

108TH CONGRESS  
1ST SESSION

# H. R. 2606

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

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 25, 2003

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

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## A BILL

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

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

1 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECUR-**  
 2 **RITY ACT; REFERENCES TO BIPA AND SEC-**  
 3 **RETARY; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the  
 5 “Prescription Drug and Medicare Improvement Act of  
 6 2003”.

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

13 (c) **BIPA; SECRETARY.**—In this Act:

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

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

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

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

**TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT**

**Subtitle A—Medicare Voluntary Prescription Drug Delivery Program**

Sec. 101. Medicare voluntary prescription drug delivery program.

**“PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM**

“Sec. 1860D. Definitions; treatment of references to provisions in Medicare Advantage program.

“Subpart 1—Establishment of Voluntary Prescription Drug Delivery Program

“Sec. 1860D–1. Establishment of voluntary prescription drug delivery program.

“Sec. 1860D–2. Enrollment under program.

“Sec. 1860D–3. Election of a Medicare Prescription Drug plan.

“Sec. 1860D–4. Providing information to beneficiaries.

“Sec. 1860D–5. Beneficiary protections.

“Sec. 1860D–6. Prescription drug benefits.

“Sec. 1860D–7. Requirements for entities offering Medicare Prescription Drug plans; establishment of standards.

“Subpart 2—Prescription Drug Delivery System

“Sec. 1860D–10. Establishment of service areas.

“Sec. 1860D–11. Publication of risk adjusters.

“Sec. 1860D–12. Submission of bids for proposed Medicare Prescription Drug plans.

“Sec. 1860D–13. Approval of proposed Medicare Prescription Drug plans.

“Sec. 1860D–14. Computation of monthly standard prescription drug coverage premiums.

“Sec. 1860D–15. Computation of monthly national average premium.

“Sec. 1860D–16. Payments to eligible entities.

“Sec. 1860D–17. Computation of monthly beneficiary obligation.

“Sec. 1860D–18. Collection of monthly beneficiary obligation.

“Sec. 1860D–19. Premium and cost-sharing subsidies for low-income individuals.

“Sec. 1860D–20. Reinsurance payments for expenses incurred in providing prescription drug coverage above the annual out-of-pocket threshold.

“Sec. 1860D–21. Direct subsidy for sponsor of a qualified retiree prescription drug plan for plan enrollees eligible for, but not enrolled in, this part.

“Subpart 3—Miscellaneous Provisions

“Sec. 1860D–25. Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

“Sec. 1860D–26. Other related provisions.

Sec. 102. Study and report on permitting part B only individuals to enroll in medicare voluntary prescription drug delivery program.

Sec. 103. Rules relating to medigap policies that provide prescription drug coverage.

Sec. 104. Medicaid and other amendments related to low-income beneficiaries.

Sec. 105. Expansion of membership and duties of Medicare Payment Advisory Commission (MedPAC).

Sec. 106. Study regarding variations in spending and drug utilization.

Subtitle B—Medicare Prescription Drug Discount Card and Transitional Assistance for Low-Income Beneficiaries

Sec. 111. Medicare prescription drug discount card and transitional assistance for low-income beneficiaries.

Subtitle C—Standards for Electronic Prescribing

Sec. 121. Standards for electronic prescribing.

Subtitle D—Other Provisions

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

TITLE II—MEDICAREADVANTAGE

Subtitle A—MedicareAdvantage Competition

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

Subtitle B—Preferred Provider Organizations

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

Subtitle C—Other Managed Care Reforms

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

TITLE III—CENTER FOR MEDICARE CHOICES

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

TITLE IV—MEDICARE FEE-FOR-SERVICE IMPROVEMENTS

Subtitle A—Provisions Relating to Part A

Sec. 401. Equalizing urban and rural standardized payment amounts under the medicare inpatient hospital prospective payment system.  
 Sec. 402. Adjustment to the medicare inpatient hospital PPS wage index to revise the labor-related share of such index.  
 Sec. 403. Medicare inpatient hospital payment adjustment for low-volume hospitals.  
 Sec. 404. Fairness in the medicare disproportionate share hospital (DSH) adjustment for rural hospitals.  
 Sec. 405. Critical access hospital (CAH) improvements.

- Sec. 406. Authorizing use of arrangements to provide core hospice services in certain circumstances.
- Sec. 407. Services provided to hospice patients by nurse practitioners, clinical nurse specialists, and physician assistants.
- Sec. 408. Authority to include costs of training of psychologists in payments to hospitals under medicare.
- Sec. 409. Revision of Federal rate for hospitals in Puerto Rico.
- Sec. 410. Authority regarding geriatric fellowships.
- Sec. 411. Clarification of congressional intent regarding the counting of residents in a nonprovider setting and a technical amendment regarding the 3-year rolling average and the IME ratio.
- Sec. 412. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.
- Sec. 413. GAO study and report on appropriateness of payments under the prospective payment system for inpatient hospital services.

Subtitle B—Provisions Relating to Part B

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

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

#### Subtitle C—Provisions Relating to Parts A and B

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

### TITLE V—MEDICARE APPEALS, REGULATORY, AND CONTRACTING IMPROVEMENTS

#### Subtitle A—Regulatory Reform

- Sec. 501. Rules for the publication of a final regulation based on the previous publication of an interim final regulation.
- Sec. 502. Compliance with changes in regulations and policies.
- Sec. 503. Report on legal and regulatory inconsistencies.

#### Subtitle B—Appeals Process Reform

- Sec. 511. Submission of plan for transfer of responsibility for medicare appeals.
- Sec. 512. Expedited access to judicial review.
- Sec. 513. Expedited review of certain provider agreement determinations.
- Sec. 514. Revisions to medicare appeals process.
- Sec. 515. Hearing rights related to decisions by the Secretary to deny or not renew a medicare enrollment agreement; consultation before changing provider enrollment forms.
- Sec. 516. Appeals by providers when there is no other party available.
- Sec. 517. Provider access to review of local coverage determinations.

#### Subtitle C—Contracting Reform

- Sec. 521. Increased flexibility in medicare administration.

#### Subtitle D—Education and Outreach Improvements

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

#### Subtitle E—Review, Recovery, and Enforcement Reform

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

## TITLE VI—OTHER PROVISIONS

- Sec. 601. Increase in medicaid DSH allotments for fiscal years 2004 and 2005.
- Sec. 602. Increase in floor for treatment as an extremely low DSH State under the medicaid program for fiscal years 2004 and 2005.
- Sec. 603. Increased reporting requirements to ensure the appropriateness of payment adjustments to disproportionate share hospitals under the medicaid program.
- Sec. 604. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.
- Sec. 605. Assistance with coverage of legal immigrants under the medicaid program and SCHIP.
- Sec. 606. Establishment of consumer ombudsman account.
- Sec. 607. GAO study regarding impact of assets test for low-income beneficiaries.
- Sec. 608. Health care infrastructure improvement.
- Sec. 609. Capital infrastructure revolving loan program.
- Sec. 610. Federal reimbursement of emergency health services furnished to undocumented aliens.
- Sec. 611. Increase in appropriation to the health care fraud and abuse control account.
- Sec. 612. Increase in civil penalties under the False Claims Act.
- Sec. 613. Increase in civil monetary penalties under the Social Security Act.
- Sec. 614. Extension of customs user fees.

## TITLE VII—ACCESS TO AFFORDABLE PHARMACEUTICALS

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

## TITLE VIII—IMPORTATION OF PRESCRIPTION DRUGS

- Sec. 801. Importation of prescription drugs.



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

3 “(ii) a biological product described in  
4 clauses (i) through (iii) of subparagraph  
5 (B) of such section; or

6 “(iii) insulin described in subpara-  
7 graph (C) of such section; and such term  
8 includes a vaccine licensed under section  
9 351 of the Public Health Service Act and  
10 any use of a covered drug for a medically  
11 accepted indication (as defined in section  
12 1927(k)(6)).

13 “(B) EXCLUSIONS.—

14 “(i) IN GENERAL.—The term ‘covered  
15 drug’ does not include drugs or classes of  
16 drugs, or their medical uses, which may be  
17 excluded from coverage or otherwise re-  
18 stricted under section 1927(d)(2), other  
19 than subparagraph (E) thereof (relating to  
20 smoking cessation agents), or under sec-  
21 tion 1927(d)(3).

22 “(ii) AVOIDANCE OF DUPLICATE COV-  
23 ERAGE.—A drug prescribed for an indi-  
24 vidual that would otherwise be a covered  
25 drug under this part shall not be so con-

1           sidered if payment for such drug is avail-  
2           able under part A or B, but shall be so  
3           considered if such payment is not available  
4           under part A or B or because benefits  
5           under such parts have been exhausted.

6           “(C) APPLICATION OF FORMULARY RE-  
7           STRICTIONS.—A drug prescribed for an indi-  
8           vidual that would otherwise be a covered drug  
9           under this part shall not be so considered under  
10          a plan if the plan excludes the drug under a  
11          formulary and such exclusion is not successfully  
12          resolved under subsection (d) or (e)(2) of sec-  
13          tion 1860D–5.

14          “(D) APPLICATION OF GENERAL EXCLU-  
15          SION PROVISIONS.—A Medicare Prescription  
16          Drug plan or a Medicare Advantage plan may  
17          exclude from qualified prescription drug cov-  
18          erage any covered drug—

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

22                 “(ii) which are not prescribed in ac-  
23                 cordance with the plan or this part.

1           Such exclusions are determinations subject to  
2           reconsideration and appeal pursuant to section  
3           1860D–5(e).

4           “(3) ELIGIBLE BENEFICIARY.—The term ‘eligi-  
5           ble beneficiary’ means an individual who is entitled  
6           to, or enrolled for, benefits under part A and en-  
7           rolled under part B.

8           “(4) ELIGIBLE ENTITY.—The term ‘eligible en-  
9           tity’ means any risk-bearing entity that the Adminis-  
10          trator determines to be appropriate to provide eligi-  
11          ble beneficiaries with the benefits under a Medicare  
12          Prescription Drug plan, including—

13                 “(A) a pharmaceutical benefit management  
14                 company;

15                 “(B) a wholesale or retail pharmacist deliv-  
16                 ery system;

17                 “(C) an insurer (including an insurer that  
18                 offers medicare supplemental policies under sec-  
19                 tion 1882);

20                 “(D) any other risk-bearing entity; or

21                 “(E) any combination of the entities de-  
22                 scribed in subparagraphs (A) through (D).

23           “(5) INITIAL COVERAGE LIMIT.—The term ‘ini-  
24           tial coverage limit’ means the limit as established  
25           under section 1860D–6(e)(3), or, in the case of cov-

1 erage that is not standard prescription drug cov-  
2 erage, the comparable limit (if any) established  
3 under the coverage.

4 “(6) MEDICAREADVANTAGE ORGANIZATION;  
5 MEDICAREADVANTAGE PLAN.—The terms  
6 ‘MedicareAdvantage organization’ and  
7 ‘MedicareAdvantage plan’ have the meanings given  
8 such terms in subsections (a)(1) and (b)(1), respec-  
9 tively, of section 1859 (relating to definitions relat-  
10 ing to MedicareAdvantage organizations).

11 “(7) MEDICARE PRESCRIPTION DRUG PLAN.—  
12 The term ‘Medicare Prescription Drug plan’ means  
13 prescription drug coverage that is offered under a  
14 policy, contract, or plan—

15 “(A) that has been approved under section  
16 1860D–13; and

17 “(B) by an eligible entity pursuant to, and  
18 in accordance with, a contract between the Ad-  
19 ministrator and the entity under section  
20 1860D–7(b).

21 “(8) PRESCRIPTION DRUG ACCOUNT.—The  
22 term ‘Prescription Drug Account’ means the Pre-  
23 scription Drug Account (as established under section  
24 1860D–25) in the Federal Supplementary Medical  
25 Insurance Trust Fund under section 1841.

1           “(9) QUALIFIED PRESCRIPTION DRUG COV-  
2 ERAGE.—The term ‘qualified prescription drug cov-  
3 erage’ means the coverage described in section  
4 1860D–6(a)(1).

5           “(10) STANDARD PRESCRIPTION DRUG COV-  
6 ERAGE.—The term ‘standard prescription drug cov-  
7 erage’ means the coverage described in section  
8 1860D–6(c).

9           “(b) APPLICATION OF MEDICAREADVANTAGE PROVI-  
10 SIONS UNDER THIS PART.—For purposes of applying pro-  
11 visions of part C under this part with respect to a Medi-  
12 care Prescription Drug plan and an eligible entity, unless  
13 otherwise provided in this part such provisions shall be  
14 applied as if—

15           “(1) any reference to a MedicareAdvantage  
16 plan included a reference to a Medicare Prescription  
17 Drug plan;

18           “(2) any reference to a provider-sponsored or-  
19 ganization included a reference to an eligible entity;

20           “(3) any reference to a contract under section  
21 1857 included a reference to a contract under sec-  
22 tion 1860D–7(b); and

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

1 “Subpart 1—Establishment of Voluntary Prescription  
2 Drug Delivery Program

3 “ESTABLISHMENT OF VOLUNTARY PRESCRIPTION DRUG  
4 DELIVERY PROGRAM

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

6 “(1) IN GENERAL.—The Administrator shall  
7 provide for and administer a voluntary prescription  
8 drug delivery program under which each eligible ben-  
9 efiary enrolled under this part shall be provided  
10 with access to qualified prescription drug coverage  
11 as follows:

12 “(A) MEDICAREADVANTAGE ENROLLEES  
13 RECEIVE COVERAGE THROUGH  
14 MEDICAREADVANTAGE PLAN.—

15 “(i) IN GENERAL.—Except as pro-  
16 vided in clause (ii), an eligible beneficiary  
17 who is enrolled under this part and en-  
18 rolled in a MedicareAdvantage plan offered  
19 by a MedicareAdvantage organization shall  
20 receive coverage of benefits under this part  
21 through such plan.

22 “(ii) EXCEPTION FOR ENROLLEES IN  
23 MEDICAREADVANTAGE MSA PLANS.—An el-  
24 ible beneficiary who is enrolled under this  
25 part and enrolled in an MSA plan under

1 part C shall receive coverage of benefits  
2 under this part through enrollment in a  
3 Medicare Prescription Drug plan that is  
4 offered in the geographic area in which the  
5 beneficiary resides. For purposes of this  
6 part, the term ‘MSA plan’ has the meaning  
7 given such term in section 1859(b)(3).

8 “(iii) EXCEPTION FOR ENROLLEES IN  
9 MEDICAREADVANTAGE PRIVATE FEE-FOR-  
10 SERVICE PLANS.—An eligible beneficiary  
11 who is enrolled under this part and en-  
12 rolled in a private fee-for-service plan  
13 under part C shall—

14 “(I) receive benefits under this  
15 part through such plan if the plan  
16 provides qualified prescription drug  
17 coverage; and

18 “(II) if the plan does not provide  
19 qualified prescription drug coverage,  
20 receive coverage of benefits under this  
21 part through enrollment in a Medicare  
22 Prescription Drug plan that is offered  
23 in the geographic area in which the  
24 beneficiary resides. For purposes of  
25 this part, the term ‘private fee-for-

1 service plan' has the meaning given  
2 such term in section 1859(b)(2).

3 “(B) FEE-FOR-SERVICE ENROLLEES RE-  
4 CEIVE COVERAGE THROUGH A MEDICARE PRE-  
5 SCRIPTON DRUG PLAN.—An eligible beneficiary  
6 who is enrolled under this part but is not en-  
7 rolled in a MedicareAdvantage plan (except for  
8 an MSA plan or a private fee-for-service plan  
9 that does not provide qualified prescription  
10 drug coverage) shall receive coverage of benefits  
11 under this part through enrollment in a Medi-  
12 care Prescription Drug plan that is offered in  
13 the geographic area in which the beneficiary re-  
14 sides.

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

19 “(3) SCOPE OF BENEFITS.—Pursuant to sec-  
20 tion 1860D–6(b)(3)(C), the program established  
21 under this part shall provide for coverage of all  
22 therapeutic categories and classes of covered drugs  
23 (although not necessarily for all drugs within such  
24 categories and classes).

1           “(4) PROGRAM TO BEGIN IN 2006.—The Admin-  
2           istrator shall establish the program under this part  
3           in a manner so that benefits are first provided be-  
4           ginning on January 1, 2006.

5           “(b) ACCESS TO ALTERNATIVE PRESCRIPTION DRUG  
6           COVERAGE.—In the case of an eligible beneficiary who has  
7           creditable prescription drug coverage (as defined in section  
8           1860D–2(b)(1)(F)), such beneficiary—

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

11          “(2) pursuant to section 1860D–2(b)(1)(C), is  
12          permitted to subsequently enroll under this part  
13          without any penalty and obtain access to qualified  
14          prescription drug coverage in the manner described  
15          in subsection (a) if the beneficiary involuntarily loses  
16          such coverage.

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

20                        “ENROLLMENT UNDER PROGRAM

21          “SEC. 1860D–2. (a) ESTABLISHMENT OF ENROLL-  
22          MENT PROCESS.—

23                        “(1) PROCESS SIMILAR TO PART B ENROLL-  
24          MENT.—The Administrator shall establish a process  
25          through which an eligible beneficiary (including an  
26          eligible beneficiary enrolled in a Medicare Advantage

1 plan offered by a MedicareAdvantage organization)  
2 may make an election to enroll under this part. Such  
3 process shall be similar to the process for enrollment  
4 in part B under section 1837, including the deeming  
5 provisions of such section.

6 “(2) CONDITION OF ENROLLMENT.—An eligible  
7 beneficiary must be enrolled under this part in order  
8 to be eligible to receive access to qualified prescrip-  
9 tion drug coverage.

10 “(b) SPECIAL ENROLLMENT PROCEDURES.—

11 “(1) LATE ENROLLMENT PENALTY.—

12 “(A) INCREASE IN MONTHLY BENEFICIARY  
13 OBLIGATION.—Subject to the succeeding provi-  
14 sions of this paragraph, in the case of an eligi-  
15 ble beneficiary whose coverage period under this  
16 part began pursuant to an enrollment after the  
17 beneficiary’s initial enrollment period under  
18 part B (determined pursuant to section  
19 1837(d)) and not pursuant to the open enroll-  
20 ment period described in paragraph (2), the Ad-  
21 ministrator shall establish procedures for in-  
22 creasing the amount of the monthly beneficiary  
23 obligation under section 1860D–17 applicable  
24 to such beneficiary by an amount that the Ad-  
25 ministrator determines is actuarially sound for

1 each full 12-month period (in the same contin-  
2 uous period of eligibility) in which the eligible  
3 beneficiary could have been enrolled under this  
4 part but was not so enrolled.

5 “(B) PERIODS TAKEN INTO ACCOUNT.—

6 For purposes of calculating any 12-month pe-  
7 riod under subparagraph (A), there shall be  
8 taken into account—

9 “(i) the months which elapsed be-  
10 tween the close of the eligible beneficiary’s  
11 initial enrollment period and the close of  
12 the enrollment period in which the bene-  
13 ficiary enrolled; and

14 “(ii) in the case of an eligible bene-  
15 ficiary who reenrolls under this part, the  
16 months which elapsed between the date of  
17 termination of a previous coverage period  
18 and the close of the enrollment period in  
19 which the beneficiary reenrolled.

20 “(C) PERIODS NOT TAKEN INTO AC-  
21 COUNT.—

22 “(i) IN GENERAL.—For purposes of  
23 calculating any 12-month period under  
24 subparagraph (A), subject to clause (ii),  
25 there shall not be taken into account

1 months for which the eligible beneficiary  
2 can demonstrate that the beneficiary had  
3 creditable prescription drug coverage (as  
4 defined in subparagraph (F)).

5 “(ii) BENEFICIARY MUST INVOLUN-  
6 TARIPLY LOSE COVERAGE.—Clause (i) shall  
7 only apply with respect to coverage—

8 “(I) in the case of coverage de-  
9 scribed in clause (ii) of subparagraph  
10 (F), if the plan terminates, ceases to  
11 provide, or reduces the value of the  
12 prescription drug coverage under such  
13 plan to below the actuarial value of  
14 standard prescription drug coverage  
15 (as determined under section 1860D-  
16 6(f));

17 “(II) in the case of coverage de-  
18 scribed in clause (i), (iii), or (iv) of  
19 subparagraph (F), if the beneficiary is  
20 involuntarily disenrolled or becomes  
21 ineligible for such coverage; or

22 “(III) in the case of a beneficiary  
23 with coverage described in clause (v)  
24 of subparagraph (F), if the issuer of

1                   the policy terminates coverage under  
2                   the policy.

3                   “(D) PERIODS TREATED SEPARATELY.—  
4                   Any increase in an eligible beneficiary’s monthly  
5                   beneficiary obligation under subparagraph (A)  
6                   with respect to a particular continuous period  
7                   of eligibility shall not be applicable with respect  
8                   to any other continuous period of eligibility  
9                   which the beneficiary may have.

10                   “(E) CONTINUOUS PERIOD OF ELIGI-  
11                   BILITY.—

12                   “(i) IN GENERAL.—Subject to clause  
13                   (ii), for purposes of this paragraph, an eli-  
14                   gible beneficiary’s ‘continuous period of eli-  
15                   gibility’ is the period that begins with the  
16                   first day on which the beneficiary is eligi-  
17                   ble to enroll under section 1836 and ends  
18                   with the beneficiary’s death.

19                   “(ii) SEPARATE PERIOD.—Any period  
20                   during all of which an eligible beneficiary  
21                   satisfied paragraph (1) of section 1836  
22                   and which terminated in or before the  
23                   month preceding the month in which the  
24                   beneficiary attained age 65 shall be a sepa-  
25                   rate ‘continuous period of eligibility’ with

1           respect to the beneficiary (and each such  
2           period which terminates shall be deemed  
3           not to have existed for purposes of subse-  
4           quently applying this paragraph).

5           “(F) CREDITABLE PRESCRIPTION DRUG  
6           COVERAGE DEFINED.—Subject to subparagraph  
7           (G), for purposes of this part, the term ‘cred-  
8           itable prescription drug coverage’ means any of  
9           the following:

10           “(i) DRUG-ONLY COVERAGE UNDER  
11           MEDICAID.—Coverage of covered out-  
12           patient drugs (as defined in section 1927)  
13           under title XIX through a waiver under  
14           1115 where covered outpatient drugs are  
15           the sole medical assistance benefit.

16           “(ii) PRESCRIPTION DRUG COVERAGE  
17           UNDER A GROUP HEALTH PLAN.—Any out-  
18           patient prescription drug coverage under a  
19           group health plan, including a health bene-  
20           fits plan under chapter 89 of title 5,  
21           United States Code (commonly known as  
22           the Federal employees health benefits pro-  
23           gram), and a qualified retiree prescription  
24           drug plan (as defined in section 1860D-  
25           20(e)(4)).

1           “(iii) STATE PHARMACEUTICAL AS-  
2           SISTANCE PROGRAM.—Coverage of pre-  
3           scription drugs under a State pharma-  
4           ceutical assistance program.

5           “(iv) VETERANS’ COVERAGE OF PRE-  
6           SCRIPTION DRUGS.—Coverage of prescrip-  
7           tion drugs for veterans, and survivors and  
8           dependents of veterans, under chapter 17  
9           of title 38, United States Code.

10           “(v) PRESCRIPTION DRUG COVERAGE  
11           UNDER MEDIGAP POLICIES.—Coverage  
12           under a medicare supplemental policy  
13           under section 1882 that provides benefits  
14           for prescription drugs (whether or not such  
15           coverage conforms to the standards for  
16           packages of benefits under section  
17           1882(p)(1)).

18           “(G) REQUIREMENT FOR CREDITABLE  
19           COVERAGE.—Coverage described in clauses (i)  
20           through (v) of subparagraph (F) shall not be  
21           considered to be creditable coverage under this  
22           part unless the coverage provides coverage of  
23           the cost of prescription drugs the actuarial  
24           value of which (as defined by the Adminis-  
25           trator) to the beneficiary equals or exceeds the

1           actuarial value of standard prescription drug  
2           coverage (as determined under section 1860D–  
3           6(f)).

4           “(H) DISCLOSURE.—

5                   “(i) IN GENERAL.—Each entity that  
6           offers coverage of the type described in  
7           clause (ii) (iii), (iv), or (v) of subparagraph  
8           (F) shall provide for disclosure, consistent  
9           with standards established by the Adminis-  
10          trator, of whether the coverage provides  
11          coverage of the cost of prescription drugs  
12          the actuarial value of which (as defined by  
13          the Administrator) to the beneficiary  
14          equals or exceeds the actuarial value of  
15          standard prescription drug coverage (as  
16          determined under section 1860D–6(f)).

17                   “(ii) WAIVER OF LIMITATIONS.—An  
18          individual may apply to the Administrator  
19          to waive the application of subparagraph  
20          (G) if the individual establishes that the  
21          individual was not adequately informed  
22          that the coverage the beneficiary was en-  
23          rolled in did not provide the level of bene-  
24          fits required in order for the coverage to be

1           considered creditable coverage under sub-  
2           paragraph (F).

3           “(2) INITIAL ELECTION PERIODS.—

4           “(A) OPEN ENROLLMENT PERIOD FOR  
5           CURRENT BENEFICIARIES IN WHICH LATE EN-  
6           ROLLMENT PROCEDURES DO NOT APPLY.—In  
7           the case of an individual who is an eligible ben-  
8           eficiary as of November 1, 2005, there shall be  
9           an open enrollment period of 6 months begin-  
10          ning on that date under which such beneficiary  
11          may enroll under this part without the applica-  
12          tion of the late enrollment procedures estab-  
13          lished under paragraph (1)(A).

14          “(B) INDIVIDUAL COVERED IN FUTURE.—

15          In the case of an individual who becomes an eli-  
16          gible beneficiary after such date, there shall be  
17          an initial election period which is the same as  
18          the initial enrollment period under section  
19          1837(d).

20          “(3) SPECIAL ENROLLMENT PERIOD FOR BENE-  
21          FICIARIES WHO INVOLUNTARILY LOSE CREDITABLE  
22          PRESCRIPTION DRUG COVERAGE.—

23          “(A) ESTABLISHMENT.—The Adminis-  
24          trator shall establish a special open enrollment  
25          period (as described in subparagraph (B)) for

1 an eligible beneficiary that loses creditable pre-  
2 scription drug coverage.

3 “(B) SPECIAL OPEN ENROLLMENT PE-  
4 RIOD.—The special open enrollment period de-  
5 scribed in this subparagraph is the 63-day pe-  
6 riod that begins on—

7 “(i) in the case of a beneficiary with  
8 coverage described in clause (ii) of para-  
9 graph (1)(F), the later of the date on  
10 which the plan terminates, ceases to pro-  
11 vide, or substantially reduces (as defined  
12 by the Administrator) the value of the pre-  
13 scription drug coverage under such plan or  
14 the date the beneficiary is provided with  
15 notice of such termination or reduction;

16 “(ii) in the case of a beneficiary with  
17 coverage described in clause (i), (iii), or  
18 (iv) of paragraph (1)(F), the later of the  
19 date on which the beneficiary is involun-  
20 tarily disenrolled or becomes ineligible for  
21 such coverage or the date the beneficiary is  
22 provided with notice of such loss of eligi-  
23 bility; or

24 “(iii) in the case of a beneficiary with  
25 coverage described in clause (v) of para-

1 graph (1)(F), the latter of the date on  
2 which the issuer of the policy terminates  
3 coverage under the policy or the date the  
4 beneficiary is provided with notice of such  
5 termination.

6 “(c) PERIOD OF COVERAGE.—

7 “(1) IN GENERAL.—Except as provided in para-  
8 graph (2) and subject to paragraph (3), an eligible  
9 beneficiary’s coverage under the program under this  
10 part shall be effective for the period provided in sec-  
11 tion 1838, as if that section applied to the program  
12 under this part.

13 “(2) OPEN AND SPECIAL ENROLLMENT.—

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

19 “(B) SPECIAL ENROLLMENT.—Subject to  
20 paragraph (3), an eligible beneficiary who en-  
21 rolls under the program under this part pursu-  
22 ant to subsection (b)(3) shall be entitled to the  
23 benefits under this part beginning on the first  
24 day of the month following the month in which  
25 such enrollment occurs.

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

3           “(d) TERMINATION.—

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

7           “(2) COVERAGE TERMINATED BY TERMINATION  
8 OF COVERAGE UNDER PART A OR B.—

9           “(A) IN GENERAL.—In addition to the  
10 causes of termination specified in paragraph  
11 (1), the Administrator shall terminate an indi-  
12 vidual’s coverage under this part if the indi-  
13 vidual is no longer enrolled in both parts A and  
14 B.

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

19           “(3) PROCEDURES REGARDING TERMINATION  
20 OF A BENEFICIARY UNDER A PLAN.—The Adminis-  
21 trator shall establish procedures for determining the  
22 status of an eligible beneficiary’s enrollment under  
23 this part if the beneficiary’s enrollment in a Medi-  
24 care Prescription Drug plan offered by an eligible  
25 entity under this part is terminated by the entity for

1       cause (pursuant to procedures established by the  
2       Administrator under section 1860D–3(a)(1)).

3       “ELECTION OF A MEDICARE PRESCRIPTION DRUG PLAN

4       “SEC. 1860D–3. (a) IN GENERAL.—

5               “(1) PROCESS.—

6                       “(A) ELECTION.—

7                               “(i) IN GENERAL.—The Administrator  
8                               shall establish a process through which an  
9                               eligible beneficiary who is enrolled under  
10                              this part but not enrolled in a  
11                              MedicareAdvantage plan (except for an  
12                              MSA plan or a private fee-for-service plan  
13                              that does not provide qualified prescription  
14                              drug coverage) offered by a  
15                              MedicareAdvantage organization—

16                                       “(I) shall make an election to en-  
17                                       roll in any Medicare Prescription  
18                                       Drug plan that is offered by an eligi-  
19                                       ble entity and that serves the geo-  
20                                       graphic area in which the beneficiary  
21                                       resides; and

22                                       “(II) may make an annual elec-  
23                                       tion to change the election under this  
24                                       clause.

25                                       “(ii) CLARIFICATION REGARDING EN-  
26                                       ROLLMENT.—The process established

1 under clause (i) shall include, in the case  
2 of an eligible beneficiary who is enrolled  
3 under this part but who has failed to make  
4 an election of a Medicare Prescription  
5 Drug plan in an area, for the enrollment  
6 in any Medicare Prescription Drug plan  
7 that has been designated by the Adminis-  
8 trator in the area. The Administrator shall  
9 establish a process for designating a plan  
10 or plans in order to carry out the pre-  
11 ceding sentence.

12 “(B) REQUIREMENTS FOR PROCESS.—In  
13 establishing the process under subparagraph  
14 (A), the Administrator shall—

15 “(i) use rules similar to the rules for  
16 enrollment, disenrollment, and termination  
17 of enrollment with a Medicare Advantage  
18 plan under section 1851, including—

19 “(I) the establishment of special  
20 election periods under subsection  
21 (e)(4) of such section; and

22 “(II) the application of the guar-  
23 anteed issue and renewal provisions of  
24 section 1851(g) (other than clause (i)  
25 and the second sentence of clause (ii)

1 of paragraph (3)(C), relating to de-  
2 fault enrollment); and

3 “(ii) coordinate enrollments,  
4 disenrollments, and terminations of enroll-  
5 ment under part C with enrollments,  
6 disenrollments, and terminations of enroll-  
7 ment under this part.

8 “(2) FIRST ENROLLMENT PERIOD FOR PLAN  
9 ENROLLMENT.—The process developed under para-  
10 graph (1) shall ensure that eligible beneficiaries who  
11 enroll under this part during the open enrollment  
12 period under section 1860D–2(b)(2) are permitted  
13 to elect an eligible entity prior to January 1, 2006,  
14 in order to ensure that coverage under this part is  
15 effective as of such date.

16 “(b) ENROLLMENT IN A MEDICAREADVANTAGE  
17 PLAN.—

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

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

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

13           “PROVIDING INFORMATION TO BENEFICIARIES

14           “SEC. 1860D–4. (a) ACTIVITIES.—

15           “(1) IN GENERAL.—The Administrator shall  
16           conduct activities that are designed to broadly dis-  
17           seminate information to eligible beneficiaries (and  
18           prospective eligible beneficiaries) regarding the cov-  
19           erage provided under this part.

20           “(2) SPECIAL RULE FOR FIRST ENROLLMENT  
21           UNDER THE PROGRAM.—The activities described in  
22           paragraph (1) shall ensure that eligible beneficiaries  
23           are provided with such information at least 30 days  
24           prior to the first enrollment period described in sec-  
25           tion 1860D–3(a)(2).

26           “(b) REQUIREMENTS.—

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

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

5           “(B) be coordinated with the activities per-  
6 formed by—

7           “(i) the Administrator under such sec-  
8 tion; and

9           “(ii) the Secretary under section  
10 1804; and

11           “(C) provide for the dissemination of infor-  
12 mation comparing the plans offered by eligible  
13 entities under this part that are available to eli-  
14 gible beneficiaries residing in an area.

15           “(2) COMPARATIVE INFORMATION.—The com-  
16 parative information described in paragraph (1)(C)  
17 shall include a comparison of the following:

18           “(A) BENEFITS.—The benefits provided  
19 under the plan and the formularies and griev-  
20 ance and appeals processes under the plan.

21           “(B) MONTHLY BENEFICIARY OBLIGA-  
22 TION.—The monthly beneficiary obligation  
23 under the plan.

1           “(C) QUALITY AND PERFORMANCE.—The  
2           quality and performance of the eligible entity  
3           offering the plan.

4           “(D) BENEFICIARY COST-SHARING.—The  
5           cost-sharing required of eligible beneficiaries  
6           under the plan.

7           “(E) CONSUMER SATISFACTION SUR-  
8           VEYS.—The results of consumer satisfaction  
9           surveys regarding the plan and the eligible enti-  
10          ty offering such plan (conducted pursuant to  
11          section 1860D–5(h).

12          “(F) ADDITIONAL INFORMATION.—Such  
13          additional information as the Administrator  
14          may prescribe.

15          “BENEFICIARY PROTECTIONS

16          “SEC. 1860D–5. (a) DISSEMINATION OF INFORMA-  
17          TION.—

18               “(1) GENERAL INFORMATION.—An eligible enti-  
19               ty offering a Medicare Prescription Drug plan shall  
20               disclose, in a clear, accurate, and standardized form  
21               to each enrollee at the time of enrollment, and at  
22               least annually thereafter, the information described  
23               in section 1852(c)(1) relating to such plan. Such in-  
24               formation includes the following:

25                       “(A) Access to covered drugs, including ac-  
26                       cess through pharmacy networks.

1           “(B) How any formulary used by the enti-  
2           ty functions.

3           “(C) Copayments, coinsurance, and de-  
4           ductible requirements.

5           “(D) Grievance and appeals processes.

6           The information described in the preceding sentence  
7           shall also be made available on request to prospec-  
8           tive enrollees during open enrollment periods.

9           “(2) DISCLOSURE UPON REQUEST OF GENERAL  
10          COVERAGE, UTILIZATION, AND GRIEVANCE INFORMA-  
11          TION.—Upon request of an individual eligible to en-  
12          roll in a Medicare Prescription Drug plan, the eligi-  
13          ble entity offering such plan shall provide informa-  
14          tion similar (as determined by the Administrator) to  
15          the information described in subparagraphs (A),  
16          (B), and (C) of section 1852(c)(2) to such indi-  
17          vidual.

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

24          “(4) CLAIMS INFORMATION.—An eligible entity  
25          offering a Medicare Prescription Drug plan must

1 furnish to enrolled individuals in a form easily un-  
2 derstandable to such individuals—

3 “(A) an explanation of benefits (in accord-  
4 ance with section 1806(a) or in a comparable  
5 manner); and

6 “(B) when prescription drug benefits are  
7 provided under this part, a notice of the bene-  
8 fits in relation to the initial coverage limit and  
9 annual out-of-pocket limit for the current year  
10 (except that such notice need not be provided  
11 more often than monthly).

12 “(5) APPROVAL OF MARKETING MATERIAL AND  
13 APPLICATION FORMS.—The provisions of section  
14 1851(h) shall apply to marketing material and appli-  
15 cation forms under this part in the same manner as  
16 such provisions apply to marketing material and ap-  
17 plication forms under part C.

18 “(b) ACCESS TO COVERED DRUGS.—

19 “(1) ACCESS TO NEGOTIATED PRICES FOR PRE-  
20 SCRIPTON DRUGS.—An eligible entity offering a  
21 Medicare Prescription Drug plan shall have in place  
22 procedures to ensure that beneficiaries are not  
23 charged more than the negotiated price of a covered  
24 drug. Such procedures shall include the issuance of  
25 a card (or other technology) that may be used by an

1 enrolled beneficiary for the purchase of prescription  
2 drugs for which coverage is not otherwise provided  
3 under the Medicare Prescription Drug plan.

4 “(2) ASSURING PHARMACY ACCESS.—

5 “(A) IN GENERAL.—An eligible entity of-  
6 fering a Medicare Prescription Drug plan shall  
7 secure the participation in its network of a suf-  
8 ficient number of pharmacies that dispense  
9 (other than by mail order) drugs directly to pa-  
10 tients to ensure convenient access (as deter-  
11 mined by the Administrator and including ade-  
12 quate emergency access) for enrolled bene-  
13 ficiaries, in accordance with standards estab-  
14 lished by the Administrator under section  
15 1860D–7(g) that ensure such convenient ac-  
16 cess. Such standards shall take into account  
17 reasonable distances to pharmacy services in  
18 both urban and rural areas.

19 “(B) USE OF POINT-OF-SERVICE SYS-  
20 TEM.—An eligible entity offering a Medicare  
21 Prescription Drug plan shall establish an op-  
22 tional point-of-service method of operation  
23 under which—

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

4           “(ii) the plan may charge beneficiaries  
5           through adjustments in copayments any  
6           additional costs associated with the point-  
7           of-service option.

8           The additional copayments so charged shall not  
9           count toward the application of section 1860D-  
10          6(e).

11          “(3) REQUIREMENTS ON DEVELOPMENT AND  
12          APPLICATION OF FORMULARIES.—If an eligible enti-  
13          ty offering a Medicare Prescription Drug plan uses  
14          a formulary, the following requirements must be  
15          met:

16                 “(A) PHARMACY AND THERAPEUTIC (P&T)  
17          COMMITTEE.—

18                 “(i) IN GENERAL.—The eligible entity  
19                 must establish a pharmacy and therapeutic  
20                 committee that develops and reviews the  
21                 formulary.

22                 “(ii) COMPOSITION.—A pharmacy and  
23                 therapeutic committee shall include at least  
24                 1 academic expert, at least 1 practicing  
25                 physician, and at least 1 practicing phar-

1           macist, all of whom have expertise in the  
2           care of elderly or disabled persons, and a  
3           majority of the members of such committee  
4           shall consist of individuals who are a prac-  
5           ticing physician or a practicing pharmacist  
6           (or both).

7           “(B) FORMULARY DEVELOPMENT.—In de-  
8           veloping and reviewing the formulary, the com-  
9           mittee shall base clinical decisions on the  
10          strength of scientific evidence and standards of  
11          practice, including assessing peer-reviewed med-  
12          ical literature, such as randomized clinical  
13          trials, pharmacoeconomic studies, outcomes re-  
14          search data, and on such other information as  
15          the committee determines to be appropriate.

16          “(C) INCLUSION OF DRUGS IN ALL THERA-  
17          PEUTIC CATEGORIES AND CLASSES.—

18                 “(i) IN GENERAL.—The formulary  
19                 must include drugs within each therapeutic  
20                 category and class of covered drugs (as de-  
21                 fined by the Administrator), although not  
22                 necessarily for all drugs within such cat-  
23                 egories and classes.

24                 “(ii) REQUIREMENT.—In defining  
25                 therapeutic categories and classes of cov-

1           ered drugs pursuant to clause (i), the Ad-  
2           ministrator shall use—

3                   “(I) the compendia referred to  
4                   section 1927(g)(1)(B)(i); and

5                   “(II) other recognized sources of  
6                   drug classifications and categoriza-  
7                   tions determined appropriate by the  
8                   Administrator.

9                   “(D) PROVIDER EDUCATION.—The com-  
10                  mittee shall establish policies and procedures to  
11                  educate and inform health care providers con-  
12                  cerning the formulary.

13                  “(E) NOTICE BEFORE REMOVING DRUGS  
14                  FROM FORMULARY.—Any removal of a drug  
15                  from a formulary shall take effect only after ap-  
16                  propriate notice is made available to bene-  
17                  ficiaries, physicians, and pharmacists.

18                  “(F) APPEALS AND EXCEPTIONS TO APPLI-  
19                  CATION.—The eligible entity must have, as part  
20                  of the appeals process under subsection (e), a  
21                  process for timely appeals for denials of cov-  
22                  erage based on such application of the for-  
23                  mulary.

1       “(c) COST AND UTILIZATION MANAGEMENT; QUAL-  
2   ITY ASSURANCE; MEDICATION THERAPY MANAGEMENT  
3   PROGRAM.—

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

6                       “(A) A cost-effective drug utilization man-  
7                       agement program, including incentives to re-  
8                       duce costs when appropriate.

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

12                               “(i) shall include a medication therapy  
13                               management program described in para-  
14                               graph (2); and

15                               “(ii) may include beneficiary edu-  
16                               cation programs, counseling, medication  
17                               refill reminders, and special packaging.

18                       “(C) A program to control fraud, abuse,  
19                      and waste.

20       Nothing in this section shall be construed as impair-  
21       ing an eligible entity from applying cost manage-  
22       ment tools (including differential payments) under  
23       all methods of operation.

24               “(2) MEDICATION THERAPY MANAGEMENT PRO-  
25       GRAM.—

1           “(A) IN GENERAL.—A medication therapy  
2 management program described in this para-  
3 graph is a program of drug therapy manage-  
4 ment and medication administration that is de-  
5 signed to assure, with respect to beneficiaries  
6 with chronic diseases (such as diabetes, asthma,  
7 hypertension, hyperlipidemia, and congestive  
8 heart failure) or multiple prescriptions, that  
9 covered drugs under the Medicare Prescription  
10 Drug plan are appropriately used to optimize  
11 therapeutic outcomes through improved medica-  
12 tion use and to achieve therapeutic goals and  
13 reduce the risk of adverse events, including ad-  
14 verse drug interactions.

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

17           “(i) enhanced beneficiary under-  
18 standing of such appropriate use through  
19 beneficiary education, counseling, and  
20 other appropriate means;

21           “(ii) increased beneficiary adherence  
22 with prescription medication regimens  
23 through medication refill reminders, special  
24 packaging, and other appropriate means;  
25 and

1                   “(iii) detection of patterns of overuse  
2                   and underuse of prescription drugs.

3                   “(C) DEVELOPMENT OF PROGRAM IN CO-  
4                   OPERATION WITH LICENSED PHARMACISTS.—  
5                   The program shall be developed in cooperation  
6                   with licensed and practicing pharmacists and  
7                   physicians.

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

15                  “(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL  
16                  PRICES FOR EQUIVALENT DRUGS.—The eligible enti-  
17                  ty offering a Medicare Prescription Drug plan shall  
18                  provide that each pharmacy or other dispenser that  
19                  arranges for the dispensing of a covered drug shall  
20                  inform the beneficiary at the time of purchase of the  
21                  drug of any differential between the price of the pre-  
22                  scribed drug to the enrollee and the price of the low-  
23                  est cost generic drug covered under the plan that is  
24                  therapeutically equivalent and bioequivalent.

1       “(d) GRIEVANCE MECHANISM, COVERAGE DETER-  
2 MINATIONS, AND RECONSIDERATIONS.—

3           “(1) IN GENERAL.—An eligible entity shall pro-  
4 vide meaningful procedures for hearing and resolving  
5 grievances between the eligible entity (including any  
6 entity or individual through which the eligible entity  
7 provides covered benefits) and enrollees with Medi-  
8 care Prescription Drug plans of the eligible entity  
9 under this part in accordance with section 1852(f).

10          “(2) APPLICATION OF COVERAGE DETERMINA-  
11 TION AND RECONSIDERATION PROVISIONS.—The re-  
12 quirements of paragraphs (1) through (3) of section  
13 1852(g) shall apply to an eligible entity with respect  
14 to covered benefits under the Medicare Prescription  
15 Drug plan it offers under this part in the same man-  
16 ner as such requirements apply to a  
17 MedicareAdvantage organization with respect to ben-  
18 efits it offers under a MedicareAdvantage plan  
19 under part C.

20          “(3) REQUEST FOR REVIEW OF TIERED FOR-  
21 MULARY DETERMINATIONS.—In the case of a Medi-  
22 care Prescription Drug plan offered by an eligible  
23 entity that provides for tiered cost-sharing for drugs  
24 included within a formulary and provides lower cost-  
25 sharing for preferred drugs included within the for-

1       mulary, an individual who is enrolled in the plan  
2       may request coverage of a nonpreferred drug under  
3       the terms applicable for preferred drugs if the pre-  
4       scribing physician determines that the preferred  
5       drug for treatment of the same condition is not as  
6       effective for the individual or has adverse effects for  
7       the individual.

8       “(e) APPEALS.—

9               “(1) IN GENERAL.—Subject to paragraph (2),  
10       the requirements of paragraphs (4) and (5) of sec-  
11       tion 1852(g) shall apply to an eligible entity with re-  
12       spect to drugs not included on any formulary in a  
13       manner that is similar (as determined by the Admin-  
14       istrator) to the manner that such requirements  
15       apply to a MedicareAdvantage organization with re-  
16       spect to benefits it offers under a  
17       MedicareAdvantage plan under part C.

18               “(2) FORMULARY DETERMINATIONS.—An indi-  
19       vidual who is enrolled in a Medicare Prescription  
20       Drug plan offered by an eligible entity may appeal  
21       to obtain coverage for a covered drug that is not on  
22       a formulary of the entity under the terms applicable  
23       for a formulary drug if the prescribing physician de-  
24       termines that the formulary drug for treatment of

1 the same condition is not as effective for the indi-  
2 vidual or has adverse effects for the individual.

3 “(f) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF  
4 ENROLLEE RECORDS.—Insofar as an eligible entity main-  
5 tains individually identifiable medical records or other  
6 health information regarding eligible beneficiaries enrolled  
7 in the Medicare Prescription Drug plan offered by the en-  
8 tity, the entity shall have in place procedures to—

9 “(1) safeguard the privacy of any individually  
10 identifiable beneficiary information in a manner con-  
11 sistent with the Federal regulations (concerning the  
12 privacy of individually identifiable health informa-  
13 tion) promulgated under section 264(c) of the  
14 Health Insurance Portability and Accountability Act  
15 of 1996;

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

18 “(3) ensure timely access by such beneficiaries  
19 to such records and information; and

20 “(4) otherwise comply with applicable laws re-  
21 lating to patient privacy and confidentiality.

22 “(g) UNIFORM MONTHLY PLAN PREMIUM.—An eligi-  
23 ble entity shall ensure that the monthly plan premium for  
24 a Medicare Prescription Drug plan charged under this

1 part is the same for all eligible beneficiaries enrolled in  
2 the plan.

3 “(h) CONSUMER SATISFACTION SURVEYS.—An eligi-  
4 ble entity shall conduct consumer satisfaction surveys with  
5 respect to the plan and the entity. The Administrator shall  
6 establish uniform requirements for such surveys.

7 “PRESCRIPTION DRUG BENEFITS

8 “SEC. 1860D–6. (a) REQUIREMENTS.—

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

12 “(A) STANDARD PRESCRIPTION DRUG COV-  
13 ERAGE WITH ACCESS TO NEGOTIATED  
14 PRICES.—Standard prescription drug coverage  
15 (as defined in subsection (c)) and access to ne-  
16 gotiated prices under subsection (e).

17 “(B) ACTUARIALLY EQUIVALENT PRE-  
18 SCRIPTON DRUG COVERAGE WITH ACCESS TO  
19 NEGOTIATED PRICES.—Coverage of covered  
20 drugs which meets the alternative coverage re-  
21 quirements of subsection (d) and access to ne-  
22 gotiated prices under subsection (e), but only if  
23 it is approved by the Administrator as provided  
24 under subsection (d).

25 “(2) PERMITTING ADDITIONAL PRESCRIPTION  
26 DRUG COVERAGE.—

1           “(A) IN GENERAL.—Subject to subpara-  
2 graph (B) and section 1860D–13(c)(2), nothing  
3 in this part shall be construed as preventing  
4 qualified prescription drug coverage from in-  
5 cluding coverage of covered drugs that exceeds  
6 the coverage required under paragraph (1).

7           “(B) REQUIREMENT.—An eligible entity  
8 may not offer a Medicare Prescription Drug  
9 plan that provides additional benefits pursuant  
10 to subparagraph (A) in an area unless the eligi-  
11 ble entity offering such plan also offers a Medi-  
12 care Prescription Drug plan in the area that  
13 only provides the coverage of prescription drugs  
14 that is required under paragraph (1).

15           “(3) COST CONTROL MECHANISMS.—In pro-  
16 viding qualified prescription drug coverage, the enti-  
17 ty offering the Medicare Prescription Drug plan or  
18 the MedicareAdvantage plan may use a variety of  
19 cost control mechanisms, including the use of  
20 formularies, tiered copayments, selective contracting  
21 with providers of prescription drugs, and mail order  
22 pharmacies.

23           “(b) APPLICATION OF SECONDARY PAYOR PROVI-  
24 SIONS.—The provisions of section 1852(a)(4) shall apply

1 under this part in the same manner as they apply under  
2 part C.

3 “(c) STANDARD PRESCRIPTION DRUG COVERAGE.—  
4 For purposes of this part and part C, the term ‘standard  
5 prescription drug coverage’ means coverage of covered  
6 drugs that meets the following requirements:

7 “(1) DEDUCTIBLE.—

8 “(A) IN GENERAL.—The coverage has an  
9 annual deductible—

10 “(i) for 2006, that is equal to \$275;

11 or

12 “(ii) for a subsequent year, that is  
13 equal to the amount specified under this  
14 paragraph for the previous year increased  
15 by the percentage specified in paragraph  
16 (5) for the year involved.

17 “(B) ROUNDING.—Any amount determined  
18 under subparagraph (A)(ii) that is not a mul-  
19 tiple of \$1 shall be rounded to the nearest mul-  
20 tiple of \$1.

21 “(2) LIMITS ON COST-SHARING.—The coverage  
22 has cost-sharing (for costs above the annual deduct-  
23 ible specified in paragraph (1) and up to the initial  
24 coverage limit under paragraph (3)) that is equal to  
25 50 percent or that is actuarially consistent (using

1 processes established under subsection (f)) with an  
2 average expected payment of 50 percent of such  
3 costs.

4 “(3) INITIAL COVERAGE LIMIT.—

5 “(A) IN GENERAL.—Subject to paragraph  
6 (4), the coverage has an initial coverage limit  
7 on the maximum costs that may be recognized  
8 for payment purposes (including the annual de-  
9 ductible)—

10 “(i) for 2006, that is equal to \$4,500;

11 or

12 “(ii) for a subsequent year, that is  
13 equal to the amount specified in this para-  
14 graph for the previous year, increased by  
15 the annual percentage increase described  
16 in paragraph (5) for the year involved.

17 “(B) ROUNDING.—Any amount determined  
18 under subparagraph (A)(ii) that is not a mul-  
19 tiple of \$1 shall be rounded to the nearest mul-  
20 tiple of \$1.

21 “(4) LIMITATION ON OUT-OF-POCKET EXPENDI-  
22 TURES BY BENEFICIARY.—

23 “(A) IN GENERAL.—The coverage provides  
24 benefits with cost-sharing that is equal to 15  
25 percent after the individual has incurred costs

1 (as described in subparagraph (C)) for covered  
2 drugs in a year equal to the annual out-of-pock-  
3 et limit specified in subparagraph (B).

4 “(B) ANNUAL OUT-OF-POCKET LIMIT.—

5 “(i) IN GENERAL.—For purposes of  
6 this part, the ‘annual out-of-pocket limit’  
7 specified in this subparagraph—

8 “(I) for 2006, is equal to \$3,700;

9 or

10 “(II) for a subsequent year, is  
11 equal to the amount specified in this  
12 subparagraph for the previous year,  
13 increased by the annual percentage in-  
14 crease described in paragraph (5) for  
15 the year involved.

16 “(ii) ROUNDING.—Any amount deter-  
17 mined under clause (i)(II) that is not a  
18 multiple of \$1 shall be rounded to the  
19 nearest multiple of \$1.

20 “(C) APPLICATION.—In applying subpara-  
21 graph (A)—

22 “(i) incurred costs shall only include  
23 costs incurred, with respect to covered  
24 drugs, for the annual deductible (described  
25 in paragraph (1)), cost-sharing (described

1 in paragraph (2)), and amounts for which  
2 benefits are not provided because of the  
3 application of the initial coverage limit de-  
4 scribed in paragraph (3) (including costs  
5 incurred for covered drugs described in  
6 section 1860D(a)(2)(C)); and

7 “(ii) such costs shall be treated as in-  
8 curred without regard to whether the indi-  
9 vidual or another person, including a State  
10 program or other third-party coverage, has  
11 paid for such costs, except that only the  
12 applicable percent (specified in subpara-  
13 graph (D)) of the amount of portion of  
14 such costs that are paid or reimbursed  
15 through insurance, a group health plan, or  
16 other third-party payment arrangement for  
17 such costs shall not be counted.

18 “(D) APPLICABLE PERCENT DEFINED.—

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

23 “(I) for years before 2010, 25  
24 percent;

1                   “(II) for 2011, 2012, 2013,  
2                   2014, and 2015, 50 percent; and

3                   “(III) for any year thereafter,  
4                   100 percent.

5                   “(ii) SECRETARIAL LIMITATION ON  
6                   TOTAL EXPENDITURES.—The Secretary, in  
7                   consultation with the Office of Manage-  
8                   ment and Budget, shall estimate at the  
9                   time of enactment of this part, the aggre-  
10                  gate budget outlays that will result during  
11                  the 10-fiscal-year period beginning with  
12                  fiscal year 2004 from the enactment of the  
13                  Prescription Drug and Medicare Improve-  
14                  ment Act of 2003. If such estimate exceeds  
15                  \$400,000,000,000, the Secretary shall pro-  
16                  vide for such proportional reductions in the  
17                  percentages specified in clause (i) as the  
18                  Secretary determines to be necessary to as-  
19                  sure that such aggregate budget outlays  
20                  during such period do not exceed such  
21                  amount.

22                  “(E) INFORMATION REGARDING THIRD-  
23                  PARTY REIMBURSEMENT.—In order to ensure  
24                  compliance with the requirements of subpara-  
25                  graph (C)(ii), the Administrator is authorized

1 to establish procedures, in coordination with the  
2 Secretary of Treasury and the Secretary of  
3 Labor, for determining whether costs for indi-  
4 viduals are being reimbursed through insurance  
5 or otherwise, a group health plan, or other  
6 third-party payment arrangement, and for  
7 alerting the entities in which such individuals  
8 are enrolled about such reimbursement arrange-  
9 ments. An entity with a contract under this  
10 part may also periodically ask individuals en-  
11 rolled in a plan offered by the entity whether  
12 the individuals have or expect to receive such  
13 third-party reimbursement. A material mis-  
14 representation of the information described in  
15 the preceding sentence by an individual (as de-  
16 fined in standards set by the Administrator and  
17 determined through a process established by the  
18 Administrator) shall constitute grounds for ter-  
19 mination of enrollment under section 1860D-  
20 2(d).

21 “(5) ANNUAL PERCENTAGE INCREASE.—For  
22 purposes of this part, the annual percentage increase  
23 specified in this paragraph for a year is equal to the  
24 annual percentage increase in average per capita ag-  
25 gregate expenditures for covered drugs in the United

1 States for beneficiaries under this title, as deter-  
2 mined by the Administrator for the 12-month period  
3 ending in July of the previous year.

4 “(d) ALTERNATIVE COVERAGE REQUIREMENTS.—A  
5 Medicare Prescription Drug plan or Medicare Advantage  
6 plan may provide a different prescription drug benefit de-  
7 sign from the standard prescription drug coverage de-  
8 scribed in subsection (c) so long as the Administrator de-  
9 termines (based on an actuarial analysis by the Adminis-  
10 trator) that the following requirements are met and the  
11 plan applies for, and receives, the approval of the Adminis-  
12 trator for such benefit design:

13 “(1) ASSURING AT LEAST ACTUARIALLY EQUIV-  
14 ALENT PRESCRIPTION DRUG COVERAGE.—

15 “(A) ASSURING EQUIVALENT VALUE OF  
16 TOTAL COVERAGE.—The actuarial value of the  
17 total coverage (as determined under subsection  
18 (f)) is at least equal to the actuarial value (as  
19 so determined) of standard prescription drug  
20 coverage.

21 “(B) ASSURING EQUIVALENT UNSUB-  
22 SIDIZED VALUE OF COVERAGE.—The unsub-  
23 sidized value of the coverage is at least equal to  
24 the unsubsidized value of standard prescription  
25 drug coverage. For purposes of this subpara-

1 graph, the unsubsidized value of coverage is the  
2 amount by which the actuarial value of the cov-  
3 erage (as determined under subsection (f)) ex-  
4 ceeds the actuarial value of the amounts associ-  
5 ated with the application of section 1860D-  
6 17(c) and reinsurance payments under section  
7 1860D-20 with respect to such coverage.

8 “(C) ASSURING STANDARD PAYMENT FOR  
9 COSTS AT INITIAL COVERAGE LIMIT.—The cov-  
10 erage is designed, based upon an actuarially  
11 representative pattern of utilization (as deter-  
12 mined under subsection (f)), to provide for the  
13 payment, with respect to costs incurred that are  
14 equal to the initial coverage limit under sub-  
15 section (c)(3), of an amount equal to at least  
16 the product of—

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

19 “(ii) the percentage specified in sub-  
20 section (c)(2).

21 Benefits other than qualified prescription drug cov-  
22 erage shall not be taken into account for purposes  
23 of this paragraph.

24 “(2) DEDUCTIBLE AND LIMITATION ON OUT-  
25 OF-POCKET EXPENDITURES BY BENEFICIARIES MAY

1 NOT VARY.—The coverage may not vary the deduct-  
2 ible under subsection (c)(1) for the year or the limi-  
3 tation on out-of-pocket expenditures by beneficiaries  
4 described in subsection (c)(4) for the year.

5 “(e) ACCESS TO NEGOTIATED PRICES.—

6 “(1) ACCESS.—

7 “(A) IN GENERAL.—Under qualified pre-  
8 scription drug coverage offered by an eligible  
9 entity or a MedicareAdvantage organization,  
10 the entity or organization shall provide bene-  
11 ficiaries with access to negotiated prices used  
12 for payment for covered drugs, regardless of the  
13 fact that no benefits may be payable under the  
14 coverage with respect to such drugs because of  
15 the application of the deductible, any cost-shar-  
16 ing, or an initial coverage limit (described in  
17 subsection (c)(3)). For purposes of this part,  
18 the term ‘negotiated prices’ includes all dis-  
19 counts, direct or indirect subsidies, rebates, or  
20 other price concessions or direct or indirect re-  
21 munerations and shall reflect prices that are no  
22 higher than the prices negotiated by the Sec-  
23 retary under subparagraph (B).

24 “(B) SECRETARIAL NEGOTIATED PRICE.—

25 Notwithstanding any other provision of this

1 part, the Secretary shall, consistent with the re-  
2 quirements of this part and the goals of pro-  
3 viding quality care and containing costs under  
4 this part, negotiate contracts with manufactur-  
5 ers of covered outpatient prescription drugs  
6 that provide for the maximum prices that may  
7 be charged to individuals enrolled under this  
8 part by participating pharmacies for dispensing  
9 such drugs to such individuals.

10 “(C) MEDICAID RELATED PROVISIONS.—

11 Insofar as a State elects to provide medical as-  
12 sistance under title XIX for a drug based on  
13 the prices negotiated under a Medicare Pre-  
14 scription Drug plan under this part, the re-  
15 quirements of section 1927 shall not apply to  
16 such drugs. The prices negotiated under a  
17 Medicare Prescription Drug plan with respect  
18 to covered drugs, under a Medicare Advantage  
19 plan with respect to such drugs, or under a  
20 qualified retiree prescription drug plan (as de-  
21 fined in section 1860D–20(e)(4)) with respect  
22 to such drugs, on behalf of eligible beneficiaries,  
23 shall (notwithstanding any other provision of  
24 law) not be taken into account for the purposes

1 of establishing the best price under section  
2 1927(c)(1)(C).

3 “(2) CARDS OR OTHER TECHNOLOGY.—

4 “(A) IN GENERAL.—In providing the ac-  
5 cess under paragraph (1), the eligible entity or  
6 MedicareAdvantage organization shall issue a  
7 card or use other technology pursuant to sec-  
8 tion 1860D–5(b)(1).

9 “(B) NATIONAL STANDARDS.—

10 “(i) DEVELOPMENT.—The Adminis-  
11 trator shall provide for the development of  
12 national standards relating to a standard-  
13 ized format for the card or other tech-  
14 nology required under subparagraph (A).  
15 Such standards shall be compatible with  
16 parts C and D of title XI and may be  
17 based on standards developed by an appro-  
18 priate standard setting organization.

19 “(ii) CONSULTATION.—In developing  
20 the standards under clause (i), the Admin-  
21 istrator shall consult with the National  
22 Council for Prescription Drug Programs  
23 and other standard-setting organizations  
24 determined appropriate by the Adminis-  
25 trator.

1                   “(iii) IMPLEMENTATION.—The Ad-  
2                   ministrators shall implement the standards  
3                   developed under clause (i) by January 1,  
4                   2008.

5                   “(3) DISCLOSURE.—The eligible entity offering  
6                   a Medicare Prescription Drug plan and the  
7                   Medicare Advantage organization offering a  
8                   Medicare Advantage plan shall disclose to the Admin-  
9                   istrator (in a manner specified by the Administrator)  
10                  the extent to which discounts, direct or indirect sub-  
11                  sidies, rebates, or other price concessions or direct or  
12                  indirect remunerations made available to the entity  
13                  or organization by a manufacturer are passed  
14                  through to enrollees through pharmacies and other  
15                  dispensers or otherwise. The provisions of section  
16                  1927(b)(3)(D) shall apply to information disclosed  
17                  to the Administrator under this paragraph in the  
18                  same manner as such provisions apply to informa-  
19                  tion disclosed under such section.

20                  “(4) AUDITS AND REPORTS.—To protect  
21                  against fraud and abuse and to ensure proper disclo-  
22                  sures and accounting under this part, in addition to  
23                  any protections against fraud and abuse provided  
24                  under section 1860D-7(f)(1), the Administrator may  
25                  periodically audit the financial statements and

1 records of an eligible entity offering a Medicare Pre-  
2 scription Drug plan and a MedicareAdvantage orga-  
3 nization offering a MedicareAdvantage plan.

4 “(f) ACTUARIAL VALUATION; DETERMINATION OF  
5 ANNUAL PERCENTAGE INCREASES.—

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

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

11 “(i) an actuarial valuation of standard  
12 prescription drug coverage and of the rein-  
13 surance payments under section 1860D-  
14 20;

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

17 “(iii) applying the same methodology  
18 for determinations of alternative coverage  
19 under subsection (d) as is used with re-  
20 spect to determinations of standard pre-  
21 scription drug coverage under subsection  
22 (c); and

23 “(B) for determining annual percentage in-  
24 creases described in subsection (c)(5).

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

5 “(2) USE OF OUTSIDE ACTUARIES.—Under the  
6 processes under paragraph (1)(A), eligible entities  
7 and MedicareAdvantage organizations may use actu-  
8 arial opinions certified by independent, qualified ac-  
9 tuaries to establish actuarial values, but the Admin-  
10 istrator shall determine whether such actuarial val-  
11 ues meet the requirements under subsection (c)(1).

12 “REQUIREMENTS FOR ENTITIES OFFERING MEDICARE  
13 PRESCRIPTION DRUG PLANS; ESTABLISHMENT OF  
14 STANDARDS

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

18 “(1) LICENSURE.—Subject to subsection (c),  
19 the entity is organized and licensed under State law  
20 as a risk-bearing entity eligible to offer health insur-  
21 ance or health benefits coverage in each State in  
22 which it offers a Medicare Prescription Drug plan.

23 “(2) ASSUMPTION OF FINANCIAL RISK.—

24 “(A) IN GENERAL.—Subject to subpara-  
25 graph (B) and subsections (d)(2) and (e) of  
26 section 1860D–13, to the extent that the entity

1 is at risk pursuant to such section 1860D–16,  
2 the entity assumes financial risk on a prospec-  
3 tive basis for the benefits that it offers under  
4 a Medicare Prescription Drug plan and that is  
5 not covered under section 1860D–20.

6 “(B) REINSURANCE PERMITTED.—To the  
7 extent that the entity is at risk pursuant to sec-  
8 tion 1860D–16, the entity may obtain insur-  
9 ance or make other arrangements for the cost  
10 of coverage provided to any enrolled member  
11 under this part.

12 “(3) SOLVENCY FOR UNLICENSED ENTITIES.—  
13 In the case of an eligible entity that is not described  
14 in paragraph (1) and for which a waiver has been  
15 approved under subsection (c), such entity shall  
16 meet solvency standards established by the Adminis-  
17 trator under subsection (d).

18 “(b) CONTRACT REQUIREMENTS.—The Adminis-  
19 trator shall not permit an eligible beneficiary to elect a  
20 Medicare Prescription Drug plan offered by an eligible en-  
21 tity under this part, and the entity shall not be eligible  
22 for payments under section 1860D–16 or 1860D–20, un-  
23 less the Administrator has entered into a contract under  
24 this subsection with the entity with respect to the offering  
25 of such plan. Such a contract with an entity may cover

1 more than 1 Medicare Prescription Drug plan. Such con-  
2 tract shall provide that the entity agrees to comply with  
3 the applicable requirements and standards of this part and  
4 the terms and conditions of payment as provided for in  
5 this part.

6 “(c) WAIVER OF CERTAIN REQUIREMENTS IN ORDER  
7 TO ENSURE BENEFICIARY CHOICE.—

8 “(1) IN GENERAL.—In the case of an eligible  
9 entity that seeks to offer a Medicare Prescription  
10 Drug plan in a State, the Administrator shall waive  
11 the requirement of subsection (a)(1) that the entity  
12 be licensed in that State if the Administrator deter-  
13 mines, based on the application and other evidence  
14 presented to the Administrator, that any of the  
15 grounds for approval of the application described in  
16 paragraph (2) have been met.

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

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

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

3 “(4) REFERENCES TO CERTAIN PROVISIONS.—

4 For purposes of this subsection, in applying the pro-  
5 visions of section 1855(a)(2) under this subsection  
6 to Medicare Prescription Drug plans and eligible en-  
7 tities—

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

12 “(B) any reference to solvency standards  
13 were treated as a reference to solvency stand-  
14 ards established under subsection (d).

15 “(d) SOLVENCY STANDARDS FOR NON-LICENSED  
16 ENTITIES.—

17 “(1) ESTABLISHMENT AND PUBLICATION.—The  
18 Administrator, in consultation with the National As-  
19 sociation of Insurance Commissioners, shall establish  
20 and publish, by not later than January 1, 2005, fi-  
21 nancial solvency and capital adequacy standards for  
22 entities described in paragraph (2).

23 “(2) COMPLIANCE WITH STANDARDS.—An eligi-  
24 ble entity that is not licensed by a State under sub-  
25 section (a)(1) and for which a waiver application has

1       been approved under subsection (c) shall meet sol-  
2       vency and capital adequacy standards established  
3       under paragraph (1). The Administrator shall estab-  
4       lish certification procedures for such eligible entities  
5       with respect to such solvency standards in the man-  
6       ner described in section 1855(c)(2).

7       “(e) LICENSURE DOES NOT SUBSTITUTE FOR OR  
8       CONSTITUTE CERTIFICATION.—The fact that an entity is  
9       licensed in accordance with subsection (a)(1) or has a  
10      waiver application approved under subsection (c) does not  
11      deem the eligible entity to meet other requirements im-  
12      posed under this part for an eligible entity.

13      “(f)           INCORPORATION           OF           CERTAIN  
14      MEDICAREADVANTAGE CONTRACT REQUIREMENTS.—The  
15      following provisions of section 1857 shall apply, subject  
16      to subsection (c)(4), to contracts under this section in the  
17      same manner as they apply to contracts under section  
18      1857(a):

19                   “(1) PROTECTIONS AGAINST FRAUD AND BENE-  
20      FICIARY PROTECTIONS.—Section 1857(d).

21                   “(2) INTERMEDIATE    SANCTIONS.—Section  
22      1857(g), except that in applying such section—

23                   “(A)    the    reference    in    section  
24                   1857(g)(1)(B) to section 1854 is deemed a ref-  
25                   erence to this part; and

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

4           “(3) PROCEDURES FOR TERMINATION.—Section  
5           1857(h).

6           “(g) OTHER STANDARDS.—The Administrator shall  
7           establish by regulation other standards (not described in  
8           subsection (d)) for eligible entities and Medicare Prescrip-  
9           tion Drug plans consistent with, and to carry out, this  
10          part. The Administrator shall publish such regulations by  
11          January 1, 2005.

12          “(h) PERIODIC REVIEW AND REVISION OF STAND-  
13          ARDS.—

14                 “(1) IN GENERAL.—Subject to paragraph (2),  
15                 the Administrator shall periodically review the  
16                 standards established under this section and, based  
17                 on such review, may revise such standards if the Ad-  
18                 ministrator determines such revision to be appro-  
19                 priate.

