraph (B) of the number of Medi-

1 care Advantage eligible individuals who re-
2 side in the area were enrolled in a Medi-
3 care Advantage plan.
4 "(B) PERCENTAGE SPECIFIED.—
5 "(i) IN GENERAL.—For purposes of
6 subparagraph (A), subject to clause (ii),
7 the percentage specified in this subpara-
8 graph for a year is equal the lesser of 20
9 percent or to the sum of—
10 "(I) the percentage, as estimated
11 by the Administrator, of EFFS eligi-
12 ble individuals in the United States
13 who are enrolled in EFFS plans dur-
14 ing March of the previous year; and
15 "(II) the percentage, as esti-
16 mated by the Administrator, of Medi-
17 care Advantage eligible individuals in
18 the United States who are enrolled in
19 Medicare Advantage plans during
20 March of the previous year.
21 "(ii) EXCEPTION.—In the case of an
22 area that was a competitive area for the
23 previous year, the Medicare Benefits Ad-
24 ministrator may continue to treat the area
25 as meeting the requirement of subpara-

1 graph (A)(ii) if the area would meet such
2 requirement but for a de minimis reduction
3 below the percentage specified in clause (i).
4 "(2) COMPETITIVE MEDICARE ADVANTAGE
5 NON-DRUG MONTHLY BENCHMARK AMOUNT.—For
6 purposes of this part, the term 'competitive Medi-
7 care Advantage non-drug monthly benchmark
8 amount' means, with respect to a competitive Medi-
9 care Advantage area for a month in a year subject
10 to paragraph (8), the sum of the 2 components de-
11 scribed in paragraph (3) for the area and year. The
12 Administrator shall compute such benchmark
13 amount for each competitive Medicare Advantage
14 area before the beginning of each annual, coordi-
15 nated election period under section 1851(e)(3)(B)
16 for each year (beginning with 2010) in which it is
17 designated as such an area.
18 "(3) 2 COMPONENTS.—For purposes of para-
19 graph (2), the 2 components described in this para-
20 graph for a competitive Medicare Advantage area
21 and a year are the following:
22 "(A) MEDICARE ADVANTAGE COMPO-
23 NENT.—The product of the following:
24 "(i) WEIGHTED AVERAGE OF MEDI-
25 CARE ADVANTAGE PLAN BIDS IN AREA.—

1 The weighted average of the plan bids for
2 the area and year (as determined under
3 paragraph (4)(A)).
4 "(ii) NON-FFS MARKET SHARE.—1
5 minus the fee-for-service market share per-
6 centage, determined under paragraph (5)
7 for the area and year.
8 "(B) FEE-FOR-SERVICE COMPONENT.—
9 The product of the following:
10 "(i) FEE-FOR-SERVICE AREA-SPECIFIC
11 NON-DRUG AMOUNT.—The fee-for-service
12 area-specific non-drug amount (as defined
13 in paragraph (6)) for the area and year.
14 "(ii) FEE-FOR-SERVICE MARKET
15 SHARE.—The fee-for-service market share
16 percentage, determined under paragraph
17 (5) for the area and year.
18 "(4) DETERMINATION OF WEIGHTED AVERAGE
19 MEDICARE ADVANTAGE BIDS FOR AN AREA.—
20 "(A) IN GENERAL.—For purposes of para-
21 graph (3)(A)(i), the weighted average of plan
22 bids for an area and a year is the sum of the
23 following products for Medicare Advantage
24 plans described in subparagraph (C) in the area
25 and year:

1 "(i) MONTHLY MEDICARE ADVANTAGE
2 STATUTORY NON-DRUG BID AMOUNT.—The
3 unadjusted Medicare Advantage statutory
4 non-drug monthly bid amount.
5 "(ii) PLAN'S SHARE OF MEDICARE AD-
6 VANTAGE ENROLLMENT IN AREA.—The
7 number of individuals described in sub-
8 paragraph (B), divided by the total num-
9 ber of such individuals for all Medicare Ad-
10 vantage plans described in subparagraph
11 (C) for that area and year.
12 "(B) COUNTING OF INDIVIDUALS.—The
13 Administrator shall count, for each Medicare
14 Advantage plan described in subparagraph (C)
15 for an area and year, the number of individuals
16 who reside in the area and who were enrolled
17 under such plan under this part during March
18 of the previous year.
19 "(C) EXCLUSION OF PLANS NOT OFFERED
20 IN PREVIOUS YEAR.—For an area and year, the
21 Medicare Advantage plans described in this
22 subparagraph are plans described in the first
23 sentence of section 1851(a)(2)(A) that are of-
24 fered in the area and year and were offered in
25 the area in March of the previous year.

1 "(5) COMPUTATION OF FEE-FOR-SERVICE MAR-
2 KET SHARE PERCENTAGE.—The Administrator shall
3 determine, for a year and a competitive Medicare
4 Advantage area, the proportion (in this subsection
5 referred to as the 'fee-for-service market share per-
6 centage') of Medicare Advantage eligible individuals
7 residing in the area who during March of the pre-
8 vious year were not enrolled in a Medicare Advan-
9 tage plan or in an EFFS plan (or, if greater, such
10 proportion determined for individuals nationally).
11 "(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-
12 DRUG AMOUNT.—
13 "(A) IN GENERAL.—For purposes of para-
14 graph (3)(B)(i) and section 1839(h)(1)(A), sub-
15 ject to subparagraph (C), the term 'fee-for-serv-
16 ice area-specific non-drug amount' means, for a
17 competitive Medicare Advantage area and a
18 year, the adjusted average per capita cost for
19 the year involved, determined under section
20 1876(a)(4) for such area for services covered
21 under parts A and B for individuals entitled to
22 benefits under part A and enrolled under this
23 part who are not enrolled in a Medicare Advan-
24 tage plan under part C or an EFFS plan under
25 part E for the year, but adjusted to exclude

1 costs attributable to payments under section
2 1886(h).
3 "(B) USE OF FULL RISK ADJUSTMENT TO
4 STANDARDIZE FEE-FOR-SERVICE COSTS TO TYP-
5 ICAL BENEFICIARY.—In determining the ad-
6 justed average per capita cost for an area and
7 year under subparagraph (A), such costs shall
8 be adjusted to fully take into account the demo-
9 graphic and health status risk factors estab-
10 lished under subsection (a)(1)(A)(iv) so that
11 such per capita costs reflect the average costs
12 for a typical beneficiary residing in the area.
13 "(C) INCLUSION OF COSTS OF VA AND DOD
14 MILITARY FACILITY SERVICES TO MEDICARE-
15 ELIGIBLE BENEFICIARIES.—In determining the
16 adjusted average per capita cost under subpara-
17 graph (A) for a year, such cost shall be ad-
18 justed to include the Administrator's estimate,
19 on a per capita basis, of the amount of addi-
20 tional payments that would have been made in
21 the area involved under this title if individuals
22 entitled to benefits under this title had not re-
23 ceived services from facilities of the Department
24 of Veterans Affairs or the Department of De-
25 fense.

1 "(7) APPLICATION OF COMPETITION.—In the
2 case of an area that is a competitive Medicare Ad-
3 vantage area for a year, for purposes of applying
4 subsection (a)(1)(A)(ii) and sections
5 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any ref-
6 erence to a Medicare Advantage area-specific non-
7 drug monthly benchmark amount shall be treated as
8 a reference to the competitive Medicare Advantage
9 non-drug monthly benchmark amount under para-
10 graph (2) for the area and year.
11 "(8) PHASE-IN OF BENCHMARK FOR EACH
12 AREA.—
13 "(A) USE OF BLENDED BENCHMARK.—In
14 the case of an area that has not been a com-
15 petitive Medicare Advantage area for each of
16 the previous 4 years, the competitive Medicare
17 Advantage non-drug monthly benchmark
18 amount shall be equal to the sum of the fol-
19 lowing:
20 "(i) NEW COMPETITIVE COMPO-
21 NENT.—The product of—
22 "(I) the weighted average phase-
23 in proportion for that area and year,
24 as specified in subparagraph (B); and

1 "(II) the competitive Medicare
2 Advantage non-drug monthly bench-
3 mark amount for the area and year,
4 determined under paragraph (2) with-
5 out regard to this paragraph.
6 "(ii) OLD COMPETITIVE COMPO-
7 NENT.—The product of—
8 "(I) 1 minus the weighted aver-
9 age phase-in proportion for that area
10 and year; and
11 "(II) the Medicare Advantage
12 area-wide non-drug benchmark
13 amount for the area and the year.
14 "(B) COMPUTATION OF WEIGHTED AVER-
15 AGE PHASE-IN PROPORTION.—For purposes of
16 this paragraph, the 'weighted average phase-in
17 proportion' for a Medicare Advantage payment
18 area for a year shall be determined as follows:
19 "(i) FIRST YEAR (AND AREA NOT
20 COMPETITIVE AREA IN PREVIOUS YEAR).—
21 If the area was not a Medicare Advantage
22 competitive area in the previous year, the
23 weighted average phase-in proportion for
24 the area for the year is equal to ⅕.

