

1 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SE-**
2 **CURITY ACT; REFERENCES TO BIPA AND**
3 **SECRETARY; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the “Medi-
5 care Prescription Drug and Modernization Act of 2003”.

6 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as
7 otherwise specifically provided, whenever in this Act an amend-
8 ment is expressed in terms of an amendment to or repeal of
9 a section or other provision, the reference shall be considered
10 to be made to that section or other provision of the Social Se-
11 curity Act.

12 (c) BIPA; SECRETARY.—In this Act:

13 (1) BIPA.—The term “BIPA” means the Medicare,
14 Medicaid, and SCHIP Benefits Improvement and Protec-
15 tion Act of 2000, as enacted into law by section 1(a)(6) of
16 Public Law 106–554.

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

19 (d) TABLE OF CONTENTS.—The table of contents of this
20 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.

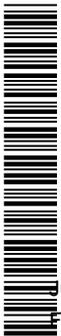
“Sec. 1860D–6. Submission of bids and premiums.

“Sec. 1860D–7. Premium and cost-sharing subsidies for low-income in-
dividuals.

“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. 1935. Special provisions relating to medicare prescription drug benefit.
- 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.

**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

CHAPTER 1—IMPLEMENTATION OF PROGRAM

- Sec. 211. Implementation of medicare advantage program.
- Sec. 212. Medicare advantage improvements.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

- Sec. 221. Competition program beginning in 2006.

CHAPTER 3—ADDITIONAL REFORMS

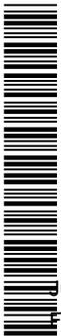
- Sec. 231. Making permanent change in medicare advantage reporting deadlines and annual, coordinated election period.
- Sec. 232. Avoiding duplicative State regulation.
- Sec. 233. Specialized medicare advantage plans for special needs beneficiaries.
- Sec. 234. Medicare MSAs.
- Sec. 235. Extension of reasonable cost contracts.

Subtitle C—Application of FEHBP-Style Competitive Reforms

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

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

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



TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

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

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

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

Subtitle B—Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services.
- Sec. 512. Coverage of hospice consultation services.

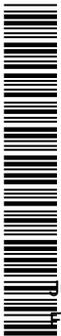
TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

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

SUBTITLE B—PREVENTIVE SERVICES

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



- Sec. 614. Improved payment for certain mammography services.
- Sec. 615. Medicare coverage of diabetes laboratory diagnostic tests.

Subtitle C—Other Services

- Sec. 621. Hospital outpatient department (HOPD) payment reform.
- Sec. 622. Payment for ambulance services.
- Sec. 623. Renal dialysis services.
- Sec. 624. One-year moratorium on therapy caps; provisions relating to reports.
- Sec. 625. Adjustment to payments for services furnished in ambulatory surgical centers.
- Sec. 626. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
- Sec. 627. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 628. Part B deductible.
- Sec. 629. Demonstration project for coverage of self-injected biologics for rheumatoid arthritis.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 701. Update in home health services.
- Sec. 702. MedPAC study on medicare margins of home health agencies.
- Sec. 703. Demonstration project to clarify the definition of homebound.

Subtitle B—Direct Graduate Medical Education

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

Subtitle C—Chronic Care Improvement

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

Subtitle D—Other Provisions

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

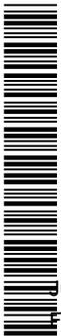
TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

- Sec. 801. Establishment of Medicare Benefits Administration.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

- Sec. 901. Construction; definition of supplier.
“Supplier
- Sec. 902. Issuance of regulations.



- Sec. 903. Compliance with changes in regulations and policies.
- Sec. 904. Reports and studies relating to regulatory reform.

Subtitle B—Contracting Reform

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

Subtitle C—Education and Outreach

- Sec. 921. Provider education and technical assistance.
- “Sec. 1889. Provider education and technical assistance.
- Sec. 922. Small provider technical assistance demonstration program.
- Sec. 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.
- Sec. 924. Beneficiary outreach demonstration program.
- Sec. 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits.
- Sec. 926. Information on medicare-certified skilled nursing facilities in hospital discharge plans.

Subtitle D—Appeals and Recovery

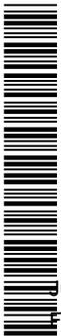
- Sec. 931. Transfer of responsibility for medicare appeals.
- Sec. 932. Process for expedited access to review.
- Sec. 933. Revisions to medicare appeals process.
- Sec. 934. Prepayment review.
- Sec. 935. Recovery of overpayments.
- Sec. 936. Provider enrollment process; right of appeal.
- Sec. 937.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

Subtitle V—Miscellaneous Provisions

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

TITLE X—MEDICAID

- Sec. 1001. Medicaid disproportionate share hospital (DSH) payments.



Sec. 1002. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.

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**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 drug coverage under section 1851(j), the individual may enroll in such plan and obtain coverage through such plan.

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

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



1 “(2) PRESCRIPTION DRUG PLAN.—If the individual is
2 not enrolled in a MA-EFFS plan , the individual may en-
3 roll under this part in a prescription drug plan (as defined
4 in section 1860D–10(a)(5)).

5 Such individuals shall have a choice of such plans under section
6 1860D–5(d).

7 “(b) GENERAL ELECTION PROCEDURES.—

8 “(1) IN GENERAL.—An individual eligible to make an
9 election under subsection (a) may elect to enroll in a pre-
10 scription drug plan under this part, or elect the option of
11 qualified prescription drug coverage under a MA-EFFS Rx
12 plan under part C or part E, and to change such election
13 only in such manner and form as may be prescribed by reg-
14 ulations of the Administrator of the Medicare Benefits Ad-
15 ministration (appointed under section 1809(b)) (in this
16 part referred to as the ‘Medicare Benefits Administrator’)
17 and only during an election period prescribed in or under
18 this subsection.

19 “(2) ELECTION PERIODS.—

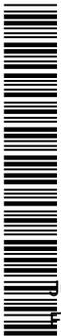
20 “(A) IN GENERAL.—Except as provided in this
21 paragraph, the election periods under this subsection
22 shall be the same as the coverage election periods
23 under the Medicare Advantage and EFFS programs
24 under section 1851(e), including—

25 “(i) annual coordinated election periods; and

26 “(ii) special election periods.

27 In applying the last sentence of section 1851(e)(4) (re-
28 lating to discontinuance of an election during the first
29 year of eligibility) under this subparagraph, in the case
30 of an election described in such section in which the in-
31 dividual had elected or is provided qualified prescrip-
32 tion drug coverage at the time of such first enrollment,
33 the individual shall be permitted to enroll in a prescrip-
34 tion drug plan under this part at the time of the elec-
35 tion of coverage under the original fee-for-service plan.

36 “(B) INITIAL ELECTION PERIODS.—



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

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

12 “(C) ADDITIONAL SPECIAL ELECTION PERIODS.—
13 The Administrator shall establish special election
14 periods—

15 “(i) in cases of individuals who have and invol-
16 untarily lose prescription drug coverage described
17 in subsection (c)(2)(C);

18 “(ii) in cases described in section 1837(h) (re-
19 lating to errors in enrollment), in the same manner
20 as such section applies to part B;

21 “(iii) in the case of an individual who meets
22 such exceptional conditions (including conditions
23 provided under section 1851(e)(4)(D)) as the Ad-
24 ministrator may provide; and

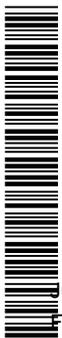
25 “(iv) in cases of individuals (as determined by
26 the Administrator) who become eligible for pre-
27 scription drug assistance under title XIX under
28 section 1935(d).

29 “(3) INFORMATION ON PLANS.—Information described
30 in section 1860D–3(b)(1) on prescription drug plans shall
31 be made available during election periods.

32 “(e) GUARANTEED ISSUE; COMMUNITY RATING; AND
33 NONDISCRIMINATION.—

34 “(1) GUARANTEED ISSUE.—

35 “(A) IN GENERAL.—An eligible individual who is
36 eligible to elect qualified prescription drug coverage



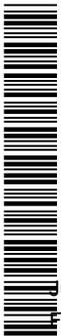
1 under a prescription drug plan or MA-EFFS Rx plan
2 at a time during which elections are accepted under
3 this part with respect to the plan shall not be denied
4 enrollment based on any health status-related factor
5 (described in section 2702(a)(1) of the Public Health
6 Service Act) or any other factor.

7 “(B) MEDICARE ADVANTAGE LIMITATIONS PER-
8 MITTED.—The provisions of paragraphs (2) and (3)
9 (other than subparagraph (C)(i), relating to default en-
10 rollment) of section 1851(g) (relating to priority and
11 limitation on termination of election) shall apply to
12 PDP sponsors under this subsection.

13 “(2) COMMUNITY-RATED PREMIUM.—

14 “(A) IN GENERAL.—In the case of an individual
15 who enrolls under a prescription drug plan or in a MA-
16 EFFS Rx plan during the individual’s initial enroll-
17 ment period under this part or maintains (as deter-
18 mined under subparagraph (C)) continuous prescription
19 drug coverage since the date the individual first quali-
20 fies to elect prescription drug coverage under this part,
21 a PDP sponsor or entity offering a prescription drug
22 plan or MA-EFFS Rx plan and in which the individual
23 is enrolled may not deny, limit, or condition the cov-
24 erage or provision of covered prescription drug benefits
25 or vary or increase the premium under the plan based
26 on any health status-related factor described in section
27 2702(a)(1) of the Public Health Service Act or any
28 other factor.

29 “(B) LATE ENROLLMENT PENALTY.—In the case
30 of an individual who does not maintain such continuous
31 prescription drug coverage (as described in subpara-
32 graph (C)), a PDP sponsor or an entity offering a MA-
33 EFFS Rx plan may (notwithstanding any provision in
34 this title) adjust the premium otherwise applicable or
35 impose a pre-existing condition exclusion with respect
36 to qualified prescription drug coverage in a manner

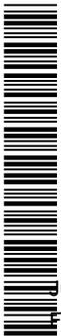


1 that reflects additional actuarial risk involved. Such a
2 risk shall be established through an appropriate actu-
3 arial opinion of the type described in subparagraphs
4 (A) through (C) of section 2103(c)(4).

5 “(C) CONTINUOUS PRESCRIPTION DRUG COV-
6 ERAGE.—An individual is considered for purposes of
7 this part to be maintaining continuous prescription
8 drug coverage on and after the date the individual first
9 qualifies to elect prescription drug coverage under this
10 part if the individual establishes that as of such date
11 the individual is covered under any of the following pre-
12 scription drug coverage and before the date that is the
13 last day of the 63-day period that begins on the date
14 of termination of the particular prescription drug cov-
15 erage involved (regardless of whether the individual
16 subsequently obtains any of the following prescription
17 drug coverage):

18 “(i) COVERAGE UNDER PRESCRIPTION DRUG
19 PLAN OR MA-EFFS RX PLAN.—Qualified prescrip-
20 tion drug coverage under a prescription drug plan
21 or under a MA-EFFS Rx plan.

22 “(ii) MEDICAID PRESCRIPTION DRUG COV-
23 ERAGE.—Prescription drug coverage under a med-
24 icaid plan under title XIX, including through the
25 Program of All-inclusive Care for the Elderly
26 (PACE) under section 1934, through a social
27 health maintenance organization (referred to in
28 section 4104(c) of the Balanced Budget Act of
29 1997), or through a demonstration project under
30 part C that demonstrates the application of capita-
31 tion payment rates for frail elderly medicare bene-
32 ficiaries through the use of an interdisciplinary
33 team and through the provision of primary care
34 services to such beneficiaries by means of such a
35 team at the nursing facility involved.

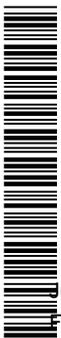


1 “(iii) PRESCRIPTION DRUG COVERAGE UNDER
2 GROUP HEALTH PLAN.—Any outpatient prescrip-
3 tion drug coverage under a group health plan, in-
4 cluding a health benefits plan under the Federal
5 Employees Health Benefit Plan under chapter 89
6 of title 5, United States Code, and a qualified re-
7 tiree prescription drug plan as defined in section
8 1860D–8(f)(1), but only if (subject to subpara-
9 graph (E)(ii)) the coverage provides benefits at
10 least equivalent to the benefits under a qualified
11 prescription drug plan.

12 “(iv) PRESCRIPTION DRUG COVERAGE UNDER
13 CERTAIN MEDIGAP POLICIES.—Coverage under a
14 medicare supplemental policy under section 1882
15 that provides benefits for prescription drugs
16 (whether or not such coverage conforms to the
17 standards for packages of benefits under section
18 1882(p)(1)), but only if the policy was in effect on
19 January 1, 2006, and if (subject to subparagraph
20 (E)(ii)) the coverage provides benefits at least
21 equivalent to the benefits under a qualified pre-
22 scription drug plan.

23 “(v) STATE PHARMACEUTICAL ASSISTANCE
24 PROGRAM.—Coverage of prescription drugs under a
25 State pharmaceutical assistance program, but only
26 if (subject to subparagraph (E)(ii)) the coverage
27 provides benefits at least equivalent to the benefits
28 under a qualified prescription drug plan.

29 “(vi) VETERANS’ COVERAGE OF PRESCRIPTION
30 DRUGS.—Coverage of prescription drugs for vet-
31 erans under chapter 17 of title 38, United States
32 Code, but only if (subject to subparagraph (E)(ii))
33 the coverage provides benefits at least equivalent to
34 the benefits under a qualified prescription drug
35 plan.



1 “(D) CERTIFICATION.—For purposes of carrying
2 out this paragraph, the certifications of the type de-
3 scribed in sections 2701(e) of the Public Health Service
4 Act and in section 9801(e) of the Internal Revenue
5 Code shall also include a statement for the period of
6 coverage of whether the individual involved had pre-
7 scription drug coverage described in subparagraph (C).

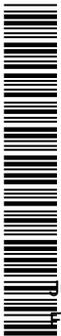
8 “(E) DISCLOSURE.—

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

16 “(ii) WAIVER OF LIMITATIONS.—An individual
17 may apply to the Administrator to waive the re-
18 quirement that coverage of such type provide bene-
19 fits at least equivalent to the benefits under a
20 qualified prescription drug plan, if the individual
21 establishes that the individual was not adequately
22 informed that such coverage did not provide such
23 level of benefits.

24 “(F) CONSTRUCTION.—Nothing in this section
25 shall be construed as preventing the disenrollment of
26 an individual from a prescription drug plan or a MA-
27 EFFS Rx plan based on the termination of an election
28 described in section 1851(g)(3), including for non-pay-
29 ment of premiums or for other reasons specified in sub-
30 section (d)(3), which takes into account a grace period
31 described in section 1851(g)(3)(B)(i).

32 “(3) NONDISCRIMINATION.—A PDP sponsor that of-
33 fers a prescription drug plan in an area designated under
34 section 1860D–4(b)(5) shall make such plan available to all
35 eligible individuals residing in the area without regard to



1 their health or economic status or their place of residence
2 within the area.

3 “(d) EFFECTIVE DATE OF ELECTIONS.—

4 “(1) IN GENERAL.—Except as provided in this section,
5 the Administrator shall provide that elections under sub-
6 section (b) take effect at the same time as the Adminis-
7 trator provides that similar elections under section 1851(e)
8 take effect under section 1851(f).

9 “(2) NO ELECTION EFFECTIVE BEFORE 2006.—In no
10 case shall any election take effect before January 1, 2006.

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

13 “(A) termination of coverage under both part A
14 and part B; and

15 “(B) termination of elections described in section
16 1851(g)(3) (including failure to pay required pre-
17 miums).

18 **“SEC. 1860D-2. REQUIREMENTS FOR QUALIFIED PRE-**
19 **SCRIPTION DRUG COVERAGE.**

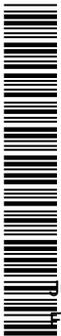
20 “(a) REQUIREMENTS.—

21 “(1) IN GENERAL.—For purposes of this part and
22 part C and part E, the term ‘qualified prescription drug
23 coverage’ means either of the following:

24 “(A) STANDARD COVERAGE WITH ACCESS TO NE-
25 GOTIATED PRICES.—Standard coverage (as defined in
26 subsection (b)) and access to negotiated prices under
27 subsection (d).

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

34 “(2) PERMITTING ADDITIONAL OUTPATIENT PRE-
35 SCRIPTIION DRUG COVERAGE.—



1 “(A) IN GENERAL.—Subject to subparagraph (B),
2 nothing in this part shall be construed as preventing
3 qualified prescription drug coverage from including cov-
4 erage of covered outpatient drugs that exceeds the cov-
5 erage required under paragraph (1), but any such addi-
6 tional coverage shall be limited to coverage of covered
7 outpatient drugs.

8 “(B) DISAPPROVAL AUTHORITY.—The Adminis-
9 trator shall review the offering of qualified prescription
10 drug coverage under this part or part C or E. If the
11 Administrator finds, in the case of a qualified prescrip-
12 tion drug coverage under a prescription drug plan or
13 a MA-EFFS Rx plan, that the organization or sponsor
14 offering the coverage is engaged in activities intended
15 to discourage enrollment of classes of eligible medicare
16 beneficiaries obtaining coverage through the plan on
17 the basis of their higher likelihood of utilizing prescrip-
18 tion drug coverage, the Administrator may terminate
19 the contract with the sponsor or organization under
20 this part or part C or E.

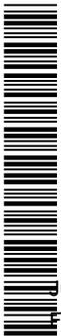
21 “(3) APPLICATION OF SECONDARY PAYOR PROVI-
22 SIONS.—The provisions of section 1852(a)(4) shall apply
23 under this part in the same manner as they apply under
24 part C.

25 “(b) STANDARD COVERAGE.—For purposes of this part,
26 the ‘standard coverage’ is coverage of covered outpatient drugs
27 (as defined in subsection (f)) that meets the following require-
28 ments:

29 “(1) DEDUCTIBLE.—The coverage has an annual
30 deductible—

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

32 “(B) for a subsequent year, that is equal to the
33 amount specified under this paragraph for the previous
34 year increased by the percentage specified in paragraph
35 (5) for the year involved.



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

4 “(2) 80:20 BENEFIT STRUCTURE.—

5 “(A) 20 PERCENT COINSURANCE.—The coverage
6 has cost-sharing (for costs above the annual deductible
7 specified in paragraph (1) and up to the initial cov-
8 erage limit under paragraph (3)) that is—

9 “(i) equal to 20 percent; or

10 “(ii) is actuarially equivalent (using processes
11 established under subsection (e)) to an average ex-
12 pected payment of 20 percent of such costs.

13 “(B) USE OF TIERS.—Nothing in this part shall
14 be construed as preventing a PDP sponsor from apply-
15 ing tiered copayments, so long as such tiered copay-
16 ments are consistent with subparagraph (A).

17 “(3) INITIAL COVERAGE LIMIT.—Subject to paragraph
18 (4), the coverage has an initial coverage limit on the max-
19 imum costs that may be recognized for payment
20 purposes—

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

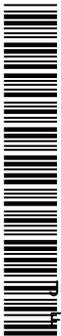
22 “(B) for a subsequent year, that is equal to the
23 amount specified in this paragraph for the previous
24 year, increased by the annual percentage increase de-
25 scribed in paragraph (5) for the year involved.

26 Any amount determined under subparagraph (B) that is
27 not a multiple of \$25 shall be rounded to the nearest mul-
28 tiple of \$25.

29 “(4) CATASTROPHIC PROTECTION.—

30 “(A) IN GENERAL.—Notwithstanding paragraph
31 (3), the coverage provides benefits with no cost-sharing
32 after the individual has incurred costs (as described in
33 subparagraph (C)) for covered outpatient drugs in a
34 year equal to the annual out-of-pocket threshold speci-
35 fied in subparagraph (B).

36 “(B) ANNUAL OUT-OF-POCKET THRESHOLD.—



1 “(i) IN GENERAL.—For purposes of this part,
2 the ‘annual out-of-pocket threshold’ specified in
3 this subparagraph is equal to \$3,500 (subject to
4 adjustment under clause (ii) and subparagraph
5 (D)).

6 “(ii) INFLATION INCREASE.—For a year after
7 2006, the dollar amount specified in clause (i) shall
8 be increased by the annual percentage increase de-
9 scribed in paragraph (5) for the year involved. Any
10 amount determined under the previous sentence
11 that is not a multiple of \$100 shall be rounded to
12 the nearest multiple of \$100.

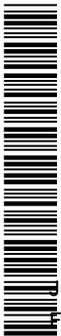
13 “(C) APPLICATION.—In applying subparagraph
14 (A)—

15 “(i) incurred costs shall only include costs in-
16 curred for the annual deductible (described in para-
17 graph (1)), cost-sharing (described in paragraph
18 (2)), and amounts for which benefits are not pro-
19 vided because of the application of the initial cov-
20 erage limit described in paragraph (3); and

21 “(ii) such costs shall be treated as incurred
22 only if they are paid by the individual (or by an-
23 other individual, such as a family member, on be-
24 half of the individual), under section 1860D-7,
25 under title XIX, or under a State pharmaceutical
26 assistance program and the individual (or other in-
27 dividual) is not reimbursed through insurance or
28 otherwise, a group health plan, or other third-party
29 payment arrangement (other than under such title
30 or such program) for such costs.

31 “(D) ADJUSTMENT OF ANNUAL OUT-OF-POCKET
32 THRESHOLDS.—

33 “(i) IN GENERAL.—For each enrollee in a pre-
34 scription drug plan or in a MA-EFFS Rx plan
35 whose adjusted gross income exceeds the income
36 threshold as defined in clause (ii) for a year, the



1 annual out-of-pocket threshold otherwise deter-
2 mined under subparagraph (B) for such year shall
3 be increased by an amount equal to the percentage
4 specified in clause (iii), multiplied by the lesser
5 of—

6 “(I) the amount of such excess; or

7 “(II) the amount by which the income
8 threshold limit exceeds the income threshold.

9 Any amount determined under the previous sen-
10 tence that is not a multiple of \$100 shall be round-
11 ed to the nearest multiple of \$100.

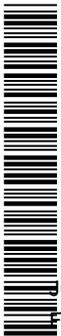
12 “(ii) INCOME THRESHOLD.—For purposes of
13 clause (i)—

14 “(I) IN GENERAL.—Subject to subclause
15 (II), the term ‘income threshold’ means
16 \$60,000 and the term ‘income threshold limit’
17 means \$200,000.

18 “(II) INCOME INFLATION ADJUSTMENT.—
19 In the case of a year beginning after 2006,
20 each of the dollar amounts in subclause (I)
21 shall be increased by an amount equal to such
22 dollar amount multiplied by the cost-of-living
23 adjustment determined under section 1(f)(3) of
24 the Internal Revenue Code of 1986 for such
25 year, determined by substituting ‘calendar year
26 2005’ for ‘calendar year 1992’. If any amount
27 increased under the previous sentence is not a
28 multiple of \$100, such amount shall be round-
29 ed to the nearest multiple of \$100.

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

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



1 “(II) the income threshold under clause
2 (ii) for that year.

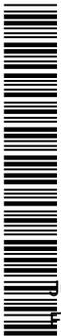
3 If any percentage determined under the previous
4 sentence that is not a multiple of $\frac{1}{10}$ th of 1 per-
5 centage point, such percentage shall be rounded to
6 the nearest multiple of $\frac{1}{10}$ th of 1 percentage point.

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

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

25 “(I) require the enrollee to provide the
26 Secretary with a copy of the relevant portion of
27 the more recent return to be used under this
28 clause;

29 “(II) provide for the Medicare Beneficiary
30 Ombudsman (under section 1810) offering as-
31 sistance to such enrollees in presenting such in-
32 formation and the toll-free number under such
33 section being a point of contact for bene-
34 ficiaries to inquire as to how to present such
35 information;



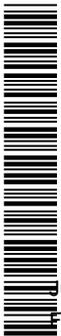
1 “(III) provide for the verification of the
2 information in such return by the Secretary of
3 the Treasury under section 6103(l)(19) of the
4 Internal Revenue Code of 1986; and

5 “(IV) provide for the payment by the Sec-
6 retary (in a manner specified by the Secretary)
7 to the enrollee of an amount equal to the excess
8 of the benefit payments that would have been
9 payable under the plan if the more recent re-
10 turn information were used, over the benefit
11 payments that were made under the plan.

12 In the case of a payment under subclause (III) for
13 an enrollee under a prescription drug plan, the
14 PDP sponsor of the plan shall pay to the Secretary
15 the amount so paid, less the applicable reinsurance
16 amount that would have applied under section
17 1860D-8(c)(1)(B) if such payment had been treat-
18 ed as an allowable cost under such section. Such
19 plan payment shall be deposited in the Treasury to
20 the credit of the Medicare Prescription Drug Ac-
21 count in the Federal Supplementary Medical Insur-
22 ance Trust Fund (under section 1841).

23 “(vi) DISSEMINATION OF INFORMATION ON
24 PROCESS.—The Secretary shall provide, through
25 the annual medicare handbook under section
26 1804(a), for a general description of the adjust-
27 ment of annual out-of-pocket thresholds provided
28 under this subparagraph, including the process for
29 adjustment based upon more recent information
30 and the confidentiality provisions of subparagraph
31 (F), and shall provide for dissemination of a table
32 for each year that sets forth the amount of the ad-
33 justment that is made under clause (i) based on the
34 amount of an enrollee’s adjusted gross income.

35 “(E) REQUESTING INFORMATION ON ENROLL-
36 EES.—



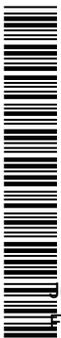
1 “(i) IN GENERAL.—The Secretary shall, peri-
2 odically as required to carry out subparagraph (D),
3 transmit to the Secretary of the Treasury a list of
4 the names and TINs of enrollees in prescription
5 drug plans (or in MA-EFFS Rx plans) and request
6 that such Secretary disclose to the Secretary infor-
7 mation under subparagraph (A) of section
8 6103(l)(19) of the Internal Revenue Code of 1986
9 with respect to those enrollees for a specified tax-
10 able year for application in a particular calendar
11 year.

12 “(ii) DISCLOSURE TO PLAN SPONSORS.—In
13 the case of a specified taxpayer (as defined in sec-
14 tion 6103(l)(19)(B) of the Internal Revenue Code
15 of 1986) who is enrolled in a prescription drug plan
16 or in an MA-EFFS Rx plan, the Secretary shall
17 disclose to the entity that offers the plan the an-
18 nual out-of-pocket threshold applicable to such in-
19 dividual under subparagraph (D).

20 “(F) MAINTAINING CONFIDENTIALITY OF INFOR-
21 MATION.—

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

28 “(ii) CRIMINAL AND CIVIL PENALTIES FOR UN-
29 AUTHORIZED DISCLOSURE.—A person who makes
30 an unauthorized disclosure of information disclosed
31 under section 6103(l)(19) of the Internal Revenue
32 Code of 1986 (including disclosure of any increase
33 in an annual out-of-pocket threshold under sub-
34 paragraph (D)) shall be subject to penalty to the
35 extent provided under—



1 “(I) section 7213 of such Code (relating to
2 criminal penalty for unauthorized disclosure of
3 information);

4 “(II) section 7213A of such Code (relating
5 to criminal penalty for unauthorized inspection
6 of returns or return information);

7 “(III) section 7431 of such Code (relating
8 to civil damages for unauthorized inspection or
9 disclosure of returns and return information);

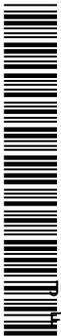
10 “(IV) any other provision of the Internal
11 Revenue Code of 1986; or

12 “(V) any other provision of law.

13 “(iii) APPLICATION OF ADDITIONAL CIVIL
14 MONETARY PENALTY FOR UNAUTHORIZED DISCLO-
15 SURES.—In addition to any penalty otherwise pro-
16 vided under law, any person who makes an unau-
17 thorized disclosure of such information shall be
18 subject to a civil monetary penalty of not to exceed
19 \$10,000 for each such unauthorized disclosure. The
20 provisions of section 1128A (other than subsections
21 (a) and (b)) shall apply to civil money penalties
22 under this subparagraph in the same manner as
23 they apply to a penalty or proceeding under section
24 1128A(a).

25 “(5) ANNUAL PERCENTAGE INCREASE.—For purposes
26 of this part, the annual percentage increase specified in
27 this paragraph for a year is equal to the annual percentage
28 increase in average per capita aggregate expenditures for
29 covered outpatient drugs in the United States for medicare
30 beneficiaries, as determined by the Administrator for the
31 12-month period ending in July of the previous year.

32 “(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A pre-
33 scription drug plan or MA-EFFS Rx plan may provide a dif-
34 ferent prescription drug benefit design from the standard cov-
35 erage described in subsection (b) so long as the Administrator
36 determines (based on an actuarial analysis by the Adminis-



1 trator) that the following requirements are met and the plan
2 applies for, and receives, the approval of the Administrator for
3 such benefit design:

4 “(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT
5 COVERAGE.—

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

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

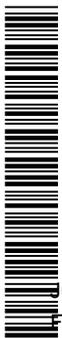
20 “(C) ASSURING STANDARD PAYMENT FOR COSTS
21 AT INITIAL COVERAGE LIMIT.—The coverage is de-
22 signed, based upon an actuarially representative pat-
23 tern of utilization (as determined under subsection (e)),
24 to provide for the payment, with respect to costs in-
25 curred that are equal to the initial coverage limit under
26 subsection (b)(3), of an amount equal to at least the
27 product of—

28 “(i) the amount by which the initial coverage
29 limit described in subsection (b)(3) exceeds the de-
30 ductible described in subsection (b)(1); and

31 “(ii) 100 percent minus the cost-sharing per-
32 centage specified in subsection (b)(2)(A)(i).

33 “(2) CATASTROPHIC PROTECTION.—The coverage pro-
34 vides for beneficiaries the catastrophic protection described
35 in subsection (b)(4).

36 “(d) ACCESS TO NEGOTIATED PRICES.—



1 “(1) IN GENERAL.—Under qualified prescription drug
2 coverage offered by a PDP sponsor or an entity offering a
3 MA-EFFS Rx plan, the sponsor or entity shall provide
4 beneficiaries with access to negotiated prices (including ap-
5 plicable discounts) used for payment for covered outpatient
6 drugs, regardless of the fact that no benefits may be pay-
7 able under the coverage with respect to such drugs because
8 of the application of cost-sharing or an initial coverage
9 limit (described in subsection (b)(3)). Insofar as a State
10 elects to provide medical assistance under title XIX for a
11 drug based on the prices negotiated by a prescription drug
12 plan or MA-EFFS Rx plan under this part, the require-
13 ments of section 1927 shall not apply to such drugs. The
14 prices negotiated by a prescription drug plan under this
15 part, by a MA-EFFS Rx plan with respect to covered out-
16 patient drugs, or by a qualified retiree prescription drug
17 plan (as defined in section 1860D–8(f)(1)) with respect to
18 such drugs on behalf of individuals entitled to benefits
19 under part A or enrolled under part B, shall (notwith-
20 standing any other provision of law) not be taken into ac-
21 count for the purposes of establishing the best price under
22 section 1927(e)(1)(C).

23 “(2) DISCLOSURE.—The PDP sponsor or entity offer-
24 ing a MA-EFFS Rx plan shall disclose to the Adminis-
25 trator (in a manner specified by the Administrator) the ex-
26 tent to which discounts or rebates or other remuneration
27 or price concessions made available to the sponsor or orga-
28 nization by a manufacturer are passed through to enrollees
29 through pharmacies and other dispensers or otherwise. The
30 provisions of section 1927(b)(3)(D) shall apply to informa-
31 tion disclosed to the Administrator under this paragraph in
32 the same manner as such provisions apply to information
33 disclosed under such section.

34 “(3) AUDITS AND REPORTS.—To protect against fraud
35 and abuse and to ensure proper disclosures and accounting
36 under this part, in addition to any protections against



1 fraud and abuse provided under section 1860D-4(b)(3)(C),
2 the Administrator may periodically audit the financial
3 statements and records of PDP sponsor or entities offering
4 a MA-EFFS Rx plan.

5 “(e) ACTUARIAL VALUATION; DETERMINATION OF AN-
6 NUAL PERCENTAGE INCREASES.—

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

9 “(A) for determining the actuarial valuation of
10 prescription drug coverage, including—

11 “(i) an actuarial valuation of standard cov-
12 erage and of the reinsurance subsidy payments
13 under section 1860D-8;

14 “(ii) the use of generally accepted actuarial
15 principles and methodologies; and

16 “(iii) applying the same methodology for de-
17 terminations of alternative coverage under sub-
18 section (e) as is used with respect to determina-
19 tions of standard coverage under subsection (b);
20 and

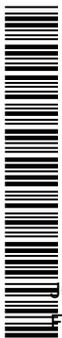
21 “(B) for determining annual percentage increases
22 described in subsection (b)(5).

23 “(2) USE OF OUTSIDE ACTUARIES.—Under the proc-
24 esses under paragraph (1)(A), PDP sponsors and entities
25 offering MA-EFFS Rx plans may use actuarial opinions
26 certified by independent, qualified actuaries to establish ac-
27 tuarial values, but the Administrator shall determine
28 whether such actuarial values meet the requirements under
29 subsection (e)(1).

30 “(f) COVERED OUTPATIENT DRUGS DEFINED.—

31 “(1) IN GENERAL.—Except as provided in this sub-
32 section, for purposes of this part, the term ‘covered out-
33 patient drug’ means—

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



1 “(B) a biological product described in clauses (i)
2 through (iii) of subparagraph (B) of such section or in-
3 sulin described in subparagraph (C) of such section and
4 medical supplies associated with the injection of insulin
5 (as defined in regulations of the Secretary),
6 and such term includes a vaccine licensed under section
7 351 of the Public Health Service Act and any use of a cov-
8 ered outpatient drug for a medically accepted indication (as
9 defined in section 1927(k)(6)).

10 “(2) EXCLUSIONS.—

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

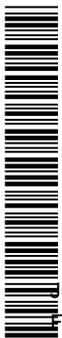
17 “(B) AVOIDANCE OF DUPLICATE COVERAGE.—A
18 drug prescribed for an individual that would otherwise
19 be a covered outpatient drug under this part shall not
20 be so considered if payment for such drug is available
21 under part A or B for an individual entitled to benefits
22 under part A and enrolled under part B.

23 “(3) APPLICATION OF FORMULARY RESTRICTIONS.—A
24 drug prescribed for an individual that would otherwise be
25 a covered outpatient drug under this part shall not be so
26 considered under a plan if the plan excludes the drug under
27 a formulary and such exclusion is not successfully appealed
28 under section 1860D–3(f)(2).

29 “(4) APPLICATION OF GENERAL EXCLUSION PROVI-
30 SIONS.—A prescription drug plan or MA-EFFS Rx plan
31 may exclude from qualified prescription drug coverage any
32 covered outpatient drug—

33 “(A) for which payment would not be made if sec-
34 tion 1862(a) applied to part D; or

35 “(B) which are not prescribed in accordance with
36 the plan or this part.



1 Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860D-3(f).

3 **“SEC. 1860D-3. BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.**

5 “(a) GUARANTEED ISSUE, COMMUNITY-RATED PREMIUMS, ACCESS TO NEGOTIATED PRICES, AND NONDISCRIMINATION.—
6 For provisions requiring guaranteed issue, community-rated
7 premiums, access to negotiated prices, and nondiscrimination,
8 see sections 1860D-1(c)(1), 1860D-1(c)(2), 1860D-2(d), and
9 1860D-6(b), respectively.
10

11 “(b) DISSEMINATION OF INFORMATION.—

12 “(1) GENERAL INFORMATION.—A PDP sponsor shall
13 disclose, in a clear, accurate, and standardized form to
14 each enrollee with a prescription drug plan offered by the
15 sponsor under this part at the time of enrollment and at
16 least annually thereafter, the information described in section
17 1852(c)(1) relating to such plan. Such information includes
18 the following:

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

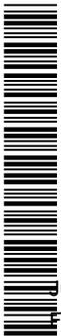
21 “(B) How any formulary used by the sponsor
22 functions, including the drugs included in the formulary.
23

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

28 “(D) Grievance and appeals procedures.

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

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



1 “(3) RESPONSE TO BENEFICIARY QUESTIONS.—Each
2 PDP sponsor offering a prescription drug plan shall have
3 a mechanism for providing specific information to enrollees
4 upon request. The sponsor shall make available on a timely
5 basis, through an Internet website and in writing upon re-
6 quest, information on specific changes in its formulary.

7 “(4) CLAIMS INFORMATION.—Each PDP sponsor of-
8 fering a prescription drug plan must furnish to each en-
9 rollee in a form easily understandable to such enrollees an
10 explanation of benefits (in accordance with section 1806(a)
11 or in a comparable manner) and a notice of the benefits
12 in relation to initial coverage limit and the annual out-of-
13 pocket threshold applicable to such enrollee for the current
14 year, whenever prescription drug benefits are provided
15 under this part (except that such notice need not be pro-
16 vided more often than monthly).

17 “(c) ACCESS TO COVERED BENEFITS.—

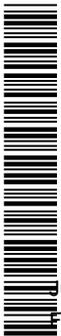
18 “(1) ASSURING PHARMACY ACCESS.—

19 “(A) SECURING SUFFICIENT PARTICIPATION.—

20 “(i) PARTICIPATION OF ANY WILLING PHAR-
21 MACY.—A PDP sponsor and an entity offering a
22 MA-EFFS Rx plan shall permit the participation
23 of any pharmacy that meets terms and conditions
24 that the plan has established.

25 “(ii) DISCOUNTS ALLOWED FOR NETWORK
26 PHARMACIES.—A prescription drug plan and a MA-
27 EFFS Rx plan may, notwithstanding clause (i), re-
28 duce coinsurance or copayments for its enrolled
29 beneficiaries below the level otherwise provided for
30 covered outpatient drugs dispensed through in-net-
31 work pharmacies, but in no case shall such a reduc-
32 tion result in an increase in payments made by the
33 Administrator under section 1860D–8 to a plan.

34 “(iii) CONVENIENT ACCESS FOR NETWORK
35 PHARMACIES.—The PDP sponsor of the prescrip-
36 tion drug plan and the entity offering a MA-EFFS



1 Rx plan shall secure the participation in its net-
2 work of a sufficient number of pharmacies that dis-
3 pense (other than by mail order) drugs directly to
4 patients to ensure convenient access (consistent
5 with rules of the Administrator established under
6 subparagraph (B)). The Administrator shall estab-
7 lish convenient access rules under this clause that
8 are no less favorable to enrollees than the rules for
9 convenient access to pharmacies of the Secretary of
10 Defense established as of June 1, 2003, for pur-
11 poses of the TRICARE Retail Pharmacy (TRRx)
12 program. Such rules shall include adequate emer-
13 gency access for enrolled beneficiaries.

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

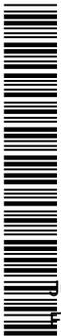
20 “(v) NOT REQUIRED TO ACCEPT INSURANCE
21 RISK.—The terms and conditions under clause (i)
22 may not require participating pharmacies to accept
23 insurance risk as a condition of participation.

24 “(2) USE OF STANDARDIZED TECHNOLOGY.—

25 “(A) IN GENERAL.—The PDP sponsor of a pre-
26 scription drug plan and an entity offering a MA-EFFS
27 Rx plan shall issue (and reissue, as appropriate) such
28 a card (or other technology) that may be used by an
29 enrollee to assure access to negotiated prices under sec-
30 tion 1860D-2(d) for the purchase of prescription drugs
31 for which coverage is not otherwise provided under the
32 plan.

33 “(B) STANDARDS.—

34 “(i) DEVELOPMENT.—The Administrator shall
35 provide for the development or utilization of uni-
36 form standards relating to a standardized format



1 for the card or other technology referred to in sub-
2 paragraph (A). Such standards shall be compatible
3 with standards established under part C of title XI.

4 “(ii) APPLICATION OF ADVISORY TASK
5 FORCE.—The advisory task force established under
6 subsection (d)(3)(B)(ii) shall provide recommenda-
7 tions to the Administrator under such subsection
8 regarding the standards developed under clause (i).

9 “(3) REQUIREMENTS ON DEVELOPMENT AND APPLICA-
10 TION OF FORMULARIES.—If a PDP sponsor of a prescrip-
11 tion drug plan or an entity offering a MA-EFFS Rx plan
12 uses a formulary, the following requirements must be met:

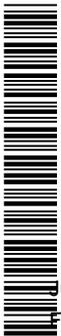
13 “(A) PHARMACY AND THERAPEUTIC (P&T) COM-
14 MITTEE.—The sponsor or entity must establish a phar-
15 macy and therapeutic committee that develops and re-
16 views the formulary. Such committee shall include at
17 least one practicing physician and at least one prac-
18 ticing pharmacist both with expertise in the care of el-
19 derly or disabled persons and a majority of its members
20 shall consist of individuals who are practicing physi-
21 cians or practicing pharmacists (or both).

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

24 “(i) base clinical decisions on the strength of
25 scientific evidence and standards of practice, in-
26 cluding assessing peer-reviewed medical literature,
27 such as randomized clinical trials,
28 pharmaco-economic studies, outcomes research data,
29 and such other information as the committee deter-
30 mines to be appropriate; and

31 “(ii) shall take into account whether including
32 in the formulary particular covered outpatient
33 drugs has therapeutic advantages in terms of safety
34 and efficacy.

35 “(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC
36 CATEGORIES.—The formulary must include drugs with-



1 in each therapeutic category and class of covered out-
2 patient drugs (although not necessarily for all drugs
3 within such categories and classes). In establishing
4 such classes, the committee shall take into account the
5 standards published in the United States Pharma-
6 copeia-Drug Information. The committee shall make
7 available to the enrollees under the plan through the
8 Internet or otherwise the clinical bases for the coverage
9 of any drug on the formulary.

10 “(D) PROVIDER AND PATIENT EDUCATION.—The
11 committee shall establish policies and procedures to
12 educate and inform health care providers and enrollees
13 concerning the formulary.

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

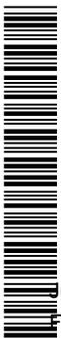
21 “(F) PERIODIC EVALUATION OF PROTOCOLS.—In
22 connection with the formulary, a prescription drug plan
23 shall provide for the periodic evaluation and analysis of
24 treatment protocols and procedures.

25 “(G) GRIEVANCES AND APPEALS RELATING TO AP-
26 PPLICATION OF FORMULARIES.—For provisions relating
27 to grievances and appeals of coverage, see subsections
28 (e) and (f).

29 “(d) COST AND UTILIZATION MANAGEMENT; QUALITY AS-
30 SURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

31 “(1) IN GENERAL.—The PDP sponsor or entity offer-
32 ing a MA-EFFS Rx plan shall have in place, directly or
33 through appropriate arrangements, with respect to covered
34 outpatient drugs—

35 “(A) an effective cost and drug utilization man-
36 agement program, including medically appropriate in-



1 centives to use generic drugs and therapeutic inter-
2 change, when appropriate;

3 “(B) quality assurance measures and systems to
4 reduce medical errors and adverse drug interactions,
5 including side-effects, and improve medication use, in-
6 cluding a medication therapy management program de-
7 scribed in paragraph (2) and for years beginning with
8 2007, an electronic prescription program described in
9 paragraph (3); and

10 “(C) a program to control fraud, abuse, and
11 waste.

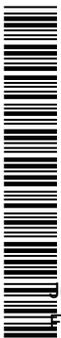
12 Nothing in this section shall be construed as impairing a
13 PDP sponsor or entity from utilizing cost management
14 tools (including differential payments) under all methods of
15 operation.

16 “(2) MEDICATION THERAPY MANAGEMENT PRO-
17 GRAM.—

18 “(A) IN GENERAL.—A medication therapy man-
19 agement program described in this paragraph is a pro-
20 gram of drug therapy management and medication ad-
21 ministration that may be furnished by a pharmacy pro-
22 vider and that is designed to assure, with respect to
23 beneficiaries at risk for potential medication problems,
24 such as beneficiaries with complex or chronic diseases
25 (such as diabetes, asthma, hypertension, and congestive
26 heart failure) or multiple prescriptions, that covered
27 outpatient drugs under the prescription drug plan are
28 appropriately used to optimize therapeutic outcomes
29 through improved medication use and reduce the risk
30 of adverse events, including adverse drug interactions.
31 Such programs may distinguish between services in am-
32 bulatory and institutional settings.

33 “(B) ELEMENTS.—Such program may include—

34 “(i) enhanced beneficiary understanding to
35 promote the appropriate use of medications by
36 beneficiaries and to reduce the risk of potential ad-



1 verse events associated with medications, through
2 beneficiary education, counseling, case manage-
3 ment, disease state management programs, and
4 other appropriate means;

5 “(ii) increased beneficiary adherence with pre-
6 scription medication regimens through medication
7 refill reminders, special packaging, and other com-
8 pliance programs and other appropriate means; and

9 “(iii) detection of patterns of overuse and
10 underuse of prescription drugs.

11 “(C) DEVELOPMENT OF PROGRAM IN COOPERA-
12 TION WITH LICENSED PHARMACISTS.—The program
13 shall be developed in cooperation with licensed and
14 practicing pharmacists and physicians.

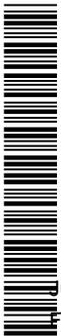
15 “(D) CONSIDERATIONS IN PHARMACY FEES.—The
16 PDP sponsor of a prescription drug program and an
17 entity offering a MA-EFFS Rx plan shall take into ac-
18 count, in establishing fees for pharmacists and others
19 providing services under the medication therapy man-
20 agement program, the resources and time used in im-
21 plementing the program. Each such sponsor or entity
22 shall disclose to the Administrator upon request the
23 amount of any such management or dispensing fees.

24 “(3) ELECTRONIC PRESCRIPTION PROGRAM.—

25 “(A) IN GENERAL.—An electronic prescription
26 drug program described in this paragraph is a program
27 that includes at least the following components, con-
28 sistent with uniform standards established under sub-
29 paragraph (B):

30 “(i) ELECTRONIC TRANSMITTAL OF PRESCRIP-
31 TIONS.—Prescriptions must be written and trans-
32 mitted electronically (other than by facsimile), ex-
33 cept in emergency cases and other exceptional cir-
34 cumstances recognized by the Administrator.

35 “(ii) PROVISION OF INFORMATION TO PRE-
36 SCRIBING HEALTH CARE PROFESSIONAL.—The pro-



1 gram provides for the electronic transmittal to the
2 prescribing health care professional of information
3 that includes—

4 “(I) information (to the extent available
5 and feasible) on the drug or drugs being pre-
6 scribed for that patient and other information
7 relating to the medical history or condition of
8 the patient that may be relevant to the appro-
9 priate prescription for that patient;

10 “(II) cost-effective alternatives (if any) for
11 the use of the drug prescribed; and

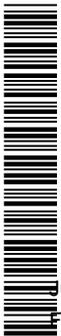
12 “(III) information on the drugs included
13 in the applicable formulary.

14 To the extent feasible, such program shall permit
15 the prescribing health care professional to provide
16 (and be provided) related information on an inter-
17 active, real-time basis.

18 “(B) STANDARDS.—

19 “(i) DEVELOPMENT.—The Administrator shall
20 provide for the development of uniform standards
21 relating to the electronic prescription drug program
22 described in subparagraph (A). Such standards
23 shall be compatible with standards established
24 under part C of title XI.

25 “(ii) ADVISORY TASK FORCE.—In developing
26 such standards and the standards described in sub-
27 section (c)(2)(B)(i) the Administrator shall estab-
28 lish a task force that includes representatives of
29 physicians, hospitals, pharmacies, beneficiaries,
30 pharmacy benefit managers, individuals with exper-
31 tise in information technology, and pharmacy ben-
32 efit experts of the Departments of Veterans Affairs
33 and Defense and other appropriate Federal agen-
34 cies to provide recommendations to the Adminis-
35 trator on such standards, including recommenda-
36 tions relating to the following:



1 “(I) The range of available computerized
2 prescribing software and hardware and their
3 costs to develop and implement.

4 “(II) The extent to which such standards
5 and systems reduce medication errors and can
6 be readily implemented by physicians, phar-
7 macies, and hospitals.

8 “(III) Efforts to develop uniform stand-
9 ards and a common software platform for the
10 secure electronic communication of medication
11 history, eligibility, benefit, and prescription in-
12 formation.

13 “(IV) Efforts to develop and promote uni-
14 versal connectivity and interoperability for the
15 secure electronic exchange of such information.

16 “(V) The cost of implementing such sys-
17 tems in the range of hospital and physician of-
18 fice settings and pharmacies, including hard-
19 ware, software, and training costs.

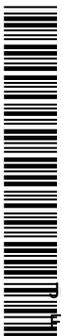
20 “(VI) Implementation issues as they relate
21 to part C of title XI, and current Federal and
22 State prescribing laws and regulations and
23 their impact on implementation of computer-
24 ized prescribing.

25 “(iii) DEADLINES.—

26 “(I) The Administrator shall constitute
27 the task force under clause (ii) by not later
28 than April 1, 2004.

29 “(II) Such task force shall submit rec-
30 ommendations to Administrator by not later
31 than January 1, 2005.

32 “(III) The Administrator shall provide for
33 the development and promulgation, by not later
34 than January 1, 2006, of national standards
35 relating to the electronic prescription drug pro-
36 gram described in clause (ii). Such standards



1 shall be issued by a standards organization ac-
2 credited by the American National Standards
3 Institute (ANSI) and shall be compatible with
4 standards established under part C of title XI.

5 “(4) TREATMENT OF ACCREDITATION.—Section
6 1852(e)(4) (relating to treatment of accreditation) shall
7 apply to prescription drug plans under this part with re-
8 spect to the following requirements, in the same manner as
9 they apply to plans under part C with respect to the re-
10 quirements described in a clause of section 1852(e)(4)(B):

11 “(A) Paragraph (1) (including quality assurance),
12 including medication therapy management program
13 under paragraph (2).

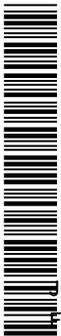
14 “(B) Subsection (c)(1) (relating to access to cov-
15 ered benefits).

16 “(C) Subsection (g) (relating to confidentiality and
17 accuracy of enrollee records).

18 “(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL
19 PRICES FOR EQUIVALENT DRUGS.—Each PDP sponsor and
20 each entity offering a MA-EFFS Rx plan shall provide that
21 each pharmacy or other dispenser that arranges for the dis-
22 pensing of a covered outpatient drug shall inform the bene-
23 ficiary at the time of purchase of the drug of any differen-
24 tial between the price of the prescribed drug to the enrollee
25 and the price of the lowest cost available generic drug cov-
26 ered under the plan that is therapeutically equivalent and
27 bioequivalent.

28 “(e) GRIEVANCE MECHANISM, COVERAGE DETERMINA-
29 TIONS, AND RECONSIDERATIONS.—

30 “(1) IN GENERAL.—Each PDP sponsor shall provide
31 meaningful procedures for hearing and resolving grievances
32 between the organization (including any entity or individual
33 through which the sponsor provides covered benefits) and
34 enrollees with prescription drug plans of the sponsor under
35 this part in accordance with section 1852(f).



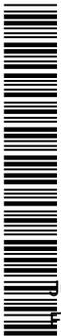
1 “(2) APPLICATION OF COVERAGE DETERMINATION
2 AND RECONSIDERATION PROVISIONS.—A PDP sponsor
3 shall meet the requirements of paragraphs (1) through (3)
4 of section 1852(g) with respect to covered benefits under
5 the prescription drug plan it offers under this part in the
6 same manner as such requirements apply to an organiza-
7 tion with respect to benefits it offers under a plan under
8 part C.

9 “(3) REQUEST FOR REVIEW OF TIERED FORMULARY
10 DETERMINATIONS.—In the case of a prescription drug plan
11 offered by a PDP sponsor or a MA-EFFS Rx plan that
12 provides for tiered cost-sharing for drugs included within a
13 formulary and provides lower cost-sharing for preferred
14 drugs included within the formulary, an individual who is
15 enrolled in the plan may request coverage of a nonpreferred
16 drug under the terms applicable for preferred drugs if the
17 prescribing physician determines that the preferred drug
18 for treatment of the same condition either would not be as
19 effective for the individual or would have adverse effects for
20 the individual or both.

21 “(f) APPEALS.—

22 “(1) IN GENERAL.—Subject to paragraph (2), a PDP
23 sponsor shall meet the requirements of paragraphs (4) and
24 (5) of section 1852(g) with respect to drugs (including a
25 determination related to the application of tiered cost-shar-
26 ing described in subsection (e)(3)) in the same manner as
27 such requirements apply to an organization with respect to
28 benefits it offers under a plan under part C.

29 “(2) FORMULARY DETERMINATIONS.—An individual
30 who is enrolled in a prescription drug plan offered by a
31 PDP sponsor or in a MA-EFFS Rx plan may appeal to ob-
32 tain coverage for a covered outpatient drug that is not on
33 a formulary of the sponsor or entity offering the plan if the
34 prescribing physician determines that the formulary drug
35 for treatment of the same condition either would not be as



1 effective for the individual or would have adverse effects for
2 the individual or both.

3 “(g) CONFIDENTIALITY AND ACCURACY OF ENROLLEE
4 RECORDS.—A PDP sponsor that offers a prescription drug
5 plan shall meet the requirements of section 1852(h) with re-
6 spect to enrollees under the plan in the same manner as such
7 requirements apply to an organization with respect to enrollees
8 under part C. A PDP sponsor shall be treated as a covered en-
9 tity for purposes of the provisions of subpart E of part 164 of
10 title 45, Code of Federal Regulations, adopted pursuant to the
11 authority of the Secretary under section 264(c) of the Health
12 Insurance Portability and Accountability Act of 1996 (42 U.S.
13 C. 1320d-2 note).

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

17 “(a) GENERAL REQUIREMENTS.—Each PDP sponsor of a
18 prescription drug plan shall meet the following requirements:

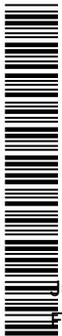
19 “(1) LICENSURE.—Subject to subsection (c), the spon-
20 sor is organized and licensed under State law as a risk-
21 bearing entity eligible to offer health insurance or health
22 benefits coverage in each State in which it offers a pre-
23 scription drug plan.

24 “(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUB-
25 SIDIZED COVERAGE.—

26 “(A) IN GENERAL.—Subject to subparagraph (B)
27 and section 1860D-5(d)(2), the entity assumes full fi-
28 nancial risk on a prospective basis for qualified pre-
29 scription drug coverage that it offers under a prescrip-
30 tion drug plan and that is not covered under section
31 1860D-8.

32 “(B) REINSURANCE PERMITTED.—The entity may
33 obtain insurance or make other arrangements for the
34 cost of coverage provided to any enrollee.

35 “(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the
36 case of a sponsor that is not described in paragraph (1),



1 the sponsor shall meet solvency standards established by
2 the Administrator under subsection (d).

3 “(b) CONTRACT REQUIREMENTS.—

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

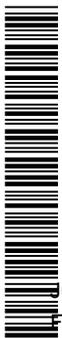
16 “(2) NEGOTIATION REGARDING TERMS AND CONDI-
17 TIONS.—The Administrator shall have the same authority
18 to negotiate the terms and conditions of prescription drug
19 plans under this part as the Director of the Office of Per-
20 sonnel Management has with respect to health benefits
21 plans under chapter 89 of title 5, United States Code. In
22 negotiating the terms and conditions regarding premiums
23 for which information is submitted under section 1860D-
24 6(a)(2), the Administrator shall take into account the sub-
25 sidy payments under section 1860D-8.

26 “(3) INCORPORATION OF CERTAIN MEDICARE ADVAN-
27 TAGE CONTRACT REQUIREMENTS.—The following provi-
28 sions of section 1857 shall apply, subject to subsection
29 (c)(5), to contracts under this section in the same manner
30 as they apply to contracts under section 1857(a):

31 “(A) MINIMUM ENROLLMENT.—Paragraphs (1)
32 and (3) of section 1857(b).

33 “(B) CONTRACT PERIOD AND EFFECTIVENESS.—
34 Paragraphs (1) through (3) and (5) of section 1857(c).

35 “(C) PROTECTIONS AGAINST FRAUD AND BENE-
36 FICIARY PROTECTIONS.—Section 1857(d).



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

4 “(i) such section shall be applied separately to
5 costs relating to this part (from costs under part
6 C and part E);

7 “(ii) in no case shall the amount of the fee es-
8 tablished under this subparagraph for a plan ex-
9 ceed 20 percent of the maximum amount of the fee
10 that may be established under subparagraph (B) of
11 such section; and

12 “(iii) no fees shall be applied under this sub-
13 paragraph with respect to MA-EFFS Rx plans.

14 “(E) INTERMEDIATE SANCTIONS.—Section
15 1857(g).

16 “(F) PROCEDURES FOR TERMINATION.—Section
17 1857(h).

18 “(4) RULES OF APPLICATION FOR INTERMEDIATE
19 SANCTIONS.—In applying paragraph (3)(E)—

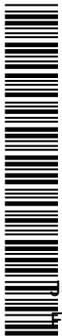
20 “(A) the reference in section 1857(g)(1)(B) to sec-
21 tion 1854 is deemed a reference to this part; and

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

24 “(5) SERVICE AREA REQUIREMENT.—For purposes of
25 this part, the Administrator shall designate at least 10
26 areas covering the entire United States and to the extent
27 practicable shall be consistent with EFFS regions estab-
28 lished under section 1860E-1(a)(2).

29 “(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND
30 CHOICE.—

31 “(1) IN GENERAL.—In the case of an entity that seeks
32 to offer a prescription drug plan in a State, the Adminis-
33 trator shall waive the requirement of subsection (a)(1) that
34 the entity be licensed in that State if the Administrator de-
35 termines, based on the application and other evidence pre-
36 sented to the Administrator, that any of the grounds for



1 approval of the application described in paragraph (2) have
2 been met.

3 “(2) GROUNDS FOR APPROVAL.—The grounds for ap-
4 proval under this paragraph are the grounds for approval
5 described in subparagraph (B), (C), and (D) of section
6 1855(a)(2), and also include the application by a State of
7 any grounds other than those required under Federal law.

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

12 “(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CON-
13 STITUTE CERTIFICATION.—The fact that an entity is li-
14 censed in accordance with subsection (a)(1) does not deem
15 the entity to meet other requirements imposed under this
16 part for a PDP sponsor.

17 “(5) REFERENCES TO CERTAIN PROVISIONS.—For
18 purposes of this subsection, in applying provisions of sec-
19 tion 1855(a)(2) under this subsection to prescription drug
20 plans and PDP sponsors—

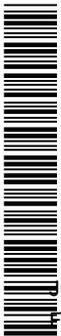
21 “(A) any reference to a waiver application under
22 section 1855 shall be treated as a reference to a waiver
23 application under paragraph (1); and

24 “(B) any reference to solvency standards shall be
25 treated as a reference to solvency standards established
26 under subsection (d).

27 “(d) SOLVENCY STANDARDS FOR NON-LICENSED SPON-
28 SORS.—

29 “(1) ESTABLISHMENT.—The Administrator shall es-
30 tablish, by not later than October 1, 2004, financial sol-
31 vency and capital adequacy standards that an entity that
32 does not meet the requirements of subsection (a)(1) must
33 meet to qualify as a PDP sponsor under this part.

34 “(2) COMPLIANCE WITH STANDARDS.—Each PDP
35 sponsor that is not licensed by a State under subsection
36 (a)(1) and for which a waiver application has been ap-



1 proved under subsection (c) shall meet solvency and capital
2 adequacy standards established under paragraph (1). The
3 Administrator shall establish certification procedures for
4 such PDP sponsors with respect to such solvency standards
5 in the manner described in section 1855(c)(2).

6 “(e) RELATION TO STATE LAWS.—

7 “(1) IN GENERAL.—The standards established under
8 this part shall supersede any State law or regulation (other
9 than State licensing laws or State laws relating to plan sol-
10 vency, except as provided in subsection (d)) with respect to
11 prescription drug plans which are offered by PDP sponsors
12 under this part.

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

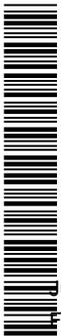
19 **“SEC. 1860D-5. PROCESS FOR BENEFICIARIES TO SE-**
20 **LECT QUALIFIED PRESCRIPTION DRUG COV-**
21 **ERAGE.**

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

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

28 “(1) Annual, coordinated election periods, in which
29 such individuals can change the qualifying plans through
30 which they obtain coverage, in accordance with section
31 1860D-1(b)(2).

32 “(2) Active dissemination of information to promote
33 an informed selection among qualifying plans based upon
34 price, quality, and other features, in the manner described
35 in (and in coordination with) section 1851(d), including the



1 provision of annual comparative information, maintenance
2 of a toll-free hotline, and the use of non-Federal entities.

3 “(3) Coordination of elections through filing with the
4 entity offering a MA-EFFS Rx plan or a PDP sponsor, in
5 the manner described in (and in coordination with) section
6 1851(e)(2).

7 “(4) Informing each enrollee before the beginning of
8 each year of the annual out-of-pocket threshold applicable
9 to the enrollee for that year under section 1860D–2(b)(4)
10 at such time.

11 “(c) MA-EFFS RX ENROLLEE MAY ONLY OBTAIN BENE-
12 FITS THROUGH THE PLAN.—An individual who is enrolled
13 under a MA-EFFS Rx plan may only elect to receive qualified
14 prescription drug coverage under this part through such plan.

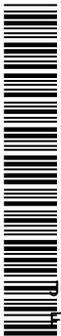
15 “(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRE-
16 SCRIPTIION DRUG COVERAGE.—

17 “(1) CHOICE OF AT LEAST TWO PLANS IN EACH
18 AREA.—

19 “(A) IN GENERAL.—The Administrator shall as-
20 sure that each individual who is entitled to benefits
21 under part A or enrolled under part B and who is re-
22 siding in an area in the United States has available,
23 consistent with subparagraph (B), a choice of enroll-
24 ment in at least two qualifying plans (as defined in
25 paragraph (5)) in the area in which the individual re-
26 sides, at least one of which is a prescription drug plan.

27 “(B) REQUIREMENT FOR DIFFERENT PLAN SPON-
28 SORS.—The requirement in subparagraph (A) is not
29 satisfied with respect to an area if only one PDP spon-
30 sor or one entity that offers a MA-EFFS Rx plan of-
31 fers all the qualifying plans in the area.

32 “(2) GUARANTEEING ACCESS TO COVERAGE.—In order
33 to assure access under paragraph (1) and consistent with
34 paragraph (3), the Administrator may provide partial un-
35 derwriting of risk for a PDP sponsor to expand the service
36 area under an existing prescription drug plan to adjoining



1 or additional areas or to establish such a plan (including
2 offering such a plan on a regional or nationwide basis), but
3 only so long as (and to the extent) necessary to assure the
4 access guaranteed under paragraph (1).

5 “(3) LIMITATION ON AUTHORITY.—In exercising au-
6 thority under this subsection, the Administrator—

7 “(A) shall not provide for the full underwriting of
8 financial risk for any PDP sponsor; and

9 “(B) shall seek to maximize the assumption of fi-
10 nancial risk by PDP sponsors or entities offering a
11 MA-EFFS Rx plan.

12 “(4) REPORTS.—The Administrator shall, in each an-
13 nual report to Congress under section 1809(f), include in-
14 formation on the exercise of authority under this sub-
15 section. The Administrator also shall include such rec-
16 ommendations as may be appropriate to minimize the exer-
17 cise of such authority, including minimizing the assumption
18 of financial risk.

19 “(5) QUALIFYING PLAN DEFINED.—For purposes of
20 this subsection, the term ‘qualifying plan’ means a pre-
21 scription drug plan or a MA-EFFS Rx plan.

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

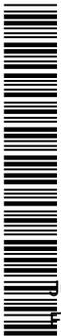
23 “(a) SUBMISSION OF BIDS, PREMIUMS, AND RELATED IN-
24 FORMATION.—

25 “(1) IN GENERAL.—Each PDP sponsor shall submit
26 to the Administrator the information described in para-
27 graph (2) in the same manner as information is submitted
28 by an organization under section 1854(a)(1).

29 “(2) INFORMATION SUBMITTED.—The information de-
30 scribed in this paragraph is the following:

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

33 “(B) ACTUARIAL VALUE.—Information on the ac-
34 tuarial value of the coverage.



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

4 “(i) the actuarial basis for such bid and pre-
5 mium;

6 “(ii) the portion of such bid and premium at-
7 tributable to benefits in excess of standard cov-
8 erage;

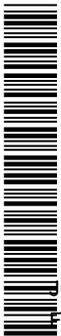
9 “(iii) the reduction in such bid resulting from
10 the reinsurance subsidy payments provided under
11 section 1860D–8(a)(2); and

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

15 “(D) ADDITIONAL INFORMATION.—Such other in-
16 formation as the Administrator may require to carry
17 out this part.

18 “(3) REVIEW OF INFORMATION; NEGOTIATION AND
19 APPROVAL OF PREMIUMS.—

20 “(A) IN GENERAL.—Subject to subparagraph (B),
21 the Administrator shall review the information filed
22 under paragraph (2) for the purpose of conducting ne-
23 gotiations under section 1860D–4(b)(2) (relating to
24 using OPM-like authority under the FEHBP). The Ad-
25 ministrator, using the information provided (including
26 the actuarial certification under paragraph (2)(C))
27 shall approve the premium submitted under this sub-
28 section only if the premium accurately reflects both (i)
29 the actuarial value of the benefits provided, and (ii) the
30 73 percent average subsidy provided under section
31 1860D–8 for the standard benefit. The Administrator
32 shall apply actuarial principles to approval of a pre-
33 mium under this part in a manner similar to the man-
34 ner in which those principles are applied in establishing
35 the monthly part B premium under section 1839.



1 “(B) EXCEPTION.—In the case of a plan described
2 in section 1851(a)(2)(C), the provisions of subpara-
3 graph (A) shall not apply and the provisions of para-
4 graph (5)(B) of section 1854(a), prohibiting the review,
5 approval, or disapproval of amounts described in such
6 paragraph, shall apply to the negotiation and rejection
7 of the monthly bid amounts and proportion referred to
8 in subparagraph (A).

9 “(b) UNIFORM BID AND PREMIUM.—

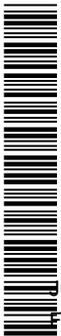
10 “(1) IN GENERAL.—The bid and premium for a pre-
11 scription drug plan under this section may not vary among
12 enrollees in the plan in the same service area.

13 “(2) CONSTRUCTION.—Nothing in paragraph (1) shall
14 be construed as preventing the imposition of a late enroll-
15 ment penalty under section 1860D-1(c)(2)(B).

16 “(c) COLLECTION.—

17 “(1) BENEFICIARY’S OPTION OF PAYMENT THROUGH
18 WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE
19 OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In ac-
20 cordance with regulations, a PDP sponsor shall permit
21 each enrollee, at the enrollee’s option, to make payment of
22 premiums under this part to the sponsor through with-
23 holding from benefit payments in the manner provided
24 under section 1840 with respect to monthly premiums
25 under section 1839 or through an electronic funds transfer
26 mechanism (such as automatic charges of an account at a
27 financial institution or a credit or debit card account) or
28 otherwise. All premium payments under this paragraph
29 shall be credited to the Medicare Prescription Drug Trust
30 Fund.

31 “(2) OFFSETTING.—Reductions in premiums for cov-
32 erage under parts A and B as a result of a selection of a
33 MA-EFFS Rx plan may be used to reduce the premium
34 otherwise imposed under paragraph (1).



1 “(d) ACCEPTANCE OF REFERENCE PREMIUM AMOUNT AS
2 FULL PREMIUM FOR SUBSIDIZED LOW-INCOME INDIVIDUALS
3 IF NO STANDARD (OR EQUIVALENT) COVERAGE IN AN AREA.—

4 “(1) IN GENERAL.—If there is no standard prescrip-
5 tion drug coverage (as defined in paragraph (2)) offered in
6 an area, in the case of an individual who is eligible for a
7 premium subsidy under section 1860D–7 and resides in the
8 area, the PDP sponsor of any prescription drug plan of-
9 fered in the area (and any entity offering a MA-EFFS Rx
10 plan in the area) shall accept the reference premium
11 amount (under paragraph (3)) as payment in full for the
12 premium charge for qualified prescription drug coverage.

13 “(2) STANDARD PRESCRIPTION DRUG COVERAGE DE-
14 FINED.—For purposes of this subsection, the term ‘stand-
15 ard prescription drug coverage’ means qualified prescrip-
16 tion drug coverage that is standard coverage or that has
17 an actuarial value equivalent to the actuarial value for
18 standard coverage.

19 “(3) REFERENCE PREMIUM AMOUNT DEFINED.—For
20 purposes of this subsection, the term ‘reference premium
21 amount’ means, with respect to qualified prescription drug
22 coverage offered under—

23 “(A) a prescription drug plan that—

24 “(i) provides standard coverage (or alternative
25 prescription drug coverage the actuarial value of
26 which is equivalent to that of standard coverage),
27 the plan’s PDP premium; or

28 “(ii) provides alternative prescription drug
29 coverage the actuarial value of which is greater
30 than that of standard coverage, the plan’s PDP
31 premium multiplied by the ratio of (I) the actuarial
32 value of standard coverage, to (II) the actuarial
33 value of the alternative coverage;

34 “(B) an EFFS plan, the EFFS monthly prescrip-
35 tion drug beneficiary premium (as defined in section
36 1860E–4(a)(3)(B)); or

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

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

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

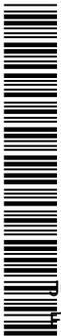
12 “(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS
13 WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY
14 LEVEL.—

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

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

25 “(B) subject to subsection (c), to the substitution
26 for the beneficiary cost-sharing described in paragraphs
27 (1) and (2) of section 1860D-2(b) (up to the initial
28 coverage limit specified in paragraph (3) of such sec-
29 tion) of amounts that do not exceed \$2 for a multiple
30 source or generic drug (as described in section
31 1927(k)(7)(A)) and \$5 for a non-preferred drug.

32 “(2) SLIDING SCALE PREMIUM SUBSIDY FOR INDIVID-
33 UALS WITH INCOME ABOVE 135, BUT BELOW 150 PERCENT,
34 OF FEDERAL POVERTY LEVEL.—In the case of a subsidy el-
35 igible individual who is determined to have income that ex-
36 ceeds 135 percent, but does not exceed 150 percent, of the



1 Federal poverty level, the individual is entitled under this
2 section to an income-related premium subsidy determined
3 on a linear sliding scale ranging from 100 percent of the
4 amount described in subsection (b)(1) for individuals with
5 incomes at 135 percent of such level to 0 percent of such
6 amount for individuals with incomes at 150 percent of such
7 level.

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

12 “(4) DETERMINATION OF ELIGIBILITY.—

13 “(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—

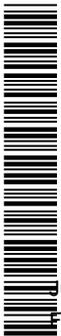
14 For purposes of this section, subject to subparagraph
15 (D), the term ‘subsidy eligible individual’ means an in-
16 dividual who—

17 “(i) is eligible to elect, and has elected, to ob-
18 tain qualified prescription drug coverage under this
19 part;

20 “(ii) has income below 150 percent of the Fed-
21 eral poverty line; and

22 “(iii) meets the resources requirement de-
23 scribed in subparagraph (D) .

24 “(B) DETERMINATIONS.—The determination of
25 whether an individual residing in a State is a subsidy
26 eligible individual and the amount of such individual’s
27 income shall be determined under the State medicaid
28 plan for the State under section 1935(a) or by the So-
29 cial Security Administration. In the case of a State
30 that does not operate such a medicaid plan (either
31 under title XIX or under a statewide waiver granted
32 under section 1115), such determination shall be made
33 under arrangements made by the Administrator. There
34 are authorized to be appropriated to the Social Security
35 Administration such sums as may be necessary for the
36 determination of eligibility under this subparagraph.



1 “(C) INCOME DETERMINATIONS.—For purposes of
2 applying this section—

3 “(i) income shall be determined in the manner
4 described in section 1905(p)(1)(B); and

5 “(ii) the term ‘Federal poverty line’ means the
6 official poverty line (as defined by the Office of
7 Management and Budget, and revised annually in
8 accordance with section 673(2) of the Omnibus
9 Budget Reconciliation Act of 1981) applicable to a
10 family of the size involved.

11 “(D) RESOURCE STANDARD APPLIED TO BE
12 BASED ON TWICE SSI RESOURCE STANDARD.—The re-
13 source requirement of this subparagraph is that an in-
14 dividual’s resources (as determined under section 1613
15 for purposes of the supplemental security income pro-
16 gram) do not exceed—

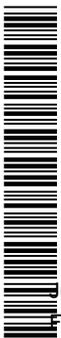
17 “(i) for 2006 twice the maximum amount of
18 resources that an individual may have and obtain
19 benefits under that program; and

20 “(ii) for a subsequent year the resource limita-
21 tion established under this clause for the previous
22 year increased by the annual percentage increase in
23 the consumer price index (all items; U.S. city aver-
24 age) as of September of such previous year.

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

28 “(E) TREATMENT OF TERRITORIAL RESIDENTS.—
29 In the case of an individual who is not a resident of
30 the 50 States or the District of Columbia, the indi-
31 vidual is not eligible to be a subsidy eligible individual
32 but may be eligible for financial assistance with pre-
33 scription drug expenses under section 1935(e).

34 “(F) TREATMENT OF CONFORMING MEDIGAP
35 POLICIES.—For purposes of this section, the term
36 ‘qualified prescription drug coverage’ includes a medi-



1 care supplemental policy described in section 1860D–
2 8(b)(4).

3 “(5) INDEXING DOLLAR AMOUNTS.—

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

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

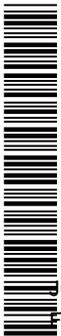
17 “(b) PREMIUM SUBSIDY AMOUNT.—

18 “(1) IN GENERAL.—The premium subsidy amount de-
19 scribed in this subsection for an individual residing in an
20 area is the benchmark premium amount (as defined in
21 paragraph (2)) for qualified prescription drug coverage of-
22 fered by the prescription drug plan or the MA-EFFS Rx
23 plan in which the individual is enrolled.

24 “(2) BENCHMARK PREMIUM AMOUNT DEFINED.—For
25 purposes of this subsection, the term ‘benchmark premium
26 amount’ means, with respect to qualified prescription drug
27 coverage offered under—

28 “(A) a prescription drug plan that—

29 “(i) provides standard coverage (or alternative
30 prescription drug coverage the actuarial value of
31 which is equivalent to that of standard coverage),
32 the premium amount for enrollment under the plan
33 under this part (determined without regard to any
34 subsidy under this section or any late enrollment
35 penalty under section 1860D–1(c)(2)(B)); or



1 “(ii) provides alternative prescription drug
2 coverage the actuarial value of which is greater
3 than that of standard coverage, the premium
4 amount described in clause (i) multiplied by the
5 ratio of (I) the actuarial value of standard cov-
6 erage, to (II) the actuarial value of the alternative
7 coverage; or

8 “(B) a MA-EFFS Rx plan, the portion of the pre-
9 mium amount that is attributable to statutory drug
10 benefits (described in section 1853(a)(1)(A)(ii)(II)).

11 “(c) RULES IN APPLYING COST-SHARING SUBSIDIES.—

12 “(1) IN GENERAL.—In applying subsection (a)(1)(B),
13 nothing in this part shall be construed as preventing a plan
14 or provider from waiving or reducing the amount of cost-
15 sharing otherwise applicable.

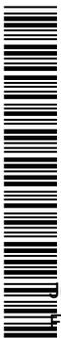
16 “(2) LIMITATION ON CHARGES.—In the case of an in-
17 dividual receiving cost-sharing subsidies under subsection
18 (a)(1)(B), the PDP sponsor or entity offering a MA-EFFS
19 Rx plan may not charge more than \$5 per prescription.

20 “(3) APPLICATION OF INDEXING RULES.—The provi-
21 sions of subsection (a)(5) shall apply to the dollar amount
22 specified in paragraph (2) in the same manner as they
23 apply to the dollar amounts specified in subsections
24 (a)(1)(B).

25 “(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The Ad-
26 ministrator shall provide a process whereby, in the case of an
27 individual who is determined to be a subsidy eligible individual
28 and who is enrolled in prescription drug plan or is enrolled in
29 a MA-EFFS Rx plan—

30 “(1) the Administrator provides for a notification of
31 the PDP sponsor or the entity offering the MA-EFFS Rx
32 plan involved that the individual is eligible for a subsidy
33 and the amount of the subsidy under subsection (a);

34 “(2) the sponsor or entity involved reduces the pre-
35 miums or cost-sharing otherwise imposed by the amount of



1 the applicable subsidy and submits to the Administrator in-
2 formation on the amount of such reduction; and

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

6 The reimbursement under paragraph (3) with respect to cost-
7 sharing subsidies may be computed on a capitated basis, taking
8 into account the actuarial value of the subsidies and with ap-
9 propriate adjustments to reflect differences in the risks actually
10 involved.

11 “(e) RELATION TO MEDICAID PROGRAM.—

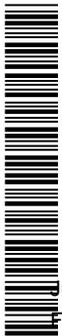
12 “(1) IN GENERAL.—For provisions providing for eligi-
13 bility determinations, and additional financing, under the
14 medicaid program, see section 1935.

15 “(2) MEDICAID PROVIDING WRAP AROUND BENE-
16 FITS.—The coverage provided under this part is primary
17 payor to benefits for prescribed drugs provided under the
18 medicaid program under title XIX consistent with section
19 1935(d)(1).

20 “(3) COORDINATION.—The Administrator shall de-
21 velop and implement a plan for the coordination of pre-
22 scription drug benefits under this part with the benefits
23 provided under the medicaid program under title XIX, with
24 particular attention to insuring coordination of payments
25 and prevention of fraud and abuse. In developing and im-
26 plementing such plan, the Administrator shall involve the
27 Secretary, the States, the data processing industry, phar-
28 macists, and pharmaceutical manufacturers, and other ex-
29 perts.

30 **“SEC. 1860D-8. SUBSIDIES FOR ALL MEDICARE BENE-**
31 **FICIARIES FOR QUALIFIED PRESCRIPTION**
32 **DRUG COVERAGE.**

33 “(a) SUBSIDY PAYMENT.—In order to reduce premium
34 levels applicable to qualified prescription drug coverage for all
35 medicare beneficiaries consistent with an overall subsidy level
36 of 73 percent, to reduce adverse selection among prescription



1 drug plans and MA-EFFS Rx plans, and to promote the partici-
2 pation of PDP sponsors under this part, the Administrator
3 shall provide in accordance with this section for payment to a
4 qualifying entity (as defined in subsection (b)) of the following
5 subsidies:

6 “(1) DIRECT SUBSIDY.—In the case of an enrollee en-
7 rolled for a month in a prescription drug plan or a MA-
8 EFFS Rx plan, a direct subsidy equal to 43 percent of the
9 national average monthly bid amount (computed under sub-
10 section (g)) for that month.

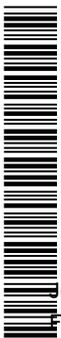
11 “(2) SUBSIDY THROUGH REINSURANCE.—In the case
12 of an enrollee enrolled for a month in a prescription drug
13 plan or a MA-EFFS Rx plan, the reinsurance payment
14 amount (as defined in subsection (c)), which in the aggre-
15 gate is 30 percent of the total payments made by qualifying
16 entities for standard coverage under the respective plan, for
17 excess costs incurred in providing qualified prescription
18 drug coverage—

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

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

22 “(3) EMPLOYER AND UNION FLEXIBILITY.—In the
23 case of an individual who is a participant or beneficiary in
24 a qualified retiree prescription drug plan (as defined in
25 subsection (f)(1)) and who is not enrolled in a prescription
26 drug plan or in a MA-EFFS Rx plan, the special subsidy
27 payments under subsection (f)(3).

28 This section constitutes budget authority in advance of appro-
29 priations Acts and represents the obligation of the Adminis-
30 trator to provide for the payment of amounts provided under
31 this section. In applying the percentages under paragraphs (1)
32 and (2), there shall be taken into account under the respective
33 paragraphs the portion of the employer and union special sub-
34 sidy payments under subsection (f)(3) that reflect payments
35 that would have been made under the respective paragraphs if



1 such paragraphs had applied to qualified retiree prescription
2 drug plans instead of paragraph (3).