20                 “(2) PROHIBITION OF MIDYEAR IMPLEMENTA-  
21                 TION OF SIGNIFICANT NEW REGULATORY REQUIRE-  
22                 MENTS.—The Administrator may not implement,  
23                 other than at the beginning of a calendar year, regu-  
24                 lations under this section that impose new, signifi-

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

3 “(i) RELATION TO STATE LAWS.—

4 “(1) IN GENERAL.—The standards established  
5 under this part shall supersede any State law or reg-  
6 ulation (including standards described in paragraph  
7 (2)) with respect to Medicare Prescription Drug  
8 plans which are offered by eligible entities under this  
9 part—

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

12 “(B) in the same manner as such laws and  
13 regulations are superseded under section  
14 1856(b)(3).

15 “(2) STANDARDS SPECIFICALLY SUPER-  
16 SEDED.—State standards relating to the following  
17 are superseded under this section:

18 “(A) Benefit requirements, including re-  
19 quirements relating to cost-sharing and the  
20 structure of formularies.

21 “(B) Premiums.

22 “(C) Requirements relating to inclusion or  
23 treatment of providers.

24 “(D) Coverage determinations (including  
25 related appeals and grievance processes).

1           “(E) Requirements relating to marketing  
2 materials and summaries and schedules of ben-  
3 efits regarding a Medicare Prescription Drug  
4 plan.

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

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

11           “(B) any payments made by the Adminis-  
12 trator under this part to an eligible entity offer-  
13 ing such a plan.

14           “Subpart 2—Prescription Drug Delivery System

15           “ESTABLISHMENT OF SERVICE AREAS

16           “SEC. 1860D–10. (a) ESTABLISHMENT.—

17           “(1) INITIAL ESTABLISHMENT.—Not later than  
18 April 15, 2005, the Administrator shall establish  
19 and publish the service areas in which Medicare Pre-  
20 scription Drug plans may offer benefits under this  
21 part.

22           “(2) PERIODIC REVIEW AND REVISION OF  
23 SERVICE AREAS.—The Administrator shall periodi-  
24 cally review the service areas applicable under this  
25 section and, based on such review, may revise such

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

3 “(b) REQUIREMENTS FOR ESTABLISHMENT OF  
4 SERVICE AREAS.—

5 “(1) IN GENERAL.—The Administrator shall es-  
6 tablish the service areas under subsection (a) in a  
7 manner that—

8 “(A) maximizes the availability of Medi-  
9 care Prescription Drug plans to eligible bene-  
10 ficiaries; and

11 “(B) minimizes the ability of eligible enti-  
12 ties offering such plans to favorably select eligi-  
13 ble beneficiaries.

14 “(2) ADDITIONAL REQUIREMENTS.—The Ad-  
15 ministrator shall establish the service areas under  
16 subsection (a) consistent with the following require-  
17 ments:

18 “(A) There shall be at least 10 service  
19 areas.

20 “(B) Each service area must include at  
21 least 1 State.

22 “(C) The Administrator may not divide  
23 States so that portions of the State are in dif-  
24 ferent service areas.

1           “(D) To the extent possible, the Adminis-  
2           trator shall include multistate metropolitan sta-  
3           tistical areas in a single service area. The Ad-  
4           ministrators may divide metropolitan statistical  
5           areas where it is necessary to establish service  
6           areas of such size and geography as to maxi-  
7           mize the participation of Medicare Prescription  
8           Drug plans.

9           “(3) MAY CONFORM TO MEDICAREADVANTAGE  
10          PREFERRED PROVIDER REGIONS.—The Adminis-  
11          trator may conform the service areas established  
12          under this section to the preferred provider regions  
13          established under section 1858(a)(3).

14          “PUBLICATION OF RISK ADJUSTERS  
15          “SEC. 1860D–11. (a) PUBLICATION.—Not later than  
16          April 15 of each year (beginning in 2005), the Adminis-  
17          trator shall publish the risk adjusters established under  
18          subsection (b) to be used in computing—

19                 “(1) the amount of payment to Medicare Pre-  
20          scription Drug plans in the subsequent year under  
21          section 1860D–16(a), insofar as it is attributable to  
22          standard prescription drug coverage (or actuarially  
23          equivalent prescription drug coverage); and

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

1 to standard prescription drug coverage (or actuari-  
2 ally equivalent prescription drug coverage).

3 “(b) ESTABLISHMENT OF RISK ADJUSTERS.—

4 “(1) IN GENERAL.—Subject to paragraph (2),  
5 the Administrator shall establish an appropriate  
6 methodology for adjusting the amount of payment to  
7 plans referred to in subsection (a) to take into ac-  
8 count variation in costs based on the differences in  
9 actuarial risk of different enrollees being served. Any  
10 such risk adjustment shall be designed in a manner  
11 as to not result in a change in the aggregate pay-  
12 ments described in paragraphs (1) and (2) of sub-  
13 section (a).

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

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

21 “(A) eligible entities to submit data re-  
22 garding drug claims that can be linked at the  
23 beneficiary level to part A and part B data and  
24 such other information as the Administrator de-  
25 termines necessary; and



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

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

6           “(2) The actuarial value of the qualified pre-  
7 scription drug coverage.

8           “(3) The amount of the monthly plan premium  
9 under the plan, including an actuarial certification  
10 of—

11           “(A) the actuarial basis for such monthly  
12 plan premium;

13           “(B) the portion of such monthly plan pre-  
14 mium attributable to standard prescription  
15 drug coverage or actuarially equivalent prescrip-  
16 tion drug coverage and, if applicable, to benefits  
17 that are in addition to such coverage; and

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

21           “(4) The service area for the plan.

22           “(5) Whether the entity plans to use any funds  
23 in the plan stabilization reserve fund in the Prescrip-  
24 tion Drug Account that are available to the entity to  
25 stabilize or reduce the monthly plan premium sub-



1       tion Drug plan unless the following requirements are  
2       met:

3               “(A) COMPLIANCE WITH REQUIRE-  
4               MENTS.—The plan and the entity offering the  
5               plan comply with the requirements under this  
6               part.

7               “(B) APPLICATION OF FEHBP STAND-  
8               ARD.—(i) The portion of the monthly plan pre-  
9               mium submitted under section 1860D–12(b)  
10              that is attributable to standard prescription  
11              drug coverage reasonably and equitably reflects  
12              the actuarial value of the standard prescription  
13              drug coverage less the actuarial value of the re-  
14              insurance payments under section 1860D–20  
15              and the amount of any funds in the plan sta-  
16              bilization reserve fund in the Prescription Drug  
17              Account used to stabilize or reduce the monthly  
18              plan premium.

19              “(ii) If the plan provides additional pre-  
20              scription drug coverage pursuant to section  
21              1860D–6(a)(2), the monthly plan premium rea-  
22              sonably and equitably reflects the actuarial  
23              value of the coverage provided less the actuarial  
24              value of the reinsurance payments under section  
25              1860D–20 and the amount of any funds in the

1           plan stabilization reserve fund in the Prescrip-  
2           tion Drug Account used to stabilize or reduce  
3           the monthly plan premium.

4           “(b) NEGOTIATION.—In exercising the authority  
5 under subsection (a), the Administrator shall have the au-  
6 thority to—

7           “(1) negotiate the terms and conditions of the  
8           proposed monthly plan premiums submitted and  
9           other terms and conditions of a proposed plan; and

10           “(2) disapprove, or limit enrollment in, a pro-  
11 posed plan based on—

12           “(A) the costs to beneficiaries under the  
13           plan;

14           “(B) the quality of the coverage and bene-  
15           fits under the plan;

16           “(C) the adequacy of the network under  
17           the plan; or

18           “(D) other factors determined appropriate  
19           by the Administrator.

20           “(c) SPECIAL RULES FOR APPROVAL.—The Adminis-  
21 trator may approve a Medicare Prescription Drug plan  
22 submitted under section 1860D–12 only if the benefits  
23 under such plan—

24           “(1) include the required benefits under section  
25           1860D–6(a)(1); and

1           “(2) are not designed in such a manner that  
2 the Administrator finds is likely to result in favor-  
3 able selection of eligible beneficiaries.

4           “(d) ACCESS TO COMPETITIVE COVERAGE.—

5           “(1) NUMBER OF CONTRACTS.—The Adminis-  
6 trator, consistent with the requirements of this part  
7 and the goal of containing costs under this title,  
8 shall, with respect to a year, approve at least 2 con-  
9 tracts to offer a Medicare Prescription Drug plan in  
10 each service area (established under section 1860D-  
11 10) for the year.

12           “(2) AUTHORITY TO REDUCE RISK TO ENSURE  
13 ACCESS.—

14           “(A) IN GENERAL.—Subject to subpara-  
15 graph (B), if the Administrator determines,  
16 with respect to an area, that the access re-  
17 quired under paragraph (1) is not going to be  
18 provided in the area during the subsequent  
19 year, the Administrator shall—

20           “(i) adjust the percents specified in  
21 paragraphs (2) and (4) of section 1860D-  
22 16(b) in an area in a year; or

23           “(ii) increase the percent specified in  
24 section 1860D-20(c)(1) in an area in a  
25 year.

1 The administrator shall exercise the authority  
2 under the preceding sentence only so long as  
3 (and to the extent) necessary to assure the ac-  
4 cess guaranteed under paragraph (1).

5 “(B) REQUIREMENTS FOR USE OF AU-  
6 THORITY.—In exercising authority under sub-  
7 paragraph (A), the Administrator—

8 “(i) shall not provide for the full un-  
9 derwriting of financial risk for any eligible  
10 entity;

11 “(ii) shall not provide for any under-  
12 writing of financial risk for a public eligi-  
13 ble entity with respect to the offering of a  
14 nationwide Medicare Prescription Drug  
15 plan; and

16 “(iii) shall seek to maximize the as-  
17 sumption of financial risk by eligible enti-  
18 ties to ensure fair competition among  
19 Medicare Prescription Drug plans.

20 “(C) REQUIREMENT TO ACCEPT 2 FULL-  
21 RISK QUALIFIED BIDS BEFORE EXERCISING AU-  
22 THORITY.—The Administrator may not exercise  
23 the authority under subparagraph (A) with re-  
24 spect to an area and year if 2 or more qualified  
25 bids are submitted by eligible entities to offer a

1 Medicare Prescription Drug plan in the area for  
2 the year under paragraph (1) before the appli-  
3 cation of subparagraph (A).

4 “(D) REPORTS.—The Administrator, in  
5 each annual report to Congress under section  
6 1808(c)(1)(D), shall include information on the  
7 exercise of authority under subparagraph (A).  
8 The Administrator also shall include such rec-  
9 ommendations as may be appropriate to limit  
10 the exercise of such authority.

11 “(e) GUARANTEED ACCESS.—

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

15 “(A) DETERMINATION.—Not later than  
16 September 1 of each year (beginning in 2005)  
17 and for each area (established under section  
18 1860D–10), the Administrator shall make a de-  
19 termination as to whether the access required  
20 under subsection (d)(1) is going to be provided  
21 in the area during the subsequent year. Such  
22 determination shall be made after the Adminis-  
23 trator has exercised the authority under sub-  
24 section (d)(2).

1           “(B) CONTRACT WITH AN ENTITY TO PRO-  
2           VIDE COVERAGE IN AN AREA.—Subject to para-  
3           graph (3), if the Administrator makes a deter-  
4           mination under subparagraph (A) that the ac-  
5           cess required under subsection (d)(1) is not  
6           going to be provided in an area during the sub-  
7           sequent year, the Administrator shall enter into  
8           a contract with an entity to provide eligible  
9           beneficiaries enrolled under this part (and not,  
10          except for an MSA plan or a private fee-for-  
11          service plan that does not provide qualified pre-  
12          scription drug coverage enrolled in a  
13          MedicareAdvantage plan) and residing in the  
14          area with standard prescription drug coverage  
15          (including access to negotiated prices for such  
16          beneficiaries pursuant to section 1860D–6(e))  
17          during the subsequent year. An entity may be  
18          awarded a contract for more than 1 of the  
19          areas for which the Administrator is required to  
20          enter into a contract under this paragraph but  
21          the Administrator may enter into only 1 such  
22          contract in each such area. An entity with a  
23          contract under this part shall meet the require-  
24          ments described in section 1860D–5 and such

1 other requirements determined appropriate by  
2 the Administrator.

3 “(C) REQUIREMENT TO ACCEPT 2 RE-  
4 DUCED-RISK QUALIFIED BIDS BEFORE ENTER-  
5 ING INTO CONTRACT.—The Administrator may  
6 not enter into a contract under subparagraph  
7 (B) with respect to an area and year if 2 or  
8 more qualified bids are submitted by eligible en-  
9 tities to offer a Medicare Prescription Drug  
10 plan in the area for the year after the Adminis-  
11 trator has exercised the authority under sub-  
12 section (d)(2) in the area for the year.

13 “(D) ENTITY REQUIRED TO MEET BENE-  
14 FICIARY PROTECTION AND OTHER REQUIRE-  
15 MENTS.—An entity with a contract under sub-  
16 paragraph (B) shall meet the requirements de-  
17 scribed in section 1860D–5 and such other re-  
18 quirements determined appropriate by the Ad-  
19 ministrator.

20 “(E) COMPETITIVE PROCEDURES.—Com-  
21 petitive procedures (as defined in section 4(5)  
22 of the Office of Federal Procurement Policy Act  
23 (41 U.S.C. 403(5))) shall be used to enter into  
24 a contract under subparagraph (B).

1           “(2) MONTHLY BENEFICIARY OBLIGATION FOR  
2 ENROLLMENT.—

3           “(A) IN GENERAL.—In the case of an eligi-  
4 ble beneficiary receiving access to qualified pre-  
5 scription drug coverage through enrollment with  
6 an entity with a contract under paragraph  
7 (1)(B), the monthly beneficiary obligation of  
8 such beneficiary for such enrollment shall be an  
9 amount equal to the applicable percent (as de-  
10 termined under section 1860D–17(c)) of the  
11 monthly national average premium (as com-  
12 puted under section 1860D–15) for the area for  
13 the year, as adjusted using the geographic ad-  
14 juster under subparagraph (B).

15           “(B) ESTABLISHMENT OF GEOGRAPHIC  
16 ADJUSTER.—The Administrator shall establish  
17 an appropriate methodology for adjusting the  
18 monthly beneficiary obligation (as computed  
19 under subparagraph (A)) for the year in an  
20 area to take into account differences in drug  
21 prices among areas. In establishing such meth-  
22 odology, the Administrator may take into ac-  
23 count differences in drug utilization between eli-  
24 gible beneficiaries in an area and eligible bene-  
25 ficiaries in other areas and the results of the

1 ongoing study required under section 106 of the  
2 Prescription Drug and Medicare Improvement  
3 Act of 2003. Any such adjustment shall be ap-  
4 plied in a manner so as to not result in a  
5 change in the aggregate payments made under  
6 this part that would have been made if the Ad-  
7 ministrator had not applied such adjustment.

8 “(3) PAYMENTS UNDER THE CONTRACT.—

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

11 “(i) payment for the negotiated costs  
12 of covered drugs provided to eligible bene-  
13 ficiaries enrolled with the entity; and

14 “(ii) payment of prescription manage-  
15 ment fees that are tied to performance re-  
16 quirements established by the Adminis-  
17 trator for the management, administration,  
18 and delivery of the benefits under the con-  
19 tract.

20 “(B) PERFORMANCE REQUIREMENTS.—

21 The performance requirements established by  
22 the Administrator pursuant to subparagraph  
23 (A)(ii) shall include the following:

24 “(i) The entity contains costs to the  
25 Prescription Drug Account and to eligible

1 beneficiaries enrolled under this part and  
2 with the entity.

3 “(ii) The entity provides such bene-  
4 ficiaries with quality clinical care.

5 “(iii) The entity provides such bene-  
6 ficiaries with quality services.

7 “(C) ENTITY ONLY AT RISK TO THE EX-  
8 TENT OF THE FEES TIED TO PERFORMANCE  
9 REQUIREMENTS.—An entity with a contract  
10 under paragraph (1)(B) shall only be at risk for  
11 the provision of benefits under the contract to  
12 the extent that the management fees paid to  
13 the entity are tied to performance requirements  
14 under subparagraph (A)(ii).

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

1 year and submitted such a bid under section  
2 1860D–12 for the year.

3 “(5) CONTRACT TO BE AVAILABLE IN DES-  
4 IGNATED AREA FOR 2 YEARS.—Notwithstanding  
5 paragraph (1), if the Administrator enters into a  
6 contract with an entity with respect to an area des-  
7 ignated under subparagraph (B) of such paragraph  
8 for a year, the following rules shall apply:

9 “(A) The contract shall be for a 2-year pe-  
10 riod.

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

15 “(C) During the second year of the con-  
16 tract, an eligible beneficiary residing in the area  
17 may continue to receive standard prescription  
18 drug coverage (including access to negotiated  
19 prices for such beneficiaries pursuant to section  
20 1860D-6(e)) under such contract or through  
21 any Medicare Prescription Drug plan that is  
22 available in the area.

23 “(6) ENTITY NOT PERMITTED TO MARKET OR  
24 BRAND THE CONTRACT.—An entity with a contract

1 under paragraph (1)(B) may not engage in any mar-  
2 keting or branding of such contract.

3 “(7) RULES FOR AREAS WHERE ONLY 1 COM-  
4 PETITIVELY BID PLAN WAS APPROVED.—In the case  
5 of an area where (before the application of this sub-  
6 section) only 1 Medicare Prescription Drug plan was  
7 approved for a year—

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

12 “(B) eligible beneficiaries described in  
13 paragraph (1)(B) may receive access to quali-  
14 fied prescription drug coverage through enroll-  
15 ment in the plan or with an entity with a con-  
16 tract under paragraph (1)(B); and

17 “(C) for purposes of applying section  
18 1860D–3(a)(1)(A)(ii), such plan shall be the  
19 plan designated in the area under such section.

20 “(f) TWO-YEAR CONTRACTS.—Except for a contract  
21 entered into under subsection (e)(1)(B), a contract ap-  
22 proved under this part (including a contract under) shall  
23 be for a 2-year period.

1 “COMPUTATION OF MONTHLY STANDARD PRESCRIPTION  
2 DRUG COVERAGE PREMIUMS

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

8 “(b) REQUIREMENTS.—The monthly standard pre-  
9 scription drug coverage premium for a plan for a year  
10 shall be equal to—

11 “(1) in the case of a plan offered by an eligible  
12 entity or Medicare Advantage organization that pro-  
13 vides standard prescription drug coverage or an ac-  
14 tuarially equivalent prescription drug coverage and  
15 does not provide additional prescription drug cov-  
16 erage pursuant to section 1860D–6(a)(2), the  
17 monthly plan premium approved for the plan under  
18 section 1860D–13 for the year; and

19 “(2) in the case of a plan offered by an eligible  
20 entity or Medicare Advantage organization that pro-  
21 vides additional prescription drug coverage pursuant  
22 to section 1860D–6(a)(2)—

23 “(A) an amount that reflects only the actu-  
24 arial value of the standard prescription drug  
25 coverage offered under the plan; or



1           “(2) WEIGHTED AVERAGE.—The monthly na-  
2           tional average premium computed under paragraph  
3           (1) shall be a weighted average, with the weight for  
4           each plan being equal to the average number of  
5           beneficiaries enrolled under such plan in the pre-  
6           vious year.

7           “(b) GEOGRAPHIC ADJUSTMENT.—The Adminis-  
8           trator shall establish an appropriate methodology for ad-  
9           justing the monthly national average premium (as com-  
10          puted under subsection (a)) for the year in an area to take  
11          into account differences in prices for covered drugs among  
12          different areas. In establishing such methodology, the Ad-  
13          ministrators may take into account differences in drug uti-  
14          lization between eligible beneficiaries in that area and  
15          other eligible beneficiaries and the results of the ongoing  
16          study required under section 106 of the Prescription Drug  
17          and Medicare Improvement Act of 2003. Any such adjust-  
18          ment shall be applied in a manner as to not result in a  
19          change in aggregate payments made under this part than  
20          would have been made if the Administrator had not ap-  
21          plied such adjustment.

22          “(c) SPECIAL RULE FOR 2006.—For purposes of ap-  
23          plying this section for 2006, the Administrator shall estab-  
24          lish procedures for determining the weighted average  
25          under subsection (a)(2) for 2005.

1                   “PAYMENTS TO ELIGIBLE ENTITIES

2           “SEC. 1860D–16. (a) PAYMENT OF MONTHLY PLAN  
3 PREMIUMS.—For each year (beginning with 2006), the  
4 Administrator shall pay to each entity offering a Medicare  
5 Prescription Drug plan in which an eligible beneficiary is  
6 enrolled an amount equal to the full amount of the month-  
7 ly plan premium approved for the plan under section  
8 1860D–13 on behalf of each eligible beneficiary enrolled  
9 in such plan for the year, as adjusted using the risk ad-  
10 justers that apply to the standard prescription drug cov-  
11 erage published under section 1860D–11.

12           “(b) PORTION OF TOTAL PAYMENTS OF MONTHLY  
13 PLAN PREMIUMS SUBJECT TO RISK.—

14                   “(1) NOTIFICATION OF SPENDING UNDER THE  
15 PLAN.—

16                           “(A) IN GENERAL.—For each year (begin-  
17 ning in 2007), the eligible entity offering a  
18 Medicare Prescription Drug plan shall notify  
19 the Administrator of the following:

20                                   “(i) TOTAL ACTUAL COSTS.—The  
21 total amount of costs that the entity in-  
22 curred in providing standard prescription  
23 drug coverage (or prescription drug cov-  
24 erage that is actuarially equivalent pursu-  
25 ant to section 1860D–6(a)(1)(B)) for all

1 enrollees under the plan in the previous  
2 year.

3 “(ii) ACTUAL COSTS FOR SPECIFIC  
4 DRUGS.—With respect to the total amount  
5 under clause (i) for the year, a breakdown  
6 of—

7 “(I) each covered drug that con-  
8 stitutes a portion of such amount;

9 “(II) the negotiated price for the  
10 eligible entity for each such drug;

11 “(III) the number of prescrip-  
12 tions; and

13 “(IV) the average beneficiary co-  
14 insurance rate for a each covered drug  
15 that constitutes a portion of such  
16 amount.

17 “(B) CERTAIN EXPENSES NOT IN-  
18 CLUDED.—The amounts under clauses (i) and  
19 (ii)(II) of subparagraph (A) may not include—

20 “(i) administrative expenses incurred  
21 in providing the coverage described in sub-  
22 paragraph (A)(i);

23 “(ii) amounts expended on providing  
24 additional prescription drug coverage pur-  
25 suant to section 1860D–6(a)(2); or

1                   “(iii) amounts expended for which the  
2                   entity is subsequently provided with rein-  
3                   surance payments under section 1860D-  
4                   20.

5                   “(2) ADJUSTMENT OF PAYMENT.—

6                   “(A) NO ADJUSTMENT IF ALLOWABLE  
7                   COSTS WITHIN RISK CORRIDOR.—If the allow-  
8                   able costs (specified in paragraph (3)) for the  
9                   plan for the year are not more than the first  
10                  threshold upper limit of the risk corridor (speci-  
11                  fied in paragraph (4)(A)(iii)) and are not less  
12                  than the first threshold lower limit of the risk  
13                  corridor (specified in paragraph (4)(A)(i)) for  
14                  the plan for the year, then no additional pay-  
15                  ments shall be made by the Administrator and  
16                  no payments shall be made by (or collected  
17                  from) the eligible entity offering the plan.

18                  “(B) INCREASE IN PAYMENT IF ALLOW-  
19                  ABLE COSTS ABOVE UPPER LIMIT OF RISK COR-  
20                  RIDOR.—

21                  “(i) IN GENERAL.—If the allowable  
22                  costs for the plan for the year are more  
23                  than the first threshold upper limit of the  
24                  risk corridor for the plan for the year, then  
25                  the Administrator shall increase the total

1 of the monthly payments made to the enti-  
2 ty offering the plan for the year under sub-  
3 section (a) by an amount equal to the sum  
4 of—

5 “(I) the applicable percent (as  
6 defined in subparagraph (D)) of such  
7 allowable costs which are more than  
8 such first threshold upper limit of the  
9 risk corridor and not more than the  
10 second threshold upper limit of the  
11 risk corridor for the plan for the year  
12 (as specified under paragraph  
13 (4)(A)(iv)); and

14 “(II) 90 percent of such allow-  
15 able costs which are more than such  
16 second threshold upper limit of the  
17 risk corridor.

18 “(ii) SPECIAL TRANSITIONAL COR-  
19 RIDOR FOR 2006 AND 2007.—If the Admin-  
20 istrator determines with respect to 2006 or  
21 2007 that at least 60 percent of Medicare  
22 Prescription Drug plans and  
23 MedicareAdvantage Plans (excluding MSA  
24 plans or private fee-for-service plans that  
25 do not provide qualified prescription drug

1 coverage) have allowable costs for the plan  
2 for the year that are more than the first  
3 threshold upper limit of the risk corridor  
4 for the plan for the year and that such  
5 plans represent at least 60 percent of eligi-  
6 ble beneficiaries enrolled under this part,  
7 clause (i)(I) shall be applied by sub-  
8 stituting ‘90 percent’ for ‘applicable per-  
9 cent’.

10 “(C) PLAN PAYMENT IF ALLOWABLE  
11 COSTS BELOW LOWER LIMIT OF RISK COR-  
12 RIDOR.—If the allowable costs for the plan for  
13 the year are less than the first threshold lower  
14 limit of the risk corridor for the plan for the  
15 year, then the entity offering the plan shall  
16 make a payment to the Administrator of an  
17 amount (or the Administrator shall otherwise  
18 recover from the plan an amount) equal to—

19 “(i) the applicable percent (as so de-  
20 fined) of such allowable costs which are  
21 less than such first threshold lower limit of  
22 the risk corridor and not less than the sec-  
23 ond threshold lower limit of the risk cor-  
24 ridor for the plan for the year (as specified  
25 under paragraph (4)(A)(ii)); and

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

4                   “(D) APPLICABLE PERCENT DEFINED.—  
5                   For purposes of this paragraph, the term ‘ap-  
6                   plicable percent’ means—

7                   “(i) for 2006 and 2007, 75 percent;

8                   and

9                   “(ii) for 2008 and subsequent years,  
10                  50 percent.

11                  “(3) ESTABLISHMENT OF ALLOWABLE  
12                  COSTS.—

13                  “(A) IN GENERAL.—For each year, the  
14                  Administrator shall establish the allowable costs  
15                  for each Medicare Prescription Drug plan for  
16                  the year. The allowable costs for a plan for a  
17                  year shall be equal to the amount described in  
18                  paragraph (1)(A)(i) for the plan for the year,  
19                  adjusted under subparagraph (B)(ii).

20                  “(B) REPRICING OF COSTS.—

21                  “(i) CALCULATION OF AVERAGE PLAN  
22                  COST.—Utilizing the information obtained  
23                  under paragraph (1)(A)(ii) and section  
24                  1860D–20(b)(1)(B), for each year (begin-  
25                  ning with 2006), the Administrator shall

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

4 “(ii) ADJUSTMENT IF ACTUAL COSTS  
5 EXCEED AVERAGE COSTS.—With respect to  
6 a Medicare Prescription Drug plan for a  
7 year, the Administrator shall reduce the  
8 amount described in paragraph (1)(A)(i)  
9 for the plan for the year to the extent such  
10 amount is based on costs of specific cov-  
11 ered drugs furnished under the plan in the  
12 year (as specified under paragraph  
13 (1)(A)(ii)) for which the negotiated prices  
14 are greater than the average negotiated  
15 price for the covered drug for the year (as  
16 determined under clause (i)).

17 “(4) ESTABLISHMENT OF RISK CORRIDORS.—

18 “(A) IN GENERAL.—For each year (begin-  
19 ning with 2006), the Administrator shall estab-  
20 lish a risk corridor for each Medicare Prescrip-  
21 tion Drug plan. The risk corridor for a plan for  
22 a year shall be equal to a range as follows:

23 “(i) FIRST THRESHOLD LOWER  
24 LIMIT.—The first threshold lower limit of  
25 such corridor shall be equal to—

1           “(I) the target amount described  
2           in subparagraph (B) for the plan;  
3           minus

4           “(II) an amount equal to the  
5           first threshold risk percentage for the  
6           plan (as determined under subpara-  
7           graph (C)(i)) of such target amount.

8           “(ii) SECOND THRESHOLD LOWER  
9           LIMIT.—The second threshold lower limit  
10          of such corridor shall be equal to—

11           “(I) the target amount described  
12           in subparagraph (B) for the plan;  
13           minus

14           “(II) an amount equal to the sec-  
15           ond threshold risk percentage for the  
16           plan (as determined under subpara-  
17           graph (C)(ii)) of such target amount.

18           “(iii) FIRST THRESHOLD UPPER  
19           LIMIT.—The first threshold upper limit of  
20          such corridor shall be equal to the sum  
21          of—

22           “(I) such target amount; and

23           “(II) the amount described in  
24          clause (i)(II).

1           “(iv) SECOND THRESHOLD UPPER  
2           LIMIT.—The second threshold upper limit  
3           of such corridor shall be equal to the sum  
4           of—

5                       “(I) such target amount; and

6                       “(II) the amount described in  
7                       clause (ii)(II).

8           “(B) TARGET AMOUNT DESCRIBED.—The  
9           target amount described in this paragraph is,  
10          with respect to a Medicare Prescription Drug  
11          plan offered by an eligible entity in a year—

12                       “(i) in the case of a plan offered by  
13                       an eligible entity that provides standard  
14                       prescription drug coverage or actuarially  
15                       equivalent prescription drug coverage and  
16                       does not provide additional prescription  
17                       drug coverage pursuant to section 1860D–  
18                       6(a)(2), an amount equal to the total of  
19                       the monthly plan premiums paid to such  
20                       entity for such plan for the year pursuant  
21                       to subsection (a), reduced by the percent-  
22                       age specified in subparagraph (D); and

23                       “(ii) in the case of a plan offered by  
24                       an eligible entity that provides additional  
25                       prescription drug coverage pursuant to sec-

1           tion 1860D–6(a)(2), an amount equal to  
2           the total of the monthly plan premiums  
3           paid to such entity for such plan for the  
4           year pursuant to subsection (a) that are  
5           related to standard prescription drug cov-  
6           erage (determined using the rules under  
7           section 1860D–14(b)), reduced by the per-  
8           centage specified in subparagraph (D).

9           “(C) FIRST AND SECOND THRESHOLD  
10          RISK PERCENTAGE DEFINED.—

11           “(i) FIRST THRESHOLD RISK PER-  
12          CENTAGE.—Subject to clause (iii), for pur-  
13          poses of this section, the first threshold  
14          risk percentage is—

15                   “(I) for 2006 and 2007, 2.5 per-  
16                   cent;

17                   “(II) for 2008 through 2011, 5  
18                   percent; and

19                   “(III) for 2012 and subsequent  
20                   years, a percentage established by the  
21                   Administrator, but in no case less  
22                   than 5 percent.

23           “(ii) SECOND THRESHOLD RISK PER-  
24          CENTAGE.—Subject to clause (iii), for pur-

1 poses of this section, the second threshold  
2 risk percentage is—

3 “(I) for 2006 and 2007, 5.0 per-  
4 cent;

5 “(II) for 2008 through 2011, 10  
6 percent

7 “(III) for 2012 and subsequent  
8 years, a percentage established by the  
9 Administrator that is greater than the  
10 percent established for the year under  
11 clause (i)(III), but in no case less  
12 than 10 percent.

13 “(iii) REDUCTION OF RISK PERCENT-  
14 AGE TO ENSURE 2 PLANS IN AN AREA.—

15 Pursuant to paragraph (2) of section  
16 1860D–13(d), the Administrator may re-  
17 duce the applicable first or second thresh-  
18 old risk percentage in an area in a year in  
19 order to ensure the access to plans re-  
20 quired under paragraph (1) of such sec-  
21 tion.

22 “(D) TARGET AMOUNT NOT TO INCLUDE  
23 ADMINISTRATIVE EXPENSES NEGOTIATED BE-  
24 TWEEN THE ADMINISTRATOR AND THE ENTITY  
25 OFFERING THE PLAN.—For each year (begin-

1           ning in 2006), the Administrator and the entity  
2           offering a Medicare Prescription Drug plan  
3           shall negotiate, as part of the negotiation proc-  
4           ess described in section 1860D–13(b) during  
5           the previous year, the percentage of the pay-  
6           ments to the entity under subsection (a) with  
7           respect to the plan that are attributable and  
8           reasonably incurred for administrative expenses  
9           for providing standard prescription drug cov-  
10          erage or actuarially equivalent prescription drug  
11          coverage in the year.

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

19           “(6) NO EFFECT ON ELIGIBLE BENE-  
20          FICIARIES.—No change in payments made by reason  
21          of this subsection shall affect the beneficiary obliga-  
22          tion under section 1860D–17 for the year in which  
23          such change in payments is made.

24           “(7) DISCLOSURE OF INFORMATION.—

1           “(A) IN GENERAL.—Each contract under  
2 this part shall provide that—

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

8           “(ii) the Administrator shall have the  
9 right to inspect and audit any books and  
10 records of the eligible entity that pertain to  
11 the information regarding costs provided to  
12 the Administrator under paragraph (1).

13           “(B) RESTRICTION ON USE OF INFORMA-  
14 TION.—Information disclosed or obtained pur-  
15 suant to the provisions of this section may be  
16 used by officers and employees of the Depart-  
17 ment of Health and Human Services only for  
18 the purposes of, and to the extent necessary in,  
19 carrying out this section.

20           “(c) STABILIZATION RESERVE FUND.—

21           “(1) ESTABLISHMENT.—

22           “(A) IN GENERAL.—There is established,  
23 within the Prescription Drug Account, a sta-  
24 bilization reserve fund in which the Adminis-  
25 trator shall deposit amounts on behalf of eligi-

1 ble entities in accordance with paragraph (2)  
2 and such amounts shall be made available by  
3 the Secretary for the use of eligible entities in  
4 contract year 2008 and subsequent contract  
5 years in accordance with paragraph (3).

6 “(B) REVERSION OF UNUSED AMOUNTS.—

7 Any amount in the stabilization reserve fund es-  
8 tablished under subparagraph (A) that is not  
9 expended by an eligible entity in accordance  
10 with paragraph (3) or that was deposited for  
11 the use of an eligible entity that no longer has  
12 a contract under this part shall revert for the  
13 use of the Prescription Drug Account.

14 “(2) DEPOSIT OF AMOUNTS FOR 5 YEARS.—

15 “(A) IN GENERAL.—If the target amount  
16 for a Medicare Prescription Drug plan for  
17 2006, 2007, 2008, 2009, or 2010 (as deter-  
18 mined under subsection (b)(4)(B)) exceeds the  
19 applicable costs for the plan for the year by  
20 more than 3 percent, then—

21 “(i) the entity offering the plan shall  
22 make a payment to the Administrator of  
23 an amount (or the Administrator shall oth-  
24 erwise recover from the plan an amount)  
25 equal to the portion of such excess that is

1 in excess of 3 percent of the target  
2 amount; and

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

8 “(B) APPLICABLE COSTS.—For purposes  
9 of subparagraph (A), the term ‘applicable costs’  
10 means, with respect to a Medicare Prescription  
11 Drug plan and year, an amount equal the sum  
12 of—

13 “(i) the allowable costs for the plan  
14 and year (as determined under subsection  
15 (b)(3)(A); and

16 “(ii) the total amount by which  
17 monthly payments to the plan were re-  
18 duced (or otherwise recovered from the  
19 plan) for the year under subsection  
20 (b)(2)(C).

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

23 “(A) IN GENERAL.—For any contract year  
24 beginning after 2007, an eligible entity offering  
25 a Medicare Prescription Drug plan may use

1 funds in the stabilization reserve fund in the  
2 Prescription Drug Account that were deposited  
3 in such fund on behalf of the entity to stabilize  
4 or reduce monthly plan premiums submitted  
5 under section 1860D–12(b)(3).

6 “(B) PROCEDURES.—The Administrator  
7 shall establish procedures for—

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

11 “(ii) making payments from the plan  
12 stabilization reserve fund in the Prescrip-  
13 tion Drug Account to eligible entities that  
14 inform the Secretary under section  
15 1860D–12(b)(5) of the entity’s intent to  
16 use funds in such reserve fund to reduce  
17 such premiums.

18 “(d) PORTION OF PAYMENTS OF MONTHLY PLAN  
19 PREMIUMS ATTRIBUTABLE TO ADMINISTRATIVE EX-  
20 PENSES TIED TO PERFORMANCE REQUIREMENTS.—

21 “(1) IN GENERAL.—The Administrator shall es-  
22 tablish procedures to adjust the portion of the pay-  
23 ments made to an entity under subsection (a) that  
24 are attributable to administrative expenses (as deter-  
25 mined pursuant to subsection (b)(4)(D)) to ensure

1 that the entity meets the performance requirements  
2 described in clauses (ii) and (iii) of section 1860D–  
3 13(e)(4)(B).

4 “(2) NO EFFECT ON ELIGIBLE BENE-  
5 FICIARIES.—No change in payments made by reason  
6 of this subsection shall affect the beneficiary obliga-  
7 tion under section 1860D–17 for the year in which  
8 such change in payments is made.

9 “(e) PAYMENT TERMS.—

10 “(1) ADMINISTRATOR PAYMENTS.—Payments  
11 to an entity offering a Medicare Prescription Drug  
12 plan under this section shall be made in a manner  
13 determined by the Administrator and based upon the  
14 manner in which payments are made under section  
15 1853(a) (relating to payments to MedicareAdvantage  
16 organizations).

17 “(2) PLAN PAYMENTS.—The Administrator  
18 shall establish a process for collecting (or otherwise  
19 recovering) amounts that an entity offering a Medi-  
20 care Prescription Drug plan is required to make to  
21 the Administrator under this section.

22 “(f) PAYMENTS TO MEDICAREADVANTAGE PLANS.—  
23 For provisions related to payments to MedicareAdvantage  
24 organizations offering MedicareAdvantage plans for quali-

1 fied prescription drug coverage made available under the  
2 plan, see section 1858A(c).

3 “(g) SECONDARY PAYER PROVISIONS.—The provi-  
4 sions of section 1862(b) shall apply to the benefits pro-  
5 vided under this part.

6 “COMPUTATION OF MONTHLY BENEFICIARY OBLIGATION

7 “SEC. 1860D–17. (a) BENEFICIARIES ENROLLED IN  
8 A MEDICARE PRESCRIPTION DRUG PLAN.—In the case of  
9 an eligible beneficiary enrolled under this part and in a  
10 Medicare Prescription Drug plan, the monthly beneficiary  
11 obligation for enrollment in such plan in a year shall be  
12 determined as follows:

13 “(1) MONTHLY PLAN PREMIUM EQUALS  
14 MONTHLY NATIONAL AVERAGE PREMIUM.—If the  
15 amount of the monthly plan premium approved by  
16 the Administrator under section 1860D–13 for a  
17 Medicare Prescription Drug plan for the year is  
18 equal to the monthly national average premium (as  
19 computed under section 1860D–15) for the area for  
20 the year, the monthly beneficiary obligation of the  
21 eligible beneficiary in that year shall be an amount  
22 equal to the applicable percent (as determined in  
23 subsection (c)) of the amount of such monthly na-  
24 tional average premium.

25 “(2) MONTHLY PLAN PREMIUM LESS THAN  
26 MONTHLY NATIONAL AVERAGE PREMIUM.—If the

1 amount of the monthly plan premium approved by  
2 the Administrator under section 1860D–13 for the  
3 Medicare Prescription Drug plan for the year is less  
4 than the monthly national average premium (as  
5 computed under section 1860D–15) for the area for  
6 the year, the monthly beneficiary obligation of the  
7 eligible beneficiary in that year shall be an amount  
8 equal to—

9 “(A) the applicable percent of the amount  
10 of such monthly national average premium;  
11 minus

12 “(B) the amount by which such monthly  
13 national average premium exceeds the amount  
14 of the monthly plan premium approved by the  
15 Administrator for the plan.

16 “(3) MONTHLY PLAN PREMIUM EXCEEDS  
17 MONTHLY NATIONAL AVERAGE PREMIUM.—If the  
18 amount of the monthly plan premium approved by  
19 the Administrator under section 1860D–13 for a  
20 Medicare Prescription Drug plan for the year ex-  
21 ceeds the monthly national average premium (as  
22 computed under section 1860D–15) for the area for  
23 the year, the monthly beneficiary obligation of the  
24 eligible beneficiary in that year shall be an amount  
25 equal to the sum of—

1           “(A) the applicable percent of the amount  
2 of such monthly national average premium; plus

3           “(B) the amount by which the monthly  
4 plan premium approved by the Administrator  
5 for the plan exceeds the amount of such month-  
6 ly national average premium.

7       “(b) BENEFICIARIES ENROLLED IN A  
8 MEDICAREADVANTAGE PLAN.—In the case of an eligible  
9 beneficiary that is enrolled in a MedicareAdvantage plan  
10 (except for an MSA plan or a private fee-for-service plan  
11 that does not provide qualified prescription drug cov-  
12 erage), the Medicare monthly beneficiary obligation for  
13 qualified prescription drug coverage shall be determined  
14 pursuant to section 1858A(d).

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

20           “(1) the numerator of which is 27.5 percent;  
21 and

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

24           “(A) the total reinsurance payments which  
25 the Administrator estimates will be made under

1 section 1860D–20 to qualifying entities de-  
2 scribed in subsection (e)(3) of such section dur-  
3 ing the year; divided by

4 “(B) the sum of—

5 “(i) the amount estimated under sub-  
6 paragraph (A) for the year; and

7 “(ii) the total payments which the Ad-  
8 ministrator estimates will be made under  
9 sections 1860D–16 and 1858A(c) during  
10 the year that relate to standard prescrip-  
11 tion drug coverage (or actuarially equiva-  
12 lent prescription drug coverage).

13 “COLLECTION OF MONTHLY BENEFICIARY OBLIGATION

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

16 “(1) IN GENERAL.—Subject to paragraph (2),  
17 the amount of the monthly beneficiary obligation  
18 (determined under section 1860D–17) applicable to  
19 an eligible beneficiary under this part (after applica-  
20 tion of any increase under section 1860D–  
21 2(b)(1)(A)) shall be collected and credited to the  
22 Prescription Drug Account in the same manner as  
23 the monthly premium determined under section  
24 1839 is collected and credited to the Federal Supple-  
25 mentary Medical Insurance Trust Fund under sec-  
26 tion 1840.

1           “(2) PROCEDURES FOR SPONSOR TO PAY OBLI-  
2           GATION ON BEHALF OF RETIREE.—The Adminis-  
3           trator shall establish procedures under which an eli-  
4           gible beneficiary enrolled in a Medicare Prescription  
5           Drug plan may elect to have the sponsor (as defined  
6           in paragraph (5) of section 1860D–20(e)) of employ-  
7           ment-based retiree health coverage (as defined in  
8           paragraph (4)(B) of such section) in which the bene-  
9           ficiary is enrolled pay the amount of the monthly  
10          beneficiary obligation applicable to the beneficiary  
11          under this part directly to the Administrator.

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

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

21                 “(2) periodically throughout the year, informa-  
22                 tion to update the information previously trans-  
23                 mitted under this paragraph for the year.

24          “(c) COLLECTION FOR BENEFICIARIES ENROLLED IN  
25          A MEDICAREADVANTAGE PLAN.—For provisions related

1 to the collection of the monthly beneficiary obligation for  
2 qualified prescription drug coverage under a  
3 Medicare Advantage plan, see section 1858A(e).

4 “PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-  
5 INCOME INDIVIDUALS

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

7 “(1) FULL PREMIUM SUBSIDY AND REDUCTION  
8 OF COST-SHARING FOR QUALIFIED MEDICARE BENE-  
9 FICIARIES.—In the case of a qualified medicare ben-  
10 eficiary (as defined in paragraph (4)(A))—

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

12 “(i) in subsection (c), by substituting  
13 ‘0 percent’ for the applicable percent that  
14 would otherwise apply under such sub-  
15 section; and

16 “(ii) in subsection (a)(3)(B), by sub-  
17 stituting ‘the amount of the monthly plan  
18 premium for the Medicare Prescription  
19 Drug plan with the lowest monthly plan  
20 premium in the area that the beneficiary  
21 resides’ for ‘the amount of such monthly  
22 national average premium’, but only if  
23 there is no Medicare Prescription Drug  
24 plan offered in the area in which the indi-  
25 vidual resides that has a monthly plan pre-  
26 mium for the year that is equal to or less

1 than the monthly national average pre-  
2 mium (as computed under section 1860D-  
3 15) for the area for the year;

4 “(B) the annual deductible applicable  
5 under section 1860D-6(c)(1) in a year shall be  
6 reduced to \$0;

7 “(C) section 1860D-6(c)(2) shall be ap-  
8 plied by substituting ‘2.5 percent’ for ‘50 per-  
9 cent’ each place it appears;

10 “(D) such individual shall be responsible  
11 for cost-sharing for the cost of any covered  
12 drug provided in the year (after the individual  
13 has reached the initial coverage limit described  
14 in section 1860D-6(c)(3) and before the indi-  
15 vidual has reached the annual out-of-pocket  
16 limit under section 1860D-6(c)(4)(A)), that is  
17 equal to 5.0 percent; and

18 “(E) section 1860D-6(c)(4)(A) shall be  
19 applied by substituting ‘2.5 percent’ for ‘10  
20 percent’.

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

24 “(2) FULL PREMIUM SUBSIDY AND REDUCTION  
25 OF COST-SHARING FOR SPECIFIED LOW INCOME

1 MEDICARE BENEFICIARIES AND QUALIFYING INDI-  
2 VIDUALS.—In the case of a specified low income  
3 medicare beneficiary (as defined in paragraph  
4 (4)(B)) or a qualifying individual (as defined in  
5 paragraph (4)(C))—

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

7 “(i) in subsection (c), by substituting  
8 ‘0 percent’ for the applicable percent that  
9 would otherwise apply under such sub-  
10 section; and

11 “(ii) in subsection (a)(3)(B), by sub-  
12 stituting ‘the amount of the monthly plan  
13 premium for the Medicare Prescription  
14 Drug plan with the lowest monthly plan  
15 premium in the area that the beneficiary  
16 resides’ for ‘the amount of such monthly  
17 national average premium’, but only if  
18 there is no Medicare Prescription Drug  
19 plan offered in the area in which the indi-  
20 vidual resides that has a monthly plan pre-  
21 mium for the year that is equal to or less  
22 than the monthly national average pre-  
23 mium (as computed under section 1860D–  
24 15) for the area for the year;

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

4           “(C) section 1860D–6(c)(2) shall be ap-  
5 plied by substituting ‘5.0 percent’ for ‘50 per-  
6 cent’ each place it appears;

7           “(D) such individual shall be responsible  
8 for cost-sharing for the cost of any covered  
9 drug provided in the year (after the individual  
10 has reached the initial coverage limit described  
11 in section 1860D–6(c)(3) and before the indi-  
12 vidual has reached the annual out-of-pocket  
13 limit under section 1860D–6(c)(4)(A)), that is  
14 equal to 10.0 percent; and

15           “(E) section 1860D–6(c)(4)(A) shall be  
16 applied by substituting ‘2.5 percent’ for ‘10  
17 percent’.

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

21           “(3) SLIDING SCALE PREMIUM SUBSIDY AND  
22 REDUCTION OF COST-SHARING FOR SUBSIDY-ELIGI-  
23 BLE INDIVIDUALS.—

1           “(A) IN GENERAL.—In the case of a sub-  
2           subsidy-eligible individual (as defined in paragraph  
3           (4)(D))—

4                   “(i) section 1860D–17 shall be ap-  
5                   plied—

6                           “(I) in subsection (c), by sub-  
7                           stituting ‘subsidy percent’ for the ap-  
8                           plicable percentage that would other-  
9                           wise apply under such subsection; and

10                           “(II) in subparagraphs (A) and  
11                           (B) of subsection (a)(3), by sub-  
12                           stituting ‘the amount of the monthly  
13                           plan premium for the Medicare Pre-  
14                           scription Drug plan with the lowest  
15                           monthly plan premium in the area  
16                           that the beneficiary resides’ for ‘the  
17                           amount of such monthly national av-  
18                           erage premium’, but only if there is  
19                           no Medicare Prescription Drug plan  
20                           offered in the area in which the indi-  
21                           vidual resides that has a monthly plan  
22                           premium for the year that is equal to  
23                           or less than the monthly national av-  
24                           erage premium (as computed under

1 section 1860D–15) for the area for  
2 the year;

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

5 “(I) for 2006, shall be reduced to  
6 \$50; and

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

13 “(iii) section 1860D–6(c)(2) shall be  
14 applied by substituting ‘10.0 percent’ for  
15 ‘50 percent’ each place it appears;

16 “(iv) such individual shall be respon-  
17 sible for cost-sharing for the cost of any  
18 covered drug provided in the year (after  
19 the individual has reached the initial cov-  
20 erage limit described in section 1860D–  
21 6(c)(3) and before the individual has  
22 reached the annual out-of-pocket limit  
23 under section 1860D–6(c)(4)(A)), that is  
24 equal to 20.0 percent; and

1           “(v) such individual shall be respon-  
2           sible for the cost-sharing described in sec-  
3           tion 1860D–6(c)(4)(A).

4           In no case may the application of clause (i) re-  
5           sult in a monthly beneficiary obligation that is  
6           below 0.

7           “(B) SUBSIDY PERCENT DEFINED.—For  
8           purposes of subparagraph (A)(i), the term ‘sub-  
9           sidy percent’ means, with respect to a State, a  
10          percent determined on a linear sliding scale  
11          ranging from—

12           “(i) 0 percent with respect to a sub-  
13          sidy-eligible individual residing in the State  
14          whose income does not exceed 135 percent  
15          of the poverty line; to

16           “(ii) the highest percentage that  
17          would otherwise apply under section  
18          1860D–17 in the service area in which the  
19          subsidy-eligible individual resides, in the  
20          case of a subsidy-eligible individual resid-  
21          ing in the State whose income equals 160  
22          percent of the poverty line.

23          “(4) DEFINITIONS.—In this part:

24           “(A) QUALIFIED MEDICARE BENE-  
25          FICIARY.—Subject to subparagraph (H), the

1 term ‘qualified medicare beneficiary’ means an  
2 individual who—

3 “(i) is enrolled under this part, in-  
4 cluding an individual who is enrolled under  
5 a MedicareAdvantage plan; and

6 “(ii) is described in section  
7 1905(p)(1).

8 “(B) SPECIFIED LOW INCOME MEDICARE  
9 BENEFCIARY.—Subject to subparagraph (H),  
10 the term ‘specified low income medicare bene-  
11 ficiary’ means an individual who—

12 “(i) is enrolled under this part, in-  
13 cluding an individual who is enrolled under  
14 a MedicareAdvantage plan; and

15 “(ii) is described in section  
16 1902(a)(10)(E)(iii).

17 “(C) QUALIFYING INDIVIDUAL.—Subject  
18 to subparagraph (H), the term ‘qualifying indi-  
19 vidual’ means an individual who—

20 “(i) is enrolled under this part, in-  
21 cluding an individual who is enrolled under  
22 a MedicareAdvantage plan; and

23 “(ii) is described in section  
24 1902(a)(10)(E)(iv) (without regard to any

1            termination of the application of such sec-  
2            tion under title XIX).

3            “(D) SUBSIDY-ELIGIBLE INDIVIDUAL.—  
4            Subject to subparagraph (H), the term ‘sub-  
5            sidy-eligible individual’ means an individual—

6                    “(i) who is enrolled under this part,  
7                    including an individual who is enrolled  
8                    under a MedicareAdvantage plan

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

11                   “(iii) who is not—

12                            “(I) a qualified medicare bene-  
13                            ficiary;

14                            “(II) a specified low-income  
15                            medicare beneficiary; or

16                            “(III) a qualifying individual.

17            “(E) POVERTY LINE.—The term ‘poverty  
18            line’ has the meaning given such term in sec-  
19            tion 673(2) of the Community Services Block  
20            Grant Act (42 U.S.C. 9902(2)), including any  
21            revision required by such section.

22            “(F) ELIGIBILITY DETERMINATIONS.—Be-  
23            ginning on November 1, 2005, the determina-  
24            tion of whether an individual residing in a State  
25            is an individual described in subparagraph (A),

1 (B), (C), or (D) and, for purposes of paragraph  
2 (3), the amount of an individual's income, shall  
3 be determined under the State medicaid plan  
4 for the State under section 1935(a). In the case  
5 of a State that does not operate such a med-  
6 icaid plan (either under title XIX or under a  
7 statewide waiver granted under section 1115),  
8 such determination shall be made under ar-  
9 rangements made by the Administrator.

10 (G) NONAPPLICATION TO DUAL ELIGIBLE  
11 INDIVIDUALS AND TERRITORIAL RESIDENTS.—  
12 In the case of an individual who is not a resi-  
13 dent of the 50 States or the District of Colum-  
14 bia—

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

17 (ii) such individuals may be provided  
18 with medical assistance for covered out-  
19 patient drugs (as such term is defined for  
20 purposes of section 1927) in accordance  
21 with section 1935 under the State med-  
22 icaid program under title XIX.

23 (b) RULES IN APPLYING COST-SHARING SUB-  
24 SIDIES.—Nothing in this section shall be construed as pre-  
25 venting an eligible entity offering a Medicare Prescription

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

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

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

15 “(2) the entity or organization involved reduces  
16 the cost-sharing otherwise imposed by the amount of  
17 the applicable subsidy and submits to the Adminis-  
18 trator information on the amount of such reduction;  
19 and

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

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

1 arial value of the subsidies and with appropriate adjust-  
2 ments to reflect differences in the risks actually involved.

3 “(d) RELATION TO MEDICAID PROGRAM.—For provi-  
4 sions providing for eligibility determinations and addi-  
5 tional Federal payments for expenditures related to pro-  
6 viding prescription drug coverage for territorial residents  
7 under the medicaid program, see section 1935.

8 “REINSURANCE PAYMENTS FOR EXPENSES INCURRED IN  
9 PROVIDING PRESCRIPTION DRUG COVERAGE ABOVE  
10 THE ANNUAL OUT-OF-POCKET THRESHOLD

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

12 “(1) IN GENERAL.—Subject to section 1860D–  
13 21(b), the Administrator shall provide in accordance  
14 with this section for payment to a qualifying entity  
15 of the reinsurance payment amount (as specified in  
16 subsection (c)(1)) for costs incurred by the entity in  
17 providing prescription drug coverage for a qualifying  
18 covered individual after the individual has reached  
19 the annual out-of-pocket threshold specified in sec-  
20 tion 1860D–6(c)(4)(B) for the year.

21 “(2) BUDGET AUTHORITY.—This section con-  
22 stitutes budget authority in advance of appropria-  
23 tions Acts and represents the obligation of the Ad-  
24 ministrator to provide for the payment of amounts  
25 provided under this section.

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

5           “(1) IN GENERAL.—Each qualifying entity shall  
6 notify the Administrator of the following with re-  
7 spect to a qualifying covered individual for a cov-  
8 erage year:

9           “(A) TOTAL ACTUAL COSTS.—The total  
10 amount (if any) of costs that the qualifying en-  
11 tity incurred in providing prescription drug cov-  
12 erage for the individual in the year after the in-  
13 dividual had reached the annual out-of-pocket  
14 threshold specified in section 1860D–6(c)(4)(B)  
15 for the year.

16           “(B) ACTUAL COSTS FOR SPECIFIC  
17 DRUGS.—With respect to the total amount  
18 under subparagraph (A) for the year, a break-  
19 down of—

20           “(i) each covered drug that con-  
21 stitutes a portion of such amount;

22           “(ii) the negotiated price for the  
23 qualifying entity for each such drug;

24           “(iii) the number of prescriptions; and

1                   “(iv) the average beneficiary coinsur-  
2                   ance rate for a each covered drug that con-  
3                   stitutes a portion of such amount.

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

7                   “(A) administrative expenses incurred in  
8                   providing the coverage described in paragraph  
9                   (1)(A); or

10                   “(B) amounts expended on providing addi-  
11                   tional prescription drug coverage pursuant to  
12                   section 1860D–6(a)(2).

13                   “(3) RESTRICTION ON USE OF INFORMATION.—  
14                   The restriction specified in section 1860D–  
15                   16(b)(7)(B) shall apply to information disclosed or  
16                   obtained pursuant to the provisions of this section.

17                   “(c) REINSURANCE PAYMENT AMOUNT.—

18                   “(1) IN GENERAL.—The reinsurance payment  
19                   amount under this subsection for a qualifying cov-  
20                   ered individual for a coverage year is an amount  
21                   equal to 80 percent of the allowable costs (as speci-  
22                   fied in paragraph (2)) incurred by the qualifying en-  
23                   tity with respect to the individual and year.

24                   “(2) ALLOWABLE COSTS.—

1           “(A) IN GENERAL.—In the case of a quali-  
2           fying entity that has incurred costs described in  
3           subsection (b)(1)(A) with respect to a quali-  
4           fying covered individual for a coverage year, the  
5           Administrator shall establish the allowable costs  
6           for the individual and year. Such allowable  
7           costs shall be equal to the amount described in  
8           such subsection for the individual and year, ad-  
9           justed under subparagraph (B).

10           “(B) REPRICING OF COSTS IF ACTUAL  
11           COSTS EXCEED AVERAGE COSTS.—The Admin-  
12           istrator shall reduce the amount described in  
13           subsection (b)(1)(A) with respect to a quali-  
14           fying covered individual for a coverage year to  
15           the extent such amount is based on costs of  
16           specific covered drugs furnished under the plan  
17           in the year (as specified under subsection  
18           (b)(1)(B)) that are greater than the average  
19           cost for the covered drug for the year (as deter-  
20           mined under section 1860D–16(b)(3)(A)).

21           “(d) PAYMENT METHODS.—

22           “(1) IN GENERAL.—Payments under this sec-  
23           tion shall be based on such a method as the Admin-  
24           istrator determines. The Administrator may estab-  
25           lish a payment method by which interim payments

1 of amounts under this section are made during a  
2 year based on the Administrator’s best estimate of  
3 amounts that will be payable after obtaining all of  
4 the information.

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

8 “(e) DEFINITIONS.—In this section:

9 “(1) COVERAGE YEAR.—The term ‘coverage  
10 year’ means a calendar year in which covered drugs  
11 are dispensed if a claim for payment is made under  
12 the plan for such drugs, regardless of when the  
13 claim is paid.

14 “(2) QUALIFYING COVERED INDIVIDUAL.—The  
15 term ‘qualifying covered individual’ means an indi-  
16 vidual who—

17 “(A) is enrolled in this part and in a Medi-  
18 care Prescription Drug plan;

19 “(B) is enrolled in this part and in a  
20 MedicareAdvantage plan (except for an MSA  
21 plan or a private fee-for-service plan that does  
22 not provide qualified prescription drug cov-  
23 erage); or

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

4           “(3) QUALIFYING ENTITY.—The term ‘quali-  
5           fying entity’ means any of the following that has en-  
6           tered into an agreement with the Administrator to  
7           provide the Administrator with such information as  
8           may be required to carry out this section:

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

11          “(B) A MedicareAdvantage organization  
12          offering a MedicareAdvantage plan under part  
13          C (except for an MSA plan or a private fee-for-  
14          service plan that does not provide qualified pre-  
15          scription drug coverage).

16          “(C) The sponsor of a qualified retiree pre-  
17          scription drug plan.

18          “(4) QUALIFIED RETIREE PRESCRIPTION DRUG  
19          PLAN.—

20          “(A) IN GENERAL.—The term ‘qualified  
21          retiree prescription drug plan’ means employ-  
22          ment-based retiree health coverage if, with re-  
23          spect to a qualifying covered individual who is  
24          covered under the plan, the following require-  
25          ments are met:

1           “(i) ASSURANCE.—The sponsor of the  
2           plan shall annually attest, and provide  
3           such assurances as the Administrator may  
4           require, that the coverage meets or exceeds  
5           the requirements for qualified prescription  
6           drug coverage.

7           “(ii) DISCLOSURE OF INFORMA-  
8           TION.—The sponsor complies with the re-  
9           quirements described in clauses (i) and (ii)  
10          of section 1860D–16(b)(7)(A).

11          “(B) EMPLOYMENT-BASED RETIREE  
12          HEALTH COVERAGE.—The term ‘employment-  
13          based retiree health coverage’ means health in-  
14          surance or other coverage, whether provided by  
15          voluntary insurance coverage or pursuant to  
16          statutory or contractual obligation, of health  
17          care costs for retired individuals (or for such in-  
18          dividuals and their spouses and dependents)  
19          based on their status as former employees or  
20          labor union members.

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

1 “DIRECT SUBSIDY FOR SPONSOR OF A QUALIFIED RE-  
2 TIREE PRESCRIPTION DRUG PLAN FOR PLAN EN-  
3 ROLLEES ELIGIBLE FOR, BUT NOT ENROLLED IN,  
4 THIS PART

5 “SEC. 1860D–21. (a) DIRECT SUBSIDY.—

6 “(1) IN GENERAL.—The Administrator shall  
7 provide for the payment to a sponsor of a qualified  
8 retiree prescription drug plan (as defined in section  
9 1860D–20(e)(4)) for each qualifying covered indi-  
10 vidual (described in subparagraph (C) of section  
11 1860D–20(e)(2)) enrolled in the plan for each  
12 month for which such individual is so enrolled.

13 “(2) AMOUNT OF PAYMENT.—

14 “(A) IN GENERAL.—The amount of the  
15 payment under paragraph (1) shall be an  
16 amount equal to the direct subsidy percent de-  
17 termined for the year of the monthly national  
18 average premium for the area for the year (de-  
19 termined under section 1860D–15), as adjusted  
20 using the risk adjusters that apply to the stand-  
21 ard prescription drug coverage published under  
22 section 1860D–11.

23 “(B) DIRECT SUBSIDY PERCENT.—For  
24 purposes of subparagraph (A), the term ‘direct

1           subsidy percent’ means the percentage equal  
2           to—

3                           “(i) 100 percent; minus

4                           “(ii) the applicable percent for the  
5                           year (as determined under section 1860D–  
6                           17(c).

7           “(b) PAYMENT METHODS.—

8                           “(1) IN GENERAL.—Payments under this sec-  
9                           tion shall be based on such a method as the Admin-  
10                           istrator determines. The Administrator may estab-  
11                           lish a payment method by which interim payments  
12                           of amounts under this section are made during a  
13                           year based on the Administrator’s best estimate of  
14                           amounts that will be payable after obtaining all of  
15                           the information.

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

19                           “Subpart 3—Miscellaneous Provisions

20                           “PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL  
21                           SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

22                           “SEC. 1860D–25. (a) ESTABLISHMENT.—

23                           “(1) IN GENERAL.—There is created within the  
24                           Federal Supplementary Medical Insurance Trust  
25                           Fund established by section 1841 an account to be

1 known as the ‘Prescription Drug Account’ (in this  
2 section referred to as the ‘Account’).

3 “(2) FUNDS.—The Account shall consist of  
4 such gifts and bequests as may be made as provided  
5 in section 201(i)(1), and such amounts as may be  
6 deposited in, or appropriated to, the Account as pro-  
7 vided in this part.

8 “(3) SEPARATE FROM REST OF TRUST FUND.—  
9 Funds provided under this part to the Account shall  
10 be kept separate from all other funds within the  
11 Federal Supplementary Medical Insurance Trust  
12 Fund.

13 “(b) PAYMENTS FROM ACCOUNT.—

14 “(1) IN GENERAL.—The Managing Trustee  
15 shall pay from time to time from the Account such  
16 amounts as the Secretary certifies are necessary to  
17 make payments to operate the program under this  
18 part, including—

19 “(A) payments to eligible entities under  
20 section 1860D–16;

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

23 “(C) reinsurance payments under section  
24 1860D–20;



1           “(1) IN GENERAL.—In the case of a Medicare  
2 Prescription Drug plan offered by an eligible entity  
3 that is a sponsor (as defined in paragraph (5) of  
4 section 1860D–20(e)) of employment-based retiree  
5 health coverage (as defined in paragraph (4)(B) of  
6 such section), notwithstanding any other provision of  
7 this part and in accordance with regulations of the  
8 Administrator, the entity offering the plan may re-  
9 strict the enrollment of eligible beneficiaries enrolled  
10 under this part to eligible beneficiaries who are en-  
11 rolled in such coverage.

12           “(2) LIMITATION.—The sponsor of the employ-  
13 ment-based retiree health coverage described in  
14 paragraph (1) may not offer enrollment in the Medi-  
15 care Prescription Drug plan described in such para-  
16 graph based on the health status of eligible bene-  
17 ficiaries enrolled for such coverage.

18           “(b) COORDINATION WITH STATE PHARMACEUTICAL  
19 ASSISTANCE PROGRAMS.—

20           “(1) IN GENERAL.—An eligible entity offering a  
21 Medicare Prescription Drug plan, or a  
22 MedicareAdvantage organization offering a  
23 MedicareAdvantage plan (other than an MSA plan  
24 or a private fee-for-service plan that does not pro-  
25 vide qualified prescription drug coverage), may enter

1 into an agreement with a State pharmaceutical as-  
2 sistance program described in paragraph (2) to co-  
3 ordinate the coverage provided under the plan with  
4 the assistance provided under the State pharma-  
5 ceutical assistance program.

6 “(2) STATE PHARMACEUTICAL ASSISTANCE  
7 PROGRAM DESCRIBED.—For purposes of paragraph  
8 (1), a State pharmaceutical assistance program de-  
9 scribed in this paragraph is a program that has been  
10 established pursuant to a waiver under section 1115  
11 or otherwise.

12 “(c) REGULATIONS TO CARRY OUT THIS PART.—

13 “(1) AUTHORITY FOR INTERIM FINAL REGULA-  
14 TIONS.—The Secretary may promulgate initial regu-  
15 lations implementing this part in interim final form  
16 without prior opportunity for public comment.

17 “(2) FINAL REGULATIONS.—A final regulation  
18 reflecting public comments must be published within  
19 1 year of the interim final regulation promulgated  
20 under paragraph (1).”.

21 (b) CONFORMING AMENDMENTS TO FEDERAL SUP-  
22 PLEMENTARY MEDICAL INSURANCE TRUST FUND.—Sec-  
23 tion 1841 (42 U.S.C. 1395t) is amended—

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

1 (A) by striking “and” before “such  
2 amounts”; and

3 (B) by inserting before the period the fol-  
4 lowing: “, and such amounts as may be depos-  
5 ited in, or appropriated to, the Prescription  
6 Drug Account established by section 1860D-  
7 25”;

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

13 (3) in subsection (h), by inserting after  
14 “1840(d)” the following: “and sections 1860D-18  
15 and 1858A(e) (in which case the payments shall be  
16 made from the Prescription Drug Account in the  
17 Trust Fund)”;

18 (4) in subsection (i), by inserting after “section  
19 1840(b)(1)” the following: “, sections 1860D-18  
20 and 1858A(e) (in which case the payments shall be  
21 made from the Prescription Drug Account in the  
22 Trust Fund),”.

23 (c) CONFORMING REFERENCES TO PREVIOUS PART  
24 D.—Any reference in law (in effect before the date of en-  
25 actment of this Act) to part D of title XVIII of the Social

1 Security Act is deemed a reference to part F of such title  
2 (as in effect after such date).

3 (d) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not  
4 later than 6 months after the date of the enactment of  
5 this Act, the Secretary shall submit to the appropriate  
6 committees of Congress a legislative proposal providing for  
7 such technical and conforming amendments in the law as  
8 are required by the provisions of this Act.

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

13 (a) STUDY.—The Administrator of the Center for  
14 Medicare Choices (as established under section 1808 of  
15 the Social Security Act, as added by section 301(a)) shall  
16 conduct a study on the need for rules relating to permit-  
17 ting individuals who are enrolled under part B of title  
18 XVIII of the Social Security Act but are not entitled to  
19 benefits under part A of such title to buy into the medicare  
20 voluntary prescription drug delivery program under part  
21 D of such title (as so added).

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

1 islation that the Administrator determines to be appro-  
2 priate as a result of such study.

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

5 (a) RULES RELATING TO MEDIGAP POLICIES THAT  
6 PROVIDE PRESCRIPTION DRUG COVERAGE.—Section  
7 1882 (42 U.S.C. 1395ss) is amended by adding at the end  
8 the following new subsection:

9 “(v) RULES RELATING TO MEDIGAP POLICIES THAT  
10 PROVIDE PRESCRIPTION DRUG COVERAGE.—

11 “(1) PROHIBITION ON SALE, ISSUANCE, AND  
12 RENEWAL OF POLICIES THAT PROVIDE PRESCRIP-  
13 TION DRUG COVERAGE TO PART D ENROLLEES.—

14 “(A) IN GENERAL.—Notwithstanding any  
15 other provision of law, on or after January 1,  
16 2006, no medicare supplemental policy that  
17 provides coverage of expenses for prescription  
18 drugs may be sold, issued, or renewed under  
19 this section to an individual who is enrolled  
20 under part D.

21 “(B) PENALTIES.—The penalties described  
22 in subsection (d)(3)(A)(ii) shall apply with re-  
23 spect to a violation of subparagraph (A).

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

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

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

17                           “(ii) may not discriminate in the prie-  
18                           ing of such policy, because of health sta-  
19                           tus, claims experience, receipt of health  
20                           care, or medical condition; and

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

24                   in the case of an individual described in sub-  
25                   paragraph (B) who seeks to enroll under the

1 policy during the open enrollment period estab-  
2 lished under section 1860D–2(b)(2) and who  
3 submits evidence that they meet the require-  
4 ments under subparagraph (B) along with the  
5 application for such medicare supplemental pol-  
6 icy.