1 "(ii) COMPETITIVE AREA IN PREVIOUS
2 YEAR.—If the area was a competitive
3 Medicare Advantage area in the previous
4 year, the weighted average phase-in pro-
5 portion for the area for the year is equal
6 to the weighted average phase-in propor-
7 tion determined under this subparagraph
8 for the area for the previous year plus ⅕,
9 but in no case more than 1.
10 "(C) MEDICARE ADVANTAGE AREA-WIDE
11 NON-DRUG BENCHMARK AMOUNT.—For pur-
12 poses of subparagraph (A)(ii)(II), the term
13 'Medicare Advantage area-wide non-drug bench-
14 mark amount' means, for an area and year, the
15 weighted average of the amounts described in
16 section 1853(j) for Medicare Advantage pay-
17 ment area or areas included in the area (based
18 on the number of traditional fee-for-service en-
19 rollees in such payment area or areas) and
20 year.".
21 (2) APPLICATION.—Section 1854 (42 U.S.C.
22 1395w–24) is amended—
23 (A) in subsection (b)(1)(C)(i), as added by
24 section 221(b)(1)(A), by striking "(i) REQUIRE-
25 MENT.—The" and inserting "(i) REQUIREMENT

1 FOR NON-COMPETITIVE AREAS.—In the case of
2 a Medicare Advantage payment area that is not
3 a competitive Medicare Advantage area des-
4 ignated under section 1853(k)(1), the'';
5 (B) in subsection (b)(1)(C), as so added,
6 by inserting after clause (i) the following new
7 clause:
8 ''(ii) REQUIREMENT FOR COMPETI-
9 TIVE MEDICARE ADVANTAGE AREAS.—In
10 the case of a Medicare Advantage payment
11 area that is designated as a competitive
12 Medicare Advantage area under section
13 1853(k)(1), if there are average per capita
14 monthly savings described in paragraph
15 (6) for a Medicare Advantage plan and
16 year, the Medicare Advantage plan shall
17 provide to the enrollee a monthly rebate
18 equal to 75 percent of such savings.''; and
19 (C) by adding at the end of subsection (b),
20 as amended by sections 221(b)(1)(B) and
21 221(b)(2), the following new paragraph:
22 ''(6) COMPUTATION OF AVERAGE PER CAPITA
23 MONTHLY SAVINGS FOR COMPETITIVE MEDICARE
24 ADVANTAGE AREAS.—For purposes of paragraph
25 (1)(C)(ii), the average per capita monthly savings

1 referred to in such paragraph for a Medicare Advan-
2 tage plan and year shall be computed in the same
3 manner as the average per capita monthly savings is
4 computed under paragraph (3) except that the ref-
5 erence to the Medicare Advantage area-specific non-
6 drug monthly benchmark amount in paragraph
7 (3)(B)(i) (or to the benchmark amount as adjusted
8 under paragraph (3)(C)(i)) is deemed to be a ref-
9 erence to the competitive Medicare Advantage non-
10 drug monthly benchmark amount (or such amount
11 as adjusted in the manner described in paragraph
12 (3)(B)(i)).''.
13 (3) ADDITIONAL CONFORMING AMENDMENTS.—
14 (A) PAYMENT OF PLANS.—Section
15 1853(a)(1)(A)(ii), as amended by section
16 221(c)(1), is amended—
17 (i) in subclauses (I) and (II), by in-
18 serting ''(or, insofar as such payment area
19 is a competitive Medicare Advantage area,
20 described in section 1854(b)(6))'' after
21 ''section 1854(b)(3)(C)''; and
22 (ii) in subclause (II), by inserting
23 ''(or, insofar as such payment area is a
24 competitive Medicare Advantage area, the
25 competitive Medicare Advantage non-drug

1 monthly benchmark amount)'' after ''Medi-
2 care Advantage area-specific non-drug
3 monthly benchmark amount''; and
4 (B) DISCLOSURE OF INFORMATION.—Sec-
5 tion 1853(b)(1)(B), as amended by section
6 221(e)(1), is amended to read as follows:
7 ''(B) COMPETITION INFORMATION.—For
8 years beginning with 2006, the following:
9 ''(i) BENCHMARKS.—The Medicare
10 Advantage area-specific non-drug bench-
11 mark under section 1853(j) and, if applica-
12 ble, the competitive Medicare Advantage
13 non-drug benchmark under section
14 1853(k)(2), for the year and competitive
15 Medicare Advantage area involved and the
16 national fee-for-service market share per-
17 centage for the area and year.
18 ''(ii) ADJUSTMENT FACTORS.—The
19 adjustment factors applied under section
20 1853(a)(1)(A)(iv) (relating to demographic
21 adjustment), section 1853(a)(1)(B) (relat-
22 ing to adjustment for end-stage renal dis-
23 ease), and section 1853(a)(3) (relating to
24 health status adjustment).

1 "(iii) CERTAIN BENCHMARKS AND
2 AMOUNTS.—In the case of a competitive
3 Medicare Advantage area, the Medicare
4 Advantage area-wide non-drug benchmark
5 amount (as defined in subsection
6 (k)(8)(C)) and the fee-for-service area-spe-
7 cific non-drug amount (as defined in sec-
8 tion 1853(k)(6)) for the area.
9 "(iv) INDIVIDUALS.—The number of
10 individuals counted under subsection
11 (k)(4)(B) and enrolled in each Medicare
12 Advantage plan in the area.".
13 (C) DEFINITION OF MONTHLY BASIC PRE-
14 MIUM.—Section 1854(b)(2)(A)(ii), as amended
15 by section 221(d)(2), is amended by inserting
16 "(or, in the case of a competitive Medicare Ad-
17 vantage area, the competitive Medicare Advan-
18 tage non-drug monthly benchmark amount or,
19 in applying this paragraph under part E in the
20 case of a competitive EFFS region, the com-
21 petitive EFFS non-drug monthly benchmark
22 amount)" after "benchmark amount".
23 (c) PREMIUM ADJUSTMENT.—

1 (1) IN GENERAL.—Section 1839 (42 U.S.C.
2 1395r) is amended by adding at the end the fol-
3 lowing new subsection:
4 "(h)(1)(A) In the case of an individual who resides
5 in a competitive Medicare Advantage area under section
6 1853(k)(1) (regardless of whether such area is in a com-
7 petitive EFFS region under section 1860E–3(e)) and who
8 is not enrolled in a Medicare Advantage plan under part
9 C or in an EFFS plan under part E, the monthly premium
10 otherwise applied under this part (determined without re-
11 gard to subsections (b) and (f) or any adjustment under
12 this subsection) shall be adjusted as follows: If the fee-
13 for-service area-specific non-drug amount (as defined in
14 section 1853(k)(6)) for the competitive Medicare Advan-
15 tage area in which the individual resides for a month—
16 "(i) does not exceed the competitive Medicare
17 Advantage non-drug benchmark (as determined
18 under paragraph (2) of section 1853(k), without re-
19 gard to paragraph (8) thereof) for such area, the
20 amount of the premium for the individual for the
21 month shall be reduced by an amount equal to the
22 product of the adjustment factor under subpara-
23 graph (C) and 75 percent of the amount by which
24 such competitive benchmark exceeds such fee-for-
25 service area-specific non-drug amount; or

1 "(ii) exceeds such competitive Medicare Advan-
2 tage non-drug benchmark, the amount of the pre-
3 mium for the individual for the month shall be ad-
4 justed to ensure, subject to subparagraph (B),
5 that—
6 "(I) the sum of the amount of the adjusted
7 premium and the competitive Medicare Advan-
8 tage non-drug benchmark for the area, is equal
9 to
10 "(II) the sum of the unadjusted premium
11 plus amount of the fee-for-service area-specific
12 non-drug amount for the area.
13 "(B) In no case shall the actual amount of an adjust-
14 ment under subparagraph (A)(ii) exceed the product of
15 the adjustment factor under subparagraph (C) and the
16 amount of the adjustment otherwise computed under sub-
17 paragraph (A)(ii) without regard to this subparagraph.
18 "(C) The adjustment factor under this subparagraph
19 for an area for a year is equal to—
20 "(i) the number of consecutive years (in the 5-
21 year period ending with the year involved) in which
22 such area was a competitive Medicare Advantage
23 area; divided by
24 "(ii) 5.