3 “(b) QUALIFYING ENTITY DEFINED.—For purposes of
4 this section, the term ‘qualifying entity’ means any of the fol-
5 lowing that has entered into an agreement with the Adminis-
6 trator to provide the Administrator with such information as
7 may be required to carry out this section:

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

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

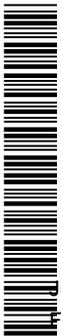
11 “(3) The sponsor of a qualified retiree prescription
12 drug plan (as defined in subsection (f)).

13 “(c) REINSURANCE PAYMENT AMOUNT.—

14 “(1) IN GENERAL.—Subject to subsection (d)(1)(B)
15 and paragraph (4), the reinsurance payment amount under
16 this subsection for a qualifying covered individual (as de-
17 fined in paragraph (5)) for a coverage year (as defined in
18 subsection (h)(2)) is equal to the sum of the following:

19 “(A) REINSURANCE BETWEEN INITIAL REINSUR-
20 ANCE THRESHOLD AND THE INITIAL COVERAGE
21 LIMIT.—For the portion of the individual’s gross cov-
22 ered prescription drug costs (as defined in paragraph
23 (3)) for the year that exceeds the initial reinsurance
24 threshold specified in paragraph (4), but does not ex-
25 ceed the initial coverage limit specified in section
26 1860D–2(b)(3), an amount equal to 20 percent of the
27 allowable costs (as defined in paragraph (2)) attrib-
28 utable to such gross covered prescription drug costs.

29 “(B) REINSURANCE ABOVE ANNUAL OUT-OF-
30 POCKET THRESHOLD.—For the portion of the individ-
31 ual’s gross covered prescription drug costs for the year
32 that exceeds the annual out-of-pocket threshold speci-
33 fied in 1860D–2(b)(4)(B), an amount equal to 80 per-
34 cent of the allowable costs attributable to such gross
35 covered prescription drug costs.



1 “(2) ALLOWABLE COSTS.—For purposes of this sec-
2 tion, the term ‘allowable costs’ means, with respect to gross
3 covered prescription drug costs under a plan described in
4 subsection (b) offered by a qualifying entity, the part of
5 such costs that are actually paid (net of discounts,
6 chargebacks, and average percentage rebates) under the
7 plan, but in no case more than the part of such costs that
8 would have been paid under the plan if the prescription
9 drug coverage under the plan were standard coverage.

10 “(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—
11 For purposes of this section, the term ‘gross covered pre-
12 scription drug costs’ means, with respect to an enrollee
13 with a qualifying entity under a plan described in sub-
14 section (b) during a coverage year, the costs incurred under
15 the plan (including costs attributable to administrative
16 costs) for covered prescription drugs dispensed during the
17 year, including costs relating to the deductible, whether
18 paid by the enrollee or under the plan, regardless of wheth-
19 er the coverage under the plan exceeds standard coverage
20 and regardless of when the payment for such drugs is
21 made.

22 “(4) INITIAL REINSURANCE THRESHOLD.—The initial
23 reinsurance threshold specified in this paragraph—

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

25 “(B) for a subsequent year, is equal to the pay-
26 ment threshold specified in this paragraph for the pre-
27 vious year, increased by the annual percentage increase
28 described in section 1860D–2(b)(5) for the year in-
29 volved.

30 Any amount determined under subparagraph (B) that is
31 not a multiple of \$10 shall be rounded to the nearest mul-
32 tiple of \$10.

33 “(5) QUALIFYING COVERED INDIVIDUAL DEFINED.—
34 For purposes of this subsection, the term ‘qualifying cov-
35 ered individual’ means an individual who—



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

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

4 “(d) ADJUSTMENT OF PAYMENTS.—

5 “(1) ADJUSTMENT OF REINSURANCE PAYMENTS TO
6 ASSURE 30 PERCENT LEVEL OF SUBSIDY THROUGH REIN-
7 SURANCE.—

8 “(A) ESTIMATION OF PAYMENTS.—The Adminis-
9 trator shall estimate—

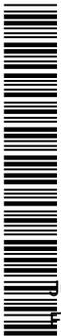
10 “(i) the total payments to be made (without
11 regard to this subsection) during a year under sub-
12 sections (a)(2) and (c); and

13 “(ii) the total payments to be made by quali-
14 fying entities for standard coverage under plans de-
15 scribed in subsection (b) during the year.

16 “(B) ADJUSTMENT.—The Administrator shall pro-
17 portionally adjust the payments made under sub-
18 sections (a)(2) and (c) for a coverage year in such
19 manner so that the total of the payments made under
20 such subsections (and under subsection (f)(3) insofar
21 as such payments reflect payments that would have
22 been made under such subsections if such subsections
23 had applied to qualified retiree prescription drug plans
24 instead of subsections (a)(3) and (f)(3)) for the year is
25 equal to 30 percent of the total payments described in
26 subparagraph (A)(ii).

27 “(2) RISK ADJUSTMENT FOR DIRECT SUBSIDIES.—To
28 the extent the Administrator determines it appropriate to
29 avoid risk selection, the payments made for direct subsidies
30 under subsection (a)(1) are subject to adjustment based
31 upon risk factors specified by the Administrator. Any such
32 risk adjustment shall be designed in a manner as to not re-
33 sult in a change in the aggregate payments made under
34 such subsection.

35 “(e) PAYMENT METHODS.—



1 “(1) IN GENERAL.—Payments under this section shall
2 be based on such a method as the Administrator deter-
3 mines. The Administrator may establish a payment method
4 by which interim payments of amounts under this section
5 are made during a year based on the Administrator’s best
6 estimate of amounts that will be payable after obtaining all
7 of the information.

8 “(2) SOURCE OF PAYMENTS.—Payments under this
9 section shall be made from the Medicare Prescription Drug
10 Trust Fund.

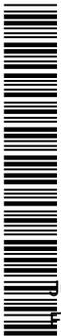
11 “(f) RULES RELATING TO QUALIFIED RETIREE PRE-
12SCRIPTION DRUG PLAN.—

13 “(1) DEFINITION.—For purposes of this section, the
14 term ‘qualified retiree prescription drug plan’ means em-
15 ployment-based retiree health coverage (as defined in para-
16 graph (4)(A)) if, with respect to an individual who is a par-
17 ticipant or beneficiary under such coverage and is eligible
18 to be enrolled in a prescription drug plan or a MA-EFFS
19 Rx plan under this part, the following requirements are
20 met:

21 “(A) ACTUARIAL EQUIVALENCE TO STANDARD
22COVERAGE.—The Administrator determines (based on
23 an actuarial analysis by the Administrator) that cov-
24 erage provides at least the same actuarial value as
25 standard coverage. Such determination may be made
26 on an annual basis.

27 “(B) AUDITS.—The sponsor (and the plan) shall
28 maintain, and afford the Administrator access to, such
29 records as the Administrator may require for purposes
30 of audits and other oversight activities necessary to en-
31 sure the adequacy of prescription drug coverage and
32 the accuracy of payments made.

33 “(C) PROVISION OF CERTIFICATION OF PRESCRIP-
34TION DRUG COVERAGE.—The sponsor of the plan shall
35 provide for issuance of certifications of the type de-
36 scribed in section 1860D–1(c)(2)(D).



1 “(2) LIMITATION ON BENEFIT ELIGIBILITY.—No pay-
2 ment shall be provided under this section with respect to
3 a participant or beneficiary in a qualified retiree prescrip-
4 tion drug plan unless the individual is—

5 “(A) is covered under the plan; and

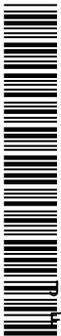
6 “(B) is eligible to obtain qualified prescription
7 drug coverage under section 1860D–1 but did not elect
8 such coverage under this part (either through a pre-
9 scription drug plan or through a MA-EFFS Rx plan).

10 “(3) EMPLOYER AND UNION SPECIAL SUBSIDY
11 AMOUNTS.—

12 “(A) IN GENERAL.—For purposes of subsection
13 (a), the special subsidy payment amount under this
14 paragraph for a qualifying covered retiree(as defined in
15 paragraph (6)) for a coverage year (as defined in sub-
16 section (h)) enrolled in a qualifying entity described in
17 subsection (b)(3) under a qualified retiree prescription
18 drug plan is, for the portion of the individual’s gross
19 covered prescription drug costs for the year that ex-
20 ceeds the deductible amount specified in subparagraph
21 (B), an amount equal to, subject to subparagraph (D),
22 28 percent of the allowable costs attributable to such
23 gross covered prescription drug costs, but not to ex-
24 ceed, subject to subparagraph (C), \$5,000 (for plan
25 years that end in 2006) in the case of any such indi-
26 vidual for the year.

27 “(B) DEDUCTIBLE APPLICABLE.—Subject to sub-
28 paragraph (C), the deductible under this subparagraph
29 is equal to \$250 for plan years that end in 2006.

30 “(C) INDEXING.—The amount specified in sub-
31 paragraph (A) and the amount of the deductible under
32 subparagraph (B) for a year after 2006 shall be ad-
33 justed in the same manner as the annual deductible
34 under section 1860D–2(b)(1) is annually adjusted
35 under such section.



1 “(D) ADJUSTMENT CONTINGENCY.—The Sec-
2 retary may adjust the percentage specified in subpara-
3 graph (A) with respect to plan years that end in a year
4 in a manner so that the aggregate expenditures in the
5 year under this section are the same as the aggregate
6 expenditures that would have been made under this
7 section (taking into account the effect of any adjust-
8 ment under subsection (d)(1)(B)) if paragraphs (1)
9 and (2) of subsection (a) had applied to qualified pre-
10 scription drug coverage instead of this paragraph and
11 subsection (a)(3).

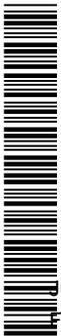
12 “(4) RELATED DEFINITIONS.—As used in this section:

13 “(A) EMPLOYMENT-BASED RETIREE HEALTH COV-
14 ERAGE.—The term ‘employment-based retiree health
15 coverage’ means health insurance or other coverage of
16 health care costs for individuals eligible to enroll in a
17 prescription drug plan or MA-EFFS Rx plan under
18 this part (or for such individuals and their spouses and
19 dependents) under a group health plan (including such
20 a plan that is established or maintained under or pur-
21 suant to one or more collective bargaining agreements)
22 based on their status as retired participants in such
23 plan.

24 “(B) QUALIFYING COVERED RETIREE.—The term
25 ‘qualifying covered retiree’ means an individual who is
26 eligible to obtain qualified prescription drug coverage
27 under section 1860D–1 but did not elect such coverage
28 under this part (either through a prescription drug
29 plan or through a MA-EFFS Rx plan) but is covered
30 under a qualified retiree prescription drug plan.

31 “(C) SPONSOR.—The term ‘sponsor’ means a plan
32 sponsor, as defined in section 3(16)(B) of the Em-
33 ployee Retirement Income Security Act of 1974.

34 “(5) CONSTRUCTION.—Nothing in this subsection
35 shall be construed as—



1 “(A) precluding an individual who is covered
2 under employment-based retiree health coverage from
3 enrolling in a prescription drug plan or in a MA-EFFS
4 plan;

5 “(B) precluding such employment-based retiree
6 health coverage or an employer or other person from
7 paying all or any portion of any premium required for
8 coverage under such a prescription drug plan or MA-
9 EFFS plan on behalf of such an individual; or

10 “(C) preventing such employment-based retiree
11 health coverage from providing coverage for retirees—

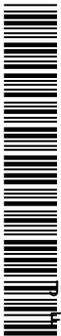
12 “(i) who are covered under a qualified retiree
13 prescription plan that is better than standard cov-
14 erage; or

15 “(ii) who are not covered under a qualified re-
16 tiree prescription plan but who are enrolled in a
17 prescription drug plan or a MA-EFFS Rx plan,
18 that is supplemental to the benefits provided under
19 such prescription drug plan or MA-EFFS Rx plan,
20 except that any such supplemental coverage (not
21 including payment of any premium referred to in
22 subparagraph (B)) shall be treated as primary cov-
23 erage to which section 1862(b)(2)(A)(i) is deemed
24 to apply.

25 “(g) COMPUTATION OF NATIONAL AVERAGE MONTHLY
26 BID AMOUNT.—

27 “(1) IN GENERAL.—For each year (beginning with
28 2006) the Administrator shall compute a national average
29 monthly bid amount equal to the average of the benchmark
30 bid amounts for each prescription drug plan and for each
31 MA-EFFS Rx plan (as computed under paragraph (2), but
32 excluding plans described in section 1851(a)(2)(C))) ad-
33 justed under paragraph (4) to take into account reinsur-
34 ance payments.

35 “(2) BENCHMARK BID AMOUNT DEFINED.—For pur-
36 poses of this subsection, the term ‘benchmark bid amount’



1 means, with respect to qualified prescription drug coverage
2 offered under—

3 “(A) a prescription drug plan that—

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

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

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

17 For purposes of subparagraph (A), the term ‘PDP bid’
18 means, with respect to a prescription drug plan, the bid
19 amount for enrollment under the plan under this part (de-
20 termined without regard to any low-income subsidy under
21 section 1860D–7 or any late enrollment penalty under sec-
22 tion 1860D–1(c)(2)(B)).

23 “(3) WEIGHTED AVERAGE.—

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

29 “(B) SPECIAL RULE FOR 2006.—For purposes of
30 applying this subsection for 2006, the Administrator
31 shall establish procedures for determining the weighted
32 average under subparagraph (A) for 2005.

33 “(4) ADJUSTMENT TO ADD BACK IN VALUE OF REIN-
34 SURANCE SUBSIDIES.—The adjustment under this para-
35 graph, to take into account reinsurance payments under
36 subsection (c) making up 30 percent of total payments, is



1 such an adjustment as will make the national average
2 monthly bid amount represent represent 100 percent, in-
3 stead of representing 70 percent, of average payments
4 under this part.

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

10 **“SEC. 1860D-9. MEDICARE PRESCRIPTION DRUG TRUST**
11 **FUND.**

12 “(a) IN GENERAL.—There is created on the books of the
13 Treasury of the United States a trust fund to be known as the
14 ‘Medicare Prescription Drug Trust Fund’ (in this section re-
15 ferred to as the ‘Trust Fund’). The Trust Fund shall consist
16 of such gifts and bequests as may be made as provided in sec-
17 tion 201(i)(1), and such amounts as may be deposited in, or
18 appropriated to, such fund as provided in this part. Except as
19 otherwise provided in this section, the provisions of subsections
20 (b) through (i) of section 1841 shall apply to the Trust Fund
21 in the same manner as they apply to the Federal Supple-
22 mentary Medical Insurance Trust Fund under such section.

23 “(b) PAYMENTS FROM TRUST FUND.—

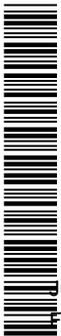
24 “(1) IN GENERAL.—The Managing Trustee shall pay
25 from time to time from the Trust Fund such amounts as
26 the Administrator certifies are necessary to make—

27 “(A) payments under section 1860D-7 (relating to
28 low-income subsidy payments);

29 “(B) payments under section 1860D-8 (relating
30 to subsidy payments); and

31 “(C) payments with respect to administrative ex-
32 penses under this part in accordance with section
33 201(g).

34 “(2) TRANSFERS TO MEDICAID ACCOUNT FOR IN-
35 CREASED ADMINISTRATIVE COSTS.—The Managing Trustee
36 shall transfer from time to time from the Trust Fund to



1 the Grants to States for Medicaid account amounts the Ad-
2 ministrator certifies are attributable to increases in pay-
3 ment resulting from the application of a higher Federal
4 matching percentage under section 1935(b).

5 “(c) DEPOSITS INTO TRUST FUND.—

6 “(1) LOW-INCOME TRANSFER.—There is hereby trans-
7 ferred to the Trust Fund, from amounts appropriated for
8 Grants to States for Medicaid, amounts equivalent to the
9 aggregate amount of the reductions in payments under sec-
10 tion 1903(a)(1) attributable to the application of section
11 1935(e).

12 “(2) APPROPRIATIONS TO COVER GOVERNMENT CON-
13 TRIBUTIONS.—There are authorized to be appropriated
14 from time to time, out of any moneys in the Treasury not
15 otherwise appropriated, to the Trust Fund, an amount
16 equivalent to the amount of payments made from the Trust
17 Fund under subsection (b), reduced by the amount trans-
18 ferred to the Trust Fund under paragraph (1).

19 “(d) RELATION TO SOLVENCY REQUIREMENTS.—Any pro-
20 vision of law that relates to the solvency of the Trust Fund
21 under this part shall take into account the Trust Fund and
22 amounts receivable by, or payable from, the Trust Fund.

23 **“SEC. 1860D-10. DEFINITIONS; APPLICATION TO MEDI-
24 CARE ADVANTAGE AND EFFS PROGRAMS;
25 TREATMENT OF REFERENCES TO PROVI-
26 SIONS IN PART C.**

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

28 “(1) COVERED OUTPATIENT DRUGS.—The term ‘cov-
29 ered outpatient drugs’ is defined in section 1860D-2(f).

30 “(2) INITIAL COVERAGE LIMIT.—The term ‘initial cov-
31 erage limit’ means such limit as established under section
32 1860D-2(b)(3), or, in the case of coverage that is not
33 standard coverage, the comparable limit (if any) established
34 under the coverage.

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

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

4 “(5) PRESCRIPTION DRUG PLAN.—The term ‘prescrip-
5 tion drug plan’ means health benefits coverage that—

6 “(A) is offered under a policy, contract, or plan by
7 a PDP sponsor pursuant to, and in accordance with, a
8 contract between the Administrator and the sponsor
9 under section 1860D–4(b);

10 “(B) provides qualified prescription drug coverage;
11 and

12 “(C) meets the applicable requirements of the sec-
13 tion 1860D–3 for a prescription drug plan.

14 “(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—
15 The term ‘qualified prescription drug coverage’ is defined
16 in section 1860D–2(a).

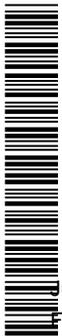
17 “(7) STANDARD COVERAGE.—The term ‘standard cov-
18 erage’ is defined in section 1860D–2(b).

19 “(b) OFFER OF QUALIFIED PRESCRIPTION DRUG COV-
20 ERAGE UNDER MEDICARE ADVANTAGE AND EFFS PRO-
21 GRAMS.—

22 “(1) AS PART OF MEDICARE ADVANTAGE PLAN.—
23 Medicare Advantage organizations are required to offer
24 Medicare Advantage plans that include qualified prescrip-
25 tion drug coverage under part C pursuant to section
26 1851(j).

27 “(2) AS PART OF EFFS PLAN.—EFFS organizations
28 are required to offer EFFS plans that include qualified
29 prescription drug coverage under part E pursuant to sec-
30 tion 1860E–2(d).

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



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

3 “(2) any reference to a provider-sponsored organiza-
4 tion included a reference to a PDP sponsor;

5 “(3) any reference to a contract under section 1857
6 included a reference to a contract under section 1860D-
7 4(b); and

8 “(4) any reference to part C included a reference to
9 this part.

10 “(d) REPORT ON PHARMACY SERVICES PROVIDED TO
11 NURSING FACILITY PATIENTS.—

12 “(1) REVIEW.—Within 6 months after the date of the
13 enactment of this section, the Secretary shall review the
14 current standards of practice for pharmacy services pro-
15 vided to patients in nursing facilities.

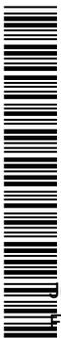
16 “(2) EVALUATIONS AND RECOMMENDATIONS.—Spe-
17 cifically in the review under paragraph (1), the Secretary
18 shall—

19 “(A) assess the current standards of practice, clin-
20 ical services, and other service requirements generally
21 utilized for pharmacy services in the long-term care set-
22 ting;

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

26 “(C) recommend (in the Secretary’s report under
27 paragraph (3)) necessary actions and appropriate reim-
28 bursement to ensure the provision of prescription drugs
29 to medicare beneficiaries residing in nursing facilities
30 in a manner consistent with existing patient safety and
31 quality of care standards under applicable State and
32 Federal laws.

33 “(3) REPORT.—The Secretary shall submit a report to
34 the Congress on the Secretary’s findings and recommenda-
35 tions under this subsection, including a detailed description
36 of the Secretary’s plans to implement this part in a manner



1 consistent with applicable State and Federal laws designed
2 to protect the safety and quality of care of nursing facility
3 patients.”.

4 (b) ADDITIONAL CONFORMING CHANGES.—

5 (1) CONFORMING REFERENCES TO PREVIOUS PART
6 D.—Any reference in law (in effect before the date of the
7 enactment of this Act) to part D of title XVIII of the So-
8 cial Security Act is deemed a reference to part F of such
9 title (as in effect after such date).

10 (2) CONFORMING AMENDMENT PERMITTING WAIVER
11 OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C.
12 1320a-7b(b)(3)) is amended—

13 (A) by striking “and” at the end of subparagraph
14 (E);

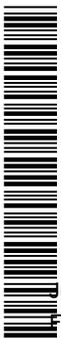
15 (B) by striking the period at the end of subpara-
16 graph (F) and inserting “; and”; and

17 (C) by adding at the end the following new sub-
18 paragraph:

19 “(G) the waiver or reduction of any cost-sharing im-
20 posed under part D of title XVIII.”.

21 (3) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not
22 later than 6 months after the date of the enactment of this
23 Act, the Secretary of Health and Human Services shall
24 submit to the appropriate committees of Congress a legisla-
25 tive proposal providing for such technical and conforming
26 amendments in the law as are required by the provisions
27 of this subtitle.

28 (c) STUDY ON TRANSITIONING PART B PRESCRIPTION
29 DRUG COVERAGE.—Not later than January 1, 2005, the Medi-
30 care Benefits Administrator shall submit a report to Congress
31 that makes recommendations regarding methods for providing
32 benefits under part D of title XVIII of the Social Security Act
33 for outpatient prescription drugs for which benefits are pro-
34 vided under part B of such title.



1 **SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION**
2 **DRUG COVERAGE UNDER MEDICARE ADVAN-**
3 **TAGE AND ENHANCED FEE-FOR-SERVICE**
4 **(EFFS) PROGRAM.**

5 (a) **MEDICARE ADVANTAGE.**—Section 1851 (42 U.S.C.
6 1395w-21) is amended by adding at the end the following new
7 subsection:

8 “(j) **AVAILABILITY OF PRESCRIPTION DRUG BENEFITS**
9 **AND SUBSIDIES.**—

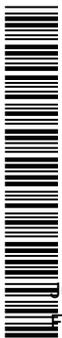
10 “(1) **OFFERING OF QUALIFIED PRESCRIPTION DRUG**
11 **COVERAGE.**—A Medicare Advantage organization on and
12 after January 1, 2006—

13 “(A) may not offer a Medicare Advantage plan de-
14 scribed in section 1851(a)(2)(A) in an area unless ei-
15 ther that plan (or another Medicare Advantage plan of-
16 fered by the organization in that area) includes quali-
17 fied prescription drug coverage; and

18 “(B) may not offer the prescription drug coverage
19 (other than that required under parts A and B) to an
20 enrollee under a Medicare Advantage plan, unless such
21 drug coverage is at least qualified prescription drug
22 coverage and unless the requirements of this subsection
23 with respect to such coverage are met.

24 “(2) **REQUIREMENT FOR ELECTION OF PART D COV-**
25 **ERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COV-**
26 **ERAGE.**—For purposes of this part, an individual who has
27 not elected qualified prescription drug coverage under sec-
28 tion 1860D-1(b) shall be treated as being ineligible to en-
29 roll in a Medicare Advantage plan under this part that of-
30 fers such coverage.

31 “(3) **COMPLIANCE WITH CERTAIN ADDITIONAL BENE-**
32 **FIICIARY PROTECTIONS FOR PRESCRIPTION DRUG COV-**
33 **ERAGE.**—With respect to the offering of qualified prescrip-
34 tion drug coverage by a Medicare Advantage organization
35 under this part on and after January 1, 2006, the organi-
36 zation and plan shall meet the requirements of subsections
37 (a) through (d) of section 1860D-3 in the same manner as



1 they apply to a PDP sponsor and a prescription drug plan
2 under part D and shall submit to the Administrator the in-
3 formation described in section 1860D-6(a)(2). The Admin-
4 istrator shall waive such requirements to the extent the Ad-
5 istrator determines that such requirements duplicate re-
6 quirements otherwise applicable to the organization or plan
7 under this part.

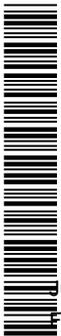
8 “(4) AVAILABILITY OF PREMIUM AND COST-SHARING
9 SUBSIDIES.—In the case of low-income individuals who are
10 enrolled in a Medicare Advantage plan that provides quali-
11 fied prescription drug coverage, premium and cost-sharing
12 subsidies are provided for such coverage under section
13 1860D-7.

14 “(5) AVAILABILITY OF DIRECT AND REINSURANCE
15 SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—Medicare
16 Advantage organizations are provided direct and reinsur-
17 ance subsidy payments for providing qualified prescription
18 drug coverage under this part under section 1860D-8.

19 “(6) CONSOLIDATION OF DRUG AND NON-DRUG PRE-
20 MIUMS.—In the case of a Medicare Advantage plan that in-
21 cludes qualified prescription drug coverage, with respect to
22 an enrollee in such plan there shall be a single premium
23 for both drug and non-drug coverage provided under the
24 plan.

25 “(7) TRANSITION IN INITIAL ENROLLMENT PERIOD.—
26 Notwithstanding any other provision of this part, the an-
27 nual, coordinated election period under subsection (e)(3)(B)
28 for 2006 shall be the 6-month period beginning with No-
29 vember 2005.

30 “(8) QUALIFIED PRESCRIPTION DRUG COVERAGE;
31 STANDARD COVERAGE.—For purposes of this part, the
32 terms ‘qualified prescription drug coverage’ and ‘standard
33 coverage’ have the meanings given such terms in section
34 1860D-2.”



1 (b) APPLICATION TO EFFS PLANS.—Subsection (d) of
2 section 1860E–2, as added by section 201(a), is amended to
3 read as follows:

4 “(d) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS
5 AND SUBSIDIES.—

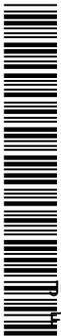
6 “(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG
7 COVERAGE.—An EFFS organization—

8 “(A) may not offer an EFFS plan in an area un-
9 less either that plan (or another EFFS plan offered by
10 the organization in that area) includes qualified pre-
11 scription drug coverage; and

12 “(B) may not offer the prescription drug coverage
13 (other than that required under parts A and B) to an
14 enrollee under an EFFS plan, unless such drug cov-
15 erage is at least qualified prescription drug coverage
16 and unless the requirements of this subsection with re-
17 spect to such coverage are met.

18 “(2) REQUIREMENT FOR ELECTION OF PART D COV-
19 ERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COV-
20 ERAGE.—For purposes of this part, an individual who has
21 not elected qualified prescription drug coverage under sec-
22 tion 1860D–1(b) shall be treated as being ineligible to en-
23 roll in an EFFS plan under this part that offers such cov-
24 erage.

25 “(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENE-
26 FICIARY PROTECTIONS FOR PRESCRIPTION DRUG COV-
27 ERAGE.—With respect to the offering of qualified prescrip-
28 tion drug coverage by an EFFS organization under this
29 part, the organization and plan shall meet the requirements
30 of subsections (a) through (d) of section 1860D–3 in the
31 same manner as they apply to a PDP sponsor and a pre-
32 scription drug plan under part D and shall submit to the
33 Administrator the information described in section 1860D–
34 6(a)(2). The Administrator shall waive such requirements
35 to the extent the Administrator determines that such re-



1 quirements duplicate requirements otherwise applicable to
2 the organization or plan under this part.

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

8 “(5) AVAILABILITY OF DIRECT AND REINSURANCE
9 SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—EFFF orga-
10 nizations are provided direct and reinsurance subsidy pay-
11 ments for providing qualified prescription drug coverage
12 under this part under section 1860D–8.

13 “(6) CONSOLIDATION OF DRUG AND NON-DRUG PRE-
14 MIUMS.—In the case of an EFFF plan that includes quali-
15 fied prescription drug coverage, with respect to an enrollee
16 in such plan there shall be a single premium for both drug
17 and non-drug coverage provided under the plan.

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

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

25 (1) in subsection (a)(1)—

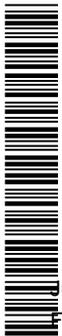
26 (A) by inserting “(other than qualified prescrip-
27 tion drug benefits)” after “benefits”;

28 (B) by striking the period at the end of subpara-
29 graph (B) and inserting a comma; and

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

32 “and may elect qualified prescription drug coverage in ac-
33 cordance with section 1860D–1.”; and

34 (2) in subsection (g)(1), by inserting “and section
35 1860D–1(c)(2)(B)” after “in this subsection”.



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

3 **SEC. 103. MEDICAID AMENDMENTS.**

4 (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME
5 SUBSIDIES.—

6 (1) REQUIREMENT.—Section 1902(a) (42 U.S.C.
7 1396a(a)) is amended—

8 (A) by striking “and” at the end of paragraph
9 (64);

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

12 (C) by inserting after paragraph (65) the following
13 new paragraph:

14 “(66) provide for making eligibility determinations
15 under section 1935(a).”.

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

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

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

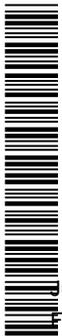
21 “SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION
22 DRUG BENEFIT

23 “SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGIBILITY
24 DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—As a condi-
25 tion of its State plan under this title under section 1902(a)(66)
26 and receipt of any Federal financial assistance under section
27 1903(a), a State shall—

28 “(1) make determinations of eligibility for premium
29 and cost-sharing subsidies under (and in accordance with)
30 section 1860D–7;

31 “(2) inform the Administrator of the Medicare Bene-
32 fits Administration of such determinations in cases in
33 which such eligibility is established; and

34 “(3) otherwise provide such Administrator with such
35 information as may be required to carry out part D of title
36 XVIII (including section 1860D–7).



1 “(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE
2 COSTS.—

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

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

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

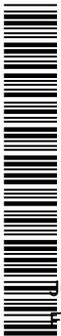
22 “(ii) For purposes of clause (i), the ‘applicable
23 percent’ for—

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

25 “(II) a subsequent year is the applicable per-
26 cent under this clause for the previous year in-
27 creased by $6\frac{2}{3}$ percentage points.

28 “(C) For expenditures attributable to costs in-
29 curred after 2018, the otherwise applicable Federal
30 matching rate shall be increased to 100 percent.

31 “(2) COORDINATION.—The State shall provide the Ad-
32 ministrator with such information as may be necessary to
33 properly allocate administrative expenditures described in
34 paragraph (1) that may otherwise be made for similar eligi-
35 bility determinations.”.



1 (b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RE-
2 SPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES
3 FOR DUALY ELIGIBLE INDIVIDUALS.—

4 (1) IN GENERAL.—Section 1903(a)(1) (42 U.S.C.
5 1396b(a)(1)) is amended by inserting before the semicolon
6 the following: “, reduced by the amount computed under
7 section 1935(e)(1) for the State and the quarter”.

8 (2) AMOUNT DESCRIBED.—Section 1935, as inserted
9 by subsection (a)(2), is amended by adding at the end the
10 following new subsection:

11 “(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION
12 DRUG COSTS FOR DUALY-ELIGIBLE BENEFICIARIES.—

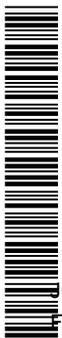
13 “(1) IN GENERAL.—For purposes of section
14 1903(a)(1), for a State that is one of the 50 States or the
15 District of Columbia for a calendar quarter in a year (be-
16 ginning with 2005) the amount computed under this sub-
17 section is equal to the product of the following:

18 “(A) MEDICARE SUBSIDIES.—The total amount of
19 payments made in the quarter under section 1860D-7
20 (relating to premium and cost-sharing prescription
21 drug subsidies for low-income medicare beneficiaries)
22 that are attributable to individuals who are residents of
23 the State and are entitled to benefits with respect to
24 prescribed drugs under the State plan under this title
25 (including such a plan operating under a waiver under
26 section 1115).

27 “(B) STATE MATCHING RATE.—A proportion com-
28 puted by subtracting from 100 percent the Federal
29 medical assistance percentage (as defined in section
30 1905(b)) applicable to the State and the quarter.

31 “(C) PHASE-OUT PROPORTION.—The phase-out
32 proportion (as defined in paragraph (2)) for the quar-
33 ter.

34 “(2) PHASE-OUT PROPORTION.—For purposes of para-
35 graph (1)(C), the ‘phase-out proportion’ for a calendar
36 quarter in—



1 “(A) 2006 is 93-1/3 percent;

2 “(B) a subsequent year before 2021, is the phase-
3 out proportion for calendar quarters in the previous
4 year decreased by 6-2/3 percentage points; or

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

6 (c) MEDICAID PROVIDING WRAP-AROUND BENEFITS.—

7 Section 1935, as so inserted and amended, is further amended
8 by adding at the end the following new subsection:

9 “(d) ADDITIONAL PROVISIONS.—

10 “(1) MEDICAID AS SECONDARY PAYOR.—In the case of
11 an individual who is entitled to qualified prescription drug
12 coverage under a prescription drug plan under part D of
13 title XVIII (or under a MA-EFFS Rx plan under part C
14 or E of such title) and medical assistance for prescribed
15 drugs under this title, medical assistance shall continue to
16 be provided under this title for prescribed drugs to the ex-
17 tent payment is not made under the prescription drug plan
18 or MA-EFFS Rx plan selected by the individual.

19 “(2) CONDITION.—A State may require, as a condition
20 for the receipt of medical assistance under this title with
21 respect to prescription drug benefits for an individual eligi-
22 ble to obtain qualified prescription drug coverage described
23 in paragraph (1), that the individual elect qualified pre-
24 scription drug coverage under section 1860D-1.”.

25 (d) TREATMENT OF TERRITORIES.—

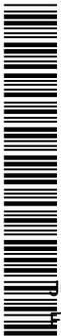
26 (1) IN GENERAL.—Section 1935, as so inserted and
27 amended, is further amended—

28 (A) in subsection (a) in the matter preceding para-
29 graph (1), by inserting “subject to subsection (e)” after
30 “section 1903(a)”;

31 (B) in subsection (c)(1), by inserting “subject to
32 subsection (e)” after “1903(a)(1)”; and

33 (C) by adding at the end the following new sub-
34 section:

35 “(e) TREATMENT OF TERRITORIES.—



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

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

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

12 “(2) PLAN.—The plan described in this paragraph is
13 a plan that—

14 “(A) provides medical assistance with respect to
15 the provision of covered outpatient drugs (as defined in
16 section 1860D–2(f)) to low-income medicare bene-
17 ficiaries; and

18 “(B) assures that additional amounts received by
19 the State that are attributable to the operation of this
20 subsection are used only for such assistance.

21 “(3) INCREASED AMOUNT.—

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

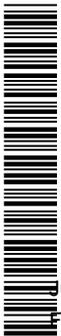
25 “(i) the aggregate amount specified in sub-
26 paragraph (B); and

27 “(ii) the amount specified in section
28 1108(g)(1) for that State, divided by the sum of
29 the amounts specified in such section for all such
30 States.

31 “(B) AGGREGATE AMOUNT.—The aggregate
32 amount specified in this subparagraph for—

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

34 “(ii) a subsequent year, is equal to the aggre-
35 gate amount specified in this subparagraph for the
36 previous year increased by annual percentage in-



1 crease specified in section 1860D–2(b)(5) for the
2 year involved.

3 “(4) REPORT.—The Administrator shall submit to
4 Congress a report on the application of this subsection and
5 may include in the report such recommendations as the Ad-
6 ministrator deems appropriate.”.

7 (2) CONFORMING AMENDMENT.—Section 1108(f) (42
8 U.S.C. 1308(f)) is amended by inserting “and section
9 1935(e)(1)(B)” after “Subject to subsection (g)”.

10 (e) AMENDMENT TO BEST PRICE.—Section
11 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

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

13 (2) by striking the period at the end of subclause (IV)
14 and inserting “; and”; and

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

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

26 **SEC. 104. MEDIGAP TRANSITION.**

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

29 “(v) COVERAGE OF PRESCRIPTION DRUGS.—

30 “(1) IN GENERAL.—Notwithstanding any other provi-
31 sion of law, except as provided in paragraph (3) no new
32 medicare supplemental policy that provides coverage of ex-
33 penses for prescription drugs may be issued under this sec-
34 tion on or after January 1, 2006, to an individual unless
35 it replaces a medicare supplemental policy that was issued
36 to that individual and that provided some coverage of ex-



1 penses for prescription drugs. Nothing in this subsection
2 shall be construed as preventing the policy holder of a
3 medicare supplemental policy issued before January 1,
4 2006, from continuing to receive benefits under such policy
5 on and after such date.

6 “(2) ISSUANCE OF SUBSTITUTE POLICIES FOR BENE-
7 FICIARIES ENROLLED WITH A PLAN UNDER PART D.—

8 “(A) IN GENERAL.—The issuer of a medicare sup-
9 plemental policy—

10 “(i) may not deny or condition the issuance or
11 effectiveness of a medicare supplemental policy that
12 has a benefit package classified as ‘A’, ‘B’, ‘C’, ‘D’,
13 ‘E’, ‘F’, or ‘G’ (under the standards established
14 under subsection (p)(2)) and that is offered and is
15 available for issuance to new enrollees by such
16 issuer;

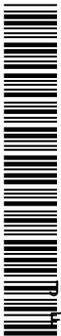
17 “(ii) may not discriminate in the pricing of
18 such policy, because of health status, claims experi-
19 ence, receipt of health care, or medical condition;
20 and

21 “(iii) may not impose an exclusion of benefits
22 based on a pre-existing condition under such policy,
23 in the case of an individual described in subparagraph
24 (B) who seeks to enroll under the policy not later than
25 63 days after the date of the termination of enrollment
26 described in such paragraph and who submits evidence
27 of the date of termination or disenrollment along with
28 the application for such medicare supplemental policy.

29 “(B) INDIVIDUAL COVERED.—An individual de-
30 scribed in this subparagraph is an individual who—

31 “(i) enrolls in a prescription drug plan under
32 part D; and

33 “(ii) at the time of such enrollment was en-
34 rolled and terminates enrollment in a medicare sup-
35 plemental policy which has a benefit package classi-
36 fied as ‘H’, ‘I’, or ‘J’ under the standards referred



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

4 “(C) ENFORCEMENT.—The provisions of para-
5 graph (4) of subsection (s) shall apply with respect to
6 the requirements of this paragraph in the same manner
7 as they apply to the requirements of such subsection.

8 “(3) NEW STANDARDS.—In applying subsection
9 (p)(1)(E) (including permitting the NAIC to revise its
10 model regulations in response to changes in law) with re-
11 spect to the change in benefits resulting from title I of the
12 Medicare Prescription Drug and Modernization Act of
13 2003, with respect to policies issued to individuals who are
14 enrolled in a plan under part D, the changes in standards
15 shall only provide for substituting (for the benefit packages
16 described in paragraph (2)(B)(ii) that included coverage for
17 prescription drugs) two benefit packages that may provide
18 for coverage of cost-sharing (other than the prescription
19 drug deductible) with respect to qualified prescription drug
20 coverage under such part. The two benefit packages shall
21 be consistent with the following:

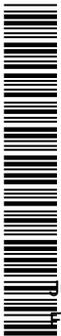
22 “(A) FIRST NEW POLICY.—The policy described in
23 this subparagraph has the following benefits, notwith-
24 standing any other provision of this section relating to
25 a core benefit package:

26 “(i) Coverage of 50 percent of the cost-sharing
27 otherwise applicable, except coverage of 100 per-
28 cent of any cost-sharing otherwise applicable for
29 preventive benefits.

30 “(ii) No coverage of the part B deductible.

31 “(iii) Coverage for all hospital coinsurance for
32 long stays (as in the current core benefit package).

33 “(iv) A limitation on annual out-of-pocket ex-
34 penditures to \$4,000 in 2005 (or, in a subsequent
35 year, to such limitation for the previous year in-



1 creased by an appropriate inflation adjustment
2 specified by the Secretary).

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

6 “(i) Substitute ‘75 percent’ for ‘50 percent’ in
7 clause (i) of such subparagraph.

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

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

15 (b) NAIC REPORT TO CONGRESS ON MEDIGAP MOD-
16 ERNIZATION.—The Secretary shall request the National Asso-
17 ciation of Insurance Commissioners to submit to Congress, not
18 later than 18 months after the date of the enactment of this
19 Act, a report that includes recommendations on the moderniza-
20 tion of coverage under the medigap program under section
21 1882 of the Social Security Act (42 U.S.C. 1395ss).

22 **SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT**
23 **CARD AND ASSISTANCE PROGRAM.**

24 (a) IN GENERAL.—Title XVIII is amended by inserting
25 after section 1806 the following new sections:

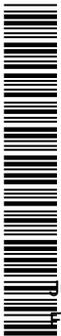
26 “MEDICARE PRESCRIPTION DRUG DISCOUNT CARD

27 ENDORSEMENT AND ASSISTANCE PROGRAM

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

29 “(1) IN GENERAL.—The Secretary (or the Medicare
30 Benefits Administrator pursuant to section 1809(c)(3)(C))
31 shall establish a program—

32 “(A) to endorse prescription drug discount card
33 programs (each such program referred to as an ‘en-
34 dorsed program’) that meet the requirements of this
35 section in order to provide access to prescription drug



1 discounts through an eligible entity for medicare bene-
2 ficiaries throughout the United States; and

3 “(B) to provide for prescription drug accounts and
4 public contributions into such accounts.

5 The Secretary shall make available to medicare bene-
6 ficiaries information regarding endorsed programs and ac-
7 counts under this section.

8 “(2) LIMITED PERIOD OF OPERATION.—The Secretary
9 shall begin—

10 “(A) the card endorsement part of the program
11 under paragraph (1)(A) as soon as possible, but in no
12 case later than 90 days after the date of the enactment
13 of this section; and

14 “(B) the prescription drug account part of the
15 program under paragraph (1)(B) as soon as possible,
16 but in no case later than September 2004.

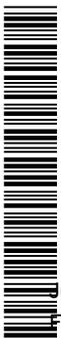
17 “(3) TRANSITION.—The program under this section
18 shall continue through 2005 throughout the United States.
19 The Secretary shall provide for an appropriate transition
20 and discontinuation of such program at the time medicare
21 prescription drug benefits become available under part D.

22 “(4) VOLUNTARY NATURE OF PROGRAM.—Nothing in
23 this section shall be construed as requiring an eligible bene-
24 ficiary to enroll in the program under this section.

25 “(b) ELIGIBLE BENEFICIARY; ELIGIBLE ENTITY; PRE-
26SCRIPTION DRUG ACCOUNT.—For purposes of this section:

27 “(1) ELIGIBLE BENEFICIARY.—The term ‘eligible ben-
28 eficiary’ means an individual who is eligible for benefits
29 under part A or enrolled under part B and who is not en-
30 rolled in a prescription drug plan or MA-EFFS Rx plan,
31 but who may be enrolled in a Medicare Advantage plan
32 that does not offer qualified prescription drug coverage.

33 “(2) ELIGIBLE ENTITY.—The term ‘eligible entity’
34 means any entity that the Secretary determines to be ap-
35 propriate to provide the benefits under this section,
36 including—



1 “(A) pharmaceutical benefit management compa-
2 nies;

3 “(B) wholesale and retail pharmacy delivery sys-
4 tems;

5 “(C) insurers;

6 “(D) Medicare Advantage or ERFSS organizations;

7 “(E) other entities; or

8 “(F) any combination of the entities described in
9 subparagraphs (A) through (E).

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

14 “(c) ENROLLMENT IN ENDORSED PLAN.—

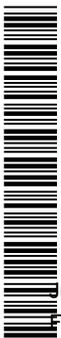
15 “(1) ESTABLISHMENT OF PROCESS.—

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

20 “(B) REQUIREMENT OF ENROLLMENT.—An eligi-
21 ble beneficiary must enroll under this section for a year
22 in order to be eligible to receive the benefits under this
23 section for that year.

24 “(C) LIMITATION ON ENROLLMENT.—

25 “(i) IN GENERAL.—Except as provided under
26 this subparagraph and under such exceptional cir-
27 cumstances as the Secretary may provide, an eligi-
28 ble individual shall have the opportunity to enroll
29 under this section during an initial, general enroll-
30 ment period as soon as possible after the date of
31 the enactment of this section and annually there-
32 after. The Secretary shall specify the form, man-
33 ner, and timing of such election but shall permit
34 the exercise of such election at the time the indi-
35 vidual is eligible to enroll. The annual open enroll-
36 ment periods shall be coordinated with those pro-



1 vided under the Medicare Advantage and EFFE
2 programs under parts C and E as well as under the
3 prescription drug program under part D.

4 “(ii) REELECTION AFTER TERMINATION OF
5 ENROLLMENT IN A MEDICARE ADVANTAGE PLAN.—
6 In the case of an individual who is enrolled under
7 this section and who subsequently enrolls in a
8 Medicare Advantage plan that provides qualified
9 prescription drug coverage under part C, the indi-
10 vidual shall be given the opportunity to reenroll
11 under this section at the time the individual discon-
12 tinues the enrollment under such part.

13 “(iii) LATE ENROLLMENT.—The Secretary
14 shall permit individuals to elect to enroll under this
15 section at times other than as permitted under the
16 previous provisions of this paragraph.

17 “(D) TERMINATION OF ENROLLMENT.—An en-
18 rollee under this section shall be disenrolled—

19 “(i) upon enrollment in a prescription drug
20 plan under part D or a Medicare Advantage or
21 EFFS plan under part C or E that provides quali-
22 fied prescription drug coverage;

23 “(ii) upon failure to pay the applicable enroll-
24 ment fee under subsection (f);

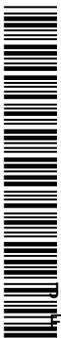
25 “(iii) upon termination of coverage under part
26 A or part B; or

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

30 Terminations of enrollment under this subparagraph
31 shall be effective as specified by the Secretary in regu-
32 lations.

33 “(2) ENROLLMENT PERIODS.—

34 “(A) IN GENERAL.—Except as provided under this
35 paragraph, an eligible beneficiary may not enroll in the
36 program under this part during any period after the



1 beneficiary's initial enrollment period under part B (as
2 determined under section 1837).

3 “(B) OPEN ENROLLMENT PERIOD FOR CURRENT
4 BENEFICIARIES.—The Secretary shall establish a pe-
5 riod, which shall begin on the date on which the Sec-
6 retary first begins to accept elections for enrollment
7 under this section and shall end not earlier than 3
8 months later, during which any eligible beneficiary may
9 enroll under this section.

10 “(C) SPECIAL ENROLLMENT PERIOD IN CASE OF
11 TERMINATION OF COVERAGE UNDER A GROUP HEALTH
12 PLAN.—The Secretary shall provide for a special enroll-
13 ment period under this section in the same manner as
14 is provided under section 1837(i) with respect to part
15 B, except that for purposes of this subparagraph any
16 reference to ‘by reason of the individual’s (or the indi-
17 vidual’s spouse’s) current employment status’ shall be
18 treated as being deleted.

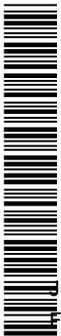
19 “(3) PERIOD OF COVERAGE.—

20 “(A) IN GENERAL.—Except as provided in sub-
21 paragraph (B) and subject to subparagraph (C), an eli-
22 gible beneficiary’s coverage under the program under
23 this section shall be effective for the period provided
24 under section 1838, as if that section applied to the
25 program under this section.

26 “(B) ENROLLMENT DURING OPEN AND SPECIAL
27 ENROLLMENT.—Subject to subparagraph (C), an eligi-
28 ble beneficiary who enrolls under the program under
29 this section under subparagraph (B) or (C) of para-
30 graph (2) shall be entitled to the benefits under this
31 section beginning on the first day of the month fol-
32 lowing the month in which such enrollment occurs.

33 “(d) SELECTION OF AN ELIGIBLE ENTITY FOR ACCESS TO
34 NEGOTIATED PRICES.—

35 “(1) PROCESS.—



1 “(A) IN GENERAL.—The Secretary shall establish
2 a process through which an eligible beneficiary who is
3 enrolled under this section shall select any eligible enti-
4 ty, that has been awarded a contract under this section
5 and serves the State in which the beneficiary resides,
6 to provide access to negotiated prices under subsection
7 (i).

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

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

16 “(ii) an individual shall only be permitted (ex-
17 cept for unusual circumstances) to change the se-
18 lection of the entity once a year.

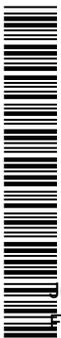
19 In carrying out clause (ii), the Secretary may consider
20 a change in residential setting (such as placement in a
21 nursing facility) to be an unusual circumstance.

22 “(C) DEFAULT SELECTION.—In establishing such
23 process, the Secretary shall provide an equitable meth-
24 od for selecting an eligible entity for individuals who
25 enroll under this section and fail to make such a selec-
26 tion.

27 “(2) COMPETITION.—Eligible entities with a contract
28 under this section shall compete for beneficiaries on the
29 basis of discounts, formularies, pharmacy networks, and
30 other services provided for under the contract.

31 “(e) PROVIDING ENROLLMENT, SELECTION, AND COV-
32 ERAGE INFORMATION TO BENEFICIARIES.—

33 “(1) ACTIVITIES.—The Secretary shall provide for ac-
34 tivities under this section to broadly disseminate informa-
35 tion to eligible beneficiaries (and prospective eligible bene-
36 ficiaries) regarding enrollment under this section, the selec-



1 tion of eligible entities, and the prescription drug coverage
2 made available by eligible entities with a contract under
3 this section.

4 “(2) SPECIAL RULE FOR FIRST ENROLLMENT UNDER
5 THE PROGRAM.—To the extent practicable, the activities
6 described in paragraph (1) shall ensure that eligible bene-
7 ficiaries are provided with such information at least 60
8 days prior to the first enrollment period described in sub-
9 section (c).

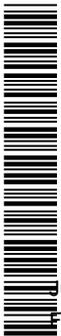
10 “(f) ENROLLMENT FEE.—

11 “(1) AMOUNT.—

12 “(A) IN GENERAL.—Except as provided in para-
13 graph (3), enrollment under the program under this
14 section is conditioned upon payment of an annual en-
15 rollment fee of \$30 for 2004 (including any portion of
16 2003 in which the program is implemented under this
17 section).

18 “(B) ANNUAL PERCENTAGE INCREASE IN ENROLL-
19 MENT FEE.—In the case of any calendar year begin-
20 ning after 2004, the dollar amount of the enrollment
21 fee in subparagraph (A) shall be the dollar amount of
22 such fee for the previous year increased by the annual
23 percentage increase in the consumer price index for all
24 urban consumers (U.S. city average; all items) as of
25 September before the beginning of the year involved. If
26 any increase determined under the previous sentence is
27 not a multiple of \$1, such increase shall be rounded to
28 the nearest multiple of \$1.

29 “(2) COLLECTION OF ENROLLMENT FEE.—The annual
30 enrollment fee shall be collected and credited to the Federal
31 Supplementary Medical Insurance Trust Fund in the same
32 manner as the monthly premium determined under section
33 1839 is collected and credited to such Trust Fund under
34 section 1840, except that it shall be collected only 1 time
35 per year.



1 “(3) PAYMENT OF ENROLLMENT FEE BY STATE FOR
2 CERTAIN BENEFICIARIES.—

3 “(A) IN GENERAL.—The Secretary shall establish
4 an arrangement under which a State may provide for
5 payment of some or all of the enrollment fee for some
6 or all low income enrollees in the State, as specified by
7 the State under the arrangement. Insofar as such a
8 payment arrangement is made with respect to an en-
9 rollee, the amount of the enrollment fee shall be paid
10 directly by the State and shall not be collected under
11 paragraph (2). In carrying out this paragraph, the Sec-
12 retary may apply procedures similar to that applied
13 under state agreements under section 1843.

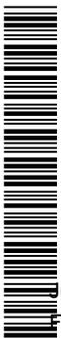
14 “(B) NO FEDERAL MATCHING AVAILABLE UNDER
15 MEDICAID OR SCHIP.—Expenditures made by a State
16 described in subparagraph (A) shall not be treated as
17 State expenditures for purposes of Federal matching
18 payments under titles XIX and XXI insofar as such ex-
19 penditures are for an enrollment fee under this sub-
20 section.

21 “(4) DISTRIBUTION OF PORTION OF ENROLLMENT
22 FEE.—Of the enrollment fee collected by the Secretary
23 under this subsection with respect to a beneficiary, $\frac{2}{3}$ of
24 that fee shall be made available to the eligible entity se-
25 lected by the eligible beneficiary.

26 “(g) ISSUANCE OF CARD AND COORDINATION.—Each eli-
27 gible entity shall—

28 “(1) issue, in a uniform standard format specified
29 by the Secretary, to each enrolled beneficiary a card
30 and an enrollment number that establishes proof of en-
31 rollment and that can be used in a coordinated
32 manner—

33 “(A) to identify the eligible entity selected to pro-
34 vide access to negotiated prices under subsection (i);
35 and



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

3 “(2) provide for electronic methods to coordinate with
4 the accounts established under section 1807A.

5 “(h) ENROLLEE PROTECTIONS.—

6 “(1) GUARANTEED ISSUE AND NONDISCRIMINATION.—

7 “(A) GUARANTEED ISSUE.—

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

18 “(ii) MEDICARE+CHOICE LIMITATIONS PER-
19 MITTED.—The provisions of paragraphs (2) and
20 (3) (other than subparagraph (C)(i), relating to de-
21 fault enrollment) of section 1851(g) (relating to
22 priority and limitation on termination of election)
23 shall apply to selection of eligible entities under
24 this paragraph.

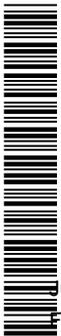
25 “(B) NONDISCRIMINATION.—An eligible entity of-
26 fering prescription drug coverage under this section
27 shall not establish a service area in a manner that
28 would discriminate based on health or economic status
29 of potential enrollees.

30 “(C) COVERAGE OF ALL PORTIONS OF A STATE.—

31 If an eligible entity with a contract under this section
32 serves any part of a State it shall serve the entire
33 State.

34 “(2) DISSEMINATION OF INFORMATION.—

35 “(A) GENERAL INFORMATION.—An eligible entity
36 with a contract under this section shall disclose, in a



1 clear, accurate, and standardized form to each eligible
2 beneficiary who has selected the entity to provide ac-
3 cess to negotiated prices under this section at the time
4 of selection and at least annually thereafter, the infor-
5 mation described in section 1852(c)(1) relating to such
6 prescription drug coverage. Such information includes
7 the following (in a manner designed to permit and pro-
8 mote competition among eligible entities):

9 “(i) Summary information regarding nego-
10 tiated prices (including discounts) for covered out-
11 patient drugs.

12 “(ii) Access to such prices through pharmacy
13 networks.

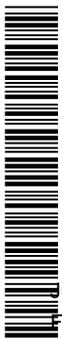
14 “(iii) How any formulary used by the eligible
15 entity functions.

16 “(B) DISCLOSURE UPON REQUEST OF GENERAL
17 COVERAGE, UTILIZATION, AND GRIEVANCE INFORMA-
18 TION.—Upon request of an eligible beneficiary, the eli-
19 gible entity shall provide the information described in
20 section 1852(c)(2) (other than subparagraph (D)) to
21 such beneficiary.

22 “(C) RESPONSE TO BENEFICIARY QUESTIONS.—
23 Each eligible entity offering prescription drug coverage
24 under this section shall have a mechanism (including a
25 toll-free telephone number) for providing upon request
26 specific information (such as negotiated prices, includ-
27 ing discounts) to individuals who have selected the enti-
28 ty. The entity shall make available, through an Internet
29 website and in writing upon request, information on
30 specific changes in its formulary.

31 “(D) COORDINATION WITH PRESCRIPTION DRUG
32 ACCOUNT BENEFITS.—Each such eligible entity shall
33 provide for coordination of such information as the Sec-
34 retary may specify to carry out section 1807A.

35 “(3) ACCESS TO COVERED BENEFITS.—



1 “(A) ENSURING PHARMACY ACCESS.—The provi-
2 sions of subsection (c)(1) of section 1860D–3 (other
3 than payment provisions under section 1860D–8 with
4 respect to sponsors under such subsection) shall apply
5 to an eligible entity under this section in the same
6 manner as they apply to a PDP sponsor under such
7 section.

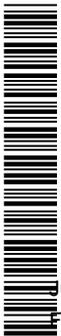
8 “(B) ACCESS TO NEGOTIATED PRICES FOR PRE-
9 SCRIPTION DRUGS.—For requirements relating to the
10 access of an eligible beneficiary to negotiated prices (in-
11 cluding applicable discounts), see subsection (i).

12 “(C) REQUIREMENTS ON DEVELOPMENT AND AP-
13 PLICATION OF FORMULARIES.—Insofar as an eligible
14 entity with a contract under this part uses a formulary,
15 the entity shall comply with the requirements of section
16 1860D–3(c)(3), insofar as the Secretary determines
17 that such requirements can be implemented on a timely
18 basis.

19 “(4) COST AND UTILIZATION MANAGEMENT; QUALITY
20 ASSURANCE; MEDICATION THERAPY MANAGEMENT PRO-
21 GRAM.—

22 “(A) IN GENERAL.—For purposes of providing ac-
23 cess to negotiated benefits under subsection (i), the eli-
24 gible entity shall have in place the programs and meas-
25 ure described in section 1860D–3(d), including an ef-
26 fective cost and drug utilization management program,
27 quality assurance measures and systems, and a pro-
28 gram to control fraud, abuse, and waste, insofar as the
29 Secretary determines that such provisions can be imple-
30 mented on a timely basis.

31 “(B) TREATMENT OF ACCREDITATION.—Section
32 1852(e)(4) (relating to treatment of accreditation) shall
33 apply to the requirements for an endorsed program
34 under this section with respect to the following require-
35 ments, in the same manner as they apply to Medicare
36 Advantage plans under part C with respect to the re-



1 quirements described in a clause of section
2 1852(e)(4)(B):

3 “(i) Paragraph (3)(A) (relating to access to
4 covered benefits).

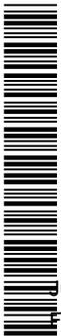
5 “(ii) Paragraph (7) (relating to confidentiality
6 and accuracy of enrollee records).

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

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

16 “(7) COVERAGE DETERMINATIONS AND RECONSIDER-
17 ATIONS.—An eligible entity shall meet the requirements of
18 section 1852(g) with respect to covered benefits under the
19 prescription drug coverage it offers under this section in
20 the same manner as such requirements apply to a Medicare
21 Advantage organization with respect to benefits it offers
22 under a Medicare Advantage plan under part C.

23 “(8) CONFIDENTIALITY AND ACCURACY OF ENROLLEE
24 RECORDS.—An eligible entity shall meet the requirements
25 of section 1852(h) with respect to enrollees under this sec-
26 tion in the same manner as such requirements apply to a
27 Medicare Advantage organization with respect to enrollees
28 under part C. The eligible entity shall implement policies
29 and procedures to safeguard the use and disclosure of en-
30 rollees’ individually identifiable health information in a
31 manner consistent with the Federal regulations (concerning
32 the privacy of individually identifiable health information)
33 promulgated under section 264(e) of the Health Insurance
34 Portability and Accountability Act of 1996. The eligible en-
35 tity shall be treated as a covered entity for purposes of the
36 provisions of subpart E of part 164 of title 45, Code of



1 Federal Regulations, adopted pursuant to the authority of
2 the Secretary under section 264(c) of the Health Insurance
3 Portability and Accountability Act of 1996 (42 U.S. C.
4 1320d-2 note).

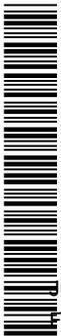
5 “(9) PERIODIC REPORTS AND OVERSIGHT.—The eligi-
6 ble entity shall submit to the Secretary periodic reports on
7 performance, utilization, finances, and such other matters
8 as the Secretary may specify. The Secretary shall provide
9 appropriate oversight to ensure compliance of eligible enti-
10 ties with the requirements of this subsection, including ver-
11 ification of the discounts and services provided.

12 “(10) ADDITIONAL BENEFICIARY PROTECTIONS.—The
13 eligible entity meets such additional requirements as the
14 Secretary identifies to protect and promote the interest of
15 enrollees, including requirements that ensure that enrollees
16 are not charged more than the lower of the negotiated re-
17 tail price or the usual and customary price.

18 “(i) BENEFITS UNDER THE PROGRAM THROUGH SAVINGS
19 TO ENROLLEES THROUGH NEGOTIATED PRICES.—

20 “(1) IN GENERAL.—Subject to paragraph (2), each el-
21 igible entity with a contract under this section shall provide
22 each eligible beneficiary enrolled with the entity with access
23 to negotiated prices (including applicable discounts). For
24 purposes of this paragraph, the term ‘prescription drugs’ is
25 not limited to covered outpatient drugs, but does not in-
26 clude any over-the-counter drug that is not a covered out-
27 patient drug. The prices negotiated by an eligible entity
28 under this paragraph shall (notwithstanding any other pro-
29 vision of law) not be taken into account for the purposes
30 of establishing the best price under section 1927(c)(1)(C).

31 “(2) FORMULARY RESTRICTIONS.—Insofar as an eligi-
32 ble entity with a contract under this part uses a formulary,
33 the negotiated prices (including applicable discounts) for
34 prescription drugs shall only be available for drugs included
35 in such formulary.



1 “(3) PROHIBITION ON APPLICATION ONLY TO MAIL
2 ORDER.—The negotiated prices under this subsection shall
3 apply to prescription drugs that are available other than
4 solely through mail order.

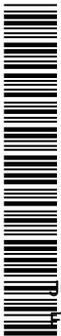
5 “(4) PROHIBITION ON CHARGES FOR REQUIRED SERV-
6 ICES.—An eligible entity (and any pharmacy contracting
7 with such entity for the provision of a discount under this
8 section) may not charge a beneficiary any amount for any
9 services required to be provided by the entity under this
10 section.

11 “(5) DISCLOSURE.—The eligible entity offering the en-
12 dorsed program shall disclose to the Secretary (in a man-
13 ner specified by the Secretary) the extent to which dis-
14 counts or rebates or other remuneration or price conces-
15 sions made available to the entity by a manufacturer are
16 passed through to enrollees through pharmacies and other
17 dispensers or otherwise. The provisions of section
18 1927(b)(3)(D) shall apply to information disclosed to the
19 Administrator under this paragraph in the same manner as
20 such provisions apply to information disclosed under such
21 section.

22 “(6) PUBLIC DISCLOSURE OF PHARMACEUTICAL
23 PRICES FOR EQUIVALENT DRUGS.—Each eligible entity
24 shall provide that each pharmacy or other dispenser that
25 arranges for the dispensing of a covered outpatient drug in
26 connection with its endorsed program shall inform the en-
27 rollee in that program at the time of purchase of the drug
28 of any differential between the price of the prescribed drug
29 to the enrollee and the price of the lowest cost available ge-
30 neric drug covered under the program that is therapeuti-
31 cally equivalent and bioequivalent.

32 “(j) CONTRIBUTION INTO PRESCRIPTION DRUG AC-
33 COUNT.—

34 “(1) IN GENERAL.—In the case of an individual en-
35 rolled under this section—



1 “(A) the Secretary shall establish a prescription
2 drug account for the individual under section 1807A;
3 and

4 “(B) shall deposit into such account on a monthly
5 or other periodic basis an amount that, on an annual
6 basis, is equivalent to the annual Federal contribution
7 amount specified in paragraph (2) for the enrollee in-
8 volved.

9 “(2) ANNUAL FEDERAL CONTRIBUTION AMOUNT.—

10 “(A) IN 2004.—Subject to paragraphs (3) and (4),
11 in the case of an accountholder whose modified ad-
12 justed gross income is—

13 “(i) not more than 135 percent of the poverty
14 line, the annual Federal contribution amount for
15 2004 is \$800;

16 “(ii) more than 135 percent, but less than 150
17 percent, of the poverty line, the annual Federal
18 contribution amount for 2004 is \$500; and

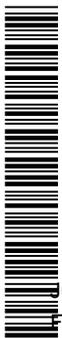
19 “(iii) more than 150 percent of the poverty
20 line, the annual Federal contribution amount for
21 2004 is \$100.

22 “(B) THEREAFTER.—For periods after 2004, the
23 amounts applicable under subparagraph (A) shall be in-
24 creased by the annual percentage increase described in
25 section 1860D-2(b)(5) for the period involved.

26 “(C) ROUNDING.—If an annual Federal contribu-
27 tion amount determined under subparagraph (B) is not
28 a multiple of \$10, it shall be rounded to the nearest
29 multiple of \$10.

30 “(3) REQUIREMENT FOR INCOME VERIFICATION TO
31 OBTAIN INCREASED CONTRIBUTION AMOUNT.—

32 “(A) IN GENERAL.—The provisions of subsections
33 clauses (i) and (ii) of subparagraphs (A) and (B) of
34 paragraph (2) shall apply to an individual only if the
35 individual—



1 “(i) provides such information as the Sec-
2 retary may require in order to determine the appro-
3 priate category of benefits under the respective pro-
4 visions; and

5 “(ii) authorizes in a form and manner speci-
6 fied by the Secretary the verification of the individ-
7 ual’s modified adjusted gross income by the Sec-
8 retary through arrangements with States.

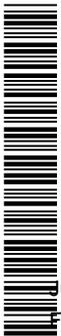
9 An arrangement with a State under clause (ii) shall
10 provide for the payment by the Secretary under this
11 section of the State’s reasonable costs of conducting in-
12 come verifications under such arrangement.

13 “(B) PENALTIES FOR UNDERSTATEMENT OF IN-
14 COME.—The provision of false information under sub-
15 paragraph (A)(i) is subject to criminal penalties under
16 section 1128B.

17 “(C) PROCEDURES FOR DETERMINING MODIFIED
18 ADJUSTED GROSS INCOME.—

19 “(i) IN GENERAL.—The Secretary shall estab-
20 lish procedures for determining the modified ad-
21 justed gross income of enrollees. The Secretary
22 shall consult with the Secretary of the Treasury in
23 making such determinations. Income determina-
24 tions under this subsection shall be valid for a pe-
25 riod (of not less than 1 year) specified by the Sec-
26 retary.

27 “(ii) DISCLOSURE OF INFORMATION.—The
28 Secretary of the Treasury may, upon written re-
29 quest from the Secretary, disclose to Secretary
30 such return information as is necessary to make
31 the determinations described in clause (i). Return
32 information disclosed under the preceding sentence
33 may be used by the Secretary only for the purposes
34 of, and to the extent necessary in, making such de-
35 terminations.



1 “(iii) PENALTY FOR UNAUTHORIZED DISCLO-
2 SURE.—The provisions of section 1860D–
3 2(b)(4)(F)(ii) shall apply to an unauthorized disclo-
4 sure of information under clause (ii) in the same
5 manner as those provisions apply to an unauthor-
6 ized disclosure of information under such section.

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

12 “(5) APPROPRIATION TO COVER NET PROGRAM EX-
13 PENDITURES.—There are authorized to be appropriated
14 from time to time, out of any moneys in the Treasury not
15 otherwise appropriated, to the Federal Supplementary Med-
16 ical Insurance Trust Fund established under section 1841,
17 an amount equal to the amount by which the benefits and
18 administrative costs of providing the benefits under this
19 section exceed the sum of the portion of the enrollment fees
20 retained by the Secretary.

21 “(k) DEFINITIONS.—In this part and section 1807A:

22 “(1) COVERED OUTPATIENT DRUG.—

23 “(A) IN GENERAL.—Except as provided in this
24 paragraph, for purposes of this section, the term ‘cov-
25 ered outpatient drug’ means—

26 “(i) a drug that may be dispensed only upon
27 a prescription and that is described in subpara-
28 graph (A)(i) or (A)(ii) of section 1927(k)(2); or

29 “(ii) a biological product described in clauses
30 (i) through (iii) of subparagraph (B) of such sec-
31 tion or insulin described in subparagraph (C) of
32 such section and medical supplies associated with
33 the injection of insulin (as defined in regulations of
34 the Secretary),

35 and such term includes a vaccine licensed under section
36 351 of the Public Health Service Act and any use of



1 a covered outpatient drug for a medically accepted indi-
2 cation (as defined in section 1927(k)(6)).

3 “(B) EXCLUSIONS.—

4 “(i) IN GENERAL.—Such term does not in-
5 clude drugs or classes of drugs, or their medical
6 uses, which may be excluded from coverage or oth-
7 erwise restricted under section 1927(d)(2), other
8 than subparagraph (E) thereof (relating to smok-
9 ing cessation agents), or under section 1927(d)(3).

10 “(ii) AVOIDANCE OF DUPLICATE COVERAGE.—
11 A drug prescribed for an individual that would oth-
12 erwise be a covered outpatient drug under this sec-
13 tion shall not be so considered if payment for such
14 drug is available under part A or B for an indi-
15 vidual entitled to benefits under part A and en-
16 rolled under part B.

17 “(C) APPLICATION OF FORMULARY RESTRIC-
18 TIONS.—A drug prescribed for an individual that would
19 otherwise be a covered outpatient drug under this sec-
20 tion shall not be so considered under an endorsed pro-
21 gram if the eligible entity offering the program ex-
22 cludes the drug under a formulary and a review of such
23 exclusion is not successfully resolved under subsection
24 (h)(5).

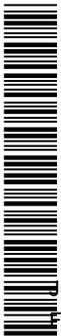
25 “(D) APPLICATION OF GENERAL EXCLUSION PRO-
26 VISIONS.—An eligible entity offering an endorsed pro-
27 gram may exclude from qualified prescription drug cov-
28 erage any covered outpatient drug—

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

31 “(ii) which are not prescribed in accordance
32 with the program or this section.

33 Such exclusions are determinations subject to review
34 pursuant to subsection (h)(5).

35 “(2) INCOME.—



1 “(A) IN GENERAL.—The term ‘income’ means,
2 with respect to benefits under this section in a year,
3 the modified adjusted gross income of the individual for
4 the taxable year ending in the previous year.

5 “(B) TREATMENT OF JOINT RETURNS.—In the
6 case of a individual who files a joint return (as defined
7 for purposes of the Internal Revenue Code of 1986),
8 the income of the modified adjusted gross income of
9 both individuals shall be treated as the income of each
10 individual.

11 “(C) TREATMENT OF SEPARATE RETURNS.—In
12 the case of an individual who is married and who does
13 not file a joint return and who is not living separate
14 and apart from the individual’s spouse during at least
15 6 months of the taxable year shall be treated for pur-
16 poses of this section as having income that exceeds 150
17 percent of the poverty line.

18 “(3) DEFINITION OF MODIFIED ADJUSTED GROSS IN-
19 COME.—The term ‘modified adjusted gross income’ means
20 adjusted gross income (as defined in section 62 of the In-
21 ternal Revenue Code of 1986)—

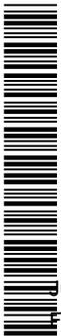
22 “(A) determined without regard to sections 911,
23 931, and 933 of such Code; and

24 “(B) increased by—

25 “(i) the amount of interest received or accrued
26 by the taxpayer during the taxable year which is
27 exempt from tax under such Code, and

28 “(ii) the amount of social security benefits not
29 includible in gross income under section 86 of such
30 Code.

31 “(4) POVERTY LINE.—The term ‘poverty line’ means
32 the income official poverty line (as defined by the Office of
33 Management and Budget, and revised annually in accord-
34 ance with section 673(2) of the Omnibus Budget Reconcili-
35 ation Act of 1981) applicable to a family of the size in-
36 volved.



1 “(1) AUTHORIZATION OF APPROPRIATIONS.—There are au-
2 thorized to be appropriated such sums as may be necessary to
3 carry out this section and section 1807A.

4 “(e) INTERIM, FINAL REGULATORY AUTHORITY.—In
5 order to carry out this section and section 1807A in a timely
6 manner, the Secretary may promulgate regulations that take
7 effect on an interim basis, after notice and pending opportunity
8 for public comment.

9 “PRESCRIPTION DRUG ACCOUNTS

10 “SEC. 1807A. “(a) ESTABLISHMENT OF ACCOUNTS.—

11 “(1) IN GENERAL.—The Secretary shall establish and
12 maintain for each eligible beneficiary who is enrolled under
13 section 1807 at the time of enrollment a prescription drug
14 account (in this section and section 1807 referred to as an
15 ‘account’).

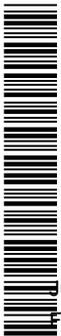
16 “(2) RESERVE ACCOUNTS.—In cases described in sub-
17 sections (b)(3)(A), (b)(3)(B)(i), and (b)(3)(B)(ii)(I), the
18 Secretary shall establish and maintain for each surviving
19 spouse who is not enrolled under section 1807 a reserve
20 prescription drug account (in this section referred to as an
21 ‘reserve account’).

22 “(3) ACCOUNTHOLDER DEFINED.—In this section and
23 section 1807A, the term ‘accountholder’ means an indi-
24 vidual for whom an account or reserve account has been es-
25 tablished under this section.

26 “(4) EXPENDITURES FROM ACCOUNT.—Nothing in
27 this section shall be construed as requiring the Federal
28 Government to obligate funds for amounts in any account
29 until such time as a withdrawal from such account is au-
30 thorized under this section.

31 “(b) USE OF ACCOUNTS.—

32 “(1) APPLICATION OF ACCOUNT.—Except as provided
33 in this subsection, amounts credited to an account shall
34 only be used for the purchase of covered outpatient drugs
35 for the accountholder. Any amounts remaining at the end



1 of a year remain available for expenditures in succeeding
2 years.

3 “(2) ACCOUNT RULES FOR PUBLIC AND PRIVATE CON-
4 TRIBUTIONS.—The Secretary shall establish a ongoing
5 process for the determination of the amount in each ac-
6 count that is attributable to public and private contribu-
7 tions (including spousal rollover contributions) based on the
8 following rules:

9 “(A) TREATMENT OF EXPENDITURES.—Expendi-
10 tures from the account shall—

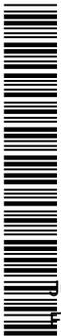
11 “(i) first be counted against any public con-
12 tribution; and

13 “(ii) next be counted against private contribu-
14 tions.

15 “(B) TREATMENT OF SPOUSAL ROLLOVER CON-
16 TRIBUTIONS.—With respect to any spousal rollover
17 contribution, the portions of such contribution that
18 were attributable to public and private contributions at
19 the time of its distribution under subsection (b)(3)
20 shall be treated under this paragraph as if it were a
21 direct public or private contribution, respectively, into
22 the account of the spouse.

23 “(3) DEATH OF ACCOUNTHOLDER.—In the case of the
24 death of an accountholder, the balance in any account (tak-
25 ing into account liabilities accrued before the time of death)
26 shall be distributed as follows:

27 “(A) TREATMENT OF PUBLIC CONTRIBUTIONS.—If
28 the accountholder is married at the time of death, the
29 amount in the account that is attributable to public
30 contributions shall be credited to the account (if any)
31 of the surviving spouse of the accountholder (or, if the
32 surviving spouse is not an eligible beneficiary, into a re-
33 serve account to be held for when that spouse becomes
34 an eligible beneficiary).



1 “(B) TREATMENT OF PRIVATE CONTRIBUTIONS.—
2 The amount in the account that is attributable to pri-
3 vate contributions shall be distributed as follows:

4 “(i) DESIGNATION OF DISTRIBUTE.—If the
5 accountholder has made a designation, in a form
6 and manner specified by the Secretary, for the dis-
7 tribution of some or all of such amount, such
8 amount shall be distributed in accordance with the
9 designation. Such designation may provide for the
10 distribution into an account (including a reserve ac-
11 count) of a surviving spouse.

12 “(ii) ABSENCE OF DESIGNATION.—Insofar as
13 the accountholder has not made such a
14 designation—

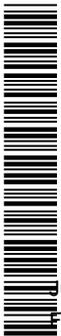
15 “(I) SURVIVING SPOUSE.—If the
16 accountholder was married at the time of
17 death, the remainder shall be credited to an ac-
18 count (including a reserve account) of the
19 accountholder’s surviving spouse.

20 “(II) NO SURVIVING SPOUSE.—If the
21 accountholder was not so married, the remain-
22 der shall be distributed to the estate of the
23 accountholder and distributed as provided by
24 law.

25 “(4) USE OF ACCOUNT FOR PREMIUMS FOR ENROLL-
26 MENT IN A MEDICARE ADVANTAGE OR EFFS PLAN.—Dur-
27 ing any period in which an accountholder is enrolled in a
28 Medicare Advantage plan under part C or an EFFS plan
29 under part E, the balance in the account may be used and
30 applied only to reimburse the amount of the premium (if
31 any) established for enrollment under the plan.

32 “(5) APPLICATION TO MEDICAID EXPENSES IN CER-
33 TAIN CASES.—

34 “(A) IN GENERAL.—Except as provided in this
35 paragraph, an account shall be treated as an asset for



1 purposes of establishing eligibility for medical assist-
2 ance under title XIX.

3 “(B) APPLICATION TOWARDS SPENDDOWN.—In
4 the case of an accountholder who is applying for such
5 medical assistance and who would, but for the applica-
6 tion of subparagraph (A), be eligible for such
7 assistance—

8 “(i) subparagraph (A) shall not apply; and

9 “(ii) the account shall be available (in accord-
10 ance with a procedure established by the Secretary)
11 to the State to reimburse the State for any expend-
12 itures made under the plan for such medical assist-
13 ance.

14 “(c) AMOUNTS CREDITED IN ACCOUNT.—The Secretary
15 shall credit to a prescription drug account of an eligible bene-
16 ficiary the following amounts:

17 “(1) PUBLIC CONTRIBUTIONS.—The following con-
18 tributions (each referred to in this section as a ‘public con-
19 tribution’):

20 “(A) FEDERAL CONTRIBUTIONS.—Federal con-
21 tributions provided under subsection (d).

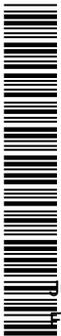
22 “(B) STATE CONTRIBUTIONS.—Contributions
23 made by a State under subsection (f).

24 “(2) SPOUSAL ROLLOVER CONTRIBUTION.—A distribu-
25 tion from a deceased spouse under subsection (b)(3) (re-
26 ferred to in this section as a ‘spousal rollover contribu-
27 tion’).

28 “(3) PRIVATE CONTRIBUTIONS.—The following con-
29 tributions (each referred to in this section as a ‘private con-
30 tribution’):

31 “(A) EMPLOYER AND INDIVIDUAL CONTRIBU-
32 TIONS.—Contributions made under subsection (e).

33 “(B) OTHER INDIVIDUAL CONTRIBUTIONS.—Con-
34 tributions made by accountholder other than under
35 subsection (e).



1 “(C) CONTRIBUTIONS BY NONPROFIT ORGANIZA-
2 TIONS.—Contributions made by a charitable, not-for-
3 profit organization (that may be a religious organiza-
4 tion).

5 Except as provided in this subsection, no amounts may be con-
6 tributed to, or credited to, a prescription drug account.

7 “(d) FEDERAL CONTRIBUTION.—For Federal contribu-
8 tions in the case of accountholders, see section 1807(j).

9 “(e) EMPLOYER AND INDIVIDUAL CONTRIBUTIONS.—

10 “(1) EMPLOYMENT-RELATED CONTRIBUTION.—

11 “(A) IN GENERAL.—In the case of any
12 accountholder who is a beneficiary or participant in a
13 group health plan (including a multi-employer plan),
14 whether as an employee, former employee or otherwise,
15 including as a dependent of an employee or former em-
16 ployee, the plan may make a contribution into the
17 accountholder’s account (but not into a reserve account
18 of the accountholder).