7 “(B) INDIVIDUAL DESCRIBED.—An indi-  
8 vidual described in this subparagraph is an in-  
9 dividual who—

10 “(i) enrolls in the medicare prescrip-  
11 tion drug delivery program under part D;  
12 and

13 “(ii) at the time of such enrollment  
14 was enrolled and terminates enrollment in  
15 a medicare supplemental policy which has  
16 a benefit package classified as ‘H’, ‘I’, or  
17 ‘J’ (including the benefit package classified  
18 as ‘J’ with a high deductible feature, as  
19 described in section 1882(p)(11)) under  
20 the standards referred to in subparagraph  
21 (A)(i) or terminates enrollment in a policy  
22 to which such standards do not apply but  
23 which provides benefits for prescription  
24 drugs.

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

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

17                 “(A) the ability to enroll in a new medicare  
18                 supplemental policy pursuant to paragraph (2);  
19                 and

20                 “(B) the fact that, so long as such indi-  
21                 vidual retains coverage under such policy, the  
22                 individual shall be ineligible for coverage of pre-  
23                 scription drugs under part D.”.

24          (b) RULE OF CONSTRUCTION.—

1           (1) IN GENERAL.—Nothing in this Act shall be  
2           construed to require an issuer of a medicare supple-  
3           mental policy under section 1882 of the Social Secu-  
4           rity Act (42 U.S.C. 1395rr) to participate as an eli-  
5           gible entity under part D of such Act, as added by  
6           section 101, as a condition for issuing such policy.

7           (2) PROHIBITION ON STATE REQUIREMENT.—A  
8           State may not require an issuer of a medicare sup-  
9           plemental policy under section 1882 of the Social  
10          Security Act (42 U.S.C. 1395rr) to participate as an  
11          eligible entity under part D of such Act, as added  
12          by section 101, as a condition for issuing such pol-  
13          icy.

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

16          (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-IN-  
17          COME SUBSIDIES.—Section 1902(a) (42 U.S.C. 1396a(a))  
18          is amended—

19               (1) by striking “and” at the end of paragraph  
20               (64);

21               (2) by striking the period at the end of para-  
22               graph (65) and inserting “; and”; and

23               (3) by inserting after paragraph (65) the fol-  
24               lowing new paragraph:

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

3           (b) NEW SECTION.—

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

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

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

10           “SPECIAL PROVISIONS RELATING TO MEDICARE

11                   PRESCRIPTION DRUG BENEFIT

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

18                   “(1) DETERMINATION OF ELIGIBILITY FOR  
19                   TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE  
20                   CARD PROGRAM FOR ELIGIBLE LOW-INCOME BENE-  
21                   FICIARIES.—For purposes of section 1807A, submit  
22                   to the Secretary an eligibility plan under which the  
23                   State—

24                           “(A) establishes eligibility standards con-  
25                           sistent with the provisions of that section;

1           “(B) establishes procedures for providing  
2           presumptive eligibility for eligible low-income  
3           beneficiaries (as defined in section 1807A(i)(2))  
4           under that section in a manner that is similar  
5           to the manner in which presumptive eligibility  
6           is provided to children and pregnant women  
7           under this title;

8           “(C) makes determinations of eligibility  
9           and income for purposes of identifying eligible  
10          low-income beneficiaries (as so defined) under  
11          that section; and

12          “(D) communicates to the Secretary deter-  
13          minations of eligibility or discontinuation of eli-  
14          gibility under that section for purposes of noti-  
15          fying prescription drug card sponsors under  
16          that section of the identity of eligible medicare  
17          low-income beneficiaries.

18          “(2) DETERMINATION OF ELIGIBILITY FOR  
19          PREMIUM AND COST-SHARING SUBSIDIES UNDER  
20          PART D OF TITLE XVIII FOR LOW-INCOME INDIVID-  
21          UALS.—Beginning November 1, 2005, for purposes  
22          of section 1860D–19—

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

1           “(B) establish procedures for providing  
2 presumptive eligibility for individuals eligible for  
3 subsidies under that section in a manner that  
4 is similar to the manner in which presumptive  
5 eligibility is provided to children and pregnant  
6 women under this title;

7           “(C) inform the Administrator of the Cen-  
8 ter for Medicare Choices of such determinations  
9 in cases in which such eligibility is established;  
10 and

11           “(D) otherwise provide such Administrator  
12 with such information as may be required to  
13 carry out part D of title XVIII (including sec-  
14 tion 1860D–19).

15           “(3) AGREEMENT TO ESTABLISH INFORMATION  
16 AND ENROLLMENT SITES AT SOCIAL SECURITY  
17 FIELD OFFICES.—Enter into an agreement with the  
18 Commissioner of Social Security to use all Social Se-  
19 curity field offices located in the State as informa-  
20 tion and enrollment sites for making the eligibility  
21 determinations required under paragraphs (1) and  
22 (2).

23           “(b) FEDERAL SUBSIDY OF ADMINISTRATIVE  
24 COSTS.—

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

9                   “(A) such calendar quarters occurring in  
10                   fiscal year 2004 or 2005, ‘75 percent’ shall be  
11                   substituted for ‘50 per centum’;

12                   “(B) calendar quarters occurring in fiscal  
13                   year 2006, ‘70 percent’ shall be substituted for  
14                   ‘50 per centum’;

15                   “(C) calendar quarters occurring in fiscal  
16                   year 2007, ‘65 percent’ shall be substituted for  
17                   ‘50 per centum’; and

18                   “(D) calendar quarters occurring in fiscal  
19                   year 2008 or any fiscal year thereafter, ‘60 per-  
20                   cent’ shall be substituted for ‘50 per centum’.

21           “(2) 100 PERCENT MATCH FOR ELIGIBILITY  
22           DETERMINATIONS FOR SUBSIDY-ELIGIBLE INDIVID-  
23           UALS.—In the case of amounts expended by a State  
24           on or after November 1, 2005, to determine whether  
25           an individual is a subsidy-eligible individual for pur-

1 poses of section 1860D–19, such expenditures shall  
2 be reimbursed under section 1903(a)(7) by sub-  
3 stituting ‘100 percent’ for ‘50 per centum’.

4 “(3) ENHANCED MATCH FOR UPDATES OR IM-  
5 PROVEMENTS TO ELIGIBILITY DETERMINATION SYS-  
6 TEMS.—With respect to calendar quarters occurring  
7 in fiscal year 2004, 2005, or 2006, the Secretary, in  
8 addition to amounts otherwise paid under section  
9 1903(a), shall pay to each State which has a plan  
10 approved under this title, for each such quarter an  
11 amount equal to 90 percent of so much of the sums  
12 expended during such quarter as are attributable to  
13 the design, development, acquisition, or installation  
14 of improved eligibility determination systems (includ-  
15 ing hardware and software for such systems) in  
16 order to carry out the requirements of subsection (a)  
17 and section 1807A(h)(1) and to the design, develop-  
18 ment, acquisition or installation of improved data  
19 systems necessary to track prescription drug spend-  
20 ing for purposes of implementing section 1935(c).  
21 No payment shall be made to a State under the pre-  
22 ceding sentence unless the State’s improved eligi-  
23 bility determination system—

24 “(A) satisfies such standards for improve-  
25 ment as the Secretary may establish; and

1           “(B) complies, and is compatible, with the  
2 standards established under part C of title XI  
3 and any regulations promulgated under section  
4 264(c) of the Health Insurance Portability and  
5 Accountability Act of 1996 (42 U.S.C. 1320d–  
6 2 note).

7           “(4) COORDINATION.—The State shall provide  
8 the Secretary with such information as may be nec-  
9 essary to properly allocate expenditures described in  
10 paragraph (1), (2), or (3) that may otherwise be  
11 made for similar eligibility determinations or expend-  
12 itures.

13           “(c) FEDERAL ASSUMPTION OF MEDICAID PRE-  
14 SCRIPTION DRUG COSTS FOR DUALY ELIGIBLE BENE-  
15 FICIARIES.—

16           “(1) IN GENERAL.—For purpose of section  
17 1903(a)(1) for a State for a calendar quarter in a  
18 year (beginning with 2006) the amount computed  
19 under this subsection is equal to the product of the  
20 following:

21           “(A) STANDARD PRESCRIPTION DRUG COV-  
22 ERAGE UNDER MEDICARE.—With respect to in-  
23 dividuals who are residents of the State, who  
24 are entitled to, or enrolled for, benefits under  
25 part A of title XVIII, or are enrolled under part

1 B of title XVIII and are receiving medical as-  
2 sistance under subparagraph (A)(i), (A)(ii), or  
3 (C) of section 1902(a)(10) (or as the result of  
4 the application of section 1902(f)) that includes  
5 covered outpatient drugs (as defined for pur-  
6 poses of section 1927) under the State plan  
7 under this title (including such a plan operated  
8 under a waiver under section 1115)—

9 “(i) the total amounts attributable to  
10 such individuals in the quarter under sec-  
11 tion 1860D–19 (relating to premium and  
12 cost-sharing subsidies for low-income medi-  
13 care beneficiaries); and

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

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

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

- 1 “(i) 2006 is 100 percent;  
2 “(ii) 2007 is 95 percent;  
3 “(iii) 2008 or 2009, is 90 percent;  
4 “(iv) 2010 is 85 percent; or  
5 “(v) 2011, 2012, or 2013 is 80 per-  
6 cent.

7 “(d) MEDICAID AS SECONDARY PAYOR.—In the case  
8 of an individual who is entitled to a Medicare Prescription  
9 Drug plan under part D or drug coverage under a  
10 MedicareAdvantage plan, and medical assistance including  
11 covered outpatient drugs under this title, medical assist-  
12 ance shall continue to be provided under this title for cov-  
13 ered outpatient drugs to the extent payment is not made  
14 under the Medicare Prescription Drug plan or a  
15 MedicareAdvantage plan.

16 “(e) TREATMENT OF TERRITORIES.—

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

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

22 “(B) if the State establishes a plan de-  
23 scribed in paragraph (2), the amount otherwise  
24 determined under section 1108(f) (as increased  
25 under section 1108(g)) for the State shall be

1 further increased by the amount specified in  
2 paragraph (3).

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

5 “(A) provides medical assistance with re-  
6 spect to the provision of covered drugs (as de-  
7 fined in section 1860D(a)(2)) to individuals de-  
8 scribed in subparagraph (A), (B), (C), or (D)  
9 of section 1860D–19(a)(3); and

10 “(B) ensures that additional amounts re-  
11 ceived by the State that are attributable to the  
12 operation of this subsection are used only for  
13 such assistance.

14 “(3) INCREASED AMOUNT.—

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

18 “(i) the aggregate amount specified in  
19 subparagraph (B); and

20 “(ii) the amount specified in section  
21 1108(g)(1) for that State, divided by the  
22 sum of the amounts specified in such sec-  
23 tion for all such States.

1           “(B) AGGREGATE AMOUNT.—The aggre-  
2           gate amount specified in this subparagraph  
3           for—

4                   “(i) the last 3 quarters of fiscal year  
5                   2006, is equal to \$22,500,000;

6                   “(ii) fiscal year 2007, is equal to  
7                   \$30,000,000; and

8                   “(iii) any subsequent fiscal year, is  
9                   equal to the aggregate amount specified in  
10                  this subparagraph for the previous fiscal  
11                  year increased by the annual percentage  
12                  increase specified in section 1860D–6(c)(5)  
13                  for the calendar year beginning in such fis-  
14                  cal year.

15           “(4) NONAPPLICATION.—Section 1927(d)(2)(E)  
16           shall not apply to a State described in paragraph (1)  
17           for purposes of providing medical assistance de-  
18           scribed in paragraph (2)(A).

19           “(5) REPORT.—The Secretary shall submit to  
20           Congress a report on the application of this sub-  
21           section and may include in the report such rec-  
22           ommendations as the Secretary deems appropriate.

23           “(f) DEFINITION.—For purposes of this section, the  
24           term ‘subsidy-eligible individual’ has the meaning given

1 that term in subparagraph (D) of section 1860D-  
2 19(a)(4).”.

3 (2) CONFORMING AMENDMENTS.—

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

9 (B) Section 1108(f) (42 U.S.C. 1308(f)) is  
10 amended by inserting “and section  
11 1935(e)(1)(B)” after “Subject to subsection  
12 (g)”.

13 (3) AMENDMENT TO BEST PRICE.—Section  
14 1927(e)(1)(C)(i) (42 U.S.C. 1396r-8(e)(1)(C)(i)), as  
15 amended by section 111(b), is amended—

16 (A) by striking “and” at the end of sub-  
17 clause (IV);

18 (B) by striking the period at the end of  
19 subclause (V) and inserting “; and”; and

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

22 “(VI) any prices charged which  
23 are negotiated under a Medicare Pre-  
24 scription Drug plan under part D of  
25 title XVIII with respect to covered

1 drugs, under a Medicare Advantage  
2 plan under part C of such title with  
3 respect to such drugs, or under a  
4 qualified retiree prescription drug  
5 plan (as defined in section 1860D–  
6 20(f)(1)) with respect to such drugs,  
7 on behalf of eligible beneficiaries (as  
8 defined in section 1860D(a)(3)).”.

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

12 (1) IN GENERAL.—Section 1902(a)(10)(E)(iv)  
13 (42 U.S.C. 1396a(a)(10)(E)(iv)) is amended to read  
14 as follows:

15 “(iv) subject to sections 1933 and  
16 1905(p)(4), for making medical assistance  
17 available (but only for premiums payable with  
18 respect to months during the period beginning  
19 with January 1998, and ending with December  
20 2008) for medicare cost-sharing described in  
21 section 1905(p)(3)(A)(ii) for individuals who  
22 would be qualified medicare beneficiaries de-  
23 scribed in section 1905(p)(1) but for the fact  
24 that their income exceeds the income level es-  
25 tablished by the State under section 1905(p)(2)

1 and is at least 120 percent, but less than 135  
2 percent, of the official poverty line (referred to  
3 in such section) for a family of the size involved  
4 and who are not otherwise eligible for medical  
5 assistance under the State plan;”.

6 (2) TOTAL AMOUNT AVAILABLE FOR ALLOCA-  
7 TION.—Section 1933(c) (42 U.S.C. 1396u–3(c)) is  
8 amended—

9 (A) in paragraph (1)—

10 (i) in subparagraph (D), by striking  
11 “and” at the end;

12 (ii) in subparagraph (E)—

13 (I) by striking “fiscal year 2002”  
14 and inserting “each of fiscal years  
15 2002 through 2008”; and

16 (II) by striking the period and  
17 inserting “; and”; and

18 (iii) by adding at the end the fol-  
19 lowing new subparagraph:

20 “(F) the first quarter of fiscal year 2009,  
21 \$100,000,000.”; and

22 (B) in paragraph (2)(A), by striking “the  
23 sum of” and all that follows through  
24 “1902(a)(10)(E)(iv)(II) in the State; to” and  
25 inserting “twice the total number of individuals

1 described in section 1902(a)(10)(E)(iv) in the  
2 State; to”.

3 (d) OUTREACH BY THE COMMISSIONER OF SOCIAL  
4 SECURITY.—Section 1144 (42 U.S.C. 1320b–14) is  
5 amended—

6 (1) in the section heading, by inserting “AND  
7 SUBSIDIES FOR LOW-INCOME INDIVIDUALS UNDER  
8 TITLE XVIII” after “COST-SHARING”;

9 (2) in subsection (a)—

10 (A) in paragraph (1)—

11 (i) in subparagraph (A), by inserting  
12 “for the transitional prescription drug as-  
13 sistance card program under section  
14 1807A, or for premium and cost-sharing  
15 subsidies under section 1860D–19” before  
16 the semicolon; and

17 (ii) in subparagraph (B), by inserting  
18 “, program, and subsidies” after “medical  
19 assistance”; and

20 (B) in paragraph (2)—

21 (i) in the matter preceding subpara-  
22 graph (A), by inserting “, the transitional  
23 prescription drug assistance card program  
24 under section 1807A, or premium and

1 cost-sharing subsidies under section  
2 1860D–19” after “assistance”; and

3 (ii) in subparagraph (A), by striking  
4 “such eligibility” and inserting “eligibility  
5 for medicare cost-sharing under the med-  
6 icaid program”; and

7 (3) in subsection (b)—

8 (A) in paragraph (1)(A), by inserting “,  
9 for the transitional prescription drug assistance  
10 card program under section 1807A, or for pre-  
11 mium and cost-sharing subsidies for low-income  
12 individuals under section 1860D–19” after  
13 “1933”; and

14 (B) in paragraph (2), by inserting “, pro-  
15 gram, and subsidies” after “medical assist-  
16 ance”.

17 **SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF**

18 **MEDICARE PAYMENT ADVISORY COMMISSION**

19 **(MEDPAC).**

20 (a) EXPANSION OF MEMBERSHIP.—

21 (1) IN GENERAL.—Section 1805(c) (42 U.S.C.  
22 1395b–6(c)) is amended—

23 (A) in paragraph (1), by striking “17” and  
24 inserting “19”; and

1 (B) in paragraph (2)(B), by inserting “ex-  
2 perts in the area of pharmacology and prescrip-  
3 tion drug benefit programs,” after “other  
4 health professionals,”.

5 (2) INITIAL TERMS OF ADDITIONAL MEM-  
6 BERS.—

7 (A) IN GENERAL.—For purposes of stag-  
8 gering the initial terms of members of the  
9 Medicare Payment Advisory Commission under  
10 section 1805(c)(3) of the Social Security Act  
11 (42 U.S.C. 1395b–6(c)(3)), the initial terms of  
12 the 2 additional members of the Commission  
13 provided for by the amendment under para-  
14 graph (1)(A) are as follows:

15 (i) One member shall be appointed for  
16 1 year.

17 (ii) One member shall be appointed  
18 for 2 years.

19 (B) COMMENCEMENT OF TERMS.—Such  
20 terms shall begin on January 1, 2005.

21 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42  
22 U.S.C. 1395b–6(b)(2)) is amended by adding at the end  
23 the following new subparagraph:

24 “(D) VOLUNTARY PRESCRIPTION DRUG  
25 DELIVERY PROGRAM.—Specifically, the Com-

1 mission shall review, with respect to the vol-  
2 untary prescription drug delivery program  
3 under part D, competition among eligible enti-  
4 ties offering Medicare Prescription Drug plans  
5 and beneficiary access to such plans and cov-  
6 ered drugs, particularly in rural areas.”.

7 **SEC. 106. STUDY REGARDING VARIATIONS IN SPENDING**  
8 **AND DRUG UTILIZATION.**

9 (a) **STUDY.**—The Secretary shall study on an ongo-  
10 ing basis variations in spending and drug utilization under  
11 part D of title XVIII of the Social Security Act for covered  
12 drugs to determine the impact of such variations on pre-  
13 miums imposed by eligible entities offering Medicare Pre-  
14 scription Drug plans under that part. In conducting such  
15 study, the Secretary shall examine the impact of geo-  
16 graphic adjustments of the monthly national average pre-  
17 mium under section 1860D–15 of such Act on—

18 (1) maximization of competition under part D  
19 of title XVIII of such Act; and

20 (2) the ability of eligible entities offering Medi-  
21 care Prescription Drug plans to contain costs for  
22 covered drugs.

23 (b) **REPORT.**—Beginning with 2007, the Secretary  
24 shall submit annual reports to Congress on the study re-  
25 quired under subsection (a).

1 **Subtitle B—Medicare Prescription**  
 2 **Drug Discount Card and Transi-**  
 3 **tional Assistance for Low-In-**  
 4 **come Beneficiaries**

5 **SEC. 111. MEDICARE PRESCRIPTION DRUG DISCOUNT**  
 6 **CARD AND TRANSITIONAL ASSISTANCE FOR**  
 7 **LOW-INCOME BENEFICIARIES.**

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

10 “MEDICARE PRESCRIPTION DRUG DISCOUNT CARD  
 11 ENDORSEMENT PROGRAM

12 “SEC. 1807. (a) ESTABLISHMENT.—There is estab-  
 13 lished a medicare prescription drug discount card endorse-  
 14 ment program under which the Secretary shall—

15 “(1) endorse prescription drug discount card  
 16 programs offered by prescription drug card sponsors  
 17 that meet the requirements of this section; and

18 “(2) make available to eligible beneficiaries in-  
 19 formation regarding such endorsed programs.

20 “(b) ELIGIBILITY, ELECTION OF PROGRAM, AND EN-  
 21 ROLLMENT FEES.—

22 “(1) ELIGIBILITY AND ELECTION OF PRO-  
 23 GRAM.—

1           “(A) IN GENERAL.—Subject to subpara-  
2 graph (B), the Secretary shall establish proce-  
3 dures—

4                   “(i) for identifying eligible bene-  
5 ficiaries; and

6                   “(ii) under which such beneficiaries  
7 may make an election to enroll in any pre-  
8 scription drug discount card program en-  
9 dored under this section and disenroll  
10 from such a program.

11           “(B) LIMITATION.—An eligible beneficiary  
12 may not be enrolled in more than 1 prescription  
13 drug discount card program at any time.

14           “(2) ENROLLMENT FEES.—

15                   “(A) IN GENERAL.—A prescription drug  
16 card sponsor may charge an annual enrollment  
17 fee to each eligible beneficiary enrolled in a pre-  
18 scription drug discount card program offered by  
19 such sponsor.

20                   “(B) AMOUNT.—No enrollment fee  
21 charged under subparagraph (A) may exceed  
22 \$25.

23                   “(C) UNIFORM ENROLLMENT FEE.—A  
24 prescription drug card sponsor shall ensure that  
25 the enrollment fee for a prescription drug dis-

1 count card program endorsed under this section  
2 is the same for all eligible medicare bene-  
3 ficiaries enrolled in the program.

4 “(D) COLLECTION.—Any enrollment fee  
5 shall be collected by the prescription drug card  
6 sponsor.

7 “(c) PROVIDING INFORMATION TO ELIGIBLE BENE-  
8 FICIARIES.—

9 “(1) PROMOTION OF INFORMED CHOICE.—

10 “(A) BY THE SECRETARY.—In order to  
11 promote informed choice among endorsed pre-  
12 scription drug discount card programs, the Sec-  
13 retary shall provide for the dissemination of in-  
14 formation which compares the costs and bene-  
15 fits of such programs. Such dissemination shall  
16 be coordinated with the dissemination of edu-  
17 cational information on other medicare options.

18 “(B) BY PRESCRIPTION DRUG CARD SPON-  
19 SORS.—Each prescription drug card sponsor  
20 shall make available to each eligible beneficiary  
21 (through the Internet and otherwise) informa-  
22 tion—

23 “(i) that the Secretary identifies as  
24 being necessary to promote informed  
25 choice among endorsed prescription drug

1 discount card programs by eligible bene-  
2 ficiaries, including information on enroll-  
3 ment fees, negotiated prices for prescrip-  
4 tion drugs charged to beneficiaries, and  
5 services relating to prescription drugs of-  
6 fered under the program; and

7 “(ii) on how any formulary used by  
8 such sponsor functions.

9 “(2) USE OF MEDICARE TOLL-FREE NUMBER.—

10 The Secretary shall provide through the 1–800–  
11 MEDICARE toll free telephone number for the re-  
12 ceipt and response to inquiries and complaints con-  
13 cerning the medicare prescription drug discount card  
14 endorsement program established under this section  
15 and prescription drug discount card programs en-  
16 dorsed under such program.

17 “(d) BENEFICIARY PROTECTIONS.—

18 “(1) IN GENERAL.—Each prescription drug dis-  
19 count card program endorsed under this section  
20 shall meet such requirements as the Secretary iden-  
21 tifies to protect and promote the interest of eligible  
22 beneficiaries, including requirements that—

23 “(A) relate to appeals by eligible bene-  
24 ficiaries and marketing practices; and

1           “(B) ensure that beneficiaries are not  
2           charged more than the lower of the negotiated  
3           retail price or the usual and customary price.

4           “(2) ENSURING PHARMACY ACCESS.—Each pre-  
5           scription drug card sponsor offering a prescription  
6           drug discount card program endorsed under this sec-  
7           tion shall secure the participation in its network of  
8           a sufficient number of pharmacies that dispense  
9           (other than by mail order) drugs directly to patients  
10          to ensure convenient access (as determined by the  
11          Secretary and including adequate emergency access)  
12          for enrolled beneficiaries. Such standards shall take  
13          into account reasonable distances to pharmacy serv-  
14          ices in both urban and rural areas.

15          “(3) QUALITY ASSURANCE.—Each prescription  
16          drug card sponsor offering a prescription drug dis-  
17          count card program endorsed under this section  
18          shall have in place adequate procedures for assuring  
19          that quality service is provided to eligible bene-  
20          ficiaries enrolled in a prescription drug discount  
21          card program offered by such sponsor.

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

1 ble beneficiaries enrolled in a prescription drug dis-  
2 count card program endorsed under this section, the  
3 prescription drug card sponsor shall have in place  
4 procedures to safeguard the privacy of any individ-  
5 ually identifiable beneficiary information in a man-  
6 ner that the Secretary determines is consistent with  
7 the Federal regulations (concerning the privacy of  
8 individually identifiable health information) promul-  
9 gated under section 264(c) of the Health Insurance  
10 Portability and Accountability Act of 1996.

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

16 “(6) PRICES.—

17 “(A) AVOIDANCE OF HIGH PRICED  
18 DRUGS.—A prescription drug card sponsor may  
19 not recommend switching an eligible beneficiary  
20 to a drug with a higher negotiated price absent  
21 a recommendation by a licensed health profes-  
22 sional that there is a clinical indication with re-  
23 spect to the patient for such a switch.

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

1 prescription drug discount card program en-  
2 dored under this section may not change more  
3 frequently than once every 60 days.

4 “(e) PRESCRIPTION DRUG BENEFITS.—

5 “(1) IN GENERAL.—Each prescription drug  
6 card sponsor may only provide benefits that relate to  
7 prescription drugs (as defined in subsection (i)(2))  
8 under a prescription drug discount card program en-  
9 dored under this section.

10 “(2) SAVINGS TO ELIGIBLE BENEFICIARIES.—

11 “(A) IN GENERAL.—Subject to subpara-  
12 graph (D), each prescription drug card sponsor  
13 shall provide eligible beneficiaries who enroll in  
14 a prescription drug discount card program of-  
15 fered by such sponsor that is endorsed under  
16 this section with access to negotiated prices  
17 used by the sponsor with respect to prescription  
18 drugs dispensed to eligible beneficiaries.

19 “(B) INAPPLICABILITY OF MEDICAID BEST  
20 PRICE RULES.—The requirements of section  
21 1927 relating to manufacturer best price shall  
22 not apply to the negotiated prices for prescrip-  
23 tion drugs made available under a prescription  
24 drug discount card program endorsed under  
25 this section.

1           “(C) GUARANTEED ACCESS TO NEGO-  
2           TIATED PRICES.—The Secretary, in consulta-  
3           tion with the Inspector General of the Depart-  
4           ment of Health and Human Services, shall es-  
5           tablish procedures to ensure that eligible bene-  
6           ficiaries have access to the negotiated prices for  
7           prescription drugs provided under subparagraph  
8           (A).

9           “(D) APPLICATION OF FORMULARY RE-  
10          STRICTIONS.—A drug prescribed for an eligible  
11          beneficiary that would otherwise be a covered  
12          drug under this section shall not be so consid-  
13          ered under a prescription drug discount card  
14          program if the program excludes the drug  
15          under a formulary.

16          “(3) BENEFICIARY SERVICES.—Each prescrip-  
17          tion drug discount card program endorsed under  
18          this section shall provide pharmaceutical support  
19          services, such as education, counseling, and services  
20          to prevent adverse drug interactions.

21          “(4) DISCOUNT CARDS.—Each prescription  
22          drug card sponsor shall issue a card to eligible bene-  
23          ficiaries enrolled in a prescription drug discount  
24          card program offered by such sponsor that the bene-

1        ficiary may use to obtain benefits under the pro-  
2        gram.

3        “(f) SUBMISSION OF APPLICATIONS FOR ENDORSE-  
4        MENT AND APPROVAL.—

5                “(1) SUBMISSION OF APPLICATIONS FOR EN-  
6        DORSEMENT.—Each prescription drug card sponsor  
7        that seeks endorsement of a prescription drug dis-  
8        count card program under this section shall submit  
9        to the Secretary, at such time and in such manner  
10       as the Secretary may specify, such information as  
11       the Secretary may require.

12               “(2) APPROVAL.—The Secretary shall review  
13       the information submitted under paragraph (1) and  
14       shall determine whether to endorse the prescription  
15       drug discount card program to which such informa-  
16       tion relates. The Secretary may not approve a pro-  
17       gram unless the program and prescription drug card  
18       sponsor offering the program comply with the re-  
19       quirements under this section.

20               “(g) REQUIREMENTS ON DEVELOPMENT AND APPLI-  
21       CATION OF FORMULARIES.—If a prescription drug card  
22       sponsor offering a prescription drug discount card pro-  
23       gram uses a formulary, the following requirements must  
24       be met:

1           “(1) PHARMACY AND THERAPEUTIC (P&T) COM-  
2           MITTEE.—

3           “(A) IN GENERAL.—The eligible entity  
4           must establish a pharmacy and therapeutic  
5           committee that develops and reviews the for-  
6           mulary.

7           “(B) COMPOSITION.—A pharmacy and  
8           therapeutic committee shall include at least 1  
9           academic expert, at least 1 practicing physician,  
10          and at least 1 practicing pharmacist, all of  
11          whom have expertise in the care of elderly or  
12          disabled persons, and a majority of the mem-  
13          bers of such committee shall consist of individ-  
14          uals who are a practicing physician or a prac-  
15          ticing pharmacist (or both).

16          “(2) FORMULARY DEVELOPMENT.—In devel-  
17          oping and reviewing the formulary, the committee  
18          shall base clinical decisions on the strength of sci-  
19          entific evidence and standards of practice, including  
20          assessing peer-reviewed medical literature, such as  
21          randomized clinical trials, pharmacoeconomic stud-  
22          ies, outcomes research data, and such other informa-  
23          tion as the committee determines to be appropriate.

24          “(3) INCLUSION OF DRUGS IN ALL THERA-  
25          PEUTIC CATEGORIES AND CLASSES.—

1           “(A) IN GENERAL.—The formulary must  
2 include drugs within each therapeutic category  
3 and class of covered outpatient drugs (as de-  
4 fined by the Secretary), although not nec-  
5 essarily for all drugs within such categories and  
6 classes.

7           “(B) REQUIREMENT.—In defining thera-  
8 peutic categories and classes of covered out-  
9 patient drugs pursuant to subparagraph (A),  
10 the Secretary shall use the compendia referred  
11 to section 1927(g)(1)(B)(i) or other recognized  
12 sources for categorizing drug therapeutic cat-  
13 egories and classes.

14           “(4) PROVIDER EDUCATION.—The committee  
15 shall establish policies and procedures to educate  
16 and inform health care providers concerning the for-  
17 mulary.

18           “(5) NOTICE BEFORE REMOVING DRUGS FROM  
19 FORMULARY.—Any removal of a drug from a for-  
20 mulary shall take effect only after appropriate notice  
21 is made available to beneficiaries and pharmacies.

22           “(h) FRAUD AND ABUSE PREVENTION.—

23           “(1) IN GENERAL.—The Secretary shall provide  
24 appropriate oversight to ensure compliance of en-  
25 dorsed programs with the requirements of this sec-

1       tion, including verification of the negotiated prices  
2       and services provided.

3               “(2) DISQUALIFICATION FOR ABUSIVE PRAC-  
4       TICES.—The Secretary may implement intermediate  
5       sanctions and may revoke the endorsement of a pro-  
6       gram that the Secretary determines no longer meets  
7       the requirements of this section or that has engaged  
8       in false or misleading marketing practices.

9               “(3) AUTHORITY WITH RESPECT TO CIVIL  
10       MONEY PENALTIES.—The Secretary may impose a  
11       civil money penalty in an amount not to exceed  
12       \$10,000 for any violation of this section. The provi-  
13       sions of section 1128A (other than subsections (a)  
14       and (b)) shall apply to a civil money penalty under  
15       the previous sentence in the same manner as such  
16       provisions apply to a penalty or proceeding under  
17       section 1128A(a).

18               “(4) REPORTING TO SECRETARY.—Each pre-  
19       scription drug card sponsor offering a prescription  
20       drug discount card program endorsed under this sec-  
21       tion shall report information relating to program  
22       performance, use of prescription drugs by eligible  
23       beneficiaries enrolled in the program, financial infor-  
24       mation of the sponsor, and such other information  
25       as the Secretary may specify. The Secretary may not

1 disclose any proprietary data reported under this  
2 paragraph.

3 “(5) DRUG UTILIZATION REVIEW.—The Sec-  
4 retary may use claims data from parts A and B for  
5 purposes of conducting a drug utilization review pro-  
6 gram.

7 “(i) DEFINITIONS.—In this section:

8 “(1) ELIGIBLE BENEFICIARY.—

9 “(A) IN GENERAL.—The term ‘eligible  
10 beneficiary’ means an individual who—

11 “(i) is entitled to, or enrolled for, ben-  
12 efits under part A and enrolled under part  
13 B; and

14 “(ii) is not a dual eligible individual  
15 (as defined in subparagraph (B)).

16 “(B) DUAL ELIGIBLE INDIVIDUAL.—

17 “(i) IN GENERAL.—The term ‘dual el-  
18 ible individual’ means an individual who  
19 is—

20 “(I) enrolled under title XIX or  
21 under a waiver under section 1115 of  
22 the requirements of such title for  
23 medical assistance that includes but is  
24 limited solely to covered outpatient

1 drugs (as such term is defined for  
2 purposes of section 1927); and

3 “(II) entitled to benefits under  
4 part A and enrolled under part B.

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

8 “(2) PRESCRIPTION DRUG.—

9 “(A) IN GENERAL.—Except as provided in  
10 subparagraph (B), the term ‘prescription drug’  
11 means—

12 “(i) a drug that may be dispensed  
13 only upon a prescription and that is de-  
14 scribed in clause (i) or (ii) of subparagraph  
15 (A) of section 1927(k)(2); or

16 “(ii) a biological product or insulin de-  
17 scribed in subparagraph (B) or (C) of such  
18 section,

19 and such term includes a vaccine licensed under  
20 section 351 of the Public Health Service Act  
21 and any use of a covered outpatient drug for a  
22 medically accepted indication (as defined in sec-  
23 tion 1927(k)(6)).

24 “(B) EXCLUSIONS.—The term ‘prescrip-  
25 tion drug’ does not include drugs or classes of

1 drugs, or their medical uses, which may be ex-  
2 cluded from coverage or otherwise restricted  
3 under section 1927(d)(2), other than subpara-  
4 graph (E) thereof (relating to smoking ces-  
5 sation agents), or under section 1927(d)(3).

6 “(3) NEGOTIATED PRICE.—The term ‘nego-  
7 tiated price’ includes all discounts, direct or indirect  
8 subsidies, rebates, price concessions, and direct or  
9 indirect remunerations.

10 “(4) PRESCRIPTION DRUG CARD SPONSOR.—  
11 The term ‘prescription drug card sponsor’ means  
12 any entity with demonstrated experience and exper-  
13 tise in operating a prescription drug discount card  
14 program, an insurance program that provides cov-  
15 erage for prescription drugs, or a similar program  
16 that the Secretary determines to be appropriate to  
17 provide eligible beneficiaries with the benefits under  
18 a prescription drug discount card program endorsed  
19 by the Secretary under this section, including—

20 “(A) a pharmaceutical benefit management  
21 company;

22 “(B) a wholesale or retail pharmacist deliv-  
23 ery system;

1           “(C) an insurer (including an insurer that  
2           offers medicare supplemental policies under sec-  
3           tion 1882);

4           “(D) any other entity; or

5           “(E) any combination of the entities de-  
6           scribed in subparagraphs (A) through (D).

7   “TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE CARD  
8   PROGRAM FOR ELIGIBLE LOW-INCOME BENEFICIARIES

9       “SEC. 1807A. (a) ESTABLISHMENT.—

10           “(1) IN GENERAL.—There is established a pro-  
11           gram under which the Secretary shall award con-  
12           tracts to prescription drug card sponsors offering a  
13           prescription drug discount card that has been en-  
14           dorsed by the Secretary under section 1807 under  
15           which such sponsors shall offer a prescription drug  
16           assistance card program to eligible low-income bene-  
17           ficiaries in accordance with the requirements of this  
18           section.

19           “(2) APPLICATION OF DISCOUNT CARD PROVI-  
20           SIONS.—Except as otherwise provided in this sec-  
21           tion, the provisions of section 1807 shall apply to  
22           the program established under this section.

23           “(b) ELIGIBILITY, ELECTION OF PROGRAM, AND EN-  
24           ROLLMENT FEES.—

25           “(1) ELIGIBILITY AND ELECTION OF PRO-  
26           GRAM.—

1           “(A) IN GENERAL.—Subject to the suc-  
2 ceeding provisions of this paragraph, the enroll-  
3 ment procedures established under section  
4 1807(b)(1)(A)(ii) shall apply for purposes of  
5 this section.

6           “(B) ENROLLMENT OF ANY ELIGIBLE  
7 LOW-INCOME BENEFICIARY.—Each prescription  
8 drug card sponsor offering a prescription drug  
9 assistance card program under this section shall  
10 permit any eligible low-income beneficiary to en-  
11 roll in such program if it serves the geographic  
12 area in which the beneficiary resides.

13           “(C) SIMULTANEOUS ENROLLMENT IN  
14 PRESCRIPTION DRUG DISCOUNT CARD PRO-  
15 GRAM.—An eligible low-income beneficiary who  
16 enrolls in a prescription drug assistance card  
17 program offered by a prescription drug card  
18 sponsor under this section shall be simulta-  
19 neously enrolled in a prescription drug discount  
20 card program offered by such sponsor.

21           “(2) WAIVER OF ENROLLMENT FEES.—

22           “(A) IN GENERAL.—A prescription drug  
23 card sponsor may not charge an enrollment fee  
24 to any eligible low-income beneficiary enrolled

1 in a prescription drug discount card program  
2 offered by such sponsor.

3 “(B) PAYMENT BY SECRETARY.—Under a  
4 contract awarded under subsection (f)(2), the  
5 Secretary shall pay to each prescription drug  
6 card sponsor an amount equal to any enroll-  
7 ment fee charged under section 1807(b)(2)(A)  
8 on behalf of each eligible low-income beneficiary  
9 enrolled in a prescription drug discount card  
10 program under paragraph (1)(C) offered by  
11 such sponsor.

12 “(c) ADDITIONAL BENEFICIARY PROTECTIONS.—

13 “(1) PROVIDING INFORMATION TO ELIGIBLE  
14 LOW-INCOME BENEFICIARIES.—In addition to the in-  
15 formation provided to eligible beneficiaries under  
16 section 1807(c), the prescription drug card sponsor  
17 shall—

18 “(A) periodically notify each eligible low-in-  
19 come beneficiary enrolled in a prescription drug  
20 assistance card program offered by such spon-  
21 sor of the amount of coverage for prescription  
22 drugs remaining under subsection (d)(2)(A);  
23 and

24 “(B) notify each eligible low-income bene-  
25 ficiary enrolled in a prescription drug assistance

1 card program offered by such sponsor of the  
2 grievance and appeals processes under the pro-  
3 gram.

4 “(2) CONVENIENT ACCESS IN LONG-TERM CARE  
5 FACILITIES.—For purposes of determining whether  
6 convenient access has been provided under section  
7 1807(d)(2) with respect to eligible low-income bene-  
8 ficiaries enrolled in a prescription drug assistance  
9 card program, the Secretary may only make a deter-  
10 mination that such access has been provided if an  
11 appropriate arrangement is in place for eligible low-  
12 income beneficiaries who are in a long-term care fa-  
13 cility (as defined by the Secretary) to receive pre-  
14 scription drug benefits under the program.

15 “(3) COORDINATION OF BENEFITS.—

16 “(A) IN GENERAL.—The Secretary shall  
17 establish procedures under which eligible low-in-  
18 come beneficiaries who are enrolled for coverage  
19 described in subparagraph (B) and enrolled in  
20 a prescription drug assistance card program  
21 have access to the prescription drug benefits  
22 available under such program.

23 “(B) COVERAGE DESCRIBED.—Coverage  
24 described in this subparagraph is as follows:

1                   “(i) Coverage of prescription drugs  
2                   under a State pharmaceutical assistance  
3                   program.

4                   “(ii) Enrollment in a  
5                   Medicare+Choice plan under part C.

6                   “(4) GRIEVANCE MECHANISM.—Each prescrip-  
7                   tion drug card sponsor with a contract under this  
8                   section shall provide in accordance with section  
9                   1852(f) meaningful procedures for hearing and re-  
10                  solving grievances between the prescription drug  
11                  card sponsor (including any entity or individual  
12                  through which the prescription drug card sponsor  
13                  provides covered benefits) and enrollees in a pre-  
14                  scription drug assistance card program offered by  
15                  such sponsor.

16                  “(5) APPLICATION OF COVERAGE DETERMINA-  
17                  TION AND RECONSIDERATION PROVISIONS.—

18                  “(A) IN GENERAL.—The requirements of  
19                  paragraphs (1) through (3) of section 1852(g)  
20                  shall apply with respect to covered benefits  
21                  under a prescription drug assistance card pro-  
22                  gram under this section in the same manner as  
23                  such requirements apply to a Medicare+Choice  
24                  organization with respect to benefits it offers  
25                  under a Medicare+Choice plan under part C.

1           “(B) REQUEST FOR REVIEW OF TIERED  
2           FORMULARY DETERMINATIONS.—In the case of  
3           a prescription drug assistance card program of-  
4           fered by a prescription drug card sponsor that  
5           provides for tiered pricing for drugs included  
6           within a formulary and provides lower prices for  
7           preferred drugs included within the formulary,  
8           an eligible low-income beneficiary who is en-  
9           rolled in the program may request coverage of  
10          a nonpreferred drug under the terms applicable  
11          for preferred drugs if the prescribing physician  
12          determines that the preferred drug for treat-  
13          ment of the same condition is not as effective  
14          for the eligible low-income beneficiary or has  
15          adverse effects for the eligible low-income bene-  
16          ficiary.

17          “(C) FORMULARY DETERMINATIONS.—An  
18          eligible low-income beneficiary who is enrolled  
19          in a prescription drug assistance card program  
20          offered by a prescription drug card sponsor may  
21          appeal to obtain coverage for a covered drug  
22          that is not on a formulary of the entity if the  
23          prescribing physician determines that the for-  
24          mulary drug for treatment of the same condi-  
25          tion is not as effective for the eligible low-in-

1           come beneficiary or has adverse effects for the  
2           eligible low-income beneficiary.

3           “(6) APPEALS.—

4                   “(A) IN GENERAL.—Subject to subpara-  
5                   graph (B), a prescription drug card sponsor  
6                   shall meet the requirements of paragraphs (4)  
7                   and (5) of section 1852(g) with respect to  
8                   drugs not included on any formulary in a simi-  
9                   lar manner (as determined by the Secretary) as  
10                  such requirements apply to a Medicare+Choice  
11                  organization with respect to benefits it offers  
12                  under a Medicare+Choice plan under part C.

13                  “(B) FORMULARY DETERMINATIONS.—An  
14                  eligible low-income beneficiary who is enrolled  
15                  in a prescription drug assistance card program  
16                  offered by a prescription drug card sponsor may  
17                  appeal to obtain coverage for a covered drug  
18                  that is not on a formulary of the entity if the  
19                  prescribing physician determines that the for-  
20                  mulary drug for treatment of the same condi-  
21                  tion is not as effective for the eligible low-in-  
22                  come beneficiary or has adverse effects for the  
23                  eligible low-income beneficiary.

24                  “(C) APPEALS AND EXCEPTIONS TO APPLI-  
25                  CATION.—The prescription drug card sponsor

1           must have, as part of the appeals process under  
2           this paragraph, a process for timely appeals for  
3           denials of coverage based on the application of  
4           the formulary.

5           “(d) PRESCRIPTION DRUG BENEFITS.—

6                 “(1) IN GENERAL.—Subject to paragraph (5),  
7           all the benefits available under a prescription drug  
8           discount card program offered by a prescription  
9           drug card sponsor and endorsed under section 1807  
10          shall be available to eligible low-income beneficiaries  
11          enrolled in a prescription drug assistance card pro-  
12          gram offered by such sponsor.

13                 “(2) ASSISTANCE FOR ELIGIBLE LOW-INCOME  
14          BENEFICIARIES.—

15                 “(A) \$600 ANNUAL ASSISTANCE.—Subject  
16          to subparagraphs (B) and (C) and paragraph  
17          (5), each prescription drug card sponsor with a  
18          contract under this section shall provide cov-  
19          erage for the first \$600 of expenses for pre-  
20          scription drugs incurred during each calendar  
21          year by an eligible low-income beneficiary en-  
22          rolled in a prescription drug assistance card  
23          program offered by such sponsor.

24                 “(B) COINSURANCE.—

1           “(i) IN GENERAL.—The prescription  
2           drug card sponsor shall determine an  
3           amount of coinsurance to collect from each  
4           eligible low-income beneficiary enrolled in a  
5           prescription drug assistance card program  
6           offered by such sponsor for which coverage  
7           is available under subparagraph (A).

8           “(ii) AMOUNT.—The amount of coin-  
9           surance collected under clause (i) shall be  
10          at least 10 percent of the negotiated price  
11          of each prescription drug dispensed to an  
12          eligible low-income beneficiary.

13          “(iii) CONSTRUCTION.—Amounts col-  
14          lected under clause (i) shall not be counted  
15          against the total amount of coverage avail-  
16          able under subparagraph (A).

17          “(C) REDUCTION FOR LATE ENROLL-  
18          MENT.—For each month during a calendar  
19          quarter in which an eligible low-income bene-  
20          ficiary is not enrolled in a prescription drug as-  
21          sistance card program offered by a prescription  
22          drug card sponsor with a contract under this  
23          section, the amount of assistance available  
24          under subparagraph (A) shall be reduced by  
25          \$50.

1           “(D) CREDITING OF UNUSED BENEFITS  
2           TOWARD FUTURE YEARS.—The dollar amount  
3           of coverage described in subparagraph (A) shall  
4           be increased by any amount of coverage de-  
5           scribed in such subparagraph that was not used  
6           during the previous calendar year.

7           “(E) WAIVER TO ENSURE PROVISION OF  
8           BENEFIT.—The Secretary may waive such re-  
9           quirements of this section and section 1807 as  
10          may be necessary to ensure that each eligible  
11          low-income beneficiaries has access to the as-  
12          sistance described in subparagraph (A).

13          “(3) ADDITIONAL DISCOUNTS.—A prescription  
14          drug card sponsor with a contract under this section  
15          shall provide each eligible low-income beneficiary en-  
16          rolled in a prescription drug assistance program of-  
17          fered by the sponsor with access to negotiated prices  
18          that reflect a minimum average discount of at least  
19          20 percent of the average wholesale price for pre-  
20          scription drugs covered under that program.

21          “(4) ASSISTANCE CARDS.—Each prescription  
22          drug card sponsor shall permit eligible low-income  
23          beneficiaries enrolled in a prescription drug assist-  
24          ance card program offered by such sponsor to use

1 the discount card issued under section 1807(e)(4) to  
2 obtain benefits under the program.

3 “(5) APPLICATION OF FORMULARY RESTRIC-  
4 TIONS.—A drug prescribed for an eligible low-income  
5 beneficiary that would otherwise be a covered drug  
6 under this section shall not be so considered under  
7 a prescription drug assistance card program if the  
8 program excludes the drug under a formulary and  
9 such exclusion is not successfully resolved under  
10 paragraph (4), (5), or (6) of subsection (c).

11 “(e) REQUIREMENTS FOR PRESCRIPTION DRUG  
12 CARD SPONSORS THAT OFFER PRESCRIPTION DRUG AS-  
13 SISTANCE CARD PROGRAMS.—

14 “(1) IN GENERAL.—Each prescription drug  
15 card sponsor shall—

16 “(A) process claims made by eligible low-  
17 income beneficiaries;

18 “(B) negotiate with brand name and ge-  
19 neric prescription drug manufacturers and oth-  
20 ers for low prices on prescription drugs;

21 “(C) track individual beneficiary expendi-  
22 tures in a format and periodicity specified by  
23 the Secretary; and

24 “(D) perform such other functions as the  
25 Secretary may assign.

1           “(2) DATA EXCHANGES.—Each prescription  
2 drug card sponsor shall receive data exchanges in a  
3 format specified by the Secretary and shall maintain  
4 real-time beneficiary files.

5           “(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL  
6 PRICES FOR EQUIVALENT DRUGS.—The prescription  
7 drug card sponsor offering the prescription drug as-  
8 sistance card program shall provide that each phar-  
9 macy or other dispenser that arranges for the dis-  
10 pensing of a covered drug shall inform the eligible  
11 low-income beneficiary at the time of purchase of the  
12 drug of any differential between the price of the pre-  
13 scribed drug to the enrollee and the price of the low-  
14 est priced generic drug covered under the plan that  
15 is therapeutically equivalent and bioequivalent and  
16 available at such pharmacy or other dispenser.

17           “(f) SUBMISSION OF BIDS AND AWARDING OF CON-  
18 TRACTS.—

19           “(1) SUBMISSION OF BIDS.—Each prescription  
20 drug card sponsor that seeks to offer a prescription  
21 drug assistance card program under this section  
22 shall submit to the Secretary, at such time and in  
23 such manner as the Secretary may specify, such in-  
24 formation as the Secretary may require.

1           “(2) AWARDING OF CONTRACTS.—The Sec-  
2           retary shall review the information submitted under  
3           paragraph (1) and shall determine whether to award  
4           a contract to the prescription drug card sponsor of-  
5           fering the program to which such information re-  
6           lates. The Secretary may not approve a program un-  
7           less the program and prescription drug card sponsor  
8           offering the program comply with the requirements  
9           under this section.

10           “(3) NUMBER OF CONTRACTS.—There shall be  
11           no limit on the number of prescription drug card  
12           sponsors that may be awarded contracts under para-  
13           graph (2).

14           “(4) CONTRACT PROVISIONS.—

15           “(A) DURATION.—A contract awarded  
16           under paragraph (2) shall be for the lifetime of  
17           the program under this section.

18           “(B) WITHDRAWAL.—A prescription drug  
19           card sponsor that desires to terminate the con-  
20           tract awarded under paragraph (2) may termi-  
21           nate such contract without penalty if such spon-  
22           sor gives notice—

23                   “(i) to the Secretary 90 days prior to  
24                   the termination of such contract; and

1           “(ii) to each eligible low-income bene-  
2           ficiary that is enrolled in a prescription  
3           drug assistance card program offered by  
4           such sponsor 60 days prior to such termi-  
5           nation.

6           “(C) SERVICE AREA.—The service area  
7           under the contract shall be the same as the  
8           area served by the prescription drug card spon-  
9           sor under section 1807.

10          “(5) SIMULTANEOUS APPROVAL OF DISCOUNT  
11          CARD AND ASSISTANCE PROGRAMS.—A prescription  
12          drug card sponsor may submit an application for en-  
13          dorsement under section 1807 as part of the bid  
14          submitted under paragraph (1) and the Secretary  
15          may approve such application at the same time as  
16          the Secretary awards a contract under this section.

17          “(g) PAYMENTS TO PRESCRIPTION DRUG CARD  
18          SPONSORS.—

19          “(1) IN GENERAL.—The Secretary shall pay to  
20          each prescription drug card sponsor offering a pre-  
21          scription drug assistance card program in which an  
22          eligible low-income beneficiary is enrolled an amount  
23          equal to the amount agreed to by the Secretary and  
24          the sponsor in the contract awarded under sub-  
25          section (f)(2).

1           “(2) PAYMENT FROM PART B TRUST FUND.—

2           The costs of providing benefits under this section  
3           shall be payable from the Federal Supplementary  
4           Medical Insurance Trust Fund established under  
5           section 1841.

6           “(h) ELIGIBILITY DETERMINATIONS MADE BY  
7           STATES; PRESUMPTIVE ELIGIBILITY.—States shall per-  
8           form the functions described in section 1935(a)(1).

9           “(i) APPROPRIATIONS.—There are appropriated from  
10          the Federal Supplementary Medical Insurance Trust  
11          Fund established under section 1841 such sums as may  
12          be necessary to carry out the program under this section.

13          “(j) DEFINITIONS.—In this section:

14                 “(1) ELIGIBLE BENEFICIARY; NEGOTIATED  
15                 PRICE; PRESCRIPTION DRUG.—The terms ‘eligible  
16                 beneficiary’, ‘negotiated price’, and ‘prescription  
17                 drug’ have the meanings given those terms in section  
18                 1807(i).

19                 “(2) ELIGIBLE LOW-INCOME BENEFICIARY.—  
20                 The term ‘eligible low-income beneficiary’ means an  
21                 individual who—

22                         “(A) is an eligible beneficiary (as defined  
23                         in section 1807(i));

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

1           “(C) is described in clause (iii) or (iv) of  
2           section 1902(a)(10)(E) or in section  
3           1905(p)(1).

4           “(3) PRESCRIPTION DRUG CARD SPONSOR.—  
5           The term ‘prescription drug card sponsor’ has the  
6           meaning given that term in section 1807(i), except  
7           that such sponsor shall also be an entity that the  
8           Secretary determines—

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

13           “(B) is able to manage the monetary as-  
14           sistance made available under subsection (d)(2);

15           “(C) agrees to submit to audits by the Sec-  
16           retary; and

17           “(D) provides such other assurances as the  
18           Secretary may require.

19           “(4) STATE.—The term ‘State’ has the mean-  
20           ing given such term for purposes of title XIX.”.

21           (b) EXCLUSION OF PRICES FROM DETERMINATION  
22           OF BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C.  
23           1396r-8(c)(1)(C)(i)) is amended—

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

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

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

5                               “(V) any negotiated prices  
6 charged under the medicare prescrip-  
7 tion drug discount card endorsement  
8 program under section 1807 or under  
9 the transitional prescription drug as-  
10 sistance card program for eligible low-  
11 income beneficiaries under section  
12 1807A.”.

13           (c) EXCLUSION OF PRESCRIPTION DRUG ASSIST-  
14 ANCE CARD COSTS FROM DETERMINATION OF PART B  
15 MONTHLY PREMIUM.—Section 1839(g) of the Social Se-  
16 curity Act (42 U.S.C. 1395r(g)) is amended—

17           (1) by striking “attributable to the application  
18 of section” and inserting “attributable to—

19                               “(1) the application of section”;

20           (2) by striking the period and inserting “;  
21 and”; and

22           (3) by adding at the end the following new  
23 paragraph:

24                               “(2) the prescription drug assistance card pro-  
25 gram under section 1807A.”.

1 (d) REGULATIONS.—

2 (1) AUTHORITY FOR INTERIM FINAL REGULA-  
3 TIONS.—The Secretary may promulgate initial regu-  
4 lations implementing sections 1807 and 1807A of  
5 the Social Security Act (as added by this section)  
6 in interim final form without prior opportunity for  
7 public comment.

8 (2) FINAL REGULATIONS.—A final regulation  
9 reflecting public comments must be published within  
10 1 year of the interim final regulation promulgated  
11 under paragraph (1).

12 (3) EXEMPTION FROM THE PAPERWORK RE-  
13 DUCATION ACT.—The promulgation of the regulations  
14 under this subsection and the administration the  
15 programs established by sections 1807 and 1807A of  
16 the Social Security Act (as added by this section)  
17 shall be made without regard to chapter 35 of title  
18 44, United States Code (commonly known as the  
19 “Paperwork Reduction Act”).

20 (e) IMPLEMENTATION; TRANSITION.—

21 (1) IMPLEMENTATION.—The Secretary shall  
22 implement the amendments made by this section in  
23 a manner that discounts are available to eligible  
24 beneficiaries under section 1807 of the Social Secu-  
25 rity Act and assistance is available to eligible low-in-

1       come beneficiaries under section 1807A of such Act  
2       not later than January 1, 2004.

3               (2) TRANSITION.—The Secretary shall provide  
4       for an appropriate transition and discontinuation of  
5       the programs under section 1807 and 1807A of the  
6       Social Security Act. Such transition and discontinu-  
7       ation shall ensure that such programs continue to  
8       operate until the date on which the first enrollment  
9       period under part D ends.

## 10                   **Subtitle C—Standards for** 11                   **Electronic Prescribing**

### 12       **SEC. 121. STANDARDS FOR ELECTRONIC PRESCRIBING.**

13               Title XI (42 U.S.C. 1301 et seq.) is amended by add-  
14       ing at the end the following new part:

15                   “PART D—ELECTRONIC PRESCRIBING

16                   “STANDARDS FOR ELECTRONIC PRESCRIBING

17                   “SEC. 1180. (a) STANDARDS.—

18                   “(1) DEVELOPMENT AND ADOPTION.—

19                   “(A) IN GENERAL.—The Secretary shall  
20       develop or adopt standards for transactions and  
21       data elements for such transactions (in this sec-  
22       tion referred to as ‘standards’) to enable the  
23       electronic transmission of medication history,  
24       eligibility, benefit, and other prescription infor-  
25       mation.

1           “(B) CONSULTATION.—In developing and  
2           adopting the standards under subparagraph  
3           (A), the Secretary shall consult with representa-  
4           tives of physicians, hospitals, pharmacists,  
5           standard setting organizations, pharmacy ben-  
6           efit managers, beneficiary information exchange  
7           networks, technology experts, and representa-  
8           tives of the Departments of Veterans Affairs  
9           and Defense and other interested parties.

10           “(2) OBJECTIVE.—Any standards developed or  
11           adopted under this part shall be consistent with the  
12           objectives of improving—

13                   “(A) patient safety; and

14                   “(B) the quality of care provided to pa-  
15           tients.

16           “(3) REQUIREMENTS.—Any standards devel-  
17           oped or adopted under this part shall comply with  
18           the following:

19                   “(A) ELECTRONIC TRANSMITTAL OF PRE-  
20           SCRIPTIONS.—

21                   “(i) IN GENERAL.—Except as pro-  
22           vided in clause (ii), the standards require  
23           that prescriptions be written and trans-  
24           mitted electronically.

1           “(ii) EXCEPTIONS.—The standards  
2 shall not require a prescription to be writ-  
3 ten and transmitted electronically—

4           “(I) in emergency cases and  
5 other exceptional circumstances recog-  
6 nized by the Administrator; or

7           “(II) if the patient requests that  
8 the prescription not be transmitted  
9 electronically.

10           If a patient makes a request under sub-  
11 clause (II), no additional charges may be  
12 imposed on the patient for making such re-  
13 quest.

14           “(B) PATIENT-SPECIFIC MEDICATION HIS-  
15 TORY, ELIGIBILITY, BENEFIT, AND OTHER PRE-  
16 SCRIPTION INFORMATION.—

17           “(i) IN GENERAL.—The standards  
18 shall accommodate electronic transmittal of  
19 patient-specific medication history, eligi-  
20 bility, benefit, and other prescription infor-  
21 mation among prescribing and dispensing  
22 professionals at the point of care.

23           “(ii) REQUIRED INFORMATION.—The  
24 information described in clause (i) shall in-  
25 clude the following:

1           “(I) Information (to the extent  
2           available and feasible) on the drugs  
3           being prescribed for that patient and  
4           other information relating to the  
5           medication history of the patient that  
6           may be relevant to the appropriate  
7           prescription for that patient.

8           “(II) Cost-effective alternatives  
9           (if any) to the drug prescribed.

10          “(III) Information on eligibility  
11          and benefits, including the drugs in-  
12          cluded in the applicable formulary and  
13          any requirements for prior authoriza-  
14          tion.

15          “(IV) Information on potential  
16          interactions with drugs listed on the  
17          medication history, graded by severity  
18          of the potential interaction.

19          “(V) Other information to im-  
20          prove the quality of patient care and  
21          to reduce medical errors.

22          “(C) UNDUE BURDEN.—The standards  
23          shall be designed so that, to the extent prac-  
24          ticable, the standards do not impose an undue

1 administrative burden on the practice of medi-  
2 cine, pharmacy, or other health professions.

3 “(D) COMPATIBILITY WITH ADMINISTRA-  
4 TIVE SIMPLIFICATION AND PRIVACY LAWS.—

5 The standards shall be—

6 “(i) consistent with the Federal regu-  
7 lations (concerning the privacy of individ-  
8 ually identifiable health information) pro-  
9 mulgated under section 264(c) of the  
10 Health Insurance Portability and Account-  
11 ability Act of 1996; and

12 “(ii) compatible with the standards  
13 adopted under part C.

14 “(4) TRANSFER OF INFORMATION.—The Sec-  
15 retary shall develop and adopt standards for trans-  
16 ferring among prescribing and insurance entities and  
17 other necessary entities appropriate standard data  
18 elements needed for the electronic exchange of medi-  
19 cation history, eligibility, benefit, and other prescrip-  
20 tion drug information and other health information  
21 determined appropriate in compliance with the  
22 standards adopted or modified under this part.

23 “(b) TIMETABLE FOR ADOPTION OF STANDARDS.—

24 “(1) IN GENERAL.—The Secretary shall adopt  
25 the standards under this part by January 1, 2006.

1           “(2) ADDITIONS AND MODIFICATIONS TO  
2 STANDARDS.—The Secretary shall, in consultation  
3 with appropriate representatives of interested par-  
4 ties, review the standards developed or adopted  
5 under this part and adopt modifications to the  
6 standards (including additions to the standards), as  
7 determined appropriate. Any addition or modifica-  
8 tion to such standards shall be completed in a man-  
9 ner which minimizes the disruption and cost of com-  
10 pliance.

11           “(c) COMPLIANCE WITH STANDARDS.—

12           “(1) REQUIREMENT FOR ALL INDIVIDUALS AND  
13 ENTITIES THAT TRANSMIT OR RECEIVE PRESCRIP-  
14 TIONS ELECTRONICALLY.—

15           “(A) IN GENERAL.—Individuals or entities  
16 that transmit or receive electronic medication  
17 history, eligibility, benefit and prescription in-  
18 formation, shall comply with the standards  
19 adopted or modified under this part.

20           “(B) RELATION TO STATE LAWS.—The  
21 standards adopted or modified under this part  
22 shall supersede any State law or regulations  
23 pertaining to the electronic transmission of  
24 medication history, eligibility, benefit and pre-  
25 scription information.



1 prescription programs that comply with the standards  
2 adopted or modified under this part.

3 “(b) APPLICATION.—No grant may be made under  
4 this section except pursuant to a grant application that  
5 is submitted in a time, manner, and form approved by the  
6 Secretary.

7 “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
8 are authorized to be appropriated for each of fiscal years  
9 2006, 2007, and 2008, such sums as may be necessary  
10 to carry out this section.”.

## 11 **Subtitle D—Other Provisions**

### 12 **SEC. 131. ADDITIONAL REQUIREMENTS FOR ANNUAL FI-** 13 **NANCIAL REPORT AND OVERSIGHT ON MEDI-** 14 **CARE PROGRAM.**

15 (a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i)  
16 is amended by adding at the end the following new sub-  
17 section:

18 “(l) COMBINED REPORT ON OPERATION AND STATUS  
19 OF THE TRUST FUND AND THE FEDERAL SUPPLE-  
20 MENTARY MEDICAL INSURANCE TRUST FUND (INCLUD-  
21 ING THE PRESCRIPTION DRUG ACCOUNT).—In addition  
22 to the duty of the Board of Trustees to report to Congress  
23 under subsection (b), on the date the Board submits the  
24 report required under subsection (b)(2), the Board shall  
25 submit to Congress a report on the operation and status

1 of the Trust Fund and the Federal Supplementary Med-  
2 ical Insurance Trust Fund established under section 1841  
3 (including the Prescription Drug Account within such  
4 Trust Fund), in this subsection referred to as the ‘Trust  
5 Funds’. Such report shall include the following informa-  
6 tion:

7           “(1) OVERALL SPENDING FROM THE GENERAL  
8           FUND OF THE TREASURY.—A statement of total  
9           amounts obligated during the preceding fiscal year  
10          from the General Revenues of the Treasury to the  
11          Trust Funds, separately stated in terms of the total  
12          amount and in terms of the percentage such amount  
13          bears to all other amounts obligated from such Gen-  
14          eral Revenues during such fiscal year, for each of  
15          the following amounts:

16                 “(A) MEDICARE BENEFITS.—The amount  
17                 expended for payment of benefits covered under  
18                 this title.

19                 “(B) ADMINISTRATIVE AND OTHER EX-  
20                 PENSES.—The amount expended for payments  
21                 not related to the benefits described in subpara-  
22                 graph (A).

23           “(2) HISTORICAL OVERVIEW OF SPENDING.—  
24          From the date of the inception of the program of in-  
25          surance under this title through the fiscal year in-

1       involved, a statement of the total amounts referred to  
2       in paragraph (1), separately stated for the amounts  
3       described in subparagraphs (A) and (B) of such  
4       paragraph.

5               “(3) 10-YEAR AND 50-YEAR PROJECTIONS.—An  
6       estimate of total amounts referred to in paragraph  
7       (1), separately stated for the amounts described in  
8       subparagraphs (A) and (B) of such paragraph, re-  
9       quired to be obligated for payment for benefits cov-  
10      ered under this title for each of the 10 fiscal years  
11      succeeding the fiscal year involved and for the 50-  
12      year period beginning with the succeeding fiscal  
13      year.

14              “(4) RELATION TO OTHER MEASURES OF  
15      GROWTH.—A comparison of the rate of growth of  
16      the total amounts referred to in paragraph (1), sepa-  
17      rately stated for the amounts described in subpara-  
18      graphs (A) and (B) of such paragraph, to the rate  
19      of growth for the same period in—

20                      “(A) the gross domestic product;

21                      “(B) health insurance costs in the private  
22      sector;

23                      “(C) employment-based health insurance  
24      costs in the public and private sectors; and

1           “(D) other areas as determined appro-  
2           priate by the Board of Trustees.”.

3           (b) **EFFECTIVE DATE.**—The amendment made by  
4 subsection (a) shall apply with respect to fiscal years be-  
5 ginning on or after the date of enactment of this Act.

6           (c) **CONGRESSIONAL HEARINGS.**—It is the sense of  
7 Congress that the committees of jurisdiction of Congress  
8 shall hold hearings on the reports submitted under section  
9 1817(l) of the Social Security Act (as added by subsection  
10 (a)).

11 **SEC. 132. TRUSTEES’ REPORT ON MEDICARE’S UNFUNDED**  
12 **OBLIGATIONS.**

13           (a) **REPORT.**—The report submitted under sections  
14 1817(b)(2) and 1841(b)(2) of the Social Security Act (42  
15 U.S.C. 1395i(b)(2) and 1395t(b)(2)) during 2004 shall in-  
16 clude an analysis of the total amount of the unfunded obli-  
17 gations of the Medicare program under title XVIII of the  
18 Social Security Act.

19           (b) **MATTERS ANALYZED.**—The analysis described in  
20 subsection (A) shall compare the long-term obligations of  
21 the Medicare program to the dedicated funding sources  
22 for that program (other than general revenue transfers),  
23 including the combined obligations of the Federal Hospital  
24 Insurance Trust Fund established under section 1817 of  
25 such Act (42 U.S.C. 1395i) and the Federal Supple-

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

3 **TITLE II—**  
4 **MEDICAREADVANTAGE**  
5 **Subtitle A—MedicareAdvantage**  
6 **Competition**

7 **SEC. 201. ELIGIBILITY, ELECTION, AND ENROLLMENT.**

8 Section 1851 (42 U.S.C. 1395w–21) is amended to  
9 read as follows:

10 “ELIGIBILITY, ELECTION, AND ENROLLMENT

11 “SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS  
12 THROUGH MEDICAREADVANTAGE PLANS.—

13 “(1) IN GENERAL.—Subject to the provisions of  
14 this section, each MedicareAdvantage eligible indi-  
15 vidual (as defined in paragraph (3)) is entitled to  
16 elect to receive benefits under this title—

17 “(A) through—

18 “(i) the original Medicare fee-for-serv-  
19 ice program under parts A and B; and

20 “(ii) the voluntary prescription drug  
21 delivery program under part D; or

22 “(B) through enrollment in a  
23 MedicareAdvantage plan under this part.

24 “(2) TYPES OF MEDICAREADVANTAGE PLANS  
25 THAT MAY BE AVAILABLE.—A MedicareAdvantage

1 plan may be any of the following types of plans of  
2 health insurance:

3 “(A) COORDINATED CARE PLANS.—Coordi-  
4 nated care plans which provide health care serv-  
5 ices, including health maintenance organization  
6 plans (with or without point of service options)  
7 and plans offered by provider-sponsored organi-  
8 zations (as defined in section 1855(d)).

9 “(B) COMBINATION OF MSA PLAN AND  
10 CONTRIBUTIONS TO MEDICAREADVANTAGE  
11 MSA.—An MSA plan, as defined in section  
12 1859(b)(3), and a contribution into a  
13 MedicareAdvantage medical savings account  
14 (MSA).

15 “(C) PRIVATE FEE-FOR-SERVICE PLANS.—  
16 A MedicareAdvantage private fee-for-service  
17 plan, as defined in section 1859(b)(2).

18 “(3) MEDICAREADVANTAGE ELIGIBLE INDI-  
19 VIDUAL.—

20 “(A) IN GENERAL.—Subject to subpara-  
21 graph (B), in this title, the term  
22 ‘MedicareAdvantage eligible individual’ means  
23 an individual who is entitled to (or enrolled for)  
24 benefits under part A, enrolled under part B,  
25 and enrolled under part D.