1 "(2)(A) In the case of an individual who resides in
2 an area that is within a competitive EFFS region under
3 section 1860E–3(e) but is not within a competitive Medi-
4 care Advantage area under section 1853(k)(1) and who
5 is not enrolled in a Medicare Advantage plan under part
6 C or in an EFFS plan under part E, the monthly premium
7 otherwise applied under this part (determined without re-
8 gard to subsections (b) and (f) or any adjustment under
9 this subsection) shall be adjusted as follows: If the fee-
10 for-service region-specific non-drug amount (as defined in
11 section 1860E–3(e)(6)) for a region for a month—
12 "(i) does not exceed the competitive EFFS non-
13 drug monthly benchmark amount (as determined
14 under paragraph (2) of section 1860E–3(e), without
15 regard to paragraph (8) thereof) for such region, the
16 amount of the premium for the individual for the
17 month shall be reduced by an amount equal to the
18 product of the adjustment factor under subpara-
19 graph (C) and 75 percent of the amount by which
20 such competitive benchmark amount exceeds such
21 fee-for-service region-specific non-drug benchmark
22 amount; or
23 "(ii) exceeds such competitive EFFS non-drug
24 monthly benchmark amount, the amount of the pre-
25 mium for the individual for the month shall be ad-

1 justed to ensure, subject to subparagraph (B),
2 that—
3 "(I) the sum of the amount of the adjusted
4 premium and the competitive EFFS non-drug
5 monthly benchmark amount for the region, is
6 equal to
7 "(II) the sum of the unadjusted premium
8 plus the amount of the EFFS region-specific
9 non-drug monthly bidfor the region.
10 "(B) In no case shall the actual amount of an adjust-
11 ment under subparagraph (A)(ii) exceed the product of
12 the adjustment factor under subparagraph (C) and the
13 amount of the adjustment otherwise computed under sub-
14 paragraph (A)(ii) without regard to this subparagraph.
15 "(C) The adjustment factor under this subparagraph
16 for an EFFS region for a year is equal to—
17 "(i) the number of consecutive years (in the 5-
18 year period ending with the year involved) in which
19 such region was a competitive EFFS region; divided
20 by
21 "(ii) 5.
22 "(3) Nothing in this subsection shall be construed as
23 preventing a reduction under paragraph (1)(A) or para-
24 graph (2)(A) in the premium otherwise applicable under
25 this part to zero or from requiring the provision of a re-

1 bate to the extent such premium would otherwise be re-
2 quired to be less than zero.
3 ''(4) The adjustment in the premium under this sub-
4 section shall be effected in such manner as the Medicare
5 Benefits Administrator determines appropriate.
6 ''(5) In order to carry out this subsection (insofar as
7 it is effected through the manner of collection of premiums
8 under 1840(a)), the Medicare Benefits Administrator shall
9 transmit to the Commissioner of Social Security—
10 ''(A) at the beginning of each year, the name,
11 social security account number, and the amount of
12 the adjustment (if any) under this subsection for
13 each individual enrolled under this part for each
14 month during the year; and
15 ''(B) periodically throughout the year, informa-
16 tion to update the information previously trans-
17 mitted under this paragraph for the year.''.
18 (2) NO CHANGE IN MEDICARE'S DEFINED BEN-
19 EFIT PACKAGE.—Nothing in this part (or the
20 amendments made by this part) shall be construed
21 as changing the entitlement to defined benefits
22 under parts A and B of title XVIII of the Social Se-
23 curity Act.
24 (3) CONFORMING AMENDMENT.—Section
25 1844(c) (42 U.S.C. 1395w(c)) is amended by insert-

ing "and without regard to any premium adjustment effected under section 1839(h)" before the period at the end.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

(1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(A) in subparagraph (A)(ii), by striking "promptly (as determined in accordance with regulations)";

(B) in subparagraph (B)—

(i) by redesignating clauses (i) through (iii) as clauses (ii) through (iv), respectively; and

(ii) by inserting before clause (ii), as so redesignated, the following new clause:

1 "(i) AUTHORITY TO MAKE CONDI-
2 TIONAL PAYMENT.—The Secretary may
3 make payment under this title with respect
4 to an item or service if a primary plan de-
5 scribed in subparagraph (A)(ii) has not
6 made or cannot reasonably be expected to
7 make payment with respect to such item or
8 service promptly (as determined in accord-
9 ance with regulations). Any such payment
10 by the Secretary shall be conditioned on
11 reimbursement to the appropriate Trust
12 Fund in accordance with the succeeding
13 provisions of this subsection.".
14 (2) EFFECTIVE DATE.—The amendments made
15 by paragraph (1) shall be effective as if included in
16 the enactment of title III of the Medicare and Med-
17 icaid Budget Reconciliation Amendments of 1984
18 (Public Law 98-369).
19 (b) CLARIFYING AMENDMENTS TO CONDITIONAL
20 PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.
21 1395y(b)(2)) is further amended—
22 (1) in subparagraph (A), in the matter fol-
23 lowing clause (ii), by inserting the following sentence
24 at the end: "An entity that engages in a business,
25 trade, or profession shall be deemed to have a self-

1 insured plan if it carries its own risk (whether by a
2 failure to obtain insurance, or otherwise) in whole or
3 in part.'';
4 (2) in subparagraph (B)(ii), as redesignated by
5 subsection (a)(2)(B)—
6 (A) by striking the first sentence and in-
7 serting the following: ''A primary plan, and an
8 entity that receives payment from a primary
9 plan, shall reimburse the appropriate Trust
10 Fund for any payment made by the Secretary
11 under this title with respect to an item or serv-
12 ice if it is demonstrated that such primary plan
13 has or had a responsibility to make payment
14 with respect to such item or service. A primary
15 plan's responsibility for such payment may be
16 demonstrated by a judgment, a payment condi-
17 tioned upon the recipient's compromise, waiver,
18 or release (whether or not there is a determina-
19 tion or admission of liability) of payment for
20 items or services included in a claim against the
21 primary plan or the primary plan's insured, or
22 by other means.''; and
23 (B) in the final sentence, by striking ''on
24 the date such notice or other information is re-
25 ceived'' and inserting ''on the date notice of, or

information related to, a primary plan's responsibility for such payment or other information is received''; and

(3) in subparagraph (B)(iii), , as redesignated by subsection (a)(2)(B), by striking the first sentence and inserting the following: ''In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.''.

(c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking ''such'' before ''paragraphs''.

SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:

''COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

''SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

''(1) IMPLEMENTATION OF PROGRAMS.—

''(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

''(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in—

''(i) among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

1 "(I) at least ⅓ of such areas in
2 2005; and
3 "(II) at least ⅔ of such areas in
4 2006; and
5 "(ii) among items and services in a
6 manner such that the programs apply to
7 the highest cost and highest volume items
8 and services first.
9 "(C) WAIVER OF CERTAIN PROVISIONS.—
10 In carrying out the programs, the Secretary
11 may waive such provisions of the Federal Ac-
12 quisition Regulation as are necessary for the ef-
13 ficient implementation of this section, other
14 than provisions relating to confidentiality of in-
15 formation and such other provisions as the Sec-
16 retary determines appropriate.
17 "(2) ITEMS AND SERVICES DESCRIBED.—The
18 items and services referred to in paragraph (1) are
19 the following:
20 "(A) DURABLE MEDICAL EQUIPMENT AND
21 MEDICAL SUPPLIES.—Covered items (as defined
22 in section 1834(a)(13)) for which payment is
23 otherwise made under section 1834(a), includ-
24 ing items used in infusion and drugs and sup-
25 plies used in conjunction with durable medical

1 equipment, but excluding class III devices
2 under the Federal Food, Drug, and Cosmetic
3 Act.
4 "(B) OTHER EQUIPMENT AND SUP-
5 PLIES.—Items, equipment, and supplies (as de-
6 scribed in section 1842(s)(2)(D) other than en-
7 teral nutrients).
8 "(C) OFF-THE-SHELF ORTHOTICS.—
9 Orthotics (described in section 1861(s)(9)) for
10 which payment is otherwise made under section
11 1834(h) which require minimal self-adjustment
12 for appropriate use and does not require exper-
13 tise in trimming, bending, molding, assembling,
14 or customizing to fit to the patient.
15 "(3) EXCEPTION AUTHORITY.—In carrying out
16 the programs under this section, the Secretary may
17 exempt—
18 "(A) rural areas and areas with low popu-
19 lation density within urban areas that are not
20 competitive, unless there is a significant na-
21 tional market through mail order for a par-
22 ticular item or service; and
23 "(B) items and services for which the ap-
24 plication of competitive acquisition is not likely
25 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 QUISITION; 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

adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.''.