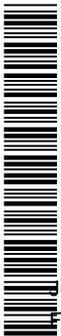
19 “(B) LIMITATION.—The total amount that may be
20 contributed under subparagraph (A) under a plan to an
21 account during any year may not exceed \$5,000.

22 “(C) CONDITION.—A group health plan may con-
23 dition a contribution with respect to an accountholder
24 under this paragraph on the accountholder’s enrollment
25 under section 1807 with an eligible entity that is recog-
26 nized or approved by that plan.

27 “(2) OTHER INDIVIDUALS.—

28 “(A) IN GENERAL.—Any individual may also con-
29 tribute to the account of that individual or the account
30 of any other individual under this subsection.

31 “(B) LIMITATION.—The total amount that may be
32 contributed to an account under subparagraph (A) dur-
33 ing any year may not exceed \$5,000, regardless of who
34 makes such contribution.



1 “(3) NO CONTRIBUTION PERMITTED TO RESERVE AC-
2 COUNT.—No contribution may be made under this sub-
3 section to a reserve account.

4 “(4) FORM AND MANNER OF CONTRIBUTION.—The
5 Secretary shall specify the form and manner of contribu-
6 tions under this subsection.

7 “(5) INDEXING OF DOLLAR AMOUNTS.—The dollar
8 amounts of the limitation amounts specified in paragraphs
9 (1)(B) and (2)(B) shall be subject to annual increases for
10 each year after 2004 in the same manner as the annual de-
11 ductible is subject to an annual increase under subpara-
12 graph (B) and the last sentence of section 1860D–2(b)(1).

13 “(f) STATE CONTRIBUTIONS.—

14 “(1) IN GENERAL.—A State may enter into arrange-
15 ments with the Secretary for the crediting of amounts for
16 accountholders.

17 “(2) FORM AND MANNER OF CONTRIBUTION.—The
18 Secretary shall specify the form and manner of contribu-
19 tions under this subsection.

20 “(3) MEDICAID TREATMENT.—Amounts credited
21 under this subsection shall not be treated as medical assist-
22 ance for purposes of title XIX or child health assistance for
23 purposes of title XXI for individuals who are not qualifying
24 low income enrollees.”.

25 (b) EXCLUSION OF COSTS FROM DETERMINATION OF
26 PART B MONTHLY PREMIUM.—Section 1839(g) (42 U.S.C.
27 1395r(g)) is amended—

28 (1) by striking “attributable to the application of sec-
29 tion” and inserting “attributable to—

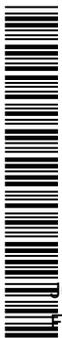
30 “(1) the application of section”;

31 (2) by striking the period and inserting “; and”; and

32 (3) by adding at the end the following new paragraph:

33 “(2) the Voluntary Medicare Outpatient Prescription
34 Drug Discount and Security Program under sections 1807
35 and 1807A.”.

36 (c) MEDICAID AMENDMENTS.—



1 (1) VERIFICATION OF ELIGIBILITY FOR IMPROVED AC-
2 COUNT CONTRIBUTIONS.—

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

5 (i) by striking “and” at the end of paragraph
6 (64);

7 (ii) by striking the period at the end of para-
8 graph (65) and inserting “; and”; and

9 (iii) by inserting after paragraph (65) the fol-
10 lowing new paragraph:

11 “(66) provide for verification of income under section
12 1807(j)(3).”.

13 (B) NEW SECTION.—Title XIX is further
14 amended—

15 (i) by redesignating section 1935 as section
16 1936; and

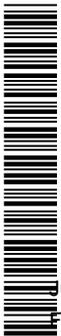
17 (ii) by inserting after section 1934 the fol-
18 lowing new section:

19 “SPECIAL PROVISIONS RELATING TO MEDICARE PART D
20 BENEFITS

21 “SEC. 1935. (a) REQUIREMENT FOR VERIFICATION OF
22 ELIGIBILITY DETERMINATIONS FOR IMPROVED ACCOUNT CON-
23 TRIBUTIONS.—As a condition of its State plan under this title
24 under section 1902(a)(66) and receipt of any Federal financial
25 assistance under section 1903(a), a State shall provide for ver-
26 ification of income statements in accordance with arrangements
27 under section 1807(j)(1).

28 “(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE
29 COSTS.—

30 “(1) IN GENERAL.—The amounts expended by a State
31 in carrying out subsection (a) are, subject to paragraph
32 (2), expenditures reimbursable under the appropriate para-
33 graph of section 1903(a); except that, notwithstanding any
34 other provision of such section, the applicable Federal
35 matching rates with respect to such expenditures under
36 such section shall be 90 percent.



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

6 **SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR**
7 **PURPOSES OF CARRYING OUT MEDICARE**
8 **CATASTROPHIC PRESCRIPTION DRUG PRO-**
9 **GRAM.**

10 (a) IN GENERAL.—Subsection (l) of section 6103 of the
11 Internal Revenue Code of 1986 (relating to disclosure of re-
12 turns and return information for purposes other than tax ad-
13 ministration) is amended by adding at the end the following
14 new paragraph:

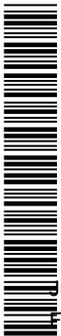
15 “(19) DISCLOSURE OF RETURN INFORMATION FOR
16 PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC
17 PRESCRIPTION DRUG PROGRAM.—

18 “(A) IN GENERAL.—The Secretary may, upon
19 written request from the Secretary of Health and
20 Human Services under section 1860D–2(b)(4)(E)(i) of
21 the Social Security Act, disclose to officers and employ-
22 ees of the Department of Health and Human Services
23 with respect to a specified taxpayer for the taxable year
24 specified by the Secretary of Health and Human Serv-
25 ices in such request—

26 “(i) the taxpayer identity information with re-
27 spect to such taxpayer, and

28 “(ii) the adjusted gross income of such tax-
29 payer for the taxable year (or, if less, the income
30 threshold limit specified in section 1860D–
31 2(b)(4)(D)(ii) for the calendar year specified by
32 such Secretary in such request).

33 “(B) SPECIFIED TAXPAYER.—For purposes of this
34 paragraph, the term ‘specified taxpayer’ means any
35 taxpayer who—



1 “(i) is identified by the Secretary of Health
2 and Human Services in the request referred to in
3 subparagraph (A), and

4 “(ii) either—

5 “(I) has an adjusted gross income for the
6 taxable year referred to in subparagraph (A) in
7 excess of the income threshold specified in sec-
8 tion 1860D-2(b)(4)(D)(ii) of such Act for the
9 calendar year referred to in such subparagraph,
10 or

11 “(II) is identified by such Secretary under
12 subparagraph (A) as being an individual who
13 elected to use more recent information under
14 section 1860D-2(b)(4)(D)(v) of such Act.

15 “(C) JOINT RETURNS.—In the case of a joint re-
16 turn, the Secretary shall, for purposes of applying this
17 paragraph, treat each spouse as a separate taxpayer
18 having an adjusted gross income equal to one-half of
19 the adjusted gross income determined with respect to
20 such return.

21 “(D) RESTRICTION ON USE OF DISCLOSED INFOR-
22 MATION.—Return information disclosed under subpara-
23 graph (A) may be used by officers and employees of the
24 Department of Health and Human Services only for
25 the purpose of administering the prescription drug ben-
26 efit under title XVIII of the Social Security Act. Such
27 officers and employees may disclose the annual out-of-
28 pocket threshold which applies to an individual under
29 such part to the entity that offers the plan referred to
30 in section 1860D-2(b)(4)(E)(ii) of such Act in which
31 such individual is enrolled. Such sponsor may use such
32 information only for purposes of administering such
33 benefit.”.

34 (b) CONFIDENTIALITY.—Paragraph (3) of section 6103(a)
35 of such Code is amended by striking “or (16)” and inserting
36 “(16), or (19)”.

1 (c) PROCEDURES AND RECORDKEEPING RELATED TO DIS-
2 CLOSURES.—Subsection (p)(4) of section 6103 of such Code is
3 amended by striking “any other person described in subsection
4 (l)(16) or (17)” each place it appears and inserting “any other
5 person described in subsection (l)(16), (17), or (19)”.

6 (d) UNAUTHORIZED DISCLOSURE.—Paragraph (2) of sec-
7 tion 7213(a) of such Code is amended by striking “or (16)”
8 and inserting “(16), or (19)”.

9 (e) UNAUTHORIZED INSPECTION.—Subparagraph (B) of
10 section 7213A(a)(1) of such Code is amended by inserting “or
11 (19)” after “subsection (l)(18)”.

12 **SEC. 107. STATE PHARMACEUTICAL ASSISTANCE TRAN-**
13 **SITION COMMISSION.**

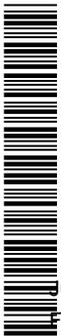
14 (a) ESTABLISHMENT.—

15 (1) IN GENERAL.—There is established, as of the first
16 day of the third month beginning after the date of the en-
17 actment of this Act, a State Pharmaceutical Assistance
18 Transition Commission (in this section referred to as the
19 “Commission”) to develop a proposal for addressing the
20 unique transitional issues facing State pharmaceutical as-
21 sistance programs, and program participants, due to the
22 implementation of the medicare prescription drug program
23 under part D of title XVIII of the Social Security Act.

24 (2) DEFINITIONS.—For purposes of this section:

25 (A) STATE PHARMACEUTICAL ASSISTANCE PRO-
26 GRAM DEFINED.—The term “State pharmaceutical as-
27 sistance program” means a program (other than the
28 medicaid program) operated by a State (or under con-
29 tract with a State) that provides as of the date of the
30 enactment of this Act assistance to low-income medi-
31 care beneficiaries for the purchase of prescription
32 drugs.

33 (B) PROGRAM PARTICIPANT.—The term “program
34 participant” means a low-income medicare beneficiary
35 who is a participant in a State pharmaceutical assist-
36 ance program.



1 (b) COMPOSITION.—The Commission shall include the fol-
2 lowing:

3 (1) A representative of each governor of each State
4 that the Secretary identifies as operating on a statewide
5 basis a State pharmaceutical assistance program that pro-
6 vides for eligibility and benefits that are comparable or
7 more generous than the low-income assistance eligibility
8 and benefits offered under part D of title XVIII of the So-
9 cial Security Act.

10 (2) Representatives from other States that the Sec-
11 retary identifies have in operation other State pharma-
12 ceutical assistance programs, as appointed by the Sec-
13 retary.

14 (3) Representatives of organizations that have an in-
15 herent interest in program participants or the program
16 itself, as appointed by the Secretary but not to exceed the
17 number of representatives under paragraphs (1) and (2).

18 (4) Representatives of Medicare Advantage organiza-
19 tions and other private health insurance plans, as ap-
20 pointed by the Secretary.

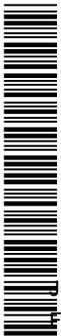
21 (5) The Secretary (or the Secretary's designee) and
22 such other members as the Secretary may specify

23 The Secretary shall designate a member to serve as chair of
24 the Commission and the Commission shall meet at the call of
25 the chair.

26 (c) DEVELOPMENT OF PROPOSAL.—The Commission shall
27 develop the proposal described in subsection (a) in a manner
28 consistent with the following principles:

29 (1) Protection of the interests of program participants
30 in a manner that is the least disruptive to such participants
31 and that includes a single point of contact for enrollment
32 and processing of benefits.

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



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

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

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

11 (f) TERMINATION.—The Commission shall terminate 30
12 days after the date of submission of the report under sub-
13 section (d).

14 **TITLE II—MEDICARE ENHANCED**
15 **FEE-FOR-SERVICE AND MEDI-**
16 **CARE ADVANTAGE PROGRAMS;**
17 **MEDICARE COMPETITION**

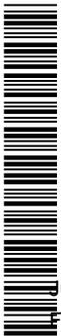
18 **SEC. 200. MEDICARE MODERNIZATION AND REVITALIZA-**
19 **TION.**

20 This title provides for—

21 (1) establishment of the medicare enhanced fee-for-
22 service (EFFS) program under which medicare bene-
23 ficiaries are provided access to a range of enhanced fee-for-
24 service (EFFS) plans that may use preferred provider net-
25 works to offer an enhanced range of benefits;

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

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



1 **Subtitle A—Medicare Enhanced Fee-**
2 **for-Service Program**

3 **SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-**
4 **SERVICE (EFFS) PROGRAM UNDER MEDI-**
5 **CARE.**

6 (a) IN GENERAL.—Title XVIII, as amended by section
7 101(a), is amended—

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

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

10 “PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

11 “OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS

12 THROUGHOUT THE UNITED STATES

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

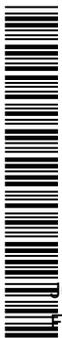
14 “(1) IN GENERAL.—The Administrator shall establish
15 under this part beginning January 1, 2006, an enhanced
16 fee-for-service program under which enhanced fee-for-serv-
17 ice plans (as defined in subsection (b)) are offered to
18 EFFS-eligible individuals (as so defined) in EFFS regions
19 throughout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

20 “(2) EFFS REGIONS.—For purposes of this part the
21 Administrator shall establish EFFS regions throughout the
22 United States by dividing the entire United States into at
23 least 10 such regions. Before establishing such regions, the
24 Administrator shall conduct a market survey and analysis,
25 including an examination of current insurance markets, to
26 determine how the regions should be established. The re-
27 gions shall be established in a manner to take into consid-
28 eration maximizing full access for all EFFS-eligible individ-
29 uals, especially those residing in rural areas.

30 “(b) DEFINITIONS.—For purposes of this part:

31 “(1) EFFS ORGANIZATION.—The ‘EFFS organiza-
32 tion’ means an entity that the Administrator certifies as
33 meeting the requirements and standards applicable to such
34 organization under this part.

35 “(2) ENHANCED FEE-FOR-SERVICE PLAN; EFFS
36 PLAN.—The terms ‘enhanced fee-for-service plan’ and



1 'EFFS plan' mean health benefits coverage offered under
2 a policy, contract, or plan by an EFFF organization pursu-
3 ant to and in accordance with a contract pursuant to sec-
4 tion 1860E-4(c), but only if the plan provides either fee-
5 for-service coverage described in the following subpara-
6 graph (A) or preferred provider coverage described in the
7 following subparagraph (B):

8 "(A) FEE-FOR-SERVICE COVERAGE.—The plan—

9 "(i) reimburses hospitals, physicians, and
10 other providers at a rate determined by the plan on
11 a fee-for-service basis without placing the provider
12 at financial risk;

13 "(ii) does not vary such rates for such a pro-
14 vider based on utilization relating to such provider;
15 and

16 "(iii) does not restrict the selection of pro-
17 viders among those who are lawfully authorized to
18 provide the covered services and agree to accept the
19 terms and conditions of payment established by the
20 plan.

21 "(B) PREFERRED PROVIDER COVERAGE.—The
22 plan—

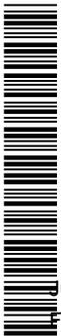
23 "(i) has a network of providers that have
24 agreed to a contractually specified reimbursement
25 for covered benefits with the organization offering
26 the plan; and

27 "(ii) provides for reimbursement for all cov-
28 ered benefits regardless of whether such benefits
29 are provided within such network of providers.

30 "(3) EFFF ELIGIBLE INDIVIDUAL.—The term 'EFFF
31 eligible individual' means an eligible individual described in
32 section 1851(a)(3).

33 "(4) EFFF REGION.—The term 'EFFF region' means
34 a region established under subsection (a)(2).

35 "(c) APPLICATION OF CERTAIN ELIGIBILITY, ENROLL-
36 MENT, ETC. REQUIREMENTS.—The provisions of section 1851



1 (other than subsection (h)(4)(A)) shall apply to EFFFs plans
2 offered by an EFFFs organization in an EFFFs region, including
3 subsection (g) (relating to guaranteed issue and renewal).

4 “OFFERING OF ENHANCED FEE-FOR-SERVICE (EFFF) PLANS

5 “SEC. 1860E-2. (a) PLAN REQUIREMENTS.—No EFFFs
6 plan may be offered under this part in an EFFFs region unless
7 the requirements of this part are met with respect to the plan
8 and EFFFs organization offering the plan.

9 “(b) AVAILABLE TO ALL EFFFs BENEFICIARIES IN THE
10 ENTIRE REGION.—With respect to an EFFFs plan offered in an
11 EFFFs region—

12 “(1) IN GENERAL.—The plan must be offered to all
13 EFFFs-eligible individuals residing in the region.

14 “(2) ASSURING ACCESS TO SERVICES.—The plan shall
15 comply with the requirements of section 1852(d)(4).

16 “(c) BENEFITS.—

17 “(1) IN GENERAL.—Each EFFFs plan shall provide to
18 members enrolled in the plan under this part benefits,
19 through providers and other persons that meet the applica-
20 ble requirements of this title and part A of title XI—

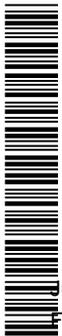
21 “(A) for the items and services described in sec-
22 tion 1852(a)(1);

23 “(B) that are uniform for the plan for all EFFFs
24 eligible individuals residing in the same EFFFs region;

25 “(C) that include a single deductible applicable to
26 benefits under parts A and B and include a cata-
27 strophic limit on out-of-pocket expenditures for such
28 covered benefits; and

29 “(D) that include benefits for prescription drug
30 coverage for each enrollee who elects under part D to
31 be provided qualified prescription drug coverage
32 through the plan.

33 “(2) DISAPPROVAL AUTHORITY.—The Administrator
34 shall not approve a plan of an EFFFs organization if the
35 Administrator determines (pursuant to the last sentence of
36 section 1852(b)(1)(A)) that the benefits are designed to



1 substantially discourage enrollment by certain EFFS eligi-
2 ble individuals with the organization.

3 “(d) OUTPATIENT PRESCRIPTION DRUG COVERAGE.—For
4 rules concerning the offering of prescription drug coverage
5 under EFFS plans, see the amendment made by section 102(b)
6 of the Medicare Prescription Drug and Modernization Act of
7 2003.

8 “(e) OTHER ADDITIONAL PROVISIONS.—The provisions of
9 section 1852 (other than subsection (a)(1)) shall apply under
10 this part to EFFS plans. For the application of chronic care
11 improvement provisions, see the amendment made by section
12 722(b).

13 “SUBMISSION OF BIDS; BENEFICIARY SAVINGS; PAYMENT OF
14 PLANS

15 “SEC. 1860E–3. (a) SUBMISSION OF BIDS.—

16 “(1) REQUIREMENT.—

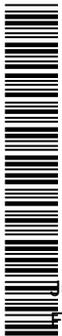
17 “(A) EFFS MONTHLY BID AMOUNT.—For each
18 year (beginning with 2006), an EFFS organization
19 shall submit to the Administrator an EFFS monthly
20 bid amount for each EFFS plan offered in each region.
21 Each such bid is referred to in this section as the
22 ‘EFFS monthly bid amount’.

23 “(B) FORM.—Such bid amounts shall be sub-
24 mitted for each such plan and region in a form and
25 manner and time specified by the Administrator, and
26 shall include information described in paragraph
27 (3)(A).

28 “(2) UNIFORM BID AMOUNTS.—Each EFFS monthly
29 bid amount submitted under paragraph (1) by an EFFS
30 organization under this part for an EFFS plan in an
31 EFFS region may not vary among EFFS eligible individ-
32 uals residing in the EFFS region involved.

33 “(3) SUBMISSION OF BID AMOUNT INFORMATION BY
34 EFFS ORGANIZATIONS.—

35 “(A) INFORMATION TO BE SUBMITTED.—The in-
36 formation described in this subparagraph is as follows:



1 “(i) The EFFE monthly bid amount for provi-
2 sion of all items and services under this part, which
3 amount shall be based on average costs for a typ-
4 ical enrollee residing in the region, and the actu-
5 arial basis for determining such amount.

6 “(ii) The proportions of such bid amount that
7 are attributable to—

8 “(I) the provision of statutory non-drug
9 benefits (such portion referred to in this part
10 as the ‘unadjusted EFFE statutory non-drug
11 monthly bid amount’);

12 “(II) the provision of statutory prescrip-
13 tion drug benefits; and

14 “(III) the provision of non-statutory bene-
15 fits;

16 and the actuarial basis for determining such pro-
17 portions.

18 “(iii) Such additional information as the Ad-
19 ministrators may require to verify the actuarial
20 bases described in clauses (i) and (ii).

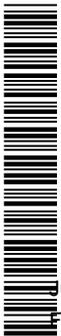
21 “(B) STATUTORY BENEFITS DEFINED.—For pur-
22 poses of this part:

23 “(i) The term ‘statutory non-drug benefits’
24 means benefits under section 1852(a)(1).

25 “(ii) The term ‘statutory prescription drug
26 benefits’ means benefits under part D.

27 “(iii) The term ‘statutory benefits’ means stat-
28 utory prescription drug benefits and statutory non-
29 drug benefits.

30 “(C) ACCEPTANCE AND NEGOTIATION OF BID
31 AMOUNTS.—The Administrator has the authority to ne-
32 gotiate regarding monthly bid amounts submitted
33 under subparagraph (A) (and the proportion described
34 in subparagraph (A)(ii)), and for such purpose, the Ad-
35 ministrators has negotiation authority that the Director
36 of the Office of Personnel Management has with re-



1 spect to health benefits plans under chapter 89 of title
2 5, United States Code. The Administrator may reject
3 such a bid amount or proportion if the Administrator
4 determines that such amount or proportion is not sup-
5 ported by the actuarial bases provided under subpara-
6 graph (A).

7 “(D) CONTRACT AUTHORITY.—The Administrator
8 may, taking into account the unadjusted EFFFs statu-
9 tory non-drug monthly bid amounts accepted under
10 subparagraph (C), enter into contracts for the offering
11 of up to 3 EFFFs plans in any region.

12 “(b) PROVISION OF BENEFICIARY SAVINGS FOR CERTAIN
13 PLANS.—

14 “(1) BENEFICIARY REBATE RULE.—

15 “(A) REQUIREMENT.—The EFFFs plan shall pro-
16 vide to the enrollee a monthly rebate equal to 75 per-
17 cent of the average per capita savings (if any) de-
18 scribed in paragraph (2) applicable to the plan and
19 year involved.

20 “(B) FORM OF REBATE.—A rebate required under
21 this paragraph shall be provided—

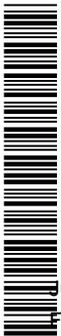
22 “(i) through the crediting of the amount of the
23 rebate towards the EFFFs monthly prescription
24 drug beneficiary premium (as defined in section
25 1860E–4(a)(3)(B)) and the EFFFs monthly supple-
26 mental beneficiary premium (as defined in section
27 1860E–4(a)(3)(C));

28 “(ii) through a direct monthly payment
29 (through electronic funds transfer or otherwise); or

30 “(iii) through other means approved by the
31 Medicare Benefits Administrator,

32 or any combination thereof.

33 “(2) COMPUTATION OF AVERAGE PER CAPITA MONTH-
34 LY SAVINGS.—For purposes of paragraph (1)(A), the aver-
35 age per capita monthly savings referred to in such para-
36 graph for an EFFFs plan and year is computed as follows:



1 “(A) DETERMINATION OF REGION-WIDE AVERAGE
2 RISK ADJUSTMENT.—

3 “(i) IN GENERAL.—The Medicare Benefits Ad-
4 ministrators shall determine, at the same time rates
5 are promulgated under section 1853(b)(1) (begin-
6 ning with 2006), for each EFFE region the average
7 of the risk adjustment factors described in sub-
8 section (c)(3) to be applied to enrollees under this
9 part in that region. In the case of an EFFE region
10 in which an EFFE plan was offered in the previous
11 year, the Administrator may compute such average
12 based upon risk adjustment factors applied under
13 subsection (c)(3) in that region in a previous year.

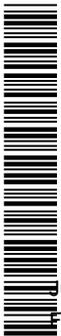
14 “(ii) TREATMENT OF NEW REGIONS.—In the
15 case of a region in which no EFFE plan was of-
16 fered in the previous year, the Administrator shall
17 estimate such average. In making such estimate,
18 the Administrator may use average risk adjustment
19 factors applied to comparable EFFE regions or ap-
20 plied on a national basis.

21 “(B) DETERMINATION OF RISK ADJUSTED BENCH-
22 MARK AND RISK-ADJUSTED BID.—For each EFFE plan
23 offered in an EFFE region, the Administrator shall—

24 “(i) adjust the EFFE region-specific non-drug
25 monthly benchmark amount (as defined in para-
26 graph (3)) by the applicable average risk adjust-
27 ment factor computed under subparagraph (A);
28 and

29 “(ii) adjust the unadjusted EFFE statutory
30 non-drug monthly bid amount by such applicable
31 average risk adjustment factor.

32 “(C) DETERMINATION OF AVERAGE PER CAPITA
33 MONTHLY SAVINGS.—The average per capita monthly
34 savings described in this subparagraph is equal to the
35 amount (if any) by which—



1 “(i) the risk-adjusted benchmark amount com-
2 puted under subparagraph (B)(i), exceeds

3 “(ii) the risk-adjusted bid computed under
4 subparagraph (B)(ii).

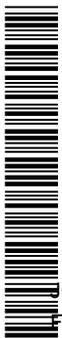
5 “(3) COMPUTATION OF EFFS REGION-SPECIFIC NON-
6 DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of
7 this part, the term ‘EFFS region-specific non-drug monthly
8 benchmark amount’ means, with respect to an EFFS re-
9 gion for a month in a year, an amount equal to $\frac{1}{12}$ of the
10 average (weighted by number of EFFS eligible individuals
11 in each payment area described in section 1853(d)) of the
12 annual capitation rate as calculated under section
13 1853(e)(1) for that area.

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

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

22 “(A) PLANS WITH BIDS BELOW BENCHMARK.—In
23 the case of a plan for which there are average per cap-
24 ita monthly savings described in subsection (b)(2)(C),
25 the payment under this subsection is equal to the
26 unadjusted EFFS statutory non-drug monthly bid
27 amount, adjusted under paragraphs (3) and (4), plus
28 the amount of the monthly rebate computed under sub-
29 section (b)(1)(A) for that plan and year.

30 “(B) PLANS WITH BIDS AT OR ABOVE BENCH-
31 MARK.—In the case of a plan for which there are no
32 average per capita monthly savings described in sub-
33 section (b)(2)(C), the payment amount under this sub-
34 section is equal to the EFFS region-specific non-drug
35 monthly benchmark amount, adjusted under para-
36 graphs (3) and (4).



1 “(2) FOR FEDERAL DRUG SUBSIDIES.—In the case in
2 which an enrollee who elects under part D to be provided
3 qualified prescription drug coverage through the plan, the
4 EFFS organization offering such plan also is entitled—

5 “(A) to direct subsidy payment under section
6 1860D–8(a)(1);

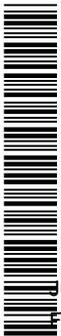
7 “(B) to reinsurance subsidy payments under sec-
8 tion 1860D–8(a)(2); and

9 “(C) to reimbursement for premium and cost-shar-
10 ing reductions for low-income individuals under section
11 1860D–7(c)(3).

12 “(3) DEMOGRAPHIC RISK ADJUSTMENT, INCLUDING
13 ADJUSTMENT FOR HEALTH STATUS.—The Administrator
14 shall adjust under paragraph (1)(A) the unadjusted EFFS
15 statutory non-drug monthly bid amount and under para-
16 graph (1)(B) the EFFS region-specific non-drug monthly
17 benchmark amount for such risk factors as age, disability
18 status, gender, institutional status, and such other factors
19 as the Administrator determines to be appropriate, includ-
20 ing adjustment for health status under section 1853(a)(3)
21 (as applied under subsection (d)), so as to ensure actuarial
22 equivalence. The Administrator may add to, modify, or sub-
23 stitute for such adjustment factors if such changes will im-
24 prove the determination of actuarial equivalence.

25 “(4) ADJUSTMENT FOR INTRA-REGIONAL GEOGRAPHIC
26 VARIATIONS.—The Administrator shall also adjust such
27 amounts in a manner to take into account variations in
28 payments rates under part C among the different payment
29 areas under such part included in each EFFS region.

30 “(d) APPLICATION OF ADDITIONAL PAYMENT RULES.—
31 The provisions of section 1853 (other than subsections
32 (a)(1)(A), (d), and (e)) shall apply to an EFFS plan under this
33 part, except as otherwise provided in this section.



1 “PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIREMENTS;
2 ESTABLISHMENT OF STANDARDS; CONTRACTS WITH EFFS
3 ORGANIZATIONS

4 “SEC. 1860E-4. (a) PREMIUMS.—

5 “(1) IN GENERAL.—The provisions of section 1854
6 (other than subsections (a)(6)(C) and (h)), including sub-
7 section (b)(5) relating to the consolidation of drug and non-
8 drug beneficiary premiums and subsection (e) relating to
9 uniform bids and premiums, shall apply to an EFFS plan
10 under this part, subject to paragraph (2).

11 “(2) CROSS-WALK.—In applying paragraph (1), any
12 reference in section 1854(b)(1)(A) or 1854(d) to—

13 “(A) a Medicare Advantage monthly basic bene-
14 ficiary premium is deemed a reference to the EFFS
15 monthly basic beneficiary premium (as defined in para-
16 graph (3)(A));

17 “(B) a Medicare Advantage monthly prescription
18 drug beneficiary premium is deemed a reference to the
19 EFFS monthly prescription drug beneficiary premium
20 (as defined in paragraph (3)(B)); and

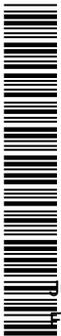
21 “(C) a Medicare Advantage monthly supplemental
22 beneficiary premium is deemed a reference to the
23 EFFS monthly supplemental beneficiary premium (as
24 defined in paragraph (3)(C)).

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

26 “(A) EFFS MONTHLY BASIC BENEFICIARY PRE-
27 MIUM.—The term ‘EFFS monthly basic beneficiary
28 premium’ means, with respect to an EFFS plan—

29 “(i) described in section 1860E-3(c)(1)(A)
30 (relating to plans providing rebates), zero; or

31 “(ii) described in section 1860E-3(c)(1)(B),
32 the amount (if any) by which the unadjusted
33 EFFS statutory non-drug monthly bid amount ex-
34 ceeds the EFFS region-specific non-drug monthly
35 benchmark amount (as defined in section 1860E-
36 3(b)(3)).



1 “(B) EFFS MONTHLY PRESCRIPTION DRUG BENE-
2 FICIARY PREMIUM.—The term ‘EFFS monthly pre-
3 scription drug beneficiary premium’ means, with re-
4 spect to an EFFS plan, the portion of the aggregate
5 monthly bid amount submitted under clause (i) of sec-
6 tion 1860E–3(a)(3)(A) for the year that is attributable
7 under such section to the provision of statutory pre-
8 scription drug benefits.

9 “(C) EFFS MONTHLY SUPPLEMENTAL BENE-
10 FICIARY PREMIUM.—The term ‘EFFS monthly supple-
11 mental beneficiary premium’ means, with respect to an
12 EFFS plan, the portion of the aggregate monthly bid
13 amount submitted under clause (i) of section 1860E–
14 3(a)(3)(A) for the year that is attributable under such
15 section to the provision of nonstatutory benefits.

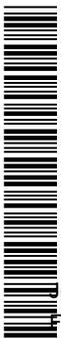
16 “(b) ORGANIZATIONAL AND FINANCIAL REQUIRE-
17 MENTS.—The provisions of section 1855 shall apply to an
18 EFFS plan offered by an EFFS organization under this part.

19 “(c) CONTRACTS WITH EFFS ORGANIZATIONS.—The pro-
20 visions of section 1857 shall apply to an EFFS plan offered by
21 an EFFS organization under this part, except that any ref-
22 erence in such section to part C is deemed a reference to this
23 part.”.

24 (b) PROHIBITION ON COVERAGE UNDER MEDIGAP PLANS
25 OF DEDUCTIBLE IMPOSED UNDER EFFS PLANS.—Section
26 1882 (42 U.S.C. 1395ss), as amended by section 104(a), is
27 amended by adding at the end the following new subsection:

28 “(w) PROHIBITION ON COVERAGE OF DEDUCTIBLE AND
29 CERTAIN COST-SHARING IMPOSED UNDER EFFS PLANS.—
30 Notwithstanding any other provision of law, no medicare sup-
31 plemental policy (other than the 2 benefit packages described
32 in subsection (v)(3)) may provide for coverage of the single de-
33 ductible or more than 50 percent of other cost-sharing imposed
34 under an EFFS plan under part E.”.

35 (c) CONFORMING PROVISIONS.—Section 1882 of the Social
36 Security Act (42 U.S.C. 1395ss) shall be administered as if any



1 reference to a Medicare+Choice organization offering a
2 Medicare+Choice plan under part C of title XVIII of such Act
3 were a reference both to a Medicare Advantage organization of-
4 fering a Medicare Advantage plan under such part and an
5 EFFS organization offering an EFFS plan under part E of
6 such title.

7 **Subtitle B—Medicare Advantage** 8 **Program**

9 **CHAPTER 1—IMPLEMENTATION OF PROGRAM**

10 **SEC. 211. IMPLEMENTATION OF MEDICARE ADVANTAGE** 11 **PROGRAM.**

12 (a) IN GENERAL.—There is hereby established the Medi-
13 care Advantage program. The Medicare Advantage program
14 shall consist of the program under part C of title XVIII of the
15 Social Security Act, as amended by this title.

16 (b) REFERENCES.—Any reference to the program under
17 part C of title XVIII of the Social Security Act shall be deemed
18 a reference to the Medicare Advantage program and, with re-
19 spect to such part, any reference to “Medicare+Choice” is
20 deemed a reference to “Medicare Advantage”.

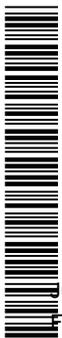
21 **SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.**

22 (a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

23 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
24 1395w-23(c)(1)) is amended by adding at the end the fol-
25 lowing:

26 “(D) BASED ON 100 PERCENT OF FEE-FOR-SERV-
27 ICE COSTS.—

28 “(i) IN GENERAL.—For 2004, the adjusted av-
29 erage per capita cost for the year involved, deter-
30 mined under section 1876(a)(4) for the Medicare
31 Advantage payment area for services covered under
32 parts A and B for individuals entitled to benefits
33 under part A and enrolled under part B who are
34 not enrolled in a Medicare Advantage under this
35 part for the year, but adjusted to exclude costs at-
36 tributable to payments under section 1886(h).



1 “(ii) INCLUSION OF COSTS OF VA AND DOD
2 MILITARY FACILITY SERVICES TO MEDICARE-ELIGI-
3 BLE BENEFICIARIES.—In determining the adjusted
4 average per capita cost under clause (i) for a year,
5 such cost shall be adjusted to include the Sec-
6 retary’s estimate, on a per capita basis, of the
7 amount of additional payments that would have
8 been made in the area involved under this title if
9 individuals entitled to benefits under this title had
10 not received services from facilities of the Depart-
11 ment of Veterans Affairs or the Department of De-
12 fense.”.

13 (2) CONFORMING AMENDMENT.—Such section is fur-
14 ther amended, in the matter before subparagraph (A), by
15 striking “or (C)” and inserting “(C), or (D)”.

16 (b) REVISION OF BLEND.—

17 (1) REVISION OF NATIONAL AVERAGE USED IN CAL-
18 CULATION OF BLEND.—Section 1853(c)(4)(B)(i)(II) (42
19 U.S.C. 1395w-23(c)(4)(B)(i)(II)) is amended by inserting
20 “who (with respect to determinations for 2004) are enrolled
21 in a Medicare+Choice plan” after “the average number of
22 medicare beneficiaries”.

23 (2) CHANGE IN BUDGET NEUTRALITY.—Section
24 1853(c) (42 U.S.C. 1395w-23(c)) is amended—

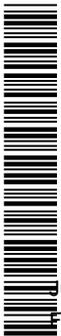
25 (A) in paragraph (1)(A), by inserting “(for a year
26 before 2004)” after “multiplied”; and

27 (B) in paragraph (5), by inserting “(before 2004)”
28 after “for each year”.

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

31 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
32 1395w-23(c)(1)) is amended—

33 (A) in subparagraph (B)(iv), by striking “and
34 each succeeding year” and inserting “, 2003, and
35 2004”;



1 (B) in subparagraph (C)(iv), by striking “and each
2 succeeding year” and inserting “and 2003”; and

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

5 “(v) For 2004 and each succeeding year, the
6 greater of—

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

10 “(II) the annual Medicare Advantage capi-
11 tation rate under this paragraph for the area
12 for the previous year increased by the national
13 per capita Medicare Advantage growth percent-
14 age, described in paragraph (6) for that suc-
15 ceeding year, but not taking into account any
16 adjustment under paragraph (6)(C) for a year
17 before 2004.”.

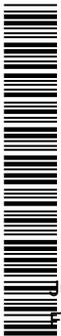
18 (2) CONFORMING AMENDMENT.—Section
19 1853(e)(6)(C) (42 U.S.C. 1395w-23(e)(6)(C)) is amended
20 by inserting before the period at the end the following: “,
21 except that for purposes of paragraph (1)(C)(v)(II), no
22 such adjustment shall be made for a year before 2004”.

23 (d) INCLUSION OF COSTS OF DOD AND VA MILITARY FA-
24 CILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN
25 CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—
26 Section 1853(e)(3) (42 U.S.C. 1395w-23(e)(3)) is amended—

27 (1) in subparagraph (A), by striking “subparagraph
28 (B)” and inserting “subparagraphs (B) and (E)”, and

29 (2) by adding at the end the following new subpara-
30 graph:

31 “(E) INCLUSION OF COSTS OF DOD AND VA MILI-
32 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
33 BENEFICIARIES.—In determining the area-specific
34 Medicare+Choice capitation rate under subparagraph
35 (A) for a year (beginning with 2004), the annual per
36 capita rate of payment for 1997 determined under sec-



1 tion 1876(a)(1)(C) shall be adjusted to include in the
2 rate the Secretary's estimate, on a per capita basis, of
3 the amount of additional payments that would have
4 been made in the area involved under this title if indi-
5 viduals entitled to benefits under this title had not re-
6 ceived services from facilities of the Department of De-
7 fense or the Department of Veterans Affairs.”.

8 (e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT
9 HOSPITAL STAYS TO REHABILITATION HOSPITALS.—

10 (1) IN GENERAL.—Section 1853(g) (42 U.S.C.
11 1395w-23(g)) is amended—

12 (A) by inserting “or from a rehabilitation facility
13 (as defined in section 1886(j)(1)(A))” after
14 “1886(d)(1)(B)”;

15 (B) in paragraph (2)(B), by inserting “or section
16 1886(j), as the case may be,” after “1886(d)”.

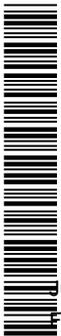
17 (2) EFFECTIVE DATE.—The amendments made by
18 paragraph (1) shall apply to contract years beginning on or
19 after January 1, 2004.

20 (f) APPLICATION OF PRIVACY REGULATIONS.—Section
21 1852(h) (42 U.S.C. 1395w-22(h)) is amended by adding after
22 and below paragraph (3) the following:

23 “A Medicare Advantage organization shall be treated as a cov-
24 ered entity for purposes of the provisions of subpart E of part
25 164 of title 45, Code of Federal Regulations, adopted pursuant
26 to the authority of the Secretary under section 264(e) of the
27 Health Insurance Portability and Accountability Act of 1996
28 (42 U.S. C. 1320d-2 note).”.

29 (g) MEDPAC STUDY OF AAPCC.—

30 (1) STUDY.—The Medicare Payment Advisory Com-
31 mission shall conduct a study that assesses the method
32 used for determining the adjusted average per capita cost
33 (AAPCC) under section 1876(a)(4) of the Social Security
34 Act (42 U.S.C. 1395mm(a)(4)) as applied under section
35 1853(e)(1)(A) of such Act (as amended by subsection (a)).
36 Such study shall include an examination of—



1 (A) the bases for variation in such costs between
2 different areas, including differences in input prices,
3 utilization, and practice patterns;

4 (B) the appropriate geographic area for payment
5 under the Medicare Advantage program under part C
6 of title XVIII of such Act; and

7 (C) the accuracy of risk adjustment methods in re-
8 flecting differences in costs of providing care to dif-
9 ferent groups of beneficiaries served under such pro-
10 gram.

11 (2) REPORT.—Not later than 18 months after the
12 date of the enactment of this Act, the Commission shall
13 submit to Congress a report on the study conducted under
14 paragraph (1).

15 (h) REPORT ON IMPACT OF INCREASED FINANCIAL AS-
16 SISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than
17 July 1, 2006, the Medicare Benefits Administrator shall submit
18 to Congress a report that describes the impact of additional fi-
19 nancing provided under this Act and other Acts (including the
20 Medicare, Medicaid, and SCHIP Balanced Budget Refinement
21 Act of 1999 and BIPA) on the availability of Medicare Advan-
22 tage plans in different areas and its impact on lowering pre-
23 miums and increasing benefits under such plans.

24 **CHAPTER 2—IMPLEMENTATION OF**
25 **COMPETITION PROGRAM**

26 **SEC. 221. COMPETITION PROGRAM BEGINNING IN 2006.**

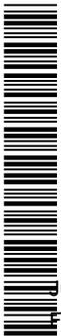
27 (a) SUBMISSION OF EFFS-LIKE BIDDING INFORMATION
28 BEGINNING IN 2006.—Section 1854 (42 U.S.C. 1395w-24) is
29 amended—

30 (1) by amending the section heading to read as fol-
31 lows:

32 “PREMIUMS AND BID AMOUNT”;

33 (2) in subsection (a)(1)(A)—

34 (A) by striking “(A)” and inserting “(A)(i) if the
35 following year is before 2006,”; and



1 (B) by inserting before the semicolon at the end
2 the following: “or (ii) if the following year is 2006 or
3 later, the information described in paragraph (3) or
4 (6)(A) for the type of plan involved”; and

5 (3) by adding at the end of subsection (a) the fol-
6 lowing:

7 “(6) SUBMISSION OF BID AMOUNTS BY MEDICARE AD-
8 VANTAGE ORGANIZATIONS.—

9 “(A) INFORMATION TO BE SUBMITTED.—The in-
10 formation described in this subparagraph is as follows:

11 “(i) The monthly aggregate bid amount for
12 provision of all items and services under this part,
13 which amount shall be based on average costs for
14 a typical enrollee residing in the area, and the ac-
15 tuarial basis for determining such amount.

16 “(ii) The proportions of such bid amount that
17 are attributable to—

18 “(I) the provision of statutory non-drug
19 benefits (such portion referred to in this part
20 as the ‘unadjusted Medicare Advantage statu-
21 tory non-drug monthly bid amount’);

22 “(II) the provision of statutory prescrip-
23 tion drug benefits; and

24 “(III) the provision of non-statutory bene-
25 fits;

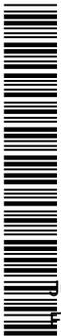
26 and the actuarial basis for determining such pro-
27 portions.

28 “(iii) Such additional information as the Ad-
29 ministrator may require to verify the actuarial
30 bases described in clauses (i) and (ii).

31 “(B) STATUTORY BENEFITS DEFINED.—For pur-
32 poses of this part:

33 “(i) The term ‘statutory non-drug benefits’
34 means benefits under section 1852(a)(1).

35 “(ii) The term ‘statutory prescription drug
36 benefits’ means benefits under part D.



1 “(iii) The term ‘statutory benefits’ means stat-
2 utory prescription drug benefits and statutory non-
3 drug benefits.

4 “(C) ACCEPTANCE AND NEGOTIATION OF BID
5 AMOUNTS.—

6 “(i) IN GENERAL.—Subject to clause (ii)—

7 “(I) the Administrator has the authority
8 to negotiate regarding monthly bid amounts
9 submitted under subparagraph (A) (and the
10 proportion described in subparagraph (A)(ii)),
11 and for such purpose and subject to such
12 clause, the Administrator has negotiation au-
13 thority that the Director of the Office of Per-
14 sonnel Management has with respect to health
15 benefits plans under chapter 89 of title 5,
16 United States Code; and

17 “(II) the Administrator may reject such a
18 bid amount or proportion if the Administrator
19 determines that such amount or proportion is
20 not supported by the actuarial bases provided
21 under subparagraph (A).

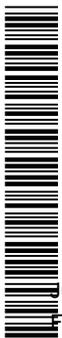
22 “(ii) EXCEPTION.—In the case of a plan de-
23 scribed in section 1851(a)(2)(C), the provisions of
24 clause (i) shall not apply and the provisions of
25 paragraph (5)(B), prohibiting the review, approval,
26 or disapproval of amounts described in such para-
27 graph, shall apply to the negotiation and rejection
28 of the monthly bid amounts and proportion re-
29 ferred to in subparagraph (A).”.

30 (b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN
31 PLANS.—

32 (1) IN GENERAL.—Section 1854(b) (42 U.S.C.
33 1395w-24(b)) is amended—

34 (A) by adding at the end of paragraph (1) the fol-
35 lowing new subparagraph:

36 “(C) BENEFICIARY REBATE RULE.—



1 “(i) REQUIREMENT.—The Medicare Advan-
2 tage plan shall provide to the enrollee a monthly re-
3 bate equal to 75 percent of the average per capita
4 savings (if any) described in paragraph (3) applica-
5 ble to the plan and year involved.

6 “(iii) FORM OF REBATE.—A rebate required
7 under this subparagraph shall be provided—

8 “(I) through the crediting of the amount
9 of the rebate towards the Medicare Advantage
10 monthly supplementary beneficiary premium or
11 the premium imposed for prescription drug cov-
12 erage under part D;

13 “(II) through a direct monthly payment
14 (through electronic funds transfer or other-
15 wise); or

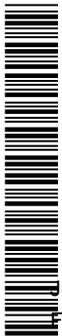
16 “(III) through other means approved by
17 the Medicare Benefits Administrator,
18 or any combination thereof.”; and

19 (B) by adding at the end the following new para-
20 graphs:

21 “(3) COMPUTATION OF AVERAGE PER CAPITA MONTH-
22 LY SAVINGS.—For purposes of paragraph (1)(C)(i), the av-
23 erage per capita monthly savings referred to in such para-
24 graph for a Medicare Advantage plan and year is computed
25 as follows:

26 “(A) DETERMINATION OF STATE-WIDE AVERAGE
27 RISK ADJUSTMENT.—

28 “(i) IN GENERAL.—The Medicare Benefits Ad-
29 ministrators shall determine, at the same time rates
30 are promulgated under section 1853(b)(1) (begin-
31 ning with 2006), for each State the average of the
32 risk adjustment factors to be applied under section
33 1853(a)(1)(A) to payment for enrollees in that
34 State. In the case of a State in which a Medicare
35 Advantage plan was offered in the previous year,
36 the Administrator may compute such average based



1 upon risk adjustment factors applied in that State
2 in a previous year.

3 “(ii) TREATMENT OF NEW STATES.—In the
4 case of a State in which no Medicare Advantage
5 plan was offered in the previous year, the Adminis-
6 trator shall estimate such average. In making such
7 estimate, the Administrator may use average risk
8 adjustment factors applied to comparable States or
9 applied on a national basis.

10 “(B) DETERMINATION OF RISK ADJUSTED BENCH-
11 MARK AND RISK-ADJUSTED BID.—For each Medicare
12 Advantage plan offered in a State, the Administrator
13 shall—

14 “(i) adjust the Medicare Advantage area-spe-
15 cific non-drug monthly benchmark amount (as de-
16 fined in subsection (j)) by the applicable average
17 risk adjustment factor computed under subpara-
18 graph (A); and

19 “(ii) adjust the unadjusted Medicare Advan-
20 tage statutory non-drug monthly bid amount by
21 such applicable average risk adjustment factor.

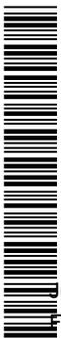
22 “(C) DETERMINATION OF AVERAGE PER CAPITA
23 MONTHLY SAVINGS.—The average per capita monthly
24 savings described in this subparagraph is equal to the
25 amount (if any) by which—

26 “(i) the risk-adjusted benchmark amount com-
27 puted under subparagraph (B)(i), exceeds

28 “(ii) the risk-adjusted bid computed under
29 subparagraph (B)(ii).

30 “(D) AUTHORITY TO DETERMINE RISK ADJUST-
31 MENT FOR AREAS OTHER THAN STATES.—The Adminis-
32 trator may provide for the determination and applica-
33 tion of risk adjustment factors under this paragraph on
34 the basis of areas other than States.

35 “(4) BENEFICIARY’S OPTION OF PAYMENT THROUGH
36 WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE



1 OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In ac-
2 cordance with regulations, a Medicare Advantage organiza-
3 tion shall permit each enrollee, at the enrollee’s option, to
4 make payment of premiums under this part to the organi-
5 zation indirectly through withholding from benefit pay-
6 ments in the manner provided under section 1840 with re-
7 spect to monthly premiums under section 1839 or through
8 an electronic funds transfer mechanism (such as automatic
9 charges of an account at a financial institution or a credit
10 or debit card account) or otherwise.”.

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

15 “(5) SINGLE CONSOLIDATED PREMIUM.—In the case
16 of an enrollee in a Medicare Advantage plan who elects
17 under part D to be provided qualified prescription drug
18 coverage through the plan, the Administrator shall provide
19 a mechanism for the consolidation of the beneficiary pre-
20 mium amount for non-drug benefits under this part with
21 the premium amount for prescription drug coverage under
22 part D provided through the plan.”.

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

27 “(j) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPE-
28 CIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For pur-
29 poses of this part, the term ‘Medicare Advantage area-specific
30 non-drug monthly benchmark amount’ means, with respect to
31 a Medicare Advantage payment area for a month in a year, an
32 amount equal to $\frac{1}{12}$ of the annual Medicare Advantage capita-
33 tion rate under section 1853(c)(1) for the area for the year.”.

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

35 (1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C.
36 1395w–23) is amended by striking “in an amount” and all



1 that follows and inserting the following: “in an amount de-
2 termined as follows:

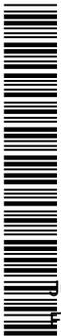
3 “(i) PAYMENT BEFORE 2006.—For years be-
4 fore 2006, the payment amount shall be equal to
5 $\frac{1}{12}$ of the annual Medicare Advantage capitation
6 rate (as calculated under subsection (e)(1)) with re-
7 spect to that individual for that area, reduced by
8 the amount of any reduction elected under section
9 1854(f)(1)(E) and adjusted under clause (iv).

10 “(ii) PAYMENT FOR STATUTORY NON-DRUG
11 BENEFITS BEGINNING WITH 2006.—For years be-
12 ginning with 2006—

13 “(I) PLANS WITH BIDS BELOW BENCH-
14 MARK.—In the case of a plan for which there
15 are average per capita monthly savings de-
16 scribed in section 1854(b)(3)(C), the payment
17 under this subsection is equal to the
18 unadjusted Medicare Advantage statutory non-
19 drug monthly bid amount, adjusted under
20 clause (iv), plus the amount of the monthly re-
21 bate computed under section 1854(b)(1)(C)(i)
22 for that plan and year.

23 “(II) PLANS WITH BIDS AT OR ABOVE
24 BENCHMARK.—In the case of a plan for which
25 there are no average per capita monthly sav-
26 ings described in section 1854(b)(3)(C), the
27 payment amount under this subsection is equal
28 to the Medicare Advantage area-specific non-
29 drug monthly benchmark amount, adjusted
30 under clause (iv).

31 “(iii) FOR FEDERAL DRUG SUBSIDIES.—In the
32 case in which an enrollee who elects under part D
33 to be provided qualified prescription drug coverage
34 through the plan, the Medicare Advantage organi-
35 zation offering such plan also is entitled—



1 “(I) to direct subsidy payment under sec-
2 tion 1860D–8(a)(1);

3 “(II) to reinsurance subsidy payments
4 under section 1860D–8(a)(2); and

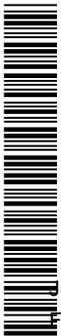
5 “(III) to reimbursement for premium and
6 cost-sharing reductions for low-income individ-
7 uals under section 1860D–7(c)(3).

8 “(iv) DEMOGRAPHIC ADJUSTMENT, INCLUDING
9 ADJUSTMENT FOR HEALTH STATUS.—The Admin-
10 istrator shall adjust the payment amount under
11 clause (i), the unadjusted Medicare Advantage stat-
12 utory non-drug monthly bid amount under clause
13 (ii)(I), and the Medicare Advantage area-specific
14 non-drug monthly benchmark amount under clause
15 (ii)(II) for such risk factors as age, disability sta-
16 tus, gender, institutional status, and such other
17 factors as the Administrator determines to be ap-
18 propriate, including adjustment for health status
19 under paragraph (3), so as to ensure actuarial
20 equivalence. The Administrator may add to, mod-
21 ify, or substitute for such adjustment factors if
22 such changes will improve the determination of ac-
23 tuarial equivalence.”.

24 (d) CONFORMING AMENDMENTS.—

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

32 (2) CONFORMING AMENDMENT TO PREMIUM TERMI-
33 NOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2))
34 is amended by redesignating subparagraph (C) as subpara-
35 graph (D) and by striking subparagraphs (A) and (B) and
36 inserting the following:



1 “(A) MEDICARE ADVANTAGE MONTHLY BASIC
2 BENEFICIARY PREMIUM.—The term ‘Medicare Advan-
3 tage monthly basic beneficiary premium’ means, with
4 respect to a Medicare Advantage plan—

5 “(i) described in section 1853(a)(1)(A)(ii)(I)
6 (relating to plans providing rebates), zero; or

7 “(ii) described in section 1853(a)(1)(A)(ii)(II),
8 the amount (if any) by which the unadjusted Medi-
9 care Advantage statutory non-drug monthly bid
10 amount exceeds the Medicare Advantage area-spe-
11 cific non-drug monthly benchmark amount;

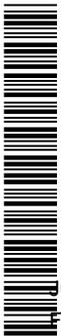
12 except that, in the case of a Medicare Advantage pri-
13 vate fee-for-service plan, such term means such pre-
14 mium as the plan files with the Administrator under
15 this section.

16 “(B) MEDICARE ADVANTAGE MONTHLY PRESCRIP-
17 TION DRUG BENEFICIARY PREMIUM.—The term ‘Medi-
18 care Advantage monthly prescription drug beneficiary
19 premium’ means, with respect to a Medicare Advantage
20 plan, that portion of the bid amount submitted under
21 clause (i) of subsection (a)(6)(A) for the year that is
22 attributable under such section to the provision of stat-
23 utory prescription drug benefits.

24 “(C) MEDICARE ADVANTAGE MONTHLY SUPPLE-
25 MENTAL BENEFICIARY PREMIUM.—The term ‘Medicare
26 Advantage monthly supplemental beneficiary premium’
27 means, with respect to a Medicare Advantage plan, the
28 portion of the aggregate monthly bid amount submitted
29 under clause (i) of subsection (a)(6)(A) for the year
30 that is attributable under such section to the provision
31 of nonstatutory benefits.”.

32 (3) REQUIREMENT FOR UNIFORM PREMIUM AND BID
33 AMOUNTS.—Section 1854(c) (42 U.S.C. 1395w-24(c)) is
34 amended to read as follows:

35 “(c) UNIFORM PREMIUM AND BID AMOUNTS.—The Medi-
36 care Advantage monthly bid amount submitted under sub-



1 section (a)(6), the Medicare Advantage monthly basic, prescrip-
2 tion drug, and supplemental beneficiary premiums, and the
3 Medicare Advantage monthly MSA premium charged under
4 subsection (b) of a Medicare Advantage organization under this
5 part may not vary among individuals enrolled in the plan.”.

6 (4) PERMITTING BENEFICIARY REBATES.—

7 (A) Section 1851(h)(4)(A) (42 U.S.C. 1395w-
8 21(h)(4)(A)) is amended by inserting “except as pro-
9 vided under section 1854(b)(1)(C)” after “or other-
10 wise”.

11 (B) Section 1854(d) (42 U.S.C. 1395w-24(d)) is
12 amended by inserting “, except as provided under sub-
13 section (b)(1)(C),” after “and may not provide”.

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

16 (A) in the heading of subsection (a), by inserting
17 “AND BID AMOUNTS” after “PREMIUMS”; and

18 (B) in subsection (a)(5)(A), by inserting “para-
19 graphs (2), (3), and (4) of” after “filed under”.

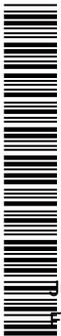
20 (e) ADDITIONAL CONFORMING AMENDMENTS.—

21 (1) ANNUAL DETERMINATION AND ANNOUNCEMENT
22 OF CERTAIN FACTORS.—Section 1853(b)(1) (42 U.S.C.
23 1395w-23(b)(1)) is amended by striking “the respective
24 calendar year” and all that follows and inserting the fol-
25 lowing: “the calendar year concerned with respect to each
26 Medicare Advantage payment area, the following:

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

29 “(i) MEDICARE ADVANTAGE CAPITATION
30 RATES.—The annual Medicare Advantage capita-
31 tion rate for each Medicare Advantage payment
32 area for the year.

33 “(ii) ADJUSTMENT FACTORS.—The risk and
34 other factors to be used in adjusting such rates
35 under subsection (a)(1)(A) for payments for
36 months in that year.



1 “(B) COMPETITION INFORMATION.—For years be-
2 ginning with 2006, the following:

3 “(i) BENCHMARK.—The Medicare Advantage
4 area-specific non-drug benchmark under section
5 1853(j).

6 “(ii) ADJUSTMENT FACTORS.—The adjust-
7 ment factors applied under section
8 1853(a)(1)(A)(iv) (relating to demographic adjust-
9 ment), section 1853(a)(1)(B) (relating to adjust-
10 ment for end-stage renal disease), and section
11 1853(a)(3) (relating to health status adjust-
12 ment).”.

13 (2) REPEAL OF PROVISIONS RELATING TO ADJUSTED
14 COMMUNITY RATE (ACR).—

15 (A) IN GENERAL.—Subsections (e) and (f) of sec-
16 tion 1854 (42 U.S.C. 1395w-24) are repealed.

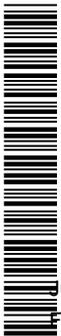
17 (B) CONFORMING AMENDMENTS.—(i) Section
18 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by
19 striking “, and to reflect” and all that follows and in-
20 serting a period.

21 (ii) Section 1852(a)(1) (42 U.S.C. 1395w-
22 22(a)(1)) is amended by striking “title XI” and all that
23 follows and inserting the following: “title XI those
24 items and services (other than hospice care) for which
25 benefits are available under parts A and B to individ-
26 uals residing in the area served by the plan.”.

27 (iii) Section 1857(d)(1) (42 U.S.C. 1395w-
28 27(d)(1)) is amended by striking “, costs, and com-
29 putation of the adjusted community rate” and inserting
30 “and costs”.

31 (f) REFERENCES UNDER PART E.—Section 1859 (42
32 U.S.C. 1395w-29) is amended by adding at the end the fol-
33 lowing new subsection:

34 “(f) APPLICATION UNDER PART E.—In the case of any
35 reference under part E to a requirement or provision of this
36 part in the relation to an EFFS plan or organization under



1 such part, except as otherwise specified any such requirement
2 or provision shall be applied to such organization or plan in the
3 same manner as such requirement or provision applies to a
4 Medicare Advantage private fee-for-service plan (and the Medi-
5 care Advantage organization that offers such plan) under this
6 part.”.

7 (g) EFFECTIVE DATE.—The amendments made by this
8 section shall apply to payments and premiums for months be-
9 ginning with January 2006.

10 **CHAPTER 3—ADDITIONAL REFORMS**

11 **SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE** 12 **ADVANTAGE REPORTING DEADLINES AND** 13 **ANNUAL, COORDINATED ELECTION PERIOD.**

14 (a) CHANGE IN REPORTING DEADLINE.—Section
15 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by sec-
16 tion 532(b)(1) of the Public Health Security and Bioterrorism
17 Preparedness and Response Act of 2002, is amended by strik-
18 ing “2002, 2003, and 2004 (or July 1 of each other year)” and
19 inserting “2002 and each subsequent year”.

20 (b) DELAY IN ANNUAL, COORDINATED ELECTION PE-
21 RIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)),
22 as amended by section 532(e)(1)(A) of the Public Health Secu-
23 rity and Bioterrorism Preparedness and Response Act of 2002,
24 is amended—

25 (1) by striking “and after 2005”; and

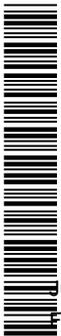
26 (2) by striking “, 2004, and 2005” and inserting “and
27 any subsequent year”.

28 (c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Sec-
29 tion 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)), as amended by
30 section 532(d)(1) of the Public Health Security and Bioter-
31 rorism Preparedness and Response Act of 2002, is amended—

32 (1) by striking “and after 2005”; and

33 (2) by striking “and 2005” and inserting “and each
34 subsequent year”.

35 (d) REQUIRING PROVISION OF AVAILABLE INFORMATION
36 COMPARING PLAN OPTIONS.—The first sentence of section



1 1851(d)(2)(A)(ii) (42 U.S.C. 1395w-21(d)(2)(A)(ii)) is amend-
2 ed by inserting before the period the following: “to the extent
3 such information is available at the time of preparation of ma-
4 terials for the mailing”.

5 **SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.**

6 (a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w-
7 26(b)(3)) is amended to read as follows:

8 “(3) RELATION TO STATE LAWS.—The standards es-
9 tablished under this subsection shall supersede any State
10 law or regulation (other than State licensing laws or State
11 laws relating to plan solvency) with respect to Medicare Ad-
12 vantage plans which are offered by Medicare Advantage or-
13 ganizations under this part.”.

14 (b) EFFECTIVE DATE.—The amendment made by sub-
15 section (a) shall take effect on the date of the enactment of this
16 Act.

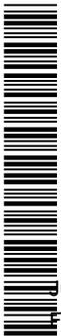
17 **SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS**
18 **FOR SPECIAL NEEDS BENEFICIARIES.**

19 (a) TREATMENT AS COORDINATED CARE PLAN.—Section
20 1851(a)(2)(A) (42 U.S.C. 1395w-21(a)(2)(A)) is amended by
21 adding at the end the following new sentence: “Specialized
22 Medicare Advantage plans for special needs beneficiaries (as
23 defined in section 1859(b)(4)) may be any type of coordinated
24 care plan.”.

25 (b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR SPE-
26 CIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42
27 U.S.C. 1395w-29(b)) is amended by adding at the end the fol-
28 lowing new paragraph:

29 “(4) SPECIALIZED MEDICARE ADVANTAGE PLANS FOR
30 SPECIAL NEEDS BENEFICIARIES.—

31 “(A) IN GENERAL.—The term ‘specialized Medi-
32 care Advantage plan for special needs beneficiaries’
33 means a Medicare Advantage plan that exclusively
34 serves special needs beneficiaries (as defined in sub-
35 paragraph (B)).



1 “(B) SPECIAL NEEDS BENEFICIARY.—The term
2 ‘special needs beneficiary’ means a Medicare Advantage
3 eligible individual who—

4 “(i) is institutionalized (as defined by the Sec-
5 retary);

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

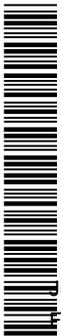
8 “(iii) meets such requirements as the Sec-
9 retary may determine would benefit from enroll-
10 ment in such a specialized Medicare Advantage
11 plan described in subparagraph (A) for individuals
12 with severe or disabling chronic conditions.”.

13 (c) RESTRICTION ON ENROLLMENT PERMITTED.—Section
14 1859 (42 U.S.C. 1395w-29) is amended by adding at the end
15 the following new subsection:

16 “(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED
17 MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENE-
18 FICIARIES.—In the case of a specialized Medicare Advantage
19 plan (as defined in subsection (b)(4)), notwithstanding any
20 other provision of this part and in accordance with regulations
21 of the Secretary and for periods before January 1, 2007, the
22 plan may restrict the enrollment of individuals under the plan
23 to individuals who are within one or more classes of special
24 needs beneficiaries.”.

25 (d) AUTHORITY TO DESIGNATE OTHER PLANS AS SPE-
26 CIALIZED MEDICARE ADVANTAGE PLANS.—In promulgating
27 regulations to carry out the last sentence of section
28 1851(a)(2)(A) of the Social Security Act (as added by sub-
29 section (a)) and section 1859(b)(4) of such Act (as added by
30 subsection (b)), the Secretary may provide (notwithstanding
31 section 1859(b)(4)(A) of such Act) for the offering of special-
32 ized Medicare Advantage plans by Medicare Advantage plans
33 that disproportionately serve special needs beneficiaries who are
34 frail, elderly medicare beneficiaries.

35 (e) REPORT TO CONGRESS.—Not later than December 31,
36 2005, the Medicare Benefits Administrator shall submit to



1 Congress a report that assesses the impact of specialized Medi-
2 care Advantage plans for special needs beneficiaries on the cost
3 and quality of services provided to enrollees. Such report shall
4 include an assessment of the costs and savings to the medicare
5 program as a result of amendments made by subsections (a),
6 (b), and (c).

7 (f) EFFECTIVE DATES.—

8 (1) IN GENERAL.—The amendments made by sub-
9 sections (a), (b), and (c) shall take effect upon the date of
10 the enactment of this Act.

11 (2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR
12 SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later
13 than 6 months after the date of the enactment of this Act,
14 the Secretary of Health and Human Services shall issue
15 final regulations to establish requirements for special needs
16 beneficiaries under section 1859(b)(4)(B)(iii) of the Social
17 Security Act, as added by subsection (b).

18 **SEC. 234. MEDICARE MSAS.**

19 (a) EXEMPTION FROM REPORTING ENROLLEE ENCOUN-
20 TER DATA.—

21 (1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C.
22 1395w-22(e)(1)) is amended by inserting “(other than
23 MSA plans)” after “plans”.

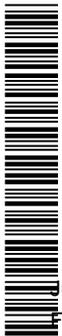
24 (2) CONFORMING AMENDMENTS.—Section 1852 (42
25 U.S.C. 1395w-22) is amended—

26 (A) in subsection (e)(1)(I), by inserting before the
27 period at the end the following: “if required under such
28 section”; and

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

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

35 (1) in the heading, by striking “ON A DEMONSTRATION
36 BASIS”;



1 (2) by striking the first sentence of subparagraph (A);
2 and
3 (3) by striking the second sentence of subparagraph
4 (C).

5 (c) APPLYING LIMITATIONS ON BALANCE BILLING.—Sec-
6 tion 1852(k)(1) (42 U.S.C. 1395w-22(k)(1)) is amended by in-
7 serting “or with an organization offering a MSA plan” after
8 “section 1851(a)(2)(A)”.

9 (d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A)
10 (42 U.S.C. 1395w-21(e)(5)(A)) is amended—

11 (1) by adding “or” at the end of clause (i);
12 (2) by striking “, or” at the end of clause (ii) and in-
13 serting a semicolon; and
14 (3) by striking clause (iii).

15 **SEC. 235. EXTENSION OF REASONABLE COST CON-**
16 **TRACTS.**

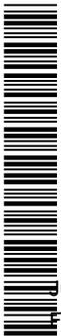
17 Subparagraph (C) of section 1876(h)(5) (42 U.S.C.
18 1395mm(h)(5)) is amended to read as follows:

19 “(C)(i) Subject to clause (ii), may be extended or renewed
20 under this subsection indefinitely.

21 “(ii) For any period beginning on or after January 1,
22 2008, a reasonable cost reimbursement contract under this sub-
23 section may not be extended or renewed for a service area inso-
24 far as such area, during the entire previous year, was within
25 the service area of 2 or more plans which were coordinated care
26 Medicare Advantage plans under part C or 2 or more enhanced
27 fee-for-service plans under part E and each of which plan for
28 that previous year for the area involved meets the following
29 minimum enrollment requirements:

30 “(I) With respect to any portion of the area involved
31 that is within a Metropolitan Statistical Area with a popu-
32 lation of more than 250,000 and counties contiguous to
33 such Metropolitan Statistical Area, 5,000 individuals.

34 “(II) With respect to any other portion of such area,
35 1,500 individuals.”



**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 BENCH-
MARKS UNDER EFFS PROGRAM.—

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

“(e) APPLICATION OF COMPETITION.—

“(1) DETERMINATION OF COMPETITIVE EFFS RE-
GIONS.—

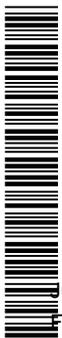
“(A) IN GENERAL.—For purposes of this part, the
term ‘competitive EFFS region’ means, for a year be-
ginning with 2010, an EFFS region that the Adminis-
trator finds—

“(i) there will be offered in the region during
the annual, coordinated election period under sec-
tion 1851(e)(3)(B) (as applied under section
1860E–1(e)) before the beginning of the year at
least 2 EFFS plans (in addition to the fee-for-serv-
ice program under parts A and B), each offered by
a different EFFS organization and each of which
met the minimum enrollment requirements of para-
graph (1) of section 1857(b) (as applied without
regard to paragraph (3) thereof) as of March of the
previous year; and

“(ii) during March of the previous year at
least the percentage specified in subparagraph (C)
of the number of EFFS eligible individuals who re-
side in the region were enrolled in an EFFS plan.

“(B) PERCENTAGE SPECIFIED.—

“(i) IN GENERAL.—For purposes of subpara-
graph (A), subject to clause (ii), the percentage



1 specified in this subparagraph for a year is equal
2 the lesser of 20 percent or to the sum of—

3 “(I) the percentage, as estimated by the
4 Administrator, of EFFE eligible individuals in
5 the United States who are enrolled in EFFE
6 plans during March of the previous year; and

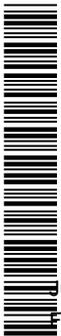
7 “(II) the percentage, as estimated by the
8 Administrator, of Medicare Advantage eligible
9 individuals in the United States who are en-
10 rolled in Medicare Advantage plans during
11 March of the previous year.

12 “(ii) EXCEPTION.—In the case of an EFFE
13 region that was a competitive EFFE region for the
14 previous year, the Medicare Benefits Administrator
15 may continue to treat the region as meeting the re-
16 quirement of subparagraph (A)(ii) if the region
17 would meet such requirement but for a de minimis
18 reduction below the percentage specified in clause
19 (i).

20 “(2) COMPETITIVE EFFE NON-DRUG MONTHLY BENCH-
21 MARK AMOUNT.—For purposes of this part, the term ‘com-
22 petitive EFFE non-drug monthly benchmark amount’
23 means, with respect to an EFFE region for a month in a
24 year and subject to paragraph (8), the sum of the 2 compo-
25 nents described in paragraph (3) for the region and year.
26 The Administrator shall compute such benchmark amount
27 for each competitive EFFE region before the beginning of
28 each annual, coordinated election period under section
29 1851(e)(3)(B) for each year (beginning with 2010) in
30 which it is designated as such a region.

31 “(3) 2 COMPONENTS.—For purposes of paragraph (2),
32 the 2 components described in this paragraph for an EFFE
33 region and a year are the following:

34 “(A) EFFE COMPONENT.—The product of the fol-
35 lowing:



1 “(i) WEIGHTED AVERAGE OF PLAN BIDS IN
2 REGION.—The weighted average of the EFFS plan
3 bids for the region and year (as determined under
4 paragraph (4)(A)).

5 “(ii) NON-EFFS MARKET SHARE.—1 minus the
6 fee-for-service market share percentage determined
7 under paragraph (5) for the region and the year.

8 “(B) FEE-FOR-SERVICE COMPONENT.—The prod-
9 uct of the following:

10 “(i) FEE-FOR-SERVICE REGION-SPECIFIC NON-
11 DRUG AMOUNT.—The fee-for-service region-specific
12 non-drug amount (as defined in paragraph (6)) for
13 the region and year.

14 “(ii) FEE-FOR-SERVICE MARKET SHARE.—The
15 fee-for-service market share percentage (determined
16 under paragraph (5)) for the region and the year.

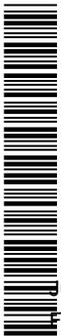
17 “(4) DETERMINATION OF WEIGHTED AVERAGE EFFS
18 PLAN BIDS FOR A REGION.—

19 “(A) IN GENERAL.—For purposes of paragraph
20 (3)(A)(i), the weighted average of EFFS plan bids for
21 an EFFS region and a year is the sum of the following
22 products for EFFS plans described in subparagraph
23 (C) in the region and year:

24 “(i) UNADJUSTED EFFS STATUTORY NON-
25 DRUG MONTHLY BID AMOUNT.—The unadjusted
26 EFFS statutory non-drug monthly bid amount (as
27 defined in subsection (a)(3)(A)(ii)(I)) for the region
28 and year.

29 “(ii) PLAN’S SHARE OF EFFS ENROLLMENT IN
30 REGION.—The number of individuals described in
31 subparagraph (B), divided by the total number of
32 such individuals for all EFFS plans described in
33 subparagraph (C) for that region and year.

34 “(B) COUNTING OF INDIVIDUALS.—The Adminis-
35 trator shall count, for each EFFS plan described in
36 subparagraph (C) for an EFFS region and year, the



1 number of individuals who reside in the region and who
2 were enrolled under such plan under this part during
3 March of the previous year.

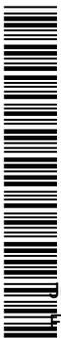
4 “(C) EXCLUSION OF PLANS NOT OFFERED IN PRE-
5 VIOUS YEAR.—For an EFFF region and year, the
6 EFFF plans described in this subparagraph are plans
7 that are offered in the region and year and were of-
8 fered in the region in March of the previous year.

9 “(5) COMPUTATION OF FEE-FOR-SERVICE MARKET
10 SHARE PERCENTAGE.—The Administrator shall determine,
11 for a year and an EFFF region, the proportion (in this
12 subsection referred to as the ‘fee-for-service market share
13 percentage’) of the EFFF eligible individuals who are resi-
14 dents of the region during March of the previous year, of
15 such individuals who were not enrolled in an EFFF plan
16 or in a Medicare Advantage plan (or, if greater, such pro-
17 portion determined for individuals nationally).

18 “(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG
19 AMOUNT.—

20 “(A) IN GENERAL.—For purposes of paragraph
21 (3)(B)(i) and section 1839(h)(2)(A), subject to sub-
22 paragraph (B), the term ‘fee-for-service region-specific
23 non-drug amount’ means, for a competitive EFFF re-
24 gion and a year, the adjusted average per capita cost
25 for the year involved, determined under section
26 1876(a)(4) for such region for services covered under
27 parts A and B for individuals entitled to benefits under
28 part A and enrolled under this part who are not en-
29 rolled in an EFFF plan under part E or a Medicare
30 Advantage plan under part C for the year, but adjusted
31 to exclude costs attributable to payments under section
32 1886(h).

33 “(B) INCLUSION OF COSTS OF VA AND DOD MILI-
34 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
35 BENEFICIARIES.—In determining the adjusted average
36 per capita cost under subparagraph (A) for a year,



1 such cost shall be adjusted to include the Administra-
2 tor's estimate, on a per capita basis, of the amount of
3 additional payments that would have been made in the
4 region involved under this title if individuals entitled to
5 benefits under this title had not received services from
6 facilities of the Department of Veterans Affairs or the
7 Department of Defense.

8 “(7) APPLICATION OF COMPETITION.—In the case of
9 an EFFF region that is a competitive EFFF region for a
10 year, for purposes of applying subsections (b) and (c)(1)
11 and section 1860E-4(a), any reference to an EFFF region-
12 specific non-drug monthly benchmark amount shall be
13 treated as a reference to the competitive EFFF non-drug
14 monthly benchmark amount under paragraph (2) for the
15 region and year.

16 “(8) PHASE-IN OF BENCHMARK FOR EACH REGION.—

17 “(A) USE OF BLENDED BENCHMARK.—In the case
18 of a region that has not been a competitive EFFF re-
19 gion for each of the previous 4 years, the competitive
20 EFFF non-drug monthly benchmark amount shall be
21 equal to the sum of the following:

22 “(i) NEW COMPETITIVE COMPONENT.—The
23 product of—

24 “(I) the weighted average phase-in propor-
25 tion for that area and year, as specified in sub-
26 paragraph (B); and

27 “(II) the competitive EFFF non-drug
28 monthly benchmark amount for the region and
29 year, determined under paragraph (2) without
30 regard to this paragraph.

31 “(ii) OLD COMPETITIVE COMPONENT.—The
32 product of—

33 “(I) 1 minus the weighted average phase-
34 in proportion for that region and year; and

35 “(II) the EFFF region-specific non-drug
36 benchmark amount for the area and the year.



1 “(B) COMPUTATION OF WEIGHTED AVERAGE
2 PHASE-IN PROPORTION.—For purposes of this para-
3 graph, the ‘weighted average phase-in proportion’ for
4 an EFFF region for a year shall be determined as fol-
5 lows:

6 “(i) FIRST YEAR (AND REGION NOT COMPETI-
7 TIVE REGION IN PREVIOUS YEAR).—If the area was
8 not a competitive EFFF region in the previous
9 year, the weighted average phase-in proportion for
10 the region for the year is equal to $\frac{1}{5}$.

11 “(ii) COMPETITIVE REGION IN PREVIOUS
12 YEAR.—If the region was a competitive EFFF re-
13 gion in the previous year, the weighted average
14 phase-in proportion for the region for the year is
15 equal to the weighted average phase-in proportion
16 determined under this subparagraph for the region
17 for the previous year plus $\frac{1}{5}$, but in no case more
18 than 1.”.

19 (2) CONFORMING AMENDMENTS.—

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

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

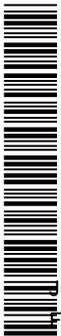
23 “(4) APPLICATION IN COMPETITIVE REGIONS.—
24 For special rules applying this subsection in competi-
25 tive EFFF regions, see subsection (e)(7).”;

26 (ii) in subsection (c)(1), by inserting “and
27 subsection (e)(7)” after “(as made applicable under
28 subsection (d))”; and

29 (iii) in subsection (d) , by striking “and (e)”
30 and inserting “(e), and (k) ”.

31 (B) Section 1860E–4(a)(1), as inserted by section
32 201(a)(2), is amended by inserting “, except as pro-
33 vided in section 1860E–3(e)(7)” after “paragraph (2)”.

34 (b) IDENTIFICATION OF COMPETITIVE MEDICARE ADVAN-
35 TAGE AREAS; APPLICATION OF COMPETITIVE MEDICARE AD-



1 VANTAGE NON-DRUG BENCHMARKS UNDER MEDICARE AD-
2 VANTAGE PROGRAM.—

3 (1) IN GENERAL.—Section 1853, as amended by sec-
4 tion 221(b)(3), is amended by adding at the end the fol-
5 lowing new subsection:

6 “(k) APPLICATION OF COMPETITION.—

7 “(1) DETERMINATION OF COMPETITIVE MEDICARE AD-
8 VANTAGE AREAS.—

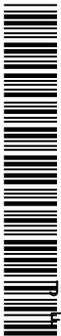
9 “(A) IN GENERAL.—For purposes of this part, the
10 terms ‘competitive Medicare Advantage area’ and ‘CMA
11 area’ mean, for a year beginning with 2010, an area
12 (which is a metropolitan statistical area or other area
13 with a substantial number of Medicare Advantage en-
14 rollees) that the Administrator finds—

15 “(i) there will be offered during the annual,
16 coordinated election period under section
17 1851(e)(3)(B) under this part before the beginning
18 of the year at least 2 Medicare Advantage plans (in
19 addition to the fee-for-service program under parts
20 A and B), each offered by a different Medicare Ad-
21 vantage organization and each of which met the
22 minimum enrollment requirements of paragraph
23 (1) of section 1857(b) (as applied without regard
24 to paragraph (3) thereof) as of March of the pre-
25 vious year with respect to the area; and

26 “(ii) during March of the previous year at
27 least the percentage specified in subparagraph (B)
28 of the number of Medicare Advantage eligible indi-
29 viduals who reside in the area were enrolled in a
30 Medicare Advantage plan.