1           “(B) SPECIAL RULE FOR END-STAGE  
2 RENAL DISEASE.—Such term shall not include  
3 an individual medically determined to have end-  
4 stage renal disease, except that—

5           “(i) an individual who develops end-  
6 stage renal disease while enrolled in a  
7 Medicare+Choice or a MedicareAdvantage  
8 plan may continue to be enrolled in that  
9 plan; and

10           “(ii) in the case of such an individual  
11 who is enrolled in a Medicare+Choice plan  
12 or a MedicareAdvantage plan under clause  
13 (i) (or subsequently under this clause), if  
14 the enrollment is discontinued under cir-  
15 cumstances described in section  
16 1851(e)(4)(A), then the individual will be  
17 treated as a ‘MedicareAdvantage eligible  
18 individual’ for purposes of electing to con-  
19 tinue enrollment in another  
20 MedicareAdvantage plan.

21           “(b) SPECIAL RULES.—

22           “(1) RESIDENCE REQUIREMENT.—

23           “(A) IN GENERAL.—Except as the Sec-  
24 retary may otherwise provide and except as pro-  
25 vided in subparagraph (C), an individual is eli-

1           gible to elect a MedicareAdvantage plan offered  
2           by a MedicareAdvantage organization only if  
3           the plan serves the geographic area in which  
4           the individual resides.

5           “(B) CONTINUATION OF ENROLLMENT  
6           PERMITTED.—Pursuant to rules specified by  
7           the Secretary, the Secretary shall provide that  
8           a plan may offer to all individuals residing in  
9           a geographic area the option to continue enroll-  
10          ment in the plan, notwithstanding that the indi-  
11          vidual no longer resides in the service area of  
12          the plan, so long as the plan provides that indi-  
13          viduals exercising this option have, as part of  
14          the basic benefits described in section  
15          1852(a)(1)(A), reasonable access within that  
16          geographic area to the full range of basic bene-  
17          fits, subject to reasonable cost-sharing liability  
18          in obtaining such benefits.

19          “(C) CONTINUATION OF ENROLLMENT  
20          PERMITTED WHERE SERVICE CHANGED.—Not-  
21          withstanding subparagraph (A) and in addition  
22          to subparagraph (B), if a MedicareAdvantage  
23          organization eliminates from its service area a  
24          MedicareAdvantage payment area that was pre-  
25          viously within its service area, the organization

1 may elect to offer individuals residing in all or  
2 portions of the affected area who would other-  
3 wise be ineligible to continue enrollment the op-  
4 tion to continue enrollment in a  
5 MedicareAdvantage plan it offers so long as—

6 “(i) the enrollee agrees to receive the  
7 full range of basic benefits (excluding  
8 emergency and urgently needed care) ex-  
9 clusively at facilities designated by the or-  
10 ganization within the plan service area;  
11 and

12 “(ii) there is no other  
13 MedicareAdvantage plan offered in the  
14 area in which the enrollee resides at the  
15 time of the organization’s election.

16 “(2) SPECIAL RULE FOR CERTAIN INDIVIDUALS  
17 COVERED UNDER FEHBP OR ELIGIBLE FOR VET-  
18 ERANS OR MILITARY HEALTH BENEFITS.—

19 “(A) FEHBP.—An individual who is en-  
20 rolled in a health benefit plan under chapter 89  
21 of title 5, United States Code, is not eligible to  
22 enroll in an MSA plan until such time as the  
23 Director of the Office of Management and  
24 Budget certifies to the Secretary that the Office  
25 of Personnel Management has adopted policies

1           which will ensure that the enrollment of such  
2           individuals in such plans will not result in in-  
3           creased expenditures for the Federal Govern-  
4           ment for health benefit plans under such chap-  
5           ter.

6           “(B) VA AND DOD.—The Secretary may  
7           apply rules similar to the rules described in  
8           subparagraph (A) in the case of individuals who  
9           are eligible for health care benefits under chap-  
10          ter 55 of title 10, United States Code, or under  
11          chapter 17 of title 38 of such Code.

12          “(3) LIMITATION ON ELIGIBILITY OF QUALI-  
13          FIED MEDICARE BENEFICIARIES AND OTHER MED-  
14          ICAID BENEFICIARIES TO ENROLL IN AN MSA  
15          PLAN.—An individual who is a qualified medicare  
16          beneficiary (as defined in section 1905(p)(1)), a  
17          qualified disabled and working individual (described  
18          in section 1905(s)), an individual described in sec-  
19          tion 1902(a)(10)(E)(iii), or otherwise entitled to  
20          medicare cost-sharing under a State plan under title  
21          XIX is not eligible to enroll in an MSA plan.

22          “(4) COVERAGE UNDER MSA PLANS ON A DEM-  
23          ONSTRATION BASIS.—

1           “(A) IN GENERAL.—An individual is not  
2 eligible to enroll in an MSA plan under this  
3 part—

4           “(i) on or after January 1, 2004, un-  
5 less the enrollment is the continuation of  
6 such an enrollment in effect as of such  
7 date; or

8           “(ii) as of any date if the number of  
9 such individuals so enrolled as of such date  
10 has reached 390,000.

11 Under rules established by the Secretary, an in-  
12 dividual is not eligible to enroll (or continue en-  
13 rollment) in an MSA plan for a year unless the  
14 individual provides assurances satisfactory to  
15 the Secretary that the individual will reside in  
16 the United States for at least 183 days during  
17 the year.

18           “(B) EVALUATION.—The Secretary shall  
19 regularly evaluate the impact of permitting en-  
20 rollment in MSA plans under this part on selec-  
21 tion (including adverse selection), use of preven-  
22 tive care, access to care, and the financial sta-  
23 tus of the Trust Funds under this title.

24           “(C) REPORTS.—The Secretary shall sub-  
25 mit to Congress periodic reports on the num-

1           bers of individuals enrolled in such plans and  
2           on the evaluation being conducted under sub-  
3           paragraph (B).

4           “(c) PROCESS FOR EXERCISING CHOICE.—

5           “(1) IN GENERAL.—The Secretary shall estab-  
6           lish a process through which elections described in  
7           subsection (a) are made and changed, including the  
8           form and manner in which such elections are made  
9           and changed. Such elections shall be made or  
10          changed only during coverage election periods speci-  
11          fied under subsection (e) and shall become effective  
12          as provided in subsection (f).

13          “(2)           COORDINATION           THROUGH  
14          MEDICAREADVANTAGE ORGANIZATIONS.—

15          “(A) ENROLLMENT.—Such process shall  
16          permit an individual who wishes to elect a  
17          MedicareAdvantage plan offered by a  
18          MedicareAdvantage organization to make such  
19          election through the filing of an appropriate  
20          election form with the organization.

21          “(B) DISENROLLMENT.—Such process  
22          shall permit an individual, who has elected a  
23          MedicareAdvantage plan offered by a  
24          MedicareAdvantage organization and who wish-  
25          es to terminate such election, to terminate such

1 election through the filing of an appropriate  
2 election form with the organization.

3 “(3) DEFAULT.—

4 “(A) INITIAL ELECTION.—

5 “(i) IN GENERAL.—Subject to clause  
6 (ii), an individual who fails to make an  
7 election during an initial election period  
8 under subsection (e)(1) is deemed to have  
9 chosen the original medicare fee-for-service  
10 program option.

11 “(ii) SEAMLESS CONTINUATION OF  
12 COVERAGE.—The Secretary may establish  
13 procedures under which an individual who  
14 is enrolled in a Medicare+Choice plan or  
15 another health plan (other than a  
16 MedicareAdvantage plan) offered by a  
17 MedicareAdvantage organization at the  
18 time of the initial election period and who  
19 fails to elect to receive coverage other than  
20 through the organization is deemed to have  
21 elected the MedicareAdvantage plan of-  
22 fered by the organization (or, if the organi-  
23 zation offers more than 1 such plan, such  
24 plan or plans as the Secretary identifies  
25 under such procedures).

1           “(B) CONTINUING PERIODS.—An indi-  
2           vidual who has made (or is deemed to have  
3           made) an election under this section is consid-  
4           ered to have continued to make such election  
5           until such time as—

6                   “(i) the individual changes the elec-  
7                   tion under this section; or

8                   “(ii) the Medicare Advantage plan with  
9                   respect to which such election is in effect  
10                  is discontinued or, subject to subsection  
11                  (b)(1)(B), no longer serves the area in  
12                  which the individual resides.

13          “(d) PROVIDING INFORMATION TO PROMOTE IN-  
14 FORMED CHOICE.—

15                  “(1) IN GENERAL.—The Secretary shall provide  
16                  for activities under this subsection to broadly dis-  
17                  seminate information to medicare beneficiaries (and  
18                  prospective medicare beneficiaries) on the coverage  
19                  options provided under this section in order to pro-  
20                  mote an active, informed selection among such op-  
21                  tions.

22                  “(2) PROVISION OF NOTICE.—

23                          “(A) OPEN SEASON NOTIFICATION.—At  
24                          least 15 days before the beginning of each an-  
25                          nual, coordinated election period (as defined in

1 subsection (e)(3)(B)), the Secretary shall mail  
2 to each MedicareAdvantage eligible individual  
3 residing in an area the following:

4 “(i) GENERAL INFORMATION.—The  
5 general information described in paragraph  
6 (3).

7 “(ii) LIST OF PLANS AND COMPARI-  
8 SON OF PLAN OPTIONS.—A list identifying  
9 the MedicareAdvantage plans that are (or  
10 will be) available to residents of the area  
11 and information described in paragraph  
12 (4) concerning such plans. Such informa-  
13 tion shall be presented in a comparative  
14 form.

15 “(iii) ADDITIONAL INFORMATION.—  
16 Any other information that the Secretary  
17 determines will assist the individual in  
18 making the election under this section.

19 The mailing of such information shall be coordi-  
20 nated, to the extent practicable, with the mail-  
21 ing of any annual notice under section 1804.

22 “(B) NOTIFICATION TO NEWLY ELIGIBLE  
23 MEDICAREADVANTAGE ELIGIBLE INDIVID-  
24 UALS.—To the extent practicable, the Secretary  
25 shall, not later than 30 days before the begin-

1           ning of the initial MedicareAdvantage enroll-  
2           ment period for an individual described in sub-  
3           section (e)(1), mail to the individual the infor-  
4           mation described in subparagraph (A).

5           “(C) FORM.—The information dissemi-  
6           nated under this paragraph shall be written and  
7           formatted using language that is easily under-  
8           standable by medicare beneficiaries.

9           “(D) PERIODIC UPDATING.—The informa-  
10          tion described in subparagraph (A) shall be up-  
11          dated on at least an annual basis to reflect  
12          changes in the availability of  
13          MedicareAdvantage plans, the benefits under  
14          such plans, and the MedicareAdvantage month-  
15          ly basic beneficiary premium,  
16          MedicareAdvantage monthly beneficiary pre-  
17          mium for enhanced medical benefits, and  
18          MedicareAdvantage monthly beneficiary obliga-  
19          tion for qualified prescription drug coverage for  
20          such plans.

21          “(3) GENERAL INFORMATION.—General infor-  
22          mation under this paragraph, with respect to cov-  
23          erage under this part during a year, shall include  
24          the following:

1           “(A) BENEFITS UNDER THE ORIGINAL  
2           MEDICARE FEE-FOR-SERVICE PROGRAM OP-  
3           TION.—A general description of the benefits  
4           covered under parts A and B of the original  
5           medicare fee-for-service program, including—

6                   “(i) covered items and services;

7                   “(ii) beneficiary cost-sharing, such as  
8                   deductibles, coinsurance, and copayment  
9                   amounts; and

10                  “(iii) any beneficiary liability for bal-  
11                  ance billing.

12           “(B) CATASTROPHIC COVERAGE AND COM-  
13           BINED DEDUCTIBLE.—A description of the cat-  
14           astrophic coverage and unified deductible appli-  
15           cable under the plan.

16           “(C) OUTPATIENT PRESCRIPTION DRUG  
17           COVERAGE BENEFITS.—The information re-  
18           quired under section 1860D–4 with respect to  
19           coverage for prescription drugs under the plan.

20           “(D) ELECTION PROCEDURES.—Informa-  
21           tion and instructions on how to exercise election  
22           options under this section.

23           “(E) RIGHTS.—A general description of  
24           procedural rights (including grievance and ap-  
25           peals procedures) of beneficiaries under the

1 original medicare fee-for-service program (in-  
2 cluding such rights under part D) and the  
3 MedicareAdvantage program and the right to  
4 be protected against discrimination based on  
5 health status-related factors under section  
6 1852(b).

7 “(F) INFORMATION ON MEDIGAP AND  
8 MEDICARE SELECT.—A general description of  
9 the benefits, enrollment rights, and other re-  
10 quirements applicable to medicare supplemental  
11 policies under section 1882 and provisions relat-  
12 ing to medicare select policies described in sec-  
13 tion 1882(t).

14 “(G) POTENTIAL FOR CONTRACT TERMI-  
15 NATION.—The fact that a MedicareAdvantage  
16 organization may terminate its contract, refuse  
17 to renew its contract, or reduce the service area  
18 included in its contract, under this part, and  
19 the effect of such a termination, nonrenewal, or  
20 service area reduction may have on individuals  
21 enrolled with the MedicareAdvantage plan  
22 under this part.

23 “(4) INFORMATION COMPARING PLAN OP-  
24 TIONS.—Information under this paragraph, with re-

1 spect to a MedicareAdvantage plan for a year, shall  
2 include the following:

3 “(A) BENEFITS.—The benefits covered  
4 under the plan, including the following:

5 “(i) Covered items and services be-  
6 yond those provided under the original  
7 medicare fee-for-service program option.

8 “(ii) Beneficiary cost-sharing for any  
9 items and services described in clause (i)  
10 and paragraph (3)(A)(i), including infor-  
11 mation on the unified deductible under sec-  
12 tion 1852(a)(1)(C).

13 “(iii) The maximum limitations on  
14 out-of-pocket expenses under section  
15 1852(a)(1)(C).

16 “(iv) In the case of an MSA plan, dif-  
17 ferences in cost-sharing, premiums, and  
18 balance billing under such a plan compared  
19 to under other MedicareAdvantage plans.

20 “(v) In the case of a  
21 MedicareAdvantage private fee-for-service  
22 plan, differences in cost-sharing, pre-  
23 miums, and balance billing under such a  
24 plan compared to under other  
25 MedicareAdvantage plans.

1           “(vi) The extent to which an enrollee  
2 may obtain benefits through out-of-net-  
3 work health care providers.

4           “(vii) The extent to which an enrollee  
5 may select among in-network providers and  
6 the types of providers participating in the  
7 plan’s network.

8           “(viii) The organization’s coverage of  
9 emergency and urgently needed care.

10           “(ix) The comparative information de-  
11 scribed in section 1860D–4(b)(2) relating  
12 to prescription drug coverage under the  
13 plan.

14           “(B) PREMIUMS.—

15           “(i)           IN           GENERAL.—The  
16 MedicareAdvantage monthly basic bene-  
17 ficiary premium and MedicareAdvantage  
18 monthly beneficiary premium for enhanced  
19 medical benefits, if any, for the plan or, in  
20 the case of an MSA plan, the  
21 MedicareAdvantage monthly MSA pre-  
22 mium.

23           “(ii) REDUCTIONS.—The reduction in  
24 part B premiums, if any.

1                   “(iii) NATURE OF THE PREMIUM FOR  
2                   ENHANCED MEDICAL BENEFITS.—Whether  
3                   the MedicareAdvantage monthly premium  
4                   for enhanced benefits is optional or manda-  
5                   tory.

6                   “(C) SERVICE AREA.—The service area of  
7                   the plan.

8                   “(D) QUALITY AND PERFORMANCE.—Plan  
9                   quality and performance indicators for the ben-  
10                  efits under the plan (and how such indicators  
11                  compare to quality and performance indicators  
12                  under the original medicare fee-for-service pro-  
13                  gram under parts A and B and under the vol-  
14                  untary prescription drug delivery program  
15                  under part D in the area involved), including—

16                   “(i) disenrollment rates for medicare  
17                   enrollees electing to receive benefits  
18                   through the plan for the previous 2 years  
19                   (excluding disenrollment due to death or  
20                   moving outside the plan’s service area);

21                   “(ii) information on medicare enrollee  
22                   satisfaction;

23                   “(iii) information on health outcomes;  
24                   and

1                   “(iv) the recent record regarding com-  
2                   pliance of the plan with requirements of  
3                   this part (as determined by the Secretary).

4                   “(5) MAINTAINING A TOLL-FREE NUMBER AND  
5                   INTERNET SITE.—The Secretary shall maintain a  
6                   toll-free number for inquiries regarding  
7                   MedicareAdvantage options and the operation of this  
8                   part in all areas in which MedicareAdvantage plans  
9                   are offered and an Internet site through which indi-  
10                  viduals may electronically obtain information on  
11                  such options and MedicareAdvantage plans.

12                  “(6) USE OF NON-FEDERAL ENTITIES.—The  
13                  Secretary may enter into contracts with non-Federal  
14                  entities to carry out activities under this subsection.

15                  “(7) PROVISION OF INFORMATION.—A  
16                  MedicareAdvantage organization shall provide the  
17                  Secretary with such information on the organization  
18                  and each MedicareAdvantage plan it offers as may  
19                  be required for the preparation of the information  
20                  referred to in paragraph (2)(A).

21                  “(e) COVERAGE ELECTION PERIODS.—

22                  “(1) INITIAL CHOICE UPON ELIGIBILITY TO  
23                  MAKE ELECTION IF MEDICAREADVANTAGE PLANS  
24                  AVAILABLE TO INDIVIDUAL.—If, at the time an indi-  
25                  vidual first becomes eligible to elect to receive bene-

1 fits under part B or D (whichever is later), there is  
2 1 or more MedicareAdvantage plans offered in the  
3 area in which the individual resides, the individual  
4 shall make the election under this section during a  
5 period specified by the Secretary such that if the in-  
6 dividual elects a MedicareAdvantage plan during the  
7 period, coverage under the plan becomes effective as  
8 of the first date on which the individual may receive  
9 such coverage.

10 “(2) OPEN ENROLLMENT AND DISENROLLMENT  
11 OPPORTUNITIES.—Subject to paragraph (5), the fol-  
12 lowing rules shall apply:

13 “(A) CONTINUOUS OPEN ENROLLMENT  
14 AND DISENROLLMENT THROUGH 2005.—At any  
15 time during the period beginning January 1,  
16 1998, and ending on December 31, 2005, a  
17 Medicare+Choice eligible individual may change  
18 the election under subsection (a)(1).

19 “(B) CONTINUOUS OPEN ENROLLMENT  
20 AND DISENROLLMENT FOR FIRST 6 MONTHS  
21 DURING 2006.—

22 “(i) IN GENERAL.—Subject to clause  
23 (ii) and subparagraph (D), at any time  
24 during the first 6 months of 2006, or, if  
25 the individual first becomes a

1 MedicareAdvantage eligible individual dur-  
2 ing 2006, during the first 6 months during  
3 2006 in which the individual is a  
4 MedicareAdvantage eligible individual, a  
5 MedicareAdvantage eligible individual may  
6 change the election under subsection  
7 (a)(1).

8 “(ii) LIMITATION OF 1 CHANGE.—An  
9 individual may exercise the right under  
10 clause (i) only once. The limitation under  
11 this clause shall not apply to changes in  
12 elections effected during an annual, coordi-  
13 nated election period under paragraph (3)  
14 or during a special enrollment period under  
15 the first sentence of paragraph (4).

16 “(C) CONTINUOUS OPEN ENROLLMENT  
17 AND DISENROLLMENT FOR FIRST 3 MONTHS IN  
18 SUBSEQUENT YEARS.—

19 “(i) IN GENERAL.—Subject to clause  
20 (ii) and subparagraph (D), at any time  
21 during the first 3 months of 2007 and  
22 each subsequent year, or, if the individual  
23 first becomes a MedicareAdvantage eligible  
24 individual during 2007 or any subsequent  
25 year, during the first 3 months of such

1 year in which the individual is a  
2 MedicareAdvantage eligible individual, a  
3 MedicareAdvantage eligible individual may  
4 change the election under subsection  
5 (a)(1).

6 “(ii) LIMITATION OF 1 CHANGE DUR-  
7 ING OPEN ENROLLMENT PERIOD EACH  
8 YEAR.—An individual may exercise the  
9 right under clause (i) only once during the  
10 applicable 3-month period described in  
11 such clause in each year. The limitation  
12 under this clause shall not apply to  
13 changes in elections effected during an an-  
14 nual, coordinated election period under  
15 paragraph (3) or during a special enroll-  
16 ment period under paragraph (4).

17 “(D) CONTINUOUS OPEN ENROLLMENT  
18 FOR INSTITUTIONALIZED INDIVIDUALS.—At  
19 any time during 2006 or any subsequent year,  
20 in the case of a MedicareAdvantage eligible in-  
21 dividual who is institutionalized (as defined by  
22 the Secretary), the individual may elect under  
23 subsection (a)(1)—

24 “(i) to enroll in a MedicareAdvantage  
25 plan; or

1                   “(ii)           to           change           the  
2                   MedicareAdvantage plan in which the indi-  
3                   vidual is enrolled.

4                   “(3) ANNUAL, COORDINATED ELECTION PE-  
5                   RIOD.—

6                   “(A) IN GENERAL.—Subject to paragraph  
7                   (5), each individual who is eligible to make an  
8                   election under this section may change such  
9                   election during an annual, coordinated election  
10                  period.

11                  “(B) ANNUAL, COORDINATED ELECTION  
12                  PERIOD.—For purposes of this section, the  
13                  term ‘annual, coordinated election period’  
14                  means, with respect to a year before 2003 and  
15                  after 2006, the month of November before such  
16                  year and with respect to 2003, 2004, 2005, and  
17                  2006, the period beginning on November 15  
18                  and ending on December 31 of the year before  
19                  such year.

20                  “(C) MEDICAREADVANTAGE HEALTH IN-  
21                  FORMATION FAIRS.—During the fall season of  
22                  each year (beginning with 2006), in conjunction  
23                  with the annual coordinated election period de-  
24                  fined in subparagraph (B), the Secretary shall  
25                  provide for a nationally coordinated educational

1           and    publicity    campaign    to    inform  
2           MedicareAdvantage   eligible   individuals   about  
3           MedicareAdvantage   plans   and   the   election   proc-  
4           ess   provided   under   this   section.

5           “(D) SPECIAL INFORMATION CAMPAIGN IN  
6           2005.—During the period beginning on Novem-  
7           ber 15, 2005, and ending on December 31,  
8           2005, the Secretary shall provide for an edu-  
9           cational and publicity campaign to inform  
10          MedicareAdvantage   eligible   individuals   about  
11          the   availability   of   MedicareAdvantage   plans,  
12          and   eligible   organizations   with   risk-sharing   con-  
13          tracts   under   section   1876,   offered   in   different  
14          areas   and   the   election   process   provided   under  
15          this   section.

16          “(4) SPECIAL ELECTION PERIODS.—Effective  
17          on   and   after   January   1,   2006,   an   individual   may  
18          discontinue   an   election   of   a   MedicareAdvantage   plan  
19          offered   by   a   MedicareAdvantage   organization   other  
20          than   during   an   annual,   coordinated   election   period  
21          and   make   a   new   election   under   this   section   if—

22                  “(A)(i) the certification of the organization  
23                  or   plan   under   this   part   has   been   terminated,   or  
24                  the   organization   or   plan   has   notified   the   indi-

1 individual of an impending termination of such cer-  
2 tification; or

3 “(ii) the organization has terminated or  
4 otherwise discontinued providing the plan in the  
5 area in which the individual resides, or has no-  
6 tified the individual of an impending termi-  
7 nation or discontinuation of such plan;

8 “(B) the individual is no longer eligible to  
9 elect the plan because of a change in the indi-  
10 vidual’s place of residence or other change in  
11 circumstances (specified by the Secretary, but  
12 not including termination of the individual’s en-  
13 rollment on the basis described in clause (i) or  
14 (ii) of subsection (g)(3)(B));

15 “(C) the individual demonstrates (in ac-  
16 cordance with guidelines established by the Sec-  
17 retary) that—

18 “(i) the organization offering the plan  
19 substantially violated a material provision  
20 of the organization’s contract under this  
21 part in relation to the individual (including  
22 the failure to provide an enrollee on a  
23 timely basis medically necessary care for  
24 which benefits are available under the plan  
25 or the failure to provide such covered care

1 in accordance with applicable quality  
2 standards); or

3 “(ii) the organization (or an agent or  
4 other entity acting on the organization’s  
5 behalf) materially misrepresented the  
6 plan’s provisions in marketing the plan to  
7 the individual; or

8 “(D) the individual meets such other ex-  
9 ceptional conditions as the Secretary may pro-  
10 vide.

11 Effective on and after January 1, 2006, an indi-  
12 vidual who, upon first becoming eligible for benefits  
13 under part A at age 65, enrolls in a  
14 MedicareAdvantage plan under this part, the indi-  
15 vidual may discontinue the election of such plan, and  
16 elect coverage under the original fee-for-service plan,  
17 at any time during the 12-month period beginning  
18 on the effective date of such enrollment.

19 “(5) SPECIAL RULES FOR MSA PLANS.—Not-  
20 withstanding the preceding provisions of this sub-  
21 section, an individual—

22 “(A) may elect an MSA plan only during—

23 “(i) an initial open enrollment period  
24 described in paragraph (1);

1                   “(ii) an annual, coordinated election  
2                   period described in paragraph (3)(B); or

3                   “(iii) the month of November 1998;

4                   “(B) subject to subparagraph (C), may not  
5                   discontinue an election of an MSA plan except  
6                   during the periods described in clause (ii) or  
7                   (iii) of subparagraph (A) and under the first  
8                   sentence of paragraph (4); and

9                   “(C) who elects an MSA plan during an  
10                  annual, coordinated election period, and who  
11                  never previously had elected such a plan, may  
12                  revoke such election, in a manner determined  
13                  by the Secretary, by not later than December  
14                  15 following the date of the election.

15                  “(6) OPEN ENROLLMENT PERIODS.—Subject to  
16                  paragraph (5), a MedicareAdvantage organization—

17                  “(A) shall accept elections or changes to  
18                  elections during the initial enrollment periods  
19                  described in paragraph (1), during the period  
20                  beginning on November 15, 2005, and ending  
21                  on December 31, 2005, and during the annual,  
22                  coordinated election period under paragraph (3)  
23                  for each subsequent year, and during special  
24                  election periods described in the first sentence  
25                  of paragraph (4); and

1           “(B) may accept other changes to elections  
2           at such other times as the organization pro-  
3           vides.

4           “(f) EFFECTIVENESS OF ELECTIONS AND CHANGES  
5 OF ELECTIONS.—

6           “(1) DURING INITIAL COVERAGE ELECTION PE-  
7           RIOD.—An election of coverage made during the ini-  
8           tial coverage election period under subsection  
9           (e)(1)(A) shall take effect upon the date the indi-  
10          vidual becomes entitled to (or enrolled for) benefits  
11          under part A, enrolled under part B, and enrolled  
12          under part D, except as the Secretary may provide  
13          (consistent with sections 1838 and 1860D–2)) in  
14          order to prevent retroactive coverage.

15          “(2) DURING CONTINUOUS OPEN ENROLLMENT  
16          PERIODS.—An election or change of coverage made  
17          under subsection (e)(2) shall take effect with the  
18          first day of the first calendar month following the  
19          date on which the election or change is made.

20          “(3) ANNUAL, COORDINATED ELECTION PE-  
21          RIOD.—An election or change of coverage made dur-  
22          ing an annual, coordinated election period (as de-  
23          fined in subsection (e)(3)(B)) in a year shall take ef-  
24          fect as of the first day of the following year.

1           “(4) OTHER PERIODS.—An election or change  
2 of coverage made during any other period under  
3 subsection (e)(4) shall take effect in such manner as  
4 the Secretary provides in a manner consistent (to  
5 the extent practicable) with protecting continuity of  
6 health benefit coverage.

7           “(g) GUARANTEED ISSUE AND RENEWAL.—

8           “(1) IN GENERAL.—Except as provided in this  
9 subsection, a MedicareAdvantage organization shall  
10 provide that at any time during which elections are  
11 accepted under this section with respect to a  
12 MedicareAdvantage plan offered by the organization,  
13 the organization will accept without restrictions indi-  
14 viduals who are eligible to make such election.

15           “(2) PRIORITY.—If the Secretary determines  
16 that a MedicareAdvantage organization, in relation  
17 to a MedicareAdvantage plan it offers, has a capac-  
18 ity limit and the number of MedicareAdvantage eli-  
19 gible individuals who elect the plan under this sec-  
20 tion exceeds the capacity limit, the organization may  
21 limit the election of individuals of the plan under  
22 this section but only if priority in election is pro-  
23 vided—

1           “(A) first to such individuals as have elect-  
2           ed the plan at the time of the determination;  
3           and

4           “(B) then to other such individuals in such  
5           a manner that does not discriminate, on a basis  
6           described in section 1852(b), among the individ-  
7           uals (who seek to elect the plan).

8           The preceding sentence shall not apply if it would  
9           result in the enrollment of enrollees substantially  
10          nonrepresentative, as determined in accordance with  
11          regulations of the Secretary, of the medicare popu-  
12          lation in the service area of the plan.

13          “(3) LIMITATION ON TERMINATION OF ELEC-  
14          TION.—

15                 “(A) IN GENERAL.—Subject to subpara-  
16                 graph (B), a MedicareAdvantage organization  
17                 may not for any reason terminate the election  
18                 of any individual under this section for a  
19                 MedicareAdvantage plan it offers.

20                 “(B) BASIS FOR TERMINATION OF ELEC-  
21                 TION.—A MedicareAdvantage organization may  
22                 terminate an individual’s election under this  
23                 section with respect to a MedicareAdvantage  
24                 plan it offers if—

1           “(i) any MedicareAdvantage monthly  
2           basic           beneficiary           premium,  
3           MedicareAdvantage monthly beneficiary  
4           obligation for qualified prescription drug  
5           coverage, or MedicareAdvantage monthly  
6           beneficiary premium for required or op-  
7           tional enhanced medical benefits required  
8           with respect to such plan are not paid on  
9           a timely basis (consistent with standards  
10          under section 1856 that provide for a  
11          grace period for late payment of such pre-  
12          miums);

13           “(ii) the individual has engaged in  
14          disruptive behavior (as specified in such  
15          standards); or

16           “(iii) the plan is terminated with re-  
17          spect to all individuals under this part in  
18          the area in which the individual resides.

19          “(C) CONSEQUENCE OF TERMINATION.—

20           “(i) TERMINATIONS FOR CAUSE.—  
21          Any individual whose election is terminated  
22          under clause (i) or (ii) of subparagraph  
23          (B) is deemed to have elected to receive  
24          benefits under the original medicare fee-  
25          for-service program option.

1                   “(ii) TERMINATION BASED ON PLAN  
2                   TERMINATION OR SERVICE AREA REDUC-  
3                   TION.—Any individual whose election is  
4                   terminated under subparagraph (B)(iii)  
5                   shall have a special election period under  
6                   subsection (e)(4)(A) in which to change  
7                   coverage to coverage under another  
8                   MedicareAdvantage plan. Such an indi-  
9                   vidual who fails to make an election during  
10                  such period is deemed to have chosen to  
11                  change coverage to the original medicare  
12                  fee-for-service program option.

13                  “(D) ORGANIZATION OBLIGATION WITH  
14                  RESPECT TO ELECTION FORMS.—Pursuant to a  
15                  contract under section 1857858, each  
16                  MedicareAdvantage organization receiving an  
17                  election form under subsection (c)(2) shall  
18                  transmit to the Secretary (at such time and in  
19                  such manner as the Secretary may specify) a  
20                  copy of such form or such other information re-  
21                  specting the election as the Secretary may  
22                  specify.

23                  “(h) APPROVAL OF MARKETING MATERIAL AND AP-  
24                  PLICATION FORMS.—

1           “(1) SUBMISSION.—No marketing material or  
2 application form may be distributed by a  
3 MedicareAdvantage organization to (or for the use  
4 of) MedicareAdvantage eligible individuals unless—

5                   “(A) at least 45 days (or 10 days in the  
6 case described in paragraph (5)) before the date  
7 of distribution the organization has submitted  
8 the material or form to the Secretary for re-  
9 view; and

10                   “(B) the Secretary has not disapproved the  
11 distribution of such material or form.

12           “(2) REVIEW.—The standards established  
13 under section 1856 shall include guidelines for the  
14 review of any material or form submitted and under  
15 such guidelines the Secretary shall disapprove (or  
16 later require the correction of) such material or form  
17 if the material or form is materially inaccurate or  
18 misleading or otherwise makes a material misrepre-  
19 sentation.

20           “(3) DEEMED APPROVAL (1-STOP SHOPPING).—  
21 In the case of material or form that is submitted  
22 under paragraph (1)(A) to the Secretary or a re-  
23 gional office of the Department of Health and  
24 Human Services and the Secretary or the office has  
25 not disapproved the distribution of marketing mate-

1       rial or form under paragraph (1)(B) with respect to  
2       a MedicareAdvantage plan in an area, the Secretary  
3       is deemed not to have disapproved such distribution  
4       in all other areas covered by the plan and organiza-  
5       tion except with regard to that portion of such mate-  
6       rial or form that is specific only to an area involved.

7           “(4) PROHIBITION OF CERTAIN MARKETING  
8       PRACTICES.—Each MedicareAdvantage organization  
9       shall conform to fair marketing standards, in rela-  
10      tion to MedicareAdvantage plans offered under this  
11      part, included in the standards established under  
12      section 1856. Such standards—

13           “(A) shall not permit a MedicareAdvantage  
14      organization to provide for cash or other mone-  
15      etary rebates as an inducement for enrollment or  
16      otherwise (other than as an additional benefit  
17      described in section 1854(g)(1)(C)(i)); and

18           “(B) may include a prohibition against a  
19      MedicareAdvantage organization (or agent of  
20      such an organization) completing any portion of  
21      any election form used to carry out elections  
22      under this section on behalf of any individual.

23           “(5) SPECIAL TREATMENT OF MARKETING MA-  
24      TERIAL FOLLOWING MODEL MARKETING LAN-  
25      GUAGE.—In the case of marketing material of an or-

1 organization that uses, without modification, proposed  
2 model language specified by the Secretary, the pe-  
3 riod specified in paragraph (1)(A) shall be reduced  
4 from 45 days to 10 days.

5 “(i) EFFECT OF ELECTION OF  
6 MEDICAREADVANTAGE PLAN OPTION.—

7 “(1) PAYMENTS TO ORGANIZATIONS.—Subject  
8 to sections 1852(a)(5), 1853(h), 1853(i),  
9 1886(d)(11), and 1886(h)(3)(D), payments under a  
10 contract with a MedicareAdvantage organization  
11 under section 1853(a) with respect to an individual  
12 electing a MedicareAdvantage plan offered by the or-  
13 ganization shall be instead of the amounts which (in  
14 the absence of the contract) would otherwise be pay-  
15 able under parts A, B, and D for items and services  
16 furnished to the individual.

17 “(2) ONLY ORGANIZATION ENTITLED TO PAY-  
18 MENT.—Subject to sections 1853(f), 1853(h),  
19 1853(i), 1857(f)(2), 1886(d)(11), and  
20 1886(h)(3)(D), only the MedicareAdvantage organi-  
21 zation shall be entitled to receive payments from the  
22 Secretary under this title for services furnished to  
23 the individual.”.

1 **SEC. 202. BENEFITS AND BENEFICIARY PROTECTIONS.**

2 Section 1852 (42 U.S.C. 1395w-22) is amended to  
3 read as follows:

4 “BENEFITS AND BENEFICIARY PROTECTIONS

5 “SEC. 1852. (a) BASIC BENEFITS.—

6 “(1) IN GENERAL.—Except as provided in sec-  
7 tion 1859(b)(3) for MSA plans, each  
8 MedicareAdvantage plan shall provide to members  
9 enrolled under this part, through providers and  
10 other persons that meet the applicable requirements  
11 of this title and part A of title XI—

12 “(A) those items and services (other than  
13 hospice care) for which benefits are available  
14 under parts A and B to individuals residing in  
15 the area served by the plan;

16 “(B) except as provided in paragraph  
17 (2)(D), qualified prescription drug coverage  
18 under part D to individuals residing in the area  
19 served by the plan;

20 “(C) a maximum limitation on out-of-pock-  
21 et expenses and a unified deductible; and

22 “(D) additional benefits required under  
23 section 1854(d)(1).

24 “(2) SATISFACTION OF REQUIREMENT.—

25 “(A) IN GENERAL.—A MedicareAdvantage  
26 plan (other than an MSA plan) offered by a

1 MedicareAdvantage organization satisfies para-  
2 graph (1)(A), with respect to benefits for items  
3 and services furnished other than through a  
4 provider or other person that has a contract  
5 with the organization offering the plan, if the  
6 plan provides payment in an amount so that—

7 “(i) the sum of such payment amount  
8 and any cost-sharing provided for under  
9 the plan; is equal to at least

10 “(ii) the total dollar amount of pay-  
11 ment for such items and services as would  
12 otherwise be authorized under parts A and  
13 B (including any balance billing permitted  
14 under such parts).

15 “(B) REFERENCE TO RELATED PROVI-  
16 SIONS.—For provisions relating to—

17 “(i) limitations on balance billing  
18 against MedicareAdvantage organizations  
19 for noncontract providers, see sections  
20 1852(k) and 1866(a)(1)(O); and

21 “(ii) limiting actuarial value of en-  
22 rollee liability for covered benefits, see sec-  
23 tion 1854(f).

24 “(C) ELECTION OF UNIFORM COVERAGE  
25 POLICY.—In the case of a MedicareAdvantage

1 organization that offers a MedicareAdvantage  
2 plan in an area in which more than 1 local cov-  
3 erage policy is applied with respect to different  
4 parts of the area, the organization may elect to  
5 have the local coverage policy for the part of  
6 the area that is most beneficial to  
7 MedicareAdvantage enrollees (as identified by  
8 the Secretary) apply with respect to all  
9 MedicareAdvantage enrollees enrolled in the  
10 plan.

11 “(D) SPECIAL RULE FOR PRIVATE FEE-  
12 FOR-SERVICE PLANS.—

13 “(i) IN GENERAL.—A private fee-for-  
14 service plan may elect not to provide quali-  
15 fied prescription drug coverage under part  
16 D to individuals residing in the area served  
17 by the plan.

18 “(ii) AVAILABILITY OF DRUG COV-  
19 ERAGE FOR ENROLLEES.—If a beneficiary  
20 enrolls in a plan making the election de-  
21 scribed in clause (i), the beneficiary may  
22 enroll for drug coverage under part D with  
23 an eligible entity under such part.

24 “(3) ENHANCED MEDICAL BENEFITS.—



1 private fee-for-service plan from offering en-  
2 hanced medical benefits that include payment  
3 for some or all of the balance billing amounts  
4 permitted consistent with section 1852(k) and  
5 coverage of additional services that the plan  
6 finds to be medically necessary.

7 “(D) RULE FOR APPROVAL OF MEDICAL  
8 AND PRESCRIPTION DRUG BENEFITS.—Notwith-  
9 standing the preceding provisions of this para-  
10 graph, the Secretary may not approve any en-  
11 hanced medical benefit that provides for the  
12 coverage of any prescription drug (other than  
13 that relating to prescription drugs covered  
14 under the original medicare fee-for-service pro-  
15 gram option).

16 “(4) ORGANIZATION AS SECONDARY PAYER.—  
17 Notwithstanding any other provision of law, a  
18 MedicareAdvantage organization may (in the case of  
19 the provision of items and services to an individual  
20 under a MedicareAdvantage plan under cir-  
21 cumstances in which payment under this title is  
22 made secondary pursuant to section 1862(b)(2))  
23 charge or authorize the provider of such services to  
24 charge, in accordance with the charges allowed

1 under a law, plan, or policy described in such sec-  
2 tion—

3 “(A) the insurance carrier, employer, or  
4 other entity which under such law, plan, or pol-  
5 icy is to pay for the provision of such services;  
6 or

7 “(B) such individual to the extent that the  
8 individual has been paid under such law, plan,  
9 or policy for such services.

10 “(5) NATIONAL COVERAGE DETERMINATIONS  
11 AND LEGISLATIVE CHANGES IN BENEFITS.—If there  
12 is a national coverage determination or legislative  
13 change in benefits required to be provided under this  
14 part made in the period beginning on the date of an  
15 announcement under section 1853(b) and ending on  
16 the date of the next announcement under such sec-  
17 tion and the Secretary projects that the determina-  
18 tion will result in a significant change in the costs  
19 to a MedicareAdvantage organization of providing  
20 the benefits that are the subject of such national  
21 coverage determination and that such change in  
22 costs was not incorporated in the determination of  
23 the benchmark amount announced under section  
24 1853(b)(1)(A) at the beginning of such period, then,  
25 unless otherwise required by law—

1           “(A) such determination or legislative  
2 change in benefits shall not apply to contracts  
3 under this part until the first contract year that  
4 begins after the end of such period; and

5           “(B) if such coverage determination or leg-  
6 islative change provides for coverage of addi-  
7 tional benefits or coverage under additional cir-  
8 cumstances, section 1851(i)(1) shall not apply  
9 to payment for such additional benefits or bene-  
10 fits provided under such additional cir-  
11 cumstances until the first contract year that be-  
12 gins after the end of such period.

13       The projection under the previous sentence shall be  
14 based on an analysis by the Secretary of the actu-  
15 arial costs associated with the coverage determina-  
16 tion or legislative change in benefits.

17           “(6) AUTHORITY TO PROHIBIT RISK SELEC-  
18 TION.—The Secretary shall have the authority to  
19 disapprove any MedicareAdvantage plan that the  
20 Secretary determines is designed to attract a popu-  
21 lation that is healthier than the average population  
22 residing in the service area of the plan.

23           “(7) UNIFIED DEDUCTIBLE DEFINED.—In this  
24 part, the term ‘unified deductible’ means an annual  
25 deductible amount that is applied in lieu of the inpa-

1       tient hospital deductible under section 1813(b)(1)  
2       and the deductible under section 1833(b). Nothing  
3       in this part shall be construed as preventing a  
4       MedicareAdvantage organization from requiring co-  
5       insurance or a copayment for inpatient hospital serv-  
6       ices after the unified deductible is satisfied, subject  
7       to the limitation on enrollee liability under section  
8       1854(f).

9       “(b) ANTIDISCRIMINATION.—

10           “(1) BENEFICIARIES.—

11                   “(A) IN GENERAL.—A MedicareAdvantage  
12                   organization may not deny, limit, or condition  
13                   the coverage or provision of benefits under this  
14                   part, for individuals permitted to be enrolled  
15                   with the organization under this part, based on  
16                   any health status-related factor described in  
17                   section 2702(a)(1) of the Public Health Service  
18                   Act.

19                   “(B) CONSTRUCTION.—Except as provided  
20                   under section 1851(a)(3)(B), subparagraph (A)  
21                   shall not be construed as requiring a  
22                   MedicareAdvantage organization to enroll indi-  
23                   viduals who are determined to have end-stage  
24                   renal disease.

1           “(2) PROVIDERS.—A MedicareAdvantage orga-  
2 nization shall not discriminate with respect to par-  
3 ticipation, reimbursement, or indemnification as to  
4 any provider who is acting within the scope of the  
5 provider’s license or certification under applicable  
6 State law, solely on the basis of such license or cer-  
7 tification. This paragraph shall not be construed to  
8 prohibit a plan from including providers only to the  
9 extent necessary to meet the needs of the plan’s en-  
10 rollees or from establishing any measure designed to  
11 maintain quality and control costs consistent with  
12 the responsibilities of the plan.

13           “(c) DISCLOSURE REQUIREMENTS.—

14           “(1) DETAILED DESCRIPTION OF PLAN PROVI-  
15 SIONS.—A MedicareAdvantage organization shall  
16 disclose, in clear, accurate, and standardized form to  
17 each enrollee with a MedicareAdvantage plan offered  
18 by the organization under this part at the time of  
19 enrollment and at least annually thereafter, the fol-  
20 lowing information regarding such plan:

21           “(A) SERVICE AREA.—The plan’s service  
22 area.

23           “(B) BENEFITS.—Benefits offered under  
24 the plan, including information described sec-  
25 tion 1852(a)(1) (relating to benefits under the

1 original medicare fee-for-service program op-  
2 tion, the maximum limitation in out-of-pocket  
3 expenses and the unified deductible, and quali-  
4 fied prescription drug coverage under part D,  
5 respectively) and exclusions from coverage and,  
6 if it is an MSA plan, a comparison of benefits  
7 under such a plan with benefits under other  
8 MedicareAdvantage plans.

9 “(C) ACCESS.—The number, mix, and dis-  
10 tribution of plan providers, out-of-network cov-  
11 erage (if any) provided by the plan, and any  
12 point-of-service option (including the  
13 MedicareAdvantage monthly beneficiary pre-  
14 mium for enhanced medical benefits for such  
15 option).

16 “(D) OUT-OF-AREA COVERAGE.—Out-of-  
17 area coverage provided by the plan.

18 “(E) EMERGENCY COVERAGE.—Coverage  
19 of emergency services, including—

20 “(i) the appropriate use of emergency  
21 services, including use of the 911 telephone  
22 system or its local equivalent in emergency  
23 situations and an explanation of what con-  
24 stitutes an emergency situation;

1 “(ii) the process and procedures of the  
2 plan for obtaining emergency services; and

3 “(iii) the locations of—

4 “(I) emergency departments; and

5 “(II) other settings, in which  
6 plan physicians and hospitals provide  
7 emergency services and post-stabiliza-  
8 tion care.

9 “(F) ENHANCED MEDICAL BENEFITS.—

10 Enhanced medical benefits available from the  
11 organization offering the plan, including—

12 “(i) whether the enhanced medical  
13 benefits are optional;

14 “(ii) the enhanced medical benefits  
15 covered; and

16 “(iii) the MedicareAdvantage monthly  
17 beneficiary premium for enhanced medical  
18 benefits.

19 “(G) PRIOR AUTHORIZATION RULES.—

20 Rules regarding prior authorization or other re-  
21 view requirements that could result in non-  
22 payment.

23 “(H) PLAN GRIEVANCE AND APPEALS PRO-  
24 CEDURES.—All plan appeal or grievance rights  
25 and procedures.

1           “(I) QUALITY ASSURANCE PROGRAM.—A  
2           description of the organization’s quality assur-  
3           ance program under subsection (e).

4           “(2) DISCLOSURE UPON REQUEST.—Upon re-  
5           quest of a MedicareAdvantage eligible individual, a  
6           MedicareAdvantage organization must provide the  
7           following information to such individual:

8           “(A) The general coverage information and  
9           general comparative plan information made  
10          available under clauses (i) and (ii) of section  
11          1851(d)(2)(A).

12          “(B) Information on procedures used by  
13          the organization to control utilization of serv-  
14          ices and expenditures.

15          “(C) Information on the number of griev-  
16          ances, reconsiderations, and appeals and on the  
17          disposition in the aggregate of such matters.

18          “(D) An overall summary description as to  
19          the method of compensation of participating  
20          physicians.

21          “(E) The information described in sub-  
22          paragraphs (A) through (C) in relation to the  
23          qualified prescription drug coverage provided by  
24          the organization.

25          “(d) ACCESS TO SERVICES.—

1           “(1) IN GENERAL.—A MedicareAdvantage or-  
2           ganization offering a MedicareAdvantage plan may  
3           select the providers from whom the benefits under  
4           the plan are provided so long as—

5                   “(A) the organization makes such benefits  
6                   available and accessible to each individual elect-  
7                   ing the plan within the plan service area with  
8                   reasonable promptness and in a manner which  
9                   assures continuity in the provision of benefits;

10                   “(B) when medically necessary the organi-  
11                   zation makes such benefits available and acces-  
12                   sible 24 hours a day and 7 days a week;

13                   “(C) the plan provides for reimbursement  
14                   with respect to services which are covered under  
15                   subparagraphs (A) and (B) and which are pro-  
16                   vided to such an individual other than through  
17                   the organization, if—

18                           “(i) the services were not emergency  
19                           services (as defined in paragraph (3)),  
20                           but—

21                                   “(I) the services were medically  
22                                   necessary and immediately required  
23                                   because of an unforeseen illness, in-  
24                                   jury, or condition; and

1                   “(II) it was not reasonable given  
2                   the circumstances to obtain the serv-  
3                   ices through the organization;

4                   “(ii) the services were renal dialysis  
5                   services and were provided other than  
6                   through the organization because the indi-  
7                   vidual was temporarily out of the plan’s  
8                   service area; or

9                   “(iii) the services are maintenance  
10                  care or post-stabilization care covered  
11                  under the guidelines established under  
12                  paragraph (2);

13                  “(D) the organization provides access to  
14                  appropriate providers, including credentialed  
15                  specialists, for medically necessary treatment  
16                  and services; and

17                  “(E) coverage is provided for emergency  
18                  services (as defined in paragraph (3)) without  
19                  regard to prior authorization or the emergency  
20                  care provider’s contractual relationship with the  
21                  organization.

22                  “(2) GUIDELINES RESPECTING COORDINATION  
23                  OF                   POST-STABILIZATION                   CARE.—A  
24                  MedicareAdvantage plan shall comply with such  
25                  guidelines as the Secretary may prescribe relating to

1 promoting efficient and timely coordination of appro-  
2 priate maintenance and post-stabilization care of an  
3 enrollee after the enrollee has been determined to be  
4 stable under section 1867.

5 “(3) DEFINITION OF EMERGENCY SERVICES.—

6 In this subsection—

7 “(A) IN GENERAL.—The term ‘emergency  
8 services’ means, with respect to an individual  
9 enrolled with an organization, covered inpatient  
10 and outpatient services that—

11 “(i) are furnished by a provider that  
12 is qualified to furnish such services under  
13 this title; and

14 “(ii) are needed to evaluate or sta-  
15 bilize an emergency medical condition (as  
16 defined in subparagraph (B)).

17 “(B) EMERGENCY MEDICAL CONDITION  
18 BASED ON PRUDENT LAYPERSON.—The term  
19 ‘emergency medical condition’ means a medical  
20 condition manifesting itself by acute symptoms  
21 of sufficient severity (including severe pain)  
22 such that a prudent layperson, who possesses  
23 an average knowledge of health and medicine,  
24 could reasonably expect the absence of imme-  
25 diate medical attention to result in—

1           “(i) placing the health of the indi-  
2           vidual (or, with respect to a pregnant  
3           woman, the health of the woman or her  
4           unborn child) in serious jeopardy;

5           “(ii) serious impairment to bodily  
6           functions; or

7           “(iii) serious dysfunction of any bodily  
8           organ or part.

9           “(4) ASSURING ACCESS TO SERVICES IN  
10          MEDICAREADVANTAGE PRIVATE FEE-FOR-SERV-  
11          ICE PLANS.—In addition to any other require-  
12          ments under this part, in the case of a  
13          MedicareAdvantage private fee-for-service plan,  
14          the organization offering the plan must dem-  
15          onstrate to the Secretary that the organization  
16          has sufficient number and range of health care  
17          professionals and providers willing to provide  
18          services under the terms of the plan. The Sec-  
19          retary shall find that an organization has met  
20          such requirement with respect to any category  
21          of health care professional or provider if, with  
22          respect to that category of provider—

23                 “(A) the plan has established payment  
24                 rates for covered services furnished by that  
25                 category of provider that are not less than

1 the payment rates provided for under part  
2 A, B, or D for such services; or

3 “(B) the plan has contracts or agree-  
4 ments with a sufficient number and range  
5 of providers within such category to pro-  
6 vide covered services under the terms of  
7 the plan,

8 or a combination of both. The previous sentence  
9 shall not be construed as restricting the persons  
10 from whom enrollees under such a plan may ob-  
11 tain covered benefits.

12 “(e) QUALITY ASSURANCE PROGRAM.—

13 “(1) IN GENERAL.—Each MedicareAdvantage  
14 organization must have arrangements, consistent  
15 with any regulation, for an ongoing quality assur-  
16 ance program for health care services it provides to  
17 individuals enrolled with MedicareAdvantage plans  
18 of the organization.

19 “(2) ELEMENTS OF PROGRAM.—

20 “(A) IN GENERAL.—The quality assurance  
21 program of an organization with respect to a  
22 MedicareAdvantage plan (other than a  
23 MedicareAdvantage private fee-for-service plan  
24 or a nonnetwork MSA plan) it offers shall—

1           “(i) stress health outcomes and pro-  
2           vide for the collection, analysis, and report-  
3           ing of data (in accordance with a quality  
4           measurement system that the Secretary  
5           recognizes) that will permit measurement  
6           of outcomes and other indices of the qual-  
7           ity of MedicareAdvantage plans and orga-  
8           nizations;

9           “(ii) monitor and evaluate high vol-  
10          ume and high risk services and the care of  
11          acute and chronic conditions;

12          “(iii) provide access to disease man-  
13          agement and chronic care services;

14          “(iv) provide access to preventive ben-  
15          efits and information for enrollees on such  
16          benefits;

17          “(v) evaluate the continuity and co-  
18          ordination of care that enrollees receive;

19          “(vi) be evaluated on an ongoing basis  
20          as to its effectiveness;

21          “(vii) include measures of consumer  
22          satisfaction;

23          “(viii) provide the Secretary with such  
24          access to information collected as may be

1 appropriate to monitor and ensure the  
2 quality of care provided under this part;

3 “(ix) provide review by physicians and  
4 other health care professionals of the proc-  
5 ess followed in the provision of such health  
6 care services;

7 “(x) provide for the establishment of  
8 written protocols for utilization review,  
9 based on current standards of medical  
10 practice;

11 “(xi) have mechanisms to detect both  
12 underutilization and overutilization of serv-  
13 ices;

14 “(xii) after identifying areas for im-  
15 provement, establish or alter practice pa-  
16 rameters;

17 “(xiii) take action to improve quality  
18 and assesses the effectiveness of such ac-  
19 tion through systematic followup; and

20 “(xiv) make available information on  
21 quality and outcomes measures to facilitate  
22 beneficiary comparison and choice of  
23 health coverage options (in such form and  
24 on such quality and outcomes measures as

1           the Secretary determines to be appro-  
2           priate).

3           Such program shall include a separate focus  
4           (with respect to all the elements described in  
5           this subparagraph) on racial and ethnic minori-  
6           ties.

7           “(B) ELEMENTS OF PROGRAM FOR ORGA-  
8           NIZATIONS OFFERING MEDICAREADVANTAGE  
9           PRIVATE FEE-FOR-SERVICE PLANS, AND NON-  
10          NETWORK MSA PLANS.—The quality assurance  
11          program of an organization with respect to a  
12          MedicareAdvantage private fee-for-service plan  
13          or a nonnetwork MSA plan it offers shall—

14                 “(i) meet the requirements of clauses  
15                 (i) through (viii) of subparagraph (A);

16                 “(ii) insofar as it provides for the es-  
17                 tablishment of written protocols for utiliza-  
18                 tion review, base such protocols on current  
19                 standards of medical practice; and

20                 “(iii) have mechanisms to evaluate  
21                 utilization of services and inform providers  
22                 and enrollees of the results of such evalua-  
23                 tion.

24          Such program shall include a separate focus  
25          (with respect to all the elements described in

1 this subparagraph) on racial and ethnic minori-  
2 ties.

3 “(C) DEFINITION OF NONNETWORK MSA  
4 PLAN.—In this subsection, the term ‘nonnet-  
5 work MSA plan’ means an MSA plan offered by  
6 a MedicareAdvantage organization that does  
7 not provide benefits required to be provided by  
8 this part, in whole or in part, through a defined  
9 set of providers under contract, or under an-  
10 other arrangement, with the organization.

11 “(3) EXTERNAL REVIEW.—

12 “(A) IN GENERAL.—Each MedicareAdvan-  
13 tage organization shall, for each  
14 MedicareAdvantage plan it operates, have an  
15 agreement with an independent quality review  
16 and improvement organization approved by the  
17 Secretary to perform functions of the type de-  
18 scribed in paragraphs (4)(B) and (14) of sec-  
19 tion 1154(a) with respect to services furnished  
20 by MedicareAdvantage plans for which payment  
21 is made under this title. The previous sentence  
22 shall not apply to a MedicareAdvantage private  
23 fee-for-service plan or a nonnetwork MSA plan  
24 that does not employ utilization review.

1           “(B) NONDUPLICATION OF ACCREDITA-  
2           TION.—Except in the case of the review of qual-  
3           ity complaints, and consistent with subpara-  
4           graph (C), the Secretary shall ensure that the  
5           external review activities conducted under sub-  
6           paragraph (A) are not duplicative of review ac-  
7           tivities conducted as part of the accreditation  
8           process.

9           “(C) WAIVER AUTHORITY.—The Secretary  
10          may waive the requirement described in sub-  
11          paragraph (A) in the case of an organization if  
12          the Secretary determines that the organization  
13          has consistently maintained an excellent record  
14          of quality assurance and compliance with other  
15          requirements under this part.

16          “(4) TREATMENT OF ACCREDITATION.—

17          “(A) IN GENERAL.—The Secretary shall  
18          provide that a MedicareAdvantage organization  
19          is deemed to meet all the requirements de-  
20          scribed in any specific clause of subparagraph  
21          (B) if the organization is accredited (and peri-  
22          odically reaccredited) by a private accrediting  
23          organization under a process that the Secretary  
24          has determined assures that the accrediting or-  
25          ganization applies and enforces standards that

1 meet or exceed the standards established under  
2 section 1856 to carry out the requirements in  
3 such clause.

4 “(B) REQUIREMENTS DESCRIBED.—The  
5 provisions described in this subparagraph are  
6 the following:

7 “(i) Paragraphs (1) and (2) of this  
8 subsection (relating to quality assurance  
9 programs).

10 “(ii) Subsection (b) (relating to anti-  
11 discrimination).

12 “(iii) Subsection (d) (relating to ac-  
13 cess to services).

14 “(iv) Subsection (h) (relating to con-  
15 fidentiality and accuracy of enrollee  
16 records).

17 “(v) Subsection (i) (relating to infor-  
18 mation on advance directives).

19 “(vi) Subsection (j) (relating to pro-  
20 vider participation rules).

21 “(C) TIMELY ACTION ON APPLICATIONS.—  
22 The Secretary shall determine, within 210 days  
23 after the date the Secretary receives an applica-  
24 tion by a private accrediting organization and  
25 using the criteria specified in section

1 1865(b)(2), whether the process of the private  
2 accrediting organization meets the requirements  
3 with respect to any specific clause in subpara-  
4 graph (B) with respect to which the application  
5 is made. The Secretary may not deny such an  
6 application on the basis that it seeks to meet  
7 the requirements with respect to only one, or  
8 more than one, such specific clause.

9 “(D) CONSTRUCTION.—Nothing in this  
10 paragraph shall be construed as limiting the au-  
11 thority of the Secretary under section 1857, in-  
12 cluding the authority to terminate contracts  
13 with MedicareAdvantage organizations under  
14 subsection (c)(2) of such section.

15 “(5) REPORT TO CONGRESS.—

16 “(A) IN GENERAL.—The Secretary shall  
17 submit to Congress a biennial report regarding  
18 how quality assurance programs conducted  
19 under this subsection focus on racial and ethnic  
20 minorities.

21 “(B) CONTENTS OF REPORT.—Each such  
22 report shall include the following:

23 “(i) A description of the means by  
24 which such programs focus on such racial  
25 and ethnic minorities.

1                   “(ii) An evaluation of the impact of  
2                   such programs on eliminating health dis-  
3                   parities and on improving health outcomes,  
4                   continuity and coordination of care, man-  
5                   agement of chronic conditions, and con-  
6                   sumer satisfaction.

7                   “(iii) Recommendations on ways to re-  
8                   duce clinical outcome disparities among ra-  
9                   cial and ethnic minorities.

10           “(f)           GRIEVANCE           MECHANISM.—Each  
11 MedicareAdvantage organization must provide meaningful  
12 procedures for hearing and resolving grievances between  
13 the organization (including any entity or individual  
14 through which the organization provides health care serv-  
15 ices) and enrollees with MedicareAdvantage plans of the  
16 organization under this part.

17           “(g) COVERAGE DETERMINATIONS, RECONSIDER-  
18 ATIONS, AND APPEALS.—

19                   “(1) DETERMINATIONS BY ORGANIZATION.—

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

1 the individual is required to pay with respect to  
2 such service. Subject to paragraph (3), such  
3 procedures shall provide for such determination  
4 to be made on a timely basis.

5 “(B) EXPLANATION OF DETERMINA-  
6 TION.—Such a determination that denies cov-  
7 erage, in whole or in part, shall be in writing  
8 and shall include a statement in understandable  
9 language of the reasons for the denial and a de-  
10 scription of the reconsideration and appeals  
11 processes.

12 “(2) RECONSIDERATIONS.—

13 “(A) IN GENERAL.—The organization shall  
14 provide for reconsideration of a determination  
15 described in paragraph (1)(B) upon request by  
16 the enrollee involved. The reconsideration shall  
17 be within a time period specified by the Sec-  
18 retary, but shall be made, subject to paragraph  
19 (3), not later than 60 days after the date of the  
20 receipt of the request for reconsideration.

21 “(B) PHYSICIAN DECISION ON CERTAIN  
22 RECONSIDERATIONS.—A reconsideration relat-  
23 ing to a determination to deny coverage based  
24 on a lack of medical necessity shall be made  
25 only by a physician with appropriate expertise

1 in the field of medicine which necessitates treat-  
2 ment who is other than a physician involved in  
3 the initial determination.

4 “(3) EXPEDITED DETERMINATIONS AND RE-  
5 CONSIDERATIONS.—

6 “(A) RECEIPT OF REQUESTS.—

7 “(i) ENROLLEE REQUESTS.—An en-  
8 rollee in a MedicareAdvantage plan may  
9 request, either in writing or orally, an ex-  
10 pedited determination under paragraph (1)  
11 or an expedited reconsideration under  
12 paragraph (2) by the MedicareAdvantage  
13 organization.

14 “(ii) PHYSICIAN REQUESTS.—A physi-  
15 cian, regardless whether the physician is  
16 affiliated with the organization or not, may  
17 request, either in writing or orally, such an  
18 expedited determination or reconsideration.

19 “(B) ORGANIZATION PROCEDURES.—

20 “(i) IN GENERAL.—The  
21 MedicareAdvantage organization shall  
22 maintain procedures for expediting organi-  
23 zation determinations and reconsiderations  
24 when, upon request of an enrollee, the or-  
25 ganization determines that the application

1 of the normal timeframe for making a de-  
2 termination (or a reconsideration involving  
3 a determination) could seriously jeopardize  
4 the life or health of the enrollee or the en-  
5 rollee's ability to regain maximum func-  
6 tion.

7 “(ii) EXPEDITION REQUIRED FOR  
8 PHYSICIAN REQUESTS.—In the case of a  
9 request for an expedited determination or  
10 reconsideration made under subparagraph  
11 (A)(ii), the organization shall expedite the  
12 determination or reconsideration if the re-  
13 quest indicates that the application of the  
14 normal timeframe for making a determina-  
15 tion (or a reconsideration involving a de-  
16 termination) could seriously jeopardize the  
17 life or health of the enrollee or the enroll-  
18 ee's ability to regain maximum function.

19 “(iii) TIMELY RESPONSE.—In cases  
20 described in clauses (i) and (ii), the organi-  
21 zation shall notify the enrollee (and the  
22 physician involved, as appropriate) of the  
23 determination or reconsideration under  
24 time limitations established by the Sec-  
25 retary, but not later than 72 hours of the

1           time of receipt of the request for the deter-  
2           mination or reconsideration (or receipt of  
3           the information necessary to make the de-  
4           termination or reconsideration), or such  
5           longer period as the Secretary may permit  
6           in specified cases.

7           “(4) INDEPENDENT REVIEW OF CERTAIN COV-  
8           ERAGE DENIALS.—The Secretary shall contract with  
9           an independent, outside entity to review and resolve  
10          in a timely manner reconsiderations that affirm de-  
11          nial of coverage, in whole or in part. The provisions  
12          of section 1869(c)(5) shall apply to independent out-  
13          side entities under contract with the Secretary under  
14          this paragraph.

15          “(5) APPEALS.—An enrollee with a  
16          MedicareAdvantage plan of a MedicareAdvantage or-  
17          ganization under this part who is dissatisfied by rea-  
18          son of the enrollee’s failure to receive any health  
19          service to which the enrollee believes the enrollee is  
20          entitled and at no greater charge than the enrollee  
21          believes the enrollee is required to pay is entitled, if  
22          the amount in controversy is \$100 or more, to a  
23          hearing before the Secretary to the same extent as  
24          is provided in section 205(b), and in any such hear-  
25          ing the Secretary shall make the organization a

1 party. If the amount in controversy is \$1,000 or  
2 more, the individual or organization shall, upon noti-  
3 fying the other party, be entitled to judicial review  
4 of the Secretary's final decision as provided in sec-  
5 tion 205(g), and both the individual and the organi-  
6 zation shall be entitled to be parties to that judicial  
7 review. In applying subsections (b) and (g) of section  
8 205 as provided in this paragraph, and in applying  
9 section 205(l) thereto, any reference therein to the  
10 Commissioner of Social Security or the Social Secu-  
11 rity Administration shall be considered a reference  
12 to the Secretary or the Department of Health and  
13 Human Services, respectively.

14 “(h) CONFIDENTIALITY AND ACCURACY OF EN-  
15 ROLLEE RECORDS.—Insofar as a MedicareAdvantage or-  
16 ganization maintains medical records or other health in-  
17 formation regarding enrollees under this part, the  
18 MedicareAdvantage organization shall establish proce-  
19 dures—

20 “(1) to safeguard the privacy of any individ-  
21 ually identifiable enrollee information;

22 “(2) to maintain such records and information  
23 in a manner that is accurate and timely; and

24 “(3) to assure timely access of enrollees to such  
25 records and information.

1       “(i) INFORMATION ON ADVANCE DIRECTIVES.—Each  
2 MedicareAdvantage organization shall meet the require-  
3 ment of section 1866(f) (relating to maintaining written  
4 policies and procedures respecting advance directives).

5       “(j) RULES REGARDING PROVIDER PARTICIPA-  
6 TION.—

7           “(1) PROCEDURES.—Insofar as a  
8 MedicareAdvantage organization offers benefits  
9 under a MedicareAdvantage plan through agree-  
10 ments with physicians, the organization shall estab-  
11 lish reasonable procedures relating to the participa-  
12 tion (under an agreement between a physician and  
13 the organization) of physicians under such a plan.  
14 Such procedures shall include—

15           “(A) providing notice of the rules regard-  
16 ing participation;

17           “(B) providing written notice of participa-  
18 tion decisions that are adverse to physicians;  
19 and

20           “(C) providing a process within the organi-  
21 zation for appealing such adverse decisions, in-  
22 cluding the presentation of information and  
23 views of the physician regarding such decision.

24       “(2) CONSULTATION IN MEDICAL POLICIES.—A  
25 MedicareAdvantage organization shall consult with

1 physicians who have entered into participation  
2 agreements with the organization regarding the or-  
3 ganization’s medical policy, quality, and medical  
4 management procedures.

5 “(3) PROHIBITING INTERFERENCE WITH PRO-  
6 VIDER ADVICE TO ENROLLEES.—

7 “(A) IN GENERAL.—Subject to subpara-  
8 graphs (B) and (C), a MedicareAdvantage orga-  
9 nization (in relation to an individual enrolled  
10 under a MedicareAdvantage plan offered by the  
11 organization under this part) shall not prohibit  
12 or otherwise restrict a covered health care pro-  
13 fessional (as defined in subparagraph (D)) from  
14 advising such an individual who is a patient of  
15 the professional about the health status of the  
16 individual or medical care or treatment for the  
17 individual’s condition or disease, regardless of  
18 whether benefits for such care or treatment are  
19 provided under the plan, if the professional is  
20 acting within the lawful scope of practice.

21 “(B) CONSCIENCE PROTECTION.—Sub-  
22 paragraph (A) shall not be construed as requir-  
23 ing a MedicareAdvantage plan to provide, reim-  
24 burse for, or provide coverage of a counseling or

1 referral service if the MedicareAdvantage orga-  
2 nization offering the plan—

3 “(i) objects to the provision of such  
4 service on moral or religious grounds; and

5 “(ii) in the manner and through the  
6 written instrumentalities such  
7 MedicareAdvantage organization deems ap-  
8 propriate, makes available information on  
9 its policies regarding such service to pro-  
10 spective enrollees before or during enroll-  
11 ment and to enrollees within 90 days after  
12 the date that the organization or plan  
13 adopts a change in policy regarding such a  
14 counseling or referral service.

15 “(C) CONSTRUCTION.—Nothing in sub-  
16 paragraph (B) shall be construed to affect dis-  
17 closure requirements under State law or under  
18 the Employee Retirement Income Security Act  
19 of 1974.

20 “(D) HEALTH CARE PROFESSIONAL DE-  
21 FINED.—For purposes of this paragraph, the  
22 term ‘health care professional’ means a physi-  
23 cian (as defined in section 1861(r)) or other  
24 health care professional if coverage for the pro-  
25 fessional’s services is provided under the

1 MedicareAdvantage plan for the services of the  
2 professional. Such term includes a podiatrist,  
3 optometrist, chiropractor, psychologist, dentist,  
4 licensed pharmacist, physician assistant, phys-  
5 ical or occupational therapist and therapy as-  
6 sistant, speech-language pathologist, audiol-  
7 ogist, registered or licensed practical nurse (in-  
8 cluding nurse practitioner, clinical nurse spe-  
9 cialist, certified registered nurse anesthetist,  
10 and certified nurse-midwife), licensed certified  
11 social worker, registered respiratory therapist,  
12 and certified respiratory therapy technician.