(c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Secretary shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

(d) GAO STUDY ON SAFE AND EFFECTIVE HOME INFUSION AND INHALATION THERAPY; STANDARDS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study of the standards, professional services, and related functions necessary for the provision of safe and effective home infusion therapy and home inhalation therapy.

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report 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(c)(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.''; and

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

5 ''(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR 2005.—

7 ''(i) IN GENERAL.—As part of the annual process of establishing the physician fee schedule under subsection (b) for 2005, the Secretary shall increase the practice expense relative value units for 2005 consistent with clauses (ii) and (iii).

13 ''(ii) USE OF SUPPLEMENTAL SURVEY DATA.—For 2005 for any specialty that submitted survey data that included expenses for the administration of drugs and biologicals for which payment is made under section 1842(o) (or section 1847A), the Secretary shall use such supplemental survey data in carrying out this subparagraph insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced

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 (c)(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

1848(c)(2)(C)(ii) of the Social Security Act so that the practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of other services not determined under such non-physician work pool methodology, as the result of amendments made by paragraph (1).

(b) PAYMENT BASED ON COMPETITION.—Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w–3), as amended by section 302, the following new sections:

"COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS

"SEC. 1847A. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

"(1) IMPLEMENTATION OF PROGRAM.—

"(A) IN GENERAL.—The Secretary shall establish and implement a competitive acquisition program under which—

"(i) competitive acquisition areas are established throughout the United States for contract award purposes for acquisition of and payment for categories of covered outpatient drugs and biologicals (as defined in paragraph (2)) under this part;

"(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program or under section 1847B; and

"(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

"(B) IMPLEMENTATION.—The Secretary shall implement the program so that the program applies to—

"(i) the oncology category beginning in 2005; and

"(ii) the non-oncology category beginning in 2006.

This section shall not apply in the case of a physician who elects section 1847B to apply.

"(C) WAIVER OF CERTAIN PROVISIONS.—In order to promote competition, efficient service, and product quality, in carrying out the 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

this section that will supply the drugs and biologicals within that category and area. Such selection shall also include the election described in section 1847B(a).

"(B) INFORMATION ON CONTRACTORS.—The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Department's Internet website or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

"(C) SELECTING PHYSICIAN DEFINED.—For purposes of this section, the term 'selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has not elected section 1847B to apply and has selected to apply under this section such contractor for such category and area.

"(b) PROGRAM REQUIREMENTS.—

"(1) CONTRACT FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—The Secretary shall conduct a competition among entities for the acquisition 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 METHOD-
25 OLOGY.—The entity has arrangements

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,
13 including—
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 immmunosuppressives 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

(such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.

"(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) computed as follows:

"(A) Compute the sum of the products (for each national drug code assigned to such drug products) of—

"(i) the manufacturer's average sales price (as defined in subsection (c)); and

"(ii) the total number of units specified under paragraph (2) sold, as reported under section 1927(b)(3)(A)(iii).

"(B) Divide the sum computed under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all national drug codes assigned to such drug products.

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 facturer, 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—

(A) in paragraph (1), by inserting ", subject to section 1847A and 1847B," before "the amount payable for the drug or biological"; and

(B) by adding at the end of paragraph (2) the following: "This paragraph shall not apply in the case of payment under section 1847A or 1847B.".

(2) NO CHANGE IN COVERAGE BASIS.—Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting "(or would have been so included but for the application of section 1847A or 1847B)" after "included in the physicians' bills".

(3) PAYMENT.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(or, if applicable, under section 1847A or 1847B)" after "1842(o)".

(4) CONSOLIDATED REPORTING OF PRICING INFORMATION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (a)(1), by inserting "or under part B of title XVIII" after "section 1903(a)";

(B) in subsection (b)(3)(A)—

(i) in clause (i), by striking "and" at the end;

(ii) in clause (ii), by striking the period and inserting "; and"; and

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

"(iii) for calendar quarters beginning on or after April 1, 2004, in conjunction with reporting required under clause (i) and by national drug code (NDC)—

"(I) the manufacturer's average sales price (as defined in section 1847B(c)) and the total number of units specified under section 1847B(b)(2)(A);

"(II) if required to make payment under section 1847B, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

"(III) information on those sales that were made at a nominal price or otherwise described in section 1847B(c)(2)(B), which information is subject to audit by the Inspector General of the Department of Health and Human Services;

for a covered outpatient drug or biological for which payment is made under section 1847B.";

(C) in subsection (b)(3)(B)—

(i) in the heading, by inserting "AND MANUFACTURER'S AVERAGE SALES PRICE" after "PRICE"; and

(ii) by inserting "and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment" after "manufacturer prices"; and

(D) in subsection (b)(3)(D)(i), by inserting "and section 1847B" after "this section".

(e) GAO STUDY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to assess the impact of the amendments made by this section on the delivery of services, including their impact on—

(A) beneficiary access to drugs and biologicals for which payment is made under part B of title XVIII of the Social Security Act; and

(B) the site of delivery of such services.

(2) REPORT.—Not later than 2 years after the 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

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking ''For purposes'' and inserting ''Subject to clause (xiv), for purposes''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to discharges occurring on or after October 1, 2003.

SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS.

(a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C. 1395ww(d)(3)(A)) is amended—

(1) in clause (iv), by inserting ''and ending on or before September 30, 2003,'' after ''October 1, 1995,''; and

(2) by redesignating clauses (v) and (vi) as clauses (vii) and (viii), respectively, and inserting after clause (iv) the following new clauses:

''(v) For discharges occurring in the fiscal year beginning on October 1, 2003, the average standardized amount for hospitals located in areas other than a large urban area shall be equal to the average standardized amount for hospitals located in a large urban area.''.

(b) CONFORMING AMENDMENTS.—

1 (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—

"(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

"(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.".

(2) TECHNICAL CONFORMING SUNSET.—Section 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting ", for fiscal years before fiscal year 1997," before "a regional adjusted DRG prospective payment rate"; and

(B) in subparagraph (D), in the matter preceding clause (i), by inserting ", for fiscal years before fiscal year 1997," before "a regional DRG prospective payment rate for each region,".

SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOSPITAL CLASSIFICATION.

(a) CLASSIFICATION.—Section 1861(mm) (42 U.S.C. 1395x(mm)) is amended—

(1) in the heading by adding "ESSENTIAL RURAL HOSPITALS" at the end; and

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 qualify 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 stablize 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 serting ''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) in subsection (c)(2)(B)(iii), by inserting "subject to paragraph (3)" after "(iii) provides";

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

"(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—

"(A) IN GENERAL.—Subject to subparagraph (C), in the case of a hospital that demonstrates that it meets the standards established under subparagraph (B) and has not made the election described in subsection (f)(2)(A), the bed limitations otherwise applicable under paragraph (2)(B)(iii) and subsection (f) shall be increased by 5 beds.

"(B) STANDARDS.—The Secretary shall specify standards for determining whether a critical access hospital has sufficiently strong seasonal variations in patient admissions to justify the increase in bed limitation provided under subparagraph (A)."; and

(3) in subsection (f)—

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

(B) by adding at the end the following new 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 vided for under subparagraph (A) for a fiscal
2 year exceed $25,000,000.''.
3 (2) CONFORMING AMENDMENT.—Section 1820
4 (42 U.S.C. 1395i–4) is amended by striking sub-
5 section (j).

6 **SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSI-**
7 **TIONS.**

8 (a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C.
9 1395ww(h)(4)) is amended—
10 (1) in subparagraph (F)(i), by inserting ''sub-
11 ject to subparagraph (I),'' after ''October 1, 1997,'';
12 (2) in subparagraph (H)(i), by inserting ''sub-
13 ject to subparagraph (I),'' after ''subparagraphs (F)
14 and (G),''; and
15 (3) by adding at the end the following new sub-
16 paragraph:
17 ''(I) REDISTRIBUTION OF UNUSED RESI-
18 DENT POSITIONS.—
19 ''(i) REDUCTION IN LIMIT BASED ON
20 UNUSED POSITIONS.—
21 ''(I) IN GENERAL.—If a hos-
22 pital's resident level (as defined in
23 clause (iii)(I)) is less than the other-
24 wise applicable resident limit (as de-
25 fined in clause (iii)(II)) for each of

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

otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.''.

(b) CONFORMING AMENDMENT TO IME.—Section 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended by adding at the end the following: ''The provisions of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentece of this clause in the same manner as it applies with respect to subparagraph (F) of such subsection.''.

(c) REPORT ON EXTENSION OF APPLICATIONS UNDER REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND SOLE COMMUNITY HOSPITALS UNDER PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.

(a) HOLD HARMLESS PROVISIONS.—

1 (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

urban providers of services, the Secretary shall provide for an appropriate adjustment under such section 1833(t) to reflect those higher costs by January 1, 2005.

SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended—

(1) in clause (i)(II), by striking ''clauses (ii) and (iii)'' and inserting ''clauses (ii), (iii), and (iv)''; and

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

''(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Services described in this clause are—

''(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

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))".

SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.

Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–486), as paragraph (9); and

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

"(10) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW MEDICARE POPULATION DENSITY AREAS.—

"(A) IN GENERAL.—In the case of ground ambulance services furnished on or after January 1, 2004, for which the transportation originates in a qualified rural area (as defined in subparagraph (B)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for the base rate in the lowest quartile as compared to the average cost for the base rate for such services that is in the highest quartile of all rural county populations.

"(B) QUALIFIED RURAL AREA DEFINED.—For purposes of subparagraph (A), the term 'qualified rural area' is a rural area (as defined in section 1886(d)(2)(D)) with a population density of medicare beneficiaries residing in the area that is in the lowest quartile of all rural county populations.".

SEC. 411. TWO-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during 2004 and 2005, the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

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

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.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) INTERIM FINAL EFFECT.—No later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1)(B). Such rule shall be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period of not more than 60 days) for public comment, as is consistent with this subsection.

SEC. 413. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for

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 curring 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 1395*l*) 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),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

"(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall periodically determine, for each county or equivalent area in the United States, the following:

"(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

"(i) primary care physicians; or

"(ii) physicians who are not primary care physicians.

"(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the 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

that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph; and

"(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph.

There is no administrative or judicial review respecting the identification of a county or area or the assignment of a specialty of any physician under this paragraph.

"(5) RURAL CENSUS TRACKS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed.

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 1395*l*(m)) is amended—

(A) by inserting "(1)" after "(m)"; and

(B) by adding at the end the following new paragraphs:

"(2) The Secretary shall establish procedures under which the Secretary, and not the physician furnishing the service, is responsible for determining when a payment is required to be made under paragraph (1).

"(3) In carrying out paragraph (1) for a year, the Secretary shall include, as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a health professional shortage area under paragraph (1) for the year involved.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to physicians' services furnished or after January 1, 2004.

SEC. 418. RURAL HOSPICE DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project for the delivery of hospice care to medicare beneficiaries in rural areas. Under the project medicare beneficiaries who are unable to receive hospice care in the home for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided

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.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended—

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

(2) by striking subclause (XIX); and

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

''(XIX) for each of fiscal years 2004 through 2006, the market basket percentage increase minus 0.4 percentage points for hospitals in all areas; and

''(XX) for fiscal year 2007 and each subsequent fiscal year, the market basket percentage increase for hospitals in all areas.''.

SEC. 502. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

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) in subparagraph (A)—

(A) in clause (i), by striking "for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)" and inserting "the applicable Puerto Rico percentage (specified in subparagraph (E))"; and

(B) in clause (ii), by striking "for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)" and inserting "the applicable Federal percentage (specified in subparagraph (E))"; and

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

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

"(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

"(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico 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
9 examine—

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.

Subtitle B—Other Provisions

SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

"(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

"(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable shall be increased by 128 percent to reflect increased costs associated with such residents.

"(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.".

(b) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2003.

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
5 amended—

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. l395f(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.

(d) CLERICAL ERROR DEFINED.—For purposes of this section, the term ''clerical error'' means the failure to have transferred the correct amount from the general fund to the Trust Fund, which failure occurred on April 15, 2001.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

SEC. 601. REVISION OF UPDATES FOR PHYSICIANS' SERVICES.

(a) UPDATE FOR 2004 AND 2005.—

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraph:

''(5) UPDATE FOR 2004 AND 2005.—The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.''.

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting ''and paragraph (5)'' after ''subparagraph (D)''.

(3) NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The amendments made by this 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.

SEC. 604. INCLUSION OF PODIATRISTS AND DENTISTS UNDER PRIVATE CONTRACTING AUTHORITY.

Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is amended by striking ''section 1861(r)(1)'' and inserting ''paragraphs (1), (2), and (3) of section 1861(r)''.

SEC. 605. ESTABLISHMENT OF FLOOR ON WORK GEOGRAPHIC ADJUSTMENT.

(a) MINIMUM INDEX.—Section 1848(e)(1) (42 U.S.C. 1395w–4(e)(1)) is amended by adding at the end the following new subparagraph:

''(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDEX.—

''(i) IN GENERAL.—Subject to clause (ii), after calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2006, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.

''(ii) SECRETARIAL DISCRETION.—Clause (i) shall have no force or effect in law if the Secretary determines, taking into account the report of the Comptroller 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.

(C) The appropriateness of establishing a floor of 1.0 for the work geographic index.

(2) REPORT.—By not later than September 1, 2004, the Comptroller General shall submit to Congress and to the Secretary a report on the evaluation conducted under paragraph (1).

Subtitle B—Preventive Services

SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (U), by striking ''and'' at the end;

(2) in subparagraph (V), by inserting ''and'' at the end; and

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

''(W) an initial preventive physical examination (as defined in subsection (ww));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Initial Preventive Physical Examination

''(ww) The term 'initial preventive physical examination' means physicians' services consisting of a physical

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(ww))''.

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(ww))'' 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(ww))'' 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.''.

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section 611(e), is amended—

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

(2) by striking the semicolon at the end of subparagraph (J) and inserting ''; and''; and

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

''(K) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(xx)(1)), which is performed more frequently than is covered under section 1861(xx)(2).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL CANCER SCREENING TESTS.

(a) IN GENERAL.—The first sentence of section 1833(b) (42 U.S.C. 1395*l*(b)), as amended by section 611(c)(1), is amended—

(1) by striking ''and'' before ''(7)''; and

(2) by inserting before the period at the end the following: '', and (8) such deductible shall not apply

with respect to colorectal cancer screening tests (as described in section 1861(pp)(1))''.

(b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii) and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are each amended—

(1) by striking ''DEDUCTIBLE AND'' in the heading; and

(2) in subclause (I), by striking ''deductible or'' each place it appears.

(c) EFFECTIVE DATE.—The amendment made by this section shall apply to items and services furnished on or after Janaury 1, 2004.

SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: ''and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

Subtitle C—Other Services

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.—

(1) MODIFICATION OF AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) by redesignating paragraph (13) as paragraph (14); and

(B) by inserting after paragraph (12) the following new paragraph:

"(13) DRUG APC PAYMENT RATES.—

"(A) IN GENERAL.—With respect to payment for covered OPD services that includes a specified covered outpatient drug (defined in subparagraph (B)), the amount provided for payment for such drug under the payment system under this subsection for services furnished in—

"(i) 2004, 2005, or 2006, shall in no case—

"(I) exceed 95 percent of the average wholesale price for the drug; or

"(II) be less than the transition percentage (under subparagraph (C))

of the average wholesale price for the drug; or

"(ii) a subsequent year, shall be equal to the average price for the drug for that area and year established under the competitive acquisition program under section 1847A as calculated and applied by the Secretary for purposes of this paragraph.

"(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

"(i) IN GENERAL.—In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in 1927(k)(2), that is—

"(I) a radiopharmaceutical; or

"(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

"(ii) EXCEPTION.—Such term does not include—

"(I) a drug for which payment is first made on or after January 1, 2003, under paragraph (6); or

"(II) a drug for a which a temporary HCPCS code has not been assigned.

"(C) TRANSITION TOWARDS HISTORICAL AVERAGE ACQUISITION COST.—The transition percentage under this subparagraph for drugs furnished in a year is determined in accordance with the following table:

For the year—	The transition percentage for—		
	Single source drugs are—	Innovator multiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	46%

"(D) PAYMENT FOR NEW DRUGS UNTIL TEMPORARY HCPCS CODE ASSIGNED.—With respect to payment for covered OPD services that includes a covered outpatient drug (as defined in 1927(k)) for a which a temporary HCPCS code has not been assigned, the amount provided for payment for such drug under the payment system under this subsection shall be equal to 95 percent of the average wholesale price for the drug.

"(E) CLASSES OF DRUGS.—For purposes of this paragraph, each of the following shall be treated as a separate class of drugs:

"(i) SOLE SOURCE DRUGS.—A sole source drug which for purposes of this paragraph means a drug or biological that is not a multiple source drug (as defined in subclauses (I) and (II) of section 1927(k)(7)(A)(i)) and is not a drug approved under an abbreviated new drug application under section 355(j) of the Federal Food, Drug, and Cosmetic Act.

"(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—Innovator multiple source drugs (as defined in section 1927(k)(7)(A)(ii)).

"(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—Noninnovator multiple source drugs (as defined in section 1927(k)(7)(A)(iii)).

"(F) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION FACTORS.—Additional expenditures resulting from this paragraph and paragraph (14)(C) in a year shall not be taken into account in establishing the conversion factor for that year.".