31 “(B) PERCENTAGE SPECIFIED.—

32 “(i) IN GENERAL.—For purposes of subpara-
33 graph (A), subject to clause (ii), the percentage
34 specified in this subparagraph for a year is equal
35 the lesser of 20 percent or to the sum of—



1 “(I) the percentage, as estimated by the
2 Administrator, of EFFE eligible individuals in
3 the United States who are enrolled in EFFE
4 plans during March of the previous year; and

5 “(II) the percentage, as estimated by the
6 Administrator, of Medicare Advantage eligible
7 individuals in the United States who are en-
8 rolled in Medicare Advantage plans during
9 March of the previous year.

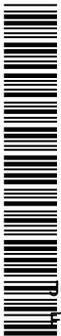
10 “(ii) EXCEPTION.—In the case of an area that
11 was a competitive area for the previous year, the
12 Medicare Benefits Administrator may continue to
13 treat the area as meeting the requirement of sub-
14 paragraph (A)(ii) if the area would meet such re-
15 quirement but for a de minimis reduction below the
16 percentage specified in clause (i).

17 “(2) COMPETITIVE MEDICARE ADVANTAGE NON-DRUG
18 MONTHLY BENCHMARK AMOUNT.—For purposes of this
19 part, the term ‘competitive Medicare Advantage non-drug
20 monthly benchmark amount’ means, with respect to a com-
21 petitive Medicare Advantage area for a month in a year
22 subject to paragraph (8), the sum of the 2 components de-
23 scribed in paragraph (3) for the area and year. The Admin-
24 istrator shall compute such benchmark amount for each
25 competitive Medicare Advantage area before the beginning
26 of each annual, coordinated election period under section
27 1851(e)(3)(B) for each year (beginning with 2010) in
28 which it is designated as such an area.

29 “(3) 2 COMPONENTS.—For purposes of paragraph (2),
30 the 2 components described in this paragraph for a com-
31 petitive Medicare Advantage area and a year are the fol-
32 lowing:

33 “(A) MEDICARE ADVANTAGE COMPONENT.—The
34 product of the following:

35 “(i) WEIGHTED AVERAGE OF MEDICARE AD-
36 VANTAGE PLAN BIDS IN AREA.—The weighted aver-



1 age of the plan bids for the area and year (as de-
2 termined under paragraph (4)(A)).

3 “(ii) NON-FFS MARKET SHARE.—1 minus the
4 fee-for-service market share percentage, determined
5 under paragraph (5) for the area and year.

6 “(B) FEE-FOR-SERVICE COMPONENT.—The prod-
7 uct of the following:

8 “(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-
9 DRUG AMOUNT.—The fee-for-service area-specific
10 non-drug amount (as defined in paragraph (6)) for
11 the area and year.

12 “(ii) FEE-FOR-SERVICE MARKET SHARE.—The
13 fee-for-service market share percentage, determined
14 under paragraph (5) for the area and year.

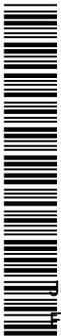
15 “(4) DETERMINATION OF WEIGHTED AVERAGE MEDI-
16 CARE ADVANTAGE BIDS FOR AN AREA.—

17 “(A) IN GENERAL.—For purposes of paragraph
18 (3)(A)(i), the weighted average of plan bids for an area
19 and a year is the sum of the following products for
20 Medicare Advantage plans described in subparagraph
21 (C) in the area and year:

22 “(i) MONTHLY MEDICARE ADVANTAGE STATU-
23 TORY NON-DRUG BID AMOUNT.—The unadjusted
24 Medicare Advantage statutory non-drug monthly
25 bid amount.

26 “(ii) PLAN’S SHARE OF MEDICARE ADVANTAGE
27 ENROLLMENT IN AREA.—The number of individ-
28 uals described in subparagraph (B), divided by the
29 total number of such individuals for all Medicare
30 Advantage plans described in subparagraph (C) for
31 that area and year.

32 “(B) COUNTING OF INDIVIDUALS.—The Adminis-
33 trator shall count, for each Medicare Advantage plan
34 described in subparagraph (C) for an area and year,
35 the number of individuals who reside in the area and



1 who were enrolled under such plan under this part dur-
2 ing March of the previous year.

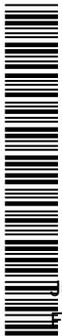
3 “(C) EXCLUSION OF PLANS NOT OFFERED IN PRE-
4 VIOUS YEAR.—For an area and year, the Medicare Ad-
5 vantage plans described in this subparagraph are plans
6 described in the first sentence of section 1851(a)(2)(A)
7 that are offered in the area and year and were offered
8 in the area in March of the previous year.

9 “(5) COMPUTATION OF FEE-FOR-SERVICE MARKET
10 SHARE PERCENTAGE.—The Administrator shall determine,
11 for a year and a competitive Medicare Advantage area, the
12 proportion (in this subsection referred to as the ‘fee-for-
13 service market share percentage’) of Medicare Advantage
14 eligible individuals residing in the area who during March
15 of the previous year were not enrolled in a Medicare Advan-
16 tage plan or in an EFFEFS plan (or, if greater, such propor-
17 tion determined for individuals nationally).

18 “(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG
19 AMOUNT.—

20 “(A) IN GENERAL.—For purposes of paragraph
21 (3)(B)(i) and section 1839(h)(1)(A), subject to sub-
22 paragraph (B), the term ‘fee-for-service area-specific
23 non-drug amount’ means, for a competitive Medicare
24 Advantage area and a year, the adjusted average per
25 capita cost for the year involved, determined under sec-
26 tion 1876(a)(4) for such area for services covered
27 under parts A and B for individuals entitled to benefits
28 under part A and enrolled under this part who are not
29 enrolled in a Medicare Advantage plan under part C or
30 an EFFEFS plan under part E for the year, but adjusted
31 to exclude costs attributable to payments under section
32 1886(h).

33 “(B) INCLUSION OF COSTS OF VA AND DOD MILI-
34 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
35 BENEFICIARIES.—In determining the adjusted average
36 per capita cost under subparagraph (A) for a year,



1 such cost shall be adjusted to include the Administra-
2 tor's estimate, on a per capita basis, of the amount of
3 additional payments that would have been made in the
4 area involved under this title if individuals entitled to
5 benefits under this title had not received services from
6 facilities of the Department of Veterans Affairs or the
7 Department of Defense.

8 “(7) APPLICATION OF COMPETITION.—In the case of
9 an area that is a competitive Medicare Advantage area for
10 a year, for purposes of applying subsection (a)(1)(A)(ii)
11 and sections 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any
12 reference to a Medicare Advantage area-specific non-drug
13 monthly benchmark amount shall be treated as a reference
14 to the competitive Medicare Advantage non-drug monthly
15 benchmark amount under paragraph (2) for the area and
16 year.

17 “(8) PHASE-IN OF BENCHMARK FOR EACH AREA.—

18 “(A) USE OF BLENDED BENCHMARK.—In the case
19 of an area that has not been a competitive Medicare
20 Advantage area for each of the previous 5 years, the
21 competitive Medicare Advantage non-drug monthly
22 benchmark amount shall be equal to the sum of the fol-
23 lowing:

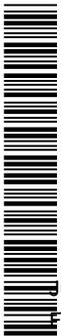
24 “(i) NEW COMPETITIVE COMPONENT.—The
25 product of—

26 “(I) the weighted average phase-in propor-
27 tion for that area and year, as specified in sub-
28 paragraph (B); and

29 “(II) the competitive Medicare Advantage
30 non-drug monthly benchmark amount for the
31 area and year, determined under paragraph (2)
32 without regard to this paragraph.

33 “(ii) OLD COMPETITIVE COMPONENT.—The
34 product of—

35 “(I) 1 minus the weighted average phase-
36 in proportion for that area and year; and



1 “(II) the Medicare Advantage area-wide
2 non-drug benchmark amount for the area and
3 the year.

4 “(B) COMPUTATION OF WEIGHTED AVERAGE
5 PHASE-IN PROPORTION.—For purposes of this para-
6 graph, the ‘weighted average phase-in proportion’ for a
7 Medicare Advantage payment area for a year shall be
8 determined as follows:

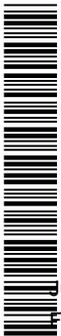
9 “(i) FIRST YEAR (AND AREA NOT COMPETI-
10 TIVE AREA IN PREVIOUS YEAR).—If the area was
11 not a Medicare Advantage competitive area in the
12 previous year, the weighted average phase-in pro-
13 portion for the area for the year is equal to $\frac{1}{5}$.

14 “(ii) COMPETITIVE AREA IN PREVIOUS
15 YEAR.—If the area was a competitive Medicare Ad-
16 vantage area in the previous year, the weighted av-
17 erage phase-in proportion for the area for the year
18 is equal to the weighted average phase-in propor-
19 tion determined under this subparagraph for the
20 area for the previous year plus $\frac{1}{5}$, but in no case
21 more than 1.

22 “(C) MEDICARE ADVANTAGE AREA-WIDE NON-
23 DRUG BENCHMARK AMOUNT.—For purposes of sub-
24 paragraph (A)(ii)(II), the term ‘Medicare Advantage
25 area-wide non-drug benchmark amount’ means, for an
26 area and year, the weighted average of the amounts de-
27 scribed in section 1853(j) for Medicare Advantage pay-
28 ment area or areas included in the area (based on the
29 number of traditional fee-for-service enrollees in such
30 payment area or areas) and year.”.

31 (2) APPLICATION.—Section 1854 (42 U.S.C. 1395w-
32 24) is amended—

33 (A) in subsection (b)(1)(C)(i), as added by section
34 221(b)(1)(A), by striking “(i) REQUIREMENT.—The”
35 and inserting “(i) REQUIREMENT FOR NON-COMPETI-
36 TIVE AREAS.—In the case of a Medicare Advantage



1 payment area that is not a competitive Medicare Ad-
2 vantage area designated under section 1853(k)(1),
3 the”;

4 (B) in subsection (b)(1)(C), as so added, by insert-
5 ing after clause (i) the following new clause:

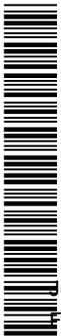
6 “(ii) REQUIREMENT FOR COMPETITIVE MEDI-
7 CARE ADVANTAGE AREAS.—In the case of a Medi-
8 care Advantage payment area that is designated as
9 a competitive Medicare Advantage area under sec-
10 tion 1853(k)(1), if there are average per capita
11 monthly savings described in paragraph (6) for a
12 Medicare Advantage plan and year, the Medicare
13 Advantage plan shall provide to the enrollee a
14 monthly rebate equal to 75 percent of such sav-
15 ings.”; and

16 (C) by adding at the end of subsection (b), as
17 amended by sections 221(b)(1)(B) and 221(b)(2), the
18 following new paragraph:

19 “(6) COMPUTATION OF AVERAGE PER CAPITA MONTH-
20 LY SAVINGS FOR COMPETITIVE MEDICARE ADVANTAGE
21 AREAS.—For purposes of paragraph (1)(C)(ii), the average
22 per capita monthly savings referred to in such paragraph
23 for a Medicare Advantage plan and year shall be computed
24 in the same manner as the average per capita monthly sav-
25 ings is computed under paragraph (3) except that the ref-
26 erence to the Medicare Advantage area-specific non-drug
27 monthly benchmark amount in paragraph (3)(B)(i) (or to
28 the benchmark amount as adjusted under paragraph
29 (3)(C)(i)) is deemed to be a reference to the competitive
30 Medicare Advantage non-drug monthly benchmark amount
31 (or such amount as adjusted in the manner described in
32 paragraph (3)(B)(i)).”.

33 (3) ADDITIONAL CONFORMING AMENDMENTS.—

34 (A) PAYMENT OF PLANS.—Section
35 1853(a)(1)(A)(ii), as amended by section 221(e)(1), is
36 amended—



1 (i) in subclauses (I) and (II), by inserting
2 “(or, insofar as such payment area is a competitive
3 Medicare Advantage area, described in section
4 1854(b)(6))” after “section 1854(b)(3)(C)”; and

5 (ii) in subclause (II), by inserting “(or, insofar
6 as such payment area is a competitive Medicare
7 Advantage area, the competitive Medicare Advan-
8 tage non-drug monthly benchmark amount)” after
9 “Medicare Advantage area-specific non-drug
10 monthly benchmark amount”; and

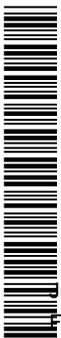
11 (B) DISCLOSURE OF INFORMATION.—Section
12 1853(b)(1)(B), as amended by section 221(e)(1), is
13 amended to read as follows:

14 “(B) COMPETITION INFORMATION.—For years be-
15 ginning with 2006, the following:

16 “(i) BENCHMARKS.—The Medicare Advantage
17 area-specific non-drug benchmark under section
18 1853(j) and, if applicable, the competitive Medicare
19 Advantage non-drug benchmark under section
20 1853(k)(2), for the year and competitive Medicare
21 Advantage area involved and the national fee-for-
22 service market share percentage for the area and
23 year.

24 “(ii) ADJUSTMENT FACTORS.—The adjust-
25 ment factors applied under section
26 1853(a)(1)(A)(iv) (relating to demographic adjust-
27 ment), section 1853(a)(1)(B) (relating to adjust-
28 ment for end-stage renal disease), and section
29 1853(a)(3) (relating to health status adjustment).

30 “(iii) CERTAIN BENCHMARKS AND
31 AMOUNTS.—In the case of a competitive Medicare
32 Advantage area, the Medicare Advantage area-wide
33 non-drug benchmark amount (as defined in sub-
34 section (k)(8)(C)) and the fee-for-service area-spe-
35 cific non-drug amount (as defined in section
36 1853(k)(6)) for the area.



1 “(iv) INDIVIDUALS.—The number of individ-
2 uals counted under subsection (k)(4)(B) and en-
3 rolled in each Medicare Advantage plan in the
4 area.”.

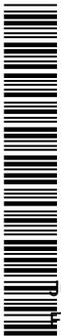
5 (C) DEFINITION OF MONTHLY BASIC PREMIUM.—
6 Section 1854(b)(2)(A)(ii), as amended by section
7 221(d)(2), is amended by inserting “(or, in the case of
8 a competitive Medicare Advantage area, the competitive
9 Medicare Advantage non-drug monthly benchmark
10 amount or, in applying this paragraph under part E in
11 the case of a competitive EFFS region, the competitive
12 EFFS non-drug monthly benchmark amount)” after
13 “benchmark amount”.

14 (c) PREMIUM ADJUSTMENT.—

15 (1) IN GENERAL.—Section 1839 (42 U.S.C. 1395r) is
16 amended by adding at the end the following new sub-
17 section:

18 “(h)(1)(A) In the case of an individual who resides in a
19 competitive Medicare Advantage area under section 1853(k)(1)
20 (regardless of whether such area is in a competitive EFFS re-
21 gion under section 1860E-3(e)) and who is not enrolled in a
22 Medicare Advantage plan under part C or in an EFFS plan
23 under part E, the monthly premium otherwise applied under
24 this part (determined without regard to subsections (b) and (f)
25 or any adjustment under this subsection) shall be adjusted as
26 follows: If the fee-for-service area-specific non-drug amount (as
27 defined in section 1853(k)(6)) for the competitive Medicare Ad-
28 vantage area in which the individual resides for a month—

29 “(i) does not exceed the competitive Medicare Advan-
30 tage non-drug benchmark (as determined under section
31 1853(k)(2)) for such area, the amount of the premium for
32 the individual for the month shall be reduced by an amount
33 equal to the product of the adjustment factor under sub-
34 paragraph (C) and 75 percent of the amount by which such
35 competitive benchmark exceeds such fee-for-service area-
36 specific non-drug amount; or



1 “(ii) exceeds such competitive Medicare Advantage
2 non-drug benchmark, the amount of the premium for the
3 individual for the month shall be adjusted to ensure, sub-
4 ject to subparagraph (B), that—

5 “(I) the sum of the amount of the adjusted pre-
6 mium and the competitive Medicare Advantage non-
7 drug benchmark for the area, is equal to

8 “(II) the sum of the unadjusted premium plus
9 amount of the fee-for-service area-specific non-drug
10 amount for the area.

11 “(B) In no case shall the actual amount of an adjustment
12 under subparagraph (A)(ii) exceed the product of the adjust-
13 ment factor under subparagraph (C) and the amount of the ad-
14 justment otherwise computed under subparagraph (A)(ii) with-
15 out regard to this subparagraph.

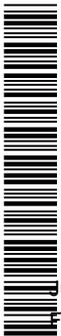
16 “(C) The adjustment factor under this subparagraph for
17 an area for a year is equal to—

18 “(i) the number of consecutive years (in the 5-year pe-
19 riod ending with the year involved) in which such area was
20 a competitive Medicare Advantage area; divided by

21 “(ii) 5.

22 “(2)(A) In the case of an individual who resides in an area
23 that is within a competitive EFFF region under section
24 1860E-3(e) but is not within a competitive Medicare Advan-
25 tage area under section 1853(k)(1) and who is not enrolled in
26 a Medicare Advantage plan under part C or in an EFFF plan
27 under part E, the monthly premium otherwise applied under
28 this part (determined without regard to subsections (b) and (f)
29 or any adjustment under this subsection) shall be adjusted as
30 follows: If the fee-for-service region-specific non-drug amount
31 (as defined in section 1860E-3(e)(6)) for a region for a
32 month—

33 “(i) does not exceed the competitive EFFF non-drug
34 monthly benchmark amount (as determined under section
35 1860E-3(e)(2)) for such region, the amount of the pre-
36 mium for the individual for the month shall be reduced by



1 an amount equal to the product of the adjustment factor
2 under subparagraph (C) and 75 percent of the amount by
3 which such competitive benchmark amount exceeds such
4 fee-for-service region-specific non-drug benchmark amount;
5 or

6 “(ii) exceeds such competitive EFFS non-drug month-
7 ly benchmark amount, the amount of the premium for the
8 individual for the month shall be adjusted to ensure, sub-
9 ject to subparagraph (B), that—

10 “(I) the sum of the amount of the adjusted pre-
11 mium and the competitive EFFS non-drug monthly
12 benchmark amount for the region, is equal to

13 “(II) the sum of the unadjusted premium plus the
14 amount of the EFFS region-specific non-drug monthly
15 bid for the region.

16 “(B) In no case shall the actual amount of an adjustment
17 under subparagraph (A)(ii) exceed the product of the adjust-
18 ment factor under subparagraph (C) and the amount of the ad-
19 justment otherwise computed under subparagraph (A)(ii) with-
20 out regard to this subparagraph.

21 “(C) The adjustment factor under this subparagraph for
22 an EFFS region for a year is equal to—

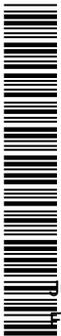
23 “(i) the number of consecutive years (in the 5-year pe-
24 riod ending with the year involved) in which such region
25 was a competitive EFFS region; divided by

26 “(ii) 5.

27 “(3) Nothing in this subsection shall be construed as pre-
28 venting a reduction under paragraph (1)(A) or paragraph
29 (2)(A) in the premium otherwise applicable under this part to
30 zero or from requiring the provision of a rebate to the extent
31 such premium would otherwise be required to be less than zero.

32 “(4) The adjustment in the premium under this subsection
33 shall be effected in such manner as the Medicare Benefits Ad-
34 ministrators determine appropriate.

35 “(5) In order to carry out this subsection (insofar as it is
36 effected through the manner of collection of premiums under



1 1840(a)), the Medicare Benefits Administrator shall transmit
2 to the Commissioner of Social Security—

3 “(A) at the beginning of each year, the name, social
4 security account number, and the amount of the adjust-
5 ment (if any) under this subsection for each individual en-
6 rolled under this part for each month during the year; and

7 “(B) periodically throughout the year, information to
8 update the information previously transmitted under this
9 paragraph for the year.”

10 (2) CONFORMING AMENDMENT.—Section 1844(c) (42
11 U.S.C. 1395w(c)) is amended by inserting “and without re-
12 gard to any premium adjustment effected under section
13 1839(h)” before the period at the end.

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

16 **TITLE III—COMBATTING WASTE,**
17 **FRAUD, AND ABUSE**

18 **SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVI-**
19 **SIONS.**

20 (a) TECHNICAL AMENDMENT CONCERNING SECRETARY’S
21 AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CER-
22 TAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

23 (1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C.
24 1395y(b)(2)) is amended—

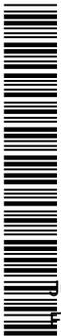
25 (A) in subparagraph (A)(ii), by striking “promptly
26 (as determined in accordance with regulations)”;

27 (B) in subparagraph (B)—

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

30 (ii) by inserting before clause (ii), as so redesi-
31 gnated, the following new clause:

32 “(i) AUTHORITY TO MAKE CONDITIONAL PAY-
33 MENT.—The Secretary may make payment under
34 this title with respect to an item or service if a pri-
35 mary plan described in subparagraph (A)(ii) has
36 not made or cannot reasonably be expected to make



1 payment with respect to such item or service
2 promptly (as determined in accordance with regula-
3 tions). Any such payment by the Secretary shall be
4 conditioned on reimbursement to the appropriate
5 Trust Fund in accordance with the succeeding pro-
6 visions of this subsection.”.

7 (2) EFFECTIVE DATE.—The amendments made by
8 paragraph (1) shall be effective as if included in the enact-
9 ment of title III of the Medicare and Medicaid Budget Rec-
10 onciliation Amendments of 1984 (Public Law 98-369).

11 (b) CLARIFYING AMENDMENTS TO CONDITIONAL PAY-
12 MENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.
13 1395y(b)(2)) is further amended—

14 (1) in subparagraph (A), in the matter following
15 clause (ii), by inserting the following sentence at the end:
16 “An entity that engages in a business, trade, or profession
17 shall be deemed to have a self-insured plan if it carries its
18 own risk (whether by a failure to obtain insurance, or oth-
19 erwise) in whole or in part.”;

20 (2) in subparagraph (B)(ii), as redesignated by sub-
21 section (a)(2)(B)—

22 (A) by striking the first sentence and inserting the
23 following: “A primary plan, and an entity that receives
24 payment from a primary plan, shall reimburse the ap-
25 propriate Trust Fund for any payment made by the
26 Secretary under this title with respect to an item or
27 service if it is demonstrated that such primary plan has
28 or had a responsibility to make payment with respect
29 to such item or service. A primary plan’s responsibility
30 for such payment may be demonstrated by a judgment,
31 a payment conditioned upon the recipient’s com-
32 promise, waiver, or release (whether or not there is a
33 determination or admission of liability) of payment for
34 items or services included in a claim against the pri-
35 mary plan or the primary plan’s insured, or by other
36 means.”; and



1 (B) in the final sentence, by striking “on the date
2 such notice or other information is received” and in-
3 serting “on the date notice of, or information related
4 to, a primary plan’s responsibility for such payment or
5 other information is received”; and

6 (3) in subparagraph (B)(iii), , as redesignated by sub-
7 section (a)(2)(B), by striking the first sentence and insert-
8 ing the following: “In order to recover payment made under
9 this title for an item or service, the United States may
10 bring an action against any or all entities that are or were
11 required or responsible (directly, as an insurer or self-in-
12 surer, as a third-party administrator, as an employer that
13 sponsors or contributes to a group health plan, or large
14 group health plan, or otherwise) to make payment with re-
15 spect to the same item or service (or any portion thereof)
16 under a primary plan. The United States may, in accord-
17 ance with paragraph (3)(A) collect double damages against
18 any such entity. In addition, the United States may recover
19 under this clause from any entity that has received pay-
20 ment from a primary plan or from the proceeds of a pri-
21 mary plan’s payment to any entity.”.

22 (c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C.
23 1395y(b)) is amended—

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

26 (2) in paragraph (3)(A), by striking “such” before
27 “paragraphs”.

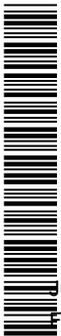
28 **SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN**
29 **ITEMS AND SERVICES.**

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

32 “COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

33 “SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE AC-
34 QUISSION PROGRAMS.—

35 “(1) IMPLEMENTATION OF PROGRAMS.—



1 “(A) IN GENERAL.—The Secretary shall establish
2 and implement programs under which competitive ac-
3 quisition areas are established throughout the United
4 States for contract award purposes for the furnishing
5 under this part of competitively priced items and serv-
6 ices (described in paragraph (2)) for which payment is
7 made under this part. Such areas may differ for dif-
8 ferent items and services.

9 “(B) PHASED-IN IMPLEMENTATION.—The pro-
10 grams shall be phased-in—

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

15 “(I) at least $\frac{1}{3}$ of such areas in 2005; and

16 “(II) at least $\frac{2}{3}$ of such areas in 2006;

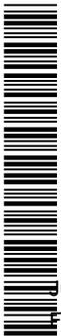
17 and

18 “(ii) among items and services in a manner
19 such that the programs apply to the highest cost
20 and highest volume items and services first.

21 “(C) WAIVER OF CERTAIN PROVISIONS.—In car-
22 rying out the programs, the Secretary may waive such
23 provisions of the Federal Acquisition Regulation as are
24 necessary for the efficient implementation of this sec-
25 tion, other than provisions relating to confidentiality of
26 information and such other provisions as the Secretary
27 determines appropriate.

28 “(2) ITEMS AND SERVICES DESCRIBED.—The items
29 and services referred to in paragraph (1) are the following:

30 “(A) DURABLE MEDICAL EQUIPMENT AND MED-
31 ICAL SUPPLIES.—Covered items (as defined in section
32 1834(a)(13)) for which payment is otherwise made
33 under section 1834(a), including items used in infusion
34 and drugs and supplies used in conjunction with dura-
35 ble medical equipment, but excluding class III devices
36 under the Federal Food, Drug, and Cosmetic Act.



1 “(B) OFF-THE-SHELF ORTHOTICS.—Orthotics (de-
2 scribed in section 1861(s)(9)) for which payment is
3 otherwise made under section 1834(h) which require
4 minimal self-adjustment for appropriate use and does
5 not require expertise in trimming, bending, molding,
6 assembling, or customizing to fit to the patient.

7 “(3) EXCEPTION AUTHORITY.—In carrying out the
8 programs under this section, the Secretary may exempt—

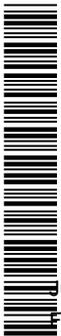
9 “(A) rural areas and areas with low population
10 density within urban areas that are not competitive,
11 unless there is a significant national market through
12 mail order for a particular item or service; and

13 “(B) items and services for which the application
14 of competitive acquisition is not likely to result in sig-
15 nificant savings.

16 “(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF
17 DURABLE MEDICAL EQUIPMENT.—In the case of a covered
18 item for which payment is made on a rental basis under
19 section 1834(a), the Secretary shall establish a process by
20 which rental agreements for the covered items entered into
21 before the application of the competitive acquisition pro-
22 gram under this section for the item may be continued not-
23 withstanding this section. In the case of any such continu-
24 ation, the supplier involved shall provide for appropriate
25 servicing and replacement, as required under section
26 1834(a).

27 “(5) PHYSICIAN AUTHORIZATION.—The Secretary may
28 establish a process under which a physician may prescribe
29 a particular brand or mode of delivery of an item or service
30 if the item or service involved is clinically more appropriate
31 than other similar items or services.

32 “(6) APPLICATION.—For each competitive acquisition
33 area in which the program is implemented under this sub-
34 section with respect to items and services, the payment
35 basis determined under the competition conducted under



1 subsection (b) shall be substituted for the payment basis
2 otherwise applied under section 1834(a).

3 “(b) PROGRAM REQUIREMENTS.—

4 “(1) IN GENERAL.—The Secretary shall conduct a
5 competition among entities supplying items and services de-
6 scribed in subsection (a)(2) for each competitive acquisition
7 area in which the program is implemented under subsection
8 (a) with respect to such items and services.

9 “(2) CONDITIONS FOR AWARDING CONTRACT.—

10 “(A) IN GENERAL.—The Secretary may not award
11 a contract to any entity under the competition con-
12 ducted in an competitive acquisition area pursuant to
13 paragraph (1) to furnish such items or services unless
14 the Secretary finds all of the following:

15 “(i) The entity meets quality and financial
16 standards specified by the Secretary or developed
17 by the Program Advisory and Oversight Committee
18 established under subsection (c).

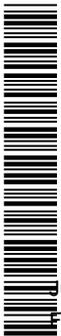
19 “(ii) The total amounts to be paid under the
20 contract (including costs associated with the ad-
21 ministration of the contract) are expected to be less
22 than the total amounts that would otherwise be
23 paid.

24 “(iii) Beneficiary access to a choice of multiple
25 suppliers in the area is maintained.

26 “(iv) Beneficiary liability is limited to 20 per-
27 cent of the applicable contract award price, except
28 in such cases where a supplier has furnished an up-
29 graded item and has executed an advanced bene-
30 ficiary notice.

31 “(B) DEVELOPMENT OF QUALITY STANDARDS FOR
32 DME PRODUCTS.—

33 “(i) IN GENERAL.—The quality standards
34 specified under subparagraph (A)(i) shall not be
35 less than the quality standards that would other-
36 wise apply if this section did not apply and shall



1 include consumer services standards. Not later than
2 July 1, 2004, the Secretary shall establish new
3 quality standards for products subject to competi-
4 tive acquisition under this section. Such standards
5 shall be applied prospectively and shall be published
6 on the website of the Department of Health and
7 Human Services.

8 “(ii) CONSULTATION WITH PROGRAM ADVI-
9 SORY AND OVERSIGHT COMMITTEE.—The Secretary
10 shall consult with the Program Advisory and Over-
11 sight Committee (established under subsection (c))
12 to review (and advise the Secretary concerning) the
13 quality standards referred to in clause (i).

14 “(3) CONTENTS OF CONTRACT.—

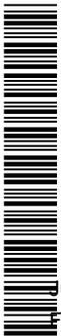
15 “(A) IN GENERAL.—A contract entered into with
16 an entity under the competition conducted pursuant to
17 paragraph (1) is subject to terms and conditions that
18 the Secretary may specify.

19 “(B) TERM OF CONTRACTS.—The Secretary shall
20 recompetete contracts under this section not less often
21 than once every 3 years.

22 “(4) LIMIT ON NUMBER OF CONTRACTORS.—

23 “(A) IN GENERAL.—The Secretary may limit the
24 number of contractors in a competitive acquisition area
25 to the number needed to meet projected demand for
26 items and services covered under the contracts. In
27 awarding contracts, the Secretary shall take into ac-
28 count the ability of bidding entities to furnish items or
29 services in sufficient quantities to meet the anticipated
30 needs of beneficiaries for such items or services in the
31 geographic area covered under the contract on a timely
32 basis.

33 “(B) MULTIPLE WINNERS.—The Secretary shall
34 award contracts to multiple entities submitting bids in
35 each area for an item or service.



1 “(5) PAYMENT.—Payment under this part for com-
2 petitively priced items and services described in subsection
3 (a)(2) shall be based on the bids submitted and accepted
4 under this section for such items and services.

5 “(6) PARTICIPATING CONTRACTORS.—Payment shall
6 not be made for items and services described in subsection
7 (a)(2) furnished by a contractor and for which competition
8 is conducted under this section unless—

9 “(A) the contractor has submitted a bid for such
10 items and services under this section; and

11 “(B) the Secretary has awarded a contract to the
12 contractor for such items and services under this sec-
13 tion.

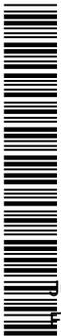
14 In this section, the term ‘bid’ means a request for a pro-
15 posal for an item or service that includes the cost of the
16 item or service, and where appropriate, any services that
17 are attendant to the provision of the item or service.

18 “(7) CONSIDERATION IN DETERMINING CATEGORIES
19 FOR BIDS.—The Secretary shall consider the similarity of
20 the clinical efficiency and value of specific codes and prod-
21 ucts, including products that may provide a therapeutic ad-
22 vantage to beneficiaries, before delineating the categories
23 and products that will be subject to bidding.

24 “(8) AUTHORITY TO CONTRACT FOR EDUCATION, MON-
25 ITORING, OUTREACH AND COMPLAINT SERVICES.—The Sec-
26 retary may enter into a contract with an appropriate entity
27 to address complaints from beneficiaries who receive items
28 and services from an entity with a contract under this sec-
29 tion and to conduct appropriate education of and outreach
30 to such beneficiaries and monitoring quality of services with
31 respect to the program.

32 “(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

33 “(1) ESTABLISHMENT.—There is established a Pro-
34 gram Advisory and Oversight Committee (hereinafter in
35 this section referred to as the ‘Committee’).



1 “(2) MEMBERSHIP; TERMS.—The Committee shall
2 consist of such members as the Secretary may appoint who
3 shall serve for such term as the Secretary may specify.

4 “(3) DUTIES.—

5 “(A) TECHNICAL ASSISTANCE.—The Committee
6 shall provide advice and technical assistance to the Sec-
7 retary with respect to the following functions:

8 “(i) The implementation of the program under
9 this section.

10 “(ii) The establishment of requirements for
11 collection of data.

12 “(iii) The development of proposals for effi-
13 cient interaction among manufacturers and dis-
14 tributors of the items and services and providers
15 and beneficiaries.

16 “(B) ADDITIONAL DUTIES.—The Committee shall
17 perform such additional functions to assist the Sec-
18 retary in carrying out this section as the Secretary may
19 specify.

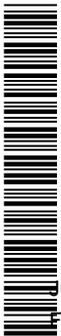
20 “(4) INAPPLICABILITY OF FACA.—The provisions of
21 the Federal Advisory Committee Act (5 U.S.C. App.) shall
22 not apply.

23 “(d) ANNUAL REPORTS.—The Secretary shall submit to
24 Congress an annual management report on the programs under
25 this section. Each such report shall include information on sav-
26 ings, reductions in beneficiary cost-sharing, access to and qual-
27 ity of items and services, and beneficiary satisfaction.

28 “(e) DEMONSTRATION PROJECT FOR CLINICAL LABORA-
29 TORY SERVICES.—

30 “(1) IN GENERAL.—The Secretary shall conduct a
31 demonstration project on the application of competitive ac-
32 quisition under this section to clinical diagnostic laboratory
33 tests—

34 “(A) for which payment is otherwise made under
35 section 1833(h) or 1834(d)(1) (relating to colorectal
36 cancer screening tests); and



1 “(B) which are furnished by entities that did not
2 have a face-to-face encounter with the individual.

3 “(2) TERMS AND CONDITIONS.—Such project shall be
4 under the same conditions as are applicable to items and
5 services described in subsection (a)(2).

6 “(3) REPORT.—The Secretary shall submit to
7 Congress—

8 “(A) an initial report on the project not later than
9 December 31, 2005; and

10 “(B) such progress and final reports on the
11 project after such date as the Secretary determines ap-
12 propriate.”.

13 (b) CONFORMING AMENDMENTS.—

14 (1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF
15 INHERENT REASONABLENESS AUTHORITY.—Section
16 1834(a) (42 U.S.C. 1395m(a)) is amended—

17 (A) in paragraph (1)(B), by striking “The pay-
18 ment basis” and inserting “Subject to subparagraph
19 (E)(i), the payment basis”;

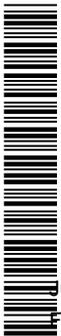
20 (B) in paragraph (1)(C), by striking “This sub-
21 section” and inserting “Subject to subparagraph
22 (E)(ii), this subsection”;

23 (C) by adding at the end of paragraph (1) the fol-
24 lowing new subparagraph:

25 “(E) APPLICATION OF COMPETITIVE ACQUISITION;
26 ELIMINATION OF INHERENT REASONABLENESS AU-
27 THORITY.—In the case of covered items and services
28 that are included in a competitive acquisition program
29 in a competitive acquisition area under section
30 1847(a)—

31 “(i) the payment basis under this subsection
32 for such items and services furnished in such area
33 shall be the payment basis determined under such
34 competitive acquisition program; and

35 “(ii) the Secretary may use information on the
36 payment determined under such competitive acqui-



1 sition programs to adjust the payment amount oth-
2 erwise recognized under subparagraph (B)(ii) for
3 an area that is not a competitive acquisition area
4 under section 1847 and in the case of such adjust-
5 ment, paragraph (10)(B) shall not be applied.”;
6 and

7 (D) in paragraph (10)(B), by inserting “in an
8 area and with respect to covered items and services for
9 which the Secretary does not make a payment amount
10 adjustment under paragraph (1)(E)” after “under this
11 subsection”.

12 (2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF IN-
13 HERENT REASONABLENESS AUTHORITY.—Section 1834(h)
14 (42 U.S.C. 1395m(h)) is amended—

15 (A) in paragraph (1)(B), by striking “and (E)”
16 and inserting “, (E) , and (H)(i)”;

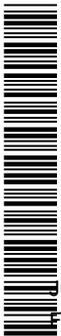
17 (B) in paragraph (1)(D), by striking “This sub-
18 section” and inserting “Subject to subparagraph
19 (H)(ii), this subsection”;

20 (C) by adding at the end of paragraph (1) the fol-
21 lowing new subparagraph:

22 “(H) APPLICATION OF COMPETITIVE ACQUISITION
23 TO ORTHOTICS; ELIMINATION OF INHERENT REASON-
24 ABLENESS AUTHORITY.—In the case of orthotics de-
25 scribed in paragraph (2)(B) of section 1847(a) that are
26 included in a competitive acquisition program in a com-
27 petitive acquisition area under such section—

28 “(i) the payment basis under this subsection
29 for such orthotics furnished in such area shall be
30 the payment basis determined under such competi-
31 tive acquisition program; and

32 “(ii) the Secretary may use information on the
33 payment determined under such competitive acqui-
34 sition programs to adjust the payment amount oth-
35 erwise recognized under subparagraph (B)(ii) for
36 an area that is not a competitive acquisition area



1 under section 1847, and in the case of such adjust-
2 ment, paragraphs (8) and (9) of section 1842(b)
3 shall not be applied.”.

4 (c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Sec-
5 retary shall conduct a study to determine the extent to which
6 (if any) suppliers of covered items of durable medical equip-
7 ment that are subject to the competitive acquisition program
8 under section 1847 of the Social Security Act, as amended by
9 subsection (a), are soliciting physicians to prescribe certain
10 brands or modes of delivery of covered items based on profit-
11 ability.

12 (d) GAO STUDY ON SAFE AND EFFECTIVE HOME INFU-
13 SION AND INHALATION THERAPY; STANDARDS.—

14 (1) STUDY.—The Comptroller General of the United
15 States shall conduct a study of the standards, professional
16 services, and related functions necessary for the provision
17 of safe and effective home infusion therapy and home inha-
18 lation therapy.

19 (2) REPORT.—Not later than May 1, 2004, the Comp-
20 troller General shall submit to Congress a report on the
21 study conducted under paragraph (1).

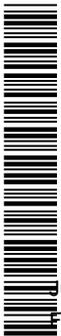
22 (3) USE OF FINDINGS IN DEVELOPING STANDARDS.—
23 In promulgating regulations to carry out section 1847 of
24 the Social Security Act, as amended by subsection (a), the
25 Secretary shall ensure that quality standards developed
26 under subsection (b)(2)(B) of such section reflect the find-
27 ings of the Comptroller General set forth in the report
28 under paragraph (2).

29 **SEC. 303. COMPETITIVE ACQUISITION OF COVERED**
30 **OUTPATIENT DRUGS AND BIOLOGICALS.**

31 (a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

32 (1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE
33 VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w-
34 4(c)(2)) is amended—

35 (A) in subparagraph (B)—



1 (i) in clause (ii)(II), by striking “The adjust-
2 ments” and inserting “Subject to clause (iv), the
3 adjustments”; and

4 (ii) by adding at the end of subparagraph (B),
5 the following new clause:

6 “(iv) EXCEPTION TO BUDGET NEUTRALITY.—
7 The additional expenditures attributable to clause
8 (ii) of subparagraph (H) shall not be taken into ac-
9 count in applying clause (ii)(II) for 2005.”; and

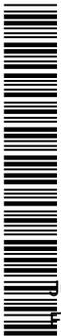
10 (B) by adding at the end the following new sub-
11 paragraph:

12 “(H) ADJUSTMENTS IN PRACTICE EXPENSE REL-
13 ATIVE VALUE UNITS FOR 2005.—

14 “(i) IN GENERAL.—As part of the annual
15 process of establishing the physician fee schedule
16 under subsection (b) for 2005, the Secretary shall
17 increase the practice expense relative value units
18 for 2005 consistent with clause (ii).

19 “(ii) USE OF SUPPLEMENTAL SURVEY DATA.—
20 For 2005 for any specialty that submitted survey
21 data that included expenses for the administration
22 of drugs and biologicals for which payment is made
23 under section 1842(o) (or section 1847A), the Sec-
24 retary shall use such supplemental survey data in
25 carrying out this subparagraph insofar as they are
26 collected and provided by entities and organizations
27 consistent with the criteria established by the Sec-
28 retary pursuant to section 212(a) of the Medicare,
29 Medicaid, and SCHIP Balanced Budget Refine-
30 ment Act of 1999 and insofar as such data are
31 submitted to the Secretary by December 31, 2004.

32 “(iii) SUBSEQUENT, BUDGET NEUTRAL AD-
33 JUSTMENTS PERMITTED.—Nothing in this subpara-
34 graph shall be construed as preventing the Sec-
35 retary from providing for adjustments in practice



1 expense relative value units under (and consistent
2 with) subparagraph (B) for years after 2005.

3 “(iv) CONSULTATION.—Before publishing the
4 notice of proposed rulemaking to carry out this
5 subparagraph, the Secretary shall consult with the
6 Comptroller General of the United States and with
7 groups representing the physician specialties in-
8 volved.

9 “(v) TREATMENT AS CHANGE IN LAW AND
10 REGULATION IN SUSTAINABLE GROWTH RATE DE-
11 TERMINATION.—The enactment of subparagraph
12 (B)(iv) and this subparagraph shall be treated as
13 a change in law for purposes of applying subsection
14 (f)(2)(D).”.

15 (2) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL
16 REVIEW.—Section 1848(i)(1) (42 U.S.C. 1395w-4(i)(1)) is
17 amended—

18 (A) by striking “and” at the end of subparagraph (D);

19 (B) by striking the period at the end of subparagraph
20 (E) and inserting “, and”; and

21 (C) by adding at the end the following new subpara-
22 graph:

23 “(F) adjustments in practice expense relative
24 value units for 2005 under subsection (c)(2)(H).”.

25 (3) TREATMENT OF OTHER SERVICES CURRENTLY IN
26 THE NON-PHYSICIAN WORK POOL.—The Secretary shall
27 make adjustments to the non-physician work pool method-
28 ology (as such term is used in the regulations promulgated
29 by the Secretary in the Federal Register as of December
30 31, 2002) for determination of practice expense relative
31 value units under the physician fee schedule described in
32 section 1848(c)(2)(C)(ii) of the Social Security Act so that
33 the practice expense relative value units for services deter-
34 mined under such methodology are not disproportionately
35 reduced relative to the practice expense relative value units
36 of other services not determined under such non-physician



1 work pool methodology, as the result of amendments made
2 by paragraph (1).

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

6 “COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS
7 AND BIOLOGICALS

8 “SEC. 1847A. (a) IMPLEMENTATION OF COMPETITIVE AC-
9 QUISTION.—

10 “(1) IMPLEMENTATION OF PROGRAM.—

11 “(A) IN GENERAL.—The Secretary shall establish
12 and implement a competitive acquisition program under
13 which—

14 “(i) competitive acquisition areas are estab-
15 lished throughout the United States for contract
16 award purposes for acquisition of and payment for
17 categories of covered outpatient drugs and
18 biologicals (as defined in paragraph (2)) under this
19 part;

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

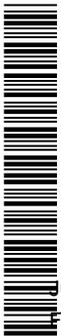
23 “(iii) each physician who elects to obtain drugs
24 and biologicals under the program makes an an-
25 nual selection under paragraph (5) of the con-
26 tractor through which drugs and biologicals within
27 a category of drugs and biologicals will be acquired
28 and delivered to the physician under this part.

29 “(B) IMPLEMENTATION.—The Secretary shall im-
30 plement the program so that the program applies to—

31 “(i) the oncology category beginning in 2005;
32 and

33 “(ii) the non-oncology category beginning in
34 2006.

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



1 “(C) EXCLUSION AUTHORITY.—The Secretary
2 may exclude covered outpatient drugs and biologicals
3 (including a class of such drugs and biologicals) from
4 the competitive bidding system under this section if the
5 drugs or biologicals (or class) are not appropriate for
6 competitive bidding due to low volume of utilization by
7 beneficiaries under this part or a unique mode or meth-
8 od of delivery.

9 “(2) COVERED OUTPATIENT DRUGS AND BIOLOGICALS,
10 CATEGORIES, PROGRAM DEFINED.—For purposes of this
11 section—

12 “(A) COVERED OUTPATIENT DRUGS AND
13 BIOLOGICALS DEFINED.—The term ‘covered outpatient
14 drugs and biologicals’ means drugs and biologicals to
15 which section 1842(o) applies and which are not cov-
16 ered under section 1847 (relating to competitive acqui-
17 sition for items of durable medical equipment). Such
18 term does not include the following:

19 “(i) Blood clotting factors.

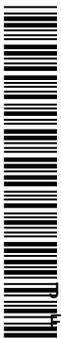
20 “(ii) Drugs and biologicals furnished to indi-
21 viduals in connection with the treatment of end
22 stage renal disease.

23 “(iii) Radiopharmaceuticals.

24 “(B) 2 CATEGORIES.—Each of the following shall
25 be a separate category of covered outpatient drugs and
26 biologicals, as identified by the Secretary:

27 “(i) ONCOLOGY CATEGORY.—A category (in
28 this section referred to as the ‘oncology category’)
29 consisting of those covered outpatient drugs and
30 biologicals that, as determined by the Secretary,
31 are typically primarily billed by oncologists or are
32 otherwise used to treat cancer.

33 “(ii) NON-ONCOLOGY CATEGORIES.—Such
34 numbers of categories (in this section referred to as
35 the ‘non-oncology categories’) consisting of covered
36 outpatient drugs and biologicals not described in



1 clause (i), and appropriate subcategories of such
2 drugs and biologicals as the Secretary may specify.

3 “(C) PROGRAM.—The term ‘program’ means the
4 competitive acquisition program under this section.

5 “(D) COMPETITIVE ACQUISITION AREA; AREA.—
6 The terms ‘competitive acquisition area’ and ‘area’
7 mean an appropriate geographic region established by
8 the Secretary under the program.

9 “(E) CONTRACTOR.—The term ‘contractor’ means
10 an entity that has entered into a contract with the Sec-
11 retary under this section.

12 “(3) APPLICATION OF PROGRAM PAYMENT METHOD-
13 OLOGY.—With respect to covered outpatient drugs and
14 biologicals which are supplied under the program in an
15 area and which are prescribed by a physician who has not
16 elected section 1847B to apply—

17 “(A) the claim for such drugs and biologicals shall
18 be submitted by the contractor that supplied the drugs
19 and biologicals;

20 “(B) collection of amounts of any deductible and
21 coinsurance applicable with respect to such drugs and
22 biologicals shall be the responsibility of such contractor
23 and shall not be collected unless the drug or biological
24 is administered to the beneficiary involved; and

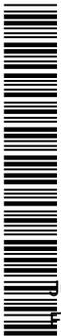
25 “(C) the payment under this section (and related
26 coinsurance amounts) for such drugs and biologicals—

27 “(i) shall be made only to such contractor;

28 “(ii) shall be conditioned upon the administra-
29 tion of such drugs and biologicals; and

30 “(iii) shall be based on the average of the bid
31 prices for such drugs and biologicals in the area, as
32 computed under subsection (d).

33 The Secretary shall provide a process for recoupment
34 in the case in which payment is made for drugs and
35 biologicals which were billed at the time of dispensing
36 but which were not actually administered.



1 “(4) CONTRACT REQUIRED.—

2 “(A) IN GENERAL.—Payment may not be made
3 under this part for covered outpatient drugs and
4 biologicals prescribed by a physician who has not elect-
5 ed section 1847B to apply within a category and a
6 competitive acquisition area with respect to which the
7 program applies unless—

8 “(i) the drugs or biologicals are supplied by a
9 contractor with a contract under this section for
10 such category of drugs and biologicals and area;
11 and

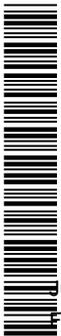
12 “(ii) the physician has elected such contractor
13 under paragraph (5) for such category and area.

14 “(B) PHYSICIAN CHOICE.—Subparagraph (A)
15 shall not apply for a category of drugs for an area if
16 the physician prescribing the covered outpatient drug
17 in such category and area has elected to apply section
18 1847B instead of this section.

19 “(5) CONTRACTOR SELECTION PROCESS.—

20 “(A) IN GENERAL.—The Secretary shall provide a
21 process for the selection of a contractor, on an annual
22 basis and in such exigent circumstances as the Sec-
23 retary may provide and with respect to each category
24 of covered outpatient drugs and biologicals for an area,
25 by physicians prescribing such drugs and biologicals in
26 the area of the contractor under this section that will
27 supply the drugs and biologicals within that category
28 and area. Such selection shall also include the election
29 described in section 1847B(a).

30 “(B) INFORMATION ON CONTRACTORS.—The Sec-
31 retary shall make available to physicians on an ongoing
32 basis, through a directory posted on the Department’s
33 Internet website or otherwise and upon request, a list
34 of the contractors under this section in the different
35 competitive acquisition areas.



1 “(C) SELECTING PHYSICIAN DEFINED.—For pur-
2 poses of this section, the term ‘selecting physician’
3 means, with respect to a contractor and category and
4 competitive acquisition area, a physician who has not
5 elected section 1847B to apply and has selected to
6 apply under this section such contractor for such cat-
7 egory and area.

8 “(b) PROGRAM REQUIREMENTS.—

9 “(1) CONTRACT FOR COVERED OUTPATIENT DRUGS
10 AND BIOLOGICALS.—The Secretary shall conduct a com-
11 petition among entities for the acquisition of a covered out-
12 patient drug or biological within each HCPCS code within
13 each category for each competitive acquisition area.

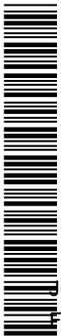
14 “(2) CONDITIONS FOR AWARDING CONTRACT.—

15 “(A) IN GENERAL.—The Secretary may not award
16 a contract to any entity under the competition con-
17 ducted in a competitive acquisition area pursuant to
18 paragraph (1) with respect to the acquisition of covered
19 outpatient drugs and biologicals within a category un-
20 less the Secretary finds that the entity meets all of the
21 following with respect to the contract period involved:

22 “(i) CAPACITY TO SUPPLY COVERED OUT-
23 PATIENT DRUG OR BIOLOGICAL WITHIN CAT-
24 EGORY.—

25 “(I) IN GENERAL.—The entity has suffi-
26 cient arrangements to acquire and to deliver
27 covered outpatient drugs and biologicals within
28 such category in the area specified in the con-
29 tract at the bid price specified in the contract
30 for all physicians that may elect such entity.

31 “(II) SHIPMENT METHODOLOGY.—The en-
32 tity has arrangements in effect for the ship-
33 ment at least 5 days each week of covered out-
34 patient drugs and biologicals under the con-
35 tract and for the timely delivery (including for



1 emergency situations) of such drugs and
2 biologicals in the area under the contract.

3 “(ii) QUALITY, SERVICE, FINANCIAL PERFORM-
4 ANCE AND SOLVENCY STANDARDS.—The entity
5 meets quality, service, financial performance, and
6 solvency standards specified by the Secretary,
7 including—

8 “(I) the establishment of procedures for
9 the prompt response and resolution of physi-
10 cian and beneficiary complaints and inquiries
11 regarding the shipment of covered outpatient
12 drugs and biologicals; and

13 “(II) a grievance process for the resolution
14 of disputes.

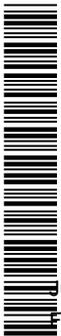
15 “(B) ADDITIONAL CONSIDERATIONS.—The Sec-
16 retary may refuse to award a contract under this sec-
17 tion, and may terminate such a contract, with an entity
18 based upon—

19 “(i) the suspension or revocation, by the Fed-
20 eral Government or a State government, of the en-
21 tity’s license for the distribution of drugs or
22 biologicals (including controlled substances); or

23 “(ii) the exclusion of the entity under section
24 1128 from participation under this title.

25 “(C) APPLICATION OF MEDICARE PROVIDER OM-
26 BUDSMAN.—For provision providing for a program-
27 wide Medicare Provider Ombudsman to review com-
28 plaints, see section 1868(b), as added by section 923
29 of the Medicare Prescription Drug and Modernization
30 Act of 2003.

31 “(3) AWARDED MULTIPLE CONTRACTS FOR A CAT-
32 EGORY AND AREA.—In order to provide a choice of at least
33 2 contractors in each competitive acquisition area for a cat-
34 egory of drugs and biologicals, the Secretary may limit (but
35 not below 2) the number of qualified entities that are
36 awarded such contracts for any category and area. The



1 Secretary shall select among qualified entities based on the
2 following:

3 “(A) The bid prices for covered outpatient drugs
4 and biologicals within the category and area.

5 “(B) Bid price for distribution of such drugs and
6 biologicals.

7 “(C) Ability to ensure product integrity.

8 “(D) Customer service.

9 “(E) Past experience in the distribution of drugs
10 and biologicals, including controlled substances.

11 “(F) Such other factors as the Secretary may
12 specify.

13 “(4) TERMS OF CONTRACTS.—

14 “(A) IN GENERAL.—A contract entered into with
15 an entity under the competition conducted pursuant to
16 paragraph (1) is subject to terms and conditions that
17 the Secretary may specify consistent with this section.

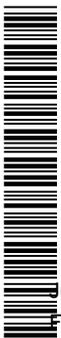
18 “(B) PERIOD OF CONTRACTS.—A contract under
19 this section shall be for a term of 2 years, but may be
20 terminated by the Secretary or the entity with appro-
21 priate, advance notice.

22 “(C) INTEGRITY OF DRUG AND BIOLOGICAL DIS-
23 TRIBUTION SYSTEM.—The Secretary—

24 “(i) shall require that for all drug and biologi-
25 cal products distributed by a contractor under this
26 section be acquired directly from the manufacturer
27 or from a distributor that has acquired the prod-
28 ucts directly from the manufacturer; and

29 “(ii) may require, in the case of such products
30 that are particularly susceptible to counterfeit or
31 diversion, that the contractor comply with such ad-
32 ditional product integrity safeguards as may be de-
33 termined to be necessary.

34 “(D) IMPLEMENTATION OF ANTI-COUNTER-
35 FEITING, QUALITY, SAFETY, AND RECORD KEEPING RE-
36 QUIREMENTS.—The Secretary shall require each con-



1 tractor to implement (through its officers, agents, rep-
2 resentatives, and employees) requirements relating to
3 the storage and handling of covered outpatient drugs
4 and biologicals and for the establishment and mainte-
5 nance of distribution records for such drugs and
6 biologicals. A contract under this section may include
7 requirements relating to the following:

8 “(i) Secure facilities.

9 “(ii) Safe and appropriate storage of drugs
10 and biologicals.

11 “(iii) Examination of drugs and biologicals re-
12 ceived and dispensed.

13 “(iv) Disposition of damaged and outdated
14 drugs and biologicals.

15 “(v) Record keeping and written policies and
16 procedures.

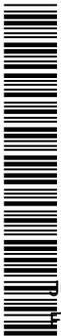
17 “(vi) Compliance personnel.

18 “(E) COMPLIANCE WITH CODE OF CONDUCT AND
19 FRAUD AND ABUSE RULES.—Under the contract—

20 “(i) the contractor shall comply with a code of
21 conduct, specified or recognized by the Secretary,
22 that includes standards relating to conflicts of in-
23 terest; and

24 “(ii) the contractor shall comply with all appli-
25 cable provisions relating to prevention of fraud and
26 abuse, including compliance with applicable guide-
27 lines of the Department of Justice and the Inspec-
28 tor General of the Department of Health and
29 Human Services.

30 “(F) DIRECT DELIVERY OF DRUGS AND
31 BIOLOGICALS TO PHYSICIANS.—Under the contract the
32 contractor shall only supply covered outpatient drugs
33 and biologicals directly to the selecting physicians and
34 not directly to beneficiaries, except under circumstances
35 and settings where a beneficiary currently receives a
36 drug or biological in the beneficiary’s home or other



1 non-physician office setting as the Secretary may pro-
2 vide. The contractor shall not deliver drugs and
3 biologicals to a selecting physician except upon receipt
4 of a prescription for such drugs and biologicals, and
5 such necessary data as may be required by the Sec-
6 retary to carry out this section. This section permits a
7 physician to submit a prescription for each individual
8 treatment but does not change the physician's flexi-
9 bility in terms of writing a prescription for drugs for
10 a single treatment or a course of treatment.

11 “(5) PERMITTING ACCESS TO DRUGS AND
12 BIOLOGICALS.—The Secretary shall provide for the reim-
13 bursement at the average sales price under section 1847B
14 for drugs and biologicals if the physician demonstrates all
15 of the following:

16 “(A) The drugs or biologicals are immediately re-
17 quired.

18 “(B) The physician could not have reasonably an-
19 ticipated the immediate requirement for the drugs or
20 biologicals.

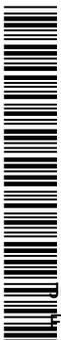
21 “(C) The contractor could not deliver to the physi-
22 cian the drugs or biologicals in a timely manner.

23 “(6) CONSTRUCTION.—Nothing in this section shall be
24 construed as waiving applicable State requirements relating
25 to licensing of pharmacies.

26 “(c) BIDDING PROCESS.—

27 “(1) IN GENERAL.—In awarding a contract for a cat-
28 egory of drugs and biologicals in an area under the pro-
29 gram, the Secretary shall consider with respect to each en-
30 tity seeking to be awarded a contract the prices bid to ac-
31 quire and supply the covered outpatient drugs and
32 biologicals for that category and area and the other factors
33 referred to in subsection (b)(3).

34 “(2) PRICES BID.—The prices bid by an entity under
35 paragraph (1) shall be the prices in effect and available for



1 the supply of contracted drugs and biologicals in the area
2 through the entity for the contract period.

3 “(3) REJECTION OF CONTRACT OFFER.—The Sec-
4 retary shall reject the contract offer of an entity with re-
5 spect to a category of drugs and biologicals for an area if
6 the Secretary estimates that the prices bid, in the aggre-
7 gate on average, would exceed 120 percent of the average
8 sales price (as determined under section 1847B).

9 “(4) BIDDING ON A NATIONAL OR REGIONAL BASIS.—
10 Nothing in this section shall be construed as precluding a
11 bidder from bidding for contracts in all areas of the United
12 States or as requiring a bidder to submit a bid for all areas
13 of the United States.

14 “(5) UNIFORMITY OF BIDS WITHIN AREA.—The
15 amount of the bid submitted under a contract offer for any
16 covered outpatient drug or biological for an area shall be
17 the same for that drug or biological for all portions of that
18 area.

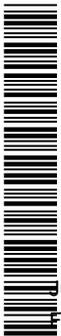
19 “(6) CONFIDENTIALITY OF BIDS.—The provisions of
20 subparagraph (D) of section 1927(b)(3) shall apply to a bid
21 submitted in a contract offer for a covered outpatient drug
22 or biological under this section in the same manner as it
23 applies to information disclosed under such section, except
24 that any reference—

25 “(A) in that subparagraph to a ‘manufacturer or
26 wholesaler’ is deemed a reference to a ‘bidder’ under
27 this section;

28 “(B) in that section to ‘prices charged for drugs’
29 is deemed a reference to a ‘bid’ submitted under this
30 section; and

31 “(C) in clause (i) of that section to ‘this section’,
32 is deemed a reference to ‘part B of title XVIII’.

33 “(7) INCLUSION OF COSTS.—The bid price submitted
34 in a contract offer for a covered outpatient drug or biologi-
35 cal shall—



1 “(A) include all costs related to the delivery of the
2 drug or biological to the selecting physician (or other
3 point of delivery); and

4 “(B) include the costs of dispensing (including
5 shipping) of such drug or biological and management
6 fees, but shall not include any costs related to the ad-
7 ministration of the drug or biological, or wastage, spill-
8 age, or spoilage.

9 “(8) PRICE ADJUSTMENTS DURING CONTRACT PERIOD;
10 DISCLOSURE OF COSTS.—Each contract awarded shall pro-
11 vide for—

12 “(A) disclosure to the Secretary the contractor’s
13 reasonable, net acquisition costs for periods specified by
14 the Secretary, not more often than quarterly, of the
15 contract; and

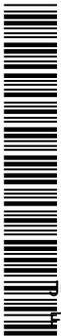
16 “(B) appropriate price adjustments over the pe-
17 riod of the contract to reflect significant increases or
18 decreases in a contractor’s reasonable, net acquisition
19 costs, as so disclosed.

20 “(d) COMPUTATION OF AVERAGE BID PRICES FOR A CAT-
21 EGORY AND AREA.—

22 “(1) IN GENERAL.—For each year or other contract
23 period for each covered outpatient drug or biological and
24 area with respect to which a competition is conducted
25 under the program, the Secretary shall compute an area
26 average of the bid prices submitted, in contract offers ac-
27 cepted for the category and area, for that year or other
28 contract period.

29 “(2) SPECIAL RULES.—The Secretary shall establish
30 rules regarding the use under this section of the alternative
31 payment amount provided under section 1847B to the use
32 of a price for specific covered outpatient drugs and
33 biologicals in the following cases:

34 “(A) NEW DRUGS AND BIOLOGICALS.—A covered
35 outpatient drug or biological for which an average bid
36 price has not been previously determined.



1 “(B) OTHER CASES.—Such other exceptional cases
2 as the Secretary may specify in regulations.

3 “(C) EXCLUSION CASES.—A covered outpatient
4 drug or biological that has been excluded under sub-
5 section (a)(1)(C).

6 Such alternative payment amount shall be based upon ac-
7 tual market price information and in no case shall it exceed
8 the average sales price (as determined under section
9 1847B).

10 “(e) COINSURANCE.—

11 “(1) IN GENERAL.—Coinsurance under this part with
12 respect to a covered outpatient drug or biological for which
13 payment is payable under this section shall be based on 20
14 percent of the payment basis under this section.

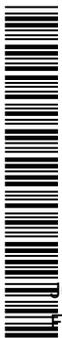
15 “(2) COLLECTION.—Such coinsurance shall be col-
16 lected by the contractor that supplies the drug or biological
17 involved and, subject to subsection (a)(3)(B), in the same
18 manner as coinsurance is collected for durable medical
19 equipment under this part.

20 “(f) SPECIAL PAYMENT RULES.—

21 “(1) IN GENERAL.—The Secretary may not provide
22 for an adjustment to reimbursement for covered outpatient
23 drugs and biologicals unless adjustments to the practice ex-
24 pense payment adjustment are made on the basis of supple-
25 mental surveys under section 1848(c)(2)(H)(ii) of the So-
26 cial Security Act, as added by subsection (a)(1)(B).

27 “(B) USE IN EXCLUSION CASES.—If the Secretary
28 excludes a drug or biological (or class of drugs or
29 biologicals) under subsection (a)(1)(D), the Secretary
30 may provide for reimbursement to be made under this
31 part for such drugs and biologicals (or class) using the
32 payment methodology under section 1847B or other
33 market based pricing system.

34 “(2) COORDINATION RULES.—The provisions of sec-
35 tion 1842(h)(3) shall apply to a contractor with respect to
36 covered outpatients drugs and biologicals supplied by that



1 contractor in the same manner as they apply to a partici-
2 pating supplier. In order to administer this section, the
3 Secretary may condition payment under this part to a per-
4 son for the administration of a drug or biological supplied
5 under this section upon person's provision of information
6 on such administration.

7 “(3) APPLICATION OF REQUIREMENT FOR ASSIGN-
8 MENT.—For provision requiring assignment of claims for
9 covered outpatient drugs and biologicals, see section
10 1842(o)(3).

11 “(4) PROTECTION FOR BENEFICIARY IN CASE OF MED-
12 ICAL NECESSITY DENIAL.—For protection of beneficiaries
13 against liability in the case of medical necessity determina-
14 tions, see section 1842(b)(3)(B)(ii)(III).

15 “(5) PHYSICIAN ROLE IN APPEALS PROCESS.—The
16 Secretary shall establish a procedure under which a physi-
17 cian who prescribes a drug or biological for which payment
18 is made under this section has appeal rights that are simi-
19 lar to those provided to a physician who prescribes durable
20 medical equipment or a laboratory test.

21 “(g) ADVISORY COMMITTEE.—The Secretary shall estab-
22 lish an advisory committee that includes representatives of par-
23 ties affected by the program under this section, including phy-
24 sicians, specialty pharmacies, distributors, manufacturers, and
25 beneficiaries. The committee shall advise the Secretary on
26 issues relating to the effective implementation of this section.

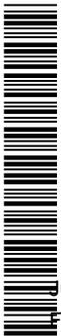
27 “OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT

28 METHODOLOGY

29 “SEC. 1847B. (a) ELECTION AND IMPLEMENTATION.—

30 “(1) ELECTION.—In connection with the annual elec-
31 tion made by a physician under section 1847A(a)(5), the
32 physician may elect to apply this section to the payment for
33 covered outpatient drugs and biologicals instead of the pay-
34 ment methodology under section 1847A.

35 “(2) IMPLEMENTATION.—This section shall be imple-
36 mented with respect to categories of covered outpatient



1 “(3) COVERED OUTPATIENT DRUGS AND BIOLOGICALS
2 DEFINED.—For purposes of this section, the term ‘covered
3 outpatient drugs and biologicals’ has the meaning given
4 such term in section 1847A(a)(2)(A).

5 “(b) COMPUTATION OF PAYMENT AMOUNT.—

6 “(1) IN GENERAL.—If this section applies with respect
7 to a covered outpatient drug or biological, the amount pay-
8 able for the drug or biological (based on a minimum dosage
9 unit) is, subject to applicable deductible and coinsurance—

10 “(A) in the case of a multiple source drug (as de-
11 fined in subsection (c)(6)(C)), 112 percent of the
12 amount determined under paragraph (3); or

13 “(B) in the case of a single source drug (as de-
14 fined in subsection (c)(6)(D)), 112 percent of the
15 amount determined under paragraph (4).

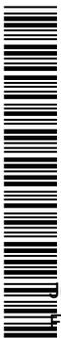
16 “(2) SPECIFICATION OF UNIT.—

17 “(A) SPECIFICATION BY MANUFACTURER.—The
18 manufacturer of a covered outpatient drug or biological
19 shall specify the unit associated with each National
20 Drug Code as part of the submission of data under sec-
21 tion 1927(b)(3)(A)(iii).

22 “(B) UNIT DEFINED.—In this section, the term
23 ‘unit’ means, with respect to a covered outpatient drug
24 or biological, the lowest identifiable quantity (such as
25 a capsule or tablet, milligram of molecules, or grams)
26 of the drug or biological that is dispensed, exclusive of
27 any diluent without reference to volume measures per-
28 taining to liquids.

29 “(3) MULTIPLE SOURCE DRUG.—For all drug prod-
30 ucts included within the same multiple source drug, the
31 amount specified in this paragraph is the volume-weighted
32 average of the average sales prices reported under section
33 1927(b)(3)(A)(iii) computed as follows:

34 “(A) Compute the sum of the products (for each
35 national drug code assigned to such drug products)
36 of—



1 “(i) the manufacturer’s average sales price (as
2 defined in subsection (c)); and

3 “(ii) the total number of units specified under
4 paragraph (2) sold, as reported under section
5 1927(b)(3)(A)(iii).

6 “(B) Divide the sum computed under subpara-
7 graph (A) by the sum of the total number of units
8 under subparagraph (A)(ii) for all national drug codes
9 assigned to such drug products.

10 “(4) SINGLE SOURCE DRUG.—The amount specified in
11 this paragraph for a single source drug is the lesser of the
12 following:

13 “(A) MANUFACTURER’S AVERAGE SALES PRICE.—
14 The manufacturer’s average sales price for a national
15 drug code, as computed using the methodology applied
16 under paragraph (3).

17 “(B) WHOLESALE ACQUISITION COST (WAC).—The
18 wholesale acquisition cost (as defined in subsection
19 (c)(6)(B)) reported for the single source drug.

20 “(5) BASIS FOR DETERMINATION.—The payment
21 amount shall be determined under this subsection based on
22 information reported under subsection (e) and without re-
23 gard to any special packaging, labeling, or identifiers on
24 the dosage form or product or package.

25 “(6) STUDY AND AUTHORIZATION.—Not later than 2
26 years after the date of the enactment of this section, the
27 Secretary shall conduct and complete a study on the ade-
28 quacy of the payment rates provided under this subsection,
29 taking into account the acquisition costs for the covered
30 outpatient drugs and biologicals as well as provider-related
31 costs, in rural and urban areas. The Secretary shall submit
32 the results of such study to Congress. For calendar years
33 after the date such results are submitted, the Secretary
34 may adjust the percentage specified in paragraphs (1)(A)
35 and (1)(B) based upon such results.

36 “(c) MANUFACTURER’S AVERAGE SALES PRICE.—



1 “(1) IN GENERAL.—For purposes of this subsection,
2 subject to paragraphs (2) and (3), the manufacturer’s ‘av-
3 erage sales price’ means, of a covered outpatient drug or
4 biological for a NDC code for a calendar quarter for a
5 manufacturer for a unit—

6 “(A) the manufacturer’s total sales (as defined by
7 the Secretary in regulations for purposes of section
8 1927(c)(1)) in the United States for such drug or bio-
9 logical in the calendar quarter; divided by

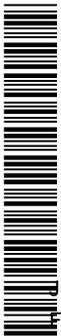
10 “(B) the total number of such units of such drug
11 or biological sold by the manufacturer in such quarter.

12 “(2) CERTAIN SALES EXEMPTED FROM COMPUTA-
13 TION.—In calculating the manufacturer’s average sales
14 price under this subsection, the following sales shall be ex-
15 cluded:

16 “(A) SALES EXEMPT FROM BEST PRICE.—Sales
17 exempt from the inclusion in the determination of ‘best
18 price’ under section 1927(c)(1)(C)(i).

19 “(B) SALES AT NOMINAL CHARGE.—Such other
20 sales as the Secretary identifies by regulation as sales
21 to an entity that are nominal in price or do not reflect
22 a market price paid by an entity to which payment is
23 made under this section.

24 “(3) SALE PRICE NET OF DISCOUNTS.—In calculating
25 the manufacturer’s average sales price under this sub-
26 section, such price shall be determined taking into account
27 volume discounts, prompt pay discounts, cash discounts,
28 the free goods that are contingent on any purchase require-
29 ment, chargebacks, and rebates (other than rebates under
30 section 1927), that result in a reduction of the cost to the
31 purchaser. A rebate to a payor or other entity that does not
32 take title to a covered outpatient drug or biological shall
33 not be taken into account in determining such price unless
34 the manufacturer has an agreement with the payor or other
35 entity under which the purchaser’s price for the drug or bi-
36 ological is reduced as a consequence of such rebate.



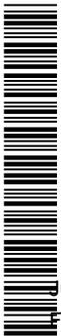
1 “(4) AUTHORITY TO DISREGARD AVERAGE SALES
2 PRICE DURING FIRST QUARTER OF SALES.—In the case of
3 a covered outpatient drug or biological during an initial pe-
4 riod (not to exceed a full calendar quarter) in which data
5 on the prices for sales for the drug or biological is not
6 available from the manufacturer to compute an average
7 sales price for the drug or biological, the Secretary may de-
8 termine the amount payable under this section for the drug
9 or biological without considering the manufacturer’s aver-
10 age sales price of that manufacturer for that drug or bio-
11 logical.

12 “(5) FREQUENCY OF DETERMINATIONS.—

13 “(A) IN GENERAL ON A QUARTERLY BASIS.—The
14 manufacturer’s average sales price, for a covered out-
15 patient drug or biological of a manufacturer, shall be
16 determined by such manufacturer under this subsection
17 on a quarterly basis. In making such determination in-
18 sofar as there is a lag in the reporting of the informa-
19 tion on rebates and chargebacks under paragraph (3)
20 so that adequate data are not available on a timely
21 basis, the manufacturer shall apply a methodology es-
22 tablished by the Secretary based on a 12-month rolling
23 average for the manufacturer to estimate costs attrib-
24 utable to rebates and chargebacks.

25 “(B) UPDATES IN RATES.—The payment rates
26 under subsection (b)(1) and (b)(2)(A) shall be updated
27 by the Secretary on a quarterly basis and shall be ap-
28 plied based upon the manufacturer’s average sales price
29 determined for the most recent calendar quarter.

30 “(C) USE OF CONTRACTORS; IMPLEMENTATION.—
31 The Secretary may use a carrier, fiscal intermediary, or
32 other contractor to determine the payment amount
33 under subsection (b). Notwithstanding any other provi-
34 sion of law, the Secretary may implement, by program
35 memorandum or otherwise, any of the provisions of this
36 section.



1 “(6) DEFINITIONS AND OTHER RULES.—In this sec-
2 tion:

3 “(A) MANUFACTURER.—The term ‘manufacturer’
4 means, with respect to a covered outpatient drug or bi-
5 ological, the manufacturer (as defined in section
6 1927(k)(5)) whose national drug code appears on such
7 drug or biological.

8 “(ii) WHOLESALE ACQUISITION COST.—The term
9 ‘wholesale acquisition cost’ means, with respect to a
10 covered outpatient drug or biological, the manufactur-
11 er’s list price for the drug or biological to wholesalers
12 or direct purchasers in the United States, not including
13 prompt pay or other discounts, rebates or reductions in
14 price, for the most recent month for which the informa-
15 tion is available, as reported in wholesale price guides
16 or other publications of drug pricing data.

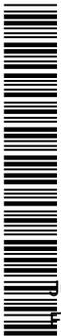
17 “(C) MULTIPLE SOURCE DRUG.—The term ‘mul-
18 tiple source drug’ means, for a calendar quarter, a cov-
19 ered outpatient drug or biological for which there are
20 2 or more drug products which—

21 “(i) are rated as therapeutically equivalent
22 (under the Food and Drug Administration’s most
23 recent publication of ‘Approved Drug Products
24 with Therapeutic Equivalence Evaluations’),

25 “(ii) except as provided in subparagraph (E),
26 are pharmaceutically equivalent and bioequivalent,
27 as determined under subparagraph (F) and as de-
28 termined by the Food and Drug Administration,
29 and

30 “(iii) are sold or marketed in the United
31 States during the quarter.

32 “(D) SINGLE SOURCE DRUG.—The term ‘single
33 source drug’ means a covered outpatient drug or bio-
34 logical which is not a multiple source drug and which
35 is produced or distributed under an original new drug
36 application approved by the Food and Drug Adminis-



1 tration, including a drug product marketed by any
2 cross-licensed producers or distributors operating under
3 the new drug application, or which is a biological.

4 “(E) EXCEPTION FROM PHARMACEUTICAL
5 EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—
6 Subparagraph (C)(ii) shall not apply if the Food and
7 Drug Administration changes by regulation the require-
8 ment that, for purposes of the publication described in
9 subparagraph (C)(i), in order for drug products to be
10 rated as therapeutically equivalent, they must be phar-
11 maceutically equivalent and bioequivalent, as defined in
12 subparagraph (F).

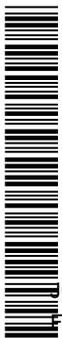
13 “(F) DETERMINATION OF PHARMACEUTICAL
14 EQUIVALENCE AND BIOEQUIVALENCE.—For purposes
15 of this paragraph—

16 “(i) drug products are pharmaceutically equiv-
17 alent if the products contain identical amounts of
18 the same active drug ingredient in the same dosage
19 form and meet compendial or other applicable
20 standards of strength, quality, purity, and identity;
21 and

22 “(ii) drugs are bioequivalent if they do not
23 present a known or potential bioequivalence prob-
24 lem, or, if they do present such a problem, they are
25 shown to meet an appropriate standard of bio-
26 equivalence.

27 “(G) INCLUSION OF VACCINES.—In applying pro-
28 visions of section 1927 under this section, ‘other than
29 a vaccine’ is deemed deleted from section
30 1927(k)(2)(B).

31 “(d) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RE-
32 SPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a
33 public health emergency under section 319 of the Public Health
34 Service Act in which there is a documented inability to access
35 covered outpatient drugs and biologicals, and a concomitant in-
36 crease in the price, of a drug or biological which is not reflected



1 in the manufacturer's average sales price for one or more quar-
2 ters, the Secretary may use the wholesale acquisition cost (or
3 other reasonable measure of drug price) instead of the manu-
4 facturer's average sales price for such quarters and for subse-
5 quent quarters until the price and availability of the drug or
6 biological has stabilized and is substantially reflected in the ap-
7 plicable manufacturer's average sales price.

8 “(e) REPORTS.—

9 “(1) QUARTERLY REPORT ON AVERAGE SALES
10 PRICE.—For requirements for reporting the manufacturer's
11 average sales price (and, if required to make payment, the
12 manufacturer's wholesale acquisition cost) for the covered
13 outpatient drug or biological, see section 1927(b)(3).

14 “(2) ANNUAL REPORT TO CONGRESS.—The Secretary
15 shall submit to the Committees on Energy and Commerce
16 and Ways and Means of the House of Representatives and
17 the Committee on Finance of the Senate an annual report
18 on the operation of this section and section 1847A. Such
19 report shall include information on the following:

20 “(A) Information on savings, reductions in cost-
21 sharing, access to covered outpatient drugs and
22 biologicals.

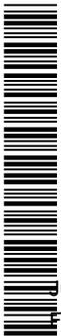
23 “(B) In the case of section 1847A, the range of
24 choices of contractors available to providers, and bene-
25 ficiary and provider satisfaction.

26 “(C) Trends in average sales price under sub-
27 section (b).

28 “(D) Administrative costs associated with compli-
29 ance with this section.

30 “(E) Total value of payments made under this sec-
31 tion.

32 “(F) Comparison of the average manufacturer
33 price as applied under section 1927 for a covered out-
34 patient drug or biological with the manufacturer's aver-
35 age sales price for the drug or biological under this sec-
36 tion.



1 “(f) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL RE-
2 VIEW.—There shall be no administrative or judicial review
3 under section 1869, section 1878, or otherwise, of determina-
4 tions of manufacturer’s average sales price under subsection
5 (c).”.

6 (c) CONTINUATION OF PAYMENT METHODOLOGY FOR
7 RADIOPHARMACEUTICALS.—Nothing in the amendments made
8 by this section shall be construed as changing the payment
9 methodology under part B of title XVIII of the Social Security
10 Act for radiopharmaceuticals, including the use by carriers of
11 invoice pricing methodology.

12 (d) CONFORMING AMENDMENTS.—

13 (1) IN GENERAL.—Section 1842(o) (42 U.S.C.
14 1395u(o)) is amended—

15 (A) in paragraph (1), by inserting “, subject to
16 section 1847A and 1847B,” before “the amount pay-
17 able for the drug or biological”; and

18 (B) by adding at the end of paragraph (2) the fol-
19 lowing: “This paragraph shall not apply in the case of
20 payment under section 1847A or 1847B.”.

21 (2) NO CHANGE IN COVERAGE BASIS.—Section
22 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by
23 inserting “(or would have been so included but for the ap-
24 plication of section 1847A or 1847B)” after “included in
25 the physicians’ bills”.

26 (3) PAYMENT.—Section 1833(a)(1)(S) (42 U.S.C.
27 1395l(a)(1)(S)) is amended by inserting “(or, if applicable,
28 under section 1847A or 1847B)” after “1842(o)”.