13 “(4) LIMITATIONS ON PHYSICIAN INCENTIVE  
14 PLANS.—

15 “(A) IN GENERAL.—No MedicareAdvan-  
16 tage organization may operate any physician in-  
17 centive plan (as defined in subparagraph (B))  
18 unless the following requirements are met:

19 “(i) No specific payment is made di-  
20 rectly or indirectly under the plan to a  
21 physician or physician group as an induce-  
22 ment to reduce or limit medically necessary  
23 services provided with respect to a specific  
24 individual enrolled with the organization.

1           “(ii) If the plan places a physician or  
2           physician group at substantial financial  
3           risk (as determined by the Secretary) for  
4           services not provided by the physician or  
5           physician group, the organization—

6                       “(I) provides stop-loss protection  
7                       for the physician or group that is ade-  
8                       quate and appropriate, based on  
9                       standards developed by the Secretary  
10                      that take into account the number of  
11                      physicians placed at such substantial  
12                      financial risk in the group or under  
13                      the plan and the number of individ-  
14                      uals enrolled with the organization  
15                      who receive services from the physi-  
16                      cian or group; and

17                      “(II) conducts periodic surveys of  
18                      both individuals enrolled and individ-  
19                      uals previously enrolled with the orga-  
20                      nization to determine the degree of  
21                      access of such individuals to services  
22                      provided by the organization and sat-  
23                      isfaction with the quality of such serv-  
24                      ices.

1           “(iii) The organization provides the  
2           Secretary with descriptive information re-  
3           garding the plan, sufficient to permit the  
4           Secretary to determine whether the plan is  
5           in compliance with the requirements of this  
6           subparagraph.

7           “(B) PHYSICIAN INCENTIVE PLAN DE-  
8           FINED.—In this paragraph, the term ‘physician  
9           incentive plan’ means any compensation ar-  
10          rangement between a MedicareAdvantage orga-  
11          nization and a physician or physician group  
12          that may directly or indirectly have the effect of  
13          reducing or limiting services provided with re-  
14          spect to individuals enrolled with the organiza-  
15          tion under this part.

16          “(5) LIMITATION ON PROVIDER INDEMNIFICA-  
17          TION.—A MedicareAdvantage organization may not  
18          provide (directly or indirectly) for a health care pro-  
19          fessional, provider of services, or other entity pro-  
20          viding health care services (or group of such profes-  
21          sionals, providers, or entities) to indemnify the orga-  
22          nization against any liability resulting from a civil  
23          action brought for any damage caused to an enrollee  
24          with a MedicareAdvantage plan of the organization

1 under this part by the organization’s denial of medi-  
2 cally necessary care.

3 “(6) SPECIAL RULES FOR MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—For pur-  
4 poses of applying this part (including subsection  
5 (k)(1)) and section 1866(a)(1)(O), a hospital (or  
6 other provider of services), a physician or other  
7 health care professional, or other entity furnishing  
8 health care services is treated as having an agree-  
9 ment or contract in effect with a MedicareAdvantage  
10 organization (with respect to an individual enrolled  
11 in a MedicareAdvantage private fee-for-service plan  
12 it offers), if—

14 “(A) the provider, professional, or other  
15 entity furnishes services that are covered under  
16 the plan to such an enrollee; and

17 “(B) before providing such services, the  
18 provider, professional, or other entity—

19 “(i) has been informed of the individ-  
20 ual’s enrollment under the plan; and

21 “(ii) either—

22 “(I) has been informed of the  
23 terms and conditions of payment for  
24 such services under the plan; or

1                   “(II) is given a reasonable oppor-  
2                   tunity to obtain information con-  
3                   cerning such terms and conditions,  
4                   in a manner reasonably designed to effect  
5                   informed agreement by a provider.

6           The previous sentence shall only apply in the ab-  
7           sence of an explicit agreement between such a pro-  
8           vider, professional, or other entity and the  
9           MedicareAdvantage organization.

10          “(k) TREATMENT OF SERVICES FURNISHED BY CER-  
11 TAIN PROVIDERS.—

12                   “(1) IN GENERAL.—Except as provided in para-  
13                   graph (2), a physician or other entity (other than a  
14                   provider of services) that does not have a contract  
15                   establishing payment amounts for services furnished  
16                   to an individual enrolled under this part with a  
17                   MedicareAdvantage organization described in section  
18                   1851(a)(2)(A) shall accept as payment in full for  
19                   covered services under this title that are furnished to  
20                   such an individual the amounts that the physician or  
21                   other entity could collect if the individual were not  
22                   so enrolled. Any penalty or other provision of law  
23                   that applies to such a payment with respect to an  
24                   individual entitled to benefits under this title (but  
25                   not enrolled with a MedicareAdvantage organization

1 under this part) also applies with respect to an indi-  
2 vidual so enrolled.

3 “(2) APPLICATION TO MEDICAREADVANTAGE  
4 PRIVATE FEE-FOR-SERVICE PLANS.—

5 “(A) BALANCE BILLING LIMITS UNDER  
6 MEDICAREADVANTAGE PRIVATE FEE-FOR-SERV-  
7 ICE PLANS IN CASE OF CONTRACT PRO-  
8 VIDERS.—

9 “(i) IN GENERAL.—In the case of an  
10 individual enrolled in a MedicareAdvantage  
11 private fee-for-service plan under this part,  
12 a physician, provider of services, or other  
13 entity that has a contract (including  
14 through the operation of subsection (j)(6))  
15 establishing a payment rate for services  
16 furnished to the enrollee shall accept as  
17 payment in full for covered services under  
18 this title that are furnished to such an in-  
19 dividual an amount not to exceed (includ-  
20 ing any deductibles, coinsurance, copay-  
21 ments, or balance billing otherwise per-  
22 mitted under the plan) an amount equal to  
23 115 percent of such payment rate.

24 “(ii) PROCEDURES TO ENFORCE LIM-  
25 ITS.—The MedicareAdvantage organization

1 that offers such a plan shall establish pro-  
2 cedures, similar to the procedures de-  
3 scribed in section 1848(g)(1)(A), in order  
4 to carry out clause (i).

5 “(iii) ASSURING ENFORCEMENT.—If  
6 the MedicareAdvantage organization fails  
7 to establish and enforce procedures re-  
8 quired under clause (ii), the organization is  
9 subject to intermediate sanctions under  
10 section 1857(g).

11 “(B) ENROLLEE LIABILITY FOR NONCON-  
12 TRACT PROVIDERS.—For provisions—

13 “(i) establishing a minimum payment  
14 rate in the case of noncontract providers  
15 under a MedicareAdvantage private fee-  
16 for-service plan, see section 1852(a)(2); or

17 “(ii) limiting enrollee liability in the  
18 case of covered services furnished by such  
19 providers, see paragraph (1) and section  
20 1866(a)(1)(O).

21 “(C) INFORMATION ON BENEFICIARY LI-  
22 ABILITY.—

23 “(i) IN GENERAL.—Each  
24 MedicareAdvantage organization that of-  
25 fers a MedicareAdvantage private fee-for-

1 service plan shall provide that enrollees  
2 under the plan who are furnished services  
3 for which payment is sought under the  
4 plan are provided an appropriate expla-  
5 nation of benefits (consistent with that  
6 provided under parts A, B, and D, and, if  
7 applicable, under medicare supplemental  
8 policies) that includes a clear statement of  
9 the amount of the enrollee's liability (in-  
10 cluding any liability for balance billing con-  
11 sistent with this subsection) with respect to  
12 payments for such services.

13 “(ii) ADVANCE NOTICE BEFORE RE-  
14 CEIPT OF INPATIENT HOSPITAL SERVICES  
15 AND CERTAIN OTHER SERVICES.—In addi-  
16 tion, such organization shall, in its terms  
17 and conditions of payments to hospitals for  
18 inpatient hospital services and for other  
19 services identified by the Secretary for  
20 which the amount of the balance billing  
21 under subparagraph (A) could be substan-  
22 tial, require the hospital to provide to the  
23 enrollee, before furnishing such services  
24 and if the hospital imposes balance billing  
25 under subparagraph (A)—

1                   “(I) notice of the fact that bal-  
2                   ance billing is permitted under such  
3                   subparagraph for such services; and

4                   “(II) a good faith estimate of the  
5                   likely amount of such balance billing  
6                   (if any), with respect to such services,  
7                   based upon the presenting condition  
8                   of the enrollee.

9           “(l) RETURN TO HOME SKILLED NURSING FACILI-  
10 TIES FOR COVERED POST-HOSPITAL EXTENDED CARE  
11 SERVICES.—

12                   “(1) ENSURING RETURN TO HOME SNF.—

13                   “(A) IN GENERAL.—In providing coverage  
14                   of post-hospital extended care services, a  
15                   MedicareAdvantage plan shall provide for such  
16                   coverage through a home skilled nursing facility  
17                   if the following conditions are met:

18                   “(i) ENROLLEE ELECTION.—The en-  
19                   rollee elects to receive such coverage  
20                   through such facility.

21                   “(ii) SNF AGREEMENT.—The facility  
22                   has a contract with the MedicareAdvantage  
23                   organization for the provision of such serv-  
24                   ices, or the facility agrees to accept sub-  
25                   stantially similar payment under the same

1 terms and conditions that apply to simi-  
2 larly situated skilled nursing facilities that  
3 are under contract with the  
4 MedicareAdvantage organization for the  
5 provision of such services and through  
6 which the enrollee would otherwise receive  
7 such services.

8 “(B) MANNER OF PAYMENT TO HOME  
9 SNF.—The organization shall provide payment  
10 to the home skilled nursing facility consistent  
11 with the contract or the agreement described in  
12 subparagraph (A)(ii), as the case may be.

13 “(2) NO LESS FAVORABLE COVERAGE.—The  
14 coverage provided under paragraph (1) (including  
15 scope of services, cost-sharing, and other criteria of  
16 coverage) shall be no less favorable to the enrollee  
17 than the coverage that would be provided to the en-  
18 rollee with respect to a skilled nursing facility the  
19 post-hospital extended care services of which are  
20 otherwise covered under the MedicareAdvantage  
21 plan.

22 “(3) RULE OF CONSTRUCTION.—Nothing in  
23 this subsection shall be construed to do the fol-  
24 lowing:

1           “(A) To require coverage through a skilled  
2 nursing facility that is not otherwise qualified  
3 to provide benefits under part A for medicare  
4 beneficiaries not enrolled in a  
5 MedicareAdvantage plan.

6           “(B) To prevent a skilled nursing facility  
7 from refusing to accept, or imposing conditions  
8 upon the acceptance of, an enrollee for the re-  
9 ceipt of post-hospital extended care services.

10          “(4) DEFINITIONS.—In this subsection:

11           “(A) HOME SKILLED NURSING FACIL-  
12 ITY.—The term ‘home skilled nursing facility’  
13 means, with respect to an enrollee who is enti-  
14 tled to receive post-hospital extended care serv-  
15 ices under a MedicareAdvantage plan, any of  
16 the following skilled nursing facilities:

17           “(i) SNF RESIDENCE AT TIME OF AD-  
18 MISSION.—The skilled nursing facility in  
19 which the enrollee resided at the time of  
20 admission to the hospital preceding the re-  
21 ceipt of such post-hospital extended care  
22 services.

23           “(ii) SNF IN CONTINUING CARE RE-  
24 TIREMENT COMMUNITY.—A skilled nursing  
25 facility that is providing such services

1 through a continuing care retirement com-  
 2 munity (as defined in subparagraph (B))  
 3 which provided residence to the enrollee at  
 4 the time of such admission.

5 “(iii) SNF RESIDENCE OF SPOUSE AT  
 6 TIME OF DISCHARGE.—The skilled nursing  
 7 facility in which the spouse of the enrollee  
 8 is residing at the time of discharge from  
 9 such hospital.

10 “(B) CONTINUING CARE RETIREMENT  
 11 COMMUNITY.—The term ‘continuing care retire-  
 12 ment community’ means, with respect to an en-  
 13 rollee in a MedicareAdvantage plan, an arrange-  
 14 ment under which housing and health-related  
 15 services are provided (or arranged) through an  
 16 organization for the enrollee under an agree-  
 17 ment that is effective for the life of the enrollee  
 18 or for a specified period.”.

19 **SEC. 203. PAYMENTS TO MEDICAREADVANTAGE ORGANIZA-**  
 20 **TIONS.**

21 Section 1853 (42 U.S.C. 1395w-23) is amended to  
 22 read as follows:

23 “PAYMENTS TO MEDICAREADVANTAGE ORGANIZATIONS

24 “SEC. 1853. (a) PAYMENTS TO ORGANIZATIONS.—

25 “(1) MONTHLY PAYMENTS.—

1           “(A) IN GENERAL.—Under a contract  
2 under section 1857 and subject to subsections  
3 (f), (h), and (j) and section 1859(e)(4), the Sec-  
4 retary shall make, to each MedicareAdvantage  
5 organization, with respect to coverage of an in-  
6 dividual for a month under this part in a  
7 MedicareAdvantage payment area, separate  
8 monthly payments with respect to—

9           “(i) benefits under the original medi-  
10 care fee-for-service program under parts A  
11 and B in accordance with subsection (d);  
12 and

13           “(ii) benefits under the voluntary pre-  
14 scription drug program under part D in  
15 accordance with section 1858A and the  
16 other provisions of this part.

17           “(B) SPECIAL RULE FOR END-STAGE  
18 RENAL DISEASE.—The Secretary shall establish  
19 separate rates of payment to a  
20 MedicareAdvantage organization with respect to  
21 classes of individuals determined to have end-  
22 stage renal disease and enrolled in a  
23 MedicareAdvantage plan of the organization.  
24 Such rates of payment shall be actuarially  
25 equivalent to rates paid to other enrollees in the

1 MedicareAdvantage payment area (or such  
2 other area as specified by the Secretary). In ac-  
3 cordance with regulations, the Secretary shall  
4 provide for the application of the seventh sen-  
5 tence of section 1881(b)(7) to payments under  
6 this section covering the provision of renal di-  
7 alysis treatment in the same manner as such  
8 sentence applies to composite rate payments de-  
9 scribed in such sentence. In establishing such  
10 rates, the Secretary shall provide for appro-  
11 priate adjustments to increase each rate to re-  
12 flect the demonstration rate (including the risk  
13 adjustment methodology associated with such  
14 rate) of the social health maintenance organiza-  
15 tion end-stage renal disease capitation dem-  
16 onstrations (established by section 2355 of the  
17 Deficit Reduction Act of 1984, as amended by  
18 section 13567(b) of the Omnibus Budget Rec-  
19 onciliation Act of 1993), and shall compute  
20 such rates by taking into account such factors  
21 as renal treatment modality, age, and the un-  
22 derlying cause of the end-stage renal disease.

23 “(2) ADJUSTMENT TO REFLECT NUMBER OF  
24 ENROLLEES.—

1           “(A) IN GENERAL.—The amount of pay-  
2           ment under this subsection may be retroactively  
3           adjusted to take into account any difference be-  
4           tween the actual number of individuals enrolled  
5           with an organization under this part and the  
6           number of such individuals estimated to be so  
7           enrolled in determining the amount of the ad-  
8           vance payment.

9           “(B) SPECIAL RULE FOR CERTAIN EN-  
10          ROLLEES.—

11           “(i) IN GENERAL.—Subject to clause  
12           (ii), the Secretary may make retroactive  
13           adjustments under subparagraph (A) to  
14           take into account individuals enrolled dur-  
15           ing the period beginning on the date on  
16           which the individual enrolls with a  
17           MedicareAdvantage organization under a  
18           plan operated, sponsored, or contributed to  
19           by the individual’s employer or former em-  
20           ployer (or the employer or former employer  
21           of the individual’s spouse) and ending on  
22           the date on which the individual is enrolled  
23           in the organization under this part, except  
24           that for purposes of making such retro-  
25           active adjustments under this subpara-

1 graph, such period may not exceed 90  
2 days.

3 “(ii) EXCEPTION.—No adjustment  
4 may be made under clause (i) with respect  
5 to any individual who does not certify that  
6 the organization provided the individual  
7 with the disclosure statement described in  
8 section 1852(e) at the time the individual  
9 enrolled with the organization.

10 “(C) EQUALIZATION OF FEDERAL CON-  
11 TRIBUTION.—In applying subparagraph (A),  
12 the Secretary shall ensure that the payment to  
13 the MedicareAdvantage organization for each  
14 individual enrolled with the organization shall  
15 equal the MedicareAdvantage benchmark  
16 amount for the payment area in which that in-  
17 dividual resides (as determined under para-  
18 graph (4)), as adjusted—

19 “(i) by multiplying the benchmark  
20 amount for that payment area by the ratio  
21 of—

22 “(I) the payment amount deter-  
23 mined under subsection (d)(4); to

1                   “(II) the weighted service area  
2                   benchmark amount determined under  
3                   subsection (d)(2); and

4                   “(ii) using such risk adjustment fac-  
5                   tor as specified by the Secretary under  
6                   subsection (b)(1)(B).

7                   “(3) COMPREHENSIVE RISK ADJUSTMENT  
8                   METHODOLOGY.—

9                   “(A) APPLICATION OF METHODOLOGY.—

10                   The Secretary shall apply the comprehensive  
11                   risk adjustment methodology described in sub-  
12                   paragraph (B) to 100 percent of the amount of  
13                   payments to plans under subsection (d)(4)(B).

14                   “(B) COMPREHENSIVE RISK ADJUSTMENT

15                   METHODOLOGY DESCRIBED.—The comprehen-

16                   sive risk adjustment methodology described in

17                   this subparagraph is the risk adjustment meth-

18                   odology that would apply with respect to

19                   MedicareAdvantage plans offered by

20                   MedicareAdvantage organizations in 2005, ex-

21                   cept that if such methodology does not apply

22                   to groups of beneficiaries who are aged or dis-

23                   abled and groups of beneficiaries who have end-

24                   stage renal disease, the Secretary shall revise

25                   such methodology to apply to such groups.

1           “(C) UNIFORM APPLICATION TO ALL  
2 TYPES OF PLANS.—Subject to section  
3 1859(e)(4), the comprehensive risk adjustment  
4 methodology established under this paragraph  
5 shall be applied uniformly without regard to the  
6 type of plan.

7           “(D) DATA COLLECTION.—In order to  
8 carry out this paragraph, the Secretary shall re-  
9 quire MedicareAdvantage organizations to sub-  
10 mit such data and other information as the Sec-  
11 retary deems necessary.

12           “(E) IMPROVEMENT OF PAYMENT ACCU-  
13 RACY.—Notwithstanding any other provision of  
14 this paragraph, the Secretary may revise the  
15 comprehensive risk adjustment methodology de-  
16 scribed in subparagraph (B) from time to time  
17 to improve payment accuracy.

18           “(4) ANNUAL CALCULATION OF BENCHMARK  
19 AMOUNTS.—For each year, the Secretary shall cal-  
20 culate a benchmark amount for each  
21 MedicareAdvantage payment area for each month  
22 for such year with respect to coverage of the benefits  
23 available under the original medicare fee-for-service  
24 program option equal to the greater of the following  
25 amounts (adjusted as appropriate for the application

1 of the risk adjustment methodology under paragraph  
2 (3)):

3 “(A) MINIMUM AMOUNT.— $\frac{1}{12}$  of the an-  
4 nual Medicare+Choice capitation rate deter-  
5 mined under subsection (c)(1)(B) for the pay-  
6 ment area for the year.

7 “(B) LOCAL FEE-FOR-SERVICE RATE.—  
8 The local fee-for-service rate for such area for  
9 the year (as calculated under paragraph (5)).

10 “(5) ANNUAL CALCULATION OF LOCAL FEE-  
11 FOR-SERVICE RATES.—

12 “(A) IN GENERAL.—Subject to subpara-  
13 graph (B), the term ‘local fee-for-service rate’  
14 means the amount of payment for a month in  
15 a MedicareAdvantage payment area for benefits  
16 under this title and associated claims processing  
17 costs for an individual who has elected to re-  
18 ceive benefits under the original medicare fee-  
19 for-service program option and not enrolled in  
20 a MedicareAdvantage plan under this part. The  
21 Secretary shall annually calculate such amount  
22 in a manner similar to the manner in which the  
23 Secretary calculated the adjusted average per  
24 capita cost under section 1876.

1           “(B) REMOVAL OF MEDICAL EDUCATION  
2 COSTS FROM CALCULATION OF LOCAL FEE-FOR-  
3 SERVICE RATE.—

4           “(i) IN GENERAL.—In calculating the  
5 local fee-for-service rate under subpara-  
6 graph (A) for a year, the amount of pay-  
7 ment described in such subparagraph shall  
8 be adjusted to exclude from such payment  
9 the payment adjustments described in  
10 clause (ii).

11           “(ii) PAYMENT ADJUSTMENTS DE-  
12 SCRIBED.—

13           “(I) IN GENERAL.—Subject to  
14 subclause (II), the payment adjust-  
15 ments described in this subparagraph  
16 are payment adjustments which the  
17 Secretary estimates are payable dur-  
18 ing the year—

19           “(aa) for the indirect costs  
20 of medical education under sec-  
21 tion 1886(d)(5)(B); and

22           “(bb) for direct graduate  
23 medical education costs under  
24 section 1886(h).

1                   “(II) TREATMENT OF PAYMENTS  
2                   COVERED UNDER STATE HOSPITAL  
3                   REIMBURSEMENT SYSTEM.—To the  
4                   extent that the Secretary estimates  
5                   that the amount of the local fee-for-  
6                   service rates reflects payments to hos-  
7                   pitals reimbursed under section  
8                   1814(b)(3), the Secretary shall esti-  
9                   mate a payment adjustment that is  
10                  comparable to the payment adjust-  
11                  ment that would have been made  
12                  under clause (i) if the hospitals had  
13                  not been reimbursed under such sec-  
14                  tion.

15                  “(b) ANNUAL ANNOUNCEMENT OF PAYMENT FAC-  
16                  TORS.—

17                   “(1) ANNUAL ANNOUNCEMENT.—Beginning in  
18                   2005, at the same time as the Secretary publishes  
19                   the risk adjusters under section 1860D–11, the Sec-  
20                   retary shall annually announce (in a manner in-  
21                   tended to provide notice to interested parties) the  
22                   following payment factors:

23                   “(A) The benchmark amount for each  
24                   MedicareAdvantage payment area (as calculated  
25                   under subsection (a)(4)) for the year.

1           “(B) The factors to be used for adjusting  
2           payments under the comprehensive risk adjust-  
3           ment methodology described in subsection  
4           (a)(3)(B) with respect to each  
5           MedicareAdvantage payment area for the year.

6           “(2) ADVANCE NOTICE OF METHODOLOGICAL  
7           CHANGES.—At least 45 days before making the an-  
8           nouncement under paragraph (1) for a year, the  
9           Secretary shall—

10           “(A) provide for notice to  
11           MedicareAdvantage organizations of proposed  
12           changes to be made in the methodology from  
13           the methodology and assumptions used in the  
14           previous announcement; and

15           “(B) provide such organizations with an  
16           opportunity to comment on such proposed  
17           changes.

18           “(3) EXPLANATION OF ASSUMPTIONS.—In each  
19           announcement made under paragraph (1), the Sec-  
20           retary shall include an explanation of the assump-  
21           tions and changes in methodology used in the an-  
22           nouncement in sufficient detail so that  
23           MedicareAdvantage organizations can compute each  
24           payment factor described in paragraph (1).

1       “(c) CALCULATION OF ANNUAL MEDICARE+CHOICE  
2 CAPITATION RATES.—

3           “(1) IN GENERAL.—For purposes of making  
4 payments under this part for years before 2006 and  
5 for purposes of calculating the annual  
6 Medicare+Choice capitation rates under paragraph  
7 (7) beginning with such year, subject to paragraph  
8 (6)(C), each annual Medicare+Choice capitation  
9 rate, for a Medicare+Choice payment area before  
10 2006 or a MedicareAdvantage payment area begin-  
11 ning with such year for a contract year consisting of  
12 a calendar year, is equal to the largest of the  
13 amounts specified in the following subparagraph (A),  
14 (B), or (C):

15           “(A) BLENDED CAPITATION RATE.—The  
16 sum of—

17           “(i) the area-specific percentage (as  
18 specified under paragraph (2) for the year)  
19 of the annual area-specific  
20 Medicare+Choice capitation rate for the  
21 MedicareAdvantage payment area, as de-  
22 termined under paragraph (3) for the year;  
23 and

24           “(ii) the national percentage (as speci-  
25 fied under paragraph (2) for the year) of

1 the input-price-adjusted annual national  
2 Medicare+Choice capitation rate, as deter-  
3 mined under paragraph (4) for the year,  
4 multiplied by the budget neutrality adjustment  
5 factor determined under paragraph (5).

6 “(B) MINIMUM AMOUNT.—12 multiplied  
7 by the following amount:

8 “(i) For 1998, \$367 (but not to ex-  
9 ceed, in the case of an area outside the 50  
10 States and the District of Columbia, 150  
11 percent of the annual per capita rate of  
12 payment for 1997 determined under sec-  
13 tion 1876(a)(1)(C) for the area).

14 “(ii) For 1999 and 2000, the min-  
15 imum amount determined under clause (i)  
16 or this clause, respectively, for the pre-  
17 ceding year, increased by the national per  
18 capita Medicare+Choice growth percentage  
19 described in paragraph (6)(A) applicable to  
20 1999 or 2000, respectively.

21 “(iii)(I) Subject to subclause (II), for  
22 2001, for any area in a Metropolitan Sta-  
23 tistical Area with a population of more  
24 than 250,000, \$525, and for any other  
25 area \$475.

1           “(II) In the case of an area outside  
2           the 50 States and the District of Colum-  
3           bia, the amount specified in this clause  
4           shall not exceed 120 percent of the amount  
5           determined under clause (ii) for such area  
6           for 2000.

7           “(iv) For 2002 through 2013, the  
8           minimum amount specified in this clause  
9           (or clause (iii)) for the preceding year in-  
10          creased by the national per capita  
11          Medicare+Choice growth percentage, de-  
12          scribed in paragraph (6)(A) for that suc-  
13          ceeding year.

14          “(v) For 2014 and each succeeding  
15          year, the minimum amount specified in  
16          this clause (or clause (iv)) for the pre-  
17          ceding year increased by the percentage in-  
18          crease in the Consumer Price Index for all  
19          urban consumers (U.S. urban average) for  
20          the 12-month period ending with June of  
21          the previous year.

22          “(C) MINIMUM PERCENTAGE INCREASE.—

23                 “(i) For 1998, 102 percent of the an-  
24                 nual per capita rate of payment for 1997

1           determined under section 1876(a)(1)(C)  
2           for the Medicare+Choice payment area.

3           “(ii) For 1999 and 2000, 102 percent  
4           of the annual Medicare+Choice capitation  
5           rate under this paragraph for the area for  
6           the previous year.

7           “(iii) For 2001, 103 percent of the  
8           annual Medicare+Choice capitation rate  
9           under this paragraph for the area for  
10          2000.

11          “(iv) For 2002 and each succeeding  
12          year, 102 percent of the annual  
13          Medicare+Choice capitation rate under  
14          this paragraph for the area for the pre-  
15          vious year.

16          “(2) AREA-SPECIFIC AND NATIONAL PERCENT-  
17          AGES.—For purposes of paragraph (1)(A)—

18                 “(A) for 1998, the ‘area-specific percent-  
19                 age’ is 90 percent and the ‘national percentage’  
20                 is 10 percent;

21                 “(B) for 1999, the ‘area-specific percent-  
22                 age’ is 82 percent and the ‘national percentage’  
23                 is 18 percent;

1           “(C) for 2000, the ‘area-specific percent-  
2           age’ is 74 percent and the ‘national percentage’  
3           is 26 percent;

4           “(D) for 2001, the ‘area-specific percent-  
5           age’ is 66 percent and the ‘national percentage’  
6           is 34 percent;

7           “(E) for 2002, the ‘area-specific percent-  
8           age’ is 58 percent and the ‘national percentage’  
9           is 42 percent; and

10           “(F) for a year after 2002, the ‘area-spe-  
11           cific percentage’ is 50 percent and the ‘national  
12           percentage’ is 50 percent.

13           “(3) ANNUAL AREA-SPECIFIC MEDICARE+  
14           CHOICE CAPITATION RATE.—

15           “(A) IN GENERAL.—For purposes of para-  
16           graph (1)(A), subject to subparagraph (B), the  
17           annual area-specific Medicare+Choice capita-  
18           tion rate for a Medicare+Choice payment  
19           area—

20           “(i) for 1998 is, subject to subpara-  
21           graph (D), the annual per capita rate of  
22           payment for 1997 determined under sec-  
23           tion 1876(a)(1)(C) for the area, increased  
24           by the national per capita

1 Medicare+Choice growth percentage for  
2 1998 (described in paragraph (6)(A)); or

3 “(ii) for a subsequent year is the an-  
4 nual area-specific Medicare+Choice capita-  
5 tion rate for the previous year determined  
6 under this paragraph for the area, in-  
7 creased by the national per capita  
8 Medicare+Choice growth percentage for  
9 such subsequent year.

10 “(B) REMOVAL OF MEDICAL EDUCATION  
11 FROM CALCULATION OF ADJUSTED AVERAGE  
12 PER CAPITA COST.—

13 “(i) IN GENERAL.—In determining  
14 the area-specific Medicare+Choice capita-  
15 tion rate under subparagraph (A) for a  
16 year (beginning with 1998), the annual per  
17 capita rate of payment for 1997 deter-  
18 mined under section 1876(a)(1)(C) shall be  
19 adjusted to exclude from the rate the ap-  
20 plicable percent (specified in clause (ii)) of  
21 the payment adjustments described in sub-  
22 paragraph (C).

23 “(ii) APPLICABLE PERCENT.—For  
24 purposes of clause (i), the applicable per-  
25 cent for—

- 1 “(I) 1998 is 20 percent;  
2 “(II) 1999 is 40 percent;  
3 “(III) 2000 is 60 percent;  
4 “(IV) 2001 is 80 percent; and  
5 “(V) a succeeding year is 100  
6 percent.

7 “(C) PAYMENT ADJUSTMENT.—

8 “(i) IN GENERAL.—Subject to clause  
9 (ii), the payment adjustments described in  
10 this subparagraph are payment adjust-  
11 ments which the Secretary estimates were  
12 payable during 1997—

13 “(I) for the indirect costs of med-  
14 ical education under section  
15 1886(d)(5)(B); and

16 “(II) for direct graduate medical  
17 education costs under section  
18 1886(h).

19 “(ii) TREATMENT OF PAYMENTS COV-  
20 ERED UNDER STATE HOSPITAL REIM-  
21 BURSEMENT SYSTEM.—To the extent that  
22 the Secretary estimates that an annual per  
23 capita rate of payment for 1997 described  
24 in clause (i) reflects payments to hospitals  
25 reimbursed under section 1814(b)(3), the

1 Secretary shall estimate a payment adjust-  
2 ment that is comparable to the payment  
3 adjustment that would have been made  
4 under clause (i) if the hospitals had not  
5 been reimbursed under such section.

6 “(D) TREATMENT OF AREAS WITH HIGHLY  
7 VARIABLE PAYMENT RATES.—In the case of a  
8 Medicare+Choice payment area for which the  
9 annual per capita rate of payment determined  
10 under section 1876(a)(1)(C) for 1997 varies by  
11 more than 20 percent from such rate for 1996,  
12 for purposes of this subsection the Secretary  
13 may substitute for such rate for 1997 a rate  
14 that is more representative of the costs of the  
15 enrollees in the area.

16 “(4) INPUT-PRICE-ADJUSTED ANNUAL NA-  
17 TIONAL MEDICARE+CHOICE CAPITATION RATE.—

18 “(A) IN GENERAL.—For purposes of para-  
19 graph (1)(A), the input-price-adjusted annual  
20 national Medicare+Choice capitation rate for a  
21 Medicare+Choice payment area for a year is  
22 equal to the sum, for all the types of medicare  
23 services (as classified by the Secretary), of the  
24 product (for each such type of service) of—

1           “(i) the national standardized annual  
2 Medicare+Choice capitation rate (deter-  
3 mined under subparagraph (B)) for the  
4 year;

5           “(ii) the proportion of such rate for  
6 the year which is attributable to such type  
7 of services; and

8           “(iii) an index that reflects (for that  
9 year and that type of services) the relative  
10 input price of such services in the area  
11 compared to the national average input  
12 price of such services.

13           In applying clause (iii), the Secretary may, sub-  
14 ject to subparagraph (C), apply those indices  
15 under this title that are used in applying (or  
16 updating) national payment rates for specific  
17 areas and localities.

18           “(B) NATIONAL STANDARDIZED ANNUAL  
19 MEDICARE+CHOICE CAPITATION RATE.—In  
20 subparagraph (A)(i), the ‘national standardized  
21 annual Medicare+Choice capitation rate’ for a  
22 year is equal to—

23           “(i) the sum (for all Medicare+Choice  
24 payment areas) of the product of—

1           “(I) the annual area-specific  
2 Medicare+Choice capitation rate for  
3 that year for the area under para-  
4 graph (3); and

5           “(II) the average number of  
6 medicare beneficiaries residing in that  
7 area in the year, multiplied by the av-  
8 erage of the risk factor weights used  
9 to adjust payments under subsection  
10 (a)(1)(A) for such beneficiaries in  
11 such area; divided by

12           “(ii) the sum of the products de-  
13 scribed in clause (i)(II) for all areas for  
14 that year.

15           “(5) PAYMENT ADJUSTMENT BUDGET NEU-  
16 TRALITY FACTOR.—For purposes of paragraph  
17 (1)(A), for each year, the Secretary shall determine  
18 a budget neutrality adjustment factor so that the  
19 aggregate of the payments under this part (other  
20 than those attributable to subsections (a)(3)(C)(iii)  
21 and (i)) shall equal the aggregate payments that  
22 would have been made under this part if payment  
23 were based entirely on area-specific capitation rates.

24           “(6) NATIONAL PER CAPITA MEDICARE+  
25 CHOICE GROWTH PERCENTAGE DEFINED.—

1           “(A) IN GENERAL.—In this part, the ‘na-  
2           tional per capita Medicare+Choice growth per-  
3           centage’ for a year is the percentage determined  
4           by the Secretary, by March 1st before the be-  
5           ginning of the year involved, to reflect the Sec-  
6           retary’s estimate of the projected per capita  
7           rate of growth in expenditures under this title  
8           for an individual entitled to (or enrolled for)  
9           benefits under part A and enrolled under part  
10          B, reduced by the number of percentage points  
11          specified in subparagraph (B) for the year. Sep-  
12          arate determinations may be made for aged en-  
13          rollees, disabled enrollees, and enrollees with  
14          end-stage renal disease.

15          “(B) ADJUSTMENT.—The number of per-  
16          centage points specified in this subparagraph  
17          is—

18                 “(i) for 1998, 0.8 percentage points;

19                 “(ii) for 1999, 0.5 percentage points;

20                 “(iii) for 2000, 0.5 percentage points;

21                 “(iv) for 2001, 0.5 percentage points;

22                 “(v) for 2002, 0.3 percentage points;

23                 and

24                 “(vi) for a year after 2002, 0 percent-  
25                 age points.

1           “(C) ADJUSTMENT FOR OVER OR UNDER  
2           PROJECTION OF NATIONAL PER CAPITA  
3           MEDICARE+CHOICE GROWTH PERCENTAGE.—  
4           Beginning with rates calculated for 1999, be-  
5           fore computing rates for a year as described in  
6           paragraph (1), the Secretary shall adjust all  
7           area-specific and national Medicare+Choice  
8           capitation rates (and beginning in 2000, the  
9           minimum amount) for the previous year for the  
10          differences between the projections of the na-  
11          tional per capita Medicare+Choice growth per-  
12          centage for that year and previous years and  
13          the current estimate of such percentage for  
14          such years.

15          “(7) TRANSITION TO MEDICAREADVANTAGE  
16          COMPETITION.—

17                 “(A) IN GENERAL.—For each year (begin-  
18                 ning with 2006) payments to  
19                 MedicareAdvantage plans shall not be computed  
20                 under this subsection, but instead shall be  
21                 based on the payment amount determined  
22                 under subsection (d).

23                 “(B) CONTINUED CALCULATION OF CAPI-  
24                 TATION RATES.—For each year (beginning with  
25                 2006) the Secretary shall calculate and publish

1 the annual Medicare+Choice capitation rates  
2 under this subsection and shall use the annual  
3 Medicare+Choice capitation rate determined  
4 under subsection (c)(1) for purposes of deter-  
5 mining the benchmark amount under subsection  
6 (a)(4).

7 “(d) SECRETARY’S DETERMINATION OF PAYMENT  
8 AMOUNT.—

9 “(1) REVIEW OF PLAN BIDS.—The Secretary  
10 shall review each plan bid submitted under section  
11 1854(a) for the coverage of benefits under the origi-  
12 nal medicare fee-for-service program option to en-  
13 sure that such bids are consistent with the require-  
14 ments under this part an are based on the assump-  
15 tions described in section 1854(a)(2)(A)(iii).

16 “(2) DETERMINATION OF WEIGHTED SERVICE  
17 AREA BENCHMARK AMOUNTS.—The Secretary shall  
18 calculate a weighted service area benchmark amount  
19 for the benefits under the original medicare fee-for-  
20 service program option for each plan equal to the  
21 weighted average of the benchmark amounts for  
22 benefits under such original medicare fee-for-service  
23 program option for the payment areas included in  
24 the service area of the plan using the assumptions  
25 described in section 1854(a)(2)(A)(iii).

1           “(3) COMPARISON TO BENCHMARK.—The Sec-  
2           retary shall determine the difference between each  
3           plan bid (as adjusted under paragraph (1)) and the  
4           weighted service area benchmark amount (as deter-  
5           mined under paragraph (2)) for purposes of deter-  
6           mining—

7                   “(A) the payment amount under para-  
8                   graph (4); and

9                   “(B) the additional benefits required and  
10                  MedicareAdvantage monthly basic beneficiary  
11                  premiums.

12           “(4) DETERMINATION OF PAYMENT AMOUNT  
13           FOR ORIGINAL MEDICARE FEE-FOR-SERVICE BENE-  
14           FITS.—

15                   “(A) IN GENERAL.—Subject to subpara-  
16                   graph (B), the Secretary shall determine the  
17                   payment amount for MedicareAdvantage plans  
18                   for the benefits under the original medicare fee-  
19                   for-service program option as follows:

20                           “(i) BIDS THAT EQUAL OR EXCEED  
21                           THE BENCHMARK.—In the case of a plan  
22                           bid that equals or exceeds the weighted  
23                           service area benchmark amount, the  
24                           amount of each monthly payment to a  
25                           MedicareAdvantage organization with re-

1           spect to each individual enrolled in a plan  
2           shall be the weighted service area bench-  
3           mark amount.

4           “(ii) BIDS BELOW THE BENCH-  
5           MARK.—In the case of a plan bid that is  
6           less than the weighted service area bench-  
7           mark amount, the amount of each monthly  
8           payment to a MedicareAdvantage organiza-  
9           tion with respect to each individual en-  
10          rolled in a plan shall be the weighted serv-  
11          ice area benchmark amount reduced by the  
12          amount of any premium reduction elected  
13          by the plan under section 1854(d)(1)(A)(i).

14          “(B) APPLICATION OF COMPREHENSIVE  
15          RISK ADJUSTMENT METHODOLOGY.—The Sec-  
16          retary shall adjust the amounts determined  
17          under subparagraph (A) using the comprehen-  
18          sive risk adjustment methodology applicable  
19          under subsection (a)(3).

20          “(6) ADJUSTMENT FOR NATIONAL COVERAGE  
21          DETERMINATIONS AND LEGISLATIVE CHANGES IN  
22          BENEFITS.—If the Secretary makes a determination  
23          with respect to coverage under this title or there is  
24          a change in benefits required to be provided under  
25          this part that the Secretary projects will result in a

1 significant increase in the costs to  
2 MedicareAdvantage organizations of providing bene-  
3 fits under contracts under this part (for periods  
4 after any period described in section 1852(a)(5)),  
5 the Secretary shall appropriately adjust the bench-  
6 mark amounts or payment amounts (as determined  
7 by the Secretary). Such projection and adjustment  
8 shall be based on an analysis by the Secretary of the  
9 actuarial costs associated with the new benefits.

10 “(7) BENEFITS UNDER THE ORIGINAL MEDI-  
11 CARE FEE-FOR-SERVICE PROGRAM OPTION DE-  
12 FINED.—For purposes of this part, the term ‘bene-  
13 fits under the original medicare fee-for-service pro-  
14 gram option’ means those items and services (other  
15 than hospice care) for which benefits are available  
16 under parts A and B to individuals entitled to, or  
17 enrolled for, benefits under part A and enrolled  
18 under part B, with cost-sharing for those services as  
19 required under parts A and B or an actuarially  
20 equivalent level of cost-sharing as determined in this  
21 part.

22 “(e) MEDICAREADVANTAGE PAYMENT AREA DE-  
23 FINED.—

24 “(1) IN GENERAL.—In this part, except as pro-  
25 vided in paragraph (3), the term

1 ‘MedicareAdvantage payment area’ means a county,  
2 or equivalent area specified by the Secretary.

3 “(2) RULE FOR ESRD BENEFICIARIES.—In the  
4 case of individuals who are determined to have end  
5 stage renal disease, the MedicareAdvantage payment  
6 area shall be a State or such other payment area as  
7 the Secretary specifies.

8 “(3) GEOGRAPHIC ADJUSTMENT.—

9 “(A) IN GENERAL.—Upon written request  
10 of the chief executive officer of a State for a  
11 contract year (beginning after 2005) made by  
12 not later than February 1 of the previous year,  
13 the Secretary shall make a geographic adjust-  
14 ment to a MedicareAdvantage payment area in  
15 the State otherwise determined under para-  
16 graph (1)—

17 “(i) to a single statewide  
18 MedicareAdvantage payment area;

19 “(ii) to the metropolitan based system  
20 described in subparagraph (C); or

21 “(iii) to consolidating into a single  
22 MedicareAdvantage payment area non-  
23 contiguous counties (or equivalent areas  
24 described in paragraph (1)) within a State.

1           Such adjustment shall be effective for payments  
2           for months beginning with January of the year  
3           following the year in which the request is re-  
4           ceived.

5           “(B) BUDGET NEUTRALITY ADJUST-  
6           MENT.—In the case of a State requesting an  
7           adjustment under this paragraph, the Secretary  
8           shall initially (and annually thereafter) adjust  
9           the payment rates otherwise established under  
10          this section for MedicareAdvantage payment  
11          areas in the State in a manner so that the ag-  
12          gregate of the payments under this section in  
13          the State shall not exceed the aggregate pay-  
14          ments that would have been made under this  
15          section for MedicareAdvantage payment areas  
16          in the State in the absence of the adjustment  
17          under this paragraph.

18          “(C) METROPOLITAN BASED SYSTEM.—  
19          The metropolitan based system described in this  
20          subparagraph is one in which—

21                  “(i) all the portions of each metropoli-  
22                  tan statistical area in the State or in the  
23                  case of a consolidated metropolitan statis-  
24                  tical area, all of the portions of each pri-  
25                  mary metropolitan statistical area within

1 the consolidated area within the State, are  
2 treated as a single MedicareAdvantage  
3 payment area; and

4 “(ii) all areas in the State that do not  
5 fall within a metropolitan statistical area  
6 are treated as a single MedicareAdvantage  
7 payment area.

8 “(D) AREAS.—In subparagraph (C), the  
9 terms ‘metropolitan statistical area’, ‘consoli-  
10 dated metropolitan statistical area’, and ‘pri-  
11 mary metropolitan statistical area’ mean any  
12 area designated as such by the Secretary of  
13 Commerce.

14 “(f) SPECIAL RULES FOR INDIVIDUALS ELECTING  
15 MSA PLANS.—

16 “(1) IN GENERAL.—If the amount of the  
17 MedicareAdvantage monthly MSA premium (as de-  
18 fined in section 1854(b)(2)(D)) for an MSA plan for  
19 a year is less than  $\frac{1}{12}$  of the annual  
20 Medicare+Choice capitation rate applied under this  
21 section for the area and year involved, the Secretary  
22 shall deposit an amount equal to 100 percent of  
23 such difference in a MedicareAdvantage MSA estab-  
24 lished (and, if applicable, designated) by the indi-  
25 vidual under paragraph (2).

1           “(2) ESTABLISHMENT AND DESIGNATION OF  
2           MEDICAREADVANTAGE MEDICAL SAVINGS ACCOUNT  
3           AS REQUIREMENT FOR PAYMENT OF CONTRIBU-  
4           TION.—In the case of an individual who has elected  
5           coverage under an MSA plan, no payment shall be  
6           made under paragraph (1) on behalf of an individual  
7           for a month unless the individual—

8                   “(A) has established before the beginning  
9                   of the month (or by such other deadline as the  
10                  Secretary may specify) a MedicareAdvantage  
11                  MSA (as defined in section 138(b)(2) of the In-  
12                  ternal Revenue Code of 1986); and

13                  “(B) if the individual has established more  
14                  than 1 such MedicareAdvantage MSA, has des-  
15                  ignated 1 of such accounts as the individual’s  
16                  MedicareAdvantage MSA for purposes of this  
17                  part.

18           Under rules under this section, such an individual  
19           may change the designation of such account under  
20           subparagraph (B) for purposes of this part.

21           “(3) LUMP-SUM DEPOSIT OF MEDICAL SAVINGS  
22           ACCOUNT CONTRIBUTION.—In the case of an indi-  
23           vidual electing an MSA plan effective beginning with  
24           a month in a year, the amount of the contribution  
25           to the MedicareAdvantage MSA on behalf of the in-

1       dividual for that month and all successive months in  
2       the year shall be deposited during that first month.  
3       In the case of a termination of such an election as  
4       of a month before the end of a year, the Secretary  
5       shall provide for a procedure for the recovery of de-  
6       posits attributable to the remaining months in the  
7       year.

8       “(g) PAYMENTS FROM TRUST FUNDS.—Except as  
9       provided in section 1858A(c) (relating to payments for  
10      qualified prescription drug coverage), the payment to a  
11      MedicareAdvantage organization under this section for in-  
12      dividuals enrolled under this part with the organization  
13      and payments to a MedicareAdvantage MSA under sub-  
14      section (e)(1) shall be made from the Federal Hospital In-  
15      surance Trust Fund and the Federal Supplementary Med-  
16      ical Insurance Trust Fund in such proportion as the Sec-  
17      retary determines reflects the relative weight that benefits  
18      under part A and under part B represents of the actuarial  
19      value of the total benefits under this title. Monthly pay-  
20      ments otherwise payable under this section for October  
21      2000 shall be paid on the first business day of such month.  
22      Monthly payments otherwise payable under this section  
23      for October 2001 shall be paid on the last business day  
24      of September 2001. Monthly payments otherwise payable

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

3 “(h) SPECIAL RULE FOR CERTAIN INPATIENT HOS-  
4 PITAL STAYS.—In the case of an individual who is receiv-  
5 ing inpatient hospital services from a subsection (d) hos-  
6 pital (as defined in section 1886(d)(1)(B)) as of the effec-  
7 tive date of the individual’s—

8 “(1) election under this part of a  
9 MedicareAdvantage plan offered by a  
10 MedicareAdvantage organization—

11 “(A) payment for such services until the  
12 date of the individual’s discharge shall be made  
13 under this title through the MedicareAdvantage  
14 plan or the original medicare fee-for-service  
15 program option (as the case may be) elected be-  
16 fore the election with such organization,

17 “(B) the elected organization shall not be  
18 financially responsible for payment for such  
19 services until the date after the date of the indi-  
20 vidual’s discharge; and

21 “(C) the organization shall nonetheless be  
22 paid the full amount otherwise payable to the  
23 organization under this part; or

24 “(2) termination of election with respect to a  
25 MedicareAdvantage organization under this part—

1           “(A) the organization shall be financially  
2 responsible for payment for such services after  
3 such date and until the date of the individual’s  
4 discharge;

5           “(B) payment for such services during the  
6 stay shall not be made under section 1886(d) or  
7 by any succeeding MedicareAdvantage organiza-  
8 tion; and

9           “(C) the terminated organization shall not  
10 receive any payment with respect to the indi-  
11 vidual under this part during the period the in-  
12 dividual is not enrolled.

13       “(i) SPECIAL RULE FOR HOSPICE CARE.—

14           “(1) INFORMATION.—A contract under this  
15 part shall require the MedicareAdvantage organiza-  
16 tion to inform each individual enrolled under this  
17 part with a MedicareAdvantage plan offered by the  
18 organization about the availability of hospice care  
19 if—

20           “(A) a hospice program participating  
21 under this title is located within the organiza-  
22 tion’s service area; or

23           “(B) it is common practice to refer pa-  
24 tients to hospice programs outside such service  
25 area.

1           “(2) PAYMENT.—If an individual who is en-  
2 rolled with a MedicareAdvantage organization under  
3 this part makes an election under section 1812(d)(1)  
4 to receive hospice care from a particular hospice pro-  
5 gram—

6                   “(A) payment for the hospice care fur-  
7 nished to the individual shall be made to the  
8 hospice program elected by the individual by  
9 the Secretary;

10                   “(B) payment for other services for which  
11 the individual is eligible notwithstanding the in-  
12 dividual’s election of hospice care under section  
13 1812(d)(1), including services not related to the  
14 individual’s terminal illness, shall be made by  
15 the Secretary to the MedicareAdvantage organi-  
16 zation or the provider or supplier of the service  
17 instead of payments calculated under subsection  
18 (a); and

19                   “(C) the Secretary shall continue to make  
20 monthly payments to the MedicareAdvantage  
21 organization in an amount equal to the value of  
22 the additional benefits required under section  
23 1854(f)(1)(A).”.

1 **SEC. 204. SUBMISSION OF BIDS; PREMIUMS.**

2 Section 1854 (42 U.S.C. 1395w-24) is amended to  
3 read as follows:

4 “SUBMISSION OF BIDS; PREMIUMS

5 “SEC. 1854. (a) SUBMISSION OF BIDS BY  
6 MEDICAREADVANTAGE ORGANIZATIONS.—

7 “(1) IN GENERAL.—Not later than the second  
8 Monday in September and except as provided in  
9 paragraph (3), each MedicareAdvantage organiza-  
10 tion shall submit to the Secretary, in such form and  
11 manner as the Secretary may specify, for each  
12 MedicareAdvantage plan that the organization in-  
13 tends to offer in a service area in the following  
14 year—

15 “(A) notice of such intent and information  
16 on the service area of the plan;

17 “(B) the plan type for each plan;

18 “(C) if the MedicareAdvantage plan is a  
19 coordinated care plan (as described in section  
20 1851(a)(2)(A)) or a private fee-for-service plan  
21 (as described in section 1851(a)(2)(C)), the in-  
22 formation described in paragraph (2) with re-  
23 spect to each payment area;

24 “(D) the enrollment capacity (if any) in re-  
25 lation to the plan and each payment area;

1           “(E) the expected mix, by health status, of  
2 enrolled individuals; and

3           “(F) such other information as the Sec-  
4 retary may specify.

5           “(2) INFORMATION REQUIRED FOR COORDI-  
6 NATED CARE PLANS AND PRIVATE FEE-FOR-SERVICE  
7 PLANS.—For a Medicare Advantage plan that is a  
8 coordinated care plan (as described in section  
9 1851(a)(2)(A)) or a private fee-for-service plan (as  
10 described in section 1851(a)(2)(C)), the information  
11 described in this paragraph is as follows:

12           “(A) INFORMATION REQUIRED WITH RE-  
13 SPECT TO BENEFITS UNDER THE ORIGINAL  
14 MEDICARE FEE-FOR-SERVICE PROGRAM OP-  
15 TION.—Information relating to the coverage of  
16 benefits under the original medicare fee-for-  
17 service program option as follows:

18           “(i) The plan bid, which shall consist  
19 of a dollar amount that represents the  
20 total amount that the plan is willing to ac-  
21 cept (not taking into account the applica-  
22 tion of the comprehensive risk adjustment  
23 methodology under section 1853(a)(3)) for  
24 providing coverage of the benefits under  
25 the original medicare fee-for-service pro-

1           gram option to an individual enrolled in  
2           the plan that resides in the service area of  
3           the plan for a month.

4           “(ii) For the enhanced medical bene-  
5           fits package offered—

6                   “(I) the adjusted community rate  
7                   (as defined in subsection (g)(3)) of  
8                   the package;

9                   “(II) the portion of the actuarial  
10                   value of such benefits package (if any)  
11                   that will be applied toward satisfying  
12                   the requirement for additional benefits  
13                   under subsection (g);

14                   “(III) the Medicare Advantage  
15                   monthly beneficiary premium for en-  
16                   hanced medical benefits (as defined in  
17                   subsection (b)(2)(C));

18                   “(IV) a description of any cost-  
19                   sharing;

20                   “(V) a description of whether the  
21                   amount of the unified deductible has  
22                   been lowered or the maximum limita-  
23                   tions on out-of-pocket expenses have  
24                   been decreased (relative to the levels  
25                   used in calculating the plan bid); and

1                   “(VI) such other information as  
2                   the Secretary considers necessary.

3                   “(iii) The assumptions that the  
4                   MedicareAdvantage organization used in  
5                   preparing the plan bid with respect to  
6                   numbers, in each payment area, of enrolled  
7                   individuals and the mix, by health status,  
8                   of such individuals.

9                   “(B) INFORMATION REQUIRED WITH RE-  
10                  SPECT TO PART D.—The information required  
11                  to be submitted by an eligible entity under sec-  
12                  tion 1860D–12, including the monthly pre-  
13                  miums for standard coverage and any other  
14                  qualified prescription drug coverage available to  
15                  individuals enrolled under part D.

16                  “(C) DETERMINING PLAN COSTS IN-  
17                  CLUDED IN PLAN BID.—For purposes of sub-  
18                  mitting its plan bid under subparagraph (A)(i)  
19                  a MedicareAdvantage plan offered by a  
20                  MedicareAdvantage organization satisfies sub-  
21                  paragraphs (A) and (C) of section 1852(a)(1) if  
22                  the actuarial value of the deductibles, coinsur-  
23                  ance, and copayments applicable on average to  
24                  individuals enrolled in such plan under this part  
25                  with respect to benefits under the original medi-

1 care fee-for-service program option on which  
2 that bid is based (ignoring any reduction in  
3 cost-sharing offered by such plan as enhanced  
4 medical benefits under paragraph (2)(A)(ii) or  
5 required under clause (ii) or (iii) of subsection  
6 (g)(1)(C)) equals the amount specified in sub-  
7 section (f)(1)(B).

8 “(3) REQUIREMENTS FOR MSA PLANS.—For an  
9 MSA plan described in section 1851(a)(2)(B), the  
10 information described in this paragraph is the infor-  
11 mation that such a plan would have been required  
12 to submit under this part if the Prescription Drug  
13 and Medicare Improvements Act of 2003 had not  
14 been enacted.

15 “(4) REVIEW.—

16 “(A) IN GENERAL.—Subject to subpara-  
17 graph (B), the Secretary shall review the ad-  
18 justed community rates (as defined in section  
19 1854(g)(3)), the amounts of the  
20 MedicareAdvantage monthly basic premium and  
21 the MedicareAdvantage monthly beneficiary  
22 premium for enhanced medical benefits filed  
23 under this subsection and shall approve or dis-  
24 approve such rates and amounts so submitted.  
25 The Secretary shall review the actuarial as-

1           sumptions and data used by the  
2           MedicareAdvantage organization with respect to  
3           such rates and amounts so submitted to deter-  
4           mine the appropriateness of such assumptions  
5           and data.

6           “(B) MSA EXCEPTION.—The Secretary  
7           shall not review, approve, or disapprove the  
8           amounts submitted under paragraph (3).

9           “(C) CLARIFICATION OF AUTHORITY RE-  
10          GARDING DISAPPROVAL OF UNREASONABLE  
11          BENEFICIARY COST-SHARING.—Under the au-  
12          thority under subparagraph (A), the Secretary  
13          may disapprove the bid if the Secretary deter-  
14          mines that the deductibles, coinsurance, or co-  
15          payments applicable under the plan discourage  
16          access to covered services or are likely to result  
17          in favorable selection of MedicareAdvantage eli-  
18          gible individuals.

19          “(5) APPLICATION OF FEHBP STANDARD; PRO-  
20          HIBITION ON PRICE GOUGING.—Each bid amount  
21          submitted under paragraph (1) for a  
22          MedicareAdvantage plan must reasonably and equi-  
23          tably reflect the cost of benefits provided under that  
24          plan.

25          “(b) MONTHLY PREMIUMS CHARGED.—

1 “(1) IN GENERAL.—

2 “(A) COORDINATED CARE AND PRIVATE  
3 FEE-FOR-SERVICE PLANS.—The monthly  
4 amount of the premium charged to an indi-  
5 vidual enrolled in a MedicareAdvantage plan  
6 (other than an MSA plan) offered by a  
7 MedicareAdvantage organization shall be equal  
8 to the sum of the following:

9 “(i) The MedicareAdvantage monthly  
10 basic beneficiary premium (if any).

11 “(ii) The MedicareAdvantage monthly  
12 beneficiary premium for enhanced medical  
13 benefits (if any).

14 “(iii) The MedicareAdvantage monthly  
15 obligation for qualified prescription drug  
16 coverage (if any).

17 “(B) MSA PLANS.—The rules under this  
18 section that would have applied with respect to  
19 an MSA plan if the Prescription Drug and  
20 Medicare Improvements Act of 2003 had not  
21 been enacted shall continue to apply to MSA  
22 plans after the date of enactment of such Act.

23 “(2) PREMIUM TERMINOLOGY.—For purposes  
24 of this part:

1           “(A)   MEDICAREADVANTAGE   MONTHLY  
2           BASIC   BENEFICIARY   PREMIUM.—The   term  
3           ‘MedicareAdvantage   monthly   basic   beneficiary  
4           premium’   means,   with   respect   to   a  
5           MedicareAdvantage   plan,   the   amount   required  
6           to   be   charged   under   subsection   (d)(2)   for   the  
7           plan.

8           “(B)   MEDICAREADVANTAGE   MONTHLY  
9           BENEFICIARY   OBLIGATION   FOR   QUALIFIED   PRE-  
10          SCRIPTION   DRUG   COVERAGE.—The   term  
11          ‘MedicareAdvantage   monthly   beneficiary   obliga-  
12          tion   for   qualified   prescription   drug   coverage’  
13          means,   with   respect   to   a   MedicareAdvantage  
14          plan,   the   amount   determined   under   section  
15          1858A(d).

16          “(C)   MEDICAREADVANTAGE   MONTHLY  
17          BENEFICIARY   PREMIUM   FOR   ENHANCED   MED-  
18          ICAL   BENEFITS.—The   term   ‘MedicareAdvan-  
19          tage   monthly   beneficiary   premium   for   enhanced  
20          medical   benefits’   means,   with   respect   to   a  
21          MedicareAdvantage   plan,   the   amount   required  
22          to   be   charged   under   subsection   (f)(2)   for   the  
23          plan,   or,   in   the   case   of   an   MSA   plan,   the  
24          amount   filed   under   subsection   (a)(3).

1           “(D) MEDICAREADVANTAGE MONTHLY  
2           MSA PREMIUM.—The term ‘MedicareAdvantage  
3           monthly MSA premium’ means, with respect to  
4           a MedicareAdvantage plan, the amount of such  
5           premium filed under subsection (a)(3) for the  
6           plan.

7           “(c) UNIFORM PREMIUM.—The MedicareAdvantage  
8           monthly basic beneficiary premium, the  
9           MedicareAdvantage monthly beneficiary obligation for  
10          qualified prescription drug coverage, the  
11          MedicareAdvantage monthly beneficiary premium for en-  
12          hanced medical benefits, and the MedicareAdvantage  
13          monthly MSA premium charged under subsection (b) of  
14          a MedicareAdvantage organization under this part may  
15          not vary among individuals enrolled in the plan.

16          “(d) DETERMINATION OF PREMIUM REDUCTIONS,  
17          REDUCED COST-SHARING, ADDITIONAL BENEFITS, AND  
18          BENEFICIARY PREMIUMS.—

19                 “(1) BIDS BELOW THE BENCHMARK.—If the  
20                 Secretary determines under section 1853(d)(3) that  
21                 the weighted service area benchmark amount ex-  
22                 ceeds the plan bid, the Secretary shall require the  
23                 plan to provide additional benefits in accordance  
24                 with subsection (g).

1           “(2) BIDS ABOVE THE BENCHMARK.—If the  
2           Secretary determines under section 1853(d)(3) that  
3           the plan bid exceeds the weighted service area  
4           benchmark amount (determined under section  
5           1853(d)(2)), the amount of such excess shall be the  
6           MedicareAdvantage monthly basic beneficiary pre-  
7           mium (as defined in section 1854(b)(2)(A)).

8           “(e) TERMS AND CONDITIONS OF IMPOSING PRE-  
9           MIUMS.—Each MedicareAdvantage organization shall per-  
10          mit the payment of any MedicareAdvantage monthly basic  
11          premium, the MedicareAdvantage monthly beneficiary ob-  
12          ligation for qualified prescription drug coverage, and the  
13          MedicareAdvantage monthly beneficiary premium for en-  
14          hanced medical benefits on a monthly basis, may termi-  
15          nate election of individuals for a MedicareAdvantage plan  
16          for failure to make premium payments only in accordance  
17          with section 1851(g)(3)(B)(i), and may not provide for  
18          cash or other monetary rebates as an inducement for en-  
19          rollment or otherwise (other than as an additional benefit  
20          described in subsection (g)(1)(C)(i)).

21          “(f) LIMITATION ON ENROLLEE LIABILITY.—

22                  “(1) FOR BENEFITS UNDER THE ORIGINAL  
23          MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—  
24          The sum of—

1           “(A) the MedicareAdvantage monthly basic  
2           beneficiary premium (multiplied by 12) and the  
3           actuarial value of the deductibles, coinsurance,  
4           and copayments (determined on the same basis  
5           as used in determining the plan’s bid under  
6           paragraph (2)(C)) applicable on average to indi-  
7           viduals enrolled under this part with a  
8           MedicareAdvantage plan described in subpara-  
9           graph (A) or (C) of section 1851(a)(2) of an or-  
10          ganization with respect to required benefits de-  
11          scribed in section 1852(a)(1)(A); must equal

12           “(B) the actuarial value of the deductibles,  
13           coinsurance, and copayments that would be ap-  
14           plicable on average to individuals who have  
15           elected to receive benefits under the original  
16           medicare fee-for-service program option if such  
17           individuals were not members of a  
18           MedicareAdvantage organization for the year  
19           (adjusted as determined appropriate by the Sec-  
20           retary to account for geographic differences and  
21           for plan cost and utilization differences).

22           “(2) FOR ENHANCED MEDICAL BENEFITS.—If  
23           the MedicareAdvantage organization provides to its  
24           members enrolled under this part in a  
25           MedicareAdvantage plan described in subparagraph

1 (A) or (C) of section 1851(a)(2) with respect to en-  
2 hanced medical benefits relating to benefits under  
3 the original medicare fee-for-service program option,  
4 the sum of the MedicareAdvantage monthly bene-  
5 ficiary premium for enhanced medical benefits (mul-  
6 tiplied by 12) charged and the actuarial value of its  
7 deductibles, coinsurance, and copayments charged  
8 with respect to such benefits for a year must equal  
9 the adjusted community rate (as defined in sub-  
10 section (g)(3)) for such benefits for the year minus  
11 the actuarial value of any additional benefits pursu-  
12 ant to clause (ii), (iii), or (iv) of subsection (g)(2)(C)  
13 that the plan specified under subsection (a)(2)(i)(II).

14 “(3) DETERMINATION ON OTHER BASIS.—If the  
15 Secretary determines that adequate data are not  
16 available to determine the actuarial value under  
17 paragraph (1)(A) or (2), the Secretary may deter-  
18 mine such amount with respect to all individuals in  
19 the same geographic area, the State, or in the  
20 United States, eligible to enroll in the  
21 MedicareAdvantage plan involved under this part or  
22 on the basis of other appropriate data.

23 “(4) SPECIAL RULE FOR PRIVATE FEE-FOR-  
24 SERVICE PLANS.—With respect to a  
25 MedicareAdvantage private fee-for-service plan

1 (other than a plan that is an MSA plan), in no event  
2 may—

3 “(A) the actuarial value of the deductibles,  
4 coinsurance, and copayments applicable on av-  
5 erage to individuals enrolled under this part  
6 with such a plan of an organization with re-  
7 spect to required benefits described in subpara-  
8 graphs (A), (C), and (D) of section 1852(a)(1);  
9 exceed

10 “(B) the actuarial value of the deductibles,  
11 coinsurance, and copayments that would be ap-  
12 plicable on average to individuals entitled to (or  
13 enrolled for) benefits under part A and enrolled  
14 under part B if they were not members of a  
15 MedicareAdvantage organization for the year.

16 “(g) REQUIREMENT FOR ADDITIONAL BENEFITS.—

17 “(1) REQUIREMENT.—

18 “(A) IN GENERAL.—Each  
19 MedicareAdvantage organization (in relation to  
20 a MedicareAdvantage plan, other than an MSA  
21 plan, it offers) shall provide that if there is an  
22 excess amount (as defined in subparagraph (B))  
23 for the plan for a contract year, subject to the  
24 succeeding provisions of this subsection, the or-  
25 ganization shall provide to individuals such ad-

1           ditional benefits described in subparagraph (C)  
2           as the organization may specify in a value  
3           which the Secretary determines is at least equal  
4           to the adjusted excess amount (as defined in  
5           subparagraph (D)).

6           “(B) EXCESS AMOUNT.—For purposes of  
7           this paragraph, the term ‘excess amount’  
8           means, for an organization for a plan, is 100  
9           percent of the amount (if any) by which the  
10          weighted service area benchmark amount (de-  
11          termined under section 1853(d)(2)) exceeds the  
12          plan bid (as adjusted under section  
13          1853(d)(1)).

14          “(C) ADDITIONAL BENEFITS DE-  
15          SCRIBED.—The additional benefits described in  
16          this subparagraph are as follows:

17                 “(i) Subject to subparagraph (F), a  
18                 monthly part B premium reduction for in-  
19                 dividuals enrolled in the plan.

20                 “(ii) Lowering the amount of the uni-  
21                 fied deductible and decreasing the max-  
22                 imum limitations on out-of-pocket expenses  
23                 for individuals enrolled in the plan.

1           “(iii) A reduction in the actuarial  
2           value of plan cost-sharing for plan enroll-  
3           ees.

4           “(iv) Subject to subparagraph (E),  
5           such additional benefits as the organization  
6           may specify.

7           “(v) Contributing to the stabilization  
8           fund under paragraph (2).

9           “(vi) Any combination of the reduc-  
10          tions and benefits described in clauses (i)  
11          through (v).

12          “(D) ADJUSTED EXCESS AMOUNT.—For  
13          purposes of this paragraph, the term ‘adjusted  
14          excess amount’ means, for an organization for  
15          a plan, is the excess amount reduced to reflect  
16          any amount withheld and reserved for the orga-  
17          nization for the year under paragraph (2).

18          “(E) RULE FOR APPROVAL OF MEDICAL  
19          AND PRESCRIPTION DRUG BENEFITS.—An orga-  
20          nization may not specify any additional benefit  
21          that provides for the coverage of any prescrip-  
22          tion drug (other than that relating to prescrip-  
23          tion drugs covered under the original medicare  
24          fee-for-service program option).

25          “(F) PREMIUM REDUCTIONS.—

1           “(i) IN GENERAL.—Subject to clause  
2           (ii), as part of providing any additional  
3           benefits required under subparagraph (A),  
4           a MedicareAdvantage organization may  
5           elect a reduction in its payments under  
6           section 1853(a)(1)(A)(i) with respect to a  
7           MedicareAdvantage plan and the Secretary  
8           shall apply such reduction to reduce the  
9           premium under section 1839 of each en-  
10          rollee in such plan as provided in section  
11          1840(i).

12          “(ii) AMOUNT OF REDUCTION.—The  
13          amount of the reduction under clause (i)  
14          with respect to any enrollee in a  
15          MedicareAdvantage plan—

16                  “(I) may not exceed 125 percent  
17                  of the premium described under sec-  
18                  tion 1839(a)(3); and

19                  “(II) shall apply uniformly to  
20                  each enrollee of the  
21                  MedicareAdvantage plan to which  
22                  such reduction applies.

23          “(G) UNIFORM APPLICATION.—This para-  
24          graph shall be applied uniformly for all enroll-  
25          ees for a plan.

1           “(H) CONSTRUCTION.—Nothing in this  
2           subsection shall be construed as preventing a  
3           MedicareAdvantage organization from providing  
4           enhanced medical benefits (described in section  
5           1852(a)(3)) that are in addition to the health  
6           care benefits otherwise required to be provided  
7           under this paragraph and from imposing a pre-  
8           mium for such enhanced medical benefits.