1 (2) REDUCTION IN THRESHOLD FOR SEPARATE
2 APCS FOR DRUGS.—Section 1833(t)(14), as redesig-
3 nated by paragraph (1)(A), is amended by adding at
4 the end the following new subparagraph:
5 "(B) THRESHOLD FOR ESTABLISHMENT
6 OF SEPARATE APCS FOR DRUGS.—The Sec-
7 retary shall reduce the threshold for the estab-
8 lishment of separate ambulatory payment clas-
9 sification groups (APCs) with respect to drugs
10 to $50 per administration.".
11 (3) EXCLUSION OF SEPARATE DRUG APCS FROM
12 OUTLIER PAYMENTS.—Section 1833(t)(5) is amend-
13 ed by adding at the end the following new subpara-
14 graph:
15 "(E) EXCLUSION OF SEPARATE DRUG
16 APCS FROM OUTLIER PAYMENTS.—No addi-
17 tional payment shall be made under subpara-
18 graph (A) in the case of ambulatory procedure
19 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 con-
25 tract under section 1847A for an area, an amount

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 (5) EFFECTIVE DATE.—The amendments made
6 by this subsection shall apply to services furnished
7 on or after January 1, 2004.
8 (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—
9 (1) IN GENERAL.—Section 1833(t)(14), as so
10 redesignated and amended by subsection (a)(2), is
11 amended by adding at the end the following new
12 subparagraph:
13 ''(C) PAYMENT FOR DEVICES OF
14 BRACHYTHERAPY AT CHARGES ADJUSTED TO
15 COST.—Notwithstanding the preceding provi-
16 sions of this subsection, for a device of
17 brachytherapy furnished on or after January 1,
18 2004, and before January 1, 2007, the payment
19 basis for the device under this subsection shall
20 be equal to the hospital's charges for each de-
21 vice furnished, adjusted to cost.''.
22 (2) SPECIFICATION OF GROUPS FOR
23 BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42
24 U.S.C. 1395l(t)(2) is amended—

(A) in subparagraph (F), by striking "and" at the end;

(B) in subparagraph (G), by striking the period at the end and inserting "; and"; and

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

"(H) with respect to devices of brachytherapy, the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.".

(3) GAO REPORT.—The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(t)(13)(B) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.

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 handing 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 ¼ 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

on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule (under section 1834(l) of the Social Security Act, as amended by this section). Not later than December 31, 2007, the Comptroller General shall submit to Congress a final report on such access and supply.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to ambulance services furnished on or after January 1, 2004.

SEC. 623. RENAL DIALYSIS SERVICES.

(a) DEMONSTRATION OF ALTERNATIVE DELIVERY MODELS.—

(1) USE OF ADVISORY BOARD.—In carrying out the demonstration project relating to improving care for people with end-stage renal disease through alternative delivery models (as published in the Federal Register of June 4, 2003), the Secretary shall establish an advisory board comprised of representatives described in paragraph (2) to provide advice and recommendations with respect to the establishment and operation of such demonstration project.

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—

(A) in subparagraph (A), by striking ''and (C)'' and inserting '', (C), and (D)'';

(B) in subparagraph (B), by striking ''In the case'' and inserting ''Subject to subparagraph (D), in the case''; and

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

''(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.''.

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amended by subsection (b), is further amended by striking ''Until'' and inserting ''Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and until''.

(c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED IN 2004.—Notwithstanding

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

under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS.

Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended in the last sentence by inserting ''and each of fiscal years 2004 through 2008'' after ''In each of the fiscal years 1998 through 2002''.

SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS UNDER THE FEE SCHEDULE FOR ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o)) is amended—

(1) in paragraph (1), by striking ''no more than the limits established under paragraph (2)'' and inserting ''no more than the amount of payment applicable under paragraph (2)''; and

(2) in paragraph (2), to read as follows:

''(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

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) by striking ''1991 and'' and inserting ''1991,''; and

(2) by striking ''and subsequent years'' and inserting ''and each subsequent year through 2003, and for a subsequent year after 2003 the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1)''.

SEC. 629. EXTENSION OF COVERAGE OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) FOR THE TREATMENT OF PRIMARY IMMUNE DEFICIENCY DISEASES IN THE HOME.

(a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as amended by sections 611(a) and 612(a) is amended—

(1) in subsection (s)(2)—

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

(B) by adding ''and'' at the end of subparagraph (X); and

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

''(Y) intravenous immune globulin for the treatment of primary immune deficiency dis-

1 eases in the home (as defined in subsection
2 (yy));''; and
3 (2) by adding at the end the following new sub-
4 section:
5 ''Intravenous Immune Globulin
6 ''(yy) The term 'intravenous immune globulin' means
7 an approved pooled plasma derivative for the treatment
8 in the patient's home of a patient with a diagnosed pri-
9 mary immune deficiency disease, but not including items
10 or services related to the administration of the derivative,
11 if a physician determines administration of the derivative
12 in the patient's home is medically appropriate.''.
13 (b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section
14 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by
15 inserting ''(including intravenous immune globulin (as de-
16 fined in section 1861(yy)))'' after ''with respect to drugs
17 and biologicals''.
18 (c) EFFECTIVE DATE.—The amendments made by
19 this section shall apply to items furnished administered
20 on or after January 1, 2004.
21 **SEC. 630. MEDICARE COVERAGE OF DIABETES LABORA-**
22 **TORY DIAGNOSTIC TESTS.**
23 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
24 1395x(s)(2)), as amended by sections 611 and 612, is
25 amended—

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

(2) by striking the semicolon at the end of subparagraph (K) and inserting ''; and''; and

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

''(L) in the case of a diabetes screening tests or service (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after the date that is 90 days after the date of enactment of this Act.

SEC. 631. DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN PRESCRIPTION DRUGS AND BIOLOGICS.

(a) DEMONSTRATION PROJECT.—The Secretary shall conduct a demonstration project under part B of title XVIII of the Social Security Act under which payment is made for drugs or biologics that are prescribed as replacements for drugs and biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q) of such Act (42 U.S.C. 1395x(s)(2)(A), 1395x(s)(2)(Q))), or both, for which payment is made under such part.

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.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 701. UPDATE IN HOME HEALTH SERVICES.

(a) CHANGE TO CALENDER YEAR UPDATE.—

(1) IN GENERAL.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

(A) in paragraph (3)(B)(i)—

(i) by striking ''each fiscal year (beginning with fiscal year 2002)'' and inserting ''fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004)''; and

(ii) by inserting ''or year'' after ''the fiscal year'';

(B) in paragraph (3)(B)(ii)(II), by striking ''any subsequent fiscal year'' and inserting ''2004 and any subsequent year'';

(C) in paragraph (3)(B)(iii), by inserting ''or year'' after ''fiscal year'' each place it appears;

(D) in paragraph (3)(B)(iv)—

(i) by inserting ''or year'' after ''fiscal year'' each place it appears; and

(ii) by inserting ''or years'' after ''fiscal years''; and

(E) in paragraph (5), by inserting ''or year'' after ''fiscal year''.

(2) TRANSITION RULE.—The standard prospective payment amount (or amounts) under section 1895(b)(3) of the Social Security Act for the calendar quarter beginning on October 1, 2003, shall be such amount (or amounts) for the previous calendar quarter.

(b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B), is amended—

(1) by striking ''or'' at the end of subclause (I);

(2) by redesignating subclause (II) as subclause (III);

(3) in subclause (III), as so redesignated, by striking ''2004'' and inserting ''2007''; and

(4) by inserting after subclause (I) the following new subclause:

''(II) each of 2004, 2005, and 2006 the home health market basket percentage increase minus 0.4 percentage points; or''.

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".

(2) Section 1866(a)(2)(A)(i) (42 U.S.C. 1395cc(a)(2)(A)(i)) is amended—

(A) by striking ''or coinsurance'' and inserting '', coinsurance, or copayment''; and

(B) by striking ''or (a)(4)'' and inserting ''(a)(4), or (a)(5)''.

SEC. 703. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

SEC. 704. DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND.

(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of the enactment of this Act, the 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)).

(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ''activities of daily living'' means eating, toileting, transferring, bathing, and dressing.

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

Subtitle B—Direct Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)—

(A) by inserting ''AND 2004 THROUGH 2013'' after ''AND 2002''; and

(B) by inserting ''or during the period beginning with fiscal year 2004 and ending with fiscal year 2013'' after ''during fiscal year 2001 or fiscal year 2002''; and

(2) in subclause (II)—

(A) by striking ''fiscal year 2004, or fiscal year 2005,'' and

(B) by striking ''For a'' and inserting ''For the''.