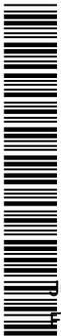
29 (4) CONSOLIDATED REPORTING OF PRICING INFORMA-
30 TION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

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

33 (B) in subsection (b)(3)(A)—

34 (i) in clause (i), by striking “and” at the end;

35 (ii) in clause (ii), by striking the period and
36 inserting “; and”; and



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

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

7 “(I) the manufacturer’s average sales
8 price (as defined in section 1847B(e)) and the
9 total number of units specified under section
10 1847B(b)(2)(A);

11 “(II) if required to make payment under
12 section 1847B, the manufacturer’s wholesale
13 acquisition cost, as defined in subsection (c)(6)
14 of such section; and

15 “(III) information on those sales that were
16 made at a nominal price or otherwise described
17 in section 1847B(e)(2)(B), which information
18 is subject to audit by the Inspector General of
19 the Department of Health and Human Serv-
20 ices;

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

23 (C) in subsection (b)(3)(B)—

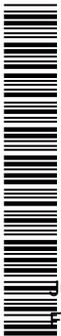
24 (i) in the heading, by inserting “AND MANU-
25 FACTURER’S AVERAGE SALES PRICE” after
26 “PRICE”; and

27 (ii) by inserting “and manufacturer’s average
28 sales prices (including wholesale acquisition cost) if
29 required to make payment” after “manufacturer
30 prices”; and

31 (D) in subsection (b)(3)(D)(i), by inserting “and
32 section 1847B” after “this section”.

33 (e) GAO STUDY.—

34 (1) STUDY.—The Comptroller General of the United
35 States shall conduct a study to assess the impact of the



1 amendments made by this section on the delivery of serv-
2 ices, including their impact on—

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

6 (B) the site of delivery of such services.

7 (2) REPORT.—Not later than 2 years after the year in
8 which the amendment made by subsection (a)(1) first takes
9 effect, the Comptroller General shall submit to Congress a
10 report on the study conducted under paragraph (1).

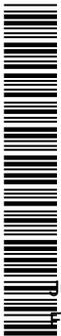
11 (f) MEDPAC RECOMMENDATIONS ON BLOOD CLOTTING
12 FACTORS.—The Medicare Payment Advisory Commission shall
13 submit to Congress, in its annual report in 2004, specific rec-
14 ommendations regarding a payment amount (or amounts) for
15 blood clotting factors and its administration under the medi-
16 care program.

17 (g) ESTABLISHMENT OF PHARMACEUTICAL MANAGEMENT
18 FEE WHERE DRUGS PROVIDED THROUGH A CONTRACTOR.—
19 Section 1848(a) (42 U.S.C. 1395w-4(a)) is amended by adding
20 at the end the following new paragraph:

21 “(5) RECOGNITION OF PHARMACEUTICAL MANAGE-
22 MENT FEE IN CERTAIN CASES.—In establishing the fee
23 schedule under this section, the Secretary shall provide for
24 a separate payment with respect to physicians’ services con-
25 sisting of the unique administrative and management costs
26 associated with covered drugs and biologicals which are fur-
27 nished to physicians through a contractor under section
28 1847A (compared with such costs if such drugs and
29 biologicals were acquired directly by such physicians).”.

30 (h) STUDY ON CODES FOR NON-ONCOLOGY CODES.—

31 (1) STUDY.—The Secretary shall conduct a study to
32 determine the appropriateness of establishing and imple-
33 menting separate CPT codes for non-oncology infusions
34 that are based on the level of complexity of the administra-
35 tion and resource consumption.



1 (2) REPORT.—Not later than 1 year after the date of
2 the enactment of this Act, the Secretary shall submit a re-
3 port to Congress on the study. To the extent the Secretary
4 determines it to be appropriate, the Secretary may imple-
5 ment appropriate changes in the payment methodology for
6 such codes.

7 **SEC. 304. DEMONSTRATION PROJECT FOR USE OF RE-**
8 **COVERY AUDIT CONTRACTORS.**

9 (a) IN GENERAL.—The Secretary of Health and Human
10 Services shall conduct a demonstration project under this sec-
11 tion (in this section referred to as the “project”) to dem-
12 onstrate the use of recovery audit contractors under the Medi-
13 care Integrity Program in identifying underpayments and over-
14 payments and recouping overpayments under the medicare pro-
15 gram for services for which payment is made under part A or
16 part B of title XVIII of the Social Security Act. Under the
17 project—

18 (1) payment may be made to such a contractor on a
19 contingent basis;

20 (2) a percentage of the amount recovered may be re-
21 tained by the Secretary and shall be available to the pro-
22 gram management account of the Centers for Medicare &
23 Medicaid Services; and

24 (3) the Secretary shall examine the efficacy of such
25 use with respect to duplicative payments, accuracy of cod-
26 ing, and other payment policies in which inaccurate pay-
27 ments arise.

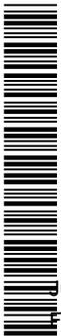
28 (b) SCOPE AND DURATION.—

29 (1) SCOPE.—The project shall cover at least 2 States
30 that are among the States with—

31 (A) the highest per capita utilization rates of
32 medicare services, and

33 (B) at least 3 contractors.

34 (2) DURATION.—The project shall last for not longer
35 than 3 years.



1 (c) WAIVER.—The Secretary of Health and Human Serv-
2 ices shall waive such provisions of title XVIII of the Social Se-
3 curity Act as may be necessary to provide for payment for serv-
4 ices under the project in accordance with subsection (a).

5 (d) QUALIFICATIONS OF CONTRACTORS.—

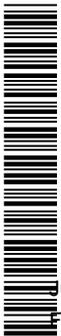
6 (1) IN GENERAL.—The Secretary shall enter into a re-
7 covery audit contract under this section with an entity only
8 if the entity has staff that has the appropriate clinical
9 knowledge of and experience with the payment rules and
10 regulations under the medicare program or the entity has
11 or will contract with another entity that has such knowl-
12 edgeable and experienced staff.

13 (2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The
14 Secretary may not enter into a recovery audit contract
15 under this section with an entity to the extent that the en-
16 tity is a fiscal intermediary under section 1816 of the So-
17 cial Security Act (42 U.S.C. 1395h), a carrier under sec-
18 tion 1842 of such Act (42 U.S.C. 1395u), or a Medicare
19 Administrative Contractor under section 1874A of such
20 Act.

21 (3) PREFERENCE FOR ENTITIES WITH DEM-
22 ONSTRATED PROFICIENCY WITH PRIVATE INSURERS.—In
23 awarding contracts to recovery audit contractors under this
24 section, the Secretary shall give preference to those risk en-
25 tities that the Secretary determines have demonstrated
26 more than 3 years direct management experience and a
27 proficiency in recovery audits with private insurers or
28 under the medicaid program under title XIX of such Act.

29 (e) CONSTRUCTION RELATING TO CONDUCT OF INVES-
30 TIGATION OF FRAUD.—A recovery of an overpayment to a pro-
31 vider by a recovery audit contractor shall not be construed to
32 prohibit the Secretary or the Attorney General from inves-
33 tigating and prosecuting, if appropriate, allegations of fraud or
34 abuse arising from such overpayment.

35 (f) REPORT.—The Secretary of Health and Human Serv-
36 ices shall submit to Congress a report on the project not later



1 than 6 months after the date of its completion. Such reports
2 shall include information on the impact of the project on sav-
3 ings to the medicare program and recommendations on the
4 cost-effectiveness of extending or expanding the project.

5 **TITLE IV—RURAL HEALTH CARE** 6 **IMPROVEMENTS**

7 **SEC. 401. ENHANCED DISPROPORTIONATE SHARE HOS-** 8 **PITAL (DSH) TREATMENT FOR RURAL HOS-** 9 **PITALS AND URBAN HOSPITALS WITH** 10 **FEWER THAN 100 BEDS.**

11 (a) DOUBLING THE CAP.—

12 (1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C.
13 1395ww(d)(5)(F)) is amended by adding at the end the fol-
14 lowing new clause:

15 “(xiv)(I) In the case of discharges in a fiscal year begin-
16 ning on or after October 1, 2003, subject to subclause (II),
17 there shall be substituted for the disproportionate share adjust-
18 ment percentage otherwise determined under clause (iv) (other
19 than subclause (I)) or under clause (viii), (x), (xi), (xii), or
20 (xiii), the disproportionate share adjustment percentage deter-
21 mined under clause (vii) (relating to large, urban hospitals).

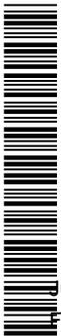
22 “(II) Under subclause (I), the disproportionate share ad-
23 justment percentage shall not exceed 10 percent for a hospital
24 that is not classified as a rural referral center under subpara-
25 graph (C).”.

26 (2) CONFORMING AMENDMENTS.—Section
27 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

28 (A) in each of subclauses (II), (III), (IV), (V), and
29 (VI) of clause (iv), by inserting “subject to clause (xiv)
30 and” before “for discharges occurring”;

31 (B) in clause (viii), by striking “The formula” and
32 inserting “Subject to clause (xiv), the formula”; and

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



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

4 **SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM**
5 **STANDARDIZED AMOUNT IN RURAL AND**
6 **SMALL URBAN AREAS.**

7 (a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C.
8 1395ww(d)(3)(A)) is amended—

9 (1) in clause (iv), by inserting “and ending on or be-
10 fore September 30, 2003,” after “October 1, 1995;” and

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

14 “(v) For discharges occurring in the fiscal year begin-
15 ning on October 1, 2003, the average standardized amount
16 for hospitals located in areas other than a large urban area
17 shall be equal to the average standardized amount for hos-
18 pitals located in a large urban area.”.

19 (b) CONFORMING AMENDMENTS.—

20 (1) COMPUTING DRG-SPECIFIC RATES.—Section
21 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

22 (A) in the heading, by striking “IN DIFFERENT
23 AREAS”;

24 (B) in the matter preceding clause (i), by striking
25 “, each of”;

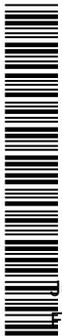
26 (C) in clause (i)—

27 (i) in the matter preceding subclause (I), by
28 inserting “for fiscal years before fiscal year 2004,”
29 before “for hospitals”; and

30 (ii) in subclause (II), by striking “and” after
31 the semicolon at the end;

32 (D) in clause (ii)—

33 (i) in the matter preceding subclause (I), by
34 inserting “for fiscal years before fiscal year 2004,”
35 before “for hospitals”; and



1 (ii) in subclause (II), by striking the period at
2 the end and inserting “; and”; and

3 (E) by adding at the end the following new clause:
4 “(iii) for a fiscal year beginning after fiscal year
5 2003, for hospitals located in all areas, to the product
6 of—

7 “(I) the applicable standardized amount (com-
8 puted under subparagraph (A)), reduced under
9 subparagraph (B), and adjusted or reduced under
10 subparagraph (C) for the fiscal year; and

11 “(II) the weighting factor (determined under
12 paragraph (4)(B)) for that diagnosis-related
13 group.”.

14 (2) TECHNICAL CONFORMING SUNSET.—Section
15 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

16 (A) in the matter preceding subparagraph (A), by
17 inserting “, for fiscal years before fiscal year 1997,”
18 before “a regional adjusted DRG prospective payment
19 rate”; and

20 (B) in subparagraph (D), in the matter preceding
21 clause (i), by inserting “, for fiscal years before fiscal
22 year 1997,” before “a regional DRG prospective pay-
23 ment rate for each region,”.

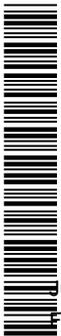
24 **SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOS-**
25 **PITAL CLASSIFICATION.**

26 (a) CLASSIFICATION.—Section 1861(mm) (42 U.S.C.
27 1395x(mm)) is amended—

28 (1) in the heading by adding “ESSENTIAL RURAL
29 HOSPITALS” at the end; and

30 (2) by adding at the end the following new para-
31 graphs:

32 “(4)(A) The term ‘essential rural hospital’ means a sub-
33 section (d) hospital (as defined in section 1886(d)(1)(B)) that
34 is located in a rural area (as defined for purposes of section
35 1886(d)), has more than 25 licensed acute care inpatient beds,
36 has applied to the Secretary for classification as such a hos-



1 pital, and with respect to which the Secretary has determined
2 that the closure of the hospital would significantly diminish the
3 ability of medicare beneficiaries to obtain essential health care
4 services.

5 “(B) The determination under subparagraph (A) shall be
6 based on the following criteria:

7 “(i) HIGH PROPORTION OF MEDICARE BENEFICIARIES
8 RECEIVING CARE FROM HOSPITAL.—(I) A high percentage
9 of such beneficiaries residing in the area of the hospital
10 who are hospitalized (during the most recent year for which
11 complete data are available) receive basic inpatient medical
12 care at the hospital.

13 “(II) For a hospital with more than 200 licensed beds,
14 a high percentage of such beneficiaries residing in such
15 area who are hospitalized (during such recent year) receive
16 specialized surgical inpatient care at the hospital.

17 “(III) Almost all physicians described in section
18 1861(r)(1) in such area have privileges at the hospital and
19 provide their inpatient services primarily at the hospital.

20 “(ii) SIGNIFICANT ADVERSE IMPACT IN ABSENCE OF
21 HOSPITAL.—If the hospital were to close—

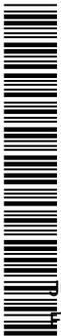
22 “(I) there would be a significant amount of time
23 needed for residents to reach emergency treatment, re-
24 sulting in a potential significant harm to beneficiaries
25 with critical illnesses or injuries;

26 “(II) there would be an inability in the community
27 to stabilize emergency cases for transfers to another
28 acute care setting, resulting in a potential for signifi-
29 cant harm to medicare beneficiaries; and

30 “(III) any other nearby hospital lacks the physical
31 and clinical capacity to take over the hospital’s typical
32 admissions.

33 “(C) In making such determination, the Secretary may
34 also consider the following:

35 “(i) Free-standing ambulatory surgery centers, office-
36 based oncology care, and imaging center services are insuf-



1 ficient in the hospital's area to handle the outpatient care
2 of the hospital.

3 "(ii) Beneficiaries in nearby areas would be adversely
4 affected if the hospital were to close as the hospital pro-
5 vides specialized knowledge and services to a network of
6 smaller hospitals and critical access hospitals.

7 "(iii) Medicare beneficiaries would have difficulty in
8 accessing care if the hospital were to close as the hospital
9 provides significant subsidies to support ambulatory care in
10 local clinics, including mental health clinics and to support
11 post acute care.

12 "(iv) The hospital has a committment to provide gradu-
13 uate medical education in a rural area.

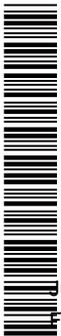
14 "(C) QUALITY CARE.—The hospital inpatient score for
15 quality of care is not less than the median hospital score
16 for qualify of care for hospitals in the State, as established
17 under standards of the utilization and quality control peer
18 review organization under part B of title XI or other qual-
19 ity standards recognized by the Secretary.

20 A hospital classified as an essential rural hospital may not
21 change such classification and a hospital so classified shall not
22 be treated as a sole community hospital, medicare dependent
23 hospital, or rural referral center for purposes of section 1886.”.

24 (b) PAYMENT BASED ON 102 PERCENT OF ALLOWED
25 COSTS.—

26 (1) INPATIENT HOSPITAL SERVICES.—Section 1886(d)
27 (42 U.S.C. 1395ww(d)) is amended by adding at the end
28 the following:

29 “(11) In the case of a hospital classified as an essential
30 rural hospital under section 1861(mm)(4) for a cost reporting
31 period, the payment under this subsection for inpatient hospital
32 services for discharges occurring during the period shall be
33 based on 102 percent of the reasonable costs for such services.
34 Nothing in this paragraph shall be construed as affecting the
35 application or amount of deductibles or copayments otherwise



1 applicable to such services under part A or as waiving any re-
2 quirement for billing for such services.”.

3 (2) HOSPITAL OUTPATIENT SERVICES.—Section
4 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by add-
5 ing at the end the following new subparagraph:

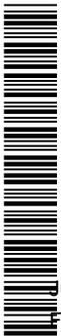
6 “(B) SPECIAL RULE FOR ESSENTIAL RURAL HOS-
7 PITALS.—In the case of a hospital classified as an es-
8 sential rural hospital under section 1861(mm)(4) for a
9 cost reporting period, the payment under this sub-
10 section for covered OPD services during the period
11 shall be based on 102 percent of the reasonable costs
12 for such services. Nothing in this subparagraph shall be
13 construed as affecting the application or amount of
14 deductibles or copayments otherwise applicable to such
15 services under this part or as waiving any requirement
16 for billing for such services.”.

17 (c) EFFECTIVE DATE.—The amendments made by this
18 section shall apply to cost reporting periods beginning on or
19 after October 1, 2004.

20 **SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED**
21 **IN HOSPITAL MARKET BASKET.**

22 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After re-
23 vising the weights used in the hospital market basket under
24 section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C.
25 1395ww(b)(3)(B)(iii)) to reflect the most current data avail-
26 able, the Secretary shall establish a frequency for revising such
27 weights, including the labor share, in such market basket to re-
28 flect the most current data available more frequently than once
29 every 5 years.

30 (b) REPORT.—Not later than October 1, 2004, the Sec-
31 retary shall submit a report to Congress on the frequency es-
32 tablished under subsection (a), including an explanation of the
33 reasons for, and options considered, in determining such fre-
34 quency.



1 **SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOS-**
2 **PITAL PROGRAM.**

3 (a) INCREASE IN PAYMENT AMOUNTS.—

4 (1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and
5 1883(a)(3) (42 U.S.C. 1395f(l); 1395m(g)(1); 42 U.S.C.
6 1395tt(a)(3)) are each amended by inserting “equal to 102
7 percent of” before “the reasonable costs”.

8 (2) EFFECTIVE DATE.—The amendments made by
9 paragraph (1) shall apply to payments for services fur-
10 nished during cost reporting periods beginning on or after
11 October 1, 2003.

12 (b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY
13 ROOM ON-CALL PROVIDERS.—

14 (1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C.
15 1395m(g)(5)) is amended—

16 (A) in the heading—

17 (i) by inserting “CERTAIN” before “EMER-
18 GENCY”; and

19 (ii) by striking “PHYSICIANS” and inserting
20 “PROVIDERS”;

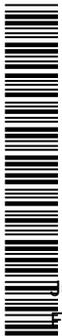
21 (B) by striking “emergency room physicians who
22 are on-call (as defined by the Secretary)” and inserting
23 “physicians, physician assistants, nurse practitioners,
24 and clinical nurse specialists who are on-call (as de-
25 fined by the Secretary) to provide emergency services”;
26 and

27 (C) by striking “physicians’ services” and insert-
28 ing “services covered under this title”.

29 (2) EFFECTIVE DATE.—The amendment made by
30 paragraph (1) shall apply with respect to costs incurred for
31 services provided on or after January 1, 2004.

32 (c) MODIFICATION OF THE ISOLATION TEST FOR COST-
33 BASED CAH AMBULANCE SERVICES.—

34 (1) IN GENERAL.—Section 1834(l)(8) (42 U.S.C.
35 1395m(l)), as added by section 205(a) of BIPA (114 Stat.
36 2763A–482), is amended by adding at the end the fol-



1 lowing: “The limitation described in the matter following
2 subparagraph (B) in the previous sentence shall not apply
3 if the ambulance services are furnished by such a provider
4 or supplier of ambulance services who is a first responder
5 to emergencies (as determined by the Secretary).”.

6 (2) EFFECTIVE DATE.—The amendment made by
7 paragraph (1) shall apply to ambulance services furnished
8 on or after the first cost reporting period that begins after
9 the date of the enactment of this Act.

10 (d) REINSTATEMENT OF PERIODIC INTERIM PAYMENT
11 (PIP).—

12 (1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C.
13 1395g(e)(2)) is amended—

14 (A) in the matter before subparagraph (A), by in-
15 serting “, in the cases described in subparagraphs (A)
16 through (D)” after “1986”; and

17 (B) by striking “and” at the end of subparagraph
18 (C);

19 (C) by adding “and” at the end of subparagraph
20 (D); and

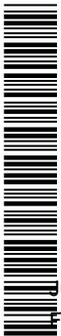
21 (D) by inserting after subparagraph (D) the fol-
22 lowing new subparagraph:

23 “(E) inpatient critical access hospital services;”.

24 (2) DEVELOPMENT OF ALTERNATIVE METHODS OF
25 PERIODIC INTERIM PAYMENTS.—With respect to periodic
26 interim payments to critical access hospitals for inpatient
27 critical access hospital services under section 1815(e)(2)(E)
28 of the Social Security Act, as added by paragraph (1), the
29 Secretary shall develop alternative methods for such pay-
30 ments that are based on expenditures of the hospital.

31 (3) REINSTATEMENT OF PIP.—The amendments made
32 by paragraph (1) shall apply to payments made on or after
33 January 1, 2004.

34 (e) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN
35 PAYMENT ADJUSTMENT.—



1 (1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C.
2 1395m(g)(2)) is amended by adding after and below sub-
3 paragraph (B) the following:

4 “The Secretary may not require, as a condition for apply-
5 ing subparagraph (B) with respect to a critical access hos-
6 pital, that each physician providing professional services in
7 the hospital must assign billing rights with respect to such
8 services, except that such subparagraph shall not apply to
9 those physicians who have not assigned such billing
10 rights.”.

11 (2) EFFECTIVE DATE.—The amendment made by
12 paragraph (1) shall be effective as if included in the enact-
13 ment of section 403(d) of the Medicare, Medicaid, and
14 SCHIP Balanced Budget Refinement Act of 1999 (113
15 Stat. 1501A–371).

16 (f) FLEXIBILITY IN BED LIMITATION FOR HOSPITALS.—
17 Section 1820 (42 U.S.C. 1395i–4) is amended—

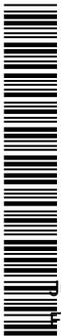
18 (1) in subsection (c)(2)(B)(iii), by inserting “subject
19 to paragraph (3)” after “(iii) provides”;

20 (2) by adding at the end of subsection (c) the fol-
21 lowing new paragraph:

22 “(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR
23 HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUA-
24 TIONS.—

25 “(A) IN GENERAL.—Subject to subparagraph (C),
26 in the case of a hospital that demonstrates that it
27 meets the standards established under subparagraph
28 (B) and has not made the election described in sub-
29 section (f)(2)(A), the bed limitations otherwise applica-
30 ble under paragraph (2)(B)(iii) and subsection (f) shall
31 be increased by 5 beds.

32 “(B) STANDARDS.—The Secretary shall specify
33 standards for determining whether a critical access hos-
34 pital has sufficiently strong seasonal variations in pa-
35 tient admissions to justify the increase in bed limitation
36 provided under subparagraph (A).”; and



1 (3) in subsection (f)—

2 (A) by inserting “(1)” after “(f)”; and

3 (B) by adding at the end the following new para-
4 graph:

5 “(2)(A) A hospital may elect to treat the reference in
6 paragraph (1) to ‘15 beds’ as a reference to ‘25 beds’, but only
7 if no more than 10 beds in the hospital are at any time used
8 for non-acute care services. A hospital that makes such an elec-
9 tion is not eligible for the increase provided under subsection
10 (c)(3)(A).

11 “(B) The limitations in numbers of beds under the first
12 sentence of paragraph (1) are subject to adjustment under sub-
13 section (c)(3).”.

14 (4) EFFECTIVE DATE.—The amendments made by
15 this subsection shall apply to designations made before, on,
16 or after January 1, 2004.

17 (g) ADDITIONAL 5-YEAR PERIOD OF FUNDING FOR
18 GRANT PROGRAM.—

19 (1) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i-
20 4(g)) is amended by adding at the end the following new
21 paragraph:

22 “(4) FUNDING.—

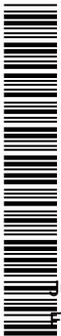
23 “(A) IN GENERAL.—Subject to subparagraph (B),
24 payment for grants made under this subsection during
25 fiscal years 2004 through 2008 shall be made from the
26 Federal Hospital Insurance Trust Fund.

27 “(B) ANNUAL AGGREGATE LIMITATION.—In no
28 case may the amount of payment provided for under
29 subparagraph (A) for a fiscal year exceed
30 \$25,000,000.”.

31 (2) CONFORMING AMENDMENT.—Section 1820 (42
32 U.S.C. 1395i-4) is amended by striking subsection (j).

33 **SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSI-**
34 **TIONS.**

35 (a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C.
36 1395ww(h)(4)) is amended—



1 (1) in subparagraph (F)(i), by inserting “subject to
2 subparagraph (I),” after “October 1, 1997,”;

3 (2) in subparagraph (H)(i), by inserting “subject to
4 subparagraph (I),” after “subparagraphs (F) and (G),”;
5 and

6 (3) by adding at the end the following new subpara-
7 graph:

8 “(I) REDISTRIBUTION OF UNUSED RESIDENT PO-
9 SITIONS.—

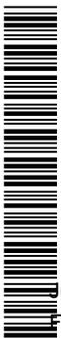
10 “(i) REDUCTION IN LIMIT BASED ON UNUSED
11 POSITIONS.—

12 “(I) IN GENERAL.—If a hospital’s resident
13 level (as defined in clause (iii)(I)) is less than
14 the otherwise applicable resident limit (as de-
15 fined in clause (iii)(II)) for each of the ref-
16 erence periods (as defined in subclause (II)),
17 effective for cost reporting periods beginning on
18 or after January 1, 2004, the otherwise appli-
19 cable resident limit shall be reduced by 75 per-
20 cent of the difference between such limit and
21 the reference resident level specified in sub-
22 clause (III) (or subclause (IV) if applicable).

23 “(II) REFERENCE PERIODS DEFINED.—In
24 this clause, the term ‘reference periods’ means,
25 for a hospital, the 3 most recent consecutive
26 cost reporting periods of the hospital for which
27 cost reports have been settled (or, if not, sub-
28 mitted) on or before September 30, 2002.

29 “(III) REFERENCE RESIDENT LEVEL.—
30 Subject to subclause (IV), the reference resi-
31 dent level specified in this subclause for a hos-
32 pital is the highest resident level for the hos-
33 pital during any of the reference periods.

34 “(IV) ADJUSTMENT PROCESS.—Upon the
35 timely request of a hospital, the Secretary may
36 adjust the reference resident level for a hospital



1 to be the resident level for the hospital for the
2 cost reporting period that includes July 1,
3 2003.

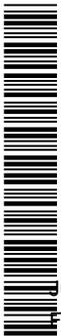
4 “(V) AFFILIATION.—With respect to hos-
5 pitals which are members of the same affiliated
6 group (as defined by the Secretary under sub-
7 paragraph (H)(ii)), the provisions of this sec-
8 tion shall be applied with respect to such an af-
9 filiated group by deeming the affiliated group
10 to be a single hospital.

11 “(ii) REDISTRIBUTION.—

12 “(I) IN GENERAL.—The Secretary is au-
13 thorized to increase the otherwise applicable
14 resident limits for hospitals by an aggregate
15 number estimated by the Secretary that does
16 not exceed the aggregate reduction in such lim-
17 its attributable to clause (i) (without taking
18 into account any adjustment under subclause
19 (IV) of such clause).

20 “(II) EFFECTIVE DATE.—No increase
21 under subclause (I) shall be permitted or taken
22 into account for a hospital for any portion of
23 a cost reporting period that occurs before July
24 1, 2004, or before the date of the hospital’s ap-
25 plication for an increase under this clause. No
26 such increase shall be permitted for a hospital
27 unless the hospital has applied to the Secretary
28 for such increase by December 31, 2005.

29 “(III) CONSIDERATIONS IN REDISTRIBU-
30 TION.—In determining for which hospitals the
31 increase in the otherwise applicable resident
32 limit is provided under subclause (I), the Sec-
33 retary shall take into account the need for such
34 an increase by specialty and location involved,
35 consistent with subclause (IV).

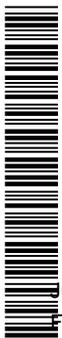


1 “(IV) PRIORITY FOR RURAL AND SMALL
2 URBAN AREAS.—In determining for which hos-
3 pitals and residency training programs an in-
4 crease in the otherwise applicable resident limit
5 is provided under subclause (I), the Secretary
6 shall first distribute the increase to programs
7 of hospitals located in rural areas or in urban
8 areas that are not large urban areas (as de-
9 fined for purposes of subsection (d)) and to
10 programs that have no other program of the
11 same specialty in the same state, on a first-
12 come-first-served basis (as determined by the
13 Secretary) based on a demonstration that the
14 hospital will fill the positions made available
15 under this clause and not to exceed an increase
16 of 25 full-time equivalent positions with respect
17 to any hospital.

18 “(V) APPLICATION OF LOCALITY AD-
19 JUSTED NATIONAL AVERAGE PER RESIDENT
20 AMOUNT.—With respect to additional residency
21 positions in a hospital attributable to the in-
22 crease provided under this clause, notwith-
23 standing any other provision of this subsection,
24 the approved FTE resident amount is deemed
25 to be equal to the locality adjusted national av-
26 erage per resident amount computed under
27 subparagraph (E) for that hospital.

28 “(VI) CONSTRUCTION.—Nothing in this
29 clause shall be construed as permitting the re-
30 distribution of reductions in residency positions
31 attributable to voluntary reduction programs
32 under paragraph (6) or as affecting the ability
33 of a hospital to establish new medical residency
34 training programs under subparagraph (H).

35 “(iii) RESIDENT LEVEL AND LIMIT DE-
36 FINED.—In this subparagraph:



1 “(I) RESIDENT LEVEL.—The term ‘resi-
2 dent level’ means, with respect to a hospital,
3 the total number of full-time equivalent resi-
4 dents, before the application of weighting fac-
5 tors (as determined under this paragraph), in
6 the fields of allopathic and osteopathic medi-
7 cine for the hospital.

8 “(II) OTHERWISE APPLICABLE RESIDENT
9 LIMIT.—The term ‘otherwise applicable resi-
10 dent limit’ means, with respect to a hospital,
11 the limit otherwise applicable under subpara-
12 graphs (F)(i) and (H) on the resident level for
13 the hospital determined without regard to this
14 subparagraph.”.

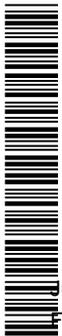
15 (b) CONFORMING AMENDMENT TO IME.—Section
16 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended
17 by adding at the end the following: “The provisions of subpara-
18 graph (I) of subsection (h)(4) shall apply with respect to the
19 first sentence of this clause in the same manner as it applies
20 with respect to subparagraph (F) of such subsection.”.

21 (c) REPORT ON EXTENSION OF APPLICATIONS UNDER
22 REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the
23 Secretary shall submit to Congress a report containing rec-
24 ommendations regarding whether to extend the deadline for ap-
25 plications for an increase in resident limits under section
26 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by
27 subsection (a)).

28 **SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS**
29 **PROVISIONS FOR SMALL RURAL HOSPITALS**
30 **AND SOLE COMMUNITY HOSPITALS UNDER**
31 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**
32 **PITAL OUTPATIENT DEPARTMENT SERV-**
33 **ICES.**

34 (a) HOLD HARMLESS PROVISIONS.—

35 (1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42
36 U.S.C. 1395l(t)(7)(D)(i)) is amended—



1 (A) in the heading, by striking “SMALL” and in-
2 serting “CERTAIN”;

3 (B) by inserting “or a sole community hospital (as
4 defined in section 1886(d)(5)(D)(iii)) located in a rural
5 area” after “100 beds”; and

6 (C) by striking “2004” and inserting “2006”.

7 (2) EFFECTIVE DATE.—The amendment made by sub-
8 section (a)(2) shall apply with respect to payment for OPD
9 services furnished on and after January 1, 2004.

10 (b) STUDY; ADJUSTMENT.—

11 (1) STUDY.—The Secretary shall conduct a study to
12 determine if, under the prospective payment system for
13 hospital outpatient department services under section
14 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)),
15 costs incurred by rural providers of services by ambulatory
16 payment classification groups (APCs) exceed those costs in-
17 curred by urban providers of services.

18 (2) ADJUSTMENT.—Insofar as the Secretary deter-
19 mines under paragraph (1) that costs incurred by rural
20 providers exceed those costs incurred by urban providers of
21 services, the Secretary shall provide for an appropriate ad-
22 justment under such section 1833(t) to reflect those higher
23 costs by January 1, 2005.

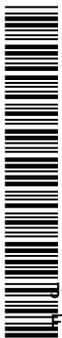
24 **SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLIN-**
25 **IC AND FEDERALLY QUALIFIED HEALTH**
26 **CENTER SERVICES FROM THE PROSPECTIVE**
27 **PAYMENT SYSTEM FOR SKILLED NURSING**
28 **FACILITIES.**

29 (a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C.
30 1395yy(e)(2)(A)) is amended—

31 (1) in clause (i)(II), by striking “clauses (ii) and (iii)”
32 and inserting “clauses (ii), (iii), and (iv)”;

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

34 “(iv) EXCLUSION OF CERTAIN RURAL HEALTH
35 CLINIC AND FEDERALLY QUALIFIED HEALTH CEN-
36 TER SERVICES.—Services described in this clause
37 are—



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

3 “(II) Federally qualified health center
4 services (as defined in paragraph (3) of such
5 section);

6 that would be described in clause (ii) if such serv-
7 ices were not furnished by an individual affiliated
8 with a rural health clinic or a Federally qualified
9 health center.”.

10 (b) EFFECTIVE DATE.—The amendments made by sub-
11 section (a) shall apply to services furnished on or after January
12 1, 2004.

13 **SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTI-**
14 **TIONERS AS ATTENDING PHYSICIANS TO**
15 **SERVE HOSPICE PATIENTS.**

16 (a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C.
17 1395x(dd)(3)(B)) is amended by inserting “or nurse practi-
18 tioner (as defined in subsection (aa)(5))” after “the physician
19 (as defined in subsection (r)(1))”.

20 (b) PROHIBITION ON NURSE PRACTITIONER CERTIFYING
21 NEED FOR HOSPICE.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C.
22 1395f(a)(7)(A)(i)(I)) is amended by inserting “(which for pur-
23 poses of this subparagraph does not include a nurse practi-
24 tioner)” after “attending physician (as defined in section
25 1861(dd)(3)(B))”.

26 **SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN**
27 **EMERGENCY CAPACITY FOR AMBULANCE**
28 **SERVICES IN RURAL AREAS.**

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

30 (1) by redesignating paragraph (8), as added by sec-
31 tion 221(a) of BIPA (114 Stat. 2763A–486), as paragraph
32 (9); and

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

34 “(10) ASSISTANCE FOR RURAL PROVIDERS FUR-
35 NISHING SERVICES IN LOW MEDICARE POPULATION DEN-
36 SITY AREAS.—



1 “(A) IN GENERAL.—In the case of ground ambu-
2 lance services furnished on or after January 1, 2004,
3 for which the transportation originates in a qualified
4 rural area (as defined in subparagraph (B)), the Sec-
5 retary shall provide for an increase in the base rate of
6 the fee schedule for mileage for a trip established under
7 this subsection. In establishing such increase, the Sec-
8 retary shall, based on the relationship of cost and vol-
9 ume, estimate the average increase in cost per trip for
10 such services as compared with the cost per trip for the
11 average ambulance service.

12 “(B) QUALIFIED RURAL AREA DEFINED.—For
13 purposes of subparagraph (A), the term ‘qualified rural
14 area’ is a rural area (as defined in section
15 1886(d)(2)(D)) with a population density of medicare
16 beneficiaries residing in the area that is in the lowest
17 three quartiles of all rural county populations.”.

18 **SEC. 411. PROVIDING SAFE HARBOR FOR CERTAIN COL-**
19 **LABORATIVE EFFORTS THAT BENEFIT MEDI-**
20 **CALLY UNDERSERVED POPULATIONS.**

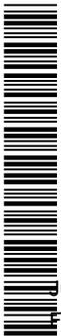
21 (a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C.
22 1320a-7(b)(3)), as amended by section 101(b)(2), is
23 amended—

24 (1) in subparagraph (F), by striking “and” after the
25 semicolon at the end;

26 (2) in subparagraph (G), by striking the period at the
27 end and inserting “; and”; and

28 (3) by adding at the end the following new subpara-
29 graph:

30 “(H) any remuneration between a public or non-
31 profit private health center entity described under
32 clause (i) or (ii) of section 1905(l)(2)(B) and any indi-
33 vidual or entity providing goods, items, services, dona-
34 tions or loans, or a combination thereof, to such health
35 center entity pursuant to a contract, lease, grant, loan,
36 or other agreement, if such agreement contributes to



1 the ability of the health center entity to maintain or in-
2 crease the availability, or enhance the quality, of serv-
3 ices provided to a medically underserved population
4 served by the health center entity.”.

5 (b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER
6 ENTITY ARRANGEMENTS.—

7 (1) ESTABLISHMENT.—

8 (A) IN GENERAL.—The Secretary of Health and
9 Human Services (in this subsection referred to as the
10 “Secretary”) shall establish, on an expedited basis,
11 standards relating to the exception described in section
12 1128B(b)(3)(H) of the Social Security Act, as added
13 by subsection (a), for health center entity arrangements
14 to the antikickback penalties.

15 (B) FACTORS TO CONSIDER.—The Secretary shall
16 consider the following factors, among others, in estab-
17 lishing standards relating to the exception for health
18 center entity arrangements under subparagraph (A):

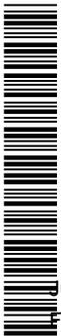
19 (i) Whether the arrangement between the
20 health center entity and the other party results in
21 savings of Federal grant funds or increased reve-
22 nues to the health center entity.

23 (ii) Whether the arrangement between the
24 health center entity and the other party restricts or
25 limits a patient’s freedom of choice.

26 (iii) Whether the arrangement between the
27 health center entity and the other party protects a
28 health care professional’s independent medical
29 judgment regarding medically appropriate treat-
30 ment.

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

34 (2) INTERIM FINAL EFFECT.—No later than 180 days
35 after the date of enactment of this Act, the Secretary shall
36 publish a rule in the Federal Register consistent with the



1 factors under paragraph (1)(B). Such rule shall be effective
2 and final immediately on an interim basis, subject to such
3 change and revision, after public notice and opportunity
4 (for a period of not more than 60 days) for public com-
5 ment, as is consistent with this subsection.

6 **SEC. 412. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN**
7 **PAYMENTS FOR PHYSICIANS' SERVICES.**

8 (a) STUDY.—The Comptroller General of the United
9 States shall conduct a study of differences in payment amounts
10 under the physician fee schedule under section 1848 of the So-
11 cial Security Act (42 U.S.C. 1395w-4) for physicians' services
12 in different geographic areas. Such study shall include—

13 (1) an assessment of the validity of the geographic ad-
14 justment factors used for each component of the fee sched-
15 ule;

16 (2) an evaluation of the measures used for such ad-
17 justment, including the frequency of revisions; and

18 (3) an evaluation of the methods used to determine
19 professional liability insurance costs used in computing the
20 malpractice component, including a review of increases in
21 professional liability insurance premiums and variation in
22 such increases by State and physician specialty and meth-
23 ods used to update the geographic cost of practice index
24 and relative weights for the malpractice component.

25 (b) REPORT.—Not later than 1 year after the date of the
26 enactment of this Act, the Comptroller General shall submit to
27 Congress a report on the study conducted under subsection (a).
28 The report shall include recommendations regarding the use of
29 more current data in computing geographic cost of practice in-
30 dices as well as the use of data directly representative of physi-
31 cians' costs (rather than proxy measures of such costs).

32 **SEC. 413. TREATMENT OF MISSING COST REPORTING**
33 **PERIODS FOR SOLE COMMUNITY HOS-**
34 **PITALS.**

35 (a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C.
36 1395ww(b)(3)(I)) is amended by adding at the end the fol-
37 lowing new clause:

1 “(iii) In no case shall a hospital be denied treatment as
2 a sole community hospital or payment (on the basis of a target
3 rate as such as a hospital) because data are unavailable for any
4 cost reporting period due to changes in ownership, changes in
5 fiscal intermediaries, or other extraordinary circumstances, so
6 long as data for at least one applicable base cost reporting pe-
7 riod is available.”.

8 (b) EFFECTIVE DATE.—The amendment made by sub-
9 section (a) shall apply to cost reporting periods beginning on
10 or after January 1, 2004.

11 **SEC. 414. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.**
12

13 Section 4207 of Balanced Budget Act of 1997 (Public
14 Law 105–33) is amended—

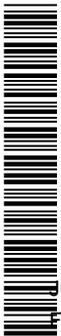
15 (1) in subsection (a)(4), by striking “4-year” and in-
16 serting “8-year”; and

17 (2) in subsection (d)(3), by striking “\$30,000,000”
18 and inserting “\$60,000,000”.

19 **SEC. 415. TWO-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.**
20

21 (a) IN GENERAL.—In the case of home health services fur-
22 nished in a rural area (as defined in section 1886(d)(2)(D) of
23 the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during
24 2004 and 2005, the Secretary shall increase the payment
25 amount otherwise made under section 1895 of such Act (42
26 U.S.C. 1395fff) for such services by 5 percent.

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



1 **TITLE V—PROVISIONS RELATING**
2 **TO PART A**
3 **Subtitle A—Inpatient Hospital**
4 **Services**

5 **SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAY-**
6 **MENT UPDATES.**

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

- 9 (1) by striking “and” at the end of subclause (XVIII);
10 (2) by striking subclause (XIX); and
11 (3) by inserting after subclause (XVIII) the following
12 new subclauses:

13 “(XIX) for each of fiscal years 2004 through 2006,
14 the market basket percentage increase minus 0.4 percent-
15 age points for hospitals in all areas; and

16 “(XX) for fiscal year 2007 and each subsequent fiscal
17 year, the market basket percentage increase for hospitals in
18 all areas.”.

19 **SEC. 502. RECOGNITION OF NEW MEDICAL TECH-**
20 **NOLOGIES UNDER INPATIENT HOSPITAL**
21 **PPS.**

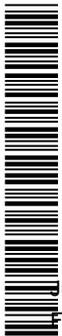
22 (a) IMPROVING TIMELINESS OF DATA COLLECTION.—Sec-
23 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended
24 by adding at the end the following new clause:

25 “(vii) Under the mechanism under this subparagraph, the
26 Secretary shall provide for the addition of new diagnosis and
27 procedure codes in April 1 of each year, but the addition of
28 such codes shall not require the Secretary to adjust the pay-
29 ment (or diagnosis-related group classification) under this sub-
30 section until the fiscal year that begins after such date.”.

31 (b) ELIGIBILITY STANDARD FOR TECHNOLOGY
32 OUTLIERS.—

33 (1) MINIMUM PERIOD FOR RECOGNITION OF NEW
34 TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C.
35 1395ww(d)(5)(K)(vi)) is amended—

36 (A) by inserting “(I)” after “(vi)”; and



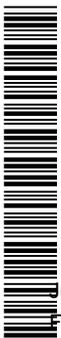
1 (B) by adding at the end the following new sub-
2 clause:

3 “(II) Under such criteria, a service or technology shall not
4 be denied treatment as a new service or technology on the basis
5 of the period of time in which the service or technology has
6 been in use if such period ends before the end of the 2-to-3-
7 year period that begins on the effective date of implementation
8 of a code under ICD-9-CM (or a successor coding method-
9 ology) that enables the identification of specific discharges in
10 which the service or technology has been used.”.

11 (2) ADJUSTMENT OF THRESHOLD.—Section
12 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is
13 amended by inserting “(applying a threshold specified by
14 the Secretary that is 75 percent of one standard deviation
15 for the diagnosis-related group involved)” after “is inad-
16 equate”.

17 (3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—
18 Section 1886(d)(5)(K)(vi) (42 U.S.C.
19 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is
20 further amended by adding at the end the following sub-
21 clause:

22 “(III) The Secretary shall by regulation provide for fur-
23 ther clarification of the criteria applied to determine whether
24 a new service or technology represents an advance in medical
25 technology that substantially improves the diagnosis or treat-
26 ment of beneficiaries. Under such criteria, in determining
27 whether a new service or technology represents an advance in
28 medical technology that substantially improves the diagnosis or
29 treatment of beneficiaries, the Secretary shall deem a service
30 or technology as meeting such requirement if the service or
31 technology is a drug or biological that is designated under sec-
32 tion 506 of the Federal Food, Drug, and Cosmetic Act, ap-
33 proved under section 314.510 or 601.41 of title 21, Code of
34 Federal Regulations, or designated for priority review when the
35 marketing application for such drug or biological was filed or
36 is a medical device for which an exemption has been granted



1 under section 520(m) of such Act, or for which priority review
2 has been provided under section 515(d)(5) of such Act. Noth-
3 ing in this subclause shall be construed as effecting the author-
4 ity of the Secretary to determine whether items and services
5 are medically necessary and appropriate under section
6 1862(a)(1).”.

7 (4) PROCESS FOR PUBLIC INPUT.—Section
8 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended
9 by paragraph (1), is amended—

10 (A) in clause (i), by adding at the end the fol-
11 lowing: “Such mechanism shall be modified to meet the
12 requirements of clause (viii).”; and

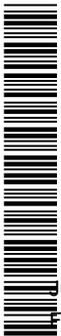
13 (B) by adding at the end the following new clause:

14 “(viii) The mechanism established pursuant to clause (i)
15 shall be adjusted to provide, before publication of a proposed
16 rule, for public input regarding whether a new service or tech-
17 nology not described in the second sentence of clause (vi)(III)
18 represents an advance in medical technology that substantially
19 improves the diagnosis or treatment of beneficiaries as follows:

20 “(I) The Secretary shall make public and periodically
21 update a list of all the services and technologies for which
22 an application for additional payment under this subpara-
23 graph is pending.

24 “(II) The Secretary shall accept comments, rec-
25 ommendations, and data from the public regarding whether
26 the service or technology represents a substantial improve-
27 ment.

28 “(III) The Secretary shall provide for a meeting at
29 which organizations representing hospitals, physicians,
30 medicare beneficiaries, manufacturers, and any other inter-
31 ested party may present comments, recommendations, and
32 data to the clinical staff of the Centers for Medicare &
33 Medicaid Services before publication of a notice of proposed
34 rulemaking regarding whether service or technology rep-
35 represents a substantial improvement.”.



1 (c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Sec-
2 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further
3 amended by adding at the end the following new clause:

4 “(ix) Before establishing any add-on payment under this
5 subparagraph with respect to a new technology, the Secretary
6 shall seek to identify one or more diagnosis-related groups as-
7 sociated with such technology, based on similar clinical or ana-
8 tomical characteristics and the cost of the technology. Within
9 such groups the Secretary shall assign an eligible new tech-
10 nology into a diagnosis-related group where the average costs
11 of care most closely approximate the costs of care of using the
12 new technology. In such case, the new technology would no
13 longer meet the threshold of exceeding 75 percent of the stand-
14 ard deviation for the diagnosis-related group involved under
15 clause (ii)(I). No add-on payment under this subparagraph
16 shall be made with respect to such new technology and this
17 clause shall not affect the application of paragraph
18 (4)(C)(iii).”.

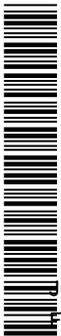
19 (d) IMPROVEMENT IN PAYMENT FOR NEW TECH-
20 NOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C.
21 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after “the
22 estimated average cost of such service or technology” the fol-
23 lowing: “(based on the marginal rate applied to costs under
24 subparagraph (A))”.

25 (e) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL
26 INPATIENT TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42
27 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking “sub-
28 ject to paragraph (4)(C)(iii).”.

29 (f) EFFECTIVE DATE.—

30 (1) IN GENERAL.—The Secretary shall implement the
31 amendments made by this section so that they apply to
32 classification for fiscal years beginning with fiscal year
33 2005.

34 (2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL
35 YEAR 2003 THAT ARE DENIED.—In the case of an applica-
36 tion for a classification of a medical service or technology



1 as a new medical service or technology under section
2 1886(d)(5)(K) of the Social Security Act (42 U.S.C.
3 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and
4 that is denied—

5 (A) the Secretary shall automatically reconsider
6 the application as an application for fiscal year 2005
7 under the amendments made by this section; and

8 (B) the maximum time period otherwise permitted
9 for such classification of the service or technology shall
10 be extended by 12 months.

11 **SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS**
12 **IN PUERTO RICO.**

13 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is
14 amended—

15 (1) in subparagraph (A)—

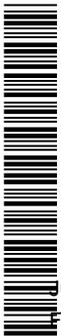
16 (A) in clause (i), by striking “for discharges begin-
17 ning on or after October 1, 1997, 50 percent (and for
18 discharges between October 1, 1987, and September
19 30, 1997, 75 percent)” and inserting “the applicable
20 Puerto Rico percentage (specified in subparagraph
21 (E))”; and

22 (B) in clause (ii), by striking “for discharges be-
23 ginning in a fiscal year beginning on or after October
24 1, 1997, 50 percent (and for discharges between Octo-
25 ber 1, 1987, and September 30, 1997, 25 percent)”
26 and inserting “the applicable Federal percentage (spec-
27 ified in subparagraph (E))”; and

28 (2) by adding at the end the following new subpara-
29 graph:

30 “(E) For purposes of subparagraph (A), for discharges
31 occurring—

32 “(i) on or after October 1, 1987, and before October
33 1, 1997, the applicable Puerto Rico percentage is 75 per-
34 cent and the applicable Federal percentage is 25 percent;



1 “(ii) on or after October 1, 1997, and before October
2 1, 2003, the applicable Puerto Rico percentage is 50 per-
3 cent and the applicable Federal percentage is 50 percent;

4 “(iii) during fiscal year 2004, the applicable Puerto
5 Rico percentage is 41 percent and the applicable Federal
6 percentage is 59 percent;

7 “(iv) during fiscal year 2005, the applicable Puerto
8 Rico percentage is 33 percent and the applicable Federal
9 percentage is 67 percent; and

10 “(v) on or after October 1, 2005, the applicable Puer-
11 to Rico percentage is 25 percent and the applicable Federal
12 percentage is 75 percent.”.

13 **SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICA-**
14 **TION REFORM .**

15 (a) IN GENERAL.—Section 1886(d) (42 U.S.C.
16 1395ww(d)) is amended by adding at the end the following:

17 “(11)(A) In order to recognize commuting patterns among
18 Metropolitan Statistical Areas and between such Areas and
19 rural areas, the Secretary shall establish a process, upon appli-
20 cation of a subsection (d) hospital that establishes that it is a
21 qualifying hospital described in subparagraph (B), for an in-
22 crease of the wage index applied under paragraph (3)(E) for
23 the hospital in the amount computed under subparagraph (D).

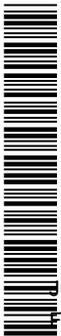
24 “(B) A qualifying hospital described in this subparagraph
25 is a subsection (d) hospital—

26 “(i) the average wages of which exceed the average
27 wages for the area in which the hospital is located; and

28 “(ii) which has at least 10 percent of its employees
29 who reside in one or more higher wage index areas.

30 “(C) For purposes of this paragraph, the term ‘higher
31 wage index area’ means, with respect to a hospital, an area
32 with a wage index that exceeds that of the area in which the
33 hospital is located.

34 “(D) The increase in the wage index under subparagraph
35 (A) for a hospital shall be equal to the percentage of the em-
36 ployees of the hospital that resides in any higher wage index



1 area multiplied by the sum of the products, for each higher
2 wage index area of—

3 “(i) the difference between (I) the wage index for such
4 area, and (II) the wage index of the area in which the hos-
5 pital is located (before the application of this paragraph);
6 and

7 “(ii) the number of employees of the hospital that re-
8 side in such higher wage index area divided by the total
9 number of such employees that reside in all high wage
10 index areas.

11 “(E) The process under this paragraph shall be based
12 upon the process used by the Medicare Geographic Classifica-
13 tion Review Board under paragraph (10) with respect to data
14 submitted by hospitals to the Board on the location of resi-
15 dence of hospital employees and wages under the applicable
16 schedule established for geographic reclassification.

17 “(F) A reclassification under this paragraph shall be effec-
18 tive for a period of 3 fiscal years, except that the Secretary
19 shall establish procedures under which a subsection (d) hospital
20 may elect to terminate such reclassification before the end of
21 such period.

22 “(G) A hospital that is reclassified under this paragraph
23 for a period is not eligible for reclassification under paragraphs
24 (8) or (10) during that period.

25 “(H) Any increase in a wage index under this paragraph
26 for a hospital shall not be taken into account for purposes of—

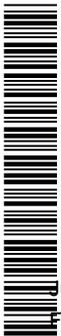
27 “(i) computing the wage index for the area in which
28 the hospital is located or any other area; or

29 “(ii) applying any budget neutrality adjustment with
30 respect to such index under paragraph (8)(D).”.

31 (b) EFFECTIVE DATE.—The amendment made by sub-
32 section (a) shall first apply to the wage index for cost reporting
33 period beginning on or after October 1, 2004.

34 **SEC. 505. MEDPAC REPORT ON SPECIALTY HOSPITALS.**

35 (a) MEDPAC STUDY.—The Medicare Payment Advisory
36 Commission shall conduct a study of specialty hospitals com-



1 pared with other similar general acute care hospitals under the
2 medicare program. Such study shall examine—

- 3 (1) whether there are excessive self-referrals;
4 (2) quality of care furnished;
5 (3) the impact of specialty hospitals on such general
6 acute care hospitals; and
7 (4) differences in the scope of services, medicaid utili-
8 zation, and uncompensated care furnished.

9 (b) REPORT.—Not later than 1 year after the date of the
10 enactment of this Act, the Secretary shall submit to Congress
11 a report on the study conducted under subsection (a), and shall
12 include any recommendations for legislation or administrative
13 change as the Secretary determines appropriate.

14 **Subtitle B—Other Provisions**

15 **SEC. 511. PAYMENT FOR COVERED SKILLED NURSING** 16 **FACILITY SERVICES.**

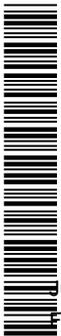
17 (a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—
18 Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is
19 amended to read as follows:

20 “(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

21 “(A) IN GENERAL.—Subject to subparagraph (B),
22 in the case of a resident of a skilled nursing facility
23 who is afflicted with acquired immune deficiency syn-
24 drome (AIDS), the per diem amount of payment other-
25 wise applicable shall be increased by 128 percent to re-
26 flect increased costs associated with such residents.

27 “(B) SUNSET.—Subparagraph (A) shall not apply
28 on and after such date as the Secretary certifies that
29 there is an appropriate adjustment in the case mix
30 under paragraph (4)(G)(i) to compensate for the in-
31 creased costs associated with residents described in
32 such subparagraph.”.

33 (b) EFFECTIVE DATE.—The amendment made by para-
34 graph (1) shall apply to services furnished on or after October
35 1, 2003.



1 **SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERV-**
2 **ICES.**

3 (a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—
4 Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

5 (1) by striking “and” at the end of paragraph (3);

6 (2) by striking the period at the end of paragraph (4)
7 and inserting “; and”; and

8 (3) by inserting after paragraph (4) the following new
9 paragraph:

10 “(5) for individuals who are terminally ill, have not
11 made an election under subsection (d)(1), and have not
12 previously received services under this paragraph, services
13 that are furnished by a physician who is either the medical
14 director or an employee of a hospice program and that con-
15 sist of—

16 “(A) an evaluation of the individual’s need for
17 pain and symptom management;

18 “(B) counseling the individual with respect to end-
19 of-life issues and care options; and

20 “(C) advising the individual regarding advanced
21 care planning.”.

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

24 “(4) The amount paid to a hospice program with respect
25 to the services under section 1812(a)(5) for which payment
26 may be made under this part shall be equal to an amount
27 equivalent to the amount established for an office or other out-
28 patient visit for evaluation and management associated with
29 presenting problems of moderate severity under the fee sched-
30 ule established under section 1848(b), other than the portion
31 of such amount attributable to the practice expense compo-
32 nent.”.

33 (c) CONFORMING AMENDMENT.—Section
34 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended
35 by inserting before the comma at the end the following: “and
36 services described in section 1812(a)(5)”.

1 (d) EFFECTIVE DATE.—The amendments made by this
2 section shall apply to services provided by a hospice program
3 on or after January 1, 2004.

4 **TITLE VI—PROVISIONS RELATING**
5 **TO PART B**
6 **Subtitle A—Physicians’ Services**

7 **SEC. 601. REVISION OF UPDATES FOR PHYSICIANS’**
8 **SERVICES.**

9 (a) UPDATE FOR 2004 AND 2005.—

10 (1) IN GENERAL.—Section 1848(d) (42 U.S.C.
11 1395w-4(d)) is amended by adding at the end the following
12 new paragraph:

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

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

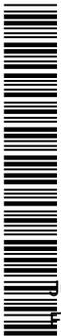
19 (3) NOT TREATED AS CHANGE IN LAW AND REGULA-
20 TION IN SUSTAINABLE GROWTH RATE DETERMINATION.—
21 The amendments made by this subsection shall not be
22 treated as a change in law for purposes of applying section
23 1848(f)(2)(D) of the Social Security Act (42 U.S.C.
24 1395w-4(f)(2)(D)).

25 (b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING
26 GROSS DOMESTIC PRODUCT.—

27 (1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C.
28 1395w-4(f)(2)(C)) is amended—

29 (A) by striking “projected” and inserting “annual
30 average”; and

31 (B) by striking “from the previous applicable pe-
32 riod to the applicable period involved” and inserting
33 “during the 10-year period ending with the applicable
34 period involved”.



1 (2) EFFECTIVE DATE.—The amendment made by
2 paragraph (1) shall apply to computations of the sustain-
3 able growth rate for years beginning with 2003.

4 **SEC. 602. STUDIES ON ACCESS TO PHYSICIANS' SERV-**
5 **ICES.**

6 (a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSI-
7 CIANS' SERVICES.—

8 (1) STUDY.—The Comptroller General of the United
9 States shall conduct a study on access of medicare bene-
10 ficiaries to physicians' services under the medicare pro-
11 gram. The study shall include—

12 (A) an assessment of the use by beneficiaries of
13 such services through an analysis of claims submitted
14 by physicians for such services under part B of the
15 medicare program;

16 (B) an examination of changes in the use by bene-
17 ficiaries of physicians' services over time;

18 (C) an examination of the extent to which physi-
19 cians are not accepting new medicare beneficiaries as
20 patients.

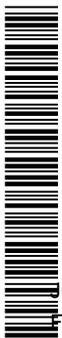
21 (2) REPORT.—Not later than 18 months after the
22 date of the enactment of this Act, the Comptroller General
23 shall submit to Congress a report on the study conducted
24 under paragraph (1). The report shall include a determina-
25 tion whether—

26 (A) data from claims submitted by physicians
27 under part B of the medicare program indicate poten-
28 tial access problems for medicare beneficiaries in cer-
29 tain geographic areas; and

30 (B) access by medicare beneficiaries to physicians'
31 services may have improved, remained constant, or de-
32 teriorated over time.

33 (b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

34 (1) STUDY.—The Secretary shall request the Institute
35 of Medicine of the National Academy of Sciences to con-
36 duct a study on the adequacy of the supply of physicians



1 (including specialists) in the United States and the factors
2 that affect such supply.

3 (2) REPORT TO CONGRESS.—Not later than 2 years
4 after the date of enactment of this section, the Secretary
5 shall submit to Congress a report on the results of the
6 study described in paragraph (1), including any rec-
7 ommendations for legislation.

8 (c) GAO STUDY OF MEDICARE PAYMENT FOR INHALA-
9 TION THERAPY.—

10 (1) STUDY.—The Comptroller General of the United
11 States shall conduct a study to examine the adequacy of
12 current reimbursements for inhalation therapy under the
13 medicare program.

14 (2) REPORT.—Not later than May 1, 2004, the Comp-
15 troller General shall submit to Congress a report on the
16 study conducted under paragraph (1).

17 **SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSI-**
18 **CIANs' SERVICES.**

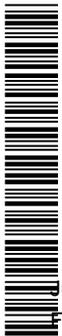
19 (a) PRACTICE EXPENSE COMPONENT.—Not later than 1
20 year after the date of the enactment of this Act, the Medicare
21 Payment Advisory Commission shall submit to Congress a re-
22 port on the effect of refinements to the practice expense compo-
23 nent of payments for physicians' services, after the transition
24 to a full resource-based payment system in 2002, under section
25 1848 of the Social Security Act (42 U.S.C. 1395w-4). Such re-
26 port shall examine the following matters by physician specialty:

27 (1) The effect of such refinements on payment for
28 physicians' services.

29 (2) The interaction of the practice expense component
30 with other components of and adjustments to payment for
31 physicians' services under such section.

32 (3) The appropriateness of the amount of compensa-
33 tion by reason of such refinements.

34 (4) The effect of such refinements on access to care
35 by medicare beneficiaries to physicians' services.



1 (5) The effect of such refinements on physician par-
2 ticipation under the medicare program.

3 (b) VOLUME OF PHYSICIAN SERVICES.—The Medicare
4 Payment Advisory Commission shall submit to Congress a re-
5 port on the extent to which increases in the volume of physi-
6 cians' services under part B of the medicare program are a re-
7 sult of care that improves the health and well-being of medicare
8 beneficiaries. The study shall include the following:

9 (1) An analysis of recent and historic growth in the
10 components that the Secretary includes under the sustain-
11 able growth rate (under section 1848(f) of the Social Secu-
12 rity Act).

13 (2) An examination of the relative growth of volume
14 in physician services between medicare beneficiaries and
15 other populations.

16 (3) An analysis of the degree to which new technology,
17 including coverage determinations of the Centers for Medi-
18 care & Medicaid Services, has affected the volume of physi-
19 cians' services.

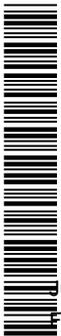
20 (4) An examination of the impact on volume of demo-
21 graphic changes.

22 (5) An examination of shifts in the site of service of
23 services that influence the number and intensity of services
24 furnished in physicians' offices and the extent to which
25 changes in reimbursement rates to other providers have af-
26 fected these changes.

27 (6) An evaluation of the extent to which the Centers
28 for Medicare & Medicaid Services takes into account the
29 impact of law and regulations on the sustainable growth
30 rate.

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

33 Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is
34 amended by striking “section 1861(r)(1)” and inserting “para-
35 graphs (1), (2), and (3) of section 1861(r)”.



1 **SEC. 605. ESTABLISHMENT OF FLOOR ON WORK GEO-**
2 **GRAPHIC ADJUSTMENT.**

3 (a) MINIMUM INDEX.—

4 (1) IN GENERAL.—Section 1848(e)(1) (42 U.S.C.
5 1395w-4(e)(1)) is amended by adding at the end the fol-
6 lowing new subparagraph:

7 “(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDI-
8 CES.—Subject to section 605(a)(2) of the Medicare
9 Prescription Drug and Modernization Act of 2003,
10 after calculating the work geographic indices in sub-
11 paragraph (A)(iii), for purposes of payment for services
12 furnished on or after January 1, 2004, and before Jan-
13 uary 1, 2006, the Secretary shall increase the work ge-
14 ographic index to 1.00 for any locality for which such
15 geographic index is less than 1.00.”.

16 (2) SECRETARIAL DISCRETION.—Section
17 1848(e)(1)(E), as added by paragraph (1) shall have no
18 force or effect in law if the Secretary determines, taking
19 into account the report of the Comptroller General under
20 subsection (b)(2), that there is no sound economic rationale
21 for the implementation of that section.

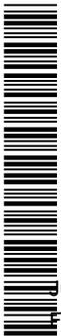
22 (b) GAO REPORT.—

23 (1) EVALUATION.—As part of the study on geographic
24 differences in payments for physicians’ services conducted
25 under section 412, the Comptroller General of the United
26 States shall evaluate the following:

27 (A) Whether there is a sound economic basis for
28 the implementation of the amendment to section
29 1848(e)(1) under subsection (a)(1) in those areas in
30 which the adjustment applies.

31 (B) The effect of such adjustment on physician lo-
32 cation and retention in areas affected by such adjust-
33 ment, taking into account—

34 (i) differences in recruitment costs and reten-
35 tion rates for physicians, including specialists, be-
36 tween large urban areas and other areas; and



1 (ii) the mobility of physicians, including spe-
2 cialists, over the last decade.

3 (C) The appropriateness of establishing a floor of
4 1.0 for the work geographic index.

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

9 **Subtitle B—Preventive Services**

10 **SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYS-** 11 **ICAL EXAMINATION.**

12 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
13 1395x(s)(2)) is amended—

14 (1) in subparagraph (U), by striking “and” at the
15 end;

16 (2) in subparagraph (V), by inserting “and” at the
17 end; and

18 (3) by adding at the end the following new subpara-
19 graph:

20 “(W) an initial preventive physical examination (as de-
21 fined in subsection (ww));”.

22 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
23 1395x) is amended by adding at the end the following new sub-
24 section:

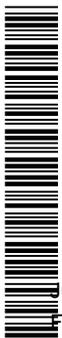
25 “Initial Preventive Physical Examination

26 “(ww) The term ‘initial preventive physical examination’
27 means physicians’ services consisting of a physical examination
28 with the goal of health promotion and disease detection and in-
29 cludes items and services (excluding clinical laboratory tests),
30 as determined by the Secretary, consistent with the rec-
31 ommendations of the United States Preventive Services Task
32 Force.”.

33 (c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

34 (1) DEDUCTIBLE.—The first sentence of section
35 1833(b) (42 U.S.C. 1395l(b)) is amended—

36 (A) by striking “and” before “(6)”, and



1 (B) by inserting before the period at the end the
2 following: “, and (7) such deductible shall not apply
3 with respect to an initial preventive physical examina-
4 tion (as defined in section 1861(wv))”.

5 (2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C.
6 1395l(a)(1)) is amended—

7 (A) in clause (N), by inserting “(or 100 percent
8 in the case of an initial preventive physical examina-
9 tion, as defined in section 1861(wv))” after “80 per-
10 cent”; and

11 (B) in clause (O), by inserting “(or 100 percent
12 in the case of an initial preventive physical examina-
13 tion, as defined in section 1861(wv))” after “80 per-
14 cent”.

15 (d) PAYMENT AS PHYSICIANS’ SERVICES.—Section
16 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by inserting
17 “(2)(W),” after “(2)(S),”.

18 (e) OTHER CONFORMING AMENDMENTS.—Section 1862(a)
19 (42 U.S.C. 1395y(a)) is amended—

20 (1) in paragraph (1)—

21 (A) by striking “and” at the end of subparagraph
22 (H);

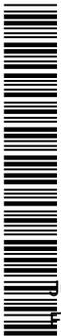
23 (B) by striking the semicolon at the end of sub-
24 paragraph (I) and inserting “, and”; and

25 (C) by adding at the end the following new sub-
26 paragraph:

27 “(J) in the case of an initial preventive physical exam-
28 ination, which is performed not later than 6 months after
29 the date the individual’s first coverage period begins under
30 part B;”; and

31 (2) in paragraph (7), by striking “or (H)” and insert-
32 ing “(H), or (J)”.

33 (f) EFFECTIVE DATE.—The amendments made by this
34 section shall apply to services furnished on or after January 1,
35 2004, but only for individuals whose coverage period begins on
36 or after such date.



1 **SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD**
2 **LIPID 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 the end;

6 (2) in subparagraph (W), by inserting “and” at the
7 end; and

8 (3) by adding at the end the following new subpara-
9 graph:

10 “(X) cholesterol and other blood lipid screening
11 tests (as defined in subsection (XX));”.

12 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
13 1395x), as amended by section 611(b), is amended by adding
14 at the end the following new subsection:

15 “Cholesterol and Other Blood Lipid Screening Test

16 “(xx)(1) The term ‘cholesterol and other blood lipid
17 screening test’ means diagnostic testing of cholesterol and other
18 lipid levels of the blood for the purpose of early detection of
19 abnormal cholesterol and other lipid levels.

20 “(2) The Secretary shall establish standards, in consulta-
21 tion with appropriate organizations, regarding the frequency
22 and type of cholesterol and other blood lipid screening tests, ex-
23 cept that such frequency may not be more often than once
24 every 2 years.”.

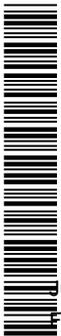
25 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
26 1395y(a)(1)), as amended by section 611(e), is amended—

27 (1) by striking “and” at the end of subparagraph (I);

28 (2) by striking the semicolon at the end of subpara-
29 graph (J) and inserting “; and”; and

30 (3) by adding at the end the following new subpara-
31 graph:

32 “(K) in the case of a cholesterol and other blood lipid
33 screening test (as defined in section 1861(xx)(1)), which is
34 performed more frequently than is covered under section
35 1861(xx)(2).”.



1 (d) EFFECTIVE DATE.—The amendments made by this
2 section shall apply to tests furnished on or after January 1,
3 2005.

4 **SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL**
5 **CANCER SCREENING TESTS.**

6 (a) IN GENERAL.—The first sentence of section 1833(b)
7 (42 U.S.C. 1395l(b)), as amended by section 611(c)(1), is
8 amended—

9 (1) by striking “and” before “(7)”; and

10 (2) by inserting before the period at the end the fol-
11 lowing: “, and (8) such deductible shall not apply with re-
12 spect to colorectal cancer screening tests (as described in
13 section 1861(pp)(1))”.

14 (b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii)
15 and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are
16 each amended—

17 (1) by striking “DEDUCTIBLE AND” in the heading;
18 and

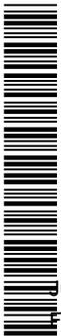
19 (2) in subclause (I), by striking “deductible or” each
20 place it appears.

21 (c) EFFECTIVE DATE.—The amendment made by this sec-
22 tion shall apply to items and services furnished on or after
23 January 1, 2004.

24 **SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
25 **RAPHY SERVICES.**

26 (a) EXCLUSION FROM OPD FEE SCHEDULE.—Section
27 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by
28 inserting before the period at the end the following: “and does
29 not include screening mammography (as defined in section
30 1861(jj)) and unilateral and bilateral diagnostic mammog-
31 raphy”.

32 (b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diag-
33 nostic mammography performed on or after January 1, 2004,
34 for which payment is made under the physician fee schedule
35 under section 1848 of the Social Security Act (42 U.S.C.
36 1395w-4), the Secretary, based on the most recent cost data



1 available, shall provide for an appropriate adjustment in the
2 payment amount for the technical component of the diagnostic
3 mammography.

4 (c) EFFECTIVE DATE.—The amendment made by sub-
5 section (a) shall apply to mammography performed on or after
6 January 1, 2004.

7 **SEC. 615. MEDICARE COVERAGE OF DIABETES LABORA-**
8 **TORY DIAGNOSTIC TESTS.**

9 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
10 1395x(s)(2)), as amended by sections 611 and 612, is
11 amended—

12 (1) in subparagraph (W), by striking “and” at the
13 end;

14 (2) in subparagraph (X), by adding “and” at the end;
15 and

16 (3) by adding at the end the following new subpara-
17 graph:

18 “(Y) diabetes screening tests and services (as defined
19 in subsection (yy));”.

20 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
21 1395x), as amended by sections 611 and 612, is further
22 amended by adding at the end the following new subsection:

23 “Diabetes Screening Tests and Services

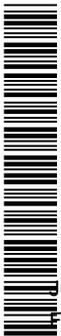
24 “(yy)(1) The term ‘diabetes screening tests’ means diag-
25 nostic testing furnished to an individual at risk for diabetes (as
26 defined in paragraph (2)) for the purpose of early detection of
27 diabetes, including—

28 “(A) a fasting plasma glucose test; and

29 “(B) such other tests, and modifications to tests, as
30 the Secretary determines appropriate, in consultation with
31 appropriate organizations.

32 “(2) For purposes of paragraph (1), the term ‘individual
33 at risk for diabetes’ means an individual who has any, a com-
34 bination of, or all of the following risk factors for diabetes:

35 “(A) A family history of diabetes.



1 “(B) Overweight defined as a body mass index greater
2 than or equal to 25 kg/m².

3 “(C) Habitual physical inactivity.

4 “(D) Belonging to a high-risk ethnic or racial group.

5 “(E) Previous identification of an elevated impaired
6 fasting glucose.

7 “(F) Identification of impaired glucose tolerance.

8 “(G) Hypertension.

9 “(H) Dyslipidemia.

10 “(I) History of gestational diabetes mellitus or delivery
11 of a baby weighing greater than 9 pounds.

12 “(J) Polycystic ovary syndrome.

13 “(3) The Secretary shall establish standards, in consulta-
14 tion with appropriate organizations, regarding the frequency of
15 diabetes screening tests, except that such frequency may not be
16 more often than twice within the 12-month period following the
17 date of the most recent diabetes screening test of that indi-
18 vidual.”.

19 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
20 1395y(a)(1)), as amended by sections 611 and 612, is
21 amended—

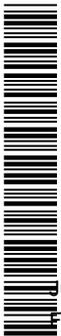
22 (1) by striking “and” at the end of subparagraph (J);

23 (2) by striking the semicolon at the end of subpara-
24 graph (K) and inserting “; and”; and

25 (3) by adding at the end the following new subpara-
26 graph:

27 “(L) in the case of a diabetes screening tests or serv-
28 ice (as defined in section 1861(yy)(1)), which is performed
29 more frequently than is covered under section
30 1861(yy)(3).”.

31 (d) EFFECTIVE DATE.—The amendments made by this
32 section shall apply to tests furnished on or after the date that
33 is 90 days after the date of enactment of this Act.



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—

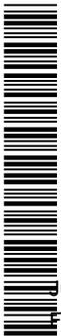
“(I) exceed 95 percent of the average wholesale price for the drug; or

“(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—



1 “(I) a radiopharmaceutical; or
 2 “(II) a drug or biological for which pay-
 3 ment was made under paragraph (6) (relating
 4 to pass-through payments) on or before Decem-
 5 ber 31, 2002.

6 “(ii) EXCEPTION.—Such term does not
 7 include—

8 “(I) a drug for which payment is first
 9 made on or after January 1, 2003, under para-
 10 graph (6); or

11 “(II) a drug for a which a temporary
 12 HCPCS code has not been assigned.

13 “(C) TRANSITION TOWARDS HISTORICAL AVERAGE
 14 ACQUISITION COST.—The transition percentage under
 15 this subparagraph for drugs furnished in a year is de-
 16 termined in accordance with the following table:

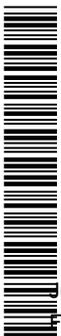
The transition percentage for—

For the year—	Single source drugs are—	Innovator mul- tiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	46%

17 “(D) PAYMENT FOR NEW DRUGS UNTIL TEM-
 18 PORARY HCPCS CODE ASSIGNED.—With respect to
 19 payment for covered OPD services that includes a cov-
 20 ered outpatient drug (as defined in 1927(k)) for a
 21 which a temporary HCPCS code has not been assigned,
 22 the amount provided for payment for such drug under
 23 the payment system under this subsection shall be
 24 equal to 95 percent of the average wholesale price for
 25 the drug.

26 “(E) CLASSES OF DRUGS.—For purposes of this
 27 paragraph, each of the following shall be treated as a
 28 separate class of drugs:

29 “(i) SOLE SOURCE DRUGS.—A sole source
 30 drug which for purposes of this paragraph means
 31 a drug or biological that is not a multiple source



1 drug (as defined in subclauses (I) and (II) of sec-
2 tion 1927(k)(7)(A)(i)) and is not a drug approved
3 under an abbreviated new drug application under
4 section 355(j) of the Federal Food, Drug, and Cos-
5 metic Act.

6 “(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—
7 Innovator multiple source drugs (as defined in sec-
8 tion 1927(k)(7)(A)(ii)).

9 “(iii) NONINNOVATOR MULTIPLE SOURCE
10 DRUGS.—Noninnovator multiple source drugs (as
11 defined in section 1927(k)(7)(A)(iii)).

12 “(F) INAPPLICABILITY OF EXPENDITURES IN DE-
13 TERMINING CONVERSION FACTORS.—Additional ex-
14 penditures resulting from this paragraph and para-
15 graph (14)(C) in a year shall not be taken into account
16 in establishing the conversion factor for that year.”.

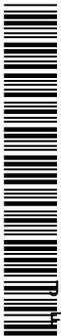
17 (2) REDUCTION IN THRESHOLD FOR SEPARATE APCS
18 FOR DRUGS.—Section 1833(t)(14), as redesignated by
19 paragraph (1)(A), is amended by adding at the end the fol-
20 lowing new subparagraph:

21 “(B) THRESHOLD FOR ESTABLISHMENT OF SEPA-
22 RATE APCS FOR DRUGS.—The Secretary shall reduce
23 the threshold for the establishment of separate ambula-
24 tory procedure classification groups (APCs) with re-
25 spect to drugs to \$50 per administration.”.

26 (3) EXCLUSION OF SEPARATE DRUG APCS FROM
27 OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by
28 adding at the end the following new subparagraph:

29 “(E) EXCLUSION OF SEPARATE DRUG APCS FROM
30 OUTLIER PAYMENTS.—No additional payment shall be
31 made under subparagraph (A) in the case of ambula-
32 tory procedure codes established separately for drugs.”.

33 (4) PAYMENT FOR PASS THROUGH DRUGS.—Clause (i)
34 of section 1833(t)(6)(D) (42 U.S.C. 1395l(t)(6)(D)) is
35 amended by inserting after “under section 1842(o)” the
36 following: “(or if the drug is covered under a competitive



1 acquisition contract under section 1847A for an area, an
2 amount determined by the Secretary equal to the average
3 price for the drug for that area and year established under
4 such section as calculated and applied by the Secretary for
5 purposes of this paragraph”.

6 (5) EFFECTIVE DATE.—The amendments made by
7 this subsection shall apply to services furnished on or after
8 January 1, 2004.

9 (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

10 (1) IN GENERAL.—Section 1833(t)(14), as so redesign-
11 ated and amended by subsection (a)(2), is amended by
12 adding at the end the following new subparagraph:

13 “(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY
14 AT CHARGES ADJUSTED TO COST.—Notwithstanding
15 the preceding provisions of this subsection, for a device
16 of brachytherapy furnished on or after January 1,
17 2004, and before January 1, 2007, the payment basis
18 for the device under this subsection shall be equal to
19 the hospital’s charges for each device furnished, ad-
20 justed to cost.”.

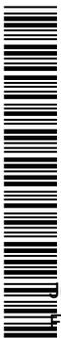
21 (2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY
22 DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2) is
23 amended—

24 (A) in subparagraph (F), by striking “and” at the
25 end;

26 (B) in subparagraph (G), by striking the period at
27 the end and inserting “; and”; and

28 (C) by adding at the end the following new sub-
29 paragraph:

30 “(H) with respect to devices of brachytherapy, the
31 Secretary shall create additional groups of covered
32 OPD services that classify such devices separately from
33 the other services (or group of services) paid for under
34 this subsection in a manner reflecting the number, iso-
35 tope, and radioactive intensity of such devices fur-



1 nished, including separate groups for palladium-103
2 and iodine-125 devices.”.

3 (3) GAO REPORT.—The Comptroller General of the
4 United States shall conduct a study to determine appro-
5 priate payment amounts under section 1833(t)(13)(B) of
6 the Social Security Act, as added by paragraph (1), for de-
7 vices of brachytherapy. Not later than January 1, 2005,
8 the Comptroller General shall submit to Congress and the
9 Secretary a report on the study conducted under this para-
10 graph, and shall include specific recommendations for ap-
11 propriate payments for such devices.

12 (c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—

13 (1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C.
14 1395l(t)(6)) is amended by adding at the end the following
15 new subparagraph:

16 “(F) LIMITATION ON APPLICATION OF FUNC-
17 TIONAL EQUIVALENCE STANDARD.—

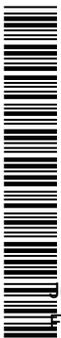
18 “(i) IN GENERAL.—The Secretary may not
19 apply a ‘functional equivalence’ or similar standard
20 to a drug or biological under this paragraph.

21 “(ii) LIMITED APPLICATION.—Clause (i) shall
22 apply to the application of a ‘functional equivalent’
23 or similar standard to a drug or biological on or
24 after the date of the enactment of this subpara-
25 graph, unless—

26 “(I) such application was being made to
27 such drug or biological before such date; and

28 “(II) the Secretary applies, or has applied,
29 such ‘functional equivalent’ or similar standard
30 to such drug or biological only for the purpose
31 of determining the eligibility of such drug or bi-
32 ological for additional payments under this
33 paragraph and not for the purpose of any other
34 payments under this title.

35 “(iii) RULE OF CONSTRUCTION.—Nothing in
36 this subparagraph shall be construed as affecting



1 the Secretary's authority to deem a particular drug
2 or biological to be identical to another drug or bio-
3 logical if the two drugs or biologicals are pharma-
4 ceutically equivalent and bioequivalent, as deter-
5 mined by the Commissioner of Food and Drugs."