9           “(2) STABILIZATION FUND.—A MedicareAdvan-  
10          tage organization may provide that a part of the  
11          value of an excess amount described in paragraph  
12          (1) be withheld and reserved in the Federal Hospital  
13          Insurance Trust Fund and in the Federal Supple-  
14          mentary Medical Insurance Trust Fund (in such  
15          proportions as the Secretary determines to be appro-  
16          priate) by the Secretary for subsequent annual con-  
17          tract periods, to the extent required to prevent  
18          undue fluctuations in the additional benefits offered  
19          in those subsequent periods by the organization in  
20          accordance with such paragraph. Any of such value  
21          of the amount reserved which is not provided as ad-  
22          ditional benefits described in paragraph (1)(A) to in-  
23          dividuals electing the MedicareAdvantage plan of the  
24          organization in accordance with such paragraph

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

3 “(3) ADJUSTED COMMUNITY RATE.—For pur-  
4 poses of this subsection, subject to paragraph (4),  
5 the term ‘adjusted community rate’ for a service or  
6 services means, at the election of a  
7 MedicareAdvantage organization, either—

8 “(A) the rate of payment for that service  
9 or services which the Secretary annually deter-  
10 mines would apply to an individual electing a  
11 MedicareAdvantage plan under this part if the  
12 rate of payment were determined under a ‘com-  
13 munity rating system’ (as defined in section  
14 1302(8) of the Public Health Service Act, other  
15 than subparagraph (C)); or

16 “(B) such portion of the weighted aggre-  
17 gate premium, which the Secretary annually es-  
18 timates would apply to such an individual, as  
19 the Secretary annually estimates is attributable  
20 to that service or services,

21 but adjusted for differences between the utilization  
22 characteristics of the individuals electing coverage  
23 under this part and the utilization characteristics of  
24 the other enrollees with the plan (or, if the Secretary  
25 finds that adequate data are not available to adjust

1 for those differences, the differences between the uti-  
2 lization characteristics of individuals selecting other  
3 MedicareAdvantage coverage, or MedicareAdvantage  
4 eligible individuals in the area, in the State, or in  
5 the United States, eligible to elect  
6 MedicareAdvantage coverage under this part and the  
7 utilization characteristics of the rest of the popu-  
8 lation in the area, in the State, or in the United  
9 States, respectively).

10 “(4) DETERMINATION BASED ON INSUFFICIENT  
11 DATA.—For purposes of this subsection, if the Sec-  
12 retary finds that there is insufficient enrollment ex-  
13 perience to determine the average amount of pay-  
14 ments to be made under this part at the beginning  
15 of a contract period or to determine (in the case of  
16 a newly operated provider-sponsored organization or  
17 other new organization) the adjusted community  
18 rate for the organization, the Secretary may deter-  
19 mine such an average based on the enrollment expe-  
20 rience of other contracts entered into under this part  
21 and may determine such a rate using data in the  
22 general commercial marketplace.

23 “(h) PROHIBITION OF STATE IMPOSITION OF PRE-  
24 MIUM TAXES.—No State may impose a premium tax or

1 similar tax with respect to payments to  
2 MedicareAdvantage organizations under section 1853.

3 “(i) PERMITTING USE OF SEGMENTS OF SERVICE  
4 AREAS.—The Secretary shall permit a MedicareAdvantage  
5 organization to elect to apply the provisions of this section  
6 uniformly to separate segments of a service area (rather  
7 than uniformly to an entire service area) as long as such  
8 segments are composed of 1 or more MedicareAdvantage  
9 payment areas.”.

10 (b) STUDY AND REPORT ON CLARIFICATION OF AU-  
11 THORITY REGARDING DISAPPROVAL OF UNREASONABLE  
12 BENEFICIARY COST-SHARING.—

13 (1) STUDY.—The Secretary, in consultation  
14 with beneficiaries, consumer groups, employers, and  
15 Medicare+Choice organizations, shall conduct a  
16 study to determine the extent to which the cost-shar-  
17 ing structures under Medicare+Choice plans under  
18 part C of title XVIII of the Social Security Act dis-  
19 courage access to covered services or discriminate  
20 based on the health status of Medicare+Choice eligi-  
21 ble individuals (as defined in section 1851(a)(3) of  
22 the Social Security Act (42 U.S.C. 1395w-  
23 21(a)(3))).

24 (2) REPORT.—Not later than December 31,  
25 2004, the Secretary shall submit a report to Con-

1       gress on the study conducted under paragraph (1)  
2       together with recommendations for such legislation  
3       and administrative actions as the Secretary con-  
4       siders appropriate.

5   **SEC. 205. SPECIAL RULES FOR PRESCRIPTION DRUG BENE-**  
6                   **FITS.**

7       (a) Part C of title XVIII (42 U.S.C. 1395w-21 et  
8       seq.) is amended by inserting after section 1857 the fol-  
9       lowing new section:

10      “SPECIAL RULES FOR PRESCRIPTION DRUG BENEFITS

11      “SEC. 1858A. (a) AVAILABILITY.—

12              “(1) PLANS REQUIRED TO PROVIDE QUALIFIED  
13      PRESCRIPTION DRUG COVERAGE TO ENROLLEES.—

14              “(A) IN GENERAL.—Except as provided in  
15      subparagraph (B), on and after January 1,  
16      2006, a MedicareAdvantage organization offer-  
17      ing a MedicareAdvantage plan (except for an  
18      MSA plan) shall make available qualified pre-  
19      scription drug coverage that meets the require-  
20      ments for such coverage under this part and  
21      part D to each enrollee of the plan.

22              “(B) PRIVATE FEE-FOR-SERVICE PLANS  
23      MAY, BUT ARE NOT REQUIRED TO, PROVIDE  
24      QUALIFIED PRESCRIPTION DRUG COVERAGE.—

25      Pursuant to section 1852(a)(2)(D), a private  
26      fee-for-service plan may elect not to provide

1 qualified prescription drug coverage under part  
2 D to individuals residing in the area served by  
3 the plan.

4 “(2) REFERENCE TO PROVISION PERMITTING  
5 ADDITIONAL PRESCRIPTION DRUG COVERAGE.—For  
6 the provisions of part D, made applicable to this  
7 part pursuant to paragraph (1), that permit a plan  
8 to make available qualified prescription drug cov-  
9 erage that includes coverage of covered drugs that  
10 exceeds the coverage required under paragraph (1)  
11 of section 1860D–6 in an area, but only if the  
12 MedicareAdvantage organization offering the plan  
13 also offers a MedicareAdvantage plan in the area  
14 that only provides the coverage that is required  
15 under such paragraph (1), see paragraph (2) of such  
16 section.

17 “(3) RULE FOR APPROVAL OF MEDICAL AND  
18 PRESCRIPTION DRUG BENEFITS.—Pursuant to sec-  
19 tions 1854(g)(1)(F) and 1852(a)(3)(D), a  
20 MedicareAdvantage organization offering a  
21 MedicareAdvantage plan that provides qualified pre-  
22 scription drug coverage may not make available cov-  
23 erage of any prescription drugs (other than that re-  
24 lating to prescription drugs covered under the origi-  
25 nal medicare fee-for-service program option) to an

1 enrollee as an additional benefit or as an enhanced  
2 medical benefit.

3 “(b) COMPLIANCE WITH ADDITIONAL BENEFICIARY  
4 PROTECTIONS.—With respect to the offering of qualified  
5 prescription drug coverage by a MedicareAdvantage orga-  
6 nization under a MedicareAdvantage plan, the organiza-  
7 tion and plan shall meet the requirements of section  
8 1860D–5, including requirements relating to information  
9 dissemination and grievance and appeals, and such other  
10 requirements under part D that the Secretary determines  
11 appropriate in the same manner as such requirements  
12 apply to an eligible entity and a Medicare Prescription  
13 Drug plan under part D. The Secretary shall waive such  
14 requirements to the extent the Secretary determines that  
15 such requirements duplicate requirements otherwise appli-  
16 cable to the organization or the plan under this part.

17 “(c) PAYMENTS FOR PRESCRIPTION DRUGS.—

18 “(1) PAYMENT OF FULL AMOUNT OF PREMIUM  
19 TO ORGANIZATIONS FOR QUALIFIED PRESCRIPTION  
20 DRUG COVERAGE.—

21 “(A) IN GENERAL.—For each year (begin-  
22 ning with 2006), the Secretary shall pay to  
23 each MedicareAdvantage organization offering a  
24 MedicareAdvantage plan that provides qualified  
25 prescription drug coverage, an amount equal to

1 the full amount of the monthly premium sub-  
2 mitted under section 1854(a)(2)(B) for the  
3 year, as adjusted using the risk adjusters that  
4 apply to the standard prescription drug cov-  
5 erage published under section 1860D–11.

6 “(B) APPLICATION OF PART D RISK COR-  
7 RIDOR, STABILIZATION RESERVE FUND, AND  
8 ADMINISTRATIVE EXPENSES PROVISIONS.—The  
9 provisions of subsections (b), (c), and (d) of  
10 section 1860D–16 shall apply to a  
11 MedicareAdvantage organization offering a  
12 MedicareAdvantage plan that provides qualified  
13 prescription drug coverage and payments made  
14 to such organization under subparagraph (A) in  
15 the same manner as such provisions apply to an  
16 eligible entity offering a Medicare Prescription  
17 Drug plan and payments made to such entity  
18 under subsection (a) of section 1860D–16.

19 “(2) PAYMENT FROM PRESCRIPTION DRUG AC-  
20 COUNT.—Payment made to MedicareAdvantage or-  
21 ganizations under this subsection shall be made from  
22 the Prescription Drug Account in the Federal Sup-  
23 plementary Medical Insurance Trust Fund under  
24 section 1841.

1       “(d) COMPUTATION OF MEDICAREADVANTAGE  
2 MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED  
3 PRESCRIPTION DRUG COVERAGE.—In the case of a  
4 MedicareAdvantage eligible individual receiving qualified  
5 prescription drug coverage under a MedicareAdvantage  
6 plan during a year after 2005, the MedicareAdvantage  
7 monthly beneficiary obligation for qualified prescription  
8 drug coverage of such individual in the year shall be deter-  
9 mined in the same manner as the monthly beneficiary obli-  
10 gation is determined under section 1860D–17 for eligible  
11 beneficiaries enrolled in a Medicare Prescription Drug  
12 plan, except that, for purposes of this subparagraph, any  
13 reference to the monthly plan premium approved by the  
14 Secretary under section 1860D–13 shall be treated as a  
15 reference to the monthly premium for qualified prescrip-  
16 tion drug coverage submitted by the MedicareAdvantage  
17 organization offering the plan under section  
18 1854(a)(2)(A) and approved by the Secretary.

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

1 quired to be paid by a MedicareAdvantage eligible indi-  
2 vidual enrolled in a MedicareAdvantage plan in the same  
3 manner as such provisions apply to the amount of the  
4 monthly beneficiary obligation required to be paid by an  
5 eligible beneficiary enrolled in a Medicare Prescription  
6 Drug plan under part D.

7 “(f) AVAILABILITY OF PREMIUM SUBSIDY AND COST-  
8 SHARING REDUCTIONS FOR LOW-INCOME ENROLLEES  
9 AND REINSURANCE PAYMENTS.—For provisions—

10 “(1) providing premium subsidies and cost-  
11 sharing reductions for low-income individuals receiv-  
12 ing qualified prescription drug coverage through a  
13 MedicareAdvantage plan, see section 1860D–19; and

14 “(2) providing a MedicareAdvantage organiza-  
15 tion with reinsurance payments for certain expenses  
16 incurred in providing qualified prescription drug cov-  
17 erage through a MedicareAdvantage plan, see sec-  
18 tion 1860D–20.”.

19 (b) TREATMENT OF REDUCTION FOR PURPOSES OF  
20 DETERMINING GOVERNMENT CONTRIBUTION UNDER  
21 PART B.—Section 1844(c) (42 U.S.C. 1395w) is amended  
22 by striking “section 1854(f)(1)(E)” and inserting “section  
23 1854(d)(1)(A)(i)”.

1 **SEC. 206. FACILITATING EMPLOYER PARTICIPATION.**

2 Section 1858(h) (as added by section 211) is amend-  
3 ed by inserting “(including subsection (i) of such section)”  
4 after “section 1857”.

5 **SEC. 207. ADMINISTRATION BY THE CENTER FOR MEDI-**  
6 **CARE CHOICES.**

7 On and after January 1, 2006, the  
8 MedicareAdvantage program under part C of title XVIII  
9 of the Social Security Act shall be administered by the  
10 Center for Medicare Choices established under section  
11 1808 such title (as added by section 301), and each ref-  
12 erence to the Secretary made in such part shall be deemed  
13 to be a reference to the Administrator of the Center for  
14 Medicare Choices.

15 **SEC. 208. CONFORMING AMENDMENTS.**

16 (a) ORGANIZATIONAL AND FINANCIAL REQUIRE-  
17 MENTS FOR MEDICAREADVANTAGE ORGANIZATIONS;  
18 PROVIDER-SPONSORED ORGANIZATIONS.—Section 1855  
19 (42 U.S.C. 1395w–25) is amended—

20 (1) in subsection (b), in the matter preceding  
21 paragraph (1), by inserting “subparagraphs (A),  
22 (B), and (D) of” before “section 1852(A)(1)”; and  
23 (2) by striking “Medicare+Choice” and insert-  
24 ing “MedicareAdvantage” each place it appears.

25 (b) ESTABLISHMENT OF PSO STANDARDS.—Section  
26 1856 (42 U.S.C. 1395w–26) is amended by striking

1 “Medicare+Choice” and inserting “MedicareAdvantage”  
2 each place it appears.

3 (c) CONTRACTS WITH MEDICAREADVANTAGE ORGA-  
4 NIZATIONS.—Section 1857 (42 U.S.C. 1395w–27) is  
5 amended—

6 (1) in subsection (g)(1)—

7 (A) in subparagraph (B), by striking  
8 “amount of the Medicare+Choice monthly basic  
9 and supplemental beneficiary premiums” and  
10 inserting “amounts of the MedicareAdvantage  
11 monthly basic premium and MedicareAdvantage  
12 monthly beneficiary premium for enhanced  
13 medical benefits”;

14 (B) in subparagraph (F), by striking “or”  
15 after the semicolon at the end;

16 (C) in subparagraph (G), by adding “or”  
17 after the semicolon at the end; and

18 (D) by inserting after subparagraph (G)  
19 the following new subparagraph:

20 “(H)(i) charges any individual an amount  
21 in excess of the MedicareAdvantage monthly  
22 beneficiary obligation for qualified prescription  
23 drug coverage under section 1858A(d);

1           “(ii) provides coverage for prescription  
2 drugs that is not qualified prescription drug  
3 coverage;

4           “(iii) offers prescription drug coverage, but  
5 does not make standard prescription drug cov-  
6 erage available; or

7           “(iv) provides coverage for prescription  
8 drugs (other than that relating to prescription  
9 drugs covered under the original medicare fee-  
10 for-service program option described in section  
11 1851(a)(1)(A)(i)) as an enhanced medical ben-  
12 efit under section 1852(a)(3)(D) or as an addi-  
13 tional benefit under section 1854(g)(1)(F),”;  
14 and

15           (2) by striking “Medicare+Choice” and insert-  
16 ing “MedicareAdvantage” each place it appears.

17           (d) DEFINITIONS; MISCELLANEOUS PROVISIONS.—  
18 Section 1859 (42 U.S.C. 1395w-28) is amended—

19           (1) by striking subsection (c) and inserting the  
20 following new subsection:

21           “(c) OTHER REFERENCES TO OTHER TERMS.—

22           “(1) ENHANCED MEDICAL BENEFITS.—The  
23 term ‘enhanced medical benefits’ is defined in sec-  
24 tion 1852(a)(3)(E).

1           “(2) MEDICAREADVANTAGE ELIGIBLE INDI-  
2           VIDUAL.—The term ‘MedicareAdvantage eligible in-  
3           dividual’ is defined in section 1851(a)(3).

4           “(3) MEDICAREADVANTAGE PAYMENT AREA.—  
5           The term ‘MedicareAdvantage payment area’ is de-  
6           fined in section 1853(d).

7           “(4) NATIONAL PER CAPITA  
8           MEDICARE+CHOICE GROWTH PERCENTAGE.—The  
9           ‘national per capita Medicare+Choice growth per-  
10          centage’ is defined in section 1853(c)(6).

11          “(5) MEDICAREADVANTAGE MONTHLY BASIC  
12          BENEFICIARY PREMIUM; MEDICAREADVANTAGE  
13          MONTHLY BENEFICIARY OBLIGATION FOR QUALI-  
14          FIED PRESCRIPTION DRUG COVERAGE;  
15          MEDICAREADVANTAGE MONTHLY BENEFICIARY PRE-  
16          MIUM FOR ENHANCED MEDICAL BENEFITS.—The  
17          terms ‘MedicareAdvantage monthly basic beneficiary  
18          premium’, ‘MedicareAdvantage monthly beneficiary  
19          obligation for qualified prescription drug coverage’,  
20          and ‘MedicareAdvantage monthly beneficiary pre-  
21          mium for enhanced medical benefits’ are defined in  
22          section 1854(b)(2).

23          “(6) QUALIFIED PRESCRIPTION DRUG COV-  
24          ERAGE.—The term ‘qualified prescription drug cov-

1        erage’ has the meaning given such term in section  
2        1860D(9).

3            “(7) STANDARD PRESCRIPTION DRUG COV-  
4        ERAGE.—The term ‘standard prescription drug cov-  
5        erage’ has the meaning given such term in section  
6        1860D(10).”; and

7            (2) by striking “Medicare+Choice” and insert-  
8        ing “MedicareAdvantage” each place it appears.

9        (e) CONFORMING AMENDMENTS EFFECTIVE BEFORE  
10    2006.—

11            (1) EXTENSION OF MSAs.—Section 1851(b)(4)  
12        (42 U.S.C. 1395w–21(b)(4)) is amended by striking  
13        “January 1, 2003” and inserting “January 1,  
14        2004”.

15            (2) CONTINUOUS OPEN ENROLLMENT AND  
16        DISENROLLMENT THROUGH 2005.—Section 1851(e)  
17        of the Social Security Act (42 U.S.C. 1395w–21(e))  
18        is amended—

19            (A) in paragraph (2)(A), by striking  
20        “THROUGH 2004” and “December 31, 2004”  
21        and inserting “THROUGH 2005” and “December  
22        31, 2005”, respectively;

23            (B) in the heading of paragraph (2)(B), by  
24        striking “DURING 2005” and inserting “DURING  
25        2006”;

1 (C) in paragraphs (2)(B)(i) and (2)(C)(i),  
2 by striking “2005” and inserting “2006” each  
3 place it appears;

4 (D) in paragraph (2)(D), by striking  
5 “2004” and inserting “2005”; and

6 (E) in paragraph (4), by striking “2005”  
7 and inserting “2006” each place it appears.

8 (3) EFFECTIVE DATE.—The amendments made  
9 by this subsection shall take effect on the date of en-  
10 actment of this Act.

11 (f) OTHER CONFORMING AMENDMENTS.—

12 (1) CONFORMING MEDICARE CROSS-REF-  
13 ERENCES.—

14 (A) Section 1839(a)(2) (42 U.S.C.  
15 1395r(a)(2)) is amended by striking “section  
16 1854(f)(1)(E)” and inserting “section  
17 1854(g)(1)(C)(i)”.

18 (B) Section 1840(i) (42 U.S.C. 1395s(i))  
19 is amended by striking “section 1854(f)(1)(E)”  
20 and inserting “section 1854(g)(1)(C)(i)”.

21 (C) Section 1844(c) (42 U.S.C. 1395w(e))  
22 is amended by striking “section 1854(f)(1)(E)”  
23 and inserting “section 1854(g)(1)(C)(i)”.

24 (D) Section 1876(k)(3)(A) (42 U.S.C.  
25 1395mm(k)(3)(A)) is amended by inserting

1 “(as in effect immediately before the enactment  
2 of the Prescription Drug and Medicare Im-  
3 provements Act of 2003)” after section  
4 1853(a).

5 (E) Section 1876(k)(4) (42 U.S.C.  
6 1395mm(k)(4)(A)) is amended—

7 (i) in subparagraph (A), by striking  
8 “section 1853(a)(3)(B)” and inserting  
9 “section 1853(a)(3)(D)”; and

10 (ii) in subparagraph (B), by striking  
11 “section 1854(g)” and inserting “section  
12 1854(h)”.

13 (F) Section 1876(k)(4)(C) (42 U.S.C.  
14 1395mm(k)(4)(C)) is amended by inserting  
15 “(as in effect immediately before the enactment  
16 of the Prescription Drug and Medicare Im-  
17 provements Act of 2003)” after “section  
18 1851(e)(6)”.

19 (G) Section 1894(d) (42 U.S.C.  
20 1395eee(d)) is amended by adding at the end  
21 the following new paragraph:

22 “(3) APPLICATION OF PROVISIONS.—For pur-  
23 poses of paragraphs (1) and (2), the references to  
24 section 1853 and subsection (a)(2) of such section in  
25 such paragraphs shall be deemed to be references to

1 those provisions as in effect immediately before the  
2 enactment of the Prescription Drug and Medicare  
3 Improvements Act of 2003.”.

4 (2) CONFORMING MEDICARE TERMINOLOGY.—  
5 Title XVIII (42 U.S.C. 1395 et seq.), except for  
6 part C of such title (42 U.S.C. 1395w–21 et seq.),  
7 and title XIX (42 U.S.C. 1396 et seq.) are each  
8 amended by striking “Medicare+Choice” and insert-  
9 ing “MedicareAdvantage” each place it appears.

10 **SEC. 209. EFFECTIVE DATE.**

11 (a) IN GENERAL.—Except as provided in section  
12 208(d)(3) and subsection (b), the amendments made by  
13 this title shall apply with respect to plan years beginning  
14 on and after January 1, 2006.

15 (b) MEDICAREADVANTAGE MSA PLANS.—Notwith-  
16 standing any provision of this title, the Secretary shall  
17 apply the payment and other rules that apply with respect  
18 to an MSA plan described in section 1851(a)(2)(B) of the  
19 Social Security Act (42 U.S.C. 1395w–21(a)(2)(B)) as if  
20 this title had not been enacted.

1           **Subtitle B—Preferred Provider**  
2                           **Organizations**

3   **SEC. 211. ESTABLISHMENT OF MEDICAREADVANTAGE PRE-**  
4                           **FERRED PROVIDER PROGRAM OPTION.**

5           (a) ESTABLISHMENT OF PREFERRED PROVIDER  
6 PROGRAM OPTION.—Section 1851(a)(2) is amended by  
7 adding at the end the following new subparagraph:

8                           “(D) PREFERRED PROVIDER ORGANIZA-  
9                           TION PLANS.—A MedicareAdvantage preferred  
10                           provider organization plan under the program  
11                           established under section 1858.”.

12           (b) PROGRAM SPECIFICATIONS.—Part C of title  
13 XVIII (42 U.S.C. 1395w–21 et seq.) is amended by insert-  
14 ing after section 1857 the following new section:

15                           “PREFERRED PROVIDER ORGANIZATIONS

16                           “SEC. 1858. (a) ESTABLISHMENT OF PROGRAM.—

17                           “(1) IN GENERAL.—Beginning on January 1,  
18                           2006, there is established a preferred provider pro-  
19                           gram under which preferred provider organization  
20                           plans offered by preferred provider organizations are  
21                           offered to MedicareAdvantage eligible individuals in  
22                           preferred provider regions.

23                           “(2) DEFINITIONS.—

24                           “(A) PREFERRED PROVIDER ORGANIZA-  
25                           TION.—The term ‘preferred provider organiza-

1           tion’ means an entity with a contract under sec-  
2           tion 1857 that meets the requirements of this  
3           section applicable with respect to preferred pro-  
4           vider organizations.

5           “(B) PREFERRED PROVIDER ORGANIZA-  
6           TION PLAN.—The term ‘preferred provider or-  
7           ganization plan’ means a Medicare Advantage  
8           plan that—

9                   “(i) has a network of providers that  
10                   have agreed to a contractually specified re-  
11                   imbursement for covered benefits with the  
12                   organization offering the plan;

13                   “(ii) provides for reimbursement for  
14                   all covered benefits regardless of whether  
15                   such benefits are provided within such net-  
16                   work of providers; and

17                   “(iii) is offered by a preferred pro-  
18                   vider organization.

19           “(C) PREFERRED PROVIDER REGION.—  
20           The term ‘preferred provider region’ means—

21                   “(i) a region established under para-  
22                   graph (3); and

23                   “(ii) a region that consists of the en-  
24                   tire United States.

1           “(3) PREFERRED PROVIDER REGIONS.—For  
2 purposes of this part the Secretary shall establish  
3 preferred provider regions as follows:

4                   “(A) There shall be at least 10 regions.

5                   “(B) Each region must include at least 1  
6 State.

7                   “(C) The Secretary may not divide States  
8 so that portions of the State are in different re-  
9 gions.

10                   “(D) To the extent possible, the Secretary  
11 shall include multistate metropolitan statistical  
12 areas in a single region. The Secretary may di-  
13 vide metropolitan statistical areas where it is  
14 necessary to establish regions of such size and  
15 geography as to maximize the participation of  
16 preferred provider organization plans.

17                   “(E) The Secretary may conform the pre-  
18 ferred provider regions to the service areas es-  
19 tablished under section 1860D–10.

20           “(b) ELIGIBILITY, ELECTION, AND ENROLLMENT;  
21 BENEFITS AND BENEFICIARY PROTECTIONS.—

22                   “(1) IN GENERAL.—Except as provided in the  
23 succeeding provisions of this subsection, the provi-  
24 sions of sections 1851 and 1852 that apply with re-  
25 spect to coordinated care plans shall apply to pre-

1 preferred provider organization plans offered by a pre-  
2 ferred provider organization.

3 “(2) SERVICE AREA.—The service area of a  
4 preferred provider organization plan shall be a pre-  
5 ferred provider region.

6 “(3) AVAILABILITY.—Each preferred provider  
7 organization plan must be offered to each  
8 MedicareAdvantage eligible individual who resides in  
9 the service area of the plan.

10 “(4) AUTHORITY TO PROHIBIT RISK SELEC-  
11 TION.—The provisions of section 1852(a)(6) shall  
12 apply to preferred provider organization plans.

13 “(5) ASSURING ACCESS TO SERVICES IN PRE-  
14 FERRED PROVIDER ORGANIZATION PLANS.—

15 “(A) IN GENERAL.—In addition to any  
16 other requirements under this section, in the  
17 case of a preferred provider organization plan,  
18 the organization offering the plan must dem-  
19 onstrate to the Secretary that the organization  
20 has sufficient number and range of health care  
21 professionals and providers willing to provide  
22 services under the terms of the plan.

23 “(B) DETERMINATION OF SUFFICIENT AC-  
24 CESS.—The Secretary shall find that an organi-  
25 zation has met the requirement under subpara-

1 graph (A) with respect to any category of  
2 health care professional or provider if, with re-  
3 spect to that category of provider the plan has  
4 contracts or agreements with a sufficient num-  
5 ber and range of providers within such category  
6 to provide covered services under the terms of  
7 the plan.

8 “(C) CONSTRUCTION.—Subparagraph (B)  
9 shall not be construed as restricting the persons  
10 from whom enrollees under such a plan may ob-  
11 tain covered benefits.

12 “(c) PAYMENTS TO PREFERRED PROVIDER ORGANI-  
13 ZATIONS.—

14 “(1) PAYMENTS TO ORGANIZATIONS.—

15 “(A) MONTHLY PAYMENTS.—

16 “(i) IN GENERAL.—Under a contract  
17 under section 1857 and subject to para-  
18 graph (5), subsection (e), and section  
19 1859(e)(4), the Secretary shall make, to  
20 each preferred provider organization, with  
21 respect to coverage of an individual for a  
22 month under this part in a preferred pro-  
23 vider region, separate monthly payments  
24 with respect to—

1                   “(I) benefits under the original  
2                   medicare fee-for-service program  
3                   under parts A and B in accordance  
4                   with paragraph (4); and

5                   “(II) benefits under the vol-  
6                   untary prescription drug program  
7                   under part D in accordance with sec-  
8                   tion 1858A and the other provisions  
9                   of this part.

10                   “(ii) SPECIAL RULE FOR END-STAGE  
11                   RENAL DISEASE.—The Secretary shall es-  
12                   tablish separate rates of payment applica-  
13                   ble with respect to classes of individuals  
14                   determined to have end-stage renal disease  
15                   and enrolled in a preferred provider orga-  
16                   nization plan under this clause that are  
17                   similar to the separate rates of payment  
18                   described in section 1853(a)(1)(B).

19                   “(B) ADJUSTMENT TO REFLECT NUMBER  
20                   OF ENROLLEES.—The Secretary may retro-  
21                   actively adjust the amount of payment under  
22                   this paragraph in a manner that is similar to  
23                   the manner in which payment amounts may be  
24                   retroactively adjusted under section 1853(a)(2).

1           “(C) COMPREHENSIVE RISK ADJUSTMENT  
2           METHODOLOGY.—The Secretary shall apply the  
3           comprehensive risk adjustment methodology de-  
4           scribed in section 1853(a)(3)(B) to 100 percent  
5           of the amount of payments to plans under para-  
6           graph (4)(D)(ii).

7           “(D) ADJUSTMENT FOR SPENDING VARI-  
8           ATIONS WITHIN A REGION.—The Secretary  
9           shall establish a methodology for adjusting the  
10          amount of payments to plans under paragraph  
11          (4)(D)(ii) that achieves the same objective as  
12          the adjustment described in paragraph  
13          1853(a)(2)(C).

14          “(2) ANNUAL CALCULATION OF BENCHMARK  
15          AMOUNTS FOR PREFERRED PROVIDER REGIONS.—  
16          For each year (beginning in 2006), the Secretary  
17          shall calculate a benchmark amount for each pre-  
18          ferred provider region for each month for such year  
19          with respect to coverage of the benefits available  
20          under the original medicare fee-for-service program  
21          option equal to the average of each benchmark  
22          amount calculated under section 1853(a)(4) for each  
23          MedicareAdvantage payment area for the year with-  
24          in such region, weighted by the number of

1 MedicareAdvantage eligible individuals residing in  
2 each such payment area for the year.

3 “(3) ANNUAL ANNOUNCEMENT OF PAYMENT  
4 FACTORS.—

5 “(A) ANNUAL ANNOUNCEMENT.—Begin-  
6 ning in 2005, at the same time as the Secretary  
7 publishes the risk adjusters under section  
8 1860D–11, the Secretary shall annually an-  
9 nounce (in a manner intended to provide notice  
10 to interested parties) the following payment fac-  
11 tors:

12 “(i) The benchmark amount for each  
13 preferred provider region (as calculated  
14 under paragraph (2)(A)) for the year.

15 “(ii) The factors to be used for ad-  
16 justing payments described under—

17 “(I) the comprehensive risk ad-  
18 justment methodology described in  
19 paragraph (1)(C) with respect to each  
20 preferred provider region for the year;  
21 and

22 “(II) the methodology used for  
23 adjustment for geographic variations  
24 within such region established under  
25 paragraph (1)(D).

1           “(B) ADVANCE NOTICE OF METHODO-  
2 LOGICAL CHANGES.—At least 45 days before  
3 making the announcement under subparagraph  
4 (A) for a year, the Secretary shall—

5                   “(i) provide for notice to preferred  
6 provider organizations of proposed changes  
7 to be made in the methodology from the  
8 methodology and assumptions used in the  
9 previous announcement; and

10                   “(ii) provide such organizations with  
11 an opportunity to comment on such pro-  
12 posed changes.

13           “(C) EXPLANATION OF ASSUMPTIONS.—In  
14 each announcement made under subparagraph  
15 (A), the Secretary shall include an explanation  
16 of the assumptions and changes in methodology  
17 used in the announcement in sufficient detail so  
18 that preferred provider organizations can com-  
19 pute each payment factor described in such  
20 subparagraph.

21           “(4) SECRETARY’S DETERMINATION OF PAY-  
22 MENT AMOUNT FOR BENEFITS UNDER THE ORIGI-  
23 NAL MEDICARE FEE-FOR-SERVICE PROGRAM.—The  
24 Secretary shall determine the payment amount for  
25 plans as follows:

1           “(A) REVIEW OF PLAN BIDS.—The Sec-  
2           retary shall review each plan bid submitted  
3           under subsection (d)(1) for the coverage of ben-  
4           efits under the original medicare fee-for-service  
5           program option to ensure that such bids are  
6           consistent with the requirements under this  
7           part and are based on the assumptions de-  
8           scribed in section 1854(a)(2)(A)(iii) that the  
9           plan used with respect to numbers of enrolled  
10          individuals.

11          “(B) DETERMINATION OF PREFERRED  
12          PROVIDER REGIONAL BENCHMARK AMOUNTS.—  
13          The Secretary shall calculate a preferred pro-  
14          vider regional benchmark amount for that plan  
15          for the benefits under the original medicare fee-  
16          for-service program option for each plan equal  
17          to the regional benchmark adjusted by using  
18          the assumptions described in section  
19          1854(a)(2)(A)(iii) that the plan used with re-  
20          spect to numbers of enrolled individuals.

21          “(C) COMPARISON TO BENCHMARK.—The  
22          Secretary shall determine the difference be-  
23          tween each plan bid (as adjusted under sub-  
24          paragraph (A)) and the preferred provider re-  
25          gional benchmark amount (as determined under

1           subparagraph (B)) for purposes of deter-  
2           mining—

3                   “(i) the payment amount under sub-  
4                   paragraph (D); and

5                   “(ii) the additional benefits required  
6                   and MedicareAdvantage monthly basic ben-  
7                   eficiary premiums.

8                   “(D) DETERMINATION OF PAYMENT  
9                   AMOUNT.—

10                   “(i) IN GENERAL.—Subject to clause  
11                   (ii), the Secretary shall determine the pay-  
12                   ment amount to a preferred provider orga-  
13                   nization for a preferred provider organiza-  
14                   tion plan as follows:

15                           “(I) BIDS THAT EQUAL OR EX-  
16                           CEED THE BENCHMARK.—In the case  
17                           of a plan bid that equals or exceeds  
18                           the preferred provider regional bench-  
19                           mark amount, the amount of each  
20                           monthly payment to the organization  
21                           with respect to each individual en-  
22                           rolled in a plan shall be the preferred  
23                           provider regional benchmark amount.

24                           “(II) BIDS BELOW THE BENCH-  
25                           MARK.—In the case of a plan bid that

1 is less than the preferred provider re-  
2 gional benchmark amount, the  
3 amount of each monthly payment to  
4 the organization with respect to each  
5 individual enrolled in a plan shall be  
6 the preferred provider regional bench-  
7 mark amount reduced by the amount  
8 of any premium reduction elected by  
9 the plan under section  
10 1854(d)(1)(A)(i).

11 “(ii) APPLICATION OF ADJUSTMENT  
12 METHODOLOGIES.—The Secretary shall ad-  
13 just the amounts determined under sub-  
14 paragraph (A) using the factors described  
15 in paragraph (3)(A)(ii).

16 “(E) FACTORS USED IN ADJUSTING BIDS  
17 AND BENCHMARKS FOR PREFERRED PROVIDER  
18 ORGANIZATIONS AND IN DETERMINING EN-  
19 ROLLEE PREMIUMS.—Subject to subparagraph  
20 (F), in addition to the factors used to adjust  
21 payments to plans described in section  
22 1853(d)(6), the Secretary shall use the adjust-  
23 ment for geographic variation within the region  
24 established under paragraph (1)(D).

1           “(F) ADJUSTMENT FOR NATIONAL COV-  
2           ERAGE DETERMINATIONS AND LEGISLATIVE  
3           CHANGES IN BENEFITS.—The Secretary shall  
4           provide for adjustments for national coverage  
5           determinations and legislative changes in bene-  
6           fits applicable with respect to preferred provider  
7           organizations in the same manner as the Sec-  
8           retary provides for adjustments under section  
9           1853(d)(7).

10           “(5) PAYMENTS FROM TRUST FUND.—The pay-  
11           ment to a preferred provider organization under this  
12           section shall be made from the Federal Hospital In-  
13           surance Trust Fund and the Federal Supplementary  
14           Medical Insurance Trust Fund in a manner similar  
15           to the manner described in section 1853(g).

16           “(6) SPECIAL RULE FOR CERTAIN INPATIENT  
17           HOSPITAL STAYS.—Rules similar to the rules appli-  
18           cable under section 1853(h) shall apply with respect  
19           to preferred provider organizations.

20           “(7) SPECIAL RULE FOR HOSPICE CARE.—  
21           Rules similar to the rules applicable under section  
22           1853(i) shall apply with respect to preferred pro-  
23           vider organizations.

24           “(d) SUBMISSION OF BIDS BY PPOS; PREMIUMS.—

1           “(1) SUBMISSION OF BIDS BY PREFERRED PRO-  
2           VIDER ORGANIZATIONS.—

3           “(A) IN GENERAL.—For the requirements  
4           on submissions by MedicareAdvantage preferred  
5           provider organization plans, see section  
6           1854(a)(1).

7           “(B) UNIFORM PREMIUMS.—Each bid  
8           amount submitted under subparagraph (A) for  
9           a preferred provider organization plan in a pre-  
10          ferred provider region may not vary among  
11          MedicareAdvantage eligible individuals residing  
12          in such preferred provider region.

13          “(C) APPLICATION OF FEHBP STANDARD;  
14          PROHIBITION ON PRICE GOUGING.—Each bid  
15          amount submitted under subparagraph (A) for  
16          a preferred provider organization plan must  
17          reasonably and equitably reflect the cost of ben-  
18          efits provided under that plan.

19          “(D) REVIEW.—The Secretary shall review  
20          the adjusted community rates (as defined in  
21          section 1854(g)(3)), the amounts of the  
22          MedicareAdvantage monthly basic premium and  
23          the MedicareAdvantage monthly beneficiary  
24          premium for enhanced medical benefits filed  
25          under this paragraph and shall approve or dis-

1 approve such rates and amounts so submitted.  
2 The Secretary shall review the actuarial as-  
3 sumptions and data used by the preferred pro-  
4 vider organization with respect to such rates  
5 and amounts so submitted to determine the ap-  
6 propriateness of such assumptions and data.

7 “(E) AUTHORITY TO LIMIT NUMBER OF  
8 PLANS IN A REGION.—If there are bids for  
9 more than 3 preferred provider organization  
10 plans in a preferred provider region, the Sec-  
11 retary shall accept only the 3 lowest-cost cred-  
12 ible bids for that region that meet or exceed the  
13 quality and minimum standards applicable  
14 under this section.

15 “(2) MONTHLY PREMIUMS CHARGED.—The  
16 amount of the monthly premium charged to an indi-  
17 vidual enrolled in a preferred provider organization  
18 plan offered by a preferred provider organization  
19 shall be equal to the sum of the following:

20 “(A) The MedicareAdvantage monthly  
21 basic beneficiary premium, as defined in section  
22 1854(b)(2)(A) (if any).

23 “(B) The MedicareAdvantage monthly ben-  
24 efiary premium for enhanced medical benefits,  
25 as defined in section 1854(b)(2)(C) (if any).

1           “(C) The Medicare Advantage monthly obli-  
2           gation for qualified prescription drug coverage,  
3           as defined in section 1854(b)(2)(B) (if any).

4           “(3) DETERMINATION OF PREMIUM REDUC-  
5           TIONS, REDUCED COST-SHARING, ADDITIONAL BENE-  
6           FITS, AND BENEFICIARY PREMIUMS.—The rules for  
7           determining premium reductions, reduced cost-shar-  
8           ing, additional benefits, and beneficiary premiums  
9           under section 1854(d) shall apply with respect to  
10          preferred provider organizations.

11          “(4) PROHIBITION OF SEGMENTING PRE-  
12          FERRED PROVIDER REGIONS.—The Secretary may  
13          not permit a preferred provider organization to elect  
14          to apply the provisions of this section uniformly to  
15          separate segments of a preferred provider region  
16          (rather than uniformly to an entire preferred pro-  
17          vider region).

18          “(e) PORTION OF TOTAL PAYMENTS TO AN ORGANI-  
19          ZATION SUBJECT TO RISK FOR 2 YEARS.—

20          “(1) NOTIFICATION OF SPENDING UNDER THE  
21          PLAN.—

22                 “(A) IN GENERAL.—For 2007 and 2008,  
23                 the preferred provider organization offering a  
24                 preferred provider organization plan shall notify  
25                 the Secretary of the total amount of costs that

1 the organization incurred in providing benefits  
2 covered under parts A and B of the original  
3 medicare fee-for-service program for all enroll-  
4 ees under the plan in the previous year.

5 “(B) CERTAIN EXPENSES NOT IN-  
6 CLUDED.—The total amount of costs specified  
7 in subparagraph (A) may not include—

8 “(i) subject to subparagraph (C), ad-  
9 ministrative expenses incurred in providing  
10 the benefits described in such subpara-  
11 graph; or

12 “(ii) amounts expended on providing  
13 enhanced medical benefits under section  
14 1852(a)(3)(D).

15 “(C) ESTABLISHMENT OF ALLOWABLE AD-  
16 MINISTRATIVE EXPENSES.—For purposes of ap-  
17 plying subparagraph (B)(i), the administrative  
18 expenses incurred in providing benefits de-  
19 scribed in subparagraph (A) under a preferred  
20 provider organization plan may not exceed an  
21 amount determined appropriate by the Adminis-  
22 trator.

23 “(2) ADJUSTMENT OF PAYMENT.—

24 “(A) NO ADJUSTMENT IF COSTS WITHIN  
25 RISK CORRIDOR.—If the total amount of costs

1 specified in paragraph (1)(A) for the plan for  
2 the year are not more than the first threshold  
3 upper limit of the risk corridor (specified in  
4 paragraph (3)(A)(iii)) and are not less than the  
5 first threshold lower limit of the risk corridor  
6 (specified in paragraph (3)(A)(i)) for the plan  
7 for the year, then no additional payments shall  
8 be made by the Secretary and no reduced pay-  
9 ments shall be made to the preferred provider  
10 organization offering the plan.

11 “(B) INCREASE IN PAYMENT IF COSTS  
12 ABOVE UPPER LIMIT OF RISK CORRIDOR.—

13 “(i) IN GENERAL.—If the total  
14 amount of costs specified in paragraph  
15 (1)(A) for the plan for the year are more  
16 than the first threshold upper limit of the  
17 risk corridor for the plan for the year, then  
18 the Secretary shall increase the total of the  
19 monthly payments made to the preferred  
20 provider organization offering the plan for  
21 the year under subsection (c)(1)(A) by an  
22 amount equal to the sum of—

23 “(I) 50 percent of the amount of  
24 such total costs which are more than  
25 such first threshold upper limit of the

1 risk corridor and not more than the  
2 second threshold upper limit of the  
3 risk corridor for the plan for the year  
4 (as specified under paragraph  
5 (3)(A)(iv)); and

6 “(II) 90 percent of the amount of  
7 such total costs which are more than  
8 such second threshold upper limit of  
9 the risk corridor.

10 “(C) REDUCTION IN PAYMENT IF COSTS  
11 BELOW LOWER LIMIT OF RISK CORRIDOR.—If  
12 the total amount of costs specified in paragraph  
13 (1)(A) for the plan for the year are less than  
14 the first threshold lower limit of the risk cor-  
15 ridor for the plan for the year, then the Sec-  
16 retary shall reduce the total of the monthly pay-  
17 ments made to the preferred provider organiza-  
18 tion offering the plan for the year under sub-  
19 section (c)(1)(A) by an amount (or otherwise  
20 recover from the plan an amount) equal to—

21 “(i) 50 percent of the amount of such  
22 total costs which are less than such first  
23 threshold lower limit of the risk corridor  
24 and not less than the second threshold  
25 lower limit of the risk corridor for the plan

1 for the year (as specified under paragraph  
2 (3)(A)(ii)); and

3 “(ii) 90 percent of the amount of such  
4 total costs which are less than such second  
5 threshold lower limit of the risk corridor.

6 “(3) ESTABLISHMENT OF RISK CORRIDORS.—

7 “(A) IN GENERAL.—For 2006 and 2007,  
8 the Secretary shall establish a risk corridor for  
9 each preferred provider organization plan. The  
10 risk corridor for a plan for a year shall be equal  
11 to a range as follows:

12 “(i) FIRST THRESHOLD LOWER  
13 LIMIT.—The first threshold lower limit of  
14 such corridor shall be equal to—

15 “(I) the target amount described  
16 in subparagraph (B) for the plan;  
17 minus

18 “(II) an amount equal to 5 per-  
19 cent of such target amount.

20 “(ii) SECOND THRESHOLD LOWER  
21 LIMIT.—The second threshold lower limit  
22 of such corridor shall be equal to—

23 “(I) the target amount described  
24 in subparagraph (B) for the plan;  
25 minus

1                   “(II) an amount equal to 10 per-  
2                   cent of such target amount.

3                   “(iii) FIRST THRESHOLD UPPER  
4                   LIMIT.—The first threshold upper limit of  
5                   such corridor shall be equal to the sum  
6                   of—

7                   “(I) such target amount; and

8                   “(II) the amount described in  
9                   clause (i)(II).

10                  “(iv) SECOND THRESHOLD UPPER  
11                  LIMIT.—The second threshold upper limit  
12                  of such corridor shall be equal to the sum  
13                  of—

14                  “(I) such target amount; and

15                  “(II) the amount described in  
16                  clause (ii)(II).

17                  “(B) TARGET AMOUNT DESCRIBED.—The  
18                  target amount described in this paragraph is,  
19                  with respect to a preferred provider organiza-  
20                  tion plan offered by a preferred provider organi-  
21                  zation in a year, an amount equal to the sum  
22                  of—

23                  “(i) the total monthly payments made  
24                  to the organization for enrollees in the

1 plan for the year under subsection  
2 (c)(1)(A); and

3 “(ii) the total MedicareAdvantage  
4 basic beneficiary premiums collected for  
5 such enrollees for the year under sub-  
6 section (d)(2)(A).

7 “(4) PLANS AT RISK FOR ENTIRE AMOUNT OF  
8 ENHANCED MEDICAL BENEFITS.—A preferred pro-  
9 vider organization that offers a preferred provider  
10 organization plan that provides enhanced medical  
11 benefits under section 1852(a)(3)(D) shall be at full  
12 financial risk for the provision of such benefits.

13 “(5) NO EFFECT ON ELIGIBLE BENE-  
14 FICIARIES.—No change in payments made by reason  
15 of this subsection shall affect the amount of the  
16 MedicareAdvantage basic beneficiary premium that a  
17 beneficiary is otherwise required to pay under the  
18 plan for the year under subsection (d)(2)(A).

19 “(6) DISCLOSURE OF INFORMATION.—The pro-  
20 visions of section 1860D–16(b)(7), including sub-  
21 paragraph (B) of such section, shall apply to a pre-  
22 ferred provider organization and a preferred pro-  
23 vider organization plan in the same manner as such  
24 provisions apply to an eligible entity and a Medicare  
25 Prescription Drug plan under part D.

1       “(f) ORGANIZATIONAL AND FINANCIAL REQUIRE-  
2 MENTS FOR PREFERRED PROVIDER ORGANIZATIONS.—A  
3 preferred provider organization shall be organized and li-  
4 censed under State law as a risk-bearing entity eligible  
5 to offer health insurance or health benefits coverage in  
6 each State within the preferred provider region in which  
7 it offers a preferred provider organization plan.

8       “(g) INAPPLICABILITY OF PROVIDER-SPONSORED  
9 ORGANIZATION SOLVENCY STANDARDS.—The require-  
10 ments of section 1856 shall not apply with respect to pre-  
11 ferred provider organizations.

12       “(h) CONTRACTS WITH PREFERRED PROVIDER OR-  
13 GANIZATIONS.—The provisions of section 1857 shall apply  
14 to a preferred provider organization plan offered by a pre-  
15 ferred provider organization under this section.”.

16       “(c) PREFERRED PROVIDER TERMINOLOGY DE-  
17 FINED.—Section 1859(a) is amended by adding at the end  
18 the following new paragraph:

19               “(3) PREFERRED PROVIDER ORGANIZATION;  
20 PREFERRED PROVIDER ORGANIZATION PLAN; PRE-  
21 FERRED PROVIDER REGION.—The terms ‘preferred  
22 provider organization’, ‘preferred provider organiza-  
23 tion plan’, and ‘preferred provider region’ have the  
24 meaning given such terms in section 1858(a)(2).”.

1     **Subtitle C—Other Managed Care**  
2                     **Reforms**

3     **SEC. 221. EXTENSION OF REASONABLE COST CONTRACTS.**

4             (a) FIVE-YEAR EXTENSION.—Section 1876(h)(5)(C)  
5 (42 U.S.C. 1395mm(h)(5)(C)) is amended by striking  
6 “2004” and inserting “2009”.

7             (b) APPLICATION OF CERTAIN MEDICARE+CHOICE  
8 REQUIREMENTS TO COST CONTRACTS EXTENDED OR RE-  
9 NEWED AFTER 2003.—Section 1876(h) (42 U.S.C.  
10 1395mm(h)(5)), as amended by subsection (a), is amend-  
11 ed—

12                 (1) by redesignating paragraph (5) as para-  
13 graph (6); and

14                 (2) by inserting after paragraph (4) the fol-  
15 lowing new paragraph:

16             “(5) Any reasonable cost reimbursement contract  
17 with an eligible organization under this subsection that is  
18 extended or renewed on or after the date of enactment  
19 of the Prescription Drug and Medicare Improvements Act  
20 of 2003 for plan years beginning on or after January 1,  
21 2004, shall provide that the following provisions of the  
22 Medicare+Choice program under part C (and, on and  
23 after January 1, 2006, the provisions of the  
24 MedicareAdvantage program under such part) shall apply  
25 to such organization and such contract in a substantially

1 similar manner as such provisions apply to  
2 Medicare+Choice organizations and Medicare+Choice  
3 plans (or, on and after January 1, 2006,  
4 MedicareAdvantage organizations and MedicareAdvantage  
5 plans, respectively) under such part:

6           “(A) Paragraph (1) of section 1852(e) (relating  
7 to the requirement of having an ongoing quality as-  
8 surance program) and paragraph (2)(B) of such sec-  
9 tion (relating to the required elements for such a  
10 program).

11           “(B) Section 1852(j)(4) (relating to limitations  
12 on physician incentive plans).

13           “(C) Section 1854(c) (relating to the require-  
14 ment of uniform premiums among individuals en-  
15 rolled in the plan).

16           “(D) Section 1854(g), or, on and after January  
17 1, 2006, section 1854(h) (relating to restrictions on  
18 imposition of premium taxes with respect to pay-  
19 ments to organizations).

20           “(E) Section 1856(b) (regarding compliance  
21 with the standards established by regulation pursu-  
22 ant to such section, including the provisions of para-  
23 graph (3) of such section relating to relation to  
24 State laws).

1           “(F) Section 1852(a)(3)(A) (regarding the au-  
2           thority of organizations to include supplemental  
3           health care benefits and, on and after January 1,  
4           2006, enhanced medical benefits under the plan sub-  
5           ject to the approval of the Secretary).

6           “(G) The provisions of part C relating to  
7           timelines for benefit filings, contract renewal, and  
8           beneficiary notification.

9           “(H) Section 1854(e), or, on and after January  
10          1, 2006, section 1854(f) (relating to proposed cost-  
11          sharing under the contract being subject to review  
12          by the Secretary).”.

13          (c) PERMITTING DEDICATED GROUP PRACTICE  
14 HEALTH MAINTENANCE ORGANIZATIONS TO PARTICIPATE  
15 IN THE MEDICARE COST CONTRACT PROGRAM.—Section  
16 1876(h)(6) of the Social Security Act (42 U.S.C.  
17 1395mm(h)(6)), as redesignated and amended by sub-  
18 sections (a) and (b), is amended—

19           (1) in subparagraph (A), by striking “After the  
20           date of the enactment” and inserting “Except as  
21           provided in subparagraph (C), after the date of the  
22           enactment”;

23           (2) in subparagraph (B), by striking “subpara-  
24           graph (C)” and inserting “subparagraph (D)”;

1           (3) by redesignating subparagraph (C) as sub-  
2           paragraph (D); and

3           (4) by inserting after subparagraph (B), the  
4           following new subparagraph:

5           “(C) Subject to paragraph (5) and subparagraph  
6 (D), the Secretary shall approve an application to enter  
7 into a reasonable cost contract under this section if—

8           “(i) the application is submitted to the Sec-  
9           retary by a health maintenance organization (as de-  
10          fined in section 1301(a) of the Public Health Service  
11          Act) that, as of January 1, 2004, and except as pro-  
12          vided in section 1301(b)(3)(B) of such Act, provides  
13          at least 85 percent of the services of a physician  
14          which are provided as basic health services through  
15          a medical group (or groups), as defined in section  
16          1302(4) of such Act; and

17          “(ii) the Secretary determines that the organi-  
18          zation meets the requirements applicable to such or-  
19          ganizations and contracts under this section.”.

20 **SEC. 222. SPECIALIZED MEDICARE+CHOICE PLANS FOR**  
21 **SPECIAL NEEDS BENEFICIARIES.**

22          (a) TREATMENT AS COORDINATED CARE PLAN.—  
23 Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is  
24 amended by adding at the end the following new sentence:  
25 “Specialized Medicare+Choice plans for special needs

1 beneficiaries (as defined in section 1859(b)(4)) may be  
2 any type of coordinated care plan.”.

3 (b) SPECIALIZED MEDICARE+CHOICE PLAN FOR  
4 SPECIAL NEEDS BENEFICIARIES DEFINED.—Section  
5 1859(b) (42 U.S.C. 1395w–28(b)) is amended by adding  
6 at the end the following new paragraph:

7 “(4) SPECIALIZED MEDICARE+CHOICE PLANS  
8 FOR SPECIAL NEEDS BENEFICIARIES.—

9 “(A) IN GENERAL.—The term ‘specialized  
10 Medicare+Choice plan for special needs bene-  
11 ficiaries’ means a Medicare+Choice plan that  
12 exclusively serves special needs beneficiaries (as  
13 defined in subparagraph (B)).

14 “(B) SPECIAL NEEDS BENEFICIARY.—The  
15 term ‘special needs beneficiary’ means a  
16 Medicare+Choice eligible individual who—

17 “(i) is institutionalized (as defined by  
18 the Secretary);

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

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

1 paragraph (A) for individuals with severe  
2 or disabling chronic conditions.”.

3 (c) RESTRICTION ON ENROLLMENT PERMITTED.—  
4 Section 1859 (42 U.S.C. 1395w-28) is amended by add-  
5 ing at the end the following new subsection:

6 “(f) RESTRICTION ON ENROLLMENT FOR SPECIAL-  
7 IZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS  
8 BENEFICIARIES.—In the case of a specialized  
9 Medicare+Choice plan (as defined in subsection (b)(4)),  
10 notwithstanding any other provision of this part and in  
11 accordance with regulations of the Secretary and for peri-  
12 ods before January 1, 2008, the plan may restrict the en-  
13 rollment of individuals under the plan to individuals who  
14 are within 1 or more classes of special needs bene-  
15 ficiaries.”.

16 (d) REPORT TO CONGRESS.—Not later than Decem-  
17 ber 31, 2006, the Secretary shall submit to Congress a  
18 report that assesses the impact of specialized  
19 Medicare+Choice plans for special needs beneficiaries on  
20 the cost and quality of services provided to enrollees. Such  
21 report shall include an assessment of the costs and savings  
22 to the medicare program as a result of amendments made  
23 by subsections (a), (b), and (c).

24 (e) EFFECTIVE DATES.—

1           (1) IN GENERAL.—The amendments made by  
2 subsections (a), (b), and (c) shall take effect on the  
3 date of enactment of this Act.

4           (2) DEADLINE FOR ISSUANCE OF REQUIRE-  
5 MENTS FOR SPECIAL NEEDS BENEFICIARIES; TRAN-  
6 SITION.—No later than 1 year after the date of en-  
7 actment of this Act, the Secretary shall issue final  
8 regulations to establish requirements for special  
9 needs beneficiaries under section 1859(b)(4)(B)(iii)  
10 of the Social Security Act, as added by subsection  
11 (b).

12 **SEC. 223. PAYMENT BY PACE PROVIDERS FOR MEDICARE**  
13 **AND MEDICAID SERVICES FURNISHED BY**  
14 **NONCONTRACT PROVIDERS.**

15 (a) MEDICARE SERVICES.—

16           (1) MEDICARE SERVICES FURNISHED BY PRO-  
17 VIDERS OF SERVICES.—Section 1866(a)(1)(O) (42  
18 U.S.C. 1395cc(a)(1)(O)) is amended—

19           (A) by striking “part C or” and inserting  
20 “part C, with a PACE provider under section  
21 1894 or 1934, or”;

22           (B) by striking “(i)”;

23           (C) by striking “and (ii)”; and

24           (D) by striking “members of the organiza-  
25 tion” and inserting “members of the organiza-

1           tion or PACE program eligible individuals en-  
2           rolled with the PACE provider,”.

3           (2) MEDICARE SERVICES FURNISHED BY PHYSI-  
4           CIANS AND OTHER ENTITIES.—Section 1894(b) (42  
5           U.S.C. 1395eee(b)) is amended by adding at the end  
6           the following new paragraphs:

7           “(3) TREATMENT OF MEDICARE SERVICES FUR-  
8           NISHED BY NONCONTRACT PHYSICIANS AND OTHER  
9           ENTITIES.—

10           “(A) APPLICATION OF MEDICARE+CHOICE  
11           REQUIREMENT WITH RESPECT TO MEDICARE  
12           SERVICES FURNISHED BY NONCONTRACT PHY-  
13           SICIANS AND OTHER ENTITIES.—Section  
14           1852(k)(1) (relating to limitations on balance  
15           billing against Medicare+Choice organizations  
16           for noncontract physicians and other entities  
17           with respect to services covered under this title)  
18           shall apply to PACE providers, PACE program  
19           eligible individuals enrolled with such PACE  
20           providers, and physicians and other entities  
21           that do not have a contract establishing pay-  
22           ment amounts for services furnished to such an  
23           individual in the same manner as such section  
24           applies to Medicare+Choice organizations, indi-  
25           viduals enrolled with such organizations, and

1 physicians and other entities referred to in such  
2 section.

3 “(B) REFERENCE TO RELATED PROVISION  
4 FOR NONCONTRACT PROVIDERS OF SERVICES.—  
5 For the provision relating to limitations on bal-  
6 ance billing against PACE providers for serv-  
7 ices covered under this title furnished by non-  
8 contract providers of services, see section  
9 1866(a)(1)(O).

10 “(4) REFERENCE TO RELATED PROVISION FOR  
11 SERVICES COVERED UNDER TITLE XIX BUT NOT  
12 UNDER THIS TITLE.—For provisions relating to limi-  
13 tations on payments to providers participating under  
14 the State plan under title XIX that do not have a  
15 contract with a PACE provider establishing payment  
16 amounts for services covered under such plan (but  
17 not under this title) when such services are fur-  
18 nished to enrollees of that PACE provider, see sec-  
19 tion 1902(a)(66).”.

20 (b) MEDICAID SERVICES.—

21 (1) REQUIREMENT UNDER STATE PLAN.—Sec-  
22 tion 1902(a) (42 U.S.C. 1396a(a)) is amended—

23 (A) in paragraph (64), by striking “and”  
24 at the end;

1 (B) in paragraph (65), by striking the pe-  
2 riod at the end and inserting “; and”; and

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

5 “(66) provide, with respect to services cov-  
6 ered under the State plan (but not under title  
7 XVIII) that are furnished to a PACE program  
8 eligible individual enrolled with a PACE pro-  
9 vider by a provider participating under the  
10 State plan that does not have a contract with  
11 the PACE provider that establishes payment  
12 amounts for such services, that such partici-  
13 pating provider may not require the PACE pro-  
14 vider to pay the participating provider an  
15 amount greater than the amount that would  
16 otherwise be payable for the service to the par-  
17 ticipating provider under the State plan for the  
18 State where the PACE provider is located (in  
19 accordance with regulations issued by the Sec-  
20 retary).”.

21 (2) REFERENCE IN MEDICAID STATUTE.—Sec-  
22 tion 1934(b) (42 U.S.C. 1396u–4(b)) is amended by  
23 adding at the end the following new paragraphs:

1           “(3) TREATMENT OF MEDICARE SERVICES FUR-  
2           NISHED BY NONCONTRACT PHYSICIANS AND OTHER  
3           ENTITIES.—

4           “(A) APPLICATION OF MEDICARE+CHOICE  
5           REQUIREMENT WITH RESPECT TO MEDICARE  
6           SERVICES FURNISHED BY NONCONTRACT PHY-  
7           SICIANS AND OTHER ENTITIES.—Section  
8           1852(k)(1) (relating to limitations on balance  
9           billing against Medicare+Choice organizations  
10          for noncontract physicians and other entities  
11          with respect to services covered under title  
12          XVIII) shall apply to PACE providers, PACE  
13          program eligible individuals enrolled with such  
14          PACE providers, and physicians and other enti-  
15          ties that do not have a contract establishing  
16          payment amounts for services furnished to such  
17          an individual in the same manner as such sec-  
18          tion applies to Medicare+Choice organizations,  
19          individuals enrolled with such organizations,  
20          and physicians and other entities referred to in  
21          such section.

22          “(B) REFERENCE TO RELATED PROVISION  
23          FOR NONCONTRACT PROVIDERS OF SERVICES.—  
24          For the provision relating to limitations on bal-  
25          ance billing against PACE providers for serv-

1           ices covered under title XVIII furnished by non-  
2           contract providers of services, see section  
3           1866(a)(1)(O).

4           “(4) REFERENCE TO RELATED PROVISION FOR  
5           SERVICES COVERED UNDER THIS TITLE BUT NOT  
6           UNDER TITLE XVIII.—For provisions relating to lim-  
7           itations on payments to providers participating  
8           under the State plan under this title that do not  
9           have a contract with a PACE provider establishing  
10          payment amounts for services covered under such  
11          plan (but not under title XVIII) when such services  
12          are furnished to enrollees of that PACE provider,  
13          see section 1902(a)(66).”.

14          (c) EFFECTIVE DATE.—The amendments made by  
15          this section shall apply to services furnished on or after  
16          January 1, 2004.

17       **SEC. 224. INSTITUTE OF MEDICINE EVALUATION AND RE-**  
18                               **PORT ON HEALTH CARE PERFORMANCE**  
19                               **MEASURES.**

20          (a) EVALUATION.—

21               (1) IN GENERAL.—Not later than the date that  
22               is 2 months after the date of enactment of this Act,  
23               the Secretary of Health and Human Services shall  
24               enter into an arrangement under which the Institute  
25               of Medicine of the National Academy of Sciences (in

1 this section referred to as the “Institute”) shall con-  
2 duct an evaluation of leading health care perform-  
3 ance measures and options to implement policies  
4 that align performance with payment under the  
5 medicare program under title XVIII of the Social  
6 Security Act (42 U.S.C. 1395 et seq.).

7 (2) SPECIFIC MATTERS EVALUATED.—In con-  
8 ducting the evaluation under paragraph (1), the In-  
9 stitute shall—

10 (A) catalogue, review, and evaluate the va-  
11 lidity of leading health care performance meas-  
12 ures;

13 (B) catalogue and evaluate the success and  
14 utility of alternative performance incentive pro-  
15 grams in public or private sector settings; and

16 (C) identify and prioritize options to imple-  
17 ment policies that align performance with pay-  
18 ment under the medicare program that indi-  
19 cate—

20 (i) the performance measurement set  
21 to be used and how that measurement set  
22 will be updated;

23 (ii) the payment policy that will re-  
24 ward performance; and

1 (iii) the key implementation issues  
2 (such as data and information technology  
3 requirements) that must be addressed.

4 (3) SCOPE OF HEALTH CARE PERFORMANCE  
5 MEASURES.—The health care performance measures  
6 described in paragraph (2)(A) shall encompass a va-  
7 riety of perspectives, including physicians, hospitals,  
8 health plans, purchasers, and consumers.

9 (4) CONSULTATION WITH MEDPAC.—In evalu-  
10 ating the matters described in paragraph (2)(C), the  
11 Institute shall consult with the Medicare Payment  
12 Advisory Commission established under section 1805  
13 of the Social Security Act (42 U.S.C. 1395b–6).

14 (b) REPORT.—Not later than the date that is 18  
15 months after the date of enactment of this Act, the Insti-  
16 tute shall submit to the Secretary of Health and Human  
17 Services, the Committees on Ways and Means and Energy  
18 and Commerce of the House of Representatives, and the  
19 Committee on Finance of the Senate a report on the eval-  
20 uation conducted under subsection (a)(1) describing the  
21 findings of such evaluation and recommendations for an  
22 overall strategy and approach for aligning payment with  
23 performance in the original medicare fee-for-service pro-  
24 gram under parts A and B of title XVIII of the Social  
25 Security Act, the Medicare+Choice program under part

1 C of such title, and any other programs under such title  
2 XVIII.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—There  
4 are authorized to be appropriated \$1,000,000 for purposes  
5 of conducting the evaluation and preparing the report re-  
6 quired by this section.

7 **SEC. 225. EXPANDING THE WORK OF MEDICARE QUALITY**  
8 **IMPROVEMENT ORGANIZATIONS TO INCLUDE**  
9 **PARTS C AND D.**

10 (a) APPLICATION TO MEDICARE MANAGED CARE  
11 AND PRESCRIPTION DRUG COVERAGE.—Section  
12 1154(a)(1) (42 U.S.C. 1320c–3(a)(1)) is amended by in-  
13 serting “, Medicare+Choice organizations and  
14 MedicareAdvantage organizations under part C, and pre-  
15 scription drug card sponsors and eligible entities under  
16 part D” after “under section 1876”.

17 (b) PRESCRIPTION DRUG THERAPY QUALITY IM-  
18 PROVEMENT.—Section 1154(a) (42 U.S.C. 1320c–3(a)) is  
19 amended by adding at the end the following new para-  
20 graph:

21 “(17) The organization shall execute its respon-  
22 sibilities under subparagraphs (A) and (B) of para-  
23 graph (1) by offering to providers, practitioners, pre-  
24 scription drug card sponsors and eligible entities  
25 under part D, and Medicare+Choice and

1 Medicare Advantage plans under part C quality im-  
 2 provement assistance pertaining to prescription drug  
 3 therapy. For purposes of this part and title XVIII,  
 4 the functions described in this paragraph shall be  
 5 treated as a review function.”.

6 (c) EFFECTIVE DATE.—The amendments made by  
 7 this section shall apply on and after January 1, 2004.

## 8 **TITLE III—CENTER FOR** 9 **MEDICARE CHOICES**

### 10 **SEC. 301. ESTABLISHMENT OF THE CENTER FOR MEDICARE** 11 **CHOICES.**

12 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et  
 13 seq.), as amended by section 111, is amended by inserting  
 14 after 1806 the following new section:

15 “ESTABLISHMENT OF THE CENTER FOR MEDICARE  
 16 CHOICES

17 “SEC. 1808. (a) ESTABLISHMENT.—By not later  
 18 than March 1, 2004, the Secretary shall establish within  
 19 the Department of Health and Human Services the Center  
 20 for Medicare Choices, which shall be separate from the  
 21 Centers for Medicare and Medicaid Services.

22 “(b) ADMINISTRATOR AND DEPUTY ADMINIS-  
 23 TRATOR.—

24 “(1) ADMINISTRATOR.—

25 “(A) IN GENERAL.—The Center for Medi-  
 26 care Choices shall be headed by an Adminis-

1           trator (in this section referred to as the ‘Ad-  
2           ministrator’) who shall be appointed by the  
3           President, by and with the advice and consent  
4           of the Senate. The Administrator shall report  
5           directly to the Secretary.

6           “(B) COMPENSATION.—The Administrator  
7           shall be paid at the rate of basic pay payable  
8           for level III of the Executive Schedule under  
9           section 5314 of title 5, United States Code.

10          “(C) TERM OF OFFICE.—The Adminis-  
11          trator shall be appointed for a term of 5 years.  
12          In any case in which a successor does not take  
13          office at the end of an Administrator’s term of  
14          office, that Administrator may continue in of-  
15          fice until the entry upon office of such a suc-  
16          cessor. An Administrator appointed to a term of  
17          office after the commencement of such term  
18          may serve under such appointment only for the  
19          remainder of such term.

20          “(D) GENERAL AUTHORITY.—The Admin-  
21          istrator shall be responsible for the exercise of  
22          all powers and the discharge of all duties of the  
23          Center for Medicare Choices, and shall have au-  
24          thority and control over all personnel and ac-  
25          tivities thereof.

1           “(E) RULEMAKING AUTHORITY.—The Ad-  
2           ministrators may prescribe such rules and regu-  
3           lations as the Administrator determines nec-  
4           essary or appropriate to carry out the functions  
5           of the Center for Medicare Choices. The regula-  
6           tions prescribed by the Administrator shall be  
7           subject to the rulemaking procedures estab-  
8           lished under section 553 of title 5, United  
9           States Code.

10           “(F) AUTHORITY TO ESTABLISH ORGANI-  
11           ZATIONAL UNITS.—The Administrator may es-  
12           tablish, alter, consolidate, or discontinue such  
13           organizational units or components within the  
14           Center for Medicare Choices as the Adminis-  
15           trator considers necessary or appropriate, ex-  
16           cept that this subparagraph shall not apply  
17           with respect to any unit, component, or provi-  
18           sion provided for by this section.

19           “(G) AUTHORITY TO DELEGATE.—The Ad-  
20           ministrators may assign duties, and delegate, or  
21           authorize successive redelegations of, authority  
22           to act and to render decisions, to such officers  
23           and employees of the Center for Medicare  
24           Choices as the Administrator may find nec-  
25           essary. Within the limitations of such delega-

1 tions, redelegations, or assignments, all official  
2 acts and decisions of such officers and employ-  
3 ees shall have the same force and effect as  
4 though performed or rendered by the Adminis-  
5 trator.