Subtitle C—Chronic Care Improvement

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

Title XVIII, as amended by section 105(a), is amended by inserting after section 1807 the following new section:

"CHRONIC CARE IMPROVEMENT

"SEC. 1808. (a) IN GENERAL.—

"(1) IN GENERAL.—The Secretary shall establish a process for providing chronic care improvement programs in each CCIA region for medicare beneficiaries who are not enrolled under part C or E and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke, prostate and colon cancer, hypertension, or other disease as identified by the Secretary as appropriate for chronic care improvement. Such a process shall begin to be implemented no later than 1 year after the date of the enactment of this section.

"(2) TERMINOLOGY.—For purposes of this section:

"(A) CCIA REGION.—The term 'CCIA region' means a chronic care improvement 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 CCIA
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 CCIA
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 CCIA 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 CCIA 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

means permitted consistent with applicable disclosure provisions.

"(3) INITIAL CONTACT BY SECRETARY.—The Secretary shall communicate with each beneficiary identified under paragraph (2) as a prospective participant in one or more programs concerning participation in a program. Such communication may be made by the Secretary (or on behalf of the Secretary) and shall include information on the following:

"(A) A description of the advantages to the beneficiary in participating in a program.

"(B) Notification that the contractor offering a program may contact the beneficiary directly concerning such participation.

"(C) Notification that participation in a program is voluntary.

"(D) A description of the method for the beneficiary to select the single program in which the beneficiary wishes to participate and for declining to participate and a method for obtaining additional information concerning such participation.

"(4) PARTICIPATION.—A medicare beneficiary may participate in only one program under this 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) BIANNUAL OUTCOMES REPORTS.—The Sec-
15 retary shall submit to the Congress biannual 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

other criteria as determined by the Secretary; and

"(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

"(3) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for chronic care improvement programs under this section.

"(4) ACCREDITATION.—The Secretary may provide that chronic care improvement programs that are accredited by qualified organizations may be deemed to meet such requirements under this subsection as the Secretary may specify.

"(5) OUTCOMES REPORT.—Each Medicare Advantage organization with respect to its chronic care improvement program under this subsection shall monitor and report to the Secretary information on the quality of care and efficacy of such program as the Secretary may require."; and

(2) by amending subparagraph (I) of subsection (c)(1) to read as follows:

"(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A description of the organization's

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.

SEC. 724. MEDPAC REPORT.

(a) EVALUATION.—shall conduct an evaluation that includes a description of the status of the implementation of chronic care improvement programs under section 1808 of the Social Security Act, the quality of health care services provided to individuals in such program, the health status of the participants of such program, and the cost savings attributed to implementation of such program.

(b) REPORT.—Not later than 2 years after the date of implementation of such chronic care improvement programs, the Commission shall submit a report on such evaluation.

Subtitle D—Other Provisions

SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

"(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.".

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–

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.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Congress, by not later than June 1, 2004, a report on the following:

(A) Investments, endowments, and fundraising of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project (in this section referred to as the ''demonstration project'') under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(b) PAYMENT.—

1 (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;

(C) meets such standards established by the Secretary to assure quality of care and such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day care services.

(3) MEDICAL ADULT DAY CARE SERVICES.—The term ''medical adult day care services'' means—

(A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day care facility;

(B) a program of supervised activities furnished in a group setting in the facility that—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) is designed to promote physical and mental health of the individuals; and

(C) such other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual entitled

to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.

(a) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the third sentence of subsection (a) by inserting ''consistent with subsection (k)'' after ''the Secretary shall ensure''; and

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

''(k) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

''(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents

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,

relating to coverage of, and payment for, a medical device that is the subject of an investigational device exemption by the Food and Drug Administration (except as may be necessary to implement paragraph (1)).

(3) EFFECTIVE DATE.—This subsection shall apply to clinical trials begun before, on, or after the date of the enactment of this Act and to items and services furnished on or after such date.

(c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not later than January 1, 2004, the Secretary shall implement revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act.

SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES.

(a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w–4(i)) is amended by adding at the end the following new paragraph:

"(4) TREATMENT OF CERTAIN INPATIENT PHYSICIAN PATHOLOGY SERVICES.—

"(A) IN GENERAL.—With respect to services furnished on or after January 1, 2004, and before January 1, 2009, if an independent laboratory 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-

onstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203).''.

(b) CONFORMING AMENDMENT.—Section 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–550), as enacted into law by section 1(a)(6) of Public Law 106–554, is repealed.

(c) EFFECTIVE DATES.—The amendments made by this section shall take effect as if included in the enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463), as enacted into law by section 1(a)(6) of Public Law 106–554.

SEC. 735. CLINICAL INVESTIGATION OF MEDICARE PANCREATIC ISLET CELL TRANSPLANTS.

The Secretary shall authorize payment under title XVIII of the Social Security Act for the routine costs for items and services for medicare beneficiaries received as part of a clinical investigation of pancreatic islet cell transplants conducted by the National Institutes of Health.

SEC. 736. DEMONSTRATION PROJECT FOR CONSUMER-DIRECTED CHRONIC OUTPATIENT SERVICES.

(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.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS ADMINISTRATION.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by sections 105 and 721, is amended by inserting after 1808 the following new section:

"MEDICARE BENEFITS ADMINISTRATION

"SEC. 1809. (a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

"(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF ACTUARY.—

"(1) ADMINISTRATOR.—

"(A) IN GENERAL.—The Medicare Benefits Administration shall be headed by an administrator to be known as the 'Medicare Benefits Administrator' (in this section referred to as the 'Administrator') who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

"(B) COMPENSATION.—The Administrator 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

President, by and with the advice and consent of the Senate.

"(B) COMPENSATION.—The Deputy Administrator shall be paid at the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Deputy Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of a Deputy Administrator's term of office, such Deputy Administrator may continue in office until the entry upon office of such a successor. A Deputy Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) DUTIES.—The Deputy Administrator shall perform such duties and exercise such powers as the Administrator shall from time to time assign or delegate. The Deputy Administrator shall be Acting Administrator of the Administration during the absence or disability of 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,
11 including—
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 ministrator 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.—Recommenda-
10 tions 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;

"(ii) three shall be appointed for terms of 2 years; and

"(iii) three shall be appointed for terms of 3 years.

"(C) REAPPOINTMENTS.—Any person appointed as a member of the Board may not serve for more than 8 years.

"(D) VACANCY.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Board shall be filled in the manner in which the original appointment was made.

"(7) CHAIR.—The Chair of the Board shall be elected by the members. The term of office of the Chair shall be 3 years.

"(8) MEETINGS.—The Board shall meet at the call of the Chair, but in no event less than three times during each fiscal year.

"(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.—

(A) IN GENERAL.—Section 5314 of title 5, United States Code, by adding at the end the following:

"Administrator of the Centers for Medicare & Medicaid Services.

"Administrator of the Medicare Benefits Administration.".

(B) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking "Administrator of the Health Care Financing Administration.".

(C) EFFECTIVE DATE.—The amendments made by this paragraph take effect on January 1, 2004.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.

(a) CONSTRUCTION.—Nothing in this title shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729

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 Act does not constitute con-
9 solidation of the Federal Hospital Insurance Trust Fund
10 and the Federal Supplementary Medical Insurance Trust
11 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 advi-
3 sory opinions on appropriate interpretation and ap-
4 plication 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—

"(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

"(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

"(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.".

Subtitle B—Contracting Reform

SEC. 911. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE ADMINISTRATION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

"CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

"SEC. 1874A. (a) AUTHORITY.—

1 "(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

1874A that provides for making payments under this part''.

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

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

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

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

(7) Subsection (l) is repealed.

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

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

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

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

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

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

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.

(4) Subsection (c) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking ''contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B),'' and inserting ''contract under section 1874A that provides for making payments under this part'';

(C) in paragraph (3)(A), by striking ''subsection (a)(1)(B)'' and inserting ''section 1874A(a)(3)(B)'';

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking ''carrier'' and inserting ''medicare administrative contractor''; and

(E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking ''carrier or carriers'' and inserting ''medicare administrative contractor or contractors''.

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking ''Each carrier having an agreement with the Secretary under

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 SECU-
8 RITY.—

9 "(1) DEVELOPMENT OF INFORMATION SECU-
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

subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

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 METHOD-
16 OLOGY.—Not later than October 1, 2004, the Comp-
17 troller General of the United States shall submit to
18 Congress and to the Secretary a report on the ade-
19 quacy of the methodology under section 1874A(f) of
20 the Social Security Act, as added by paragraph (1),
21 and shall include in the report such recommenda-
22 tions as the Comptroller General determines appro-
23 priate with respect to the methodology.