6 (d) HOSPITAL ACQUISITION COST STUDY.—

7 (1) IN GENERAL.—The Secretary shall conduct a
8 study on the costs incurred by hospitals in acquiring cov-
9 ered outpatient drugs for which payment is made under
10 section 1833(t) of the Social Security Act (42 U.S.C.
11 1395l(t)).

12 (2) DRUGS COVERED.—The study in paragraph (1)
13 shall not include those drugs for which the acquisition costs
14 is less than \$50 per administration.

15 (3) REPRESENTATIVE SAMPLE OF HOSPITALS.—In
16 conducting the study under paragraph (1), the Secretary
17 shall collect data from a statistically valid sample of hos-
18 pitals with an urban/rural stratification.

19 (4) REPORT.—Not later than January 1, 2006, the
20 Secretary shall submit to Congress a report on the study
21 conducted under paragraph (1), and shall include rec-
22 ommendations with respect to the following:

23 (A) Whether the study should be repeated, and if
24 so, how frequently.

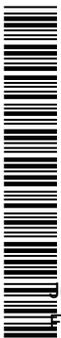
25 (B) Whether the study produced useful data on
26 hospital acquisition cost.

27 (C) Whether data produced in the study is appro-
28 priate for use in making adjustments to payments for
29 drugs and biologicals under section 1847A of the Social
30 Security Act.

31 (D) Whether separate estimates can made of over-
32 head costs, including handling and administering costs
33 for drugs.

34 **SEC. 622. PAYMENT FOR AMBULANCE SERVICES.**

35 (a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE
36 SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l)



1 (42 U.S.C. 1395m(l)), as amended by section 410(a), is
2 amended—

3 (1) in paragraph (2)(E), by inserting “consistent with
4 paragraph (11)” after “in an efficient and fair manner”;
5 and

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

7 “(11) PHASE-IN PROVIDING FLOOR USING BLEND OF
8 FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In car-
9 rying out the phase-in under paragraph (2)(E) for each
10 level of service furnished in a year, the portion of the pay-
11 ment amount that is based on the fee schedule shall be the
12 greater of the amount determined under such fee schedule
13 (without regard to this paragraph) or the following blended
14 rate of the fee schedule under paragraph (1) and of a re-
15 gional fee schedule for the region involved:

16 “(A) For 2004, the blended rate shall be based 20
17 percent on the fee schedule under paragraph (1) and
18 80 percent on the regional fee schedule.

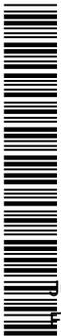
19 “(B) For 2005, the blended rate shall be based 40
20 percent on the fee schedule under paragraph (1) and
21 60 percent on the regional fee schedule.

22 “(C) For 2006, the blended rate shall be based 60
23 percent on the fee schedule under paragraph (1) and
24 40 percent on the regional fee schedule.

25 “(D) For 2007, 2008, and 2009, the blended rate
26 shall be based 80 percent on the fee schedule under
27 paragraph (1) and 20 percent on the regional fee
28 schedule.

29 “(E) For 2010 and each succeeding year, the
30 blended rate shall be based 100 percent on the fee
31 schedule under paragraph (1).

32 For purposes of this paragraph, the Secretary shall estab-
33 lish a regional fee schedule for each of the 9 Census divi-
34 sions using the methodology (used in establishing the fee
35 schedule under paragraph (1)) to calculate a regional con-
36 version factor and a regional mileage payment rate and



1 using the same payment adjustments and the same relative
2 value units as used in the fee schedule under such para-
3 graph.”.

4 (b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
5 TRIPS.—Section 1834(l), as amended by subsection (a), is fur-
6 ther amended by adding at the end the following new para-
7 graph:

8 “(12) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
9 TRIPS.—In the case of ground ambulance services fur-
10 nished on or after January 1, 2004, and before January 1,
11 2009, regardless of where the transportation originates, the
12 fee schedule established under this subsection shall provide
13 that, with respect to the payment rate for mileage for a
14 trip above 50 miles the per mile rate otherwise established
15 shall be increased by $\frac{1}{4}$ of the payment per mile otherwise
16 applicable to such miles.”.

17 (c) GAO REPORT ON COSTS AND ACCESS.—Not later than
18 December 31, 2005, the Comptroller General of the United
19 States shall submit to Congress an initial report on how costs
20 differ among the types of ambulance providers and on access,
21 supply, and quality of ambulance services in those regions and
22 States that have a reduction in payment under the medicare
23 ambulance fee schedule (under section 1834(l) of the Social Se-
24 curity Act, as amended by this section). Not later than Decem-
25 ber 31, 2007, the Comptroller General shall submit to Congress
26 a final report on such access and supply.

27 (d) EFFECTIVE DATE.—The amendments made by this
28 section shall apply to ambulance services furnished on or after
29 January 1, 2004.

30 **SEC. 623. RENAL DIALYSIS SERVICES.**

31 (a) DEMONSTRATION OF ALTERNATIVE DELIVERY MOD-
32 ELS.—

33 (1) USE OF ADVISORY BOARD.—In carrying out the
34 demonstration project relating to improving care for people
35 with end-stage renal disease through alternative delivery
36 models (as published in the Federal Register of June 4,



1 2003), the Secretary shall establish an advisory board com-
2 prised of representatives described in paragraph (2) to pro-
3 vide advice and recommendations with respect to the estab-
4 lishment and operation of such demonstration project.

5 (2) REPRESENTATIVES.—Representatives referred to
6 in paragraph (1) include representatives of the following:

7 (A) Patient organizations.

8 (B) Clinicians.

9 (C) The medicare payment advisory commission,
10 established under section 1805 of the Social Security
11 Act (42 U.S.C. 1395b–6).

12 (D) The National Kidney Foundation.

13 (E) The National Institute of Diabetes and Diges-
14 tive and Kidney Diseases of National Institutes of
15 Health.

16 (F) End-stage renal disease networks.

17 (G) Medicare contractors to monitor quality of
18 care.

19 (I) providers of services and renal dialysis facilities
20 furnishing end-stage renal disease services.

21 (J) Economists.

22 (K) Researchers.

23 (b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDI-
24 ATRIC FACILITIES.—

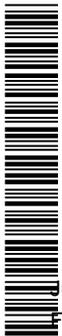
25 (1) IN GENERAL.—Section 422(a)(2) of BIPA is
26 amended—

27 (A) in subparagraph (A), by striking “and (C)”
28 and inserting “, (C), and (D)”;

29 (B) in subparagraph (B), by striking “In the
30 case” and inserting “Subject to subparagraph (D), in
31 the case”; and

32 (C) by adding at the end the following new sub-
33 paragraph:

34 “(D) INAPPLICABILITY TO PEDIATRIC FACILI-
35 TIES.—Subparagraphs (A) and (B) shall not apply, as
36 of October 1, 2002, to pediatric facilities that do not



1 have an exception rate described in subparagraph (C)
2 in effect on such date. For purposes of this subpara-
3 graph, the term ‘pediatric facility’ means a renal facil-
4 ity at least 50 percent of whose patients are individuals
5 under 18 years of age.”.

6 (2) CONFORMING AMENDMENT.—The fourth sentence
7 of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amend-
8 ed by subsection (b), is further amended by striking
9 “Until” and inserting “Subject to section 422(a)(2) of the
10 Medicare, Medicaid, and SCHIP Benefits Improvement and
11 Protection Act of 2000, and until”.

12 (c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR
13 SERVICES FURNISHED IN 2004.—Notwithstanding any other
14 provision of law, with respect to payment under part B of title
15 XVIII of the Social Security Act for renal dialysis services fur-
16 nished in 2004, the composite payment rate otherwise estab-
17 lished under section 1881(b)(7) of such Act (42 U.S.C.
18 1395rr(b)(7)) shall be increased by 1.6 percent.

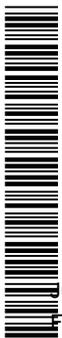
19 **SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS;
20 PROVISIONS RELATING TO REPORTS.**

21 (a) 1-YEAR MORATORIUM ON THERAPY CAPS.—Section
22 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking
23 “and 2002” and inserting “2002, and 2004”.

24 (b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAY-
25 MENT AND UTILIZATION OF OUTPATIENT THERAPY SERV-
26 ICES.—Not later than December 31, 2003, the Secretary shall
27 submit to Congress the reports required under section
28 4541(d)(2) of the Balanced Budget Act of 1997 (relating to al-
29 ternatives to a single annual dollar cap on outpatient therapy)
30 and under section 221(d) of the Medicare, Medicaid, and
31 SCHIP Balanced Budget Refinement Act of 1999 (relating to
32 utilization patterns for outpatient therapy).

33 (c) IDENTIFICATION OF CONDITIONS AND DISEASES JUS-
34 TIFYING WAIVER OF THERAPY CAP.—

35 (1) STUDY.—The Secretary shall request the Institute
36 of Medicine of the National Academy of Sciences to identify



1 conditions or diseases that should justify conducting an as-
2 sessment of the need to waive the therapy caps under sec-
3 tion 1833(g)(4) of the Social Security Act (42 U.S.C.
4 1395l(g)(4)).

5 (2) REPORTS TO CONGRESS.—

6 (A) PRELIMINARY REPORT.—Not later than July
7 1, 2004, the Secretary shall submit to Congress a pre-
8 liminary report on the conditions and diseases identi-
9 fied under paragraph (1).

10 (B) FINAL REPORT.—Not later than September 1,
11 2004, the Secretary shall submit to Congress a final re-
12 port on such conditions and diseases.

13 (C) RECOMMENDATIONS.—Not later than October
14 1, 2004, the Secretary shall submit to Congress a rec-
15 ommendation of criteria, with respect to such condi-
16 tions and disease, under which a waiver of the therapy
17 caps would apply.

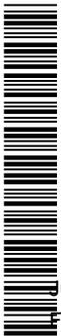
18 (d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL
19 THERAPIST SERVICES.—

20 (1) STUDY.—The Comptroller General of the United
21 States shall conduct a study on access to physical therapist
22 services in States authorizing such services without a physi-
23 cian referral and in States that require such a physician re-
24 ferral. The study shall—

25 (A) examine the use of and referral patterns for
26 physical therapist services for patients age 50 and older
27 in States that authorize such services without a physi-
28 cian referral and in States that require such a physi-
29 cian referral;

30 (B) examine the use of and referral patterns for
31 physical therapist services for patients who are medi-
32 care beneficiaries;

33 (C) examine the potential effect of prohibiting a
34 physician from referring patients to physical therapy
35 services owned by the physician and provided in the
36 physician's office;



1 (D) examine the delivery of physical therapists'
2 services within the facilities of Department of Defense;
3 and

4 (E) analyze the potential impact on medicare
5 beneficiaries and on expenditures under the medicare
6 program of eliminating the need for a physician refer-
7 ral and physician certification for physical therapist
8 services under the medicare program.

9 (2) REPORT.—The Comptroller General shall submit
10 to Congress a report on the study conducted under para-
11 graph (1) by not later than 1 year after the date of the
12 enactment of this Act.

13 **SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES**
14 **FURNISHED IN AMBULATORY SURGICAL**
15 **CENTERS.**

16 Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is
17 amended in the last sentence by inserting “and each of fiscal
18 years 2004 through 2008” after “In each of the fiscal years
19 1998 through 2002”.

20 **SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS**
21 **UNDER THE FEE SCHEDULE FOR ORTHOTICS**
22 **AND PROSTHETICS.**

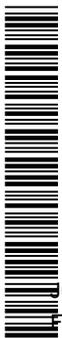
23 (a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o))
24 is amended—

25 (1) in paragraph (1), by striking “no more than the
26 limits established under paragraph (2)” and inserting “no
27 more than the amount of payment applicable under para-
28 graph (2)”; and

29 (2) in paragraph (2), to read as follows:

30 “(2)(A) Except as provided by the Secretary under sub-
31 paragraphs (B) and (C), the amount of payment under this
32 paragraph for custom molded shoes, extra depth shoes, and in-
33 serts shall be the amount determined for such items by the
34 Secretary under section 1834(h).

35 “(B) The Secretary or a carrier may establish payment
36 amounts for shoes and inserts that are lower than the amount
37 established under section 1834(h) if the Secretary finds that



1 shoes and inserts of an appropriate quality are readily available
2 at or below the amount established under such section.

3 “(C) In accordance with procedures established by the
4 Secretary, an individual entitled to benefits with respect to
5 shoes described in section 1861(s)(12) may substitute modifica-
6 tion of such shoes instead of obtaining one (or more, as speci-
7 fied by the Secretary) pair of inserts (other than the original
8 pair of inserts with respect to such shoes). In such case, the
9 Secretary shall substitute, for the payment amount established
10 under section 1834(h), a payment amount that the Secretary
11 estimates will assure that there is no net increase in expendi-
12 tures under this subsection as a result of this subparagraph.”.

13 (b) CONFORMING AMENDMENTS.—(1) Section
14 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by in-
15 serting “(and includes shoes described in section 1861(s)(12))”
16 after “in section 1861(s)(9)”.

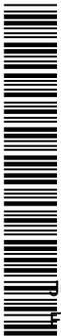
17 (2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amend-
18 ed by striking subparagraph (C).

19 (c) EFFECTIVE DATE.—The amendments made by this
20 section shall apply to items furnished on or after January 1,
21 2004.

22 **SEC. 627. WAIVER OF PART B LATE ENROLLMENT PEN-**
23 **ALTY FOR CERTAIN MILITARY RETIREES;**
24 **SPECIAL ENROLLMENT PERIOD.**

25 (a) WAIVER OF PENALTY.—

26 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.
27 1395r(b)) is amended by adding at the end the following
28 new sentence: “No increase in the premium shall be ef-
29 fected for a month in the case of an individual who is 65
30 years of age or older, who enrolls under this part during
31 2001, 2002, 2003, or 2004 and who demonstrates to the
32 Secretary before December 31, 2004, that the individual is
33 a covered beneficiary (as defined in section 1072(5) of title
34 10, United States Code). The Secretary of Health and
35 Human Services shall consult with the Secretary of De-



1 fense in identifying individuals described in the previous
2 sentence.”.

3 (2) EFFECTIVE DATE.—The amendment made by
4 paragraph (1) shall apply to premiums for months begin-
5 ning with January 2003. The Secretary of Health and
6 Human Services shall establish a method for providing re-
7 bates of premium penalties paid for months on or after
8 January 2004 for which a penalty does not apply under
9 such amendment but for which a penalty was previously
10 collected.

11 (b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

12 (1) IN GENERAL.—In the case of any individual who,
13 as of the date of the enactment of this Act, is 65 years of
14 age or older, is eligible to enroll but is not enrolled under
15 part B of title XVIII of the Social Security Act, and is a
16 covered beneficiary (as defined in section 1072(5) of title
17 10, United States Code), the Secretary of Health and
18 Human Services shall provide for a special enrollment pe-
19 riod during which the individual may enroll under such
20 part. Such period shall begin as soon as possible after the
21 date of the enactment of this Act and shall end on Decem-
22 ber 31, 2004.

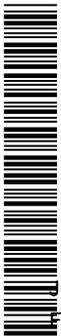
23 (2) COVERAGE PERIOD.—In the case of an individual
24 who enrolls during the special enrollment period provided
25 under paragraph (1), the coverage period under part B of
26 title XVIII of the Social Security Act shall begin on the
27 first day of the month following the month in which the in-
28 dividual enrolls.

29 **SEC. 628. PART B DEDUCTIBLE.**

30 Section 1833(b) (42 U.S.C. 1395l(b)) is amended—

31 (1) by striking “1991 and” and inserting “1991,”;
32 and

33 (2) by striking “and subsequent years” and inserting
34 “and each subsequent year through 2003, and for a subse-
35 quent year after 2003 the amount of such deductible for
36 the previous year increased by the annual percentage in-



1 crease in the monthly actuarial rate under section
2 1839(a)(1) ending with such subsequent year (rounded to
3 the nearest \$1)".

4 **SEC. 629. DEMONSTRATION PROJECT FOR COVERAGE**
5 **OF SELF-INJECTED BIOLOGICS FOR RHEU-**
6 **MATOID ARTHRITIS.**

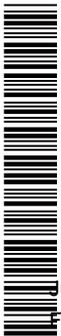
7 (a) DEMONSTRATION PROJECT.—The Secretary shall con-
8 duct a demonstration project under part B of title XVIII of the
9 Social Security Act under which payment is made for self-in-
10 jected biologics (approved by the Food and Drug Administra-
11 tion) prescribed for the treatment of rheumatoid arthritis that
12 are prescribed as replacements for drugs and biologicals de-
13 scribed in section 1861(s)(2)(A) of such Act (42 U.S.C.
14 1395x(s)(2)(A)) for which payment is made under such part.

15 (b) DEMONSTRATION PROJECT SITES.—The project estab-
16 lished under this section shall be conducted in 3 States selected
17 by the Secretary.

18 (c) DURATION.—The Secretary shall conduct the dem-
19 onstration project for the 2-year period beginning on the date
20 that is 90 days after the date of the enactment of this Act.

21 (d) REPORT.—(1) Not later than January 1, 2006, the
22 Secretary shall submit to Congress a report on the project. The
23 report shall include an evaluation of patient access to care and
24 patient outcomes under the project, as well as an analysis of
25 the cost effectiveness of the project, including an evaluation of
26 the costs savings (if any) to the medicare program attributable
27 to reduced physicians' services and hospital outpatient depart-
28 ments services for administration of the biological.

29 (2) The Secretary may use findings from the report under
30 paragraph (1) in determining appropriate settings for the ad-
31 ministration of biologics (approved by the Food and Drug Ad-
32 ministration) prescribed for medicare beneficiaries for the
33 treatment of rheumatoid arthritis.



1 **TITLE VII—PROVISIONS RELATING**
2 **TO PARTS A AND B**
3 **Subtitle A—Home Health Services**

4 **SEC. 701. UPDATE IN HOME HEALTH SERVICES.**

5 (a) CHANGE TO CALENDER YEAR UPDATE.—

6 (1) IN GENERAL.—Section 1895(b) (42 U.S.C.
7 1395fff(b)(3)) is amended—

8 (A) in paragraph (3)(B)(i)—

9 (i) by striking “each fiscal year (beginning
10 with fiscal year 2002)” and inserting “fiscal year
11 2002 and for fiscal year 2003 and for each subse-
12 quent year (beginning with 2004)”; and

13 (ii) by inserting “or year” after “the fiscal
14 year”;

15 (B) in paragraph (3)(B)(ii)(II), by striking “any
16 subsequent fiscal year” and inserting “2004 and any
17 subsequent year”;

18 (C) in paragraph (3)(B)(iii), by inserting “or
19 year” after “fiscal year” each place it appears;

20 (D) in paragraph (3)(B)(iv)—

21 (i) by inserting “or year” after “fiscal year”
22 each place it appears; and

23 (ii) by inserting “or years” after “fiscal
24 years”; and

25 (E) in paragraph (5), by inserting “or year” after
26 “fiscal year”.

27 (2) TRANSITION RULE.—The standard prospective
28 payment amount (or amounts) under section 1895(b)(3) of
29 the Social Security Act for the calendar quarter beginning
30 on October 1, 2003, shall be such amount (or amounts) for
31 the previous calendar quarter.

32 (b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—
33 Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as
34 amended by subsection (a)(1)(B), is amended—

35 (1) by striking “or” at the end of subclause (I);

36 (2) by redesignating subclause (II) as subclause (III);

1 (3) in subclause (III), as so redesignated, by striking
2 “2004” and inserting “2007”; and

3 (4) by inserting after subclause (I) the following new
4 subclause:

5 “(II) each of 2004, 2005, and 2006 the
6 home health market basket percentage increase
7 minus 0.4 percentage points; or”.

8 **SEC. 702. MEDPAC STUDY ON MEDICARE MARGINS OF**
9 **HOME HEALTH AGENCIES.**

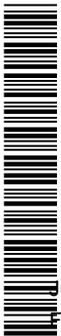
10 (a) STUDY.—The Medicare Payment Advisory Commission
11 shall conduct a study of payment margins of home health agen-
12 cies under the home health prospective payment system under
13 section 1895 of the Social Security Act (42 U.S.C. 1395fff).
14 Such study shall examine whether systematic differences in
15 payment margins are related to differences in case mix (as
16 measured by home health resource groups (HHRGs)) among
17 such agencies. The study shall use the partial or full-year cost
18 reports filed by home health agencies.

19 (b) REPORT.—Not later than 2 years after the date of the
20 enactment of this Act, the Commission shall submit to Con-
21 gress a report on the study under subsection (a).

22 **SEC. 703. DEMONSTRATION PROJECT TO CLARIFY THE**
23 **DEFINITION OF HOMEBOUND.**

24 (a) DEMONSTRATION PROJECT.—Not later than 180 days
25 after the date of the enactment of this Act, the Secretary shall
26 conduct a two-year demonstration project under part B of title
27 XVIII of the Social Security Act under which medicare bene-
28 ficiaries with chronic conditions described in subsection (b) are
29 deemed to be homebound for purposes of receiving home health
30 services under the medicare program.

31 (b) MEDICARE BENEFICIARY DESCRIBED.—For purposes
32 of subsection (a), a medicare beneficiary is eligible to be
33 deemed to be homebound, without regard to the purpose, fre-
34 quency, or duration of absences from the home, if the
35 beneficiary—



1 (1) has been certified by one physician as an indi-
2 vidual who has a permanent and severe condition that will
3 not improve;

4 (2) requires the individual to receive assistance from
5 another individual with at least 3 out of the 5 activities of
6 daily living for the rest of the individual's life;

7 (3) requires 1 or more home health services to achieve
8 a functional condition that gives the individual the ability
9 to leave home; and

10 (4) requires technological assistance or the assistance
11 of another person to leave the home.

12 (c) DEMONSTRATION PROJECT SITES.—The demonstra-
13 tion project established under this section shall be conducted in
14 3 States selected by the Secretary to represent the Northeast,
15 Midwest, and Western regions of the United States.

16 (d) LIMITATION ON NUMBER OF PARTICIPANTS.—The ag-
17 gregate number of such beneficiaries that may participate in
18 the project may not exceed 15,000.

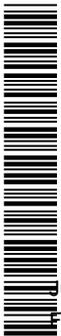
19 (e) DATA.—The Secretary shall collect such data on the
20 demonstration project with respect to the provision of home
21 health services to medicare beneficiaries that relates to quality
22 of care, patient outcomes, and additional costs, if any, to the
23 medicare program.

24 (f) REPORT TO CONGRESS.—Not later than 1 year after
25 the date of the completion of the demonstration project under
26 this section, the Secretary shall submit to Congress a report on
27 the project using the data collected under subsection (e) and
28 shall include—

29 (1) an examination of whether the provision of home
30 health services to medicare beneficiaries under the
31 project—

32 (A) adversely effects the provision of home health
33 services under the medicare program; or

34 (B) directly causes an unreasonable increase of ex-
35 penditures under the medicare program for the provi-



1 sion of such services that is directly attributable to
2 such clarification;

3 (2) the specific data evidencing the amount of any in-
4 crease in expenditures that is a directly attributable to the
5 demonstration project (expressed both in absolute dollar
6 terms and as a percentage) above expenditures that would
7 otherwise have been incurred for home health services
8 under the medicare program; and

9 (3) specific recommendations to exempt permanently
10 and severely disabled homebound beneficiaries from restric-
11 tions on the length, frequency and purpose of their ab-
12 sences from the home to qualify for home health services
13 without incurring additional unreasonable costs to the
14 medicare program.

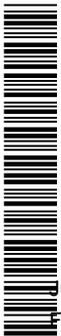
15 (g) WAIVER AUTHORITY.—The Secretary shall waive com-
16 pliance with the requirements of title XVIII of the Social Secu-
17 rity Act (42 U.S.C. 1395 et seq.) to such extent and for such
18 period as the Secretary determines is necessary to conduct
19 demonstration projects.

20 (h) CONSTRUCTION.—Nothing in this section shall be con-
21 strued as waiving any applicable civil monetary penalty, crimi-
22 nal penalty, or other remedy available to the Secretary under
23 title XI or title XVIII of the Social Security Act for acts pro-
24 hibited under such titles, including penalties for false certifi-
25 cations for purposes of receipt of items or services under the
26 medicare program.

27 (i) AUTHORIZATION OF APPROPRIATIONS.—Payments for
28 the costs of carrying out the demonstration project under this
29 section shall be made from the Federal Supplementary Insur-
30 ance Trust Fund under section 1841 of such Act (42 U.S.C.
31 1395t).

32 (j) DEFINITIONS.—In this section:

33 (1) MEDICARE BENEFICIARY.—The term “medicare
34 beneficiary” means an individual who is enrolled under part
35 B of title XVIII of the Social Security Act.



1 (2) HOME HEALTH SERVICES.—The term “home
2 health services” has the meaning given such term in section
3 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

4 (3) ACTIVITIES OF DAILY LIVING DEFINED.—The
5 term “activities of daily living” means eating, toileting,
6 transferring, bathing, and dressing.

7 (4) SECRETARY.—The term “Secretary” means the
8 Secretary of Health and Human Services.

9 **Subtitle B—Direct Graduate Medical** 10 **Education**

11 **SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH** 12 **COST PROGRAMS.**

13 Section 1886(h)(2)(D)(iv) (42 U.S.C.
14 1395ww(h)(2)(D)(iv)) is amended—

15 (1) in subclause (I)—

16 (A) by inserting “AND 2004 THROUGH 2013” after
17 “AND 2002”; and

18 (B) by inserting “or during the period beginning
19 with fiscal year 2004 and ending with fiscal year 2013”
20 after “during fiscal year 2001 or fiscal year 2002”;
21 and

22 (2) in subclause (II)—

23 (A) by striking “fiscal year 2004, or fiscal year
24 2005,” and

25 (B) by striking “For a” and inserting “For the”.

26 **Subtitle C—Chronic Care** 27 **Improvement**

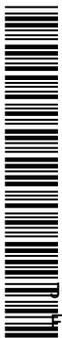
28 **SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT** 29 **UNDER TRADITIONAL FEE-FOR-SERVICE.**

30 Title XVIII, as amended by section 105(a), is amended by
31 inserting after section 1807 the following new section:

32 “CHRONIC CARE IMPROVEMENT

33 “SEC. 1808. (a) IN GENERAL.—

34 “(1) IN GENERAL.—The Secretary shall establish a
35 process for providing chronic care improvement programs
36 in each CCLIA region for medicare beneficiaries who are not



1 enrolled under part C or E and who have certain chronic
2 conditions, such as congestive heart failure, diabetes,
3 chronic obstructive pulmonary disease (COPD), stroke,
4 prostate and colon cancer, hypertension, or other disease as
5 identified by the Secretary as appropriate for chronic care
6 improvement. Such a process shall begin to be implemented
7 no later than 1 year after the date of the enactment of this
8 section.

9 “(2) TERMINOLOGY.—For purposes of this section:

10 “(A) CCLA REGION.—The term ‘CCLA region’
11 means a chronic care improvement administrative re-
12 gion delineated under subsection (b)(2).

13 “(B) CHRONIC CARE IMPROVEMENT PROGRAM.—
14 The terms ‘chronic care improvement program’ and
15 ‘program’ means such a program provided by a con-
16 tractor under this section.

17 “(C) CONTRACTOR.—The term ‘contractor’ means
18 an entity with a contract to provide a chronic care im-
19 provement program in a CCLA region under this sec-
20 tion.

21 “(D) INDIVIDUAL PLAN.—The term ‘individual
22 plan’ means a chronic care improvement plan estab-
23 lished under subsection (e)(5) for an individual.

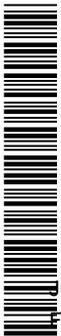
24 “(3) CONSTRUCTION.—Nothing in this section shall be
25 construed as expanding the amount, duration, or scope of
26 benefits under this title.

27 “(b) COMPETITIVE BIDDING PROCESS.—

28 “(1) IN GENERAL.—Under this section the Secretary
29 shall award contracts to qualified entities for chronic care
30 improvement programs for each CCLA region under this
31 section through a competitive bidding process.

32 “(2) PROCESS.—Under such process—

33 “(A) the Secretary shall delineate the United
34 States into multiple chronic care improvement adminis-
35 trative regions; and



1 “(B) the Secretary shall select at least 2 winning
2 bidders in each CCLIA region on the basis of the ability
3 of each bidder to carry out a chronic care improvement
4 program in accordance with this section, in order to
5 achieve improved health and financial outcomes.

6 “(3) ELIGIBLE CONTRACTOR.—A contractor may be a
7 disease improvement organization, health insurer, provider
8 organization, a group of physicians, or any other legal enti-
9 ty that the Secretary determines appropriate.

10 “(c) CHRONIC CARE IMPROVEMENT PROGRAMS.—

11 “(1) IN GENERAL.—Each contract under this section
12 shall provide for the operation of a chronic care improve-
13 ment program by a contractor in a CCLIA region consistent
14 with this subsection.

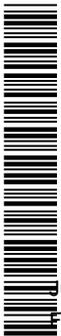
15 “(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PAR-
16 TICIPANTS.—Each contractor shall have a method for iden-
17 tifying medicare beneficiaries in the region to whom it will
18 offer services under its program. The contractor shall iden-
19 tify such beneficiaries through claims or other data and
20 other means permitted consistent with applicable disclosure
21 provisions.

22 “(3) INITIAL CONTACT BY SECRETARY.—The Sec-
23 retary shall communicate with each beneficiary identified
24 under paragraph (2) as a prospective participant in one or
25 more programs concerning participation in a program.
26 Such communication may be made by the Secretary (or on
27 behalf of the Secretary) and shall include information on
28 the following:

29 “(A) A description of the advantages to the bene-
30 ficiary in participating in a program.

31 “(B) Notification that the contractor offering a
32 program may contact the beneficiary directly con-
33 cerning such participation.

34 “(C) Notification that participation in a program
35 is voluntary.



1 “(D) A description of the method for the bene-
2 ficiary to select the single program in which the bene-
3 ficiary wishes to participate and for declining to partici-
4 pate and a method for obtaining additional information
5 concerning such participation.

6 “(4) PARTICIPATION.—A medicare beneficiary may
7 participate in only one program under this section and may
8 terminate participation at any time in a manner specified
9 by the Secretary.

10 “(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT
11 PLANS.—

12 “(A) IN GENERAL.—For each beneficiary partici-
13 pating in a program of a contractor under this section,
14 the contractor shall develop with the beneficiary an in-
15 dividualized, goal-oriented chronic care improvement
16 plan.

17 “(B) ELEMENTS OF INDIVIDUAL PLAN.—Each in-
18 dividual plan developed under subparagraph (A) shall
19 include a single point of contact to coordinate care and
20 the following, as appropriate:

21 “(i) Self-improvement education for the bene-
22 ficiary (such as education for disease management
23 through medical nutrition therapy) and support
24 education for health care providers, primary care-
25 givers, and family members.

26 “(ii) Coordination of health care services, such
27 as application of a prescription drug regimen and
28 home health services.

29 “(iii) Collaboration with physicians and other
30 providers to enhance communication of relevant
31 clinical information.

32 “(iv) The use of monitoring technologies that
33 enable patient guidance through the exchange of
34 pertinent clinical information, such as vital signs,
35 symptomatic information, and health self-assess-
36 ment.



1 “(v) The provision of information about hos-
2 pice care, pain and palliative care, and end-of-life
3 care.

4 “(C) CONTRACTOR RESPONSIBILITIES.—In estab-
5 lishing and carrying out individual plans under a pro-
6 gram, a contractor shall, directly or through
7 subcontractors—

8 “(i) guide participants in managing their
9 health, including all their co-morbidities, and in
10 performing activities as specified under the ele-
11 ments of the plan;

12 “(ii) use decision support tools such as evi-
13 dence-based practice guidelines or other criteria as
14 determined by the Secretary; and

15 “(iii) develop a clinical information database
16 to track and monitor each participant across set-
17 tings and to evaluate outcomes.

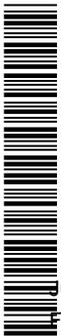
18 “(6) ADDITIONAL REQUIREMENTS.—The Secretary
19 may establish additional requirements for programs and
20 contractors under this section.

21 “(7) ACCREDITATION.—The Secretary may provide
22 that programs that are accredited by qualified organiza-
23 tions may be deemed to meet such requirements under this
24 section as the Secretary may specify.

25 “(c) CONTRACT TERMS.—

26 “(1) IN GENERAL.—A contract under this section shall
27 contain such terms and conditions as the Secretary may
28 specify consistent with this section. The Secretary may not
29 enter into a contract with an entity under this section un-
30 less the entity meets such clinical, quality improvement, fi-
31 nancial, and other requirements as the Secretary deems to
32 be appropriate for the population to be served.

33 “(2) USE OF SUBCONTRACTORS PERMITTED.—A con-
34 tractor may carry out a program directly or through con-
35 tracts with subcontractors.



1 “(3) BUDGET NEUTRAL PAYMENT CONDITION.—In entering into a contract with an entity under this subsection, the Secretary shall establish payment rates that assure that there will be no net aggregate increase in payments under this title over any period of 3 years or longer, as agreed to by the Secretary. Under this section, the Secretary shall assure that medicare program outlays plus administrative expenses (that would not have been paid under this title without implementation of this section), including contractor fees, shall not exceed the expenditures that would have been incurred under this title for a comparable population in the absence of the program under this section for the 3-year contract period.

14 “(4) AT RISK RELATIONSHIP.—For purposes of section 1128B(b)(3)(F), a contract under this section shall be treated as a risk-sharing arrangement referred to in such section.

18 “(5) PERFORMANCE STANDARDS.—Payment to contractors under this section shall be subject to the contractor’s meeting of clinical and financial performance standards set by the Secretary.

22 “(6) CONTRACTOR OUTCOMES REPORT.—Each contractor offering a program shall monitor and report to the Secretary, in a manner specified by the Secretary, the quality of care and efficacy of such program in terms of—

26 “(A) process measures, such as reductions in errors of treatment and rehospitalization rates;

28 “(B) beneficiary and provider satisfaction;

29 “(C) health outcomes; and

30 “(D) financial outcomes.

31 “(7) PHASED IN IMPLEMENTATION.—Nothing in this section shall be construed as preventing the Secretary from phasing in the implementation of programs.

34 “(d) BIENNIAL OUTCOMES REPORTS.—The Secretary shall submit to the Congress biennial reports on the implemen-

1 tation of this section. Each such report shall include informa-
2 tion on—

3 “(1) the scope of implementation (in terms of both re-
4 gions and chronic conditions);

5 “(2) program design; and

6 “(3) improvements in health outcomes and financial
7 efficiencies that result from such implementation.

8 “(e) CLINICAL TRIALS.—The Secretary shall conduct ran-
9 domized clinical trials, that compare program participants with
10 medicare beneficiaries who are offered, but decline, to partici-
11 pate, in order to assess the potential of programs to—

12 “(1) reduce costs under this title; and

13 “(2) improve health outcomes under this title.

14 “(f) AUTHORIZATION OF APPROPRIATIONS.—There are
15 authorized to be appropriated to the Secretary, in appropriate
16 part from the Hospital Insurance Trust Fund and the Supple-
17 mentary Medical Insurance Trust Fund, such sums as may be
18 necessary to provide for contracts with chronic care improve-
19 ment programs under this section.

20 “(g) LIMITATION ON FUNDING.—In no case shall the
21 funding under this section exceed \$100,000,000 over a period
22 of 3 years.”.

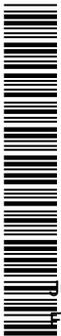
23 **SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDI-**
24 **CARE ADVANTAGE AND ENHANCED FEE-FOR-**
25 **SERVICE PROGRAMS.**

26 (a) UNDER MEDICARE ADVANTAGE PROGRAM.—Section
27 1852 (42 U.S.C. 1395w-22) is amended—

28 (1) by amending subsection (e) to read as follows:

29 “(e) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT
30 PROGRAMS FOR BENEFICIARIES WITH MULTIPLE OR SUFFI-
31 CIENTLY SEVERE CHRONIC CONDITIONS.—

32 “(1) IN GENERAL.—Each Medicare Advantage organi-
33 zation with respect to each Medicare Advantage plan it of-
34 fers shall have in effect, for enrollees with multiple or suffi-
35 ciently severe chronic conditions, a chronic care improve-
36 ment program that is designed to manage the needs of



1 such enrollees and that meets the requirements of this sub-
2 section.

3 “(2) ENROLLEE WITH MULTIPLE OR SUFFICIENTLY
4 SEVERE CHRONIC CONDITIONS.—For purposes of this sub-
5 section, the term ‘enrollee with multiple or sufficiently se-
6 vere chronic conditions’ means, with respect to an enrollee
7 in a Medicare Advantage plan of a Medicare Advantage or-
8 ganization, an enrollee in the plan who has one or more
9 chronic conditions, such as congestive heart failure, diabe-
10 tes, COPD, stroke, prostate and colon cancer, hypertension,
11 or other disease as identified by the organization as appro-
12 priate for chronic care improvement.

13 “(3) GENERAL REQUIREMENTS.—

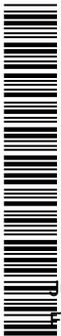
14 “(A) IN GENERAL.—Each chronic care improve-
15 ment program under this subsection shall be conducted
16 consistent with this subsection.

17 “(B) IDENTIFICATION OF ENROLLEES.—Each
18 such program shall have a method for monitoring and
19 identifying enrollees with multiple or sufficiently severe
20 chronic conditions that meet the organization’s criteria
21 for participation under the program.

22 “(C) DEVELOPMENT OF PLANS.—For an enrollee
23 identified under subparagraph (B) for participation in
24 a program, the program shall develop, with the enroll-
25 ee’s consent, an individualized, goal-oriented chronic
26 care improvement plan for chronic care improvement.

27 “(D) ELEMENTS OF PLANS.—Each chronic care
28 improvement plan developed under subparagraph (C)
29 shall include a single point of contact to coordinate
30 care and the following, as appropriate:

31 “(i) Self-improvement education for the en-
32 rollee (such as education for disease management
33 through medical nutrition therapy) and support
34 education for health care providers, primary care-
35 givers, and family members.



1 “(ii) Coordination of health care services, such
2 as application of a prescription drug regimen and
3 home health services.

4 “(iii) Collaboration with physicians and other
5 providers to enhance communication of relevant
6 clinical information.

7 “(iv) The use of monitoring technologies that
8 enable patient guidance through the exchange of
9 pertinent clinical information, such as vital signs,
10 symptomatic information, and health self-assess-
11 ment.

12 “(v) The provision of information about hos-
13 pice care, pain and palliative care, and end-of-life
14 care.

15 “(E) ORGANIZATION RESPONSIBILITIES.—In es-
16 tablishing and carrying out chronic care improvement
17 plans for participants under this paragraph, a Medicare
18 Advantage organization shall, directly or through
19 subcontractors—

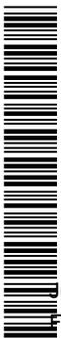
20 “(i) guide participants in managing their
21 health, including all their co-morbidities, and in
22 performing the activities as specified under the ele-
23 ments of the plan;

24 “(ii) use decision support tools such as evi-
25 dence-based practice guidelines or other criteria as
26 determined by the Secretary; and

27 “(iii) develop a clinical information database
28 to track and monitor each participant across set-
29 tings and to evaluate outcomes.

30 “(3) ADDITIONAL REQUIREMENTS.—The Secretary
31 may establish additional requirements for chronic care im-
32 provement programs under this section.

33 “(4) ACCREDITATION.—The Secretary may provide
34 that chronic care improvement programs that are accred-
35 ited by qualified organizations may be deemed to meet such



1 requirements under this subsection as the Secretary may
2 specify.

3 “(5) OUTCOMES REPORT.—Each Medicare Advantage
4 organization with respect to its chronic care improvement
5 program under this subsection shall monitor and report to
6 the Secretary information on the quality of care and effi-
7 cacy of such program as the Secretary may require.”; and

8 (2) by amending subparagraph (I) of subsection (c)(1)
9 to read as follows:

10 “(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A
11 description of the organization’s chronic care improve-
12 ment program under subsection (e).”.

13 (b) APPLICATION UNDER ENHANCED FEE-FOR-SERVICE
14 PROGRAM.—Section 1860E-2(c)(3), as inserted by section
15 201(a), is amended by inserting “, including subsection (e) (re-
16 lating to implementation of chronic care improvement pro-
17 grams)” after “The provisions of section 1852”.

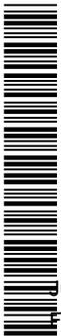
18 (c) EFFECTIVE DATE.—The amendments made by this
19 section shall apply for contract years beginning on or after 1
20 year after the date of the enactment of this Act.

21 **SEC. 723. INSTITUTE OF MEDICINE REPORT.**

22 (a) STUDY.—

23 (1) IN GENERAL.—The Secretary of Health and
24 Human Services shall contract with the Institute of Medi-
25 cine of the National Academy of Sciences to conduct a
26 study of the barriers to effective integrated care improve-
27 ment for medicare beneficiaries with multiple or severe
28 chronic conditions across settings and over time and to
29 submit a report under subsection (b).

30 (2) SPECIFIC ITEMS.—The study shall examine the
31 statutory and regulatory barriers to coordinating care
32 across settings for medicare beneficiaries in transition from
33 one setting to another (such as between hospital, nursing
34 facility, home health, hospice, and home). The study shall
35 specifically identify the following:



1 (A) Clinical, financial, or administrative require-
2 ments in the medicare program that present barriers to
3 effective, seamless transitions across care settings.

4 (B) Policies that impede the establishment of ad-
5 ministrative and clinical information systems to track
6 health status, utilization, cost, and quality data across
7 settings.

8 (C) State-level requirements that may present bar-
9 riers to better care for medicare beneficiaries.

10 (3) CONSULTATION.—The study under this subsection
11 shall be conducted in consultation with experts in the field
12 of chronic care, consumers, and family caregivers, working
13 to integrate care delivery and create more seamless transi-
14 tions across settings and over time.

15 (b) REPORT.—The report under this subsection shall be
16 submitted to the Secretary and Congress not later than 18
17 months after the date of the enactment of this Act.

18 **SEC. 724. MEDPAC REPORT.**

19 (a) EVALUATION.—shall conduct an evaluation that in-
20 cludes a description of the status of the implementation of
21 chronic care improvement programs under section 1808 of the
22 Social Security Act, the quality of health care services provided
23 to individuals in such program, the health status of the partici-
24 pants of such program, and the cost savings attributed to im-
25 plementation of such program.

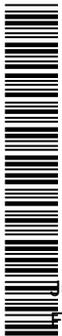
26 (b) REPORT.—Not later than 2 years after the date of im-
27 plementation of such chronic care improvement programs, the
28 Commission shall submit a report on such evaluation.

29 **Subtitle D—Other Provisions**

30 **SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT AD-
31 VISORY COMMISSION (MEDPAC).**

32 (a) EXAMINATION OF BUDGET CONSEQUENCES.—Section
33 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the
34 end the following new paragraph:

35 “(8) EXAMINATION OF BUDGET CONSEQUENCES.—Be-
36 fore making any recommendations, the Commission shall



1 examine the budget consequences of such recommendations,
2 directly or through consultation with appropriate expert en-
3 tities.”.

4 (b) CONSIDERATION OF EFFICIENT PROVISION OF SERV-
5 ICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b-
6 6(b)(2)(B)(i)) is amended by inserting “the efficient provision
7 of” after “expenditures for”.

8 (c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

9 (1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C.
10 1395b-6(c)(2)(D)) is amended by adding at the end the
11 following: “Members of the Commission shall be treated as
12 employees of the Congress for purposes of applying title I
13 of the Ethics in Government Act of 1978 (Public Law 95-
14 521).”.

15 (2) EFFECTIVE DATE.—The amendment made by
16 paragraph (1) shall take effect on January 1, 2004.

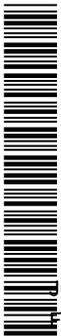
17 (d) ADDITIONAL REPORTS.—

18 (1) DATA NEEDS AND SOURCES.—The Medicare Pay-
19 ment Advisory Commission shall conduct a study, and sub-
20 mit a report to Congress by not later than June 1, 2004,
21 on the need for current data, and sources of current data
22 available, to determine the solvency and financial cir-
23 cumstances of hospitals and other medicare providers of
24 services. The Commission shall examine data on uncompen-
25 sated care, as well as the share of uncompensated care ac-
26 counted for by the expenses for treating illegal aliens.

27 (2) USE OF TAX-RELATED RETURNS.—Using return
28 information provided under Form 990 of the Internal Rev-
29 enue Service, the Commission shall submit to Congress, by
30 not later than June 1, 2004, a report on the following:

31 (A) Investments, endowments, and fundraising of
32 hospitals participating under the medicare program and
33 related foundations.

34 (B) Access to capital financing for private and for
35 not-for-profit hospitals.



1 **SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL**
2 **ADULT DAY CARE SERVICES.**

3 (a) **ESTABLISHMENT.**—Subject to the succeeding provi-
4 sions of this section, the Secretary of Health and Human Serv-
5 ices shall establish a demonstration project (in this section re-
6 ferred to as the “demonstration project”) under which the Sec-
7 retary shall, as part of a plan of an episode of care for home
8 health services established for a medicare beneficiary, permit a
9 home health agency, directly or under arrangements with a
10 medical adult day care facility, to provide medical adult day
11 care services as a substitute for a portion of home health serv-
12 ices that would otherwise be provided in the beneficiary’s home.

13 (b) **PAYMENT.**—

14 (1) **IN GENERAL.**—The amount of payment for an epi-
15 sode of care for home health services, a portion of which
16 consists of substitute medical adult day care services, under
17 the demonstration project shall be made at a rate equal to
18 95 percent of the amount that would otherwise apply for
19 such home health services under section 1895 of the Social
20 Security Act (42 u.s.c. 1395fff). In no case may a home
21 health agency, or a medical adult day care facility under
22 arrangements with a home health agency, separately charge
23 a beneficiary for medical adult day care services furnished
24 under the plan of care.

25 (2) **BUDGET NEUTRALITY FOR DEMONSTRATION**
26 **PROJECT.**—Notwithstanding any other provision of law, the
27 Secretary shall provide for an appropriate reduction in the
28 aggregate amount of additional payments made under sec-
29 tion 1895 of the Social Security Act (42 U.S.C. 1395fff)
30 to reflect any increase in amounts expended from the Trust
31 Funds as a result of the demonstration project conducted
32 under this section.

33 (c) **DEMONSTRATION PROJECT SITES.**—The project estab-
34 lished under this section shall be conducted in not more than
35 5 States selected by the Secretary that license or certify pro-
36 viders of services that furnish medical adult day care services.



1 (d) DURATION.—The Secretary shall conduct the dem-
2 onstration project for a period of 3 years.

3 (e) VOLUNTARY PARTICIPATION.—Participation of medi-
4 care beneficiaries in the demonstration project shall be vol-
5 untary. The total number of such beneficiaries that may par-
6 ticipate in the project at any given time may not exceed
7 15,000.

8 (f) PREFERENCE IN SELECTING AGENCIES.—In selecting
9 home health agencies to participate under the demonstration
10 project, the Secretary shall give preference to those agencies
11 that are currently licensed or certified through common owner-
12 ship and control to furnish medical adult day care services.

13 (g) WAIVER AUTHORITY.—The Secretary may waive such
14 requirements of title XVIII of the Social Security Act as may
15 be necessary for the purposes of carrying out the demonstra-
16 tion project, other than waiving the requirement that an indi-
17 vidual be homebound in order to be eligible for benefits for
18 home health services.

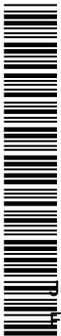
19 (h) EVALUATION AND REPORT.—The Secretary shall con-
20 duct an evaluation of the clinical and cost effectiveness of the
21 demonstration project. Not later 30 months after the com-
22 mencement of the project, the Secretary shall submit to Con-
23 gress a report on the evaluation, and shall include in the report
24 the following:

25 (1) An analysis of the patient outcomes and costs of
26 furnishing care to the medicare beneficiaries participating
27 in the project as compared to such outcomes and costs to
28 beneficiaries receiving only home health services for the
29 same health conditions.

30 (2) Such recommendations regarding the extension,
31 expansion, or termination of the project as the Secretary
32 determines appropriate.

33 (i) DEFINITIONS.—In this section:

34 (1) HOME HEALTH AGENCY.—The term “home health
35 agency” has the meaning given such term in section
36 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).



1 (2) MEDICAL ADULT DAY CARE FACILITY.—The term
2 “medical adult day care facility” means a facility that—

3 (A) has been licensed or certified by a State to
4 furnish medical adult day care services in the State for
5 a continuous 2-year period;

6 (B) is engaged in providing skilled nursing serv-
7 ices and other therapeutic services directly or under ar-
8 rangement with a home health agency;

9 (C) meets such standards established by the Sec-
10 retary to assure quality of care and such other require-
11 ments as the Secretary finds necessary in the interest
12 of the health and safety of individuals who are fur-
13 nished services in the facility; and

14 (D) provides medical adult day care services.

15 (3) MEDICAL ADULT DAY CARE SERVICES.—The term
16 “medical adult day care services” means—

17 (A) home health service items and services de-
18 scribed in paragraphs (1) through (7) of section
19 1861(m) furnished in a medical adult day care facility;

20 (B) a program of supervised activities furnished in
21 a group setting in the facility that—

22 (i) meet such criteria as the Secretary deter-
23 mines appropriate; and

24 (ii) is designed to promote physical and mental
25 health of the individuals; and

26 (C) such other services as the Secretary may
27 specify.

28 (4) MEDICARE BENEFICIARY.—The term “medicare
29 beneficiary” means an individual entitled to benefits under
30 part A of this title, enrolled under part B of this title, or
31 both.

32 **SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL**
33 **COVERAGE DETERMINATION PROCESS TO**
34 **RESPOND TO CHANGES IN TECHNOLOGY.**

35 (a) NATIONAL AND LOCAL COVERAGE DETERMINATION
36 PROCESS.—



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

3 (A) in the third sentence of subsection (a) by in-
4 serting “consistent with subsection (k)” after “the Sec-
5 retary shall ensure”; and

6 (B) by adding at the end the following new sub-
7 section:

8 “(k) NATIONAL AND LOCAL COVERAGE DETERMINATION
9 PROCESS.—

10 “(1) CRITERIA AND EVIDENCE USED IN MAKING NA-
11 TIONAL COVERAGE DETERMINATIONS.—The Secretary shall
12 make available to the public the criteria the Secretary uses
13 in making national coverage determinations, including how
14 evidence to demonstrate that a procedure or device is rea-
15 sonable and necessary is considered.

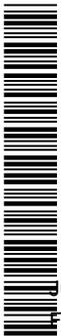
16 “(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR
17 NATIONAL COVERAGE DETERMINATIONS.—In the case of a
18 request for a national coverage determination that—

19 “(A) does not require a technology assessment
20 from an outside entity or deliberation from the Medi-
21 care Coverage Advisory Committee, the decision on the
22 request shall be made not later than 6 months after the
23 date of the request; or

24 “(B) requires such an assessment or deliberation
25 and in which a clinical trial is not requested, the deci-
26 sion on the request shall be made not later than 12
27 months after the date of the request.

28 “(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL
29 COVERAGE DETERMINATIONS.—At the end of the 6-month
30 period that begins on the date a request for a national cov-
31 erage determination is made, the Secretary shall—

32 “(A) make a draft of proposed decision on the re-
33 quest available to the public through the Medicare
34 Internet site of the Department of Health and Human
35 Services or other appropriate means;



1 “(B) provide a 30-day period for public comment
2 on such draft;

3 “(C) make a final decision on the request within
4 60 days of the conclusion of the 30-day period referred
5 to under subparagraph (B);

6 “(D) include in such final decision summaries of
7 the public comments received and responses thereto;

8 “(E) make available to the public the clinical evi-
9 dence and other data used in making such a decision
10 when the decision differs from the recommendations of
11 the Medicare Coverage Advisory Committee; and.

12 “(F) in the case of a decision to grant the cov-
13 erage determination, assign or temporary or permanent
14 code during the 60-day period referred to in subpara-
15 graph (C).

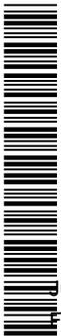
16 “(4) CONSULTATION WITH OUTSIDE EXPERTS IN CER-
17 TAIN NATIONAL COVERAGE DETERMINATIONS.—With re-
18 spect to a request for a national coverage determination for
19 which there is not a review by the Medicare Coverage Advi-
20 sory Committee, the Secretary shall consult with appro-
21 priate outside clinical experts.

22 “(5) LOCAL COVERAGE DETERMINATION PROCESS.—
23 With respect to local coverage determinations made on or
24 after January 1, 2004—

25 “(A) PLAN TO PROMOTE CONSISTENCY OF COV-
26 ERAGE DETERMINATIONS.—The Secretary shall develop
27 a plan to evaluate new local coverage determinations to
28 determine which determinations should be adopted na-
29 tionally and to what extent greater consistency can be
30 achieved among local coverage determinations.

31 “(B) CONSULTATION.—The Secretary shall re-
32 quire the fiscal intermediaries or carriers providing
33 services within the same area to consult on all new
34 local coverage determinations within the area.

35 “(C) DISSEMINATION OF INFORMATION.—The
36 Secretary should serve as a center to disseminate infor-



1 mation on local coverage determinations among fiscal
2 intermediaries and carriers to reduce duplication of ef-
3 fort.

4 “(6) NATIONAL AND LOCAL COVERAGE DETERMINA-
5 TION DEFINED.—For purposes of this subsection, the
6 terms ‘national coverage determination’ and ‘local coverage
7 determination’ have the meaning given such terms in para-
8 graphs (1)(B) and (2)(B), respectively, of section
9 1869(f).”.

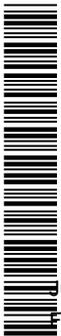
10 (2) EFFECTIVE DATE.—The amendments made by
11 paragraph (1) shall apply to national and local coverage de-
12 terminations as of January 1, 2004.

13 (b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCI-
14 ATED WITH CERTAIN CLINICAL TRIALS.—

15 (1) IN GENERAL.—With respect to the coverage of
16 routine costs of care for beneficiaries participating in a
17 qualifying clinical trial, as set forth on the date of the en-
18 actment of this Act in National Coverage Determination
19 30-1 of the Medicare Coverage Issues Manual, the Sec-
20 retary shall deem clinical trials conducted in accordance
21 with an investigational device exemption approved under
22 section 520(g) of the Federal Food, Drug, and Cosmetic
23 Act (42 U.S.C. 360j(g)) to be automatically qualified for
24 such coverage.

25 (2) RULE OF CONSTRUCTION.—Nothing in this sub-
26 section shall be construed as authorizing or requiring the
27 Secretary to modify the regulations set forth on the date
28 of the enactment of this Act at subpart B of part 405 of
29 title 42, Code of Federal Regulations, or subpart A of part
30 411 of such title, relating to coverage of, and payment for,
31 a medical device that is the subject of an investigational de-
32 vice exemption by the Food and Drug Administration (ex-
33 cept as may be necessary to implement paragraph (1)).

34 (3) EFFECTIVE DATE.—This subsection shall apply to
35 clinical trials begun before, on, or after the date of the en-



1 actment of this Act and to items and services furnished on
2 or after such date.

3 (c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not
4 later than January 1, 2004, the Secretary shall implement re-
5 vised procedures for the issuance of temporary national
6 HCPCS codes under part B of title XVIII of the Social Secu-
7 rity Act.

8 **SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOL-**
9 **OGY SERVICES.**

10 (a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w-
11 4(i)) is amended by adding at the end the following new para-
12 graph:

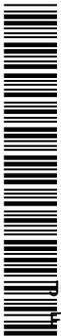
13 “(4) TREATMENT OF CERTAIN INPATIENT PHYSICIAN
14 PATHOLOGY SERVICES.—

15 “(A) IN GENERAL.—With respect to services fur-
16 nished on or after January 1, 2001, if an independent
17 laboratory furnishes the technical component of a phy-
18 sician pathology service to a fee-for-service medicare
19 beneficiary who is an inpatient of a covered hospital,
20 the Secretary shall treat such component as a service
21 for which payment shall be made to the laboratory
22 under this section and not as an inpatient hospital
23 service for which payment is made to the hospital
24 under section 1886(d).

25 “(B) DEFINITIONS.—In this paragraph:

26 “(i) COVERED HOSPITAL.—

27 “(I) IN GENERAL.—The term ‘covered
28 hospital’ means, with respect to an inpatient or
29 outpatient, a hospital that had an arrangement
30 with an independent laboratory that was in ef-
31 fect as of July 22, 1999, under which a labora-
32 tory furnished the technical component of phy-
33 sician pathology services to fee-for-service
34 medicare beneficiaries who were hospital inpa-
35 tients or outpatients, respectively, and sub-
36 mitted claims for payment for such component



1 to a carrier with a contract under section 1842
2 and not to the hospital.

3 “(II) CHANGE IN OWNERSHIP DOES NOT
4 AFFECT DETERMINATION.—A change in owner-
5 ship with respect to a hospital on or after the
6 date referred to in subclause (I) shall not affect
7 the determination of whether such hospital is a
8 covered hospital for purposes of such subclause.

9 “(ii) FEE-FOR-SERVICE MEDICARE BENE-
10 FICIARY.—The term ‘fee-for-service medicare bene-
11 ficiary’ means an individual who is entitled to bene-
12 fits under part A, or enrolled under this part, or
13 both, but is not enrolled in any of the following:

14 “(I) A Medicare+Choice plan under part
15 C.

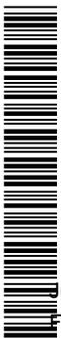
16 “(II) A plan offered by an eligible organi-
17 zation under section 1876.

18 “(III) A program of all-inclusive care for
19 the elderly (PACE) under section 1894.

20 “(IV) A social health maintenance organi-
21 zation (SHMO) demonstration project estab-
22 lished under section 4018(b) of the Omnibus
23 Budget Reconciliation Act of 1987 (Public Law
24 100–203).”.

25 (b) CONFORMING AMENDMENT.—Section 542 of the Medi-
26 care, Medicaid, and SCHIP Benefits Improvement and Protec-
27 tion Act of 2000 (114 Stat. 2763A–550), as enacted into law
28 by section 1(a)(6) of Public Law 106–554, is repealed.

29 (c) EFFECTIVE DATES.—The amendments made by this
30 section shall take effect as if included in the enactment of the
31 Medicare, Medicaid, and SCHIP Benefits Improvement and
32 Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463),
33 as enacted into law by section 1(a)(6) of Public Law 106–554.



1 **SEC. 735. MEDICARE PANCREATIC ISLET CELL TRANS-**
2 **PLANT DEMONSTRATION PROJECT.**

3 (a) ESTABLISHMENT.—In order to test the appropriate-
4 ness of pancreatic islet cell transplantation, not later than 120
5 days after the date of the enactment of this Act, the Secretary
6 shall establish a demonstration project which the Secretary,
7 provides for payment under the medicare program under title
8 XVIII of the Social Security Act for pancreatic islet cell trans-
9 plantation and related items and services in the case of medi-
10 care beneficiaries who have type I (juvenile) diabetes and have
11 end stage renal disease.

12 (b) DURATION OF PROJECT.—The authority of the Sec-
13 retary to conduct the demonstration project under this section
14 shall terminate on the date that is 5 years after the date of
15 the establishment of the project.

16 (c) EVALUATION AND REPORT.—The Secretary shall con-
17 duct an evaluation of the outcomes of the demonstration
18 project. Not later than 120 days after the date of the termi-
19 nation of the demonstration project under subsection (b), the
20 Secretary shall submit to Congress a report on the project, in-
21 cluding recommendations for such legislative and administra-
22 tive action as the Secretary deems appropriate.

23 (d) PAYMENT METHODOLOGY.—The Secretary shall estab-
24 lish an appropriate payment methodology for the provision of
25 items and services under the demonstration project, which may
26 include a payment methodology that bundles, to the maximum
27 extent feasible, payment for all such items and services.

28 (e) WAIVER AUTHORITY.—The Secretary may waive com-
29 pliance with the requirements of title XVIII of the Social Secu-
30 rity Act to such extent and for such period as the Secretary
31 determines is necessary to conduct the demonstration project.

32 **SEC. 736. DEMONSTRATION PROJECT FOR CONSUMER-**
33 **DIRECTED CHRONIC OUTPATIENT SERVICES.**

34 (a) ESTABLISHMENT.—

35 (1) IN GENERAL.—Subject to the succeeding provi-
36 sions of this section, the Secretary shall establish dem-
37 onstration projects (in this section referred to as “dem-

1 onstration projects”) under which the Secretary shall evalu-
2 ate methods that improve the quality of care provided to
3 medicare beneficiaries with chronic conditions and that re-
4 duce expenditures that would otherwise be made under the
5 medicare program on behalf of such individuals for such
6 chronic conditions, such methods to include permitting
7 those beneficiaries to direct their own health care needs
8 and services.

9 (2) MEDICARE BENEFICIARIES WITH CHRONIC CONDI-
10 TIONS DEFINED.—In this section, the term “medicare
11 beneficiaries with chronic conditions” means an individual
12 entitled to benefits under part A of title XVIII of the So-
13 cial Security Act, and enrolled under part B of such title,
14 but who is not enrolled under part C of such title who is
15 diagnosed as having one or more chronic conditions (as de-
16 fined by the Secretary), such as diabetes.

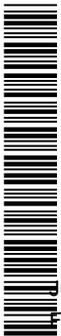
17 (b) DESIGN OF PROJECTS.—

18 (1) IN GENERAL.—In establishing the demonstration
19 projects under this section, the Secretary shall evaluate
20 practices employed by group health plans and practices
21 under State plans for medical assistance under the med-
22 icaid program under title XIX of the Social Security Act
23 that permit patients to self-direct the provision of personal
24 care services.

25 (2) SCOPE OF SERVICES.—The Secretary shall deter-
26 mine the appropriate scope of personal care services that
27 would apply under the demonstration projects.

28 (c) VOLUNTARY PARTICIPATION.—Participation of medi-
29 care beneficiaries in the demonstration projects shall be vol-
30 untary.

31 (d) DEMONSTRATION PROJECTS SITES.—Not later than 2
32 years after the date of the enactment of this Act, the Secretary
33 shall conduct no fewer than 3 demonstration projects estab-
34 lished under this section. Of those demonstration projects, the
35 Secretary shall conduct at least one in each of the following
36 areas:



- 1 (1) An urban area.
2 (2) A rural area.
3 (3) An area that the Secretary determines has a medi-
4 care population with rate of incidence of diabetes that sig-
5 nificantly exceeds the national average rate of all areas.

6 (e) EVALUATION AND REPORT.—

7 (1) EVALUATIONS.—The Secretary shall conduct eval-
8 uations of the clinical and cost effectiveness of the dem-
9 onstration projects.

10 (2) REPORTS.—Not later than 2 years after the com-
11 mencement of the demonstration projects, and biannually
12 thereafter, the Secretary shall submit to Congress a report
13 on the evaluation, and shall include in the report the fol-
14 lowing:

15 (A) An analysis of the patient outcomes and costs
16 of furnishing care to the medicare beneficiaries partici-
17 pating in the projects as compared to such outcomes
18 and costs to other beneficiaries for the same health
19 conditions.

20 (B) Evaluation of patient satisfaction under the
21 demonstration projects.

22 (C) Such recommendations regarding the exten-
23 sion, expansion, or termination of the projects as the
24 Secretary determines appropriate.

25 **TITLE VIII—MEDICARE BENEFITS**
26 **ADMINISTRATION**

27 **SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS AD-**
28 **MINISTRATION.**

29 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.),
30 as amended by sections 105 and 721, is amended by inserting
31 after 1808 the following new section:

32 “MEDICARE BENEFITS ADMINISTRATION

33 “SEC. 1809. (a) ESTABLISHMENT.—There is established
34 within the Department of Health and Human Services an agen-
35 cy to be known as the Medicare Benefits Administration.



1 “(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF
2 ACTUARY.—

3 “(1) ADMINISTRATOR.—

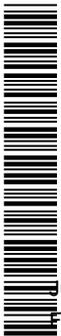
4 “(A) IN GENERAL.—The Medicare Benefits Ad-
5 ministration shall be headed by an administrator to be
6 known as the ‘Medicare Benefits Administrator’ (in
7 this section referred to as the ‘Administrator’) who
8 shall be appointed by the President, by and with the
9 advice and consent of the Senate. The Administrator
10 shall be in direct line of authority to the Secretary.

11 “(B) COMPENSATION.—The Administrator shall
12 be paid at the rate of basic pay payable for level III
13 of the Executive Schedule under section 5314 of title
14 5, United States Code.

15 “(C) TERM OF OFFICE.—The Administrator shall
16 be appointed for a term of 4 years. In any case in
17 which a successor does not take office at the end of an
18 Administrator’s term of office, that Administrator may
19 continue in office until the entry upon office of such a
20 successor. An Administrator appointed to a term of of-
21 fice after the commencement of such term may serve
22 under such appointment only for the remainder of such
23 term.

24 “(D) GENERAL AUTHORITY.—The Administrator
25 shall be responsible for the exercise of all powers and
26 the discharge of all duties of the Administration, and
27 shall have authority and control over all personnel and
28 activities thereof.

29 “(E) RULEMAKING AUTHORITY.—The Adminis-
30 trator may prescribe such rules and regulations as the
31 Administrator determines necessary or appropriate to
32 carry out the functions of the Administration. The reg-
33 ulations prescribed by the Administrator shall be sub-
34 ject to the rulemaking procedures established under
35 section 553 of title 5, United States Code. The Admin-



1 istrator shall provide for the issuance of new regula-
2 tions to carry out parts C, D, and E.

3 “(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL
4 UNITS.—The Administrator may establish, alter, con-
5 solidate, or discontinue such organizational units or
6 components within the Administration as the Adminis-
7 trator considers necessary or appropriate, except as
8 specified in this section.

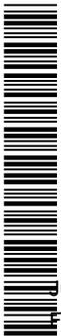
9 “(G) AUTHORITY TO DELEGATE.—The Adminis-
10 trator may assign duties, and delegate, or authorize
11 successive redelegations of, authority to act and to
12 render decisions, to such officers and employees of the
13 Administration as the Administrator may find nec-
14 essary. Within the limitations of such delegations, re-
15 delegations, or assignments, all official acts and deci-
16 sions of such officers and employees shall have the
17 same force and effect as though performed or rendered
18 by the Administrator.

19 “(2) DEPUTY ADMINISTRATOR.—

20 “(A) IN GENERAL.—There shall be a Deputy Ad-
21 ministrator of the Medicare Benefits Administration
22 who shall be appointed by the President, by and with
23 the advice and consent of the Senate.

24 “(B) COMPENSATION.—The Deputy Administrator
25 shall be paid at the rate of basic pay payable for level
26 IV of the Executive Schedule under section 5315 of
27 title 5, United States Code.

28 “(C) TERM OF OFFICE.—The Deputy Adminis-
29 trator shall be appointed for a term of 4 years. In any
30 case in which a successor does not take office at the
31 end of a Deputy Administrator’s term of office, such
32 Deputy Administrator may continue in office until the
33 entry upon office of such a successor. A Deputy Ad-
34 ministrator appointed to a term of office after the com-
35 mencement of such term may serve under such ap-
36 pointment only for the remainder of such term.



1 “(D) DUTIES.—The Deputy Administrator shall
2 perform such duties and exercise such powers as the
3 Administrator shall from time to time assign or dele-
4 gate. The Deputy Administrator shall be Acting Ad-
5 ministrator of the Administration during the absence or
6 disability of the Administrator and, unless the Presi-
7 dent designates another officer of the Government as
8 Acting Administrator, in the event of a vacancy in the
9 office of the Administrator.

10 “(3) CHIEF ACTUARY.—

11 “(A) IN GENERAL.—There is established in the
12 Administration the position of Chief Actuary. The
13 Chief Actuary shall be appointed by, and in direct line
14 of authority to, the Administrator of such Administra-
15 tion. The Chief Actuary shall be appointed from among
16 individuals who have demonstrated, by their education
17 and experience, superior expertise in the actuarial
18 sciences. The Chief Actuary may be removed only for
19 cause.

20 “(B) COMPENSATION.—The Chief Actuary shall
21 be compensated at the highest rate of basic pay for the
22 Senior Executive Service under section 5382(b) of title
23 5, United States Code.

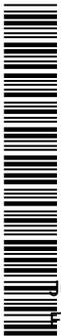
24 “(C) DUTIES.—The Chief Actuary shall exercise
25 such duties as are appropriate for the office of the
26 Chief Actuary and in accordance with professional
27 standards of actuarial independence.

28 “(4) SECRETARIAL COORDINATION OF PROGRAM AD-
29 MINISTRATION.—The Secretary shall ensure appropriate
30 coordination between the Administrator and the Adminis-
31 trator of the Centers for Medicare & Medicaid Services in
32 carrying out the programs under this title.

33 “(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

34 “(1) DUTIES.—

35 “(A) GENERAL DUTIES.—The Administrator shall
36 carry out parts C, D, and E, including—



1 “(i) negotiating, entering into, and enforcing,
2 contracts with plans for the offering of Medicare
3 Advantage plans under part C and EFFS plans
4 under part E, including the offering of qualified
5 prescription drug coverage under such plans; and

6 “(ii) negotiating, entering into, and enforcing,
7 contracts with PDP sponsors for the offering of
8 prescription drug plans under part D.

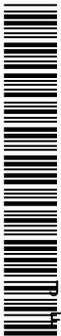
9 “(B) OTHER DUTIES.—The Administrator shall
10 carry out any duty provided for under part C, part D,
11 or part E, including demonstration projects carried out
12 in part or in whole under such parts, the programs of
13 all-inclusive care for the elderly (PACE program) under
14 section 1894, the social health maintenance organiza-
15 tion (SHMO) demonstration projects (referred to in
16 section 4104(c) of the Balanced Budget Act of 1997),
17 medicare cost contractors under section 1876(h), and
18 through a Medicare Advantage project that dem-
19 onstrates the application of capitation payment rates
20 for frail elderly medicare beneficiaries through the use
21 of a interdisciplinary team and through the provision of
22 primary care services to such beneficiaries by means of
23 such a team at the nursing facility involved).

24 “(C) PRESCRIPTION DRUG CARD.—The Adminis-
25 trator shall carry out section 1807 (relating to the
26 medicare prescription drug discount card endorsement
27 program).

28 “(D) NONINTERFERENCE.—In carrying out its
29 duties with respect to the provision of qualified pre-
30 scription drug coverage to beneficiaries under this title,
31 the Administrator may not—

32 “(i) require a particular formulary or institute
33 a price structure for the reimbursement of covered
34 outpatient drugs;

35 “(ii) interfere in any way with negotiations be-
36 tween PDP sponsors and Medicare Advantage or-



1 organizations and EFFS organizations and drug
2 manufacturers, wholesalers, or other suppliers of
3 covered outpatient drugs; and

4 “(iii) otherwise interfere with the competitive
5 nature of providing such coverage through such
6 sponsors and organizations.

7 “(E) ANNUAL REPORTS.—Not later March 31 of
8 each year, the Administrator shall submit to Congress
9 and the President a report on the administration of
10 parts C, D, and E during the previous fiscal year.

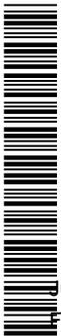
11 “(2) STAFF.—

12 “(A) IN GENERAL.—The Administrator, with the
13 approval of the Secretary, may employ, without regard
14 to chapter 31 of title 5, United States Code, other than
15 sections 3102 through 3113, 3131, 3133, 3136, 3151,
16 and 3161, such officers and employees as are necessary
17 to administer the activities to be carried out through
18 the Medicare Benefits Administration. The Adminis-
19 trator shall employ staff with appropriate and nec-
20 essary expertise in negotiating contracts in the private
21 sector.

22 “(B) FLEXIBILITY WITH RESPECT TO COMPENSA-
23 TION.—

24 “(i) IN GENERAL.—The staff of the Medicare
25 Benefits Administration shall, subject to clause (ii),
26 be paid without regard to the provisions of chapter
27 51 (other than section 5101) and chapter 53 (other
28 than section 5301, sections 5303 through 5305,
29 5311, and 5372 of such title (relating to classifica-
30 tion and schedule pay rates).

31 “(ii) MAXIMUM RATE.—In no case may the
32 rate of compensation determined under clause (i)
33 exceed the rate of basic pay payable for level IV of
34 the Executive Schedule under section 5315 of title
35 5, United States Code.



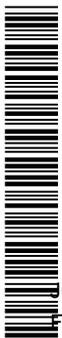
1 “(C) LIMITATION ON FULL-TIME EQUIVALENT
2 STAFFING FOR CURRENT CMS FUNCTIONS BEING
3 TRANSFERRED.—The Administrator may not employ
4 under this paragraph a number of full-time equivalent
5 employees, to carry out functions that were previously
6 conducted by the Centers for Medicare & Medicaid
7 Services and that are conducted by the Administrator
8 by reason of this section, that exceeds the number of
9 such full-time equivalent employees authorized to be
10 employed by the Centers for Medicare & Medicaid Ser-
11 vices to conduct such functions as of the date of the en-
12 actment of this Act.

13 “(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE
14 CENTERS FOR MEDICARE & MEDICAID SERVICES.—

15 “(A) IN GENERAL.—The Secretary, the Adminis-
16 trator, and the Administrator of the Centers for Medi-
17 care & Medicaid Services shall establish an appropriate
18 transition of responsibility in order to redelegate the
19 administration of part C from the Secretary and the
20 Administrator of the Centers for Medicare & Medicaid
21 Services to the Administrator as is appropriate to carry
22 out the purposes of this section.

23 “(B) TRANSFER OF DATA AND INFORMATION.—
24 The Secretary shall ensure that the Administrator of
25 the Centers for Medicare & Medicaid Services transfers
26 to the Administrator of the Medicare Benefits Adminis-
27 tration such information and data in the possession of
28 the Administrator of the Centers for Medicare & Medi-
29 caid Services as the Administrator of the Medicare
30 Benefits Administration requires to carry out the du-
31 ties described in paragraph (1).

32 “(C) CONSTRUCTION.—Insofar as a responsibility
33 of the Secretary or the Administrator of the Centers
34 for Medicare & Medicaid Services is redelegated to the
35 Administrator under this section, any reference to the
36 Secretary or the Administrator of the Centers for Medi-



1 care & Medicaid Services in this title or title XI with
2 respect to such responsibility is deemed to be a ref-
3 erence to the Administrator.

4 “(d) OFFICE OF BENEFICIARY ASSISTANCE.—

5 “(1) ESTABLISHMENT.—The Secretary shall establish
6 within the Medicare Benefits Administration an Office of
7 Beneficiary Assistance to coordinate functions relating to
8 outreach and education of medicare beneficiaries under this
9 title, including the functions described in paragraph (2).
10 The Office shall be separate operating division within the
11 Administration.

12 “(2) DISSEMINATION OF INFORMATION ON BENEFITS
13 AND APPEALS RIGHTS.—

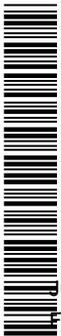
14 “(A) DISSEMINATION OF BENEFITS INFORMA-
15 TION.—The Office of Beneficiary Assistance shall dis-
16 seminate, directly or through contract, to medicare
17 beneficiaries, by mail, by posting on the Internet site
18 of the Medicare Benefits Administration and through a
19 toll-free telephone number, information with respect to
20 the following:

21 “(i) Benefits, and limitations on payment (in-
22 cluding cost-sharing, stop-loss provisions, and for-
23 mulary restrictions) under parts C, D, and E.

24 “(ii) Benefits, and limitations on payment
25 under parts A and B, including information on
26 medicare supplemental policies under section 1882.

27 Such information shall be presented in a manner so
28 that medicare beneficiaries may compare benefits under
29 parts A, B, D, and medicare supplemental policies with
30 benefits under Medicare Advantage plans under part C
31 and EFFS plans under part E.

32 “(B) DISSEMINATION OF APPEALS RIGHTS INFOR-
33 MATION.—The Office of Beneficiary Assistance shall
34 disseminate to medicare beneficiaries in the manner
35 provided under subparagraph (A) a description of pro-
36 cedural rights (including grievance and appeals proce-



1 dures) of beneficiaries under the original medicare fee-
2 for-service program under parts A and B, the Medicare
3 Advantage program under part C, the Voluntary Pre-
4 scription Drug Benefit Program under part D, and the
5 Enhanced Fee-for-Service program under part E.

6 “(e) MEDICARE POLICY ADVISORY BOARD.—

7 “(1) ESTABLISHMENT.—There is established within
8 the Medicare Benefits Administration the Medicare Policy
9 Advisory Board (in this section referred to the ‘Board’).
10 The Board shall advise, consult with, and make rec-
11 ommendations to the Administrator of the Medicare Bene-
12 fits Administration with respect to the administration of
13 parts C, D, and E, including the review of payment policies
14 under such parts.

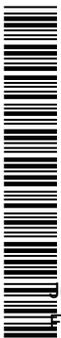
15 “(2) REPORTS.—

16 “(A) IN GENERAL.—With respect to matters of
17 the administration of parts C, D, and E the Board
18 shall submit to Congress and to the Administrator of
19 the Medicare Benefits Administration such reports as
20 the Board determines appropriate. Each such report
21 may contain such recommendations as the Board deter-
22 mines appropriate for legislative or administrative
23 changes to improve the administration of such parts,
24 including the topics described in subparagraph (B).
25 Each such report shall be published in the Federal
26 Register.

27 “(B) TOPICS DESCRIBED.—Reports required
28 under subparagraph (A) may include the following top-
29 ics:

30 “(i) FOSTERING COMPETITION.—Rec-
31 ommendations or proposals to increase competition
32 under parts C, D, and E for services furnished to
33 medicare beneficiaries.

34 “(ii) EDUCATION AND ENROLLMENT.—Rec-
35 ommendations for the improvement to efforts to
36 provide medicare beneficiaries information and edu-



1 cation on the program under this title, and speci-
2 cally parts C, D, and E, and the program for en-
3 rollment under the title.

4 “(iii) IMPLEMENTATION OF RISK-ADJUST-
5 MENT.—Evaluation of the implementation under
6 section 1853(a)(3)(C) of the risk adjustment meth-
7 odology to payment rates under that section to
8 Medicare Advantage organizations offering Medi-
9 care Advantage plans (and the corresponding pay-
10 ment provisions under part E) that accounts for
11 variations in per capita costs based on health sta-
12 tus, geography, and other demographic factors.

13 “(iv) RURAL ACCESS.—Recommendations to
14 improve competition and access to plans under
15 parts C, D, and E in rural areas.

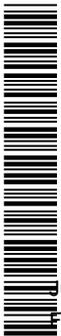
16 “(C) MAINTAINING INDEPENDENCE OF BOARD.—
17 The Board shall directly submit to Congress reports re-
18 quired under subparagraph (A). No officer or agency of
19 the United States may require the Board to submit to
20 any officer or agency of the United States for approval,
21 comments, or review, prior to the submission to Con-
22 gress of such reports.

23 “(3) DUTY OF ADMINISTRATOR OF MEDICARE BENE-
24 FITS ADMINISTRATION.—With respect to any report sub-
25 mitted by the Board under paragraph (2)(A), not later
26 than 90 days after the report is submitted, the Adminis-
27 trator of the Medicare Benefits Administration shall submit
28 to Congress and the President an analysis of recommenda-
29 tions made by the Board in such report. Each such analysis
30 shall be published in the Federal Register.

31 “(4) MEMBERSHIP.—

32 “(A) APPOINTMENT.—Subject to the succeeding
33 provisions of this paragraph, the Board shall consist of
34 seven members to be appointed as follows:

35 “(i) Three members shall be appointed by the
36 President.



1 “(ii) Two members shall be appointed by the
2 Speaker of the House of Representatives, with the
3 advice of the chairmen and the ranking minority
4 members of the Committees on Ways and Means
5 and on Energy and Commerce of the House of
6 Representatives.