6 “(2) DEPUTY ADMINISTRATOR.—

7 “(A) IN GENERAL.—There shall be a Dep-  
8 uty Administrator of the Center for Medicare  
9 Choices who shall be appointed by the Adminis-  
10 trator.

11 “(B) COMPENSATION.—The Deputy Ad-  
12 ministrator shall be paid at the rate of basic  
13 pay payable for level IV of the Executive Sched-  
14 ule under section 5315 of title 5, United States  
15 Code.

16 “(C) TERM OF OFFICE.—The Deputy Ad-  
17 ministrator shall be appointed for a term of 5  
18 years. In any case in which a successor does not  
19 take office at the end of a Deputy Administra-  
20 tor’s term of office, such Deputy Administrator  
21 may continue in office until the entry upon of-  
22 fice of such a successor. A Deputy Adminis-  
23 trator appointed to a term of office after the  
24 commencement of such term may serve under

1 such appointment only for the remainder of  
2 such term.

3 “(D) DUTIES.—The Deputy Administrator  
4 shall perform such duties and exercise such  
5 powers as the Administrator shall from time to  
6 time assign or delegate. The Deputy Adminis-  
7 trator shall be the Acting Administrator of the  
8 Center for Medicare Choices during the absence  
9 or disability of the Administrator and, unless  
10 the President designates another officer of the  
11 Government as Acting Administrator, in the  
12 event of a vacancy in the office of the Adminis-  
13 trator.

14 “(3) SECRETARIAL COORDINATION OF PROGRAM  
15 ADMINISTRATION.—The Secretary shall ensure ap-  
16 propriate coordination between the Administrator  
17 and the Administrator of the Centers for Medicare  
18 and Medicaid Services in carrying out the programs  
19 under this title.

20 “(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

21 “(1) DUTIES.—

22 “(A) GENERAL DUTIES.—The Adminis-  
23 trator shall carry out parts C and D, includ-  
24 ing—

1           “(i) negotiating, entering into, and en-  
2           forcing, contracts with plans for the offer-  
3           ing of MedicareAdvantage plans under  
4           part C, including the offering of qualified  
5           prescription drug coverage under such  
6           plans; and

7           “(ii) negotiating, entering into, and  
8           enforcing, contracts with eligible entities  
9           for the offering of Medicare Prescription  
10          Drug plans under part D.

11          “(B) OTHER DUTIES.—The Administrator  
12          shall carry out any duty provided for under  
13          part C or D, including duties relating to—

14               “(i) reasonable cost contracts with eli-  
15               gible organizations under section 1876(h);  
16               and

17               “(ii) demonstration projects carried  
18               out in part or in whole under such parts,  
19               including the demonstration project carried  
20               out through a MedicareAdvantage (for-  
21               merly Medicare+Choice) project that dem-  
22               onstrates the application of capitation pay-  
23               ment rates for frail elderly medicare bene-  
24               ficiaries through the use of an interdiscipli-  
25               nary team and through the provision of

1 primary care services to such beneficiaries  
2 by means of such a team at the nursing fa-  
3 cility involved.

4 “(C) NONINTERFERENCE.—In order to  
5 promote competition under parts C and D, the  
6 Administrator, in carrying out the duties re-  
7 quired under this section, may not, to the ex-  
8 tent possible, interfere in any way with negotia-  
9 tions between eligible entities,  
10 Medicare Advantage organizations, hospitals,  
11 physicians, other entities or individuals fur-  
12 nishing items and services under this title (in-  
13 cluding contractors for such items and serv-  
14 ices), and drug manufacturers, wholesalers, or  
15 other suppliers of covered drugs.

16 “(D) ANNUAL REPORTS.—Not later than  
17 March 31 of each year, the Administrator shall  
18 submit to Congress and the President a report  
19 on the administration of the voluntary prescrip-  
20 tion drug delivery program under this part dur-  
21 ing the previous fiscal year.

22 “(2) MANAGEMENT STAFF.—

23 “(A) IN GENERAL.—The Administrator,  
24 with the approval of the Secretary, may employ,  
25 such management staff as determined appro-

1           priate. Any such manager shall be required to  
2           have demonstrated, by their education and ex-  
3           perience (either in the public or private sector),  
4           superior expertise in the following areas:

5                   “(i) The review, negotiation, and ad-  
6                   ministration of health care contracts.

7                   “(ii) The design of health care benefit  
8                   plans.

9                   “(iii) Actuarial sciences.

10                   “(iv) Compliance with health plan  
11                   contracts.

12                   “(v) Consumer education and decision  
13                   making.

14                   “(B) COMPENSATION.—

15                   “(i) IN GENERAL.—Subject to clause  
16                   (ii), the Administrator shall establish the  
17                   rate of pay for an individual employed  
18                   under subparagraph (A).

19                   “(ii) MAXIMUM RATE.—In no case  
20                   may the rate of compensation determined  
21                   under clause (i) exceed the highest rate of  
22                   basic pay for the Senior Executive Service  
23                   under section 5382(b) of title 5, United  
24                   States Code.

1           “(3) REDELEGATION OF CERTAIN FUNCTIONS  
2           OF THE CENTERS FOR MEDICARE AND MEDICAID  
3           SERVICES.—

4                   “(A) IN GENERAL.—The Secretary, the  
5           Administrator of the Center for Medicare  
6           Choices, and the Administrator of the Centers  
7           for Medicare and Medicaid Services shall estab-  
8           lish an appropriate transition of responsibility  
9           in order to redelegate the administration of part  
10          C from the Secretary and the Administrator of  
11          the Centers for Medicare and Medicaid Services  
12          to the Administrator of the Center for Medicare  
13          Choices as is appropriate to carry out the pur-  
14          poses of this section.

15                   “(B) TRANSFER OF DATA AND INFORMA-  
16          TION.—The Secretary shall ensure that the Ad-  
17          ministrator of the Centers for Medicare and  
18          Medicaid Services transfers to the Adminis-  
19          trator such information and data in the posses-  
20          sion of the Administrator of the Centers for  
21          Medicare and Medicaid Services as the Admin-  
22          istrator requires to carry out the duties de-  
23          scribed in paragraph (1).

24                   “(C) CONSTRUCTION.—Insofar as a re-  
25          sponsibility of the Secretary or the Adminis-

1           trator of the Centers for Medicare and Medicaid  
2           Services is redelegated to the Administrator  
3           under this section, any reference to the Sec-  
4           retary or the Administrator of the Centers for  
5           Medicare and Medicaid Services in this title or  
6           title XI with respect to such responsibility is  
7           deemed to be a reference to the Administrator.

8           “(d) OFFICE OF BENEFICIARY ASSISTANCE.—

9           “(1) ESTABLISHMENT.—The Secretary shall es-  
10          tablish within the Center for Medicare Choices an  
11          Office of Beneficiary Assistance to carry out func-  
12          tions relating to medicare beneficiaries under this  
13          title, including making determinations of eligibility  
14          of individuals for benefits under this title, providing  
15          for enrollment of medicare beneficiaries under this  
16          title, and the functions described in paragraph (2).  
17          The Office shall be a separate operating division  
18          within the Center for Medicare Choices.

19          “(2) DISSEMINATION OF INFORMATION ON  
20          BENEFITS AND APPEALS RIGHTS.—

21                 “(A) DISSEMINATION OF BENEFITS INFOR-  
22                 MATION.—The Office of Beneficiary Assistance  
23                 shall disseminate to medicare beneficiaries, by  
24                 mail, by posting on the Internet site of the Cen-  
25                 ter for Medicare Choices, and through the toll-

1 free telephone number provided for under sec-  
2 tion 1804(b), information with respect to the  
3 following:

4 “(i) Benefits, and limitations on pay-  
5 ment (including cost-sharing, stop-loss pro-  
6 visions, and formulary restrictions) under  
7 parts C and D.

8 “(ii) Benefits, and limitations on pay-  
9 ment under parts A, and B, including in-  
10 formation on medicare supplemental poli-  
11 cies under section 1882.

12 “(iii) Other areas determined to be  
13 appropriate by the Administrator.

14 Such information shall be presented in a man-  
15 ner so that medicare beneficiaries may compare  
16 benefits under parts A, B, and D, and medicare  
17 supplemental policies with benefits under  
18 Medicare Advantage plans under part C.

19 “(B) DISSEMINATION OF APPEALS RIGHTS  
20 INFORMATION.—The Office of Beneficiary As-  
21 sistance shall disseminate to medicare bene-  
22 ficiaries in the manner provided under subpara-  
23 graph (A) a description of procedural rights (in-  
24 cluding grievance and appeals procedures) of  
25 beneficiaries under the original medicare fee-

1 for-service program under parts A and B, the  
2 Medicare Advantage program under part C, and  
3 the voluntary prescription drug delivery pro-  
4 gram under part D.

5 “(3) MEDICARE OMBUDSMAN.—

6 “(A) IN GENERAL.—Within the Office of  
7 Beneficiary Assistance, there shall be a Medi-  
8 care Ombudsman, appointed by the Secretary  
9 from among individuals with expertise and ex-  
10 perience in the fields of health care and advo-  
11 cacy, to carry out the duties described in sub-  
12 paragraph (B).

13 “(B) DUTIES.—The Medicare Ombudsman  
14 shall—

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

19 “(ii) provide assistance with respect to  
20 complaints, grievances, and requests re-  
21 ferred to in clause (i), including—

22 “(I) assistance in collecting rel-  
23 evant information for such bene-  
24 ficiaries, to seek an appeal of a deci-  
25 sion or determination made by a fiscal

1 intermediary, carrier, Medicare-Ad-  
2 van-tage organization, an eligible enti-  
3 ty under part D, or the Secretary; and

4 “(II) assistance to such bene-  
5 ficiaries with any problems arising  
6 from disenrollment from a  
7 MedicareAdvantage plan under part C  
8 or a prescription drug plan under part  
9 D; and

10 “(iii) submit annual reports to Con-  
11 gress, the Secretary, and the Medicare  
12 Competitive Policy Advisory Board describ-  
13 ing the activities of the Office, and includ-  
14 ing such recommendations for improve-  
15 ment in the administration of this title as  
16 the Ombudsman determines appropriate.

17 “(C) COORDINATION WITH STATE OM-  
18 BUDSMAN PROGRAMS AND CONSUMER ORGANI-  
19 ZATIONS.—The Medicare Ombudsman shall, to  
20 the extent appropriate, coordinate with State  
21 medical Ombudsman programs, and with State-  
22 and community-based consumer organizations,  
23 to—

24 “(i) provide information about the  
25 medicare program; and

1                   “(ii) conduct outreach to educate  
2                    medicare beneficiaries with respect to man-  
3                    ners in which problems under the medicare  
4                    program may be resolved or avoided.

5           “(e) MEDICARE COMPETITIVE POLICY ADVISORY  
6 BOARD.—

7                   “(1) ESTABLISHMENT.—There is established  
8                    within the Center for Medicare Choices the Medicare  
9                    Competitive Policy Advisory Board (in this section  
10                    referred to as the ‘Board’). The Board shall advise,  
11                    consult with, and make recommendations to the Ad-  
12                    ministrators with respect to the administration of  
13                    parts C and D, including the review of payment poli-  
14                    cies under such parts.

15                   “(2) REPORTS.—

16                    “(A) IN GENERAL.—With respect to mat-  
17                    ters of the administration of parts C and D, the  
18                    Board shall submit to Congress and to the Ad-  
19                    ministrators such reports as the Board deter-  
20                    mines appropriate. Each such report may con-  
21                    tain such recommendations as the Board deter-  
22                    mines appropriate for legislative or administra-  
23                    tive changes to improve the administration of  
24                    such parts, including the stability and solvency  
25                    of the programs under such parts and the top-

1           ics described in subparagraph (B). Each such  
2           report shall be published in the Federal Reg-  
3           ister.

4           “(B) TOPICS DESCRIBED.—Reports re-  
5           quired under subparagraph (A) may include the  
6           following topics:

7                   “(i) FOSTERING COMPETITION.—Rec-  
8                   ommendations or proposals to increase  
9                   competition under parts C and D for serv-  
10                  ices furnished to medicare beneficiaries.

11                  “(ii) EDUCATION AND ENROLL-  
12                  MENT.—Recommendations for the im-  
13                  provement of efforts to provide medicare  
14                  beneficiaries information and education on  
15                  the program under this title, and specifi-  
16                  cally parts C and D, and the program for  
17                  enrollment under the title.

18                  “(iii) QUALITY.—Recommendations  
19                  on ways to improve the quality of benefits  
20                  provided under plans under parts C and D.

21                  “(iv) DISEASE MANAGEMENT PRO-  
22                  GRAMS.—Recommendations on the incor-  
23                  poration of disease management programs  
24                  under parts C and D.

1                   “(v) RURAL ACCESS.—Recommendations to improve competition and access to  
2                   plans under parts C and D in rural areas.

3                   “(C) MAINTAINING INDEPENDENCE OF  
4                   BOARD.—The Board shall directly submit to  
5                   Congress reports required under subparagraph  
6                   (A). No officer or agency of the United States  
7                   may require the Board to submit to any officer  
8                   or agency of the United States for approval,  
9                   comments, or review, prior to the submission to  
10                  Congress of such reports.

11                  “(3) DUTY OF ADMINISTRATOR.—With respect  
12                  to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report  
13                  is submitted, the Administrator shall submit to Congress and the President an analysis of recommendations  
14                  made by the Board in such report. Each such  
15                  analysis shall be published in the Federal Register.

16                  “(4) MEMBERSHIP.—

17                  “(A) APPOINTMENT.—Subject to the succeeding provisions of this paragraph, the Board  
18                  shall consist of 7 members to be appointed as  
19                  follows:

20                  “(i) Three members shall be appointed by the President.  
21  
22  
23  
24  
25

1           “(ii) Two members shall be appointed  
2           by the Speaker of the House of Represent-  
3           atives, with the advice of the chairman and  
4           the ranking minority member of the Com-  
5           mittees on Ways and Means and on En-  
6           ergy and Commerce of the House of Rep-  
7           resentatives.

8           “(iii) Two members shall be appointed  
9           by the President pro tempore of the Senate  
10          with the advice of the chairman and the  
11          ranking minority member of the Com-  
12          mittee on Finance of the Senate.

13          “(B) QUALIFICATIONS.—The members  
14          shall be chosen on the basis of their integrity,  
15          impartiality, and good judgment, and shall be  
16          individuals who are, by reason of their edu-  
17          cation and experience in health care benefits  
18          management, exceptionally qualified to perform  
19          the duties of members of the Board.

20          “(C) PROHIBITION ON INCLUSION OF FED-  
21          ERAL EMPLOYEES.—No officer or employee of  
22          the United States may serve as a member of  
23          the Board.

24          “(5) COMPENSATION.—Members of the Board  
25          shall receive, for each day (including travel time)

1 they are engaged in the performance of the functions  
2 of the Board, compensation at rates not to exceed  
3 the daily equivalent to the annual rate in effect for  
4 level IV of the Executive Schedule under section  
5 5315 of title 5, United States Code.

6 “(6) TERMS OF OFFICE.—

7 “(A) IN GENERAL.—The term of office of  
8 members of the Board shall be 3 years.

9 “(B) TERMS OF INITIAL APPOINTEES.—As  
10 designated by the President at the time of ap-  
11 pointment, of the members first appointed—

12 “(i) one shall be appointed for a term  
13 of 1 year;

14 “(ii) three shall be appointed for  
15 terms of 2 years; and

16 “(iii) three shall be appointed for  
17 terms of 3 years.

18 “(C) REAPPOINTMENTS.—Any person ap-  
19 pointed as a member of the Board may not  
20 serve for more than 8 years.

21 “(D) VACANCY.—Any member appointed  
22 to fill a vacancy occurring before the expiration  
23 of the term for which the member’s predecessor  
24 was appointed shall be appointed only for the  
25 remainder of that term. A member may serve

1 after the expiration of that member's term until  
2 a successor has taken office. A vacancy in the  
3 Board shall be filled in the manner in which  
4 the original appointment was made.

5 “(7) CHAIR.—The Chair of the Board shall be  
6 elected by the members. The term of office of the  
7 Chair shall be 3 years.

8 “(8) MEETINGS.—The Board shall meet at the  
9 call of the Chair, but in no event less than 3 times  
10 during each fiscal year.

11 “(9) DIRECTOR AND STAFF.—

12 “(A) APPOINTMENT OF DIRECTOR.—The  
13 Board shall have a Director who shall be ap-  
14 pointed by the Chair.

15 “(B) IN GENERAL.—With the approval of  
16 the Board, the Director may appoint such addi-  
17 tional personnel as the Director considers ap-  
18 propriate.

19 “(C) ASSISTANCE FROM THE ADMINIS-  
20 TRATOR.—The Administrator shall make avail-  
21 able to the Board such information and other  
22 assistance as it may require to carry out its  
23 functions.

24 “(10) CONTRACT AUTHORITY.—The Board may  
25 contract with and compensate government and pri-

1 vate agencies or persons to carry out its duties  
2 under this subsection, without regard to section  
3 3709 of the Revised Statutes (41 U.S.C. 5).

4 “(f) FUNDING.—There is authorized to be appro-  
5 priated, in appropriate part from the Federal Hospital In-  
6 surance Trust Fund and from the Federal Supplementary  
7 Medical Insurance Trust Fund (including the Prescription  
8 Drug Account), such sums as are necessary to carry out  
9 this section.”.

10 (b) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-  
11 MEDICARE).—Section 1804(b) (42 U.S.C. 1395b-2(b))  
12 is amended by adding at the end the following: “By not  
13 later than 1 year after the date of the enactment of the  
14 Prescription Drug and Medicare Improvement Act of  
15 2003, the Secretary shall provide, through the toll-free  
16 number 1-800-MEDICARE, for a means by which indi-  
17 viduals seeking information about, or assistance with, such  
18 programs who phone such toll-free number are transferred  
19 (without charge) to appropriate entities for the provision  
20 of such information or assistance. Such toll-free number  
21 shall be the toll-free number listed for general information  
22 and assistance in the annual notice under subsection (a)  
23 instead of the listing of numbers of individual contrac-  
24 tors.”.

1 **SEC. 302. MISCELLANEOUS ADMINISTRATIVE PROVISIONS.**

2 (a) ADMINISTRATOR AS MEMBER AND CO-SEC-  
3 RETARY OF THE BOARD OF TRUSTEES OF THE MEDICARE  
4 TRUST FUNDS.—The fifth sentence of sections 1817(b)  
5 and 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each  
6 amended by striking “shall serve as the Secretary” and  
7 inserting “and the Administrator of the Center for Medi-  
8 care Choices shall serve as the Co-Secretaries”.

9 (b) INCREASE IN GRADE TO EXECUTIVE LEVEL III  
10 FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDI-  
11 CARE and MEDICAID SERVICES.—

12 (1) IN GENERAL.—Section 5314 of title 5,  
13 United States Code, is amended by adding at the  
14 end the following:

15 “Administrator of the Centers for Medicare and  
16 Medicaid Services.”.

17 (2) CONFORMING AMENDMENT.—Section 5315  
18 of such title is amended by striking “Administrator  
19 of the Health Care Financing Administration.”.

20 (3) EFFECTIVE DATE.—The amendments made  
21 by this subsection take effect on March 1, 2004.

1 **TITLE IV—MEDICARE FEE-FOR-**  
2 **SERVICE IMPROVEMENTS**  
3 **Subtitle A—Provisions Relating to**  
4 **Part A**

5 **SEC. 401. EQUALIZING URBAN AND RURAL STANDARDIZED**  
6 **PAYMENT AMOUNTS UNDER THE MEDICARE**  
7 **INPATIENT HOSPITAL PROSPECTIVE PAY-**  
8 **MENT SYSTEM.**

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

11 (1) by striking “(iv) For discharges” and in-  
12 sserting “(iv)(I) Subject to the succeeding provisions  
13 of this clause, for discharges”; and

14 (2) by adding at the end the following new sub-  
15 clauses:

16 “(II) For discharges occurring during fiscal  
17 year 2004, the operating standardized amount for  
18 hospitals located other than in a large urban area  
19 shall be increased by  $\frac{1}{2}$  of the difference between  
20 the operating standardized amount determined  
21 under subclause (I) for hospitals located in large  
22 urban areas for such fiscal year and such amount  
23 determined (without regard to this subclause) for  
24 other hospitals for such fiscal year.

1           “(III) For discharges occurring in a fiscal year  
2           beginning with fiscal year 2005, the Secretary shall  
3           compute an operating standardized amount for hos-  
4           pitals located in any area within the United States  
5           and within each region equal to the operating stand-  
6           ardized amount computed for the previous fiscal  
7           year under this subparagraph for hospitals located  
8           in a large urban area (or, beginning with fiscal year  
9           2006, applicable for all hospitals in the previous fis-  
10          cal year) increased by the applicable percentage in-  
11          crease under subsection (b)(3)(B)(i) for the fiscal  
12          year involved.”.

13          (b) CONFORMING AMENDMENTS.—

14                 (1) COMPUTING DRG-SPECIFIC RATES.—Section  
15          1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is  
16          amended—

17                         (A) in the heading, by striking “IN DIF-  
18                         FERENT AREAS”;

19                         (B) in the matter preceding clause (i), by  
20                         striking “each of which is”;

21                         (C) in clause (i)—

22                                 (i) in the matter preceding subclause  
23                                 (I), by inserting “for fiscal years before fis-  
24                                 cal year 2005,” before “for hospitals”; and

1 (ii) in subclause (II), by striking  
2 “and” after the semicolon at the end;

3 (D) in clause (ii)—

4 (i) in the matter preceding subclause  
5 (I), by inserting “for fiscal years before fis-  
6 cal year 2005,” before “for hospitals”; and

7 (ii) in subclause (II), by striking the  
8 period at the end and inserting “; and”;  
9 and

10 (E) by adding at the end the following new  
11 clause:

12 “(iii) for a fiscal year beginning after fiscal  
13 year 2004, for hospitals located in all areas, to  
14 the product of—

15 “(I) the applicable operating stand-  
16 ardized amount (computed under subpara-  
17 graph (A)), reduced under subparagraph  
18 (B), and adjusted or reduced under sub-  
19 paragraph (C) for the fiscal year; and

20 “(II) the weighting factor (determined  
21 under paragraph (4)(B)) for that diag-  
22 nosis-related group.”.

23 (2) TECHNICAL CONFORMING SUNSET.—Section  
24 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

1 (A) in the matter preceding subparagraph  
 2 (A), by inserting “, for fiscal years before fiscal  
 3 year 1997,” before “a regional adjusted DRG  
 4 prospective payment rate”; and

5 (B) in subparagraph (D), in the matter  
 6 preceding clause (i), by inserting “, for fiscal  
 7 years before fiscal year 1997,” before “a re-  
 8 gional DRG prospective payment rate for each  
 9 region,”.

10 **SEC. 402. ADJUSTMENT TO THE MEDICARE INPATIENT HOS-**  
 11 **PITAL PPS WAGE INDEX TO REVISE THE**  
 12 **LABOR-RELATED SHARE OF SUCH INDEX.**

13 (a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C.  
 14 1395ww(d)(3)(E)) is amended—

15 (1) by striking “WAGE LEVELS.—The Sec-  
 16 retary” and inserting “WAGE LEVELS.—

17 “(i) IN GENERAL.—Except as provided in  
 18 clause (ii), the Secretary”; and

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

21 “(ii) ALTERNATIVE PROPORTION TO BE  
 22 ADJUSTED BEGINNING IN FISCAL YEAR 2004.—

23 “(I) IN GENERAL.—Except as pro-  
 24 vided in subclause (II), for discharges oc-  
 25 ccurring on or after October 1, 2003, the

1 Secretary shall substitute ‘62 percent’ for  
2 the proportion described in the first sen-  
3 tence of clause (i).

4 “(II) HOLD HARMLESS FOR CERTAIN  
5 HOSPITALS.—If the application of sub-  
6 clause (I) would result in lower payments  
7 to a hospital than would otherwise be  
8 made, then this subparagraph shall be ap-  
9 plied as if this clause had not been en-  
10 acted.”.

11 (b) WAIVING BUDGET NEUTRALITY.—Section  
12 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended  
13 by subsection (a), is amended by adding at the end of  
14 clause (i) the following new sentence: “The Secretary shall  
15 apply the previous sentence for any period as if the  
16 amendments made by section 402(a) of the Prescription  
17 Drug and Medicare Improvement Act of 2003 had not  
18 been enacted.”.

19 **SEC. 403. MEDICARE INPATIENT HOSPITAL PAYMENT AD-**  
20 **JUSTMENT FOR LOW-VOLUME HOSPITALS.**

21 Section 1886(d) (42 U.S.C. 1395ww(d)) is amended  
22 by adding at the end the following new paragraph:

23 “(12) PAYMENT ADJUSTMENT FOR LOW-VOL-  
24 UME HOSPITALS.—

25 “(A) PAYMENT ADJUSTMENT.—

1           “(i) IN GENERAL.—Notwithstanding  
2           any other provision of this section, for each  
3           cost reporting period (beginning with the  
4           cost reporting period that begins in fiscal  
5           year 2004), the Secretary shall provide for  
6           an additional payment amount to each low-  
7           volume hospital (as defined in clause (iii))  
8           for discharges occurring during that cost  
9           reporting period which is equal to the ap-  
10          plicable percentage increase (determined  
11          under clause (ii)) in the amount paid to  
12          such hospital under this section for such  
13          discharges.

14           “(ii) APPLICABLE PERCENTAGE IN-  
15          CREASE.—The Secretary shall determine a  
16          percentage increase applicable under this  
17          paragraph that ensures that—

18                   “(I) no percentage increase in  
19                   payments under this paragraph ex-  
20                   ceeds 25 percent of the amount of  
21                   payment that would (but for this  
22                   paragraph) otherwise be made to a  
23                   low-volume hospital under this section  
24                   for each discharge;

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

7           “(III) the percentage increase in  
8           payments to any low-volume hospital  
9           due to the application of this para-  
10          graph is reduced as the number of  
11          discharges per cost reporting period  
12          increases.

13          “(iii) LOW-VOLUME HOSPITAL DE-  
14          FINED.—For purposes of this paragraph,  
15          the term ‘low-volume hospital’ means, for a  
16          cost reporting period, a subsection (d) hos-  
17          pital (as defined in paragraph (1)(B))  
18          other than a critical access hospital (as de-  
19          fined in section 1861(mm)(1)) that—

20                 “(I) the Secretary determines  
21                 had an average of less than 2,000 dis-  
22                 charges (determined with respect to  
23                 all patients and not just individuals  
24                 receiving benefits under this title)  
25                 during the 3 most recent cost report-

1 ing periods for which data are avail-  
2 able that precede the cost reporting  
3 period to which this paragraph ap-  
4 plies; and

5 “(II) is located at least 15 miles  
6 from a like hospital (or is deemed by  
7 the Secretary to be so located by rea-  
8 son of such factors as the Secretary  
9 determines appropriate, including the  
10 time required for an individual to  
11 travel to the nearest alternative source  
12 of appropriate inpatient care (after  
13 taking into account the location of  
14 such alternative source of inpatient  
15 care and any weather or travel condi-  
16 tions that may affect such travel  
17 time).

18 “(B) PROHIBITING CERTAIN REDUC-  
19 TIONS.—Notwithstanding subsection (e), the  
20 Secretary shall not reduce the payment  
21 amounts under this section to offset the in-  
22 crease in payments resulting from the applica-  
23 tion of subparagraph (A).”.

1 **SEC. 404. FAIRNESS IN THE MEDICARE DISPROPOR-**  
2 **TIONATE SHARE HOSPITAL (DSH) ADJUST-**  
3 **MENT FOR RURAL HOSPITALS.**

4 (a) EQUALIZING DSH PAYMENT AMOUNTS.—

5 (1) IN GENERAL.—Section 1886(d)(5)(F)(vii)  
6 (42 U.S.C. 1395ww(d)(5)(F)(vii)) is amended by in-  
7 sserting “, and, after October 1, 2003, for any other  
8 hospital described in clause (iv),” after “clause  
9 (iv)(I)” in the matter preceding subclause (I).

10 (2) CONFORMING AMENDMENTS.—Section  
11 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is  
12 amended—

13 (A) in clause (iv)—

14 (i) in subclause (II)—

15 (I) by inserting “and before Oc-  
16 tober 1, 2003,” after “April 1,  
17 2001,”; and

18 (II) by inserting “or, for dis-  
19 charges occurring on or after October  
20 1, 2003, is equal to the percent deter-  
21 mined in accordance with the applica-  
22 ble formula described in clause (vii)”  
23 after “clause (xiii)”;

24 (ii) in subclause (III)—

1 (I) by inserting “and before Oc-  
2 tober 1, 2003,” after “April 1,  
3 2001,”; and

4 (II) by inserting “or, for dis-  
5 charges occurring on or after October  
6 1, 2003, is equal to the percent deter-  
7 mined in accordance with the applica-  
8 ble formula described in clause (vii)”  
9 after “clause (xii)”;

10 (iii) in subclause (IV)—

11 (I) by inserting “and before Oc-  
12 tober 1, 2003,” after “April 1,  
13 2001,”; and

14 (II) by inserting “or, for dis-  
15 charges occurring on or after October  
16 1, 2003, is equal to the percent deter-  
17 mined in accordance with the applica-  
18 ble formula described in clause (vii)”  
19 after “clause (x) or (xi)”;

20 (iv) in subclause (V)—

21 (I) by inserting “and before Oc-  
22 tober 1, 2003,” after “April 1,  
23 2001,”; and

24 (II) by inserting “or, for dis-  
25 charges occurring on or after October

1 1, 2003, is equal to the percent deter-  
2 mined in accordance with the applica-  
3 ble formula described in clause (vii)”  
4 after “clause (xi)”;  
5 and  
(v) in subclause (VI)—

6 (I) by inserting “and before Oc-  
7 tober 1, 2003,” after “April 1,  
8 2001,”; and

9 (II) by inserting “or, for dis-  
10 charges occurring on or after October  
11 1, 2003, is equal to the percent deter-  
12 mined in accordance with the applica-  
13 ble formula described in clause (vii)”  
14 after “clause (x)”;

15 (B) in clause (viii), by striking “The for-  
16 mula” and inserting “For discharges occurring  
17 before October 1, 2003, the formula”; and

18 (C) in each of clauses (x), (xi), (xii), and  
19 (xiii), by striking “For purposes” and inserting  
20 “With respect to discharges occurring before  
21 October 1, 2004, for purposes”.

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

1 **SEC. 405. CRITICAL ACCESS HOSPITAL (CAH) IMPROVE-**  
2 **MENTS.**

3 (a) PERMITTING CAHS TO ALLOCATE SWING BEDS  
4 AND ACUTE CARE INPATIENT BEDS SUBJECT TO A  
5 TOTAL LIMIT OF 25 BEDS.—

6 (1) IN GENERAL.—Section 1820(c)(2)(B)(iii)  
7 (42 U.S.C. 1395i–4(c)(2)(B)(iii)) is amended to  
8 read as follows:

9 “(iii) provides not more than a total  
10 of 25 extended care service beds (pursuant  
11 to an agreement under subsection (f)) and  
12 acute care inpatient beds (meeting such  
13 standards as the Secretary may establish)  
14 for providing inpatient care for a period  
15 that does not exceed, as determined on an  
16 annual, average basis, 96 hours per pa-  
17 tient;”.

18 (2) CONFORMING AMENDMENT.—Section  
19 1820(f) (42 U.S.C. 1395i–4(f)) is amended by strik-  
20 ing “and the number of beds used at any time for  
21 acute care inpatient services does not exceed 15  
22 beds”.

23 (3) EFFECTIVE DATE.—The amendments made  
24 by this subsection shall with respect to designations  
25 made on or after October 1, 2003.

1 (b) ELIMINATION OF THE ISOLATION TEST FOR  
2 COST-BASED CAH AMBULANCE SERVICES.—

3 (1) ELIMINATION.—

4 (A) IN GENERAL.—Section 1834(l)(8) (42  
5 U.S.C. 1395m(l)(8)), as added by section  
6 205(a) of BIPA (114 Stat. 2763A–482), is  
7 amended by striking the comma at the end of  
8 subparagraph (B) and all that follows and in-  
9 serting a period.

10 (B) EFFECTIVE DATE.—The amendment  
11 made by subparagraph (A) shall apply to serv-  
12 ices furnished on or after January 1, 2004.

13 (2) TECHNICAL CORRECTION.—Section 1834(l)  
14 (42 U.S.C. 1395m(l)) is amended by redesignating  
15 paragraph (8), as added by section 221(a) of BIPA  
16 (114 Stat. 2763A–486), as paragraph (9).

17 (c) COVERAGE OF COSTS FOR CERTAIN EMERGENCY  
18 ROOM ON-CALL PROVIDERS.—

19 (1) IN GENERAL.—Section 1834(g)(5) (42  
20 U.S.C. 1395m(g)(5)) is amended—

21 (A) in the heading—

22 (i) by inserting “CERTAIN” before  
23 “EMERGENCY”; and

24 (ii) by striking “PHYSICIANS” and in-  
25 serting “PROVIDERS”;

1 (B) by striking “emergency room physi-  
2 cians who are on-call (as defined by the Sec-  
3 retary)” and inserting “physicians, physician  
4 assistants, nurse practitioners, and clinical  
5 nurse specialists who are on-call (as defined by  
6 the Secretary) to provide emergency services”;  
7 and

8 (C) by striking “physicians’ services” and  
9 inserting “services covered under this title”.

10 (2) EFFECTIVE DATE.—The amendments made  
11 by paragraph (1) shall apply to costs incurred for  
12 services provided on or after January 1, 2004.

13 (d) AUTHORIZATION OF PERIODIC INTERIM PAY-  
14 MENT (PIP).—

15 (1) IN GENERAL.—Section 1815(e)(2) (42  
16 U.S.C. 1395g(e)(2)) is amended—

17 (A) in subparagraph (C), by striking  
18 “and” after the semicolon at the end;

19 (B) in subparagraph (D), by adding “and”  
20 after the semicolon at the end; and

21 (C) by inserting after subparagraph (D)  
22 the following new subparagraph:

23 “(E) inpatient critical access hospital services;”.

24 (2) EFFECTIVE DATE.—The amendments made  
25 by paragraph (1) shall apply to payments for inpa-

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

3       (e) EXCLUSION OF NEW CAHS FROM PPS HOS-  
4       PITAL WAGE INDEX CALCULATION.—Section  
5       1886(d)(3)(E)(i) (42 U.S.C. 1395ww(d)(3)(E)(i)), as  
6       amended by section 402, is amended by inserting after the  
7       first sentence the following new sentence: “In calculating  
8       the hospital wage levels under the preceding sentence ap-  
9       plicable with respect to cost reporting periods beginning  
10      on or after January 1, 2003, the Secretary shall exclude  
11      the wage levels of any facility that became a critical access  
12      hospital prior to the cost reporting period for which such  
13      hospital wage levels are calculated.”.

14      (f) PROVISIONS RELATED TO CERTAIN RURAL  
15      GRANTS.—

16           (1) SMALL RURAL HOSPITAL IMPROVEMENT  
17      PROGRAM.—Section 1820(g) (42 U.S.C. 1395i–4(g))  
18      is amended—

19           (A) by redesignating paragraph (3)(F) as  
20           paragraph (5) and redesignating and indenting  
21           appropriately; and

22           (B) by inserting after paragraph (3) the  
23           following new paragraph:

24           “(4) SMALL RURAL HOSPITAL IMPROVEMENT  
25      PROGRAM.—

1           “(A) GRANTS TO HOSPITALS.—The Sec-  
2           retary may award grants to hospitals that have  
3           submitted applications in accordance with sub-  
4           paragraph (B) to assist eligible small rural hos-  
5           pitals (as defined in paragraph (3)(B)) in meet-  
6           ing the costs of reducing medical errors, in-  
7           creasing patient safety, protecting patient pri-  
8           vacy, and improving hospital quality and per-  
9           formance.

10           “(B) APPLICATION.—A hospital seeking a  
11           grant under this paragraph shall submit an ap-  
12           plication to the Secretary on or before such  
13           date and in such form and manner as the Sec-  
14           retary specifies.

15           “(C) AMOUNT OF GRANT.—A grant to a  
16           hospital under this paragraph may not exceed  
17           \$50,000.

18           “(D) USE OF FUNDS.—A hospital receiv-  
19           ing a grant under this paragraph may use the  
20           funds for the purchase of computer software  
21           and hardware, the education and training of  
22           hospital staff, and obtaining technical assist-  
23           ance.”.

1           (2) AUTHORIZATION FOR APPROPRIATIONS.—  
2           Section 1820(j) (42 U.S.C. 1395i–4(j)) is amended  
3           to read as follows:

4           “(j) AUTHORIZATION OF APPROPRIATIONS.—

5           “(1) HI TRUST FUND.—There are authorized to  
6           be appropriated from the Federal Hospital Insur-  
7           ance Trust Fund for making grants to all States  
8           under—

9           “(A) subsection (g), \$25,000,000 in each  
10           of the fiscal years 1998 through 2002; and

11           “(B) paragraphs (1) and (2) of subsection  
12           (g), \$40,000,000 in each of the fiscal years  
13           2004 through 2008.

14           “(2) GENERAL REVENUES.—There are author-  
15           ized to be appropriated from amounts in the Treas-  
16           ury not otherwise appropriated for making grants to  
17           all States under subsection (g)(4), \$25,000,000 in  
18           each of the fiscal years 2004 through 2008.”.

19           (3) REQUIREMENT THAT STATES AWARDED  
20           GRANTS CONSULT WITH THE STATE HOSPITAL ASSO-  
21           CIATION AND RURAL HOSPITALS ON THE MOST AP-  
22           PROPRIATE WAYS TO USE SUCH GRANTS.—

23           (A) IN GENERAL.—Section 1820(g) (42  
24           U.S.C. 1395i–4(g)), as amended by paragraph

1 (1), is amended by adding at the end the fol-  
2 lowing new paragraph:

3 “(6) REQUIRED CONSULTATION FOR STATES  
4 AWARDED GRANTS.—A State awarded a grant under  
5 paragraph (1) or (2) shall consult with the hospital  
6 association of such State and rural hospitals located  
7 in such State on the most appropriate ways to use  
8 the funds under such grant.”.

9 (B) EFFECTIVE DATE AND APPLICA-  
10 TION.—The amendment made by subparagraph  
11 (A) shall take effect on the date of enactment  
12 of this Act and shall apply to grants awarded  
13 on or after such date and to grants awarded  
14 prior to such date to the extent that funds  
15 under such grants have not been obligated as of  
16 such date.

17 **SEC. 406. AUTHORIZING USE OF ARRANGEMENTS TO PRO-**  
18 **VIDE CORE HOSPICE SERVICES IN CERTAIN**  
19 **CIRCUMSTANCES.**

20 (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.  
21 1395x(dd)(5)) is amended by adding at the end the fol-  
22 lowing:

23 “(D) In extraordinary, exigent, or other non-routine  
24 circumstances, such as unanticipated periods of high pa-  
25 tient loads, staffing shortages due to illness or other

1 events, or temporary travel of a patient outside a hospice  
2 program's service area, a hospice program may enter into  
3 arrangements with another hospice program for the provi-  
4 sion by that other program of services described in para-  
5 graph (2)(A)(ii)(I). The provisions of paragraph  
6 (2)(A)(ii)(II) shall apply with respect to the services pro-  
7 vided under such arrangements.

8 “(E) A hospice program may provide services de-  
9 scribed in paragraph (1)(A) other than directly by the pro-  
10 gram if the services are highly specialized services of a  
11 registered professional nurse and are provided non-rou-  
12 tinely and so infrequently so that the provision of such  
13 services directly would be impracticable and prohibitively  
14 expensive.”.

15 (b) CONFORMING PAYMENT PROVISION.—Section  
16 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the  
17 end the following new paragraph:

18 “(4) In the case of hospice care provided by a hospice  
19 program under arrangements under section  
20 1861(dd)(5)(D) made by another hospice program, the  
21 hospice program that made the arrangements shall bill  
22 and be paid for the hospice care.”.

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

1 **SEC. 407. SERVICES PROVIDED TO HOSPICE PATIENTS BY**  
2 **NURSE PRACTITIONERS, CLINICAL NURSE**  
3 **SPECIALISTS, AND PHYSICIAN ASSISTANTS.**

4 (a) IN GENERAL.—Section 1812(d)(2)(A) (42 U.S.C.  
5 1395d(d)(2)(A) in the matter following clause (i)(II), is  
6 amended—

7 (1) by inserting “or services described in sec-  
8 tion 1861(s)(2)(K)” after “except that clause (i)  
9 shall not apply to physicians’ services”; and

10 (2) by inserting “, or by a physician assistant,  
11 nurse practitioner, or clinical nurse specialist who is  
12 not an employee of the hospice program, and who  
13 the individual identifies as the health care provider  
14 having the most significant role in the determination  
15 and delivery of medical care to the individual at the  
16 time the individual makes an election to receive hos-  
17 pice care,” after the “(if not an employee of the hos-  
18 pice program)”.

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

22 **SEC. 408. AUTHORITY TO INCLUDE COSTS OF TRAINING OF**  
23 **PSYCHOLOGISTS IN PAYMENTS TO HOS-**  
24 **PITALS UNDER MEDICARE.**

25 Effective for cost reporting periods beginning on or  
26 after October 1, 2004, for purposes of payments to hos-

1 pitals under the medicare program under title XVIII of  
2 the Social Security Act for costs of approved educational  
3 activities (as defined in section 413.85 of title 42 of the  
4 Code of Federal Regulations), such approved educational  
5 activities shall include professional educational training  
6 programs, recognized by the Secretary, for psychologists.

7 **SEC. 409. REVISION OF FEDERAL RATE FOR HOSPITALS IN**  
8 **PUERTO RICO.**

9 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is  
10 amended—

11 (1) in subparagraph (A)—

12 (A) in clause (i), by striking “for dis-  
13 charges beginning on or after October 1, 1997,  
14 50 percent (and for discharges between October  
15 1, 1987, and September 30, 1997, 75 percent)”  
16 and inserting “the applicable Puerto Rico per-  
17 centage (specified in subparagraph (E))”; and

18 (B) in clause (ii), by striking “for dis-  
19 charges beginning in a fiscal year beginning on  
20 or after October 1, 1997, 50 percent (and for  
21 discharges between October 1, 1987, and Sep-  
22 tember 30, 1997, 25 percent)” and inserting  
23 “the applicable Federal percentage (specified in  
24 subparagraph (E))”; and

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

3           “(E) For purposes of subparagraph (A), for dis-  
4 charges occurring—

5           “(i) between October 1, 1987, and September  
6 30, 1997, the applicable Puerto Rico percentage is  
7 75 percent and the applicable Federal percentage is  
8 25 percent;

9           “(ii) on or after October 1, 1997, and before  
10 October 1, 2004, the applicable Puerto Rico percent-  
11 age is 50 percent and the applicable Federal per-  
12 centage is 50 percent;

13           “(iii) on or after October 1, 2004, and before  
14 October 1, 2009, the applicable Puerto Rico percent-  
15 age is 0 percent and the applicable Federal percent-  
16 age is 100 percent; and

17           “(iv) on or after October 1, 2009, the applica-  
18 ble Puerto Rico percentage is 50 percent and the ap-  
19 plicable Federal percentage is 50 percent.”.

20 **SEC. 410. AUTHORITY REGARDING GERIATRIC FELLOW-**  
21 **SHIPS.**

22           The Secretary shall have the authority to clarify that  
23 geriatric training programs are eligible for 2 years of fel-  
24 lowship support for purposes of making payments for di-  
25 rect graduate medical education under subsection (h) of

1 section 1886 of the Social Security Act (42 U.S.C.  
2 1395ww) and indirect medical education under subsection  
3 (d)(5)(B) of such section on or after October 1, 2003.

4 **SEC. 411. CLARIFICATION OF CONGRESSIONAL INTENT RE-**  
5 **GARDING THE COUNTING OF RESIDENTS IN A**  
6 **NONPROVIDER SETTING AND A TECHNICAL**  
7 **AMENDMENT REGARDING THE 3-YEAR ROLL-**  
8 **ING AVERAGE AND THE IME RATIO.**

9 (a) CLARIFICATION OF REQUIREMENTS FOR COUNT-  
10 ING RESIDENTS TRAINING IN NONPROVIDER SETTING.—

11 (1) D-GME.—Section 1886(h)(4)(E) (42  
12 U.S.C. 1395ww(h)(4)(E)) is amended by adding at  
13 the end the following new sentence: For purposes of  
14 the preceding sentence time shall only be counted  
15 from the effective date of a written agreement be-  
16 tween the hospital and the entity owning or oper-  
17 ating a nonprovider setting. The effective date of  
18 such written agreement shall be determined in ac-  
19 cordance with generally accepted accounting prin-  
20 ciples. All, or substantially all, of the costs for the  
21 training program in that setting shall be defined as  
22 the residents' stipends and benefits and other costs,  
23 if any, as determined by the parties.”.

24 (2) IME.—Section 1886(d)(5)(B)(iv) (42  
25 U.S.C. 1395ww(d)(5)(B)(iv)) is amended by adding

1 at the end the following new sentence: For purposes  
2 of the preceding sentence time shall only be counted  
3 from the effective date of a written agreement be-  
4 tween the hospital and the entity owning or oper-  
5 ating a nonprovider setting. The effective date of  
6 such written agreement shall be determined in ac-  
7 cordance with generally accepted accounting prin-  
8 ciples. All, or substantially all, of the costs for the  
9 training program in that setting shall be defined as  
10 the residents' stipends and benefits and other costs,  
11 if any, as determined by the parties.”.

12 (b) LIMITING ONE-YEAR LAG IN THE INDIRECT  
13 MEDICAL EDUCATION (IME) RATIO AND THREE-YEAR  
14 ROLLING AVERAGE IN RESIDENT COUNT FOR IME AND  
15 FOR DIRECT GRADUATE MEDICAL EDUCATION (D-GME)  
16 TO MEDICAL RESIDENCY PROGRAMS.—

17 (1) IME RATIO AND IME ROLLING AVERAGE.—  
18 Section 1886(d)(5)(B)(vi) of the Social Security Act  
19 (42 U.S.C. 1395ww(d)(5)(B)(vi)) is amended by  
20 adding at the end the following new sentence: “For  
21 cost reporting periods beginning during fiscal years  
22 beginning on or after October 1, 2003, subclauses  
23 (I) and (II) shall be applied only with respect to a  
24 hospital's approved medical residency training pro-

1 grams in the fields of allopathic and osteopathic  
2 medicine.”.

3 (2) D-GME ROLLING AVERAGE.—Section  
4 1886(h)(4)(G) of the Social Security Act (42 U.S.C.  
5 1395ww(h)(4)(G)) is amended by adding at the end  
6 the following new clause:

7 “(iv) APPLICATION FOR FISCAL YEAR  
8 2004 AND SUBSEQUENT YEARS.—For cost  
9 reporting periods beginning during fiscal  
10 years beginning on or after October 1,  
11 2003, clauses (i) through (iii) shall be ap-  
12 plied only with respect to a hospital’s ap-  
13 proved medical residency training program  
14 in the fields of allopathic and osteopathic  
15 medicine.”.

16 **SEC. 412. LIMITATION ON CHARGES FOR INPATIENT HOS-**  
17 **PITAL CONTRACT HEALTH SERVICES PRO-**  
18 **VIDED TO INDIANS BY MEDICARE PARTICI-**  
19 **PATING HOSPITALS.**

20 (a) IN GENERAL.—Section 1866(a)(1) (42 U.S.C.  
21 1395cc(a)(1)) is amended—

22 (1) in subparagraph (R), by striking “and” at  
23 the end;

24 (2) in subparagraph (S), by striking the period  
25 and inserting “, and”; and

1           (3) by adding at the end the following new sub-  
2 paragraph:

3           “(T) in the case of hospitals which furnish  
4 inpatient hospital services for which payment  
5 may be made under this title, to be a partici-  
6 pating provider of medical care—

7           “(i) under the contract health services  
8 program funded by the Indian Health  
9 Service and operated by the Indian Health  
10 Service, an Indian tribe, or tribal organiza-  
11 tion (as those terms are defined in section  
12 4 of the Indian Health Care Improvement  
13 Act), with respect to items and services  
14 that are covered under such program and  
15 furnished to an individual eligible for such  
16 items and services under such program;  
17 and

18           “(ii) under a program funded by the  
19 Indian Health Service and operated by an  
20 urban Indian organization with respect to  
21 the purchase of items and services for an  
22 eligible urban Indian (as those terms are  
23 defined in such section 4),

24           in accordance with regulations promulgated by  
25 the Secretary regarding admission practices,

1 payment methodology, and rates of payment  
2 (including the acceptance of no more than such  
3 payment rate as payment in full for such items  
4 and services).”.

5 (b) **EFFECTIVE DATE.**—The amendments made by  
6 this section shall apply as of a date specified by the Sec-  
7 retary of Health and Human Services (but in no case later  
8 than 6 months after the date of enactment of this Act)  
9 to medicare participation agreements in effect (or entered  
10 into) on or after such date.

11 **SEC. 413. GAO STUDY AND REPORT ON APPROPRIATENESS**  
12 **OF PAYMENTS UNDER THE PROSPECTIVE**  
13 **PAYMENT SYSTEM FOR INPATIENT HOSPITAL**  
14 **SERVICES.**

15 (a) **STUDY.**—The Comptroller General of the United  
16 States, using the most current data available, shall con-  
17 duct a study to determine—

18 (1) the appropriate level and distribution of  
19 payments in relation to costs under the prospective  
20 payment system under section 1886 of the Social  
21 Security Act (42 U.S.C. 1395ww) for inpatient hos-  
22 pital services furnished by subsection (d) hospitals  
23 (as defined in subsection (d)(1)(B) of such section);  
24 and



1           “(i) IN GENERAL.—For purposes of  
2           payment for services furnished on or after  
3           January 1, 2004, and before January 1,  
4           2008, after calculating the work geo-  
5           graphic indices in subparagraph (A)(iii),  
6           the Secretary shall increase the work geo-  
7           graphic index to the work floor index for  
8           any locality for which such geographic  
9           index is less than the work floor index.

10           “(ii) WORK FLOOR INDEX.—For pur-  
11           poses of clause (i), the term ‘applicable  
12           floor index’ means—

13                   “(I) 0.980 with respect to serv-  
14                   ices furnished during 2004; and

15                   “(II) 1.000 for services furnished  
16                   during 2005, 2006, and 2007.

17           “(F) FLOOR FOR PRACTICE EXPENSE AND  
18           MALPRACTICE GEOGRAPHIC INDICES.—For pur-  
19           poses of payment for services furnished on or  
20           after January 1, 2005, and before January 1,  
21           2008, after calculating the practice expense and  
22           malpractice indices in clauses (i) and (ii) of  
23           subparagraph (A) and in subparagraph (B), the  
24           Secretary shall increase any such index to 1.00

1           for any locality for which such index is less  
2           than 1.00.”.

3 **SEC. 422. MEDICARE INCENTIVE PAYMENT PROGRAM IM-**  
4 **PROVEMENTS.**

5           (a) PROCEDURES FOR SECRETARY, AND NOT PHYSI-  
6 CIANS, TO DETERMINE WHEN BONUS PAYMENTS UNDER  
7 MEDICARE INCENTIVE PAYMENT PROGRAM SHOULD BE  
8 MADE.—Section 1833(m) (42 U.S.C. 1395l(m)) is amend-  
9 ed—

10           (1) by inserting “(1)” after “(m)”; and

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

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

17           (b) EDUCATIONAL PROGRAM REGARDING THE MEDI-  
18 CARE INCENTIVE PAYMENT PROGRAM.—The Secretary  
19 shall establish and implement an ongoing educational pro-  
20 gram to provide education to physicians under the medi-  
21 care program on the medicare incentive payment program  
22 under section 1833(m) of the Social Security Act (42  
23 U.S.C. 1395l(m)).

24           (c) ONGOING GAO STUDY AND ANNUAL REPORT ON  
25 THE MEDICARE INCENTIVE PAYMENT PROGRAM.—

1           (1) ONGOING STUDY.—The Comptroller Gen-  
2           eral of the United States shall conduct an ongoing  
3           study on the medicare incentive payment program  
4           under section 1833(m) of the Social Security Act  
5           (42 U.S.C. 1395l(m)). Such study shall focus on  
6           whether such program increases the access of medi-  
7           care beneficiaries who reside in an area that is des-  
8           ignated (under section 332(a)(1)(A) of the Public  
9           Health Service Act (42 U.S.C. 254e(a)(1)(A))) as a  
10          health professional shortage area to physicians' serv-  
11          ices under the medicare program.

12          (2) ANNUAL REPORTS.—Not later than 1 year  
13          after the date of enactment of this Act, and annually  
14          thereafter, the Comptroller General of the United  
15          States shall submit to Congress a report on the  
16          study conducted under paragraph (1), together with  
17          recommendations as the Comptroller General con-  
18          siders appropriate.

19 **SEC. 423. INCREASE IN RENAL DIALYSIS COMPOSITE RATE.**

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

1 such Act (42 U.S.C. 1395rr(b)(7)), as added by section  
2 433(b)(5).

3 **SEC. 424. EXTENSION OF HOLD HARMLESS PROVISIONS**  
4 **FOR SMALL RURAL HOSPITALS AND TREAT-**  
5 **MENT OF CERTAIN SOLE COMMUNITY HOS-**  
6 **PITALS TO LIMIT DECLINE IN PAYMENT**  
7 **UNDER THE OPD PPS.**

8 (a) SMALL RURAL HOSPITALS.—Section  
9 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amend-  
10 ed by striking “2004” and inserting “2006”.

11 (b) SOLE COMMUNITY HOSPITALS.—Section  
12 1833(t)(7)(D) (42 U.S.C. 1395l(t)(7)(D)) is amended by  
13 adding at the end the following:

14 “(iii) TEMPORARY TREATMENT FOR  
15 SOLE COMMUNITY HOSPITALS.—In the  
16 case of a sole community hospital (as de-  
17 fined in section 1886(d)(5)(D)(iii)) located  
18 in a rural area, for covered OPD services  
19 furnished in 2004, 2005, or 2006, for  
20 which the PPS amount is less than the  
21 pre-BBA amount, the amount of payment  
22 under this subsection shall be increased by  
23 the amount of such difference.”.

1 **SEC. 425. INCREASE IN PAYMENTS FOR CERTAIN SERVICES**  
2 **FURNISHED BY SMALL RURAL AND SOLE**  
3 **COMMUNITY HOSPITALS UNDER MEDICARE**  
4 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**  
5 **PITAL OUTPATIENT DEPARTMENT SERVICES.**

6 (a) INCREASE.—

7 (1) IN GENERAL.—In the case of an applicable  
8 covered OPD service (as defined in paragraph (2))  
9 that is furnished by a hospital described in clause (i)  
10 or (iii) of paragraph (7)(D) of section 1833(t) of the  
11 Social Security Act (42 U.S.C. 1395l(t)), as amend-  
12 ed by section 424, on or after January 1, 2004, and  
13 before January 1, 2008, the Secretary shall increase  
14 the medicare OPD fee schedule amount (as deter-  
15 mined under paragraph (4)(A) of such section) that  
16 is applicable for such service in that year (deter-  
17 mined without regard to any increase under this sec-  
18 tion in a previous year) by 5 percent.

19 (2) APPLICABLE COVERED OPD SERVICES DE-  
20 FINED.—For purposes of this section, the term “ap-  
21 plicable covered OPD service” means a covered clinic  
22 or emergency room visit that is classified within the  
23 groups of covered OPD services (as defined in para-  
24 graph (1)(B) of section 1833(t) of the Social Secu-  
25 rity Act (42 U.S.C. 1395l(t))) established under  
26 paragraph (2)(B) of such section.

1 (b) NO EFFECT ON COPAYMENT AMOUNT.—The Sec-  
2 retary shall compute the copayment amount for applicable  
3 covered OPD services under section 1833(t)(8)(A) of the  
4 Social Security Act (42 U.S.C. 1395l(t)(8)(A)) as if this  
5 section had not been enacted.

6 (c) NO EFFECT ON INCREASE UNDER HOLD HARM-  
7 LESS OR OUTLIER PROVISIONS.—The Secretary shall  
8 apply the temporary hold harmless provision under clause  
9 (i) and (iii) of paragraph (7)(D) of section 1833(t) of the  
10 Social Security Act (42 U.S.C. 1395l(t)) and the outlier  
11 provision under paragraph (5) of such section as if this  
12 section had not been enacted.

13 (d) WAIVING BUDGET NEUTRALITY AND NO REVI-  
14 SION OR ADJUSTMENTS.—The Secretary shall not make  
15 any revision or adjustment under subparagraph (A), (B),  
16 or (C) of section 1833(t)(9) of the Social Security Act (42  
17 U.S.C. 1395l(t)(9)) because of the application of sub-  
18 section (a)(1).

19 (e) NO EFFECT ON PAYMENTS AFTER INCREASE PE-  
20 RIOD ENDS.—The Secretary shall not take into account  
21 any payment increase provided under subsection (a)(1) in  
22 determining payments for covered OPD services (as de-  
23 fined in paragraph (1)(B) of section 1833(t) of the Social  
24 Security Act (42 U.S.C. 1395l(t))) under such section that  
25 are furnished after January 1, 2008.

1           (f)           TECHNICAL           AMENDMENT.—Section  
2 1833(t)(2)(B) (42 U.S.C. 1395l(t)(2)(B)) is amended by  
3 inserting “(and periodically revise such groups pursuant  
4 to paragraph (9)(A))” after “establish groups”.

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

7           Section 1834(l) (42 U.S.C. 1395m(l)), as amended  
8 by section 405(b)(2), is amended by adding at the end  
9 the following new paragraph:

10                   “(10) TEMPORARY INCREASE FOR GROUND AM-  
11           BULANCE SERVICES FURNISHED IN A RURAL  
12           AREA.—

13                   “(A) IN GENERAL.—Notwithstanding any  
14           other provision of this subsection, in the case of  
15           ground ambulance services furnished on or  
16           after January 1, 2004, and before January 1,  
17           2008, for which the transportation originates in  
18           a rural area described in paragraph (9) or in a  
19           rural census tract described in such paragraph,  
20           the fee schedule established under this section,  
21           with respect to both the payment rate for serv-  
22           ice and the payment rate for mileage, shall pro-  
23           vide that such rates otherwise established, after  
24           application of any increase under such para-  
25           graph, shall be increased by 5 percent.

1           “(B) APPLICATION OF INCREASED PAY-  
2           MENTS AFTER 2007.—The increased payments  
3           under subparagraph (A) shall not be taken into  
4           account in calculating payments for services  
5           furnished on or after the period specified in  
6           such subparagraph.”.

7   **SEC. 427. ENSURING APPROPRIATE COVERAGE OF AIR AM-**  
8                   **BULANCE SERVICES UNDER AMBULANCE FEE**  
9                   **SCHEDULE.**

10       (a) COVERAGE.—Section 1834(l) (42 U.S.C.  
11 1395m(l)), as amended by section 426, is amended by  
12 adding at the end the following new paragraph:

13           “(11) ENSURING APPROPRIATE COVERAGE OF  
14           AIR AMBULANCE SERVICES.—

15           “(A) IN GENERAL.—The regulations de-  
16           scribed in section 1861(s)(7) shall ensure that  
17           air ambulance services (as defined in subpara-  
18           graph (C)) are reimbursed under this sub-  
19           section at the air ambulance rate if the air am-  
20           bulance service—

21                   “(i) is medically necessary based on  
22                   the health condition of the individual being  
23                   transported at or immediately prior to the  
24                   time of the transport; and

1           “(ii) complies with equipment and  
2           crew requirements established by the Sec-  
3           retary.

4           “(B) MEDICALLY NECESSARY.—An air  
5           ambulance service shall be considered to be  
6           medically necessary for purposes of subpara-  
7           graph (A)(i) if such service is requested—

8                   “(i) by a physician or a hospital in ac-  
9                   cordance with the physician’s or hospital’s  
10                  responsibilities under section 1867 (com-  
11                  monly known as the Emergency Medical  
12                  Treatment and Active Labor Act);

13                   “(ii) as a result of a protocol estab-  
14                  lished by a State or regional emergency  
15                  medical service (EMS) agency;

16                   “(iii) by a physician, nurse practi-  
17                  tioner, physician assistant, registered  
18                  nurse, or emergency medical responder  
19                  who reasonably determines or certifies that  
20                  the patient’s condition is such that the  
21                  time needed to transport the individual by  
22                  land or the lack of an appropriate ground  
23                  ambulance, significantly increases the med-  
24                  ical risks for the individual; or



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

3 (1) PAYMENT BASED ON REASONABLE COSTS.—

4 The amount of payment for such test shall be 100  
5 percent of the reasonable costs of the hospital in fur-  
6 nishing such test.

7 (2) NO BENEFICIARY COST-SHARING.—Notwith-

8 standing section 432, no coinsurance, deductible, co-  
9 payment, or other cost-sharing otherwise applicable  
10 under such part B shall apply with respect to such  
11 test.

12 **SEC. 429. IMPROVEMENT IN RURAL HEALTH CLINIC REIM-**  
13 **BURSEMENT.**

14 Section 1833(f) (42 U.S.C. 1395l(f)) is amended—

15 (1) in paragraph (1), by striking “, and” at the  
16 end and inserting a semicolon;

17 (2) in paragraph (2)—

18 (A) by striking “in a subsequent year” and  
19 inserting “in 1989 through 2003”; and

20 (B) by striking the period at the end and  
21 inserting a semicolon; and

22 (3) by adding at the end the following new  
23 paragraphs:

24 “(3) in 2004, at \$80 per visit; and

1           “(4) in a subsequent year, at the limit estab-  
 2           lished under this subsection for the previous year in-  
 3           creased by the percentage increase in the MEI (as  
 4           so defined) applicable to primary care services (as so  
 5           defined) furnished as of the first day of that year.”.

6 **SEC. 430. ELIMINATION OF CONSOLIDATED BILLING FOR**  
 7                           **CERTAIN SERVICES UNDER THE MEDICARE**  
 8                           **PPS FOR SKILLED NURSING FACILITY SERV-**  
 9                           **ICES.**

10           (a) CERTAIN RURAL HEALTH CLINIC AND FEDER-  
 11           ALLY QUALIFIED HEALTH CENTER SERVICES.—Section  
 12           1888(e) (42 U.S.C. 1395yy(e)) is amended—

13                   (1) in paragraph (2)(A)(i)(II), by striking  
 14                   “clauses (ii) and (iii)” and inserting “clauses (ii),  
 15                   (iii), and (iv)”; and

16                   (2) by adding at the end of paragraph (2)(A)  
 17                   the following new clause:

18                           “(iv) EXCLUSION OF CERTAIN RURAL  
 19                           HEALTH CLINIC AND FEDERALLY QUALI-  
 20                           FIED HEALTH CENTER SERVICES.—Serv-  
 21                           ices described in this clause are—

22                                   “(I) rural health clinic services  
 23                                   (as defined in paragraph (1) of sec-  
 24                                   tion 1861(aa)); and

1                   “(II) Federally qualified health  
2                   center services (as defined in para-  
3                   graph (3) of such section);  
4                   that would be described in clause (ii) if such  
5                   services were furnished by a physician or practi-  
6                   tioner not affiliated with a rural health clinic or  
7                   a Federally qualified health center.”.

8           (b) CERTAIN SERVICES FURNISHED BY AN ENTITY  
9 JOINTLY OWNED BY HOSPITALS AND CRITICAL ACCESS  
10 HOSPITALS.—For purposes of applying section  
11 411.15(p)–(3)(iii) of title 42 of the Code of Federal Regu-  
12 lations, the Secretary shall treat an entity that is 100 per-  
13 cent owned as a joint venture by 2 Medicare-participating  
14 hospitals or critical access hospitals as a Medicare-partici-  
15 pating hospital or a critical access hospital.

16           (c) TECHNICAL AMENDMENTS.—Sections  
17 1842(b)(6)(E) and 1866(a)(1)(H)(ii) (42 U.S.C.  
18 1395u(b)(6)(E); 1395cc(a)(1)(H)(ii)) are each amended  
19 by striking “section 1888(e)(2)(A)(ii)” and inserting  
20 “clauses (ii), (iii), and (iv) of section 1888(e)(2)(A)”.

21           (d) EFFECTIVE DATE.—The amendments made by  
22 this section and the provision of subsection (b) shall apply  
23 to services furnished on or after January 1, 2004.

1 **SEC. 431. FREEZE IN PAYMENTS FOR CERTAIN ITEMS OF**  
2 **DURABLE MEDICAL EQUIPMENT AND CER-**  
3 **TAIN ORTHOTICS; ESTABLISHMENT OF QUAL-**  
4 **ITY STANDARDS AND ACCREDITATION RE-**  
5 **QUIREMENTS FOR DME PROVIDERS.**

6 (a) FREEZE FOR DME.—Section 1834(a)(14) (42  
7 U.S.C. 1395m(a)(14)) is amended—

8 (1) in subparagraph (E), by striking “and” at  
9 the end;

10 (2) in subparagraph (F)—

11 (A) by striking “a subsequent year” and  
12 inserting “2003”; and

13 (B) by striking “the previous year.” and  
14 inserting “2002;”; and

15 (3) by adding at the end the following new sub-  
16 paragraphs:

17 “(G) for each of the years 2004 through  
18 2010—

19 “(i) in the case of class III medical  
20 devices described in section 513(a)(1)(C)  
21 of the Federal Food, Drug, and Cosmetic  
22 Act (21 U.S.C. 360(c)(1)(C)), the percent-  
23 age increase described in subparagraph  
24 (B) for the year involved; and

1                   “(ii) in the case of covered items not  
2                   described in clause (i), 0 percentage points;  
3                   and

4                   “(H) for a subsequent year, the percentage  
5                   increase described in subparagraph (B) for the  
6                   year involved.”.

7           (b) FREEZE FOR OFF-THE-SHELF ORTHOTICS.—  
8           Section 1834(h)(4)(A) of the Social Security Act (42  
9           U.S.C. 1395m(h)(4)(A)) is amended—

10           (1) in clause (vii), by striking “and” at the end;

11           (2) in clause (viii), by striking “a subsequent  
12           year” and inserting “2003”; and

13           (3) by adding at the end the following new  
14           clauses:

15                   “(ix) for each of the years 2004  
16                   through 2010—

17                           “(I) in the case of orthotics that  
18                           have not been custom-fabricated, 0  
19                           percent; and

20                           “(II) in the case of prosthetics,  
21                           prosthetic devices, and custom-fab-  
22                           ricated orthotics, the percentage in-  
23                           crease described in clause (viii) for the  
24                           year involved; and

1                   “(x) for 2011 and each subsequent  
2                   year, the percentage increase described in  
3                   clause (viii) for the year involved;”.

4           (c) ESTABLISHMENT OF QUALITY STANDARDS AND  
5 ACCREDITATION REQUIREMENTS FOR DURABLE MED-  
6 ICAL EQUIPMENT PROVIDERS.—Section 1834(a) (42  
7 U.S.C. 1395m(a)) is amended—

8                   (1) by redesignating paragraph (17), as added  
9                   by section 4551(c)(1) of the Balanced Budget Act of  
10                   1997 (111 Stat. 458), as paragraph (19); and

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

13                   “(20) IDENTIFICATION OF QUALITY STAND-  
14                   ARDS.—

15                   “(A) IN GENERAL.—Subject to subpara-  
16                   graph (C), the Secretary shall establish and im-  
17                   plement quality standards for providers of dura-  
18                   ble medical equipment throughout the United  
19                   States that are developed by recognized inde-  
20                   pendent accreditation organizations (as des-  
21                   ignated under subparagraph (B)(i)) and with  
22                   which such providers shall be required to com-  
23                   ply in order to—

24                   “(i) participate in the program under  
25                   this title;

1           “(ii) furnish any item or service de-  
2           scribed in subparagraph (D) for which  
3           payment is made under this part; and

4           “(iii) receive or retain a provider or  
5           supplier number used to submit claims for  
6           reimbursement for any item or service de-  
7           scribed in subparagraph (D) for which  
8           payment may be made under this title.

9           “(B) DESIGNATION OF INDEPENDENT AC-  
10          CREDITATION ORGANIZATIONS.—

11           “(i) IN GENERAL.—Not later than the  
12           date that is 6 months after the date of en-  
13           actment of the Prescription Drug and  
14           Medicare Improvement Act of 2003, the  
15           Secretary shall designate independent ac-  
16           creditation organizations for purposes of  
17           subparagraph (A).

18           “(ii) CONSULTATION.—In determining  
19           which independent accreditation organiza-  
20           tions to designate under clause (i), the  
21           Secretary shall consult with an expert out-  
22           side advisory panel composed of an appro-  
23           priate selection of representatives of physi-  
24           cians, practitioners, suppliers, and manu-  
25           facturers to review (and advise the Sec-

1           retary concerning) selection of accrediting  
2           organizations and the quality standards of  
3           such organizations.

4           “(C) QUALITY STANDARDS.—The quality  
5           standards described in subparagraph (A) may  
6           not be less stringent than the quality standards  
7           that would otherwise apply if this paragraph  
8           did not apply and shall include consumer serv-  
9           ices standards.

10          “(D) ITEMS AND SERVICES DESCRIBED.—  
11          The items and services described in this sub-  
12          paragraph are covered items (as defined in  
13          paragraph (13)) for which payment may other-  
14          wise be made under this subsection, other than  
15          items used in infusion, and inhalation drugs  
16          used in conjunction with durable medical equip-  
17          ment.

18          “(E) PHASED-IN IMPLEMENTATION.—The  
19          application of the quality standards described in  
20          subparagraph (A) shall be phased-in over a pe-  
21          riod that does not exceed 3 years.”.