24 (4) REPORT ON USE OF METHODOLOGY IN AS-
25 SESSING CONTRACTOR PERFORMANCE.—Not later

than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a) and subsection (b), is further amended by adding at the end the following new subsection:

"(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

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.

1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

''(b) ENHANCED EDUCATION AND TRAINING.—

''(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) $25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

''(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

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

with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.''.

(2) MONITORING ACCURACY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

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.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a))

with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking ''hospice services'' and inserting ''hospice care and post-hospital extended care services''; and

(B) by inserting before the period at the end the following: ''and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than October 1, 2004, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from

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
13 benefits—
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

on how to initiate such an appeal under this section;

"(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

"(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.".

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is amended—

(A) by inserting "be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)" after "in writing, "; and

(B) by inserting "and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section" after "such decision,".

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended—

(A) in the heading, by inserting "; NOTICE" after "SECRETARY"; and

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

"(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

"(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

"(B) the procedures for obtaining additional information concerning the decision; and

"(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.".

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking "prepare" and inserting "submit" and by striking "with respect to" and all that follows through "and relevant policies".

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

1 (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

individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

"(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

"(B) The individual (or authorized representative).

"(C) The health care professional that provides the items or services involved in the case.

"(D) The institution at which the items or services (or treatment) involved in the case are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

"(F) Any other party determined under any regulations to have a substantial interest in the case involved.".

(3) REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking "not fewer than 12 qualified independent contractors under this subsection" and inserting

"with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection".

(4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, (114 Stat. 2763A–534).

(5) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 934. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by sections 912(b), 921(b)(1), and 921(c)(1), is further amended by adding at the end the following new subsection:

"(h) CONDUCT OF PREPAYMENT REVIEW.—

"(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

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.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 935. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

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-

terest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

"(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section 1889(g).

"(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

"(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

"(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

"(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or 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.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

"(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term 'consent settlement' means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

"(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

"(7) PAYMENT AUDITS.—

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);

"(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

"(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

"(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

"(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.".

(b) EFFECTIVE DATES AND DEADLINES.—

(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.

(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by

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

Social Security Act for fiscal year 2004 if the hospital demonstrates on a timely basis to the satisfaction of the Secretary that the use of corrected or supplementary data under the amendment made by paragraph (1) would materially affect the approval of such an application.

(B) APPLICATION OF BUDGET NEUTRALITY.—If one or more hospital's applications are approved as a result of paragraph (1) and subparagraph (A) for fiscal year 2004, the Secretary shall make a proportional adjustment in the standardized amounts determined under section 1886(d)(3) of the Social Security Act (42 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure that approval of such applications does not result in aggregate payments under section 1886(d) of such Act that are greater or less than those that would otherwise be made if paragraph (1) and subparagraph (A) did not apply.

SEC. 938. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA

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

than 18 months after the date of the enactment of this Act.

(2) TRANSITION.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act.

(3) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)), the amendment made by subsection (a) shall not be considered to be a change in law or regulation.

(c) PROVISIONS RELATING TO ADVANCE BENEFICIARY NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

(1) DATA COLLECTION.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on

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.

Subtitle V—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new documentation guidelines for, or clinical examples of, evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary—

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test modifications to the evaluation and management documentation guidelines;

(4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

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 gency 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
16 redesignated—
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

(B) in subclause (IV), by striking ''medical review policies'' and inserting ''coverage determinations''.

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w–22(a)(2)(C)) is amended by striking ''policy'' and ''POLICY'' and inserting ''determination'' each place it appears and ''DETERMINATION'', respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended—

(1) in subparagraph (A)(iv), by striking ''subclause (I), (II), or (III)'' and inserting ''clause (i), (ii), or (iii)'';

(2) in subparagraph (B), by striking ''clause (i)(IV)'' and ''clause (i)(III)'' and inserting ''subparagraph (A)(iv)'' and ''subparagraph (A)(iii)'', respectively; and

(3) in subparagraph (C), by striking ''clause (i)'', ''subclause (IV)'' and ''subparagraph (A)'' and inserting ''subparagraph (A)'', ''clause (iv)'' and ''paragraph (1)(A)'', respectively each place it appears.

(d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section

1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

(e) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 949. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: ''Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.''.

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.

1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage under such section for that hospital for the current cost reporting year. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C. 1395u(b)(6)(A)) is amended by striking ''or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service,'' and inserting ''or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity (as defined by the Secretary), to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such other program integrity and other safeguards as the Secretary may determine to be appropriate,''.

(b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is

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

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

TITLE X—MEDICAID

SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS.

Section 1923(f)(3) (42 U.S.C. 1396r–4(f)(3)) is amended—

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

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

"(C) SPECIAL, TEMPORARY INCREASE IN ALLOTMENTS ON A ONE-TIME, NON-CUMULATIVE BASIS.—The DSH allotment for any State—

"(i) for fiscal year 2004 is equal to 120 percent of the DSH allotment for the State for fiscal year 2003 under this paragraph, notwithstanding subparagraph (B); and

"(ii) for each succeeding fiscal year is equal to the DSH allotment for the State for fiscal year 2004 or, in the case of fiscal years beginning with the fiscal year specified in subparagraph (D) for that State, the percentage change in the consumer price index for all urban consumers (all items; U.S. city average), for the previous fiscal year.

"(D) FISCAL YEAR SPECIFIED.—For purposes of subparagraph (C)(ii), the fiscal year specified in this subparagraph for a State is the first fiscal year for which the Secretary estimates that the DSH allotment for that State

will equal (or no longer exceed) the DSH allotment for that State under the law as in effect before the date of the enactment of this subparagraph.''.

SEC. 1002. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS FOR THE MEDICAID DRUG REBATE PROGRAM.

(a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is amended by inserting before the semicolon the following: ''(including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act)''.

(b) ANTI-DIVERSION PROTECTION.—Section 1927(c)(1)(C) (42 U.S.C. 1396r–8(c)(1)(C)) is amended by adding at the end the following:

''(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described

in section 340B(a)(5)(C) of the Public Health Service Act.''.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

SEC. 1101. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraph (B) and inserting the following:

''(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

''(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

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)—

(A) in subparagraph (B)—

(i) by striking ''under the following'' and inserting ''by applying the following to each certification made under paragraph (2)(A)(vii)''; and

(ii) in clause (iii)—

(I) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted.''; and

(II) in the second sentence—

(aa) by striking subclause (I) and inserting the following:

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

that there is no cause of action for patent infringement or invalidity); or

"(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

"(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;";

(cc) in subclause (III), by striking "on the date of such court decision." and inserting "as provided in subclause (I); or";

(dd) by inserting after subclause (III) the following:

"(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent 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

use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. Any person provided a right of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided a right of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

"(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

"(I) IN GENERAL.—If an owner of the patent or the holder of the 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
12 either—
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

"(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

"(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

"(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

"(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

"(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

"(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for

the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

"(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."; and

(B)(i) by redesignating paragraph (4) as paragraph (5); and

(ii) by inserting after paragraph (3) the following paragraph:

"(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

"(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength."; and

(2) in subsection (c)(3)—

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

formation submitted under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) made after the date of enactment of this Act.

SEC. 1102. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 1101) is amended—

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

"(iv) 180-DAY EXCLUSIVITY PERIOD.—

"(I) DEFINITIONS.—In this paragraph:

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

"(bb) FIRST APPLICANT.—As used in this subsection, the term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for

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 PLICATION.—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.—

"(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

"(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

"(aa) the earlier of the date that is—

"(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

"(BB) 30 months after the date of submission of the application of the first applicant; or

"(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the

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.

"(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

"(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

"(II) no applicant shall be eligible for a 180-day exclusivity period.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act.

(2) COLLUSIVE AGREEMENTS.—If a forfeiture event described in section 505(j)(5)(D)(i)(V) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(iv) of that Act without regard to when

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:

"(A)(i) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action."; and

(2) by adding at the end the following:

"(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.".

(b) EFFECT OF AMENDMENT.—The amendment made by subsection (a) does not alter the standards for approval of drugs under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

SEC. 1104. CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(F)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)''; and

(3) in subsections (e) and (l), by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''.

Subtitle B—Federal Trade Commission Review

SEC. 1111. DEFINITIONS.

In this subtitle:

(1) ANDA.—The term ''ANDA'' means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) BRAND NAME DRUG.—The term ''brand name drug'' means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act.

(3) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means the party that 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—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

SEC. 1113. FILING DEADLINES.

Any filing required under section 1112 shall be filed with the Commission not later than 10 business days after 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) take effect 30 days after the date of enactment of this Act; and

(2) shall apply to agreements described in section 1112 that are entered into 30 days after the date of enactment of this Act.

Subtitle C—Importation of Prescription Drugs

SEC. 1121. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

"SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

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
4 importer—
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)''.