7 “(iii) Two members shall be appointed by the
8 President pro tempore of the Senate with the ad-
9 vice of the chairman and the ranking minority
10 member of the Senate Committee on Finance.

11 “(B) QUALIFICATIONS.—The members shall be
12 chosen on the basis of their integrity, impartiality, and
13 good judgment, and shall be individuals who are, by
14 reason of their education and experience in health care
15 benefits management, exceptionally qualified to perform
16 the duties of members of the Board.

17 “(C) PROHIBITION ON INCLUSION OF FEDERAL
18 EMPLOYEES.—No officer or employee of the United
19 States may serve as a member of the Board.

20 “(5) COMPENSATION.—Members of the Board shall
21 receive, for each day (including travel time) they are en-
22 gaged in the performance of the functions of the board,
23 compensation at rates not to exceed the daily equivalent to
24 the annual rate in effect for level IV of the Executive
25 Schedule under section 5315 of title 5, United States Code.

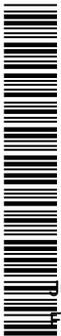
26 “(6) TERMS OF OFFICE.—

27 “(A) IN GENERAL.—The term of office of mem-
28 bers of the Board shall be 3 years.

29 “(B) TERMS OF INITIAL APPOINTEES.—As des-
30 ignated by the President at the time of appointment,
31 of the members first appointed—

32 “(i) one shall be appointed for a term of 1
33 year;

34 “(ii) three shall be appointed for terms of 2
35 years; and



1 “(iii) three shall be appointed for terms of 3
2 years.

3 “(C) REAPPOINTMENTS.—Any person appointed
4 as a member of the Board may not serve for more than
5 8 years.

6 “(D) VACANCY.—Any member appointed to fill a
7 vacancy occurring before the expiration of the term for
8 which the member’s predecessor was appointed shall be
9 appointed only for the remainder of that term. A mem-
10 ber may serve after the expiration of that member’s
11 term until a successor has taken office. A vacancy in
12 the Board shall be filled in the manner in which the
13 original appointment was made.

14 “(7) CHAIR.—The Chair of the Board shall be elected
15 by the members. The term of office of the Chair shall be
16 3 years.

17 “(8) MEETINGS.—The Board shall meet at the call of
18 the Chair, but in no event less than three times during
19 each fiscal year.

20 “(9) DIRECTOR AND STAFF.—

21 “(A) APPOINTMENT OF DIRECTOR.—The Board
22 shall have a Director who shall be appointed by the
23 Chair.

24 “(B) IN GENERAL.—With the approval of the
25 Board, the Director may appoint, without regard to
26 chapter 31 of title 5, United States Code, such addi-
27 tional personnel as the Director considers appropriate.

28 “(C) FLEXIBILITY WITH RESPECT TO COMPENSA-
29 TION.—

30 “(i) IN GENERAL.—The Director and staff of
31 the Board shall, subject to clause (ii), be paid with-
32 out regard to the provisions of chapter 51 and
33 chapter 53 of such title (relating to classification
34 and schedule pay rates).

35 “(ii) MAXIMUM RATE.—In no case may the
36 rate of compensation determined under clause (i)



1 exceed the rate of basic pay payable for level IV of
2 the Executive Schedule under section 5315 of title
3 5, United States Code.

4 “(D) ASSISTANCE FROM THE ADMINISTRATOR OF
5 THE MEDICARE BENEFITS ADMINISTRATION.—The Ad-
6 ministrator of the Medicare Benefits Administration
7 shall make available to the Board such information and
8 other assistance as it may require to carry out its func-
9 tions.

10 “(10) CONTRACT AUTHORITY.—The Board may con-
11 tract with and compensate government and private agencies
12 or persons to carry out its duties under this subsection,
13 without regard to section 3709 of the Revised Statutes (41
14 U.S.C. 5).

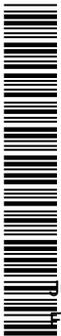
15 “(f) FUNDING.—There is authorized to be appropriated, in
16 appropriate part from the Federal Hospital Insurance Trust
17 Fund and from the Federal Supplementary Medical Insurance
18 Trust Fund (including the Medicare Prescription Drug Ac-
19 count), such sums as are necessary to carry out this section.”.

20 (b) EFFECTIVE DATE.—

21 (1) IN GENERAL.—The amendment made by sub-
22 section (a) shall take effect on the date of the enactment
23 of this Act.

24 (2) DUTIES WITH RESPECT TO ELIGIBILITY DETER-
25 MINATIONS AND ENROLLMENT.—The Administrator of the
26 Medicare Benefits Administration shall carry out enroll-
27 ment under title XVIII of the Social Security Act, make
28 eligibility determinations under such title, and carry out
29 parts C and E of such title for years beginning or after
30 January 1, 2006.

31 (3) TRANSITION.—Before the date the Administrator
32 of the Medicare Benefits Administration is appointed and
33 assumes responsibilities under this section and section
34 1807 of the Social Security Act, the Secretary of Health
35 and Human Services shall provide for the conduct of any



1 responsibilities of such Administrator that are otherwise
2 provided under law.

3 (c) MISCELLANEOUS ADMINISTRATIVE PROVISIONS.—

4 (1) ADMINISTRATOR AS MEMBER OF THE BOARD OF
5 TRUSTEES OF THE MEDICARE TRUST FUNDS.—Section
6 1817(b) and section 1841(b) (42 U.S.C. 1395i(b),
7 1395t(b)) are each amended by striking “and the Secretary
8 of Health and Human Services, all ex officio,” and insert-
9 ing “the Secretary of Health and Human Services, and the
10 Administrator of the Medicare Benefits Administration, all
11 ex officio,”.

12 (2) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR
13 THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE &
14 MEDICAID SERVICES; LEVEL FOR MEDICARE BENEFITS AD-
15 MINISTRATOR.—

16 (A) IN GENERAL.—Section 5314 of title 5, United
17 States Code, by adding at the end the following:

18 “Administrator of the Centers for Medicare & Med-
19 icaid Services.

20 “Administrator of the Medicare Benefits Administra-
21 tion.”.

22 (B) CONFORMING AMENDMENT.—Section 5315 of
23 such title is amended by striking “Administrator of the
24 Health Care Financing Administration.”.

25 (C) EFFECTIVE DATE.—The amendments made by
26 this paragraph take effect on January 1, 2004.

27 **TITLE IX—REGULATORY REDUC-**
28 **TION AND CONTRACTING RE-**
29 **FORM**

30 **Subtitle A—Regulatory Reform**

31 **SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.**

32 (a) CONSTRUCTION.—Nothing in this title shall be
33 construed—

34 (1) to compromise or affect existing legal remedies for
35 addressing fraud or abuse, whether it be criminal prosecu-
36 tion, civil enforcement, or administrative remedies, includ-



1 ing under sections 3729 through 3733 of title 31, United
2 States Code (known as the False Claims Act); or

3 (2) to prevent or impede the Department of Health
4 and Human Services in any way from its ongoing efforts
5 to eliminate waste, fraud, and abuse in the medicare pro-
6 gram.

7 Furthermore, the consolidation of medicare administrative con-
8 tracting set forth in this Act does not constitute consolidation
9 of the Federal Hospital Insurance Trust Fund and the Federal
10 Supplementary Medical Insurance Trust Fund or reflect any
11 position on that issue.

12 (b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C.
13 1395x) is amended by inserting after subsection (c) the fol-
14 lowing new subsection:

15 “Supplier

16 “(d) The term ‘supplier’ means, unless the context other-
17 wise requires, a physician or other practitioner, a facility, or
18 other entity (other than a provider of services) that furnishes
19 items or services under this title.”.

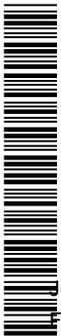
20 **SEC. 902. ISSUANCE OF REGULATIONS.**

21 (a) REGULAR TIMELINE FOR PUBLICATION OF FINAL
22 RULES.—

23 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
24 1395hh(a)) is amended by adding at the end the following
25 new paragraph:

26 “(3)(A) The Secretary, in consultation with the Director
27 of the Office of Management and Budget, shall establish and
28 publish a regular timeline for the publication of final regula-
29 tions based on the previous publication of a proposed regulation
30 or an interim final regulation.

31 “(B) Such timeline may vary among different regulations
32 based on differences in the complexity of the regulation, the
33 number and scope of comments received, and other relevant
34 factors, but shall not be longer than 3 years except under ex-
35 ceptional circumstances. If the Secretary intends to vary such
36 timeline with respect to the publication of a final regulation,



1 the Secretary shall cause to have published in the Federal Reg-
2 ister notice of the different timeline by not later than the
3 timeline previously established with respect to such regulation.
4 Such notice shall include a brief explanation of the justification
5 for such variation.

6 “(C) In the case of interim final regulations, upon the ex-
7 piration of the regular timeline established under this para-
8 graph for the publication of a final regulation after opportunity
9 for public comment, the interim final regulation shall not con-
10 tinue in effect unless the Secretary publishes (at the end of the
11 regular timeline and, if applicable, at the end of each suc-
12 ceeding 1-year period) a notice of continuation of the regulation
13 that includes an explanation of why the regular timeline (and
14 any subsequent 1-year extension) was not complied with. If
15 such a notice is published, the regular timeline (or such
16 timeline as previously extended under this paragraph) for publi-
17 cation of the final regulation shall be treated as having been
18 extended for 1 additional year.

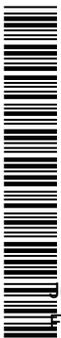
19 “(D) The Secretary shall annually submit to Congress a
20 report that describes the instances in which the Secretary failed
21 to publish a final regulation within the applicable regular
22 timeline under this paragraph and that provides an explanation
23 for such failures.”.

24 (2) EFFECTIVE DATE.—The amendment made by
25 paragraph (1) shall take effect on the date of the enact-
26 ment of this Act. The Secretary shall provide for an appro-
27 priate transition to take into account the backlog of pre-
28 viously published interim final regulations.

29 (b) LIMITATIONS ON NEW MATTER IN FINAL REGULA-
30 TIONS.—

31 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
32 1395hh(a)), as amended by subsection (a), is amended by
33 adding at the end the following new paragraph:

34 “(4) If the Secretary publishes a final regulation that in-
35 cludes a provision that is not a logical outgrowth of a pre-
36 viously published notice of proposed rulemaking or interim final



1 rule, such provision shall be treated as a proposed regulation
2 and shall not take effect until there is the further opportunity
3 for public comment and a publication of the provision again as
4 a final regulation.”.

5 (2) EFFECTIVE DATE.—The amendment made by
6 paragraph (1) shall apply to final regulations published on
7 or after the date of the enactment of this Act.

8 **SEC. 903. COMPLIANCE WITH CHANGES IN REGULA-**
9 **TIONS AND POLICIES.**

10 (a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE
11 CHANGES.—

12 (1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh),
13 as amended by section 902(a), is amended by adding at the
14 end the following new subsection:

15 “(e)(1)(A) A substantive change in regulations, manual in-
16 structions, interpretative rules, statements of policy, or guide-
17 lines of general applicability under this title shall not be applied
18 (by extrapolation or otherwise) retroactively to items and serv-
19 ices furnished before the effective date of the change, unless
20 the Secretary determines that—

21 “(i) such retroactive application is necessary to comply
22 with statutory requirements; or

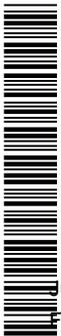
23 “(ii) failure to apply the change retroactively would be
24 contrary to the public interest.”.

25 (2) EFFECTIVE DATE.—The amendment made by
26 paragraph (1) shall apply to substantive changes issued on
27 or after the date of the enactment of this Act.

28 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE
29 CHANGES AFTER NOTICE.—

30 (1) IN GENERAL.—Section 1871(e)(1), as added by
31 subsection (a), is amended by adding at the end the fol-
32 lowing:

33 “(B)(i) Except as provided in clause (ii), a substantive
34 change referred to in subparagraph (A) shall not become effec-
35 tive before the end of the 30-day period that begins on the date



1 that the Secretary has issued or published, as the case may be,
2 the substantive change.

3 “(ii) The Secretary may provide for such a substantive
4 change to take effect on a date that precedes the end of the
5 30-day period under clause (i) if the Secretary finds that waiv-
6 er of such 30-day period is necessary to comply with statutory
7 requirements or that the application of such 30-day period is
8 contrary to the public interest. If the Secretary provides for an
9 earlier effective date pursuant to this clause, the Secretary
10 shall include in the issuance or publication of the substantive
11 change a finding described in the first sentence, and a brief
12 statement of the reasons for such finding.

13 “(C) No action shall be taken against a provider of serv-
14 ices or supplier with respect to noncompliance with such a sub-
15 stantive change for items and services furnished before the ef-
16 fective date of such a change.”

17 (2) EFFECTIVE DATE.—The amendment made by
18 paragraph (1) shall apply to compliance actions undertaken
19 on or after the date of the enactment of this Act.

20 (c) RELIANCE ON GUIDANCE.—

21 (1) IN GENERAL.—Section 1871(e), as added by sub-
22 section (a), is further amended by adding at the end the
23 following new paragraph:

24 “(2)(A) If—

25 “(i) a provider of services or supplier follows the writ-
26 ten guidance (which may be transmitted electronically) pro-
27 vided by the Secretary or by a medicare contractor (as de-
28 fined in section 1889(g)) acting within the scope of the
29 contractor’s contract authority, with respect to the fur-
30 nishing of items or services and submission of a claim for
31 benefits for such items or services with respect to such pro-
32 vider or supplier;

33 “(ii) the Secretary determines that the provider of
34 services or supplier has accurately presented the cir-
35 cumstances relating to such items, services, and claim to
36 the contractor in writing; and

1 “(iii) the guidance was in error;
2 the provider of services or supplier shall not be subject to any
3 sanction (including any penalty or requirement for repayment
4 of any amount) if the provider of services or supplier reason-
5 ably relied on such guidance.

6 “(B) Subparagraph (A) shall not be construed as pre-
7 venting the recoupment or repayment (without any additional
8 penalty) relating to an overpayment insofar as the overpayment
9 was solely the result of a clerical or technical operational
10 error.”.

11 (2) EFFECTIVE DATE.—The amendment made by
12 paragraph (1) shall take effect on the date of the enact-
13 ment of this Act but shall not apply to any sanction for
14 which notice was provided on or before the date of the en-
15 actment of this Act.

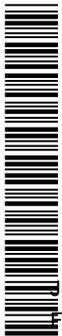
16 **SEC. 904. REPORTS AND STUDIES RELATING TO REGU-**
17 **LATORY REFORM.**

18 (a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

19 (1) STUDY.—The Comptroller General of the United
20 States shall conduct a study to determine the feasibility
21 and appropriateness of establishing in the Secretary au-
22 thority to provide legally binding advisory opinions on ap-
23 propriate interpretation and application of regulations to
24 carry out the medicare program under title XVIII of the
25 Social Security Act. Such study shall examine the appro-
26 priate timeframe for issuing such advisory opinions, as well
27 as the need for additional staff and funding to provide such
28 opinions.

29 (2) REPORT.—The Comptroller General shall submit
30 to Congress a report on the study conducted under para-
31 graph (1) by not later than one year after the date of the
32 enactment of this Act.

33 (b) REPORT ON LEGAL AND REGULATORY INCONSIST-
34 ENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by
35 section 2(a), is amended by adding at the end the following new
36 subsection:



1 “(f)(1) Not later than 2 years after the date of the enact-
2 ment of this subsection, and every 2 years thereafter, the Sec-
3 retary shall submit to Congress a report with respect to the ad-
4 ministration of this title and areas of inconsistency or conflict
5 among the various provisions under law and regulation.

6 “(2) In preparing a report under paragraph (1), the Sec-
7 retary shall collect—

8 “(A) information from individuals entitled to benefits
9 under part A or enrolled under part B, or both, providers
10 of services, and suppliers and from the Medicare Bene-
11 ficiary Ombudsman and the Medicare Provider Ombuds-
12 man with respect to such areas of inconsistency and con-
13 flict; and

14 “(B) information from medicare contractors that
15 tracks the nature of written and telephone inquiries.

16 “(3) A report under paragraph (1) shall include a descrip-
17 tion of efforts by the Secretary to reduce such inconsistency or
18 conflicts, and recommendations for legislation or administrative
19 action that the Secretary determines appropriate to further re-
20 duce such inconsistency or conflicts.”.

21 **Subtitle B—Contracting Reform**

22 **SEC. 911. INCREASED FLEXIBILITY IN MEDICARE AD-** 23 **MINISTRATION.**

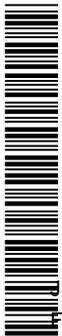
24 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE AD-
25 MINISTRATION.—

26 (1) IN GENERAL.—Title XVIII is amended by insert-
27 ing after section 1874 the following new section:

28 “CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

29 “SEC. 1874A. (a) AUTHORITY.—

30 “(1) AUTHORITY TO ENTER INTO CONTRACTS.—The
31 Secretary may enter into contracts with any eligible entity
32 to serve as a medicare administrative contractor with re-
33 spect to the performance of any or all of the functions de-
34 scribed in paragraph (4) or parts of those functions (or, to
35 the extent provided in a contract, to secure performance
36 thereof by other entities).



1 “(2) ELIGIBILITY OF ENTITIES.—An entity is eligible
2 to enter into a contract with respect to the performance of
3 a particular function described in paragraph (4) only if—

4 “(A) the entity has demonstrated capability to
5 carry out such function;

6 “(B) the entity complies with such conflict of in-
7 terest standards as are generally applicable to Federal
8 acquisition and procurement;

9 “(C) the entity has sufficient assets to financially
10 support the performance of such function; and

11 “(D) the entity meets such other requirements as
12 the Secretary may impose.

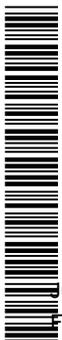
13 “(3) MEDICARE ADMINISTRATIVE CONTRACTOR DE-
14 FINED.—For purposes of this title and title XI—

15 “(A) IN GENERAL.—The term ‘medicare adminis-
16 trative contractor’ means an agency, organization, or
17 other person with a contract under this section.

18 “(B) APPROPRIATE MEDICARE ADMINISTRATIVE
19 CONTRACTOR.—With respect to the performance of a
20 particular function in relation to an individual entitled
21 to benefits under part A or enrolled under part B, or
22 both, a specific provider of services or supplier (or class
23 of such providers of services or suppliers), the ‘appro-
24 priate’ medicare administrative contractor is the medi-
25 care administrative contractor that has a contract
26 under this section with respect to the performance of
27 that function in relation to that individual, provider of
28 services or supplier or class of provider of services or
29 supplier.

30 “(4) FUNCTIONS DESCRIBED.—The functions referred
31 to in paragraphs (1) and (2) are payment functions, pro-
32 vider services functions, and functions relating to services
33 furnished to individuals entitled to benefits under part A
34 or enrolled under part B, or both, as follows:

35 “(A) DETERMINATION OF PAYMENT AMOUNTS.—
36 Determining (subject to the provisions of section 1878



1 and to such review by the Secretary as may be provided
2 for by the contracts) the amount of the payments re-
3 quired pursuant to this title to be made to providers of
4 services, suppliers and individuals.

5 “(B) MAKING PAYMENTS.—Making payments de-
6 scribed in subparagraph (A) (including receipt, dis-
7 bursement, and accounting for funds in making such
8 payments).

9 “(C) BENEFICIARY EDUCATION AND ASSIST-
10 ANCE.—Providing education and outreach to individ-
11 uals entitled to benefits under part A or enrolled under
12 part B, or both, and providing assistance to those indi-
13 viduals with specific issues, concerns or problems.

14 “(D) PROVIDER CONSULTATIVE SERVICES.—Pro-
15 viding consultative services to institutions, agencies,
16 and other persons to enable them to establish and
17 maintain fiscal records necessary for purposes of this
18 title and otherwise to qualify as providers of services or
19 suppliers.

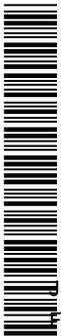
20 “(E) COMMUNICATION WITH PROVIDERS.—Com-
21 municating to providers of services and suppliers any
22 information or instructions furnished to the medicare
23 administrative contractor by the Secretary, and facili-
24 tating communication between such providers and sup-
25 pliers and the Secretary.

26 “(F) PROVIDER EDUCATION AND TECHNICAL AS-
27 SISTANCE.—Performing the functions relating to pro-
28 vider education, training, and technical assistance.

29 “(G) ADDITIONAL FUNCTIONS.—Performing such
30 other functions as are necessary to carry out the pur-
31 poses of this title.

32 “(5) RELATIONSHIP TO MIP CONTRACTS.—

33 “(A) NONDUPLICATION OF DUTIES.—In entering
34 into contracts under this section, the Secretary shall
35 assure that functions of medicare administrative con-
36 tractors in carrying out activities under parts A and B



1 do not duplicate activities carried out under the Medi-
2 care Integrity Program under section 1893. The pre-
3 vious sentence shall not apply with respect to the activ-
4 ity described in section 1893(b)(5) (relating to prior
5 authorization of certain items of durable medical equip-
6 ment under section 1834(a)(15)).

7 “(B) CONSTRUCTION.—An entity shall not be
8 treated as a medicare administrative contractor merely
9 by reason of having entered into a contract with the
10 Secretary under section 1893.

11 “(6) APPLICATION OF FEDERAL ACQUISITION REGULA-
12 TION.—Except to the extent inconsistent with a specific re-
13 quirement of this title, the Federal Acquisition Regulation
14 applies to contracts under this title.

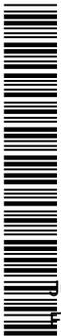
15 “(b) CONTRACTING REQUIREMENTS.—

16 “(1) USE OF COMPETITIVE PROCEDURES.—

17 “(A) IN GENERAL.—Except as provided in laws
18 with general applicability to Federal acquisition and
19 procurement or in subparagraph (B), the Secretary
20 shall use competitive procedures when entering into
21 contracts with medicare administrative contractors
22 under this section, taking into account performance
23 quality as well as price and other factors.

24 “(B) RENEWAL OF CONTRACTS.—The Secretary
25 may renew a contract with a medicare administrative
26 contractor under this section from term to term with-
27 out regard to section 5 of title 41, United States Code,
28 or any other provision of law requiring competition, if
29 the medicare administrative contractor has met or ex-
30 ceeded the performance requirements applicable with
31 respect to the contract and contractor, except that the
32 Secretary shall provide for the application of competi-
33 tive procedures under such a contract not less fre-
34 quently than once every five years.

35 “(C) TRANSFER OF FUNCTIONS.—The Secretary
36 may transfer functions among medicare administrative



1 contractors consistent with the provisions of this para-
2 graph. The Secretary shall ensure that performance
3 quality is considered in such transfers. The Secretary
4 shall provide public notice (whether in the Federal Reg-
5 ister or otherwise) of any such transfer (including a de-
6 scription of the functions so transferred, a description
7 of the providers of services and suppliers affected by
8 such transfer, and contact information for the contrac-
9 tors involved).

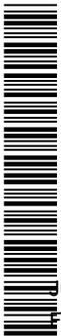
10 “(D) INCENTIVES FOR QUALITY.—The Secretary
11 shall provide incentives for medicare administrative
12 contractors to provide quality service and to promote
13 efficiency.

14 “(2) COMPLIANCE WITH REQUIREMENTS.—No con-
15 tract under this section shall be entered into with any
16 medicare administrative contractor unless the Secretary
17 finds that such medicare administrative contractor will per-
18 form its obligations under the contract efficiently and effec-
19 tively and will meet such requirements as to financial re-
20 sponsibility, legal authority, quality of services provided,
21 and other matters as the Secretary finds pertinent.

22 “(3) PERFORMANCE REQUIREMENTS.—

23 “(A) DEVELOPMENT OF SPECIFIC PERFORMANCE
24 REQUIREMENTS.—In developing contract performance
25 requirements, the Secretary shall develop performance
26 requirements applicable to functions described in sub-
27 section (a)(4).

28 “(B) CONSULTATION.— In developing such re-
29 quirements, the Secretary may consult with providers
30 of services and suppliers, organizations representing in-
31 dividuals entitled to benefits under part A or enrolled
32 under part B, or both, and organizations and agencies
33 performing functions necessary to carry out the pur-
34 poses of this section with respect to such performance
35 requirements.



1 “(C) INCLUSION IN CONTRACTS.—All contractor
2 performance requirements shall be set forth in the con-
3 tract between the Secretary and the appropriate medi-
4 care administrative contractor. Such performance
5 requirements—

6 “(i) shall reflect the performance requirements
7 developed under subparagraph (A), but may in-
8 clude additional performance requirements;

9 “(ii) shall be used for evaluating contractor
10 performance under the contract; and

11 “(iii) shall be consistent with the written state-
12 ment of work provided under the contract.

13 “(4) INFORMATION REQUIREMENTS.—The Secretary
14 shall not enter into a contract with a medicare administra-
15 tive contractor under this section unless the contractor
16 agrees—

17 “(A) to furnish to the Secretary such timely infor-
18 mation and reports as the Secretary may find nec-
19 essary in performing his functions under this title; and

20 “(B) to maintain such records and afford such ac-
21 cess thereto as the Secretary finds necessary to assure
22 the correctness and verification of the information and
23 reports under subparagraph (A) and otherwise to carry
24 out the purposes of this title.

25 “(5) SURETY BOND.—A contract with a medicare ad-
26 ministrative contractor under this section may require the
27 medicare administrative contractor, and any of its officers
28 or employees certifying payments or disbursing funds pur-
29 suant to the contract, or otherwise participating in carrying
30 out the contract, to give surety bond to the United States
31 in such amount as the Secretary may deem appropriate.

32 “(c) TERMS AND CONDITIONS.—

33 “(1) IN GENERAL.—A contract with any medicare ad-
34 ministrative contractor under this section may contain such
35 terms and conditions as the Secretary finds necessary or
36 appropriate and may provide for advances of funds to the



1 medicare administrative contractor for the making of pay-
2 ments by it under subsection (a)(4)(B).

3 “(2) PROHIBITION ON MANDATES FOR CERTAIN DATA
4 COLLECTION.—The Secretary may not require, as a condi-
5 tion of entering into, or renewing, a contract under this
6 section, that the medicare administrative contractor match
7 data obtained other than in its activities under this title
8 with data used in the administration of this title for pur-
9 poses of identifying situations in which the provisions of
10 section 1862(b) may apply.

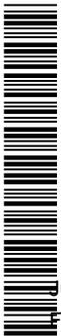
11 “(d) LIMITATION ON LIABILITY OF MEDICARE ADMINIS-
12 TRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

13 “(1) CERTIFYING OFFICER.—No individual designated
14 pursuant to a contract under this section as a certifying of-
15 ficer shall, in the absence of the reckless disregard of the
16 individual’s obligations or the intent by that individual to
17 defraud the United States, be liable with respect to any
18 payments certified by the individual under this section.

19 “(2) DISBURSING OFFICER.—No disbursing officer
20 shall, in the absence of the reckless disregard of the offi-
21 cer’s obligations or the intent by that officer to defraud the
22 United States, be liable with respect to any payment by
23 such officer under this section if it was based upon an au-
24 thorization (which meets the applicable requirements for
25 such internal controls established by the Comptroller Gen-
26 eral) of a certifying officer designated as provided in para-
27 graph (1) of this subsection.

28 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE CON-
29 TRACTOR.—

30 “(A) IN GENERAL.—No medicare administrative con-
31 tractor shall be liable to the United States for a payment
32 by a certifying or disbursing officer unless, in connection
33 with such payment, the medicare administrative contractor
34 acted with reckless disregard of its obligations under its
35 medicare administrative contract or with intent to defraud
36 the United States.



1 “(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing
2 in this subsection shall be construed to limit liability for
3 conduct that would constitute a violation of sections 3729
4 through 3731 of title 31, United States Code (commonly
5 known as the ‘False Claims Act’).

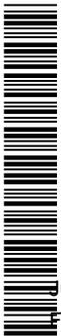
6 “(4) INDEMNIFICATION BY SECRETARY.—

7 “(A) IN GENERAL.—Subject to subparagraphs (B)
8 and (D), in the case of a medicare administrative con-
9 tractor (or a person who is a director, officer, or em-
10 ployee of such a contractor or who is engaged by the
11 contractor to participate directly in the claims adminis-
12 tration process) who is made a party to any judicial or
13 administrative proceeding arising from or relating di-
14 rectly to the claims administration process under this
15 title, the Secretary may, to the extent the Secretary de-
16 termines to be appropriate and as specified in the con-
17 tract with the contractor, indemnify the contractor and
18 such persons.

19 “(B) CONDITIONS.—The Secretary may not pro-
20 vide indemnification under subparagraph (A) insofar as
21 the liability for such costs arises directly from conduct
22 that is determined by the judicial proceeding or by the
23 Secretary to be criminal in nature, fraudulent, or
24 grossly negligent. If indemnification is provided by the
25 Secretary with respect to a contractor before a deter-
26 mination that such costs arose directly from such con-
27 duct, the contractor shall reimburse the Secretary for
28 costs of indemnification.

29 “(C) SCOPE OF INDEMNIFICATION.—Indemnifica-
30 tion by the Secretary under subparagraph (A) may in-
31 clude payment of judgments, settlements (subject to
32 subparagraph (D)), awards, and costs (including rea-
33 sonable legal expenses).

34 “(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A
35 contractor or other person described in subparagraph
36 (A) may not propose to negotiate a settlement or com-



1 promise of a proceeding described in such subpara-
2 graph without the prior written approval of the Sec-
3 retary to negotiate such settlement or compromise. Any
4 indemnification under subparagraph (A) with respect to
5 amounts paid under a settlement or compromise of a
6 proceeding described in such subparagraph are condi-
7 tioned upon prior written approval by the Secretary of
8 the final settlement or compromise.

9 “(E) CONSTRUCTION.—Nothing in this paragraph
10 shall be construed—

11 “(i) to change any common law immunity that
12 may be available to a medicare administrative con-
13 tractor or person described in subparagraph (A); or

14 “(ii) to permit the payment of costs not other-
15 wise allowable, reasonable, or allocable under the
16 Federal Acquisition Regulations.”.

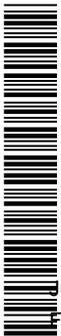
17 (2) CONSIDERATION OF INCORPORATION OF CURRENT
18 LAW STANDARDS.—In developing contract performance re-
19 quirements under section 1874A(b) of the Social Security
20 Act, as inserted by paragraph (1), the Secretary shall con-
21 sider inclusion of the performance standards described in
22 sections 1816(f)(2) of such Act (relating to timely proc-
23 essing of reconsiderations and applications for exemptions)
24 and section 1842(b)(2)(B) of such Act (relating to timely
25 review of determinations and fair hearing requests), as
26 such sections were in effect before the date of the enact-
27 ment of this Act.

28 (b) CONFORMING AMENDMENTS TO SECTION 1816 (RE-
29 LATING TO FISCAL INTERMEDIARIES).—Section 1816 (42
30 U.S.C. 1395h) is amended as follows:

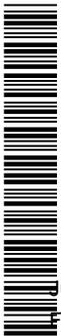
31 (1) The heading is amended to read as follows:
32 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

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

34 “(a) The administration of this part shall be conducted
35 through contracts with medicare administrative contractors
36 under section 1874A.”.



- 1 (3) Subsection (b) is repealed.
- 2 (4) Subsection (c) is amended—
- 3 (A) by striking paragraph (1); and
- 4 (B) in each of paragraphs (2)(A) and (3)(A), by
- 5 striking “agreement under this section” and inserting
- 6 “contract under section 1874A that provides for mak-
- 7 ing payments under this part”.
- 8 (5) Subsections (d) through (i) are repealed.
- 9 (6) Subsections (j) and (k) are each amended—
- 10 (A) by striking “An agreement with an agency or
- 11 organization under this section” and inserting “A con-
- 12 tract with a medicare administrative contractor under
- 13 section 1874A with respect to the administration of
- 14 this part”; and
- 15 (B) by striking “such agency or organization” and
- 16 inserting “such medicare administrative contractor”
- 17 each place it appears.
- 18 (7) Subsection (l) is repealed.
- 19 (c) CONFORMING AMENDMENTS TO SECTION 1842 (RE-
- 20 LATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is
- 21 amended as follows:
- 22 (1) The heading is amended to read as follows:
- 23 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.
- 24 (2) Subsection (a) is amended to read as follows:
- 25 “(a) The administration of this part shall be conducted
- 26 through contracts with medicare administrative contractors
- 27 under section 1874A.”.
- 28 (3) Subsection (b) is amended—
- 29 (A) by striking paragraph (1);
- 30 (B) in paragraph (2)—
- 31 (i) by striking subparagraphs (A) and (B);
- 32 (ii) in subparagraph (C), by striking “car-
- 33 riers” and inserting “medicare administrative con-
- 34 tractors”; and
- 35 (iii) by striking subparagraphs (D) and (E);
- 36 (C) in paragraph (3)—



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

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

7 (iii) in subparagraph (B), in the matter before
8 clause (i), by striking “to the policyholders and
9 subscribers of the carrier” and inserting “to the
10 policyholders and subscribers of the medicare ad-
11 ministrative contractor”;

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

14 (v) in subparagraph (H)—

15 (I) by striking “if it makes determinations
16 or payments with respect to physicians’ serv-
17 ices,” in the matter preceding clause (i); and

18 (II) by striking “carrier” and inserting
19 “medicare administrative contractor” in clause
20 (i);

21 (vi) by striking subparagraph (I);

22 (vii) in subparagraph (L), by striking the
23 semicolon and inserting a period;

24 (viii) in the first sentence, after subparagraph
25 (L), by striking “and shall contain” and all that
26 follows through the period; and

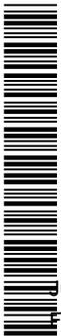
27 (ix) in the seventh sentence, by inserting
28 “medicare administrative contractor,” after “car-
29 rier,”; and

30 (D) by striking paragraph (5);

31 (E) in paragraph (6)(D)(iv), by striking “carrier”
32 and inserting “medicare administrative contractor”;
33 and

34 (F) in paragraph (7), by striking “the carrier”
35 and inserting “the Secretary” each place it appears.

36 (4) Subsection (c) is amended—



1 (A) by striking paragraph (1);

2 (B) in paragraph (2)(A), by striking “contract
3 under this section which provides for the disbursement
4 of funds, as described in subsection (a)(1)(B),” and in-
5 serting “contract under section 1874A that provides for
6 making payments under this part”;

7 (C) in paragraph (3)(A), by striking “subsection
8 (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;

9 (D) in paragraph (4), in the matter preceding sub-
10 paragraph (A), by striking “carrier” and inserting
11 “medicare administrative contractor”; and

12 (E) by striking paragraphs (5) and (6).

13 (5) Subsections (d), (e), and (f) are repealed.

14 (6) Subsection (g) is amended by striking “carrier or
15 carriers” and inserting “medicare administrative contractor
16 or contractors”.

17 (7) Subsection (h) is amended—

18 (A) in paragraph (2)—

19 (i) by striking “Each carrier having an agree-
20 ment with the Secretary under subsection (a)” and
21 inserting “The Secretary”; and

22 (ii) by striking “Each such carrier” and in-
23 serting “The Secretary”;

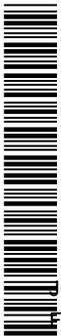
24 (B) in paragraph (3)(A)—

25 (i) by striking “a carrier having an agreement
26 with the Secretary under subsection (a)” and in-
27 serting “medicare administrative contractor having
28 a contract under section 1874A that provides for
29 making payments under this part”; and

30 (ii) by striking “such carrier” and inserting
31 “such contractor”;

32 (C) in paragraph (3)(B)—

33 (i) by striking “a carrier” and inserting “a
34 medicare administrative contractor” each place it
35 appears; and



1 (ii) by striking “the carrier” and inserting
2 “the contractor” each place it appears; and

3 (D) in paragraphs (5)(A) and (5)(B)(iii), by strik-
4 ing “carriers” and inserting “medicare administrative
5 contractors” each place it appears.

6 (8) Subsection (l) is amended—

7 (A) in paragraph (1)(A)(iii), by striking “carrier”
8 and inserting “medicare administrative contractor”;
9 and

10 (B) in paragraph (2), by striking “carrier” and in-
11 serting “medicare administrative contractor”.

12 (9) Subsection (p)(3)(A) is amended by striking “car-
13 rier” and inserting “medicare administrative contractor”.

14 (10) Subsection (q)(1)(A) is amended by striking “car-
15 rier”.

16 (d) EFFECTIVE DATE; TRANSITION RULE.—

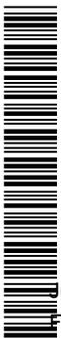
17 (1) EFFECTIVE DATE.—

18 (A) IN GENERAL.—Except as otherwise provided
19 in this subsection, the amendments made by this sec-
20 tion shall take effect on October 1, 2005, and the Sec-
21 retary is authorized to take such steps before such date
22 as may be necessary to implement such amendments on
23 a timely basis.

24 (B) CONSTRUCTION FOR CURRENT CONTRACTS.—

25 Such amendments shall not apply to contracts in effect
26 before the date specified under subparagraph (A) that
27 continue to retain the terms and conditions in effect on
28 such date (except as otherwise provided under this Act,
29 other than under this section) until such date as the
30 contract is let out for competitive bidding under such
31 amendments.

32 (C) DEADLINE FOR COMPETITIVE BIDDING.—The
33 Secretary shall provide for the letting by competitive
34 bidding of all contracts for functions of medicare ad-
35 ministrative contractors for annual contract periods
36 that begin on or after October 1, 2010.



1 (D) WAIVER OF PROVIDER NOMINATION PROVI-
2 SIONS DURING TRANSITION.—During the period begin-
3 ning on the date of the enactment of this Act and be-
4 fore the date specified under subparagraph (A), the
5 Secretary may enter into new agreements under section
6 1816 of the Social Security Act (42 U.S.C. 1395h)
7 without regard to any of the provider nomination provi-
8 sions of such section.

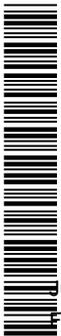
9 (2) GENERAL TRANSITION RULES.—The Secretary
10 shall take such steps, consistent with paragraph (1)(B) and
11 (1)(C), as are necessary to provide for an appropriate tran-
12 sition from contracts under section 1816 and section 1842
13 of the Social Security Act (42 U.S.C. 1395h, 1395u) to
14 contracts under section 1874A, as added by subsection
15 (a)(1).

16 (3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS
17 UNDER CURRENT CONTRACTS AND AGREEMENTS AND
18 UNDER ROLLOVER CONTRACTS.—The provisions contained
19 in the exception in section 1893(d)(2) of the Social Secu-
20 rity Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply
21 notwithstanding the amendments made by this section, and
22 any reference in such provisions to an agreement or con-
23 tract shall be deemed to include a contract under section
24 1874A of such Act, as inserted by subsection (a)(1), that
25 continues the activities referred to in such provisions.

26 (e) REFERENCES.—On and after the effective date pro-
27 vided under subsection (d)(1), any reference to a fiscal inter-
28 mediary or carrier under title XI or XVIII of the Social Secu-
29 rity Act (or any regulation, manual instruction, interpretative
30 rule, statement of policy, or guideline issued to carry out such
31 titles) shall be deemed a reference to a medicare administrative
32 contractor (as provided under section 1874A of the Social Se-
33 curity Act).

34 (f) REPORTS ON IMPLEMENTATION.—

35 (1) PLAN FOR IMPLEMENTATION.—By not later than
36 October 1, 2004, the Secretary shall submit a report to



1 Congress and the Comptroller General of the United States
2 that describes the plan for implementation of the amend-
3 ments made by this section. The Comptroller General shall
4 conduct an evaluation of such plan and shall submit to
5 Congress, not later than 6 months after the date the report
6 is received, a report on such evaluation and shall include
7 in such report such recommendations as the Comptroller
8 General deems appropriate.

9 (2) STATUS OF IMPLEMENTATION.—The Secretary
10 shall submit a report to Congress not later than October
11 1, 2008, that describes the status of implementation of
12 such amendments and that includes a description of the
13 following:

14 (A) The number of contracts that have been com-
15 petitively bid as of such date.

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

18 (C) A timeline for complete transition to full com-
19 petition.

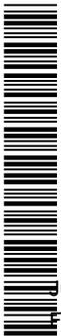
20 (D) A detailed description of how the Secretary
21 has modified oversight and management of medicare
22 contractors to adapt to full competition.

23 **SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY**
24 **FOR MEDICARE ADMINISTRATIVE CONTRAC-**
25 **TORS.**

26 (a) IN GENERAL.—Section 1874A, as added by section
27 911(a)(1), is amended by adding at the end the following new
28 subsection:

29 “(e) REQUIREMENTS FOR INFORMATION SECURITY.—

30 “(1) DEVELOPMENT OF INFORMATION SECURITY PRO-
31 GRAM.—A medicare administrative contractor that per-
32 forms the functions referred to in subparagraphs (A) and
33 (B) of subsection (a)(4) (relating to determining and mak-
34 ing payments) shall implement a contractor-wide informa-
35 tion security program to provide information security for
36 the operation and assets of the contractor with respect to



1 such functions under this title. An information security
2 program under this paragraph shall meet the requirements
3 for information security programs imposed on Federal
4 agencies under paragraphs (1) through (8) of section
5 3544(b) of title 44, United States Code (other than the re-
6 quirements under paragraphs (2)(D)(i), (5)(A), and (5)(B)
7 of such section).

8 “(2) INDEPENDENT AUDITS.—

9 “(A) PERFORMANCE OF ANNUAL EVALUATIONS.—

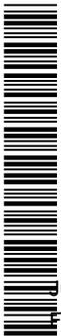
10 Each year a medicare administrative contractor that
11 performs the functions referred to in subparagraphs
12 (A) and (B) of subsection (a)(4) (relating to deter-
13 mining and making payments) shall undergo an evalua-
14 tion of the information security of the contractor with
15 respect to such functions under this title. The evalua-
16 tion shall—

17 “(i) be performed by an entity that meets such
18 requirements for independence as the Inspector
19 General of the Department of Health and Human
20 Services may establish; and

21 “(ii) test the effectiveness of information secu-
22 rity control techniques of an appropriate subset of
23 the contractor’s information systems (as defined in
24 section 3502(8) of title 44, United States Code) re-
25 lating to such functions under this title and an as-
26 sessment of compliance with the requirements of
27 this subsection and related information security
28 policies, procedures, standards and guidelines, in-
29 cluding policies and procedures as may be pre-
30 scribed by the Director of the Office of Manage-
31 ment and Budget and applicable information secu-
32 rity standards promulgated under section 11331 of
33 title 40, United States Code.

34 “(B) DEADLINE FOR INITIAL EVALUATION.—

35 “(i) NEW CONTRACTORS.—In the case of a
36 medicare administrative contractor covered by this



1 subsection that has not previously performed the
2 functions referred to in subparagraphs (A) and (B)
3 of subsection (a)(4) (relating to determining and
4 making payments) as a fiscal intermediary or car-
5 rier under section 1816 or 1842, the first inde-
6 pendent evaluation conducted pursuant subpara-
7 graph (A) shall be completed prior to commencing
8 such functions.

9 “(ii) OTHER CONTRACTORS.—In the case of a
10 medicare administrative contractor covered by this
11 subsection that is not described in clause (i), the
12 first independent evaluation conducted pursuant
13 subparagraph (A) shall be completed within 1 year
14 after the date the contractor commences functions
15 referred to in clause (i) under this section.

16 “(C) REPORTS ON EVALUATIONS.—

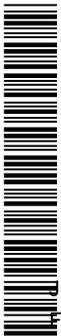
17 “(i) TO THE DEPARTMENT OF HEALTH AND
18 HUMAN SERVICES.—The results of independent
19 evaluations under subparagraph (A) shall be sub-
20 mitted promptly to the Inspector General of the
21 Department of Health and Human Services and to
22 the Secretary.

23 “(ii) TO CONGRESS.—The Inspector General
24 of Department of Health and Human Services shall
25 submit to Congress annual reports on the results of
26 such evaluations, including assessments of the
27 scope and sufficiency of such evaluations.

28 “(iii) AGENCY REPORTING.—The Secretary
29 shall address the results of such evaluations in re-
30 ports required under section 3544(c) of title 44,
31 United States Code.”.

32 (b) APPLICATION OF REQUIREMENTS TO FISCAL INTER-
33 MEDIARIES AND CARRIERS.—

34 (1) IN GENERAL.—The provisions of section
35 1874A(e)(2) of the Social Security Act (other than sub-
36 paragraph (B)), as added by subsection (a), shall apply to



1 each fiscal intermediary under section 1816 of the Social
2 Security Act (42 U.S.C. 1395h) and each carrier under
3 section 1842 of such Act (42 U.S.C. 1395u) in the same
4 manner as they apply to medicare administrative contrac-
5 tors under such provisions.

6 (2) DEADLINE FOR INITIAL EVALUATION.—In the case
7 of such a fiscal intermediary or carrier with an agreement
8 or contract under such respective section in effect as of the
9 date of the enactment of this Act, the first evaluation
10 under section 1874A(e)(2)(A) of the Social Security Act
11 (as added by subsection (a)), pursuant to paragraph (1),
12 shall be completed (and a report on the evaluation sub-
13 mitted to the Secretary) by not later than 1 year after such
14 date.

15 **Subtitle C—Education and Outreach**

16 **SEC. 921. PROVIDER EDUCATION AND TECHNICAL AS-** 17 **SISTANCE.**

18 (a) COORDINATION OF EDUCATION FUNDING.—

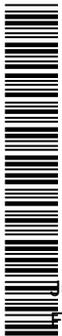
19 (1) IN GENERAL.—Title XVIII is amended by insert-
20 ing after section 1888 the following new section:

21 “PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

22 “SEC. 1889. (a) COORDINATION OF EDUCATION FUND-
23 ING.—The Secretary shall coordinate the educational activities
24 provided through medicare contractors (as defined in sub-
25 section (g), including under section 1893) in order to maximize
26 the effectiveness of Federal education efforts for providers of
27 services and suppliers.”.

28 (2) EFFECTIVE DATE.—The amendment made by
29 paragraph (1) shall take effect on the date of the enact-
30 ment of this Act.

31 (3) REPORT.—Not later than October 1, 2004, the
32 Secretary shall submit to Congress a report that includes
33 a description and evaluation of the steps taken to coordi-
34 nate the funding of provider education under section
35 1889(a) of the Social Security Act, as added by paragraph
36 (1).



1 (b) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
2 ANCE.—

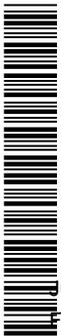
3 (1) IN GENERAL.—Section 1874A, as added by section
4 911(a)(1) and as amended by section 912(a), is amended
5 by adding at the end the following new subsection:

6 “(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
7 ANCE IN PROVIDER EDUCATION AND OUTREACH.—The Sec-
8 retary shall use specific claims payment error rates or similar
9 methodology of medicare administrative contractors in the
10 processing or reviewing of medicare claims in order to give such
11 contractors an incentive to implement effective education and
12 outreach programs for providers of services and suppliers.”.

13 (2) APPLICATION TO FISCAL INTERMEDIARIES AND
14 CARRIERS.—The provisions of section 1874A(f) of the So-
15 cial Security Act, as added by paragraph (1), shall apply
16 to each fiscal intermediary under section 1816 of the Social
17 Security Act (42 U.S.C. 1395h) and each carrier under
18 section 1842 of such Act (42 U.S.C. 1395u) in the same
19 manner as they apply to medicare administrative contrac-
20 tors under such provisions.

21 (3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—
22 Not later than October 1, 2004, the Comptroller General
23 of the United States shall submit to Congress and to the
24 Secretary a report on the adequacy of the methodology
25 under section 1874A(f) of the Social Security Act, as added
26 by paragraph (1), and shall include in the report such rec-
27 ommendations as the Comptroller General determines ap-
28 propriate with respect to the methodology.

29 (4) REPORT ON USE OF METHODOLOGY IN ASSESSING
30 CONTRACTOR PERFORMANCE.—Not later than October 1,
31 2004, the Secretary shall submit to Congress a report that
32 describes how the Secretary intends to use such method-
33 ology in assessing medicare contractor performance in im-
34 plementing effective education and outreach programs, in-
35 cluding whether to use such methodology as a basis for per-
36 formance bonuses. The report shall include an analysis of



1 the sources of identified errors and potential changes in
2 systems of contractors and rules of the Secretary that could
3 reduce claims error rates.

4 (c) PROVISION OF ACCESS TO AND PROMPT RESPONSES
5 FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

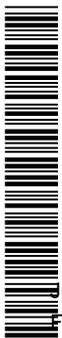
6 (1) IN GENERAL.—Section 1874A, as added by section
7 911(a)(1) and as amended by section 912(a) and sub-
8 section (b), is further amended by adding at the end the
9 following new subsection:

10 “(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS
11 OF SERVICES AND SUPPLIERS.—

12 “(1) COMMUNICATION STRATEGY.—The Secretary
13 shall develop a strategy for communications with individ-
14 uals entitled to benefits under part A or enrolled under
15 part B, or both, and with providers of services and sup-
16 pliers under this title.

17 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each medi-
18 care administrative contractor shall, for those providers of
19 services and suppliers which submit claims to the con-
20 tractor for claims processing and for those individuals enti-
21 tled to benefits under part A or enrolled under part B, or
22 both, with respect to whom claims are submitted for claims
23 processing, provide general written responses (which may
24 be through electronic transmission) in a clear, concise, and
25 accurate manner to inquiries of providers of services, sup-
26 pliers and individuals entitled to benefits under part A or
27 enrolled under part B, or both, concerning the programs
28 under this title within 45 business days of the date of re-
29 ceipt of such inquiries.

30 “(3) RESPONSE TO TOLL-FREE LINES.—The Secretary
31 shall ensure that each medicare administrative contractor
32 shall provide, for those providers of services and suppliers
33 which submit claims to the contractor for claims processing
34 and for those individuals entitled to benefits under part A
35 or enrolled under part B, or both, with respect to whom
36 claims are submitted for claims processing, a toll-free tele-



1 phone number at which such individuals, providers of serv-
2 ices and suppliers may obtain information regarding billing,
3 coding, claims, coverage, and other appropriate information
4 under this title.

5 “(4) MONITORING OF CONTRACTOR RESPONSES.—

6 “(A) IN GENERAL.—Each medicare administrative
7 contractor shall, consistent with standards developed by
8 the Secretary under subparagraph (B)—

9 “(i) maintain a system for identifying who
10 provides the information referred to in paragraphs
11 (2) and (3); and

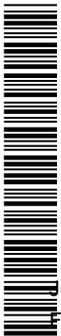
12 “(ii) monitor the accuracy, consistency, and
13 timeliness of the information so provided.

14 “(B) DEVELOPMENT OF STANDARDS.—

15 “(i) IN GENERAL.—The Secretary shall estab-
16 lish and make public standards to monitor the ac-
17 curacy, consistency, and timeliness of the informa-
18 tion provided in response to written and telephone
19 inquiries under this subsection. Such standards
20 shall be consistent with the performance require-
21 ments established under subsection (b)(3).

22 “(ii) EVALUATION.—In conducting evaluations
23 of individual medicare administrative contractors,
24 the Secretary shall take into account the results of
25 the monitoring conducted under subparagraph (A)
26 taking into account as performance requirements
27 the standards established under clause (i). The
28 Secretary shall, in consultation with organizations
29 representing providers of services, suppliers, and
30 individuals entitled to benefits under part A or en-
31 rolled under part B, or both, establish standards
32 relating to the accuracy, consistency, and timeliness
33 of the information so provided.

34 “(C) DIRECT MONITORING.—Nothing in this para-
35 graph shall be construed as preventing the Secretary



1 from directly monitoring the accuracy, consistency, and
2 timeliness of the information so provided.”.

3 (2) EFFECTIVE DATE.—The amendment made by
4 paragraph (1) shall take effect October 1, 2004.

5 (3) APPLICATION TO FISCAL INTERMEDIARIES AND
6 CARRIERS.—The provisions of section 1874A(g) of the So-
7 cial Security Act, as added by paragraph (1), shall apply
8 to each fiscal intermediary under section 1816 of the Social
9 Security Act (42 U.S.C. 1395h) and each carrier under
10 section 1842 of such Act (42 U.S.C. 1395u) in the same
11 manner as they apply to medicare administrative contrac-
12 tors under such provisions.

13 (d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

14 (1) IN GENERAL.—Section 1889, as added by sub-
15 section (a), is amended by adding at the end the following
16 new subsections:

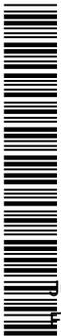
17 “(b) ENHANCED EDUCATION AND TRAINING.—

18 “(1) ADDITIONAL RESOURCES.—There are authorized
19 to be appropriated to the Secretary (in appropriate part
20 from the Federal Hospital Insurance Trust Fund and the
21 Federal Supplementary Medical Insurance Trust Fund)
22 \$25,000,000 for each of fiscal years 2005 and 2006 and
23 such sums as may be necessary for succeeding fiscal years.

24 “(2) USE.—The funds made available under para-
25 graph (1) shall be used to increase the conduct by medicare
26 contractors of education and training of providers of serv-
27 ices and suppliers regarding billing, coding, and other ap-
28 propriate items and may also be used to improve the accu-
29 racy, consistency, and timeliness of contractor responses.

30 “(c) TAILORING EDUCATION AND TRAINING ACTIVITIES
31 FOR SMALL PROVIDERS OR SUPPLIERS.—

32 “(1) IN GENERAL.—Insofar as a medicare contractor
33 conducts education and training activities, it shall tailor
34 such activities to meet the special needs of small providers
35 of services or suppliers (as defined in paragraph (2)).



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

4 “(A) a provider of services with fewer than 25 full-
5 time-equivalent employees; or

6 “(B) a supplier with fewer than 10 full-time-equiv-
7 alent employees.”.

8 (2) EFFECTIVE DATE.—The amendment made by
9 paragraph (1) shall take effect on October 1, 2004.

10 (e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

11 (1) IN GENERAL.—Section 1889, as added by sub-
12 section (a) and as amended by subsection (d), is further
13 amended by adding at the end the following new sub-
14 section:

15 “(d) INTERNET SITES; FAQs.—The Secretary, and each
16 medicare contractor insofar as it provides services (including
17 claims processing) for providers of services or suppliers, shall
18 maintain an Internet site which—

19 “(1) provides answers in an easily accessible format to
20 frequently asked questions, and

21 “(2) includes other published materials of the con-
22 tractor,

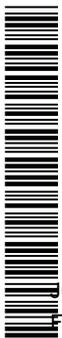
23 that relate to providers of services and suppliers under the pro-
24 grams under this title (and title XI insofar as it relates to such
25 programs).”.

26 (2) EFFECTIVE DATE.—The amendment made by
27 paragraph (1) shall take effect on October 1, 2004.

28 (f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

29 (1) IN GENERAL.—Section 1889, as added by sub-
30 section (a) and as amended by subsections (d) and (e), is
31 further amended by adding at the end the following new
32 subsections:

33 “(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION
34 PROGRAM ACTIVITIES.—A medicare contractor may not use a
35 record of attendance at (or failure to attend) educational activi-
36 ties or other information gathered during an educational pro-



1 gram conducted under this section or otherwise by the Sec-
2 retary to select or track providers of services or suppliers for
3 the purpose of conducting any type of audit or prepayment re-
4 view.

5 “(f) CONSTRUCTION.—Nothing in this section or section
6 1893(g) shall be construed as providing for disclosure by a
7 medicare contractor of information that would compromise
8 pending law enforcement activities or reveal findings of law en-
9 forcement-related audits.

10 “(g) DEFINITIONS.—For purposes of this section, the
11 term ‘medicare contractor’ includes the following:

12 “(1) A medicare administrative contractor with a con-
13 tract under section 1874A, including a fiscal intermediary
14 with a contract under section 1816 and a carrier with a
15 contract under section 1842.

16 “(2) An eligible entity with a contract under section
17 1893.

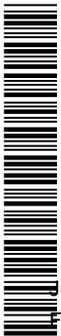
18 Such term does not include, with respect to activities of a spec-
19 ific provider of services or supplier an entity that has no au-
20 thority under this title or title IX with respect to such activities
21 and such provider of services or supplier.”.

22 (2) EFFECTIVE DATE.—The amendment made by
23 paragraph (1) shall take effect on the date of the enact-
24 ment of this Act.

25 **SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE**
26 **DEMONSTRATION PROGRAM.**

27 (a) ESTABLISHMENT.—

28 (1) IN GENERAL.—The Secretary shall establish a
29 demonstration program (in this section referred to as the
30 “demonstration program”) under which technical assist-
31 ance described in paragraph (2) is made available, upon re-
32 quest and on a voluntary basis, to small providers of serv-
33 ices or suppliers in order to improve compliance with the
34 applicable requirements of the programs under medicare
35 program under title XVIII of the Social Security Act (in-
36 cluding provisions of title XI of such Act insofar as they



1 relate to such title and are not administered by the Office
2 of the Inspector General of the Department of Health and
3 Human Services).

4 (2) FORMS OF TECHNICAL ASSISTANCE.—The tech-
5 nical assistance described in this paragraph is—

6 (A) evaluation and recommendations regarding
7 billing and related systems; and

8 (B) information and assistance regarding policies
9 and procedures under the medicare program, including
10 coding and reimbursement.

11 (3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—
12 In this section, the term “small providers of services or
13 suppliers” means—

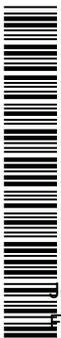
14 (A) a provider of services with fewer than 25 full-
15 time-equivalent employees; or

16 (B) a supplier with fewer than 10 full-time-equiva-
17 lent employees.

18 (b) QUALIFICATION OF CONTRACTORS.—In conducting the
19 demonstration program, the Secretary shall enter into contracts
20 with qualified organizations (such as peer review organizations
21 or entities described in section 1889(g)(2) of the Social Secu-
22 rity Act, as inserted by section 5(f)(1)) with appropriate exper-
23 tise with billing systems of the full range of providers of serv-
24 ices and suppliers to provide the technical assistance. In award-
25 ing such contracts, the Secretary shall consider any prior inves-
26 tigation of the entity’s work by the Inspector General of De-
27 partment of Health and Human Services or the Comptroller
28 General of the United States.

29 (c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The tech-
30 nical assistance provided under the demonstration program
31 shall include a direct and in-person examination of billing sys-
32 tems and internal controls of small providers of services or sup-
33 pliers to determine program compliance and to suggest more
34 efficient or effective means of achieving such compliance.

35 (d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS
36 IDENTIFIED AS CORRECTED.—The Secretary shall provide



1 that, absent evidence of fraud and notwithstanding any other
2 provision of law, any errors found in a compliance review for
3 a small provider of services or supplier that participates in the
4 demonstration program shall not be subject to recovery action
5 if the technical assistance personnel under the program deter-
6 mine that—

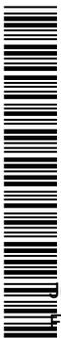
7 (1) the problem that is the subject of the compliance
8 review has been corrected to their satisfaction within 30
9 days of the date of the visit by such personnel to the small
10 provider of services or supplier; and

11 (2) such problem remains corrected for such period as
12 is appropriate.

13 The previous sentence applies only to claims filed as part of the
14 demonstration program and lasts only for the duration of such
15 program and only as long as the small provider of services or
16 supplier is a participant in such program.

17 (e) GAO EVALUATION.—Not later than 2 years after the
18 date of the date the demonstration program is first imple-
19 mented, the Comptroller General, in consultation with the In-
20 spector General of the Department of Health and Human Serv-
21 ices, shall conduct an evaluation of the demonstration program.
22 The evaluation shall include a determination of whether claims
23 error rates are reduced for small providers of services or sup-
24 pliers who participated in the program and the extent of im-
25 proper payments made as a result of the demonstration pro-
26 gram. The Comptroller General shall submit a report to the
27 Secretary and the Congress on such evaluation and shall in-
28 clude in such report recommendations regarding the continu-
29 ation or extension of the demonstration program.

30 (f) FINANCIAL PARTICIPATION BY PROVIDERS.—The pro-
31 vision of technical assistance to a small provider of services or
32 supplier under the demonstration program is conditioned upon
33 the small provider of services or supplier paying an amount es-
34 timated (and disclosed in advance of a provider's or supplier's
35 participation in the program) to be equal to 25 percent of the
36 cost of the technical assistance.



1 (g) AUTHORIZATION OF APPROPRIATIONS.—There are au-
2 thorized to be appropriated to the Secretary (in appropriate
3 part from the Federal Hospital Insurance Trust Fund and the
4 Federal Supplementary Medical Insurance Trust Fund) to
5 carry out the demonstration program—

6 (1) for fiscal year 2005, \$1,000,000, and

7 (2) for fiscal year 2006, \$6,000,000.

8 **SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDI-**
9 **CARE BENEFICIARY OMBUDSMAN.**

10 (a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868
11 (42 U.S.C. 1395ee) is amended—

12 (1) by adding at the end of the heading the following:
13 “; MEDICARE PROVIDER OMBUDSMAN”;

14 (2) by inserting “PRACTICING PHYSICIANS ADVISORY
15 COUNCIL.—(1)” after “(a)”;

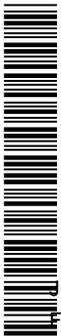
16 (3) in paragraph (1), as so redesignated under para-
17 graph (2), by striking “in this section” and inserting “in
18 this subsection”;

19 (4) by redesignating subsections (b) and (c) as para-
20 graphs (2) and (3), respectively; and

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

22 “(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary
23 shall appoint within the Department of Health and Human
24 Services a Medicare Provider Ombudsman. The Ombudsman
25 shall—

26 “(1) provide assistance, on a confidential basis, to pro-
27 viders of services and suppliers with respect to complaints,
28 grievances, and requests for information concerning the
29 programs under this title (including provisions of title XI
30 insofar as they relate to this title and are not administered
31 by the Office of the Inspector General of the Department
32 of Health and Human Services) and in the resolution of
33 unclear or conflicting guidance given by the Secretary and
34 medicare contractors to such providers of services and sup-
35 pliers regarding such programs and provisions and require-
36 ments under this title and such provisions; and



1 “(2) submit recommendations to the Secretary for im-
2 provement in the administration of this title and such pro-
3 visions, including—

4 “(A) recommendations to respond to recurring
5 patterns of confusion in this title and such provisions
6 (including recommendations regarding suspending im-
7 position of sanctions where there is widespread confu-
8 sion in program administration), and

9 “(B) recommendations to provide for an appro-
10 priate and consistent response (including not providing
11 for audits) in cases of self-identified overpayments by
12 providers of services and suppliers.

13 The Ombudsman shall not serve as an advocate for any in-
14 creases in payments or new coverage of services, but may iden-
15 tify issues and problems in payment or coverage policies.”.

16 (b) **MEDICARE BENEFICIARY OMBUDSMAN.**—Title XVIII,
17 as previously amended, is amended by inserting after section
18 1809 the following new section:

19 “**MEDICARE BENEFICIARY OMBUDSMAN**

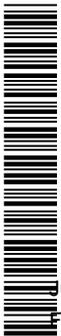
20 “**SEC. 1810. (a) IN GENERAL.**—The Secretary shall ap-
21 point within the Department of Health and Human Services a
22 Medicare Beneficiary Ombudsman who shall have expertise and
23 experience in the fields of health care and education of (and
24 assistance to) individuals entitled to benefits under this title.

25 “(b) **DUTIES.**—The Medicare Beneficiary Ombudsman
26 shall—

27 “(1) receive complaints, grievances, and requests for
28 information submitted by individuals entitled to benefits
29 under part A or enrolled under part B, or both, with re-
30 spect to any aspect of the medicare program;

31 “(2) provide assistance with respect to complaints,
32 grievances, and requests referred to in paragraph (1),
33 including—

34 “(A) assistance in collecting relevant information
35 for such individuals, to seek an appeal of a decision or



1 determination made by a fiscal intermediary, carrier,
2 Medicare+Choice organization, or the Secretary;

3 “(B) assistance to such individuals with any prob-
4 lems arising from disenrollment from a
5 Medicare+Choice plan under part C; and

6 “(C) assistance to such individuals in presenting
7 information under section 1860D-2(b)(4)(D)(v); and

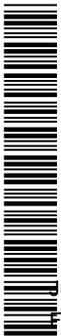
8 “(3) submit annual reports to Congress and the Sec-
9 retary that describe the activities of the Office and that in-
10 clude such recommendations for improvement in the admin-
11 istration of this title as the Ombudsman determines appro-
12 priate.

13 The Ombudsman shall not serve as an advocate for any in-
14 creases in payments or new coverage of services, but may iden-
15 tify issues and problems in payment or coverage policies.

16 “(c) WORKING WITH HEALTH INSURANCE COUNSELING
17 PROGRAMS.—To the extent possible, the Ombudsman shall
18 work with health insurance counseling programs (receiving
19 funding under section 4360 of Omnibus Budget Reconciliation
20 Act of 1990) to facilitate the provision of information to indi-
21 viduals entitled to benefits under part A or enrolled under part
22 B, or both regarding Medicare+Choice plans and changes to
23 those plans. Nothing in this subsection shall preclude further
24 collaboration between the Ombudsman and such programs.”.

25 (c) DEADLINE FOR APPOINTMENT.—The Secretary shall
26 appoint the Medicare Provider Ombudsman and the Medicare
27 Beneficiary Ombudsman, under the amendments made by sub-
28 sections (a) and (b), respectively, by not later than 1 year after
29 the date of the enactment of this Act.

30 (d) FUNDING.—There are authorized to be appropriated to
31 the Secretary (in appropriate part from the Federal Hospital
32 Insurance Trust Fund and the Federal Supplementary Medical
33 Insurance Trust Fund) to carry out the provisions of sub-
34 section (b) of section 1868 of the Social Security Act (relating
35 to the Medicare Provider Ombudsman), as added by subsection
36 (a)(5) and section 1807 of such Act (relating to the Medicare



1 Beneficiary Ombudsman), as added by subsection (b), such
2 sums as are necessary for fiscal year 2004 and each succeeding
3 fiscal year.

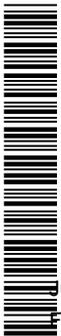
4 (e) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-
5 MEDICARE).—

6 (1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE
7 HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—
8 Section 1804(b) (42 U.S.C. 1395b-2(b)) is amended by
9 adding at the end the following: “The Secretary shall pro-
10 vide, through the toll-free number 1-800-MEDICARE, for
11 a means by which individuals seeking information about, or
12 assistance with, such programs who phone such toll-free
13 number are transferred (without charge) to appropriate en-
14 tities for the provision of such information or assistance.
15 Such toll-free number shall be the toll-free number listed
16 for general information and assistance in the annual notice
17 under subsection (a) instead of the listing of numbers of
18 individual contractors.”.

19 (2) MONITORING ACCURACY.—

20 (A) STUDY.—The Comptroller General of the
21 United States shall conduct a study to monitor the ac-
22 curacy and consistency of information provided to indi-
23 viduals entitled to benefits under part A or enrolled
24 under part B, or both, through the toll-free number 1-
25 800-MEDICARE, including an assessment of whether
26 the information provided is sufficient to answer ques-
27 tions of such individuals. In conducting the study, the
28 Comptroller General shall examine the education and
29 training of the individuals providing information
30 through such number.

31 (B) REPORT.—Not later than 1 year after the
32 date of the enactment of this Act, the Comptroller Gen-
33 eral shall submit to Congress a report on the study
34 conducted under subparagraph (A).



1 **SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION**
2 **PROGRAM.**

3 (a) IN GENERAL.—The Secretary shall establish a dem-
4 onstration program (in this section referred to as the “dem-
5 onstration program”) under which medicare specialists em-
6 ployed by the Department of Health and Human Services pro-
7 vide advice and assistance to individuals entitled to benefits
8 under part A of title XVIII of the Social Security Act, or en-
9 rolled under part B of such title, or both, regarding the medi-
10 care program at the location of existing local offices of the So-
11 cial Security Administration.

12 (b) LOCATIONS.—

13 (1) IN GENERAL.—The demonstration program shall
14 be conducted in at least 6 offices or areas. Subject to para-
15 graph (2), in selecting such offices and areas, the Secretary
16 shall provide preference for offices with a high volume of
17 visits by individuals referred to in subsection (a).

18 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—The
19 Secretary shall provide for the selection of at least 2 rural
20 areas to participate in the demonstration program. In con-
21 ducting the demonstration program in such rural areas, the
22 Secretary shall provide for medicare specialists to travel
23 among local offices in a rural area on a scheduled basis.

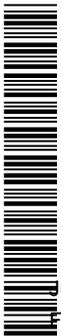
24 (c) DURATION.—The demonstration program shall be con-
25 ducted over a 3-year period.

26 (d) EVALUATION AND REPORT.—

27 (1) EVALUATION.—The Secretary shall provide for an
28 evaluation of the demonstration program. Such evaluation
29 shall include an analysis of—

30 (A) utilization of, and satisfaction of those individ-
31 uals referred to in subsection (a) with, the assistance
32 provided under the program; and

33 (B) the cost-effectiveness of providing beneficiary
34 assistance through out-stationing medicare specialists
35 at local offices of the Social Security Administration.



1 (2) REPORT.—The Secretary shall submit to Congress
2 a report on such evaluation and shall include in such report
3 recommendations regarding the feasibility of permanently
4 out-stationing medicare specialists at local offices of the So-
5 cial Security Administration.

6 **SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN**
7 **NOTICES TO BENEFICIARIES ABOUT**
8 **SKILLED NURSING FACILITY BENEFITS.**

9 (a) IN GENERAL.—The Secretary shall provide that in
10 medicare beneficiary notices provided (under section 1806(a) of
11 the Social Security Act, 42 U.S.C. 1395b–7(a)) with respect to
12 the provision of post-hospital extended care services under part
13 A of title XVIII of the Social Security Act, there shall be in-
14 cluded information on the number of days of coverage of such
15 services remaining under such part for the medicare beneficiary
16 and spell of illness involved.

17 (b) EFFECTIVE DATE.—Subsection (a) shall apply to no-
18 tices provided during calendar quarters beginning more than 6
19 months after the date of the enactment of this Act.

20 **SEC. 926. INFORMATION ON MEDICARE-CERTIFIED**
21 **SKILLED NURSING FACILITIES IN HOSPITAL**
22 **DISCHARGE PLANS.**

23 (a) AVAILABILITY OF DATA.—The Secretary shall publicly
24 provide information that enables hospital discharge planners,
25 medicare beneficiaries, and the public to identify skilled nursing
26 facilities that are participating in the medicare program.

27 (b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL
28 DISCHARGE PLANS.—

29 (1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C.
30 1395x(ee)(2)(D)) is amended—

31 (A) by striking “hospice services” and inserting
32 “hospice care and post-hospital extended care services”;
33 and

34 (B) by inserting before the period at the end the
35 following: “and, in the case of individuals who are like-
36 ly to need post-hospital extended care services, the
37 availability of such services through facilities that par-

1 ticipate in the program under this title and that serve
2 the area in which the patient resides”.

3 (2) EFFECTIVE DATE.—The amendments made by
4 paragraph (1) shall apply to discharge plans made on or
5 after such date as the Secretary shall specify, but not later
6 than 6 months after the date the Secretary provides for
7 availability of information under subsection (a).

8 **Subtitle D—Appeals and Recovery**

9 **SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDI-** 10 **CARE APPEALS.**

11 (a) TRANSITION PLAN.—

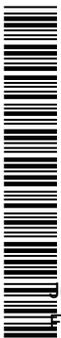
12 (1) IN GENERAL.—Not later than October 1, 2004,
13 the Commissioner of Social Security and the Secretary
14 shall develop and transmit to Congress and the Comptroller
15 General of the United States a plan under which the func-
16 tions of administrative law judges responsible for hearing
17 cases under title XVIII of the Social Security Act (and re-
18 lated provisions in title XI of such Act) are transferred
19 from the responsibility of the Commissioner and the Social
20 Security Administration to the Secretary and the Depart-
21 ment of Health and Human Services.

22 (2) GAO EVALUATION.—The Comptroller General of
23 the United States shall evaluate the plan and, not later
24 than the date that is 6 months after the date on which the
25 plan is received by the Comptroller General, shall submit
26 to Congress a report on such evaluation.

27 (b) TRANSFER OF ADJUDICATION AUTHORITY.—

28 (1) IN GENERAL.—Not earlier than July 1, 2005, and
29 not later than October 1, 2005, the Commissioner of Social
30 Security and the Secretary shall implement the transition
31 plan under subsection (a) and transfer the administrative
32 law judge functions described in such subsection from the
33 Social Security Administration to the Secretary.

34 (2) ASSURING INDEPENDENCE OF JUDGES.—The Sec-
35 retary shall assure the independence of administrative law
36 judges performing the administrative law judge functions



1 transferred under paragraph (1) from the Centers for
2 Medicare & Medicaid Services and its contractors. In order
3 to assure such independence, the Secretary shall place such
4 judges in an administrative office that is organizationally
5 and functionally separate from such Centers. Such judges
6 shall report to, and be under the general supervision of, the
7 Secretary, but shall not report to, or be subject to super-
8 vision by, another other officer of the Department.

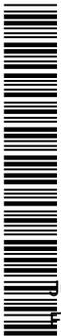
9 (3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall
10 provide for an appropriate geographic distribution of ad-
11 ministrative law judges performing the administrative law
12 judge functions transferred under paragraph (1) through-
13 out the United States to ensure timely access to such
14 judges.

15 (4) HIRING AUTHORITY.—Subject to the amounts pro-
16 vided in advance in appropriations Act, the Secretary shall
17 have authority to hire administrative law judges to hear
18 such cases, giving priority to those judges with prior experi-
19 ence in handling medicare appeals and in a manner con-
20 sistent with paragraph (3), and to hire support staff for
21 such judges.

22 (5) FINANCING.—Amounts payable under law to the
23 Commissioner for administrative law judges performing the
24 administrative law judge functions transferred under para-
25 graph (1) from the Federal Hospital Insurance Trust Fund
26 and the Federal Supplementary Medical Insurance Trust
27 Fund shall become payable to the Secretary for the func-
28 tions so transferred.

29 (6) SHARED RESOURCES.—The Secretary shall enter
30 into such arrangements with the Commissioner as may be
31 appropriate with respect to transferred functions of admin-
32 istrative law judges to share office space, support staff, and
33 other resources, with appropriate reimbursement from the
34 Trust Funds described in paragraph (5).

35 (c) INCREASED FINANCIAL SUPPORT.—In addition to any
36 amounts otherwise appropriated, to ensure timely action on ap-



1 peals before administrative law judges and the Departmental
2 Appeals Board consistent with section 1869 of the Social Secu-
3 rity Act (as amended by section 521 of BIPA, 114 Stat.
4 2763A–534), there are authorized to be appropriated (in appro-
5 priate part from the Federal Hospital Insurance Trust Fund
6 and the Federal Supplementary Medical Insurance Trust
7 Fund) to the Secretary such sums as are necessary for fiscal
8 year 2005 and each subsequent fiscal year to—

9 (1) increase the number of administrative law judges
10 (and their staffs) under subsection (b)(4);

11 (2) improve education and training opportunities for
12 administrative law judges (and their staffs); and

13 (3) increase the staff of the Departmental Appeals
14 Board.

15 (d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i)
16 (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of
17 BIPA (114 Stat. 2763A–543), is amended by striking “of the
18 Social Security Administration”.

19 **SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.**

20 (a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Section
21 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is
22 amended—

23 (1) in paragraph (1)(A), by inserting “, subject to
24 paragraph (2),” before “to judicial review of the Sec-
25 retary’s final decision”;

26 (2) in paragraph (1)(F)—

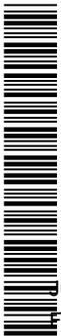
27 (A) by striking clause (ii);

28 (B) by striking “PROCEEDING” and all that follows
29 through “DETERMINATION” and inserting “DETER-
30 MINATIONS AND RECONSIDERATIONS”; and

31 (C) by redesignating subclauses (I) and (II) as
32 clauses (i) and (ii) and by moving the indentation of
33 such subclauses (and the matter that follows) 2 ems to
34 the left; and

35 (3) by adding at the end the following new paragraph:

36 “(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—



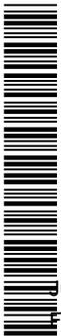
1 “(A) IN GENERAL.—The Secretary shall establish
2 a process under which a provider of services or supplier
3 that furnishes an item or service or an individual enti-
4 tled to benefits under part A or enrolled under part B,
5 or both, who has filed an appeal under paragraph (1)
6 may obtain access to judicial review when a review
7 panel (described in subparagraph (D)), on its own mo-
8 tion or at the request of the appellant, determines that
9 no entity in the administrative appeals process has the
10 authority to decide the question of law or regulation
11 relevant to the matters in controversy and that there
12 is no material issue of fact in dispute. The appellant
13 may make such request only once with respect to a
14 question of law or regulation in a case of an appeal.

15 “(B) PROMPT DETERMINATIONS.—If, after or co-
16 incident with appropriately filing a request for an ad-
17 ministrative hearing, the appellant requests a deter-
18 mination by the appropriate review panel that no re-
19 view panel has the authority to decide the question of
20 law or regulations relevant to the matters in con-
21 troversy and that there is no material issue of fact in
22 dispute and if such request is accompanied by the doc-
23 uments and materials as the appropriate review panel
24 shall require for purposes of making such determina-
25 tion, such review panel shall make a determination on
26 the request in writing within 60 days after the date
27 such review panel receives the request and such accom-
28 panying documents and materials. Such a determina-
29 tion by such review panel shall be considered a final de-
30 cision and not subject to review by the Secretary.

31 “(C) ACCESS TO JUDICIAL REVIEW.—

32 “(i) IN GENERAL.—If the appropriate review
33 panel—

34 “(I) determines that there are no material
35 issues of fact in dispute and that the only issue



1 is one of law or regulation that no review panel
2 has the authority to decide; or

3 “(II) fails to make such determination
4 within the period provided under subparagraph
5 (B);

6 then the appellant may bring a civil action as de-
7 scribed in this subparagraph.

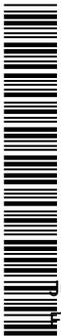
8 “(ii) DEADLINE FOR FILING.—Such action
9 shall be filed, in the case described in—

10 “(I) clause (i)(I), within 60 days of date
11 of the determination described in such subpara-
12 graph; or

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

16 “(iii) VENUE.—Such action shall be brought
17 in the district court of the United States for the ju-
18 dicial district in which the appellant is located (or,
19 in the case of an action brought jointly by more
20 than one applicant, the judicial district in which
21 the greatest number of applicants are located) or in
22 the district court for the District of Columbia.

23 “(iv) INTEREST ON AMOUNTS IN CON-
24 TROVERSY.—Where a provider of services or sup-
25 plier seeks judicial review pursuant to this para-
26 graph, the amount in controversy shall be subject
27 to annual interest beginning on the first day of the
28 first month beginning after the 60-day period as
29 determined pursuant to clause (ii) and equal to the
30 rate of interest on obligations issued for purchase
31 by the Federal Hospital Insurance Trust Fund and
32 by the Federal Supplementary Medical Insurance
33 Trust Fund for the month in which the civil action
34 authorized under this paragraph is commenced, to
35 be awarded by the reviewing court in favor of the
36 prevailing party. No interest awarded pursuant to



1 the preceding sentence shall be deemed income or
2 cost for the purposes of determining reimbursement
3 due providers of services or suppliers under this
4 Act.

5 “(D) REVIEW PANELS.—For purposes of this sub-
6 section, a ‘review panel’ is a panel consisting of 3 mem-
7 bers (who shall be administrative law judges, members
8 of the Departmental Appeals Board, or qualified indi-
9 viduals associated with a qualified independent con-
10 tractor (as defined in subsection (c)(2)) or with another
11 independent entity) designated by the Secretary for
12 purposes of making determinations under this para-
13 graph.”.

14 (b) APPLICATION TO PROVIDER AGREEMENT DETERMINA-
15 TIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is
16 amended—

17 (1) by inserting “(A)” after “(h)(1)”; and

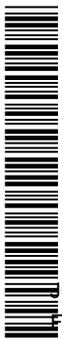
18 (2) by adding at the end the following new subpara-
19 graph:

20 “(B) An institution or agency described in subparagraph
21 (A) that has filed for a hearing under subparagraph (A) shall
22 have expedited access to judicial review under this subpara-
23 graph in the same manner as providers of services, suppliers,
24 and individuals entitled to benefits under part A or enrolled
25 under part B, or both, may obtain expedited access to judicial
26 review under the process established under section 1869(b)(2).
27 Nothing in this subparagraph shall be construed to affect the
28 application of any remedy imposed under section 1819 during
29 the pendency of an appeal under this subparagraph.”.

30 (c) EFFECTIVE DATE.—The amendments made by this
31 section shall apply to appeals filed on or after October 1, 2004.

32 (d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREE-
33 MENT DETERMINATIONS.—

34 (1) TERMINATION AND CERTAIN OTHER IMMEDIATE
35 REMEDIES.—The Secretary shall develop and implement a
36 process to expedite proceedings under sections 1866(h) of



1 the Social Security Act (42 U.S.C. 1395cc(h)) in which the
2 remedy of termination of participation, or a remedy de-
3 scribed in clause (i) or (iii) of section 1819(h)(2)(B) of
4 such Act (42 U.S.C. 1395i-3(h)(2)(B)) which is applied on
5 an immediate basis, has been imposed. Under such process
6 priority shall be provided in cases of termination.

7 (2) INCREASED FINANCIAL SUPPORT.—In addition to
8 any amounts otherwise appropriated, to reduce by 50 per-
9 cent the average time for administrative determinations on
10 appeals under section 1866(h) of the Social Security Act
11 (42 U.S.C. 1395cc(h)), there are authorized to be appro-
12 priated (in appropriate part from the Federal Hospital In-
13 surance Trust Fund and the Federal Supplementary Med-
14 ical Insurance Trust Fund) to the Secretary such addi-
15 tional sums for fiscal year 2005 and each subsequent fiscal
16 year as may be necessary. The purposes for which such
17 amounts are available include increasing the number of ad-
18 ministrative law judges (and their staffs) and the appellate
19 level staff at the Departmental Appeals Board of the De-
20 partment of Health and Human Services and educating
21 such judges and staffs on long-term care issues.

22 **SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.**

23 (a) REQUIRING FULL AND EARLY PRESENTATION OF EVI-
24 DENCE.—

25 (1) IN GENERAL.—Section 1869(b) (42 U.S.C.
26 1395ff(b)), as amended by BIPA and as amended by sec-
27 tion 932(a), is further amended by adding at the end the
28 following new paragraph:

29 “(3) REQUIRING FULL AND EARLY PRESENTATION OF
30 EVIDENCE BY PROVIDERS.—A provider of services or sup-
31 plier may not introduce evidence in any appeal under this
32 section that was not presented at the reconsideration con-
33 ducted by the qualified independent contractor under sub-
34 section (c), unless there is good cause which precluded the
35 introduction of such evidence at or before that reconsider-
36 ation.”.

1 (2) EFFECTIVE DATE.—The amendment made by
2 paragraph (1) shall take effect on October 1, 2004.

3 (b) USE OF PATIENTS' MEDICAL RECORDS.—Section
4 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended
5 by BIPA, is amended by inserting “(including the medical
6 records of the individual involved)” after “clinical experience”.

7 (c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

8 (1) INITIAL DETERMINATIONS AND REDETERMINA-
9 TIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amend-
10 ed by BIPA, is amended by adding at the end the following
11 new paragraphs:

12 “(4) REQUIREMENTS OF NOTICE OF DETERMINA-
13 TIONS.—With respect to an initial determination insofar as
14 it results in a denial of a claim for benefits—

15 “(A) the written notice on the determination shall
16 include—

17 “(i) the reasons for the determination, includ-
18 ing whether a local medical review policy or a local
19 coverage determination was used;

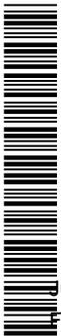
20 “(ii) the procedures for obtaining additional
21 information concerning the determination, includ-
22 ing the information described in subparagraph (B);
23 and

24 “(iii) notification of the right to seek a rede-
25 termination or otherwise appeal the determination
26 and instructions on how to initiate such a redeter-
27 mination under this section; and

28 “(B) the person provided such notice may obtain,
29 upon request, the specific provision of the policy, man-
30 ual, or regulation used in making the determination.

31 “(5) REQUIREMENTS OF NOTICE OF REDETERMINA-
32 TIONS.—With respect to a redetermination insofar as it re-
33 sults in a denial of a claim for benefits—

34 “(A) the written notice on the redetermination
35 shall include—



1 “(i) the specific reasons for the redetermina-
2 tion;

3 “(ii) as appropriate, a summary of the clinical
4 or scientific evidence used in making the redeter-
5 mination;

6 “(iii) a description of the procedures for ob-
7 taining additional information concerning the rede-
8 termination; and

9 “(iv) notification of the right to appeal the re-
10 determination and instructions on how to initiate
11 such an appeal under this section;

12 “(B) such written notice shall be provided in
13 printed form and written in a manner calculated to be
14 understood by the individual entitled to benefits under
15 part A or enrolled under part B, or both; and

16 “(C) the person provided such notice may obtain,
17 upon request, information on the specific provision of
18 the policy, manual, or regulation used in making the
19 redetermination.”.

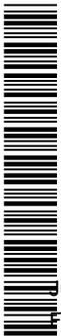
20 (2) RECONSIDERATIONS.—Section 1869(e)(3)(E) (42
21 U.S.C. 1395ff(e)(3)(E)), as amended by BIPA, is
22 amended—

23 (A) by inserting “be written in a manner cal-
24 culated to be understood by the individual entitled to
25 benefits under part A or enrolled under part B, or
26 both, and shall include (to the extent appropriate)”
27 after “in writing, ”; and

28 (B) by inserting “and a notification of the right to
29 appeal such determination and instructions on how to
30 initiate such appeal under this section” after “such de-
31 cision,”.

32 (3) APPEALS.—Section 1869(d) (42 U.S.C.
33 1395ff(d)), as amended by BIPA, is amended—

34 (A) in the heading, by inserting “; NOTICE” after
35 “SECRETARY”; and



1 (B) by adding at the end the following new para-
2 graph:

3 “(4) NOTICE.—Notice of the decision of an adminis-
4 trative law judge shall be in writing in a manner calculated
5 to be understood by the individual entitled to benefits
6 under part A or enrolled under part B, or both, and shall
7 include—

8 “(A) the specific reasons for the determination (in-
9 cluding, to the extent appropriate, a summary of the
10 clinical or scientific evidence used in making the deter-
11 mination);

12 “(B) the procedures for obtaining additional infor-
13 mation concerning the decision; and

14 “(C) notification of the right to appeal the deci-
15 sion and instructions on how to initiate such an appeal
16 under this section.”.

17 (4) SUBMISSION OF RECORD FOR APPEAL.—Section
18 1869(e)(3)(J)(i) (42 U.S.C. 1395ff(e)(3)(J)(i)) by striking
19 “prepare” and inserting “submit” and by striking “with re-
20 spect to” and all that follows through “and relevant poli-
21 cies”.

22 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

23 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDE-
24 PENDENT CONTRACTORS.—Section 1869(e)(3) (42 U.S.C.
25 1395ff(e)(3)), as amended by BIPA, is amended—

26 (A) in subparagraph (A), by striking “sufficient
27 training and expertise in medical science and legal mat-
28 ters” and inserting “sufficient medical, legal, and other
29 expertise (including knowledge of the program under
30 this title) and sufficient staffing”; and

31 (B) by adding at the end the following new sub-
32 paragraph:

33 “(K) INDEPENDENCE REQUIREMENTS.—

34 “(i) IN GENERAL.—Subject to clause (ii), a
35 qualified independent contractor shall not conduct
36 any activities in a case unless the entity—



1 “(I) is not a related party (as defined in
2 subsection (g)(5));

3 “(II) does not have a material familial, fi-
4 nancial, or professional relationship with such a
5 party in relation to such case; and

6 “(III) does not otherwise have a conflict of
7 interest with such a party.

8 “(ii) EXCEPTION FOR REASONABLE COM-
9 PENSATION.—Nothing in clause (i) shall be con-
10 strued to prohibit receipt by a qualified inde-
11 pendent contractor of compensation from the Sec-
12 retary for the conduct of activities under this sec-
13 tion if the compensation is provided consistent with
14 clause (iii).

15 “(iii) LIMITATIONS ON ENTITY COMPENSA-
16 TION.—Compensation provided by the Secretary to
17 a qualified independent contractor in connection
18 with reviews under this section shall not be contin-
19 gent on any decision rendered by the contractor or
20 by any reviewing professional.”.

21 (2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—
22 Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is
23 amended—

24 (A) by amending subsection (e)(3)(D) to read as
25 follows:

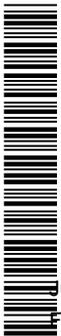
26 “(D) QUALIFICATIONS FOR REVIEWERS.—The re-
27 quirements of subsection (g) shall be met (relating to
28 qualifications of reviewing professionals).”; and

29 (B) by adding at the end the following new sub-
30 section:

31 “(g) QUALIFICATIONS OF REVIEWERS.—

32 “(1) IN GENERAL.—In reviewing determinations under
33 this section, a qualified independent contractor shall assure
34 that—

35 “(A) each individual conducting a review shall
36 meet the qualifications of paragraph (2);



1 “(B) compensation provided by the contractor to
2 each such reviewer is consistent with paragraph (3);
3 and

4 “(C) in the case of a review by a panel described
5 in subsection (c)(3)(B) composed of physicians or other
6 health care professionals (each in this subsection re-
7 ferred to as a ‘reviewing professional’), a reviewing pro-
8 fessional meets the qualifications described in para-
9 graph (4) and, where a claim is regarding the fur-
10 nishing of treatment by a physician (allopathic or os-
11 teopathic) or the provision of items or services by a
12 physician (allopathic or osteopathic), each reviewing
13 professional shall be a physician (allopathic or osteo-
14 pathic).

15 “(2) INDEPENDENCE.—

16 “(A) IN GENERAL.—Subject to subparagraph (B),
17 each individual conducting a review in a case shall—

18 “(i) not be a related party (as defined in para-
19 graph (5));

20 “(ii) not have a material familial, financial, or
21 professional relationship with such a party in the
22 case under review; and

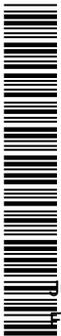
23 “(iii) not otherwise have a conflict of interest
24 with such a party.

25 “(B) EXCEPTION.—Nothing in subparagraph (A)
26 shall be construed to—

27 “(i) prohibit an individual, solely on the basis
28 of a participation agreement with a fiscal inter-
29 mediary, carrier, or other contractor, from serving
30 as a reviewing professional if—

31 “(I) the individual is not involved in the
32 provision of items or services in the case under
33 review;

34 “(II) the fact of such an agreement is dis-
35 closed to the Secretary and the individual enti-
36 tled to benefits under part A or enrolled under



1 part B, or both, (or authorized representative)
2 and neither party objects; and

3 “(III) the individual is not an employee of
4 the intermediary, carrier, or contractor and
5 does not provide services exclusively or pri-
6 marily to or on behalf of such intermediary,
7 carrier, or contractor;

8 “(ii) prohibit an individual who has staff privi-
9 leges at the institution where the treatment in-
10 volved takes place from serving as a reviewer mere-
11 ly on the basis of having such staff privileges if the
12 existence of such privileges is disclosed to the Sec-
13 retary and such individual (or authorized represent-
14 ative), and neither party objects; or

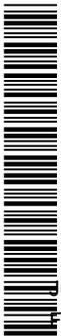
15 “(iii) prohibit receipt of compensation by a re-
16 viewing professional from a contractor if the com-
17 pensation is provided consistent with paragraph
18 (3).

19 For purposes of this paragraph, the term ‘participation
20 agreement’ means an agreement relating to the provi-
21 sion of health care services by the individual and does
22 not include the provision of services as a reviewer
23 under this subsection.

24 “(3) LIMITATIONS ON REVIEWER COMPENSATION.—
25 Compensation provided by a qualified independent con-
26 tractor to a reviewer in connection with a review under this
27 section shall not be contingent on the decision rendered by
28 the reviewer.

29 “(4) LICENSURE AND EXPERTISE.—Each reviewing
30 professional shall be—

31 “(A) a physician (allopathic or osteopathic) who is
32 appropriately credentialed or licensed in one or more
33 States to deliver health care services and has medical
34 expertise in the field of practice that is appropriate for
35 the items or services at issue; or



1 “(B) a health care professional who is legally au-
2 thorized in one or more States (in accordance with
3 State law or the State regulatory mechanism provided
4 by State law) to furnish the health care items or serv-
5 ices at issue and has medical expertise in the field of
6 practice that is appropriate for such items or services.

7 “(5) RELATED PARTY DEFINED.—For purposes of this
8 section, the term ‘related party’ means, with respect to a
9 case under this title involving a specific individual entitled
10 to benefits under part A or enrolled under part B, or both,
11 any of the following:

12 “(A) The Secretary, the medicare administrative
13 contractor involved, or any fiduciary, officer, director,
14 or employee of the Department of Health and Human
15 Services, or of such contractor.

16 “(B) The individual (or authorized representative).

17 “(C) The health care professional that provides
18 the items or services involved in the case.

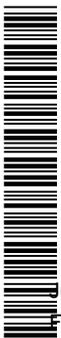
19 “(D) The institution at which the items or services
20 (or treatment) involved in the case are provided.

21 “(E) The manufacturer of any drug or other item
22 that is included in the items or services involved in the
23 case.

24 “(F) Any other party determined under any regu-
25 lations to have a substantial interest in the case in-
26 volved.”.

27 (3) REDUCING MINIMUM NUMBER OF QUALIFIED
28 INDEPENDENT CONTRACTORS.—Section 1869(e)(4) (42
29 U.S.C. 1395ff(e)(4)) is amended by striking “not fewer
30 than 12 qualified independent contractors under this sub-
31 section” and inserting “with a sufficient number of quali-
32 fied independent contractors (but not fewer than 4 such
33 contractors) to conduct reconsiderations consistent with the
34 timeframes applicable under this subsection”.

35 (4) EFFECTIVE DATE.—The amendments made by
36 paragraphs (1) and (2) shall be effective as if included in



1 the enactment of the respective provisions of subtitle C of
2 title V of BIPA, (114 Stat. 2763A-534).

3 (5) TRANSITION.—In applying section 1869(g) of the
4 Social Security Act (as added by paragraph (2)), any ref-
5 erence to a medicare administrative contractor shall be
6 deemed to include a reference to a fiscal intermediary
7 under section 1816 of the Social Security Act (42 U.S.C.
8 1395h) and a carrier under section 1842 of such Act (42
9 U.S.C. 1395u).

10 **SEC. 934. PREPAYMENT REVIEW.**

11 (a) IN GENERAL.—Section 1874A, as added by section
12 911(a)(1) and as amended by sections 912(b), 921(b)(1), and
13 921(c)(1), is further amended by adding at the end the fol-
14 lowing new subsection:

15 “(h) CONDUCT OF PREPAYMENT REVIEW.—

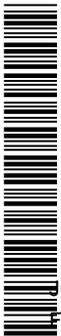
16 “(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

17 “(A) IN GENERAL.—A medicare administrative
18 contractor may conduct random prepayment review
19 only to develop a contractor-wide or program-wide
20 claims payment error rates or under such additional
21 circumstances as may be provided under regulations,
22 developed in consultation with providers of services and
23 suppliers.

24 “(B) USE OF STANDARD PROTOCOLS WHEN CON-
25 DUCTING PREPAYMENT REVIEWS.—When a medicare
26 administrative contractor conducts a random prepay-
27 ment review, the contractor may conduct such review
28 only in accordance with a standard protocol for random
29 prepayment audits developed by the Secretary.

30 “(C) CONSTRUCTION.—Nothing in this paragraph
31 shall be construed as preventing the denial of payments
32 for claims actually reviewed under a random prepay-
33 ment review.

34 “(D) RANDOM PREPAYMENT REVIEW.—For pur-
35 poses of this subsection, the term ‘random prepayment



1 review' means a demand for the production of records
2 or documentation absent cause with respect to a claim.

3 “(2) LIMITATIONS ON NON-RANDOM PREPAYMENT RE-
4 VIEW.—

5 “(A) LIMITATIONS ON INITIATION OF NON-RAN-
6 DOM PREPAYMENT REVIEW.—A medicare administra-
7 tive contractor may not initiate non-random prepay-
8 ment review of a provider of services or supplier based
9 on the initial identification by that provider of services
10 or supplier of an improper billing practice unless there
11 is a likelihood of sustained or high level of payment
12 error (as defined in subsection (i)(3)(A)).

13 “(B) TERMINATION OF NON-RANDOM PREPAY-
14 MENT REVIEW.—The Secretary shall issue regulations
15 relating to the termination, including termination
16 dates, of non-random prepayment review. Such regula-
17 tions may vary such a termination date based upon the
18 differences in the circumstances triggering prepayment
19 review.”.

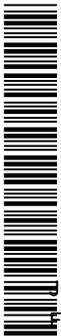
20 (b) EFFECTIVE DATE.—

21 (1) IN GENERAL.—Except as provided in this sub-
22 section, the amendment made by subsection (a) shall take
23 effect 1 year after the date of the enactment of this Act.

24 (2) DEADLINE FOR PROMULGATION OF CERTAIN REG-
25 ULATIONS.—The Secretary shall first issue regulations
26 under section 1874A(h) of the Social Security Act, as
27 added by subsection (a), by not later than 1 year after the
28 date of the enactment of this Act.

29 (3) APPLICATION OF STANDARD PROTOCOLS FOR RAN-
30 DOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of
31 the Social Security Act, as added by subsection (a), shall
32 apply to random prepayment reviews conducted on or after
33 such date (not later than 1 year after the date of the enact-
34 ment of this Act) as the Secretary shall specify.

35 (c) APPLICATION TO FISCAL INTERMEDIARIES AND CAR-
36 RIERS.—The provisions of section 1874A(h) of the Social Secu-



1 rity Act, as added by subsection (a), shall apply to each fiscal
2 intermediary under section 1816 of the Social Security Act (42
3 U.S.C. 1395h) and each carrier under section 1842 of such Act
4 (42 U.S.C. 1395u) in the same manner as they apply to medi-
5 care administrative contractors under such provisions.

6 **SEC. 935. RECOVERY OF OVERPAYMENTS.**

7 (a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is
8 amended by adding at the end the following new subsection:

9 “(f) RECOVERY OF OVERPAYMENTS.—

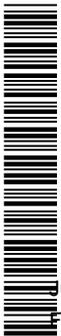
10 “(1) USE OF REPAYMENT PLANS.—

11 “(A) IN GENERAL.—If the repayment, within 30
12 days by a provider of services or supplier, of an over-
13 payment under this title would constitute a hardship
14 (as defined in subparagraph (B)), subject to subpara-
15 graph (C), upon request of the provider of services or
16 supplier the Secretary shall enter into a plan with the
17 provider of services or supplier for the repayment
18 (through offset or otherwise) of such overpayment over
19 a period of at least 6 months but not longer than 3
20 years (or not longer than 5 years in the case of extreme
21 hardship, as determined by the Secretary). Interest
22 shall accrue on the balance through the period of re-
23 payment. Such plan shall meet terms and conditions
24 determined to be appropriate by the Secretary.

25 “(B) HARDSHIP.—

26 “(i) IN GENERAL.—For purposes of subpara-
27 graph (A), the repayment of an overpayment (or
28 overpayments) within 30 days is deemed to con-
29 stitute a hardship if—

30 “(I) in the case of a provider of services
31 that files cost reports, the aggregate amount of
32 the overpayments exceeds 10 percent of the
33 amount paid under this title to the provider of
34 services for the cost reporting period covered by
35 the most recently submitted cost report; or



1 “(II) in the case of another provider of
2 services or supplier, the aggregate amount of
3 the overpayments exceeds 10 percent of the
4 amount paid under this title to the provider of
5 services or supplier for the previous calendar
6 year.

7 “(ii) RULE OF APPLICATION.—The Secretary
8 shall establish rules for the application of this sub-
9 paragraph in the case of a provider of services or
10 supplier that was not paid under this title during
11 the previous year or was paid under this title only
12 during a portion of that year.

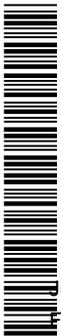
13 “(iii) TREATMENT OF PREVIOUS OVERPAY-
14 MENTS.—If a provider of services or supplier has
15 entered into a repayment plan under subparagraph
16 (A) with respect to a specific overpayment amount,
17 such payment amount under the repayment plan
18 shall not be taken into account under clause (i)
19 with respect to subsequent overpayment amounts.

20 “(C) EXCEPTIONS.—Subparagraph (A) shall not
21 apply if—

22 “(i) the Secretary has reason to suspect that
23 the provider of services or supplier may file for
24 bankruptcy or otherwise cease to do business or
25 discontinue participation in the program under this
26 title; or

27 “(ii) there is an indication of fraud or abuse
28 committed against the program.

29 “(D) IMMEDIATE COLLECTION IF VIOLATION OF
30 REPAYMENT PLAN.—If a provider of services or sup-
31 plier fails to make a payment in accordance with a re-
32 payment plan under this paragraph, the Secretary may
33 immediately seek to offset or otherwise recover the
34 total balance outstanding (including applicable interest)
35 under the repayment plan.



1 “(E) RELATION TO NO FAULT PROVISION.—Noth-
2 ing in this paragraph shall be construed as affecting
3 the application of section 1870(e) (relating to no ad-
4 justment in the cases of certain overpayments).

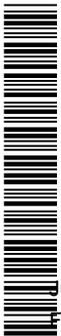
5 “(2) LIMITATION ON RECOUPMENT.—

6 “(A) IN GENERAL.—In the case of a provider of
7 services or supplier that is determined to have received
8 an overpayment under this title and that seeks a recon-
9 sideration by a qualified independent contractor on
10 such determination under section 1869(b)(1), the Sec-
11 retary may not take any action (or authorize any other
12 person, including any medicare contractor, as defined
13 in subparagraph (C)) to recoup the overpayment until
14 the date the decision on the reconsideration has been
15 rendered. If the provisions of section 1869(b)(1) (pro-
16 viding for such a reconsideration by a qualified inde-
17 pendent contractor) are not in effect, in applying the
18 previous sentence any reference to such a reconsider-
19 ation shall be treated as a reference to a redetermina-
20 tion by the fiscal intermediary or carrier involved.

21 “(B) COLLECTION WITH INTEREST.—Insofar as
22 the determination on such appeal is against the pro-
23 vider of services or supplier, interest on the overpay-
24 ment shall accrue on and after the date of the original
25 notice of overpayment. Insofar as such determination
26 against the provider of services or supplier is later re-
27 versed, the Secretary shall provide for repayment of the
28 amount recouped plus interest at the same rate as
29 would apply under the previous sentence for the period
30 in which the amount was recouped.

31 “(C) MEDICARE CONTRACTOR DEFINED.—For
32 purposes of this subsection, the term ‘medicare con-
33 tractor’ has the meaning given such term in section
34 1889(g).

35 “(3) LIMITATION ON USE OF EXTRAPOLATION.—A
36 medicare contractor may not use extrapolation to determine



1 overpayment amounts to be recovered by recoupment, off-
2 set, or otherwise unless—

3 “(A) there is a sustained or high level of payment
4 error (as defined by the Secretary by regulation); or

5 “(B) documented educational intervention has
6 failed to correct the payment error (as determined by
7 the Secretary).

8 “(4) PROVISION OF SUPPORTING DOCUMENTATION.—
9 In the case of a provider of services or supplier with respect
10 to which amounts were previously overpaid, a medicare con-
11 tractor may request the periodic production of records or
12 supporting documentation for a limited sample of sub-
13 mitted claims to ensure that the previous practice is not
14 continuing.

15 “(5) CONSENT SETTLEMENT REFORMS.—

16 “(A) IN GENERAL.—The Secretary may use a con-
17 sent settlement (as defined in subparagraph (D)) to
18 settle a projected overpayment.

19 “(B) OPPORTUNITY TO SUBMIT ADDITIONAL IN-
20 FORMATION BEFORE CONSENT SETTLEMENT OFFER.—
21 Before offering a provider of services or supplier a con-
22 sent settlement, the Secretary shall—

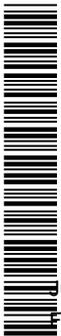
23 “(i) communicate to the provider of services or
24 supplier—

25 “(I) that, based on a review of the medical
26 records requested by the Secretary, a prelimi-
27 nary evaluation of those records indicates that
28 there would be an overpayment;

29 “(II) the nature of the problems identified
30 in such evaluation; and

31 “(III) the steps that the provider of serv-
32 ices or supplier should take to address the
33 problems; and

34 “(ii) provide for a 45-day period during which
35 the provider of services or supplier may furnish ad-



1 ditional information concerning the medical records
2 for the claims that had been reviewed.

3 “(C) CONSENT SETTLEMENT OFFER.—The Sec-
4 retary shall review any additional information furnished
5 by the provider of services or supplier under subpara-
6 graph (B)(ii). Taking into consideration such informa-
7 tion, the Secretary shall determine if there still appears
8 to be an overpayment. If so, the Secretary—

9 “(i) shall provide notice of such determination
10 to the provider of services or supplier, including an
11 explanation of the reason for such determination;
12 and

13 “(ii) in order to resolve the overpayment, may
14 offer the provider of services or supplier—

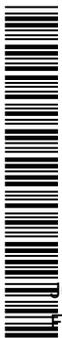
15 “(I) the opportunity for a statistically
16 valid random sample; or

17 “(II) a consent settlement.

18 The opportunity provided under clause (ii)(I) does not
19 waive any appeal rights with respect to the alleged
20 overpayment involved.

21 “(D) CONSENT SETTLEMENT DEFINED.—For pur-
22 poses of this paragraph, the term ‘consent settlement’
23 means an agreement between the Secretary and a pro-
24 vider of services or supplier whereby both parties agree
25 to settle a projected overpayment based on less than a
26 statistically valid sample of claims and the provider of
27 services or supplier agrees not to appeal the claims in-
28 volved.

29 “(6) NOTICE OF OVER-UTILIZATION OF CODES.—The
30 Secretary shall establish, in consultation with organizations
31 representing the classes of providers of services and sup-
32 pliers, a process under which the Secretary provides for no-
33 tice to classes of providers of services and suppliers served
34 by the contractor in cases in which the contractor has iden-
35 tified that particular billing codes may be overutilized by
36 that class of providers of services or suppliers under the



1 programs under this title (or provisions of title XI insofar
2 as they relate to such programs).

3 “(7) PAYMENT AUDITS.—

4 “(A) WRITTEN NOTICE FOR POST-PAYMENT AU-
5 DITS.—Subject to subparagraph (C), if a medicare con-
6 tractor decides to conduct a post-payment audit of a
7 provider of services or supplier under this title, the con-
8 tractor shall provide the provider of services or supplier
9 with written notice (which may be in electronic form)
10 of the intent to conduct such an audit.

11 “(B) EXPLANATION OF FINDINGS FOR ALL AU-
12 DITS.—Subject to subparagraph (C), if a medicare con-
13 tractor audits a provider of services or supplier under
14 this title, the contractor shall—

15 “(i) give the provider of services or supplier a
16 full review and explanation of the findings of the
17 audit in a manner that is understandable to the
18 provider of services or supplier and permits the de-
19 velopment of an appropriate corrective action plan;

20 “(ii) inform the provider of services or supplier
21 of the appeal rights under this title as well as con-
22 sent settlement options (which are at the discretion
23 of the Secretary);

24 “(iii) give the provider of services or supplier
25 an opportunity to provide additional information to
26 the contractor; and

27 “(iv) take into account information provided,
28 on a timely basis, by the provider of services or
29 supplier under clause (iii).

30 “(C) EXCEPTION.—Subparagraphs (A) and (B)
31 shall not apply if the provision of notice or findings
32 would compromise pending law enforcement activities,
33 whether civil or criminal, or reveal findings of law en-
34 forcement-related audits.

35 “(8) STANDARD METHODOLOGY FOR PROBE SAM-
36 PLING.—The Secretary shall establish a standard method-

1 ology for medicare contractors to use in selecting a sample
2 of claims for review in the case of an abnormal billing pat-
3 tern.”.

4 (b) EFFECTIVE DATES AND DEADLINES.—

5 (1) USE OF REPAYMENT PLANS.—Section 1893(f)(1)
6 of the Social Security Act, as added by subsection (a), shall
7 apply to requests for repayment plans made after the date
8 of the enactment of this Act.

9 (2) LIMITATION ON RECOUPMENT.—Section
10 1893(f)(2) of the Social Security Act, as added by sub-
11 section (a), shall apply to actions taken after the date of
12 the enactment of this Act.

13 (3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of
14 the Social Security Act, as added by subsection (a), shall
15 apply to statistically valid random samples initiated after
16 the date that is 1 year after the date of the enactment of
17 this Act.

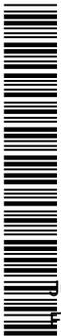
18 (4) PROVISION OF SUPPORTING DOCUMENTATION.—
19 Section 1893(f)(4) of the Social Security Act, as added by
20 subsection (a), shall take effect on the date of the enact-
21 ment of this Act.

22 (5) CONSENT SETTLEMENT.—Section 1893(f)(5) of
23 the Social Security Act, as added by subsection (a), shall
24 apply to consent settlements entered into after the date of
25 the enactment of this Act.

26 (6) NOTICE OF OVERUTILIZATION.—Not later than 1
27 year after the date of the enactment of this Act, the Sec-
28 retary shall first establish the process for notice of over-
29 utilization of billing codes under section 1893A(f)(6) of the
30 Social Security Act, as added by subsection (a).

31 (7) PAYMENT AUDITS.—Section 1893A(f)(7) of the
32 Social Security Act, as added by subsection (a), shall apply
33 to audits initiated after the date of the enactment of this
34 Act.

35 (8) STANDARD FOR ABNORMAL BILLING PATTERNS.—
36 Not later than 1 year after the date of the enactment of



1 this Act, the Secretary shall first establish a standard
2 methodology for selection of sample claims for abnormal
3 billing patterns under section 1893(f)(8) of the Social Se-
4 curity Act, as added by subsection (a).

5 **SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF**
6 **APPEAL.**

7 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
8 amended—

9 (1) by adding at the end of the heading the following:
10 “; ENROLLMENT PROCESSES”; and

11 (2) by adding at the end the following new subsection:

12 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERV-
13 ICES AND SUPPLIERS.—

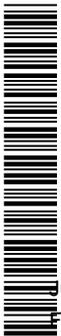
14 “(1) ENROLLMENT PROCESS.—

15 “(A) IN GENERAL.—The Secretary shall establish
16 by regulation a process for the enrollment of providers
17 of services and suppliers under this title.

18 “(B) DEADLINES.—The Secretary shall establish
19 by regulation procedures under which there are dead-
20 lines for actions on applications for enrollment (and, if
21 applicable, renewal of enrollment). The Secretary shall
22 monitor the performance of medicare administrative
23 contractors in meeting the deadlines established under
24 this subparagraph.

25 “(C) CONSULTATION BEFORE CHANGING PRO-
26 VIDER ENROLLMENT FORMS.—The Secretary shall con-
27 sult with providers of services and suppliers before
28 making changes in the provider enrollment forms re-
29 quired of such providers and suppliers to be eligible to
30 submit claims for which payment may be made under
31 this title.

32 “(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-
33 RENEWAL.—A provider of services or supplier whose appli-
34 cation to enroll (or, if applicable, to renew enrollment)
35 under this title is denied may have a hearing and judicial
36 review of such denial under the procedures that apply



1 under subsection (h)(1)(A) to a provider of services that is
2 dissatisfied with a determination by the Secretary.”.

3 (b) EFFECTIVE DATES.—

4 (1) ENROLLMENT PROCESS.—The Secretary shall pro-
5 vide for the establishment of the enrollment process under
6 section 1866(j)(1) of the Social Security Act, as added by
7 subsection (a)(2), within 6 months after the date of the en-
8 actment of this Act.

9 (2) CONSULTATION.—Section 1866(j)(1)(C) of the So-
10 cial Security Act, as added by subsection (a)(2), shall apply
11 with respect to changes in provider enrollment forms made
12 on or after January 1, 2004.

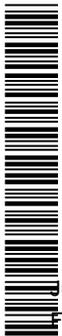
13 (3) HEARING RIGHTS.—Section 1866(j)(2) of the So-
14 cial Security Act, as added by subsection (a)(2), shall apply
15 to denials occurring on or after such date (not later than
16 1 year after the date of the enactment of this Act) as the
17 Secretary specifies.

18 **SEC. 937. PROCESS FOR CORRECTION OF MINOR ER-**
19 **RORS AND OMISSIONS WITHOUT PURSUING**
20 **APPEALS PROCESS.**

21 (a) CLAIMS.—The Secretary shall develop, in consultation
22 with appropriate medicare contractors (as defined in section
23 1889(g) of the Social Security Act, as inserted by section
24 301(a)(1)) and representatives of providers of services and sup-
25 pliers, a process whereby, in the case of minor errors or omis-
26 sions (as defined by the Secretary) that are detected in the sub-
27 mission of claims under the programs under title XVIII of such
28 Act, a provider of services or supplier is given an opportunity
29 to correct such an error or omission without the need to initiate
30 an appeal. Such process shall include the ability to resubmit
31 corrected claims.

32 (b) PERMITTING USE OF CORRECTED AND SUPPLE-
33 MENTARY DATA.—

34 (1) IN GENERAL.—Section 1886(d)(10)(D)(vi) (42
35 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after
36 subclause (II) at the end the following:



1 “Notwithstanding subclause (I), a hospital may submit, and the
2 Secretary may accept upon verification, data that corrects or
3 supplements the data described in such subclause without re-
4 gard to whether the corrected or supplementary data relate to
5 a cost report that has been settled.”

6 (2) EFFECTIVE DATE.—The amendment made by
7 paragraph (1) shall apply to fiscal years beginning with fis-
8 cal year 2004.

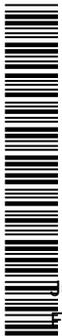
9 (3) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS
10 PERMITTED FOR FISCAL YEAR 2004.—

11 (A) IN GENERAL.—Notwithstanding any other
12 provision of law, a hospital may submit (or resubmit)
13 an application for a change described in section
14 1886(d)(10)(C)(i)(II) of the Social Security Act for fis-
15 cal year 2004 if the hospital demonstrates on a timely
16 basis to the satisfaction of the Secretary that the use
17 of corrected or supplementary data under the amend-
18 ment made by paragraph (1) would materially affect
19 the approval of such an application.

20 (B) APPLICATION OF BUDGET NEUTRALITY.—If
21 one or more hospital’s applications are approved as a
22 result of paragraph (1) and subparagraph (A) for fiscal
23 year 2004, the Secretary shall make a proportional ad-
24 justment in the standardized amounts determined
25 under section 1886(d)(3) of the Social Security Act (42
26 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure
27 that approval of such applications does not result in
28 aggregate payments under section 1886(d) of such Act
29 that are greater or less than those that would otherwise
30 be made if paragraph (1) and subparagraph (A) did
31 not apply.

32 **SEC. 938. PRIOR DETERMINATION PROCESS FOR CER-**
33 **TAIN ITEMS AND SERVICES; ADVANCE BENE-**
34 **FIICIARY NOTICES.**

35 (a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as
36 amended by sections 521 and 522 of BIPA and section



1 933(d)(2)(B), is further amended by adding at the end the fol-
2 lowing 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 medicare
7 administrative contractor that has a contract under
8 section 1874A that provides for making payments
9 under this title with respect to eligible items and serv-
10 ices described in subparagraph (C), the Secretary shall
11 establish a prior determination process that meets the
12 requirements of this subsection and that shall be ap-
13 plied by such contractor in the case of eligible request-
14 ers.

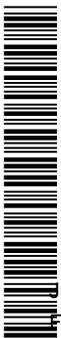
15 “(B) ELIGIBLE REQUESTER.—For purposes of
16 this subsection, each of the following shall be an eligi-
17 ble requester:

18 “(i) A physician, but only with respect to eligi-
19 ble items and services for which the physician may
20 be paid directly.

21 “(ii) An individual entitled to benefits under
22 this title, but only with respect to an item or serv-
23 iced for which the individual receives, from the phy-
24 sician who may be paid directly for the item or
25 service, an advance beneficiary notice under section
26 1879(a) that payment may not be made (or may no
27 longer be made) for the item or service under this
28 title.

29 “(C) ELIGIBLE ITEMS AND SERVICES.—For pur-
30 poses of this subsection and subject to paragraph (2),
31 eligible items and services are items and services which
32 are physicians’ services (as defined in paragraph (4)(A)
33 of section 1848(f) for purposes of calculating the sus-
34 tainable growth rate under such section).

35 “(2) SECRETARIAL FLEXIBILITY.—The Secretary shall
36 establish by regulation reasonable limits on the categories



1 of eligible items and services for which a prior determina-
2 tion of coverage may be requested under this subsection. In
3 establishing such limits, the Secretary may consider the
4 dollar amount involved with respect to the item or service,
5 administrative costs and burdens, and other relevant fac-
6 tors.

7 “(3) REQUEST FOR PRIOR DETERMINATION.—

8 “(A) IN GENERAL.—Subject to paragraph (2),
9 under the process established under this subsection an
10 eligible requester may submit to the contractor a re-
11 quest for a determination, before the furnishing of an
12 eligible item or service involved as to whether the item
13 or service is covered under this title consistent with the
14 applicable requirements of section 1862(a)(1)(A) (relat-
15 ing to medical necessity).

16 “(B) ACCOMPANYING DOCUMENTATION.—The Sec-
17 retary may require that the request be accompanied by
18 a description of the item or service, supporting docu-
19 mentation relating to the medical necessity for the item
20 or service, and any other appropriate documentation.
21 In the case of a request submitted by an eligible re-
22 quester who is described in paragraph (1)(B)(ii), the
23 Secretary may require that the request also be accom-
24 panied by a copy of the advance beneficiary notice in-
25 volved.

26 “(4) RESPONSE TO REQUEST.—

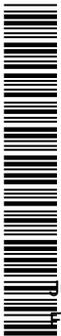
27 “(A) IN GENERAL.—Under such process, the con-
28 tractor shall provide the eligible requester with written
29 notice of a determination as to whether—

30 “(i) the item or service is so covered;

31 “(ii) the item or service is not so covered; or

32 “(iii) the contractor lacks sufficient informa-
33 tion to make a coverage determination.

34 If the contractor makes the determination described in
35 clause (iii), the contractor shall include in the notice a



1 description of the additional information required to
2 make the coverage determination.

3 “(B) DEADLINE TO RESPOND.—Such notice shall
4 be provided within the same time period as the time pe-
5 riod applicable to the contractor providing notice of ini-
6 tial determinations on a claim for benefits under sub-
7 section (a)(2)(A).

8 “(C) INFORMING BENEFICIARY IN CASE OF PHYSI-
9 CIAN REQUEST.—In the case of a request in which an
10 eligible requester is not the individual described in
11 paragraph (1)(B)(ii), the process shall provide that the
12 individual to whom the item or service is proposed to
13 be furnished shall be informed of any determination de-
14 scribed in clause (ii) (relating to a determination of
15 non-coverage) and the right (referred to in paragraph
16 (6)(B)) to obtain the item or service and have a claim
17 submitted for the item or service.

18 “(5) EFFECT OF DETERMINATIONS.—

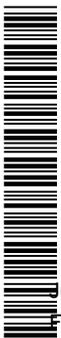
19 “(A) BINDING NATURE OF POSITIVE DETERMINA-
20 TION.—If the contractor makes the determination de-
21 scribed in paragraph (4)(A)(i), such determination
22 shall be binding on the contractor in the absence of
23 fraud or evidence of misrepresentation of facts pre-
24 sented to the contractor.

25 “(B) NOTICE AND RIGHT TO REDETERMINATION
26 IN CASE OF A DENIAL.—

27 “(i) IN GENERAL.—If the contractor makes
28 the determination described in paragraph
29 (4)(A)(ii)—

30 “(I) the eligible requester has the right to
31 a redetermination by the contractor on the de-
32 termination that the item or service is not so
33 covered; and

34 “(II) the contractor shall include in notice
35 under paragraph (4)(A) a brief explanation of
36 the basis for the determination, including on



1 what national or local coverage or noncoverage
2 determination (if any) the determination is
3 based, and the right to such a redetermination.

4 “(ii) DEADLINE FOR REDETERMINATIONS.—
5 The contractor shall complete and provide notice of
6 such redetermination within the same time period
7 as the time period applicable to the contractor pro-
8 viding notice of redeterminations relating to a
9 claim for benefits under subsection (a)(3)(C)(ii).

10 “(6) LIMITATION ON FURTHER REVIEW.—

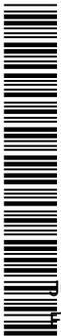
11 “(A) IN GENERAL.—Contractor determinations de-
12 scribed in paragraph (4)(A)(ii) or (4)(A)(iii) (and rede-
13 terminations made under paragraph (5)(B)), relating
14 to pre-service claims are not subject to further adminis-
15 trative appeal or judicial review under this section or
16 otherwise.

17 “(B) DECISION NOT TO SEEK PRIOR DETERMINA-
18 TION OR NEGATIVE DETERMINATION DOES NOT IMPACT
19 RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT,
20 OR APPEAL RIGHTS.—Nothing in this subsection shall
21 be construed as affecting the right of an individual
22 who—

23 “(i) decides not to seek a prior determination
24 under this subsection with respect to items or serv-
25 ices; or

26 “(ii) seeks such a determination and has re-
27 ceived a determination described in paragraph
28 (4)(A)(ii),

29 from receiving (and submitting a claim for) such items
30 services and from obtaining administrative or judicial
31 review respecting such claim under the other applicable
32 provisions of this section. Failure to seek a prior deter-
33 mination under this subsection with respect to items
34 and services shall not be taken into account in such ad-
35 ministrative or judicial review.



1 “(C) NO PRIOR DETERMINATION AFTER RECEIPT
2 OF SERVICES.—Once an individual is provided items
3 and services, there shall be no prior determination
4 under this subsection with respect to such items or
5 services.”.

6 (b) EFFECTIVE DATE; TRANSITION.—

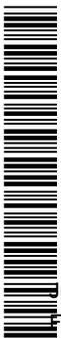
7 (1) EFFECTIVE DATE.—The Secretary shall establish
8 the prior determination process under the amendment
9 made by subsection (a) in such a manner as to provide for
10 the acceptance of requests for determinations under such
11 process filed not later than 18 months after the date of the
12 enactment of this Act.

13 (2) TRANSITION.—During the period in which the
14 amendment made by subsection (a) has become effective
15 but contracts are not provided under section 1874A of the
16 Social Security Act with medicare administrative contrac-
17 tors, any reference in section 1869(g) of such Act (as
18 added by such amendment) to such a contractor is deemed
19 a reference to a fiscal intermediary or carrier with an
20 agreement under section 1816, or contract under section
21 1842, respectively, of such Act.

22 (3) LIMITATION ON APPLICATION TO SGR.—For pur-
23 poses of applying section 1848(f)(2)(D) of the Social Secu-
24 rity Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment
25 made by subsection (a) shall not be considered to be a
26 change in law or regulation.

27 (c) PROVISIONS RELATING TO ADVANCE BENEFICIARY
28 NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

29 (1) DATA COLLECTION.—The Secretary shall establish
30 a process for the collection of information on the instances
31 in which an advance beneficiary notice (as defined in para-
32 graph (5)) has been provided and on instances in which a
33 beneficiary indicates on such a notice that the beneficiary
34 does not intend to seek to have the item or service that is
35 the subject of the notice furnished.



1 (2) OUTREACH AND EDUCATION.—The Secretary shall
2 establish a program of outreach and education for bene-
3 ficiaries and providers of services and other persons on the
4 appropriate use of advance beneficiary notices and coverage
5 policies under the medicare program.

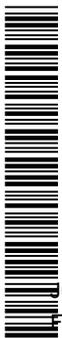
6 (3) GAO REPORT REPORT ON USE OF ADVANCE BENE-
7 FICIARY NOTICES.—Not later than 18 months after the
8 date on which section 1869(g) of the Social Security Act
9 (as added by subsection (a)) takes effect, the Comptroller
10 General of the United States shall submit to Congress a re-
11 port on the use of advance beneficiary notices under title
12 XVIII of such Act. Such report shall include information
13 concerning the providers of services and other persons that
14 have provided such notices and the response of beneficiaries
15 to such notices.

16 (4) GAO REPORT ON USE OF PRIOR DETERMINATION
17 PROCESS.—Not later than 18 months after the date on
18 which section 1869(g) of the Social Security Act (as added
19 by subsection (a)) takes effect, the Comptroller General of
20 the United States shall submit to Congress a report on the
21 use of the prior determination process under such section.
22 Such report shall include—

23 (A) information concerning the types of proce-
24 dures for which a prior determination has been sought,
25 determinations made under the process, and changes in
26 receipt of services resulting from the application of
27 such process; and

28 (B) an evaluation of whether the process was use-
29 ful for physicians (and other suppliers) and bene-
30 ficiaries, whether it was timely, and whether the
31 amount of information required was burdensome to
32 physicians and beneficiaries.

33 (5) ADVANCE BENEFICIARY NOTICE DEFINED.—In
34 this subsection, the term “advance beneficiary notice”
35 means a written notice provided under section 1879(a) of
36 the Social Security Act (42 U.S.C. 1395pp(a)) to an indi-



1 vidual entitled to benefits under part A or B of title XVIII
2 of such Act before items or services are furnished under
3 such part in cases where a provider of services or other
4 person that would furnish the item or service believes that
5 payment will not be made for some or all of such items or
6 services under such title.

7 **Subtitle V—Miscellaneous Provisions**

8 **SEC. 941. POLICY DEVELOPMENT REGARDING EVALUA-** 9 **TION AND MANAGEMENT (E & M) DOCU-** 10 **MENTATION GUIDELINES.**

11 (a) IN GENERAL.—The Secretary may not implement any
12 new documentation guidelines for, or clinical examples of, eval-
13 uation and management physician services under the title
14 XVIII of the Social Security Act on or after the date of the
15 enactment of this Act unless the Secretary—

16 (1) has developed the guidelines in collaboration with
17 practicing physicians (including both generalists and spe-
18 cialists) and provided for an assessment of the proposed
19 guidelines by the physician community;

20 (2) has established a plan that contains specific goals,
21 including a schedule, for improving the use of such guide-
22 lines;

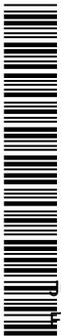
23 (3) has conducted appropriate and representative pilot
24 projects under subsection (b) to test modifications to the
25 evaluation and management documentation guidelines;

26 (4) finds that the objectives described in subsection (c)
27 will be met in the implementation of such guidelines; and

28 (5) has established, and is implementing, a program to
29 educate physicians on the use of such guidelines and that
30 includes appropriate outreach.

31 The Secretary shall make changes to the manner in which ex-
32 isting evaluation and management documentation guidelines
33 are implemented to reduce paperwork burdens on physicians.

34 (b) PILOT PROJECTS TO TEST EVALUATION AND MAN-
35 AGEMENT DOCUMENTATION GUIDELINES.—



1 (1) IN GENERAL.—The Secretary shall conduct under
2 this subsection appropriate and representative pilot projects
3 to test new evaluation and management documentation
4 guidelines referred to in subsection (a).

5 (2) LENGTH AND CONSULTATION.—Each pilot project
6 under this subsection shall—

7 (A) be voluntary;

8 (B) be of sufficient length as determined by the
9 Secretary to allow for preparatory physician and medi-
10 care contractor education, analysis, and use and assess-
11 ment of potential evaluation and management guide-
12 lines; and

13 (C) be conducted, in development and throughout
14 the planning and operational stages of the project, in
15 consultation with practicing physicians (including both
16 generalists and specialists).

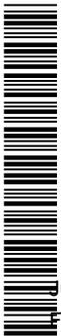
17 (3) RANGE OF PILOT PROJECTS.—Of the pilot projects
18 conducted under this subsection—

19 (A) at least one shall focus on a peer review meth-
20 od by physicians (not employed by a medicare con-
21 tractor) which evaluates medical record information for
22 claims submitted by physicians identified as statistical
23 outliers relative to definitions published in the Current
24 Procedures Terminology (CPT) code book of the Amer-
25 ican Medical Association;

26 (B) at least one shall focus on an alternative
27 method to detailed guidelines based on physician docu-
28 mentation of face to face encounter time with a patient;

29 (C) at least one shall be conducted for services
30 furnished in a rural area and at least one for services
31 furnished outside such an area; and

32 (D) at least one shall be conducted in a setting
33 where physicians bill under physicians' services in
34 teaching settings and at least one shall be conducted in
35 a setting other than a teaching setting.



1 (4) BANNING OF TARGETING OF PILOT PROJECT PAR-
2 TICIPANTS.—Data collected under this subsection shall not
3 be used as the basis for overpayment demands or post-pay-
4 ment audits. Such limitation applies only to claims filed as
5 part of the pilot project and lasts only for the duration of
6 the pilot project and only as long as the provider is a par-
7 ticipant in the pilot project.

8 (5) STUDY OF IMPACT.—Each pilot project shall ex-
9 amine the effect of the new evaluation and management
10 documentation guidelines on—

11 (A) different types of physician practices, includ-
12 ing those with fewer than 10 full-time-equivalent em-
13 ployees (including physicians); and

14 (B) the costs of physician compliance, including
15 education, implementation, auditing, and monitoring.

16 (6) PERIODIC REPORTS.—The Secretary shall submit
17 to Congress periodic reports on the pilot projects under this
18 subsection.

19 (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT
20 GUIDELINES.—The objectives for modified evaluation and man-
21 agement documentation guidelines developed by the Secretary
22 shall be to—

23 (1) identify clinically relevant documentation needed to
24 code accurately and assess coding levels accurately;

25 (2) decrease the level of non-clinically pertinent and
26 burdensome documentation time and content in the physi-
27 cian's medical record;

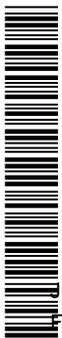
28 (3) increase accuracy by reviewers; and

29 (4) educate both physicians and reviewers.

30 (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOC-
31 UMENTATION FOR PHYSICIAN CLAIMS.—

32 (1) STUDY.—The Secretary shall carry out a study of
33 the matters described in paragraph (2).

34 (2) MATTERS DESCRIBED.—The matters referred to in
35 paragraph (1) are—



1 (A) the development of a simpler, alternative sys-
2 tem of requirements for documentation accompanying
3 claims for evaluation and management physician serv-
4 ices for which payment is made under title XVIII of
5 the Social Security Act; and

6 (B) consideration of systems other than current
7 coding and documentation requirements for payment
8 for such physician services.

9 (3) CONSULTATION WITH PRACTICING PHYSICIANS.—
10 In designing and carrying out the study under paragraph
11 (1), the Secretary shall consult with practicing physicians,
12 including physicians who are part of group practices and
13 including both generalists and specialists.

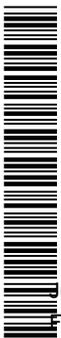
14 (4) APPLICATION OF HIPAA UNIFORM CODING RE-
15 QUIREMENTS.—In developing an alternative system under
16 paragraph (2), the Secretary shall consider requirements of
17 administrative simplification under part C of title XI of the
18 Social Security Act.

19 (5) REPORT TO CONGRESS.—(A) Not later than Octo-
20 ber 1, 2005, the Secretary shall submit to Congress a re-
21 port on the results of the study conducted under paragraph
22 (1).

23 (B) The Medicare Payment Advisory Commission shall
24 conduct an analysis of the results of the study included in
25 the report under subparagraph (A) and shall submit a re-
26 port on such analysis to Congress.

27 (e) STUDY ON APPROPRIATE CODING OF CERTAIN EX-
28 TENDED OFFICE VISITS.—The Secretary shall conduct a study
29 of the appropriateness of coding in cases of extended office vis-
30 its in which there is no diagnosis made. Not later than October
31 1, 2005, the Secretary shall submit a report to Congress on
32 such study and shall include recommendations on how to code
33 appropriately for such visits in a manner that takes into ac-
34 count the amount of time the physician spent with the patient.

35 (f) DEFINITIONS.—In this section—



1 (1) the term “rural area” has the meaning given that
2 term in section 1886(d)(2)(D) of the Social Security Act,
3 42 U.S.C. 1395ww(d)(2)(D); and

4 (2) the term “teaching settings” are those settings de-
5 scribed in section 415.150 of title 42, Code of Federal Reg-
6 ulations.

7 **SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECH-**
8 **NOLOGY AND COVERAGE.**

9 (a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Sec-
10 tion 1868 (42 U.S.C. 1395ee), as amended by section 921(a),
11 is amended by adding at the end the following new subsection:

12 “(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

13 “(1) ESTABLISHMENT.—The Secretary shall establish
14 a Council for Technology and Innovation within the Cen-
15 ters for Medicare & Medicaid Services (in this section re-
16 ferred to as ‘CMS’).

17 “(2) COMPOSITION.—The Council shall be composed
18 of senior CMS staff and clinicians and shall be chaired by
19 the Executive Coordinator for Technology and Innovation
20 (appointed or designated under paragraph (4)).

21 “(3) DUTIES.—The Council shall coordinate the activi-
22 ties of coverage, coding, and payment processes under this
23 title with respect to new technologies and procedures, in-
24 cluding new drug therapies, and shall coordinate the ex-
25 change of information on new technologies between CMS
26 and other entities that make similar decisions.

27 “(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY
28 AND INNOVATION.—The Secretary shall appoint (or des-
29 ignate) a noncareer appointee (as defined in section
30 3132(a)(7) of title 5, United States Code) who shall serve
31 as the Executive Coordinator for Technology and Innova-
32 tion. Such executive coordinator shall report to the Admin-
33 istrator of CMS, shall chair the Council, shall oversee the
34 execution of its duties, and shall serve as a single point of
35 contact for outside groups and entities regarding the cov-
36 erage, coding, and payment processes under this title.”.

1 (b) METHODS FOR DETERMINING PAYMENT BASIS FOR
2 NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is
3 amended by adding at the end the following:

4 “(8)(A) The Secretary shall establish by regulation proce-
5 dures for determining the basis for, and amount of, payment
6 under this subsection for any clinical diagnostic laboratory test
7 with respect to which a new or substantially revised HCPCS
8 code is assigned on or after January 1, 2005 (in this para-
9 graph referred to as ‘new tests’).

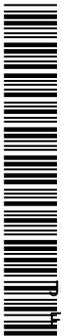
10 “(B) Determinations under subparagraph (A) shall be
11 made only after the Secretary—

12 “(i) makes available to the public (through an Internet
13 site and other appropriate mechanisms) a list that includes
14 any such test for which establishment of a payment amount
15 under this subsection is being considered for a year;

16 “(ii) on the same day such list is made available,
17 causes to have published in the Federal Register notice of
18 a meeting to receive comments and recommendations (and
19 data on which recommendations are based) from the public
20 on the appropriate basis under this subsection for estab-
21 lishing payment amounts for the tests on such list;

22 “(iii) not less than 30 days after publication of such
23 notice convenes a meeting, that includes representatives of
24 officials of the Centers for Medicare & Medicaid Services
25 involved in determining payment amounts, to receive such
26 comments and recommendations (and data on which the
27 recommendations are based);

28 “(iv) taking into account the comments and rec-
29 ommendations (and accompanying data) received at such
30 meeting, develops and makes available to the public
31 (through an Internet site and other appropriate mecha-
32 nisms) a list of proposed determinations with respect to the
33 appropriate basis for establishing a payment amount under
34 this subsection for each such code, together with an expla-
35 nation of the reasons for each such determination, the data
36 on which the determinations are based, and a request for



1 public written comments on the proposed determination;
2 and

3 “(v) taking into account the comments received during
4 the public comment period, develops and makes available to
5 the public (through an Internet site and other appropriate
6 mechanisms) a list of final determinations of the payment
7 amounts for such tests under this subsection, together with
8 the rationale for each such determination, the data on
9 which the determinations are based, and responses to com-
10 ments and suggestions received from the public.

11 “(C) Under the procedures established pursuant to sub-
12 paragraph (A), the Secretary shall—

13 “(i) set forth the criteria for making determinations
14 under subparagraph (A); and

15 “(ii) make available to the public the data (other than
16 proprietary data) considered in making such determina-
17 tions.

18 “(D) The Secretary may convene such further public meet-
19 ings to receive public comments on payment amounts for new
20 tests under this subsection as the Secretary deems appropriate.

21 “(E) For purposes of this paragraph:

22 “(i) The term ‘HCPCS’ refers to the Health Care Pro-
23 cedure Coding System.

24 “(ii) A code shall be considered to be ‘substantially re-
25 vised’ if there is a substantive change to the definition of
26 the test or procedure to which the code applies (such as a
27 new analyte or a new methodology for measuring an exist-
28 ing analyte-specific test).”.

29 (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA
30 COLLECTION FOR USE IN THE MEDICARE INPATIENT PAY-
31 MENT SYSTEM.—

32 (1) STUDY.—The Comptroller General of the United
33 States shall conduct a study that analyzes which external
34 data can be collected in a shorter time frame by the Cen-
35 ters for Medicare & Medicaid Services for use in computing
36 payments for inpatient hospital services. The study may in-

1 clude an evaluation of the feasibility and appropriateness of
2 using of quarterly samples or special surveys or any other
3 methods. The study shall include an analysis of whether
4 other executive agencies, such as the Bureau of Labor Sta-
5 tistics in the Department of Commerce, are best suited to
6 collect this information.

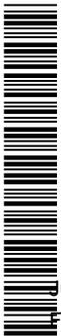
7 (2) REPORT.—By not later than October 1, 2004, the
8 Comptroller General shall submit a report to Congress on
9 the study under paragraph (1).

10 (d) PROCESS FOR ADOPTION OF ICD CODES AS DATA
11 STANDARD.—Section 1172(f) (42 U.S.C. 1320d–1(f)) is
12 amended by inserting after the first sentence the following:
13 “Notwithstanding the preceding sentence, if the National Com-
14 mittee on Vital and Health Statistics has not made a rec-
15 ommendation to the Secretary before the date of the enactment
16 of this sentence, with respect to the adoption of the Inter-
17 national Classification of Diseases, 10th Revision, Procedure
18 Coding System (‘ICD–10–PCS’) and the International Classi-
19 fication of Diseases, 10th Revision, Clinical Modification
20 (‘ICD–10–CM’) as a standard under this part for the reporting
21 of diagnoses, the Secretary may implement ICD-10-PCS only
22 with respect to inpatient services as such a standard.”.

23 **SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN**
24 **SERVICES UNDER MEDICARE SECONDARY**
25 **PAYOR (MSP) PROVISIONS.**

26 (a) IN GENERAL.—The Secretary shall not require a hos-
27 pital (including a critical access hospital) to ask questions (or
28 obtain information) relating to the application of section
29 1862(b) of the Social Security Act (relating to medicare sec-
30 ondary payor provisions) in the case of reference laboratory
31 services described in subsection (b), if the Secretary does not
32 impose such requirement in the case of such services furnished
33 by an independent laboratory.

34 (b) REFERENCE LABORATORY SERVICES DESCRIBED.—
35 Reference laboratory services described in this subsection are
36 clinical laboratory diagnostic tests (or the interpretation of



1 such tests, or both) furnished without a face-to-face encounter
2 between the individual entitled to benefits under part A or en-
3 rolled under part B, or both, and the hospital involved and in
4 which the hospital submits a claim only for such test or inter-
5 pretation.

6 **SEC. 944. EMTALA IMPROVEMENTS.**

7 (a) PAYMENT FOR EMTALA-MANDATED SCREENING AND
8 STABILIZATION SERVICES.—

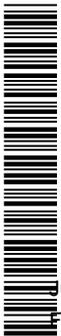
9 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
10 amended by inserting after subsection (c) the following new
11 subsection:

12 “(d) For purposes of subsection (a)(1)(A), in the case of
13 any item or service that is required to be provided pursuant to
14 section 1867 to an individual who is entitled to benefits under
15 this title, determinations as to whether the item or service is
16 reasonable and necessary shall be made on the basis of the in-
17 formation available to the treating physician or practitioner (in-
18 cluding the patient’s presenting symptoms or complaint) at the
19 time the item or service was ordered or furnished by the physi-
20 cian or practitioner (and not on the patient’s principal diag-
21 nosis). When making such determinations with respect to such
22 an item or service, the Secretary shall not consider the fre-
23 quency with which the item or service was provided to the pa-
24 tient before or after the time of the admission or visit.”.

25 (2) EFFECTIVE DATE.—The amendment made by
26 paragraph (1) shall apply to items and services furnished
27 on or after January 1, 2004.

28 (b) NOTIFICATION OF PROVIDERS WHEN EMTALA IN-
29 VESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C.
30 1395dd(d)) is amended by adding at the end the following new
31 paragraph:

32 “(4) NOTICE UPON CLOSING AN INVESTIGATION.—The
33 Secretary shall establish a procedure to notify hospitals and
34 physicians when an investigation under this section is
35 closed.”.



1 (c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN
2 EMTALA CASES INVOLVING TERMINATION OF PARTICIPA-
3 TION.—

4 (1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C.
5 1395dd(d)(3)) is amended—

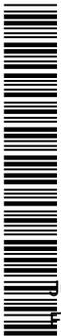
6 (A) in the first sentence, by inserting “or in termi-
7 nating a hospital’s participation under this title” after
8 “in imposing sanctions under paragraph (1)”; and

9 (B) by adding at the end the following new sen-
10 tences: “Except in the case in which a delay would
11 jeopardize the health or safety of individuals, the Sec-
12 retary shall also request such a review before making
13 a compliance determination as part of the process of
14 terminating a hospital’s participation under this title
15 for violations related to the appropriateness of a med-
16 ical screening examination, stabilizing treatment, or an
17 appropriate transfer as required by this section, and
18 shall provide a period of 5 days for such review. The
19 Secretary shall provide a copy of the organization’s re-
20 port to the hospital or physician consistent with con-
21 fidentiality requirements imposed on the organization
22 under such part B.”.

23 (2) EFFECTIVE DATE.—The amendments made by
24 paragraph (1) shall apply to terminations of participation
25 initiated on or after the date of the enactment of this Act.

26 **SEC. 945. EMERGENCY MEDICAL TREATMENT AND AC-**
27 **TIVE LABOR ACT (EMTALA) TECHNICAL AD-**
28 **VISORY GROUP.**

29 (a) ESTABLISHMENT.—The Secretary shall establish a
30 Technical Advisory Group (in this section referred to as the
31 “Advisory Group”) to review issues related to the Emergency
32 Medical Treatment and Labor Act (EMTALA) and its imple-
33 mentation. In this section, the term “EMTALA” refers to the
34 provisions of section 1867 of the Social Security Act (42 U.S.C.
35 1395dd).



1 (b) MEMBERSHIP.—The Advisory Group shall be com-
2 posed of 19 members, including the Administrator of the Cen-
3 ters for Medicare & Medicaid Services and the Inspector Gen-
4 eral of the Department of Health and Human Services and of
5 which—

6 (1) 4 shall be representatives of hospitals, including at
7 least one public hospital, that have experience with the ap-
8 plication of EMTALA and at least 2 of which have not
9 been cited for EMTALA violations;

10 (2) 7 shall be practicing physicians drawn from the
11 fields of emergency medicine, cardiology or cardiothoracic
12 surgery, orthopedic surgery, neurosurgery, pediatrics or a
13 pediatric subspecialty, obstetrics-gynecology, and psychi-
14 atry, with not more than one physician from any particular
15 field;

16 (3) 2 shall represent patients;

17 (4) 2 shall be staff involved in EMTALA investiga-
18 tions from different regional offices of the Centers for
19 Medicare & Medicaid Services; and

20 (5) 1 shall be from a State survey office involved in
21 EMTALA investigations and 1 shall be from a peer review
22 organization, both of whom shall be from areas other than
23 the regions represented under paragraph (4).

24 In selecting members described in paragraphs (1) through (3),
25 the Secretary shall consider qualified individuals nominated by
26 organizations representing providers and patients.

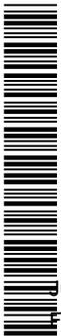
27 (c) GENERAL RESPONSIBILITIES.—The Advisory Group—

28 (1) shall review EMTALA regulations;

29 (2) may provide advice and recommendations to the
30 Secretary with respect to those regulations and their appli-
31 cation to hospitals and physicians;

32 (3) shall solicit comments and recommendations from
33 hospitals, physicians, and the public regarding the imple-
34 mentation of such regulations; and

35 (4) may disseminate information on the application of
36 such regulations to hospitals, physicians, and the public.



1 (d) ADMINISTRATIVE MATTERS.—

2 (1) CHAIRPERSON.—The members of the Advisory
3 Group shall elect a member to serve as chairperson of the
4 Advisory Group for the life of the Advisory Group.

5 (2) MEETINGS.—The Advisory Group shall first meet
6 at the direction of the Secretary. The Advisory Group shall
7 then meet twice per year and at such other times as the
8 Advisory Group may provide.

9 (e) TERMINATION.—The Advisory Group shall terminate
10 30 months after the date of its first meeting.

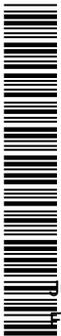
11 (f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Sec-
12 retary shall establish the Advisory Group notwithstanding any
13 limitation that may apply to the number of advisory committees
14 that may be established (within the Department of Health and
15 Human Services or otherwise).

16 **SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO**
17 **PROVIDE CORE HOSPICE SERVICES IN CER-**
18 **TAIN CIRCUMSTANCES.**

19 (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.
20 1395x(dd)(5)) is amended by adding at the end the following:

21 “(D) In extraordinary, exigent, or other non-routine cir-
22 cumstances, such as unanticipated periods of high patient
23 loads, staffing shortages due to illness or other events, or tem-
24 porary travel of a patient outside a hospice program’s service
25 area, a hospice program may enter into arrangements with an-
26 other hospice program for the provision by that other program
27 of services described in paragraph (2)(A)(ii)(I). The provisions
28 of paragraph (2)(A)(ii)(II) shall apply with respect to the serv-
29 ices provided under such arrangements.

30 “(E) A hospice program may provide services described in
31 paragraph (1)(A) other than directly by the program if the
32 services are highly specialized services of a registered profes-
33 sional nurse and are provided non-routinely and so infrequently
34 so that the provision of such services directly would be imprac-
35 ticable and prohibitively expensive.”.



1 (b) CONFORMING PAYMENT PROVISION.—Section 1814(i)
2 (42 U.S.C. 1395f(i)) is amended by adding at the end the fol-
3 lowing new paragraph:

4 “(4) In the case of hospice care provided by a hospice pro-
5 gram under arrangements under section 1861(dd)(5)(D) made
6 by another hospice program, the hospice program that made
7 the arrangements shall bill and be paid for the hospice care.”.

8 (c) EFFECTIVE DATE.—The amendments made by this
9 section shall apply to hospice care provided on or after the date
10 of the enactment of this Act.

11 **SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHO-**
12 **GENS STANDARD TO CERTAIN HOSPITALS.**

13 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
14 amended—

15 (1) in subsection (a)(1)—

16 (A) in subparagraph (R), by striking “and” at the
17 end;

18 (B) in subparagraph (S), by striking the period at
19 the end and inserting “, and”; and

20 (C) by inserting after subparagraph (S) the fol-
21 lowing new subparagraph:

22 “(T) in the case of hospitals that are not otherwise
23 subject to the Occupational Safety and Health Act of 1970,
24 to comply with the Bloodborne Pathogens standard under
25 section 1910.1030 of title 29 of the Code of Federal Regu-
26 lations (or as subsequently redesignated).”; and

27 (2) by adding at the end of subsection (b) the fol-
28 lowing new paragraph:

29 “(4)(A) A hospital that fails to comply with the require-
30 ment of subsection (a)(1)(T) (relating to the Bloodborne
31 Pathogens standard) is subject to a civil money penalty in an
32 amount described in subparagraph (B), but is not subject to
33 termination of an agreement under this section.

34 “(B) The amount referred to in subparagraph (A) is an
35 amount that is similar to the amount of civil penalties that may
36 be imposed under section 17 of the Occupational Safety and



1 Health Act of 1970 for a violation of the Bloodborne Pathogens
2 standard referred to in subsection (a)(1)(T) by a hospital that
3 is subject to the provisions of such Act.

4 “(C) A civil money penalty under this paragraph shall be
5 imposed and collected in the same manner as civil money pen-
6 alties under subsection (a) of section 1128A are imposed and
7 collected under that section.”.

8 (b) EFFECTIVE DATE.—The amendments made by this
9 subsection (a) shall apply to hospitals as of July 1, 2004.

10 **SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND**
11 **CORRECTIONS.**

12 (a) TECHNICAL AMENDMENTS RELATING TO ADVISORY
13 COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of
14 section 1114 (42 U.S.C. 1314)—

15 (A) is transferred to section 1862 and added at the
16 end of such section; and

17 (B) is redesignated as subsection (j).

18 (2) Section 1862 (42 U.S.C. 1395y) is amended—

19 (A) in the last sentence of subsection (a), by striking
20 “established under section 1114(f)”; and

21 (B) in subsection (j), as so transferred and
22 redesignated—

23 (i) by striking “under subsection (f)”; and

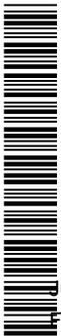
24 (ii) by striking “section 1862(a)(1)” and inserting
25 “subsection (a)(1)”.

26 (b) TERMINOLOGY CORRECTIONS.—(1) Section
27 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by
28 section 521 of BIPA, is amended—

29 (A) in subclause (III), by striking “policy” and insert-
30 ing “determination”; and

31 (B) in subclause (IV), by striking “medical review
32 policies” and inserting “coverage determinations”.

33 (2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C))
34 is amended by striking “policy” and “POLICY” and inserting
35 “determination” each place it appears and “DETERMINATION”,
36 respectively.



1 (c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42
2 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is
3 amended—

4 (1) in subparagraph (A)(iv), by striking “subclause
5 (I), (II), or (III)” and inserting “clause (i), (ii), or (iii)”;

6 (2) in subparagraph (B), by striking “clause (i)(IV)”
7 and “clause (i)(III)” and inserting “subparagraph (A)(iv)”
8 and “subparagraph (A)(iii)”, respectively; and

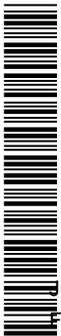
9 (3) in subparagraph (C), by striking “clause (i)”,
10 “subclause (IV)” and “subparagraph (A)” and inserting
11 “subparagraph (A)”, “clause (iv)” and “paragraph
12 (1)(A)”, respectively each place it appears.

13 (d) OTHER CORRECTIONS.—Effective as if included in the
14 enactment of section 521(c) of BIPA, section 1154(e) (42
15 U.S.C. 1320e-3(e)) is amended by striking paragraph (5).

16 (e) EFFECTIVE DATE.—Except as otherwise provided, the
17 amendments made by this section shall be effective as if in-
18 cluded in the enactment of BIPA.

19 **SEC. 949. CONFORMING AUTHORITY TO WAIVE A PRO-**
20 **GRAM EXCLUSION.**

21 The first sentence of section 1128(c)(3)(B) (42 U.S.C.
22 1320a-7(c)(3)(B)) is amended to read as follows: “Subject to
23 subparagraph (G), in the case of an exclusion under subsection
24 (a), the minimum period of exclusion shall be not less than five
25 years, except that, upon the request of the administrator of a
26 Federal health care program (as defined in section 1128B(f))
27 who determines that the exclusion would impose a hardship on
28 individuals entitled to benefits under part A of title XVIII or
29 enrolled under part B of such title, or both, the Secretary may
30 waive the exclusion under subsection (a)(1), (a)(3), or (a)(4)
31 with respect to that program in the case of an individual or en-
32 tity that is the sole community physician or sole source of es-
33 sential specialized services in a community.”.



1 **SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.**

2 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
3 amended by adding after subsection (g) the following new sub-
4 section:

5 “(h)(1) Subject to paragraph (2), a group health plan (as
6 defined in subsection (a)(1)(A)(v)) providing supplemental or
7 secondary coverage to individuals also entitled to services under
8 this title shall not require a medicare claims determination
9 under this title for dental benefits specifically excluded under
10 subsection (a)(12) as a condition of making a claims deter-
11 mination for such benefits under the group health plan.

12 “(2) A group health plan may require a claims determina-
13 tion under this title in cases involving or appearing to involve
14 inpatient dental hospital services or dental services expressly
15 covered under this title pursuant to actions taken by the Sec-
16 retary.”.

17 (b) EFFECTIVE DATE.—The amendment made by sub-
18 section (a) shall take effect on the date that is 60 days after
19 the date of the enactment of this Act.

20 **SEC. 951. FURNISHING HOSPITALS WITH INFORMATION**
21 **TO COMPUTE DSH FORMULA.**

22 Beginning not later than 1 year after the date of the en-
23 actment of this Act, the Secretary shall furnish to subsection
24 (d) hospitals (as defined in section 1886(d)(1)(B) of the Social
25 Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary
26 for such hospitals to compute the number of patient days de-
27 scribed in subclause (II) of section 1886(d)(5)(F)(vi) of the So-
28 cial Security Act (42 U.S.C. 1395ww(d)(5)(F)(vi)) used in
29 computing the disproportionate patient percentage under such
30 section for that hospital. Such data shall also be furnished to
31 other hospitals which would qualify for additional payments
32 under part A of title XVIII of the Social Security Act on the
33 basis of such data.

34 **SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.**

35 (a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C.
36 1395u(b)(6)(A)) is amended by striking “or (ii) (where the

1 service was provided in a hospital, critical access hospital, clin-
2 ic, or other facility) to the facility in which the service was pro-
3 vided if there is a contractual arrangement between such physi-
4 cian or other person and such facility under which such facility
5 submits the bill for such service,” and inserting “or (ii) where
6 the service was provided under a contractual arrangement be-
7 tween such physician or other person and an entity (as defined
8 by the Secretary), to the entity if, under the contractual ar-
9 rangement, the entity submits the bill for the service and the
10 contractual arrangement meets such other program integrity
11 and other safeguards as the Secretary may determine to be ap-
12 propriate,”.

13 (b) CONFORMING AMENDMENT.—The second sentence of
14 section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by
15 striking “except to an employer or facility” and inserting “ex-
16 cept to an employer, entity, or other person”.

17 (c) EFFECTIVE DATE.—The amendments made by section
18 shall apply to payments made on or after the date of the enact-
19 ment of this Act.

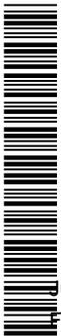
20 **SEC. 953. OTHER PROVISIONS.**

21 (a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

22 (1) SUSTAINABLE GROWTH RATE AND UPDATES.—

23 Not later than 6 months after the date of the enactment
24 of this Act, the Comptroller General of the United States
25 shall submit to Congress a report on the appropriateness
26 of the updates in the conversion factor under subsection
27 (d)(3) of section 1848 of the Social Security Act (42
28 U.S.C. 1395w-4), including the appropriateness of the sus-
29 tainable growth rate formula under subsection (f) of such
30 section for 2002 and succeeding years. Such report shall
31 examine the stability and predictability of such updates and
32 rate and alternatives for the use of such rate in the up-
33 dates.

34 (2) PHYSICIAN COMPENSATION GENERALLY.—Not
35 later than 12 months after the date of the enactment of
36 this Act, the Comptroller General shall submit to Congress



1 a report on all aspects of physician compensation for serv-
2 ices furnished under title XVIII of the Social Security Act,
3 and how those aspects interact and the effect on appro-
4 priate compensation for physician services. Such report
5 shall review alternatives for the physician fee schedule
6 under section 1848 of such title (42 U.S.C. 1395w-4).

7 (b) ANNUAL PUBLICATION OF LIST OF NATIONAL COV-
8 ERAGE DETERMINATIONS.—The Secretary shall provide, in an
9 appropriate annual publication available to the public, a list of
10 national coverage determinations made under title XVIII of the
11 Social Security Act in the previous year and information on
12 how to get more information with respect to such determina-
13 tions.

14 (c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME
15 HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO
16 ARE NOT MEDICARE BENEFICIARIES.—Not later than 6
17 months after the date of the enactment of this Act, the Comp-
18 troller General of the United States shall submit to Congress
19 a report on the implications if there were flexibility in the ap-
20 plication of the medicare conditions of participation for home
21 health agencies with respect to groups or types of patients who
22 are not medicare beneficiaries. The report shall include an
23 analysis of the potential impact of such flexible application on
24 clinical operations and the recipients of such services and an
25 analysis of methods for monitoring the quality of care provided
26 to such recipients.

27 (d) OIG REPORT ON NOTICES RELATING TO USE OF
28 HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year
29 after the date of the enactment of this Act, the Inspector Gen-
30 eral of the Department of Health and Human Services shall
31 submit a report to Congress on—

32 (1) the extent to which hospitals provide notice to
33 medicare beneficiaries in accordance with applicable re-
34 quirements before they use the 60 lifetime reserve days de-
35 scribed in section 1812(a)(1) of the Social Security Act (42
36 U.S.C. 1395d(a)(1)); and



1 (2) the appropriateness and feasibility of hospitals pro-
2 viding a notice to such beneficiaries before they completely
3 exhaust such lifetime reserve days.

4 **TITLE X—MEDICAID**

5 **SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOS-** 6 **PITAL (DSH) PAYMENTS.**

7 Section 1923(f)(3) (42 U.S.C. 1396r-4(f)(3)) is
8 amended—

9 (1) in subparagraph (A), by striking “subparagraph
10 (B)” and inserting “subparagraphs (B) and (C)”; and

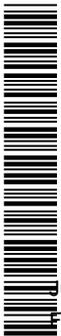
11 (2) by adding at the end the following new subpara-
12 graphs:

13 “(C) SPECIAL, TEMPORARY INCREASE IN ALLOT-
14 MENTS ON A ONE-TIME, NON-CUMULATIVE BASIS.—
15 The DSH allotment for any State—

16 “(i) for fiscal year 2004 is equal to 106 per-
17 cent of the DSH allotment for the State for fiscal
18 year 2003 under this paragraph, notwithstanding
19 subparagraph (B); and

20 “(ii) for each succeeding fiscal year is equal to
21 the DSH allotment for the State for the previous
22 fiscal year under this subparagraph increased, sub-
23 ject to subparagraph (B), by 1.9 percent or, in the
24 case of fiscal years beginning with the fiscal year
25 specified in subparagraph (D) for that State, the
26 percentage change in the consumer price index for
27 all urban consumers (all items; U.S. city average),
28 for the previous fiscal year.

29 “(D) FISCAL YEAR SPECIFIED.—For purposes of
30 subparagraph (C)(ii), the fiscal year specified in this
31 subparagraph for a State is the first fiscal year for
32 which the Secretary estimates that the DSH allotment
33 for that State will equal (or no longer exceed) the DSH
34 allotment for that State under the law as in effect be-
35 fore the date of the enactment of this subparagraph.”.



1 **SEC. 1002. CLARIFICATION OF INCLUSION OF INPA-**
2 **TIENT DRUG PRICES CHARGED TO CERTAIN**
3 **PUBLIC HOSPITALS IN THE BEST PRICE EX-**
4 **EMPTIONS FOR THE MEDICAID DRUG RE-**
5 **BATE PROGRAM.**

6 (a) IN GENERAL.—Section 1927(e)(1)(C)(i)(I) (42 U.S.C.
7 1396r-8(e)(1)(C)(i)(I)) is amended by inserting before the
8 semicolon the following: “(including inpatient prices charged to
9 hospitals described in section 340B(a)(4)(L) of the Public
10 Health Service Act)”.

11 (b) EFFECTIVE DATE.—The amendment made by this sec-
12 tion shall take effect on the date of the enactment of this Act.