22 **SEC. 432. APPLICATION OF COINSURANCE AND DEDUCT-**  
23 **IBLE FOR CLINICAL DIAGNOSTIC LABORA-**  
24 **TORY TESTS.**

25          (a) COINSURANCE.—

1           (1) IN GENERAL.—Section 1833(a) (42 U.S.C.  
2 1395l(a)) is amended—

3           (A) in paragraph (1)(D)(i), by striking  
4 “(or 100 percent, in the case of such tests for  
5 which payment is made on an assignment-re-  
6 lated basis)”; and

7           (B) in paragraph (2)(D)(i), by striking  
8 “(or 100 percent, in the case of such tests for  
9 which payment is made on an assignment-re-  
10 lated basis or to a provider having an agree-  
11 ment under section 1866)”.

12           (2) CONFORMING AMENDMENT.—The third sen-  
13 tence of section 1866(a)(2)(A) of the Social Security  
14 Act (42 U.S.C. 1395cc(a)(2)(A)) is amended by  
15 striking “and with respect to clinical diagnostic lab-  
16 oratory tests for which payment is made under part  
17 B”.

18           (b) DEDUCTIBLE.—Section 1833(b) of the Social Se-  
19 curity Act (42 U.S.C. 1395l(b)) is amended—

20           (1) by striking paragraph (3); and

21           (2) by redesignating paragraphs (4), (5), and  
22 (6) as paragraphs (3), (4), and (5), respectively.

23           (c) EFFECTIVE DATE.—The amendments made by  
24 this section shall apply to tests furnished on or after Janu-  
25 ary 1, 2004.

1 **SEC. 433. BASING MEDICARE PAYMENTS FOR COVERED**  
2 **OUTPATIENT DRUGS ON MARKET PRICES.**

3 (a) MEDICARE MARKET BASED PAYMENT  
4 AMOUNT.—Section 1842(o) (42 U.S.C. 1395u(o)) is  
5 amended—

6 (1) in paragraph (1), by striking “equal to 95  
7 percent of the average wholesale price.” and insert-  
8 ing “equal to—

9 “(A) in the case of a drug or biological fur-  
10 nished prior to January 1, 2004, 95 percent of the  
11 average wholesale price; and

12 “(B) in the case of a drug or biological fur-  
13 nished on or after January 1, 2004, the payment  
14 amount specified in—

15 “(i) in the case of such a drug or biological  
16 that is first available for payment under this  
17 part on or before April 1, 2003, paragraph (4);  
18 and

19 “(ii) in the case of such a drug or biologi-  
20 cal that is first available for payment under this  
21 part after such date, paragraph (5).”; and

22 (2) by adding at the end the following new  
23 paragraphs:

24 “(4)(A) Subject to subparagraph (C), the payment  
25 amount specified in this paragraph for a year for a drug  
26 or biological is an amount equal to the lesser of—

1           “(i) the average wholesale price for the drug or  
2 biological; or

3           “(ii) the amount determined under subpara-  
4 graph (B)

5           “(B)(i) Subject to clause (ii), the amount determined  
6 under this subparagraph is an amount equal to—

7           “(I) in the case of a drug or biological fur-  
8 nished in 2004, 85 percent of the average wholesale  
9 price for the drug or biological (determined as of  
10 April 1, 2003); and

11           “(II) in the case of a drug or biological fur-  
12 nished in 2005 or a subsequent year, the amount de-  
13 termined under this subparagraph for the previous  
14 year increased by the percentage increase in the con-  
15 sumer price index for medical care for the 12-month  
16 period ending with June of the previous year.

17           “(ii) In the case of a vaccine described in subpara-  
18 graph (A) or (B) of section 1861(s)(10), the amount de-  
19 termined under this subparagraph is an amount equal to  
20 the average wholesale price for the drug or biological.

21           “(C)(i) The Secretary shall establish a process under  
22 which the Secretary determines, for such drugs or  
23 biologicals as the Secretary determines appropriate,  
24 whether the widely available market price to physicians or  
25 suppliers for the drug or biological furnished in a year

1 is different from the payment amount established under  
2 subparagraph (B) for the year. Such determination shall  
3 be based on the information described in clause (ii) as the  
4 Secretary determines appropriate.

5 “(ii) The information described in this clause is the  
6 following information:

7 “(I) Any report on drug or biological market  
8 prices by the Inspector General of the Department  
9 of Health and Human Services or the Comptroller  
10 General of the United States that is made available  
11 after December 31, 1999.

12 “(II) A review of drug or biological market  
13 prices by the Secretary, which may include informa-  
14 tion on such market prices from insurers, private  
15 health plans, manufacturers, wholesalers, distribu-  
16 tors, physician supply houses, specialty pharmacies,  
17 group purchasing arrangements, physicians, sup-  
18 pliers, or any other source the Secretary determines  
19 appropriate.

20 “(III) Data and information submitted by the  
21 manufacturer of the drug or biological or by another  
22 entity.

23 “(IV) Other data and information as deter-  
24 mined appropriate by the Secretary.

1       “(iii) If the Secretary makes a determination under  
2 clause (i) with respect to the widely available market price  
3 for a drug or biological for a year, the following provisions  
4 shall apply:

5           “(I) Subject to clause (iv), the amount deter-  
6 mined under this subparagraph shall be substituted  
7 for the amount determined under subparagraph (B)  
8 for purposes of applying subparagraph (A)(ii)(I) for  
9 the year and all subsequent years.

10          “(II) The Secretary may make subsequent de-  
11 terminations under clause (i) with respect to the  
12 widely available market price for the drug or biologi-  
13 cal.

14          “(III) If the Secretary does not make a subse-  
15 quent determination under clause (i) with respect to  
16 the widely available market price for the drug or bio-  
17 logical for a year, the amount determined under this  
18 subparagraph shall be an amount equal to the  
19 amount determined under this subparagraph for the  
20 previous year increased by the percentage increase  
21 described in subparagraph (B)(i)(II) for the year in-  
22 volved.

23          “(iv) If the first determination made under clause (i)  
24 with respect to the widely available market price for a  
25 drug or biological would result in a payment amount in

1 a year that is more than 15 percent less than the amount  
2 determined under subparagraph (B) for the drug or bio-  
3 logical for the previous year (or, for 2004, the payment  
4 amount determined under paragraph (1)(A), determined  
5 as of April 1, 2003), the Secretary shall provide for a tran-  
6 sition to the amount determined under clause (i) so that  
7 the payment amount is reduced in annual increments  
8 equal to 15 percent of the payment amount in such pre-  
9 vious year until the payment amount is equal to the  
10 amount determined under clause (i), as increased each  
11 year by the percentage increase described in subparagraph  
12 (B)(i)(II) for the year. The preceding sentence shall not  
13 apply to a drug or biological where a generic version of  
14 the drug or biological first enters the market on or after  
15 January 1, 2004 (even if the generic version of the drug  
16 or biological is not marketed under the chemical name of  
17 such drug or biological).

18 “(5) In the case of a drug or biological that is first  
19 available for payment under this part after April 1, 2003,  
20 the following rules shall apply:

21 “(A) As a condition of obtaining a code to re-  
22 port such new drug or biological and to receive pay-  
23 ment under this part, a manufacturer shall provide  
24 the Secretary (in a time, manner, and form ap-  
25 proved by the Secretary) with data and information

1 on prices at which the manufacturer estimates phy-  
2 sicians and suppliers will be able to routinely obtain  
3 the drug or biological in the market during the first  
4 year that the drug or biological is available for pay-  
5 ment under this part and such additional informa-  
6 tion that the manufacturer determines appropriate.

7 “(B) During the year that the drug or biologi-  
8 cal is first available for payment under this part, the  
9 manufacturer of the drug or biological shall provide  
10 the Secretary (in a time, manner, and form ap-  
11 proved by the Secretary) with updated information  
12 on the actual market prices paid by such physicians  
13 or suppliers for the drug or biological in the year.

14 “(C) The amount specified in this paragraph  
15 for a drug or biological for the year described in  
16 subparagraph (B) is equal to an amount determined  
17 by the Secretary based on the information provided  
18 under subparagraph (A) and other information that  
19 the Secretary determines appropriate.

20 “(D) The amount specified in this paragraph  
21 for a drug or biological for the year after the year  
22 described in subparagraph (B) is equal to an  
23 amount determined by the Secretary based on the  
24 information provided under subparagraph (B) and

1 other information that the Secretary determines ap-  
2 propriate.

3 “(E) The amount specified in this paragraph  
4 for a drug or biological for the year beginning after  
5 the year described in subparagraph (D) and each  
6 subsequent year is equal to the lesser of—

7 “(i) the average wholesale price for the  
8 drug or biological; or

9 “(ii) the amount determined—

10 “(I) by the Secretary under paragraph  
11 (4)(C)(i) with respect to the widely avail-  
12 able market price for the drug or biological  
13 for the year, if such paragraph was applied  
14 by substituting ‘the payment determined  
15 under paragraph (5)(E)(ii)(II) for the  
16 year’ for ‘established under subparagraph  
17 (B) for the year’; and

18 “(II) if no determination described in  
19 subclause (I) is made for the drug or bio-  
20 logical for the year, under this subpara-  
21 graph with respect to the drug or biological  
22 for the previous year increased by the per-  
23 centage increase described in paragraph  
24 (4)(B)(i)(II) for the year involved.”.

1 (b) ADJUSTMENTS TO PAYMENT AMOUNTS FOR AD-  
2 MINISTRATION OF DRUGS AND BIOLOGICALS.—

3 (1) ADJUSTMENT IN PHYSICIAN PRACTICE EX-  
4 PENSE RELATIVE VALUE UNITS.—Section  
5 1848(c)(2) (42 U.S.C. 1395w-4(c)(2)) is amended—

6 (A) in subparagraph (B)—

7 (i) in clause (ii)(II), by striking “The  
8 adjustments” and inserting “Subject to  
9 clause (iv), the adjustments”; and

10 (ii) by adding at the end the following  
11 new clause:

12 “(iv) EXEMPTION FROM BUDGET  
13 NEUTRALITY IN 2004.—Any additional ex-  
14 penditures under this part that are attrib-  
15 utable to subparagraph (H) shall not be  
16 taken into account in applying clause  
17 (ii)(II) for 2004.”; and

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

20 “(H) ADJUSTMENTS IN PRACTICE EX-  
21 PENSE RELATIVE VALUE UNITS FOR DRUG AD-  
22 MINISTRATION SERVICES FOR 2004.—In estab-  
23 lishing the physician fee schedule under sub-  
24 section (b) with respect to payments for services  
25 furnished in 2004, the Secretary shall, in deter-

1 mining practice expense relative value units  
2 under this subsection, utilize a survey sub-  
3 mitted to the Secretary as of January 1, 2003,  
4 by a physician specialty organization pursuant  
5 to section 212 of the Medicare, Medicaid, and  
6 SCHIP Balanced Budget Refinement Act of  
7 1999 if the survey—

8 “(i) covers practice expenses for on-  
9 cology administration services; and

10 “(ii) meets criteria established by the  
11 Secretary for acceptance of such surveys.”.

12 (2) PAYMENT FOR MULTIPLE CHEMOTHERAPY  
13 AGENTS FURNISHED ON A SINGLE DAY THROUGH  
14 THE PUSH TECHNIQUE.—

15 (A) REVIEW OF POLICY.—The Secretary  
16 shall review the policy, as in effect on the date  
17 of enactment of this Act, with respect to pay-  
18 ment under section 1848 of the Social Security  
19 Act (42 U.S.C. 1395w-4) for the administra-  
20 tion of more than 1 anticancer  
21 chemotherapeutic agent to an individual on a  
22 single day through the push technique.

23 (B) MODIFICATION OF POLICY.—After  
24 conducting the review under subparagraph (A),  
25 the Secretary shall modify such payment policy

1 if the Secretary determines such modification to  
2 be appropriate.

3 (C) EXEMPTION FROM BUDGET NEU-  
4 TRALITY UNDER PHYSICIAN FEE SCHEDULE.—  
5 If the Secretary modifies such payment policy  
6 pursuant to subparagraph (B), any increased  
7 expenditures under title XVIII of the Social Se-  
8 curity Act resulting from such modification  
9 shall be treated as additional expenditures at-  
10 tributable to subparagraph (H) of section  
11 1848(c)(2) of the Social Security Act (42  
12 U.S.C. 1395w-4(c)(2)), as added by paragraph  
13 (1)(B), for purposes of applying the exemption  
14 to budget neutrality under subparagraph  
15 (B)(iv) of such section, as added by paragraph  
16 (1)(A).

17 (3) TREATMENT OF OTHER SERVICES CUR-  
18 RENTLY IN THE NONPHYSICIAN WORK POOL.—The  
19 Secretary shall make adjustments to the nonphysi-  
20 cian work pool methodology (as such term is used in  
21 the final rule promulgated by the Secretary in the  
22 Federal Register on December 31, 2002 (67 Fed.  
23 Reg. 251)), for the determination of practice ex-  
24 pense relative value units under the physician fee  
25 schedule under section 1848(c)(2)(C)(ii) of the So-

1       cial Security Act (42 U.S.C. 1395w-4(c)(2)(C)(ii)),  
2       so that the practice expense relative value units for  
3       services determined under such methodology are not  
4       disproportionately reduced relative to the practice  
5       expense relative value units of services not deter-  
6       mined under such methodology, as a result of the  
7       amendments to such Act made by paragraph (1).

8               (4) ADMINISTRATION OF BLOOD CLOTTING FAC-  
9       TORS.—Section 1842(o) (42 U.S.C. 1395u(o)), as  
10       amended by subsection (a)(2), is amended by adding  
11       at the end the following new paragraph:

12       “(6)(A) Subject to subparagraph (B), in the case of  
13       clotting factors furnished on or after January 1, 2004,  
14       the Secretary shall, after reviewing the January 2003 re-  
15       port to Congress by the Comptroller General of the United  
16       States entitled ‘Payment for Blood Clotting Factor Ex-  
17       ceeds Providers Acquisition Cost’ (GAO-03-184), provide  
18       for a separate payment for the administration of such  
19       blood clotting factors in an amount that the Secretary de-  
20       termines to be appropriate.

21       “(B) In determining the separate payment amount  
22       under subparagraph (A) for blood clotting factors fur-  
23       nished in 2004, the Secretary shall ensure that the total  
24       amount of payments under this part (as estimated by the  
25       Secretary) for such factors under paragraphs (4) and (5)

1 and such separate payments for such factors does not ex-  
2 ceed the total amount of payments that would have been  
3 made for such factors under this part (as estimated by  
4 the Secretary) if the amendments made by section 433  
5 of the Prescription Drug and Medicare Improvement Act  
6 of 2003 had not been enacted.

7 “(C) The separate payment amount under this sub-  
8 paragraph for blood clotting factors furnished in 2005 or  
9 a subsequent year shall be equal to the separate payment  
10 amount determined under this paragraph for the previous  
11 year increased by the percentage increase described in  
12 paragraph (4)(B)(i)(II) for the year involved.”.

13 (5) INCREASE IN COMPOSITE RATE FOR END  
14 STAGE RENAL DISEASE FACILITIES.—Section  
15 1881(b) (42 U.S.C. 1395rr(b) is amended—

16 (A) in paragraph (7), by adding at the end  
17 the following new sentence: “In the case of di-  
18 alysis services furnished in 2004 or a subse-  
19 quent year, the composite rate for such services  
20 shall be determined under paragraph (12).”;  
21 and

22 (B) by adding at the end the following new  
23 paragraph:

24 “(12)(A) In the case of dialysis services furnished  
25 during 2004, the composite rate for such services shall be

1 the composite rate that would otherwise apply under para-  
2 graph (7) for the year increased by an amount to ensure  
3 (as estimated by the Secretary) that—

4 “(i) the sum of the total amount of—

5 “(I) the composite rate payments for such  
6 services for the year, as increased under this  
7 paragraph; and

8 “(II) the payments for drugs and  
9 biologicals (other than erythropoetin) furnished  
10 in connection with the furnishing of renal dialy-  
11 sis services and separately billed by renal dialy-  
12 sis facilities under paragraphs (4) and (5) of  
13 section 1842(o) for the year; is equal to

14 “(ii) the sum of the total amount of the com-  
15 posite rate payments under paragraph (7) for the  
16 year and the payments for the separately billed  
17 drugs and biologicals described in clause (i)(II) that  
18 would have been made if the amendments made by  
19 section 433 of the Prescription Drug and Medicare  
20 Improvement Act of 2003 had not been enacted.

21 “(B) Subject to subparagraph (E), in the case of di-  
22 alysis services furnished in 2005, the composite rate for  
23 such services shall be an amount equal to the composite  
24 rate established under subparagraph (A), increased by  
25 0.05 percent and further increased pursuant to section

1 423 of the Prescription Drug and Medicare Improvement  
2 Act of 2003.

3 “(C) Subject to subparagraph (E), in the case of di-  
4 alysis services furnished in 2006, the composite rate for  
5 such services shall be an amount equal to the composite  
6 rate established under subparagraph (B), increased by  
7 0.05 percent.

8 “(D) Subject to subparagraph (E), in the case of di-  
9 alysis services furnished in 2007 or a subsequent year, the  
10 composite rate for such services shall be an amount equal  
11 to the composite rate established under this paragraph for  
12 the previous year (determined as if such section 423 had  
13 not been enacted), increased by 0.05 percent.

14 “(E) If the Secretary implements a reduction in the  
15 payment amount under paragraph (4)(C) or (5) for a drug  
16 or biological described in subparagraph (A)(i)(II) for a  
17 year after 2004, the Secretary shall, as estimated by the  
18 Secretary—

19 “(i) increase the composite rate for dialysis  
20 services furnished in such year in the same manner  
21 that the composite rate for such services for 2004  
22 was increased under subparagraph (A); and

23 “(ii) increase the percentage increase under  
24 subparagraph (C) or (D) (as applicable) for years  
25 after the year described in clause (i) to ensure that

1 such increased percentage would result in expendi-  
2 tures equal to the sum of the total composite rate  
3 payments for such services for such years and the  
4 total payments for drugs and biologicals described in  
5 subparagraph (A)(i)(II) is equal to the sum of the  
6 total amount of the composite rate payments under  
7 this paragraph for such years and the payments for  
8 the drugs and biologicals described in subparagraph  
9 (A)(i)(II) that would have been made if the reduc-  
10 tion in payment amount described in subparagraph  
11 had not been made.

12 “(F) There shall be no administrative or judicial re-  
13 view under section 1869, section 1878, or otherwise, of  
14 determinations of payment amounts, methods, or adjust-  
15 ments under this paragraph.”.

16 (6) HOME INFUSION DRUGS.—Section 1842(o)  
17 (42 U.S.C. 1395u(o)), as amended by subsection  
18 (a)(2) and paragraph (4), is amended by adding at  
19 the end the following new paragraph:

20 “(7)(A) Subject to subparagraph (B), in the case of  
21 infusion drugs and biologicals furnished through an item  
22 of durable medical equipment covered under section  
23 1861(n) on or after January 1, 2004, the Secretary may  
24 make separate payments for furnishing such drugs and  
25 biologicals in an amount determined by the Secretary if

1 the Secretary determines such separate payment to be ap-  
2 propriate.

3 “(B) In determining the amount of any separate pay-  
4 ment under subparagraph (A) for a year, the Secretary  
5 shall ensure that the total amount of payments under this  
6 part for such infusion drugs and biologicals for the year  
7 and such separate payments for the year does not exceed  
8 the total amount of payments that would have been made  
9 under this part for the year for such infusion drugs and  
10 biologicals if section 433 of the Prescription Drug and  
11 Medicare Improvement Act of 2003 had not been en-  
12 acted.”.

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

17 “(8)(A) Subject to subparagraph (B), in the case of  
18 inhalation drugs and biologicals furnished through durable  
19 medical equipment covered under section 1861(n) on or  
20 after January 1, 2004, the Secretary may increase pay-  
21 ments for such equipment under section 1834(a) and may  
22 make separate payments for furnishing such drugs and  
23 biologicals if the Secretary determines such increased or  
24 separate payments are necessary to appropriately furnish  
25 such equipment and drugs and biologicals to beneficiaries.

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

5           “(i) the total amount of payments that would  
6 have been made for such drugs and biologicals for  
7 the year if section 433 of the Prescription Drug and  
8 Medicare Improvement Act of 2003 had not been en-  
9 acted; exceeds

10          “(ii) the total amount of payments for such  
11 drugs and biologicals under paragraphs (4) and  
12 (5).”.

13           (8) PHARMACY DISPENSING FEE FOR CERTAIN  
14 DRUGS AND BIOLOGICALS.—Section 1842(o)(2) (42  
15 U.S.C. 1395u(o)(2)) is amended to read as follows:

16          “(2) If payment for a drug or biological is made to  
17 a licensed pharmacy approved to dispense drugs or  
18 biologicals under this part, the Secretary—

19           “(A) in the case of an immunosuppressive drug  
20 described in subparagraph (J) of section 1861(s)(2)  
21 and an oral drug described in subparagraph (Q) or  
22 (T) of such section, shall pay a dispensing fee deter-  
23 mined appropriate by the Secretary (less the applica-  
24 ble deductible and coinsurance amounts) to the  
25 pharmacy; and

1           “(B) in the case of a drug or biological not de-  
2           scribed in subparagraph (A), may pay a dispensing  
3           fee determined appropriate by the Secretary (less  
4           the applicable deductible and coinsurance amounts)  
5           to the pharmacy.”.

6           (9) PAYMENT FOR CHEMOTHERAPY DRUGS  
7           PURCHASED BUT NOT ADMINISTERED BY PHYSI-  
8           CIANS.—Section 1842(o) (42 U.S.C. 1395u(o)), as  
9           amended by subsection (a)(2) and paragraphs (4),  
10          (6) and (7), is amended by adding at the end the  
11          following new paragraph:

12           “(9)(A) Subject to subparagraph (B), the Sec-  
13          retary may increase (in an amount determined ap-  
14          propriate) the amount of payments to physicians for  
15          anticancer chemotherapeutic drugs or biologicals  
16          that would otherwise be made under this part in  
17          order to compensate such physicians for anticancer  
18          chemotherapeutic drugs or biologicals that are pur-  
19          chased by physicians with a reasonable intent to ad-  
20          minister to an individual enrolled under this part  
21          but which cannot be administered to such individual  
22          despite the reasonable efforts of the physician.

23           “(B) The total amount of increased payments  
24          made under subparagraph (A) in a year (as esti-  
25          mated by the Secretary) may not exceed an amount

1 equal to 1 percent of the total amount of payments  
2 made under paragraphs (4) and (5) for such  
3 anticancer chemotherapeutic drugs or biologicals fur-  
4 nished by physicians in such year (as estimated by  
5 the Secretary).”.

6 (c) LINKAGE OF REVISED DRUG PAYMENTS AND IN-  
7 CREASES FOR DRUG ADMINISTRATION.—The Secretary  
8 shall not implement the revisions in payment amounts for  
9 a category of drug or biological as a result of the amend-  
10 ments made by subsection (a) unless the Secretary concur-  
11 rently implements the adjustments to payment amounts  
12 for administration of such category of drug or biological  
13 for which the Secretary is required to make an adjust-  
14 ment, as specified in the amendments made by, and provi-  
15 sions of, subsection (b).

16 (d) PROHIBITION OF ADMINISTRATIVE AND JUDI-  
17 CIAL REVIEW.—

18 (1) DRUGS.—Section 1842(o) (42 U.S.C.  
19 1395u(o)), as amended by subsection (a)(2) and  
20 paragraphs (4), (6), (7), and (9) of subsection (b),  
21 is amended by adding at the end the following new  
22 paragraph:

23 “(10) There shall be no administrative or judicial re-  
24 view under section 1869, section 1878, or otherwise, of  
25 determinations of payment amounts, methods, or adjust-

1 ments under paragraph (2) or paragraphs (4) through  
2 (9).”.

3           (2) PHYSICIAN FEE SCHEDULE.—Section  
4 1848(i)(1) (42 U.S.C. 1395w-4(i)(1)) is amended—

5           (A) in subparagraph (D), by striking  
6 “and” at the end;

7           (B) in subparagraph (E), by striking the  
8 period at the end and inserting “, and”; and

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

11           “(F) adjustments in practice expense rel-  
12 ative value units under subsection (c)(2)(H).”.

13           (3) MULTIPLE CHEMOTHERAPY AGENTS AND  
14 OTHER SERVICES CURRENTLY ON THE NON-PHYSI-  
15 CIAN WORK POOL.—There shall be no administrative  
16 or judicial review under section 1869, section 1878,  
17 or otherwise, of determinations of payment amounts,  
18 methods, or adjustments under paragraphs (2) and  
19 (3) of subsection (b).

20           (e) STUDIES AND REPORTS.—

21           (1) GAO STUDY AND REPORT ON BENEFICIARY  
22 ACCESS TO DRUGS AND BIOLOGICALS.—

23           (A) STUDY.—The Comptroller General of  
24 the United States shall conduct a study that ex-  
25 amines the impact the provisions of, and the

1 amendments made by, this section have on ac-  
2 cess by medicare beneficiaries to drugs and  
3 biologicals covered under the medicare program.

4 (B) REPORT.—Not later than January 1,  
5 2006, the Comptroller General shall submit a  
6 report to Congress on the study conducted  
7 under subparagraph (A) together with such rec-  
8 ommendations as the Comptroller General de-  
9 termines to be appropriate.

10 (2) STUDY AND REPORT BY THE HHS INSPEC-  
11 TOR GENERAL ON MARKET PRICES OF DRUGS AND  
12 BIOLOGICALS.—

13 (A) STUDY.—The Inspector General of the  
14 Department of Health and Human Services  
15 shall conduct 1 or more studies that—

16 (i) examine the market prices that  
17 drugs and biologicals covered under the  
18 medicare program are widely available to  
19 physicians and suppliers; and

20 (ii) compare such widely available  
21 market prices to the payment amount for  
22 such drugs and biologicals under section  
23 1842(o) of the Social Security Act (42  
24 U.S.C. 1395u(o)).

1           (B) REQUIREMENT.—In conducting the  
2           study under subparagraph (A), the Inspector  
3           General shall focus on those drugs and  
4           biologicals that represent the largest portions of  
5           expenditures under the medicare program for  
6           drugs and biologicals.

7           (C) REPORT.—The Inspector General shall  
8           prepare a report on any study conducted under  
9           subparagraph (A).

10 **SEC. 434. INDEXING PART B DEDUCTIBLE TO INFLATION.**

11           The first sentence of section 1833(b) (42 U.S.C.  
12 1395l(b)) is amended by striking “and \$100 for 1991 and  
13 subsequent years” and inserting the following: “, \$100 for  
14 1991 through 2005, \$125 for 2006, and for 2007 and  
15 thereafter, the amount in effect for the previous year, in-  
16 crease by the percentage increase in the consumer price  
17 index for all urban consumers (U.S. city average) for the  
18 12-month period ending with June of the previous year,  
19 rounded to the nearest dollar”.

20 **SEC. 435. REVISIONS TO REASSIGNMENT PROVISIONS.**

21           (a) IN GENERAL.—Section 1842(b)(6)(A)(ii) (42  
22 U.S.C. 1395u(b)(6)(A)(ii)) is amended to read as follows:  
23 “(ii) where the service was provided under a contractual  
24 arrangement between such physician or other person and  
25 an entity (as defined by the Secretary), to the entity if

1 under such arrangement such entity submits the bill for  
2 such service and such arrangement meets such program  
3 integrity and other safeguards as the Secretary may deter-  
4 mine to be appropriate.”.

5 (b) CONFORMING AMENDMENT.—The second sen-  
6 tence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is  
7 amended by striking “except to an employer or facility as  
8 described in clause (A)” and inserting “except to an em-  
9 ployer or entity as described in subparagraph (A)”.

10 (c) EFFECTIVE DATE.—The amendments made by  
11 this section shall apply to payments made on or after the  
12 date of enactment of this Act.

13 **SEC. 436. EXTENSION OF TREATMENT OF CERTAIN PHYSI-**  
14 **CIAN PATHOLOGY SERVICES UNDER MEDI-**  
15 **CARE.**

16 Section 542(c) of BIPA (114 Stat. 2763A–551) is  
17 amended by inserting “, and for services furnished during  
18 2004 or 2005” before the period at the end.

19 **SEC. 437. ADEQUATE REIMBURSEMENT FOR OUTPATIENT**  
20 **PHARMACY THERAPY UNDER THE HOSPITAL**  
21 **OUTPATIENT PPS.**

22 (a) SPECIAL RULES FOR DRUGS AND  
23 BIOLOGICALS.—Section 1833(t) (42 U.S.C. 1395(t)) is  
24 amended—

1           (1) by redesignating paragraph (13) as para-  
2 graph (14); and

3           (2) by inserting after paragraph (12) the fol-  
4 lowing new paragraph:

5           “(13) SPECIAL RULES FOR CERTAIN DRUGS  
6 AND BIOLOGICALS.—

7           “(A) BEFORE 2007.—

8           “(i) IN GENERAL.—Notwithstanding  
9 paragraph (6), but subject to clause (ii),  
10 with respect to a separately payable drug  
11 or biological described in subparagraph  
12 (D) furnished on or after January 1, 2005,  
13 and before January 1, 2007, hospitals  
14 shall be reimbursed as follows:

15           “(I) DRUGS AND BIOLOGICALS  
16 FURNISHED AS PART OF A CURRENT  
17 OPD SERVICE.—The amount of pay-  
18 ment for a drug or biological de-  
19 scribed in subparagraph (D) provided  
20 as a part of a service that was a cov-  
21 ered OPD service on May 1, 2003,  
22 shall be the applicable percentage (as  
23 defined in subparagraph (C)) of the  
24 average wholesale price for the drug  
25 or biological that would have been de-

1           terminated under section 1842(o) on  
2           such date.

3           “(II) DRUGS AND BIOLOGICALS  
4           FURNISHED AS PART OF OTHER OPD  
5           SERVICES.—The amount of payment  
6           for a drug or biological described in  
7           subparagraph (D) provided as part of  
8           any other covered OPD service shall  
9           be the applicable percentage (as de-  
10          fined in subparagraph (C)) of the av-  
11          erage wholesale price that would have  
12          been determined under section  
13          1842(o) on May 1, 2003, if payment  
14          for such a drug or biological could  
15          have been made under this part on  
16          that date.

17          “(ii) UPDATE FOR 2006.—For 2006,  
18          the amounts determined under clauses (i)  
19          and (ii) shall be the amount established for  
20          2005 increased by the percentage increase  
21          in the Consumer Price Index for all urban  
22          consumers (U.S. urban average) for the  
23          12-month period ending with June of the  
24          previous year.

25          “(B) AFTER 2007.—

1                   “(i) ONGOING STUDY AND REPORTS  
2                   ON ADEQUATE REIMBURSEMENTS.—

3                   “(I) STUDY.—The Secretary  
4                   shall contract with an eligible organi-  
5                   zation (as defined in subclause (IV))  
6                   to conduct a study to determine the  
7                   hospital acquisition and handling  
8                   costs for each individual drug or bio-  
9                   logical described in subparagraph (D).

10                  “(II) STUDY REQUIREMENTS.—  
11                  The study conducted under subclause  
12                  (I) shall—

13                         “(aa) be accurate to within  
14                         3 percent of true mean hospital  
15                         acquisition and handling costs for  
16                         each drug and biological at the  
17                         95 percent confidence level;

18                         “(bb) begin not later than  
19                         January 1, 2005; and

20                         “(cc) be updated annually  
21                         for changes in hospital costs and  
22                         the addition of newly marketed  
23                         products.

24                  “(III) REPORTS.—Not later than  
25                  January 1 of each year (beginning

1 with 2006), the Secretary shall submit  
2 to Congress a report on the study  
3 conducted under clause (i) together  
4 with recommendations for such legis-  
5 lative or administrative action as the  
6 Secretary determines to be appro-  
7 priate.

8 “(IV) ELIGIBLE ORGANIZATION  
9 DEFINED.—In this clause, the term  
10 ‘eligible organization’ means a private,  
11 nonprofit organization within the  
12 meaning of section 501(c) of the In-  
13 ternal Revenue Code.

14 “(ii) ESTABLISHMENT OF PAYMENT  
15 METHODOLOGY.—Notwithstanding para-  
16 graph (6), the Secretary, in establishing a  
17 payment methodology on or after the date  
18 of enactment of the Prescription Drug and  
19 Medicare Improvement Act of 2003, shall  
20 take into consideration the findings of the  
21 study conducted under clause (i)(I) in de-  
22 termining payment amounts for each drug  
23 and biological provided as part of a covered  
24 OPD service furnished on or after January  
25 1, 2007.

1           “(C) APPLICABLE PERCENTAGE DE-  
2 FINED.—In this paragraph, the term ‘applicable  
3 percentage’ means—

4           “(i) with respect to a biological prod-  
5 uct (approved under a biologics license ap-  
6 plication under section 351 of the Public  
7 Health Service Act), a single source drug  
8 (as defined in section 1927(k)(7)(A)(iv)),  
9 or an orphan product designated under  
10 section 526 of the Food, Drug, and Cos-  
11 metic Act to which the prospective pay-  
12 ment system established under this sub-  
13 section did not apply under the final rule  
14 for 2003 payments under such system, 94  
15 percent;

16           “(ii) with respect to an innovator mul-  
17 tiple source drug (as defined in section  
18 1927(k)(7)(A)(ii)), 91 percent; and

19           “(iii) with respect to a noninnovator  
20 multiple source drug (as defined in section  
21 1927(k)(7)(A)(iii)), 71 percent.

22           “(D) DRUGS AND BIOLOGICALS DE-  
23 SCRIBED.—A drug or biological described in  
24 this paragraph is any drug or biological—



1           “(i) IN GENERAL.—The Secretary  
2           may not publish regulations that apply a  
3           functional equivalence standard to a drug  
4           or biological under this paragraph.

5           “(ii) APPLICATION.—Paragraph (1)  
6           shall apply to the application of a func-  
7           tional equivalence standard to a drug or bi-  
8           ological on or after the date of enactment  
9           of the Prescription Drug and Medicare Im-  
10          provement Act of 2003 unless—

11                   “(I) such application was being  
12                   made to such drug or biological prior  
13                   to such date of enactment; and

14                   “(II) the Secretary applies such  
15                   standard to such drug or biological  
16                   only for the purpose of determining  
17                   eligibility of such drug or biological  
18                   for additional payments under this  
19                   paragraph and not for the purpose of  
20                   any other payments under this title.

21           “(iii) RULE OF CONSTRUCTION.—  
22           Nothing in this subparagraph shall be con-  
23           strued to affect the Secretary’s authority  
24           to deem a particular drug to be identical to  
25           another drug if the 2 products are phar-

1                   maceutically equivalent and bioequivalent,  
2                   as determined by the Commissioner of  
3                   Food and Drugs.”.

4 **SEC. 439. MEDICARE COVERAGE OF ROUTINE COSTS ASSO-**  
5 **CIATED WITH CERTAIN CLINICAL TRIALS.**

6           (a) IN GENERAL.—With respect to the coverage of  
7 routine costs of care for beneficiaries participating in a  
8 qualifying clinical trial, as set forth on the date of the en-  
9 actment of this Act in National Coverage Determination  
10 30-1 of the Medicare Coverage Issues Manual, the Sec-  
11 retary shall deem clinical trials conducted in accordance  
12 with an investigational device exemption approved under  
13 section 520(g) of the Federal Food, Drug, and Cosmetic  
14 Act (42 U.S.C. 360j(g)) to be automatically qualified for  
15 such coverage.

16           (b) RULE OF CONSTRUCTION.—Nothing in this sec-  
17 tion shall be construed as authorizing or requiring the Sec-  
18 retary to modify the regulations set forth on the date of  
19 the enactment of this Act at subpart B of part 405 of  
20 title 42, Code of Federal Regulations, or subpart A of part  
21 411 of such title, relating to coverage of, and payment  
22 for, a medical device that is the subject of an investiga-  
23 tional device exemption by the Food and Drug Adminis-  
24 tration (except as may be necessary to implement sub-  
25 section (a)).

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

3 **SEC. 440. WAIVER OF PART B LATE ENROLLMENT PENALTY**  
4 **FOR CERTAIN MILITARY RETIREES; SPECIAL**  
5 **ENROLLMENT PERIOD.**

6 (a) WAIVER OF PENALTY.—

7 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.  
8 1395r(b)) is amended by adding at the end the fol-  
9 lowing new sentence: “No increase in the premium  
10 shall be effected for a month in the case of an indi-  
11 vidual who is 65 years of age or older, who enrolls  
12 under this part during 2002, 2003, 2004, or 2005  
13 and who demonstrates to the Secretary before De-  
14 cember 31, 2005, that the individual is a covered  
15 beneficiary (as defined in section 1072(5) of title 10,  
16 United States Code). The Secretary shall consult  
17 with the Secretary of Defense in identifying individ-  
18 uals described in the previous sentence.”.

19 (2) EFFECTIVE DATE.—The amendment made  
20 by paragraph (1) shall apply to premiums for  
21 months beginning with January 2005. The Secretary  
22 shall establish a method for providing rebates of pre-  
23 mium penalties paid for months on or after January  
24 2005 for which a penalty does not apply under such

1 amendment but for which a penalty was previously  
2 collected.

3 (b) MEDICARE PART B SPECIAL ENROLLMENT PE-  
4 RIOD.—

5 (1) IN GENERAL.—In the case of any individual  
6 who, as of the date of enactment of this Act, is 65  
7 years of age or older, is eligible to enroll but is not  
8 enrolled under part B of title XVIII of the Social  
9 Security Act, and is a covered beneficiary (as de-  
10 fined in section 1072(5) of title 10, United States  
11 Code), the Secretary shall provide for a special en-  
12 rollment period during which the individual may en-  
13 roll under such part. Such period shall begin 1 year  
14 after the date of the enactment of this Act and shall  
15 end on December 31, 2005.

16 (2) COVERAGE PERIOD.—In the case of an indi-  
17 vidual who enrolls during the special enrollment pe-  
18 riod provided under paragraph (1), the coverage pe-  
19 riod under part B of title XVIII of the Social Secu-  
20 rity Act shall begin on the first day of the month  
21 following the month in which the individual enrolls.

22 **SEC. 441. DEMONSTRATION OF COVERAGE OF CHIRO-**  
23 **PRACTIC SERVICES UNDER MEDICARE.**

24 (a) DEFINITIONS.—In this section:

1           (1) CHIROPRACTIC SERVICES.—The term  
2 “chiropractic services” has the meaning given that  
3 term by the Secretary for purposes of the dem-  
4 onstration projects, but shall include, at a min-  
5 imum—

6           (A) care for neuromusculoskeletal condi-  
7 tions typical among eligible beneficiaries; and

8           (B) diagnostic and other services that a  
9 chiropractor is legally authorized to perform by  
10 the State or jurisdiction in which such treat-  
11 ment is provided.

12           (2) DEMONSTRATION PROJECT.—The term  
13 “demonstration project” means a demonstration  
14 project established by the Secretary under sub-  
15 section (b)(1).

16           (3) ELIGIBLE BENEFICIARY.—The term “eligi-  
17 ble beneficiary” means an individual who is enrolled  
18 under part B of the medicare program.

19           (4) MEDICARE PROGRAM.—The term “medicare  
20 program” means the health benefits program under  
21 title XVIII of the Social Security Act (42 U.S.C.  
22 1395 et seq.).

23           (b) DEMONSTRATION OF COVERAGE OF CHIRO-  
24 PRACTIC SERVICES UNDER MEDICARE.—

1           (1) ESTABLISHMENT.—The Secretary shall es-  
2           tablish demonstration projects in accordance with  
3           the provisions of this section for the purpose of eval-  
4           uating the feasibility and advisability of covering  
5           chiropractic services under the medicare program (in  
6           addition to the coverage provided for services con-  
7           sisting of treatment by means of manual manipula-  
8           tion of the spine to correct a subluxation described  
9           in section 1861(r)(5) of the Social Security Act (42  
10          U.S.C. 1395x(r)(5))).

11          (2) NO PHYSICIAN APPROVAL REQUIRED.—In  
12          establishing the demonstration projects, the Sec-  
13          retary shall ensure that an eligible beneficiary who  
14          participates in a demonstration project, including an  
15          eligible beneficiary who is enrolled for coverage  
16          under a Medicare+Choice plan (or, on and after  
17          January 1, 2006, under a MedicareAdvantage plan),  
18          is not required to receive approval from a physician  
19          or other health care provider in order to receive a  
20          chiropractic service under a demonstration project.

21          (3) CONSULTATION.—In establishing the dem-  
22          onstration projects, the Secretary shall consult with  
23          chiropractors, organizations representing chiroprac-  
24          tors, eligible beneficiaries, and organizations rep-  
25          resenting eligible beneficiaries.

1           (4) PARTICIPATION.—Any eligible beneficiary  
2           may participate in the demonstration projects on a  
3           voluntary basis.

4           (c) CONDUCT OF DEMONSTRATION PROJECTS.—

5           (1) DEMONSTRATION SITES.—

6           (A) SELECTION OF DEMONSTRATION  
7           SITES.—The Secretary shall conduct dem-  
8           onstration projects at 6 demonstration sites.

9           (B) GEOGRAPHIC DIVERSITY.—Of the sites  
10          described in subparagraph (A)—

11           (i) 3 shall be in rural areas; and

12           (ii) 3 shall be in urban areas.

13          (C) SITES LOCATED IN HPSAS.—At least 1  
14          site described in clause (i) of subparagraph (B)  
15          and at least 1 site described in clause (ii) of  
16          such subparagraph shall be located in an area  
17          that is designated under section 332(a)(1)(A) of  
18          the Public Health Service Act (42 U.S.C.  
19          254e(a)(1)(A)) as a health professional short-  
20          age area.

21          (2) IMPLEMENTATION; DURATION.—

22          (A) IMPLEMENTATION.—The Secretary  
23          shall not implement the demonstration projects  
24          before October 1, 2004.

1           (B) DURATION.—The Secretary shall com-  
2           plete the demonstration projects by the date  
3           that is 3 years after the date on which the first  
4           demonstration project is implemented.

5           (d) EVALUATION AND REPORT.—

6           (1) EVALUATION.—The Secretary shall conduct  
7           an evaluation of the demonstration projects—

8                   (A) to determine whether eligible bene-  
9                   ficiaries who use chiropractic services use a  
10                  lesser overall amount of items and services for  
11                  which payment is made under the medicare pro-  
12                  gram than eligible beneficiaries who do not use  
13                  such services;

14                  (B) to determine the cost of providing pay-  
15                  ment for chiropractic services under the medi-  
16                  care program;

17                  (C) to determine the satisfaction of eligible  
18                  beneficiaries participating in the demonstration  
19                  projects and the quality of care received by such  
20                  beneficiaries; and

21                  (D) to evaluate such other matters as the  
22                  Secretary determines is appropriate.

23           (2) REPORT.—Not later than the date that is  
24           1 year after the date on which the demonstration  
25           projects conclude, the Secretary shall submit to Con-

1       gress a report on the evaluation conducted under  
2       paragraph (1) together with such recommendations  
3       for legislation or administrative action as the Sec-  
4       retary determines is appropriate.

5       (e) WAIVER OF MEDICARE REQUIREMENTS.—The  
6       Secretary shall waive compliance with such requirements  
7       of the medicare program to the extent and for the period  
8       the Secretary finds necessary to conduct the demonstra-  
9       tion projects.

10       (f) FUNDING.—

11           (1) DEMONSTRATION PROJECTS.—

12               (A) IN GENERAL.—Subject to subpara-  
13               graph (B) and paragraph (2), the Secretary  
14               shall provide for the transfer from the Federal  
15               Supplementary Insurance Trust Fund under  
16               section 1841 of the Social Security Act (42  
17               U.S.C. 1395t) of such funds as are necessary  
18               for the costs of carrying out the demonstration  
19               projects under this section.

20               (B) LIMITATION.—In conducting the dem-  
21               onstration projects under this section, the Sec-  
22               retary shall ensure that the aggregate payments  
23               made by the Secretary under the medicare pro-  
24               gram do not exceed the amount which the Sec-  
25               retary would have paid under the medicare pro-

1           gram if the demonstration projects under this  
2           section were not implemented.

3           (2) EVALUATION AND REPORT.—There are au-  
4           thorized to be appropriated such sums as are nec-  
5           essary for the purpose of developing and submitting  
6           the report to Congress under subsection (d).

7   **SEC. 442. MEDICARE HEALTH CARE QUALITY DEMONSTRA-**  
8                                   **TION PROGRAMS.**

9           Title XVIII (42 U.S.C. 1395 et seq.) is amended by  
10          inserting after section 1866B the following new section:

11          “HEALTH CARE QUALITY DEMONSTRATION PROGRAM

12           “SEC. 1866C. (a) DEFINITIONS.—In this section:

13                   “(1) BENEFICIARY.—The term ‘beneficiary’  
14           means a beneficiary who is enrolled in the original  
15           medicare fee-for-service program under parts A and  
16           B or a beneficiary in a staff model or dedicated  
17           group model health maintenance organization under  
18           the Medicare+Choice program (or, on and after  
19           January 1, 2006, under the MedicareAdvantage pro-  
20           gram) under part C.

21                   “(2) HEALTH CARE GROUP.—

22                           “(A) IN GENERAL.—The term ‘health care  
23           group’ means—

24                                   “(i) a group of physicians that is or-  
25           ganized at least in part for the purpose of

1 providing physician's services under this  
2 title;

3 “(ii) an integrated health care delivery  
4 system that delivers care through coordi-  
5 nated hospitals, clinics, home health agen-  
6 cies, ambulatory surgery centers, skilled  
7 nursing facilities, rehabilitation facilities  
8 and clinics, and employed, independent, or  
9 contracted physicians; or

10 “(iii) an organization representing re-  
11 gional coalitions of groups or systems de-  
12 scribed in clause (i) or (ii).

13 “(B) INCLUSION.—As the Secretary deter-  
14 mines appropriate, a health care group may in-  
15 clude a hospital or any other individual or enti-  
16 ty furnishing items or services for which pay-  
17 ment may be made under this title that is affili-  
18 ated with the health care group under an ar-  
19 rangement structured so that such hospital, in-  
20 dividual, or entity participates in a demonstra-  
21 tion project under this section.

22 “(3) PHYSICIAN.—Except as otherwise provided  
23 for by the Secretary, the term ‘physician’ means any  
24 individual who furnishes services that may be paid  
25 for as physicians’ services under this title.

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

6               “(1) the provision of incentives to improve the  
7 safety of care provided to beneficiaries;

8               “(2) the appropriate use of best practice guide-  
9 lines by providers and services by beneficiaries;

10              “(3) reduced scientific uncertainty in the deliv-  
11 ery of care through the examination of variations in  
12 the utilization and allocation of services, and out-  
13 comes measurement and research;

14              “(4) encourage shared decision making between  
15 providers and patients;

16              “(5) the provision of incentives for improving  
17 the quality and safety of care and achieving the effi-  
18 cient allocation of resources;

19              “(6) the appropriate use of culturally and eth-  
20 nically sensitive health care delivery; and

21              “(7) the financial effects on the health care  
22 marketplace of altering the incentives for care deliv-  
23 ery and changing the allocation of resources.

24       “(c) ADMINISTRATION BY CONTRACT.—

1           “(1) IN GENERAL.—Except as otherwise pro-  
2           vided in this section, the Secretary may administer  
3           the demonstration program established under this  
4           section in a manner that is similar to the manner in  
5           which the demonstration program established under  
6           section 1866A is administered in accordance with  
7           section 1866B.

8           “(2) ALTERNATIVE PAYMENT SYSTEMS.—A  
9           health care group that receives assistance under this  
10          section may, with respect to the demonstration  
11          project to be carried out with such assistance, in-  
12          clude proposals for the use of alternative payment  
13          systems for items and services provided to bene-  
14          ficiaries by the group that are designed to—

15                 “(A) encourage the delivery of high quality  
16                 care while accomplishing the objectives de-  
17                 scribed in subsection (b); and

18                 “(B) streamline documentation and report-  
19                 ing requirements otherwise required under this  
20                 title.

21          “(3) BENEFITS.—A health care group that re-  
22          ceives assistance under this section may, with re-  
23          spect to the demonstration project to be carried out  
24          with such assistance, include modifications to the  
25          package of benefits available under the traditional

1 fee-for-service program under parts A and B or the  
2 package of benefits available through a staff model  
3 or a dedicated group model health maintenance or-  
4 ganization under part C. The criteria employed  
5 under the demonstration program under this section  
6 to evaluate outcomes and determine best practice  
7 guidelines and incentives shall not be used as a basis  
8 for the denial of medicare benefits under the dem-  
9 onstration program to patients against their wishes  
10 (or if the patient is incompetent, against the wishes  
11 of the patient’s surrogate) on the basis of the pa-  
12 tient’s age or expected length of life or of the pa-  
13 tient’s present or predicted disability, degree of med-  
14 ical dependency, or quality of life.

15 “(d) ELIGIBILITY CRITERIA.—To be eligible to re-  
16 ceive assistance under this section, an entity shall—

17 “(1) be a health care group;

18 “(2) meet quality standards established by the  
19 Secretary, including—

20 “(A) the implementation of continuous  
21 quality improvement mechanisms that are  
22 aimed at integrating community-based support  
23 services, primary care, and referral care;

1           “(B) the implementation of activities to in-  
2           crease the delivery of effective care to bene-  
3           ficiaries;

4           “(C) encouraging patient participation in  
5           preference-based decisions;

6           “(D) the implementation of activities to  
7           encourage the coordination and integration of  
8           medical service delivery; and

9           “(E) the implementation of activities to  
10          measure and document the financial impact on  
11          the health care marketplace of altering the in-  
12          centives of health care delivery and changing  
13          the allocation of resources; and

14          “(3) meet such other requirements as the Sec-  
15          retary may establish.

16          “(e) WAIVER AUTHORITY.—The Secretary may waive  
17          such requirements of titles XI and XVIII as may be nec-  
18          essary to carry out the purposes of the demonstration pro-  
19          gram established under this section.

20          “(f) BUDGET NEUTRALITY.—With respect to the 5-  
21          year period of the demonstration program under sub-  
22          section (b), the aggregate expenditures under this title for  
23          such period shall not exceed the aggregate expenditures  
24          that would have been expended under this title if the pro-

1 gram established under this section had not been imple-  
2 mented.

3 “(g) NOTICE REQUIREMENTS.—In the case of an in-  
4 dividual that receives health care items or services under  
5 a demonstration program carried out under this section,  
6 the Secretary shall ensure that such individual is notified  
7 of any waivers of coverage or payment rules that are appli-  
8 cable to such individual under this title as a result of the  
9 participation of the individual in such program.

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

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

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

23 “(3) the Administrator of the Centers for Medi-  
24 care and Medicaid Services and the Administrator of  
25 the Center for Medicare Choices to support linkages

1 of relevant medicare data to registry information  
2 from participating health care groups for the bene-  
3 ficiary populations served by the participating  
4 groups, for analysis supporting the purposes of the  
5 demonstration program, consistent with the applica-  
6 ble provisions of the Health Insurance Portability  
7 and Accountability Act of 1996.

8 “(i) IMPLEMENTATION.—The Secretary shall not im-  
9 plement the demonstration program before October 1,  
10 2004.”.

11 **SEC. 443. MEDICARE COMPLEX CLINICAL CARE MANAGE-**  
12 **MENT PAYMENT DEMONSTRATION.**

13 (a) ESTABLISHMENT.—

14 (1) IN GENERAL.—The Secretary shall establish  
15 a demonstration program to make the medicare pro-  
16 gram more responsive to needs of eligible bene-  
17 ficiaries by promoting continuity of care, helping  
18 stabilize medical conditions, preventing or mini-  
19 mizing acute exacerbations of chronic conditions,  
20 and reducing adverse health outcomes, such as ad-  
21 verse drug interactions related to polypharmacy.

22 (2) SITES.—The Secretary shall designate 6  
23 sites at which to conduct the demonstration program  
24 under this section, of which at least 3 shall be in an  
25 urban area and at least 1 shall be in a rural area.

1 One of the sites shall be located in the State of Ar-  
2 kansas.

3 (3) DURATION.—The Secretary shall conduct  
4 the demonstration program under this section for a  
5 3-year period.

6 (4) IMPLEMENTATION.—The Secretary shall  
7 not implement the demonstration program before  
8 October 1, 2004.

9 (b) PARTICIPANTS.—Any eligible beneficiary who re-  
10 sides in an area designated by the Secretary as a dem-  
11 onstration site under subsection (a)(2) may participate in  
12 the demonstration program under this section if such ben-  
13 efiary identifies a principal care physician who agrees to  
14 manage the complex clinical care of the eligible beneficiary  
15 under the demonstration program.

16 (c) PRINCIPAL CARE PHYSICIAN RESPONSIBIL-  
17 ITIES.—The Secretary shall enter into an agreement with  
18 each principal care physician who agrees to manage the  
19 complex clinical care of an eligible beneficiary under sub-  
20 section (b) under which the principal care physician  
21 shall—

22 (1) serve as the primary contact of the eligible  
23 beneficiary in accessing items and services for which  
24 payment may be made under the medicare program;

1           (2) maintain medical information related to  
2           care provided by other health care providers who  
3           provide health care items and services to the eligible  
4           beneficiary, including clinical reports, medication  
5           and treatments prescribed by other physicians, hos-  
6           pital and hospital outpatient services, skilled nursing  
7           home care, home health care, and medical equipment  
8           services;

9           (3) monitor and advocate for the continuity of  
10          care of the eligible beneficiary and the use of evi-  
11          dence-based guidelines;

12          (4) promote self-care and family caregiver in-  
13          volvement where appropriate;

14          (5) have appropriate staffing arrangements to  
15          conduct patient self-management and other care co-  
16          ordination activities as specified by the Secretary;

17          (6) refer the eligible beneficiary to community  
18          services organizations and coordinate the services of  
19          such organizations with the care provided by health  
20          care providers; and

21          (7) meet such other complex care management  
22          requirements as the Secretary may specify.

23          (d) COMPLEX CLINICAL CARE MANAGEMENT FEE.—

24                  (1) PAYMENT.—Under an agreement entered  
25          into under subsection (c), the Secretary shall pay to

1 each principal care physician, on behalf of each eligi-  
2 ble beneficiary under the care of that physician, the  
3 complex clinical care management fee developed by  
4 the Secretary under paragraph (2).

5 (2) DEVELOPMENT OF FEE.—The Secretary  
6 shall develop a complex care management fee under  
7 this paragraph that is paid on a monthly basis and  
8 which shall be payment in full for all the functions  
9 performed by the principal care physician under the  
10 demonstration program, including any functions per-  
11 formed by other qualified practitioners acting on be-  
12 half of the physician, appropriate staff under the su-  
13 pervision of the physician, and any other person  
14 under a contract with the physician, including any  
15 person who conducts patient self-management and  
16 caregiver education under subsection (c)(4).

17 (e) FUNDING.—

18 (1) IN GENERAL.—The Secretary shall provide  
19 for the transfer from the Federal Supplementary In-  
20 surance Trust Fund established under section 1841  
21 of the Social Security Act (42 U.S.C. 1395t) of such  
22 funds as are necessary for the costs of carrying out  
23 the demonstration program under this section.

24 (2) BUDGET NEUTRALITY.—In conducting the  
25 demonstration program under this section, the Sec-

1       retary shall ensure that the aggregate payments  
2       made by the Secretary do not exceed the amount  
3       which the Secretary would have paid if the dem-  
4       onstration program under this section was not im-  
5       plemented.

6       (f) WAIVER AUTHORITY.—The Secretary may waive  
7       such requirements of titles XI and XVIII of the Social  
8       Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as  
9       may be necessary for the purpose of carrying out the dem-  
10      onstration program under this section.

11      (g) REPORT.—Not later than 6 months after the  
12      completion of the demonstration program under this sec-  
13      tion, the Secretary shall submit to Congress a report on  
14      such program, together with recommendations for such  
15      legislation and administrative action as the Secretary de-  
16      termines to be appropriate.

17      (h) DEFINITIONS.—In this section:

18           (1) ACTIVITY OF DAILY LIVING.—The term “ac-  
19      tivity of daily living” means eating, toiling, transfer-  
20      ring, bathing, dressing, and continence.

21           (2) CHRONIC CONDITION.—The term “chronic  
22      condition” means a biological, physical, or mental  
23      condition that is likely to last a year or more, for  
24      which there is no known cure, for which there is a  
25      need for ongoing medical care, and which may affect

1 an individual's ability to carry out activities of daily  
2 living or instrumental activities of daily living, or  
3 both.

4 (3) ELIGIBLE BENEFICIARY.—The term “eligi-  
5 ble beneficiary” means any individual who—

6 (A) is enrolled for benefits under part B of  
7 the medicare program;

8 (B) has at least 4 complex medical condi-  
9 tions (one of which may be cognitive impair-  
10 ment); and

11 (C) has—

12 (i) an inability to self-manage their  
13 care; or

14 (ii) a functional limitation defined as  
15 an impairment in 1 or more activity of  
16 daily living or instrumental activity of daily  
17 living.

18 (4) INSTRUMENTAL ACTIVITY OF DAILY LIV-  
19 ING.—The term “instrumental activity of daily liv-  
20 ing” means meal preparation, shopping, house-  
21 keeping, laundry, money management, telephone  
22 use, and transportation use.

23 (5) MEDICARE PROGRAM.—The term “medicare  
24 program” means the health care program under title

1 XVIII of the Social Security Act (42 U.S.C. 1395 et  
2 seq.).

3 (6) PRINCIPAL CARE PHYSICIAN.—The term  
4 “principal care physician” means the physician with  
5 primary responsibility for overall coordination of the  
6 care of an eligible beneficiary (as specified in a writ-  
7 ten plan of care) who may be a primary care physi-  
8 cian or a specialist.

9 **SEC. 444. MEDICARE FEE-FOR-SERVICE CARE COORDINA-**  
10 **TION DEMONSTRATION PROGRAM.**

11 (a) ESTABLISHMENT.—

12 (1) IN GENERAL.—The Secretary shall establish  
13 a demonstration program to contract with qualified  
14 care management organizations to provide health  
15 risk assessment and care management services to el-  
16 igible beneficiaries who receive care under the origi-  
17 nal medicare fee-for-service program under parts A  
18 and B of title XVIII of the Social Security Act to  
19 eligible beneficiaries.

20 (2) SITES.—The Secretary shall designate 6  
21 sites at which to conduct the demonstration program  
22 under this section. In selecting sites under this para-  
23 graph, the Secretary shall give preference to sites lo-  
24 cated in rural areas.

1           (3) DURATION.—The Secretary shall conduct  
2           the demonstration program under this section for a  
3           5-year period.

4           (4) IMPLEMENTATION.—The Secretary shall  
5           not implement the demonstration program before  
6           October 1, 2004.

7           (b) PARTICIPANTS.—Any eligible beneficiary who re-  
8           sides in an area designated by the Secretary as a dem-  
9           onstration site under subsection (a)(2) may participate in  
10          the demonstration program under this section if such ben-  
11          eficiary identifies a care management organization who  
12          agrees to furnish care management services to the eligible  
13          beneficiary under the demonstration program.

14          (c) CONTRACTS WITH CMOS.—

15               (1) IN GENERAL.—The Secretary shall enter  
16               into a contract with care management organizations  
17               to provide care management services to eligible bene-  
18               ficiaries residing in the area served by the care man-  
19               agement organization.

20               (2) CANCELLATION.—The Secretary may cancel  
21               a contract entered into under paragraph (1) if the  
22               care management organization does not meet nego-  
23               tiated savings or quality outcomes targets for the  
24               year.

1           (3) NUMBER OF CMOS.—The Secretary may  
2 contract with more than 1 care management organi-  
3 zation in a geographic area.

4           (d) PAYMENT TO CMOS.—

5           (1) PAYMENT.—Under an contract entered into  
6 under subsection (c), the Secretary shall pay care  
7 management organizations a fee for which the care  
8 management organization is partially at risk based  
9 on bids submitted by care management organiza-  
10 tions.

11           (2) PORTION OF PAYMENT AT RISK.—The Sec-  
12 retary shall establish a benchmark for quality and  
13 cost against which the results of the care manage-  
14 ment organization are to be measured. The Sec-  
15 retary may not pay a care management organization  
16 the portion of the fee described in paragraph (1)  
17 that is at risk unless the Secretary determines that  
18 the care management organization has met the  
19 agreed upon savings and outcomes targets for the  
20 year.

21           (e) FUNDING.—

22           (1) IN GENERAL.—The Secretary shall provide  
23 for the transfer from the Federal Hospital Insurance  
24 Trust Fund under section 1817 of the Social Secu-  
25 rity Act (42 U.S.C. 1395i) and the Federal Supple-

1       mentary Insurance Trust Fund established under  
2       section 1841 of such Act (42 U.S.C. 1395t), in such  
3       proportion as the Secretary determines to be appro-  
4       priate, of such funds as are necessary for the costs  
5       of carrying out the demonstration program under  
6       this section.

7               (2) BUDGET NEUTRALITY.—In conducting the  
8       demonstration program under this section, the Sec-  
9       retary shall ensure that the aggregate payments  
10      made by the Secretary do not exceed the amount  
11      which the Secretary would have paid if the dem-  
12      onstration program under this section was not im-  
13      plemented.

14      (f) WAIVER AUTHORITY.—

15              (1) IN GENERAL.—The Secretary may waive  
16      such requirements of titles XI and XVIII of the So-  
17      cial Security Act (42 U.S.C. 1301 et seq.; 1395 et  
18      seq.) as may be necessary for the purpose of car-  
19      rying out the demonstration program under this sec-  
20      tion.

21              (2) WAIVER OF MEDIGAP PREEMPTIONS.—The  
22      Secretary shall waive any provision of section 1882  
23      of the Social Security Act that would prevent an in-  
24      surance carrier described in subsection (h)(3)(D)

1 from participating in the demonstration program  
2 under this section.

3 (g) REPORT.—Not later than 6 months after the  
4 completion of the demonstration program under this sec-  
5 tion, the Secretary shall submit to Congress a report on  
6 such program, together with recommendations for such  
7 legislation and administrative action as the Secretary de-  
8 termines to be appropriate.

9 (h) DEFINITIONS.—In this section:

10 (1) CARE MANAGEMENT SERVICES.—The term  
11 “care management services” means services that are  
12 furnished to an eligible beneficiary (as defined in  
13 paragraph (2)) by a care management organization  
14 (as defined in paragraph (3)) in accordance with  
15 guidelines established by the Secretary that are con-  
16 sistent with guidelines established by the American  
17 Geriatrics Society.

18 (2) ELIGIBLE BENEFICIARY.—The term “eligi-  
19 ble beneficiary” means an individual who is—

20 (A) entitled to (or enrolled for) benefits  
21 under part A and enrolled for benefits under  
22 part B of the Social Security Act (42 U.S.C.  
23 1395e et seq.; 1395j et seq.);

1 (B) not enrolled with a Medicare+Choice  
2 plan or a MedicareAdvantage plan under part  
3 C; and

4 (C) at high-risk (as defined by the Sec-  
5 retary, but including eligible beneficiaries with  
6 multiple sclerosis or another disabling chronic  
7 condition, eligible beneficiaries residing in a  
8 nursing home or at risk for nursing home place-  
9 ment, or eligible beneficiaries eligible for assist-  
10 ance under a State plan under title XIX).

11 (3) CARE MANAGEMENT ORGANIZATION.—The  
12 term “care management organization” means an or-  
13 ganization that meets such qualifications as the Sec-  
14 retary may specify and includes any of the following:

15 (A) A physician group practice, hospital,  
16 home health agency, or hospice program.

17 (B) A disease management organization.

18 (C) A Medicare+Choice or MedicareAd-  
19 vantage organization.

20 (D) Insurance carriers offering medicare  
21 supplemental policies under section 1882 of the  
22 Social Security Act (42 U.S.C. 1395ss).

23 (E) Such other entity as the Secretary de-  
24 termines to be appropriate.

1 **SEC. 445. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN**  
2 **PAYMENTS FOR PHYSICIANS' SERVICES.**

3 (a) STUDY.—The Comptroller General of the United  
4 States shall conduct a study of differences in payment  
5 amounts under the physician fee schedule under section  
6 1848 of the Social Security Act (42 U.S.C. 1395w–4) for  
7 physicians' services in different geographic areas. Such  
8 study shall include—

9 (1) an assessment of the validity of the geo-  
10 graphic adjustment factors used for each component  
11 of the fee schedule;

12 (2) an evaluation of the measures used for such  
13 adjustment, including the frequency of revisions;

14 (3) an evaluation of the methods used to deter-  
15 mine professional liability insurance costs used in  
16 computing the malpractice component, including a  
17 review of increases in professional liability insurance  
18 premiums and variation in such increases by State  
19 and physician specialty and methods used to update  
20 the geographic cost of practice index and relative  
21 weights for the malpractice component;

22 (4) an evaluation of whether there is a sound  
23 economic basis for the implementation of the adjust-  
24 ment under subparagraphs (E) and (F) of section  
25 1848(e)(1) of the Social Security Act (42 U.S.C.

1 1395w-4(e)(1)), as added by section 421, in those  
2 areas in which the adjustment applies;

3 (5) an evaluation of the effect of such adjust-  
4 ment on physician location and retention in areas af-  
5 fected by such adjustment, taking into account—

6 (A) differences in recruitment costs and re-  
7 tention rates for physicians, including special-  
8 ists, between large urban areas and other areas;  
9 and

10 (B) the mobility of physicians, including  
11 specialists, over the last decade; and

12 (6) an evaluation of appropriateness of extend-  
13 ing such adjustment or making such adjustment per-  
14 manent.

15 (b) REPORT.—Not later than 1 year after the date  
16 of enactment of this Act, the Comptroller General of the  
17 United States shall submit to Congress a report on the  
18 study conducted under subsection (a). The report shall in-  
19 clude recommendations regarding the use of more current  
20 data in computing geographic cost of practice indices as  
21 well as the use of data directly representative of physi-  
22 cians' costs (rather than proxy measures of such costs).

1     **Subtitle C—Provisions Relating to**  
2                     **Parts A and B**

3     **SEC. 451. INCREASE FOR HOME HEALTH SERVICES FUR-**  
4                     **NISHED IN A RURAL AREA.**

5             (a) IN GENERAL.—In the case of home health serv-  
6     ices furnished in a rural area (as defined in section  
7     1886(d)(2)(D) of the Social Security Act (42 U.S.C.  
8     1395ww(d)(2)(D))) on or after October 1, 2003, and be-  
9     fore October 1, 2005, the Secretary shall increase the pay-  
10    ment amount otherwise made under section 1895 of such  
11    Act (42 U.S.C. 1395fff) for such services by 5 percent.

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

18            (c) NO EFFECT ON SUBSEQUENT PERIODS.—The  
19    payment increase provided under subsection (a) for a pe-  
20    riod under such subsection—

21                (1) shall not apply to episodes and visits ending  
22                after such period; and

23                (2) shall not be taken into account in calcu-  
24                lating the payment amounts applicable for episodes  
25                and visits occurring after such period.

1 **SEC. 452. LIMITATION ON REDUCTION IN AREA WAGE AD-**  
2 **JUSTMENT FACTORS UNDER THE PROSPEC-**  
3 **TIVE PAYMENT SYSTEM FOR HOME HEALTH**  
4 **SERVICES.**

5 Section 1895(b)(4)(C) (42 U.S.C. 1395fff(b)(4)(C))  
6 is amended—

7 (1) by striking “FACTORS.—The Secretary” and  
8 inserting “FACTORS.—

9 “(i) IN GENERAL.—Subject to clause  
10 (ii), the Secretary”; and

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

13 “(ii) LIMITATION ON REDUCTION IN  
14 FISCAL YEAR 2005 AND 2006.—For fiscal  
15 years 2004, 2005, and 2006, the area  
16 wage adjustment factor applicable to home  
17 health services furnished in an area in the  
18 fiscal year may not be more than 3 percent  
19 less than the area wage adjustment factor  
20 applicable to home health services for the  
21 area for the previous year.”.

22 **SEC. 453. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO**  
23 **MEDICARE LIMITS ON PHYSICIAN REFER-**  
24 **RALS.**

25 (a) LIMITS ON PHYSICIAN REFERRALS.—

1           (1) OWNERSHIP AND INVESTMENT INTERESTS  
2           IN WHOLE HOSPITALS.—

3                   (A) IN GENERAL.—Section 1877(d)(3) (42  
4           U.S.C. 1395nn(d)(3)) is amended—

5                           (i) by striking “and” at the end of  
6           subparagraph (A); and

7                           (ii) by redesignating subparagraph  
8           (B) as subparagraph (C) and inserting  
9           after subparagraph (A) the following:

10                           “(B) the hospital is not a specialty hospital  
11           (as defined in subsection (h)(7)); and”.

12                   (B) DEFINITION.—Section 1877(h) (42  
13           U.S.C. 1395nn(h)) is amended by adding at the  
14           end the following:

15                   “(7) SPECIALTY HOSPITAL.—

16                           “(A) IN GENERAL.—For purposes of this  
17           section, except as provided in subparagraph  
18           (B), the term ‘specialty hospital’ means a hos-  
19           pital that is primarily or exclusively engaged in  
20           the care and treatment of one of the following:

21                                   “(i) patients with a cardiac condition;

22                                   “(ii) patients with an orthopedic con-  
23           dition;

24                                   “(iii) patients receiving a surgical pro-  
25           cedure; or

1           “(iv) any other specialized category of  
2 patients or cases that the Secretary des-  
3 ignates as inconsistent with the purpose of  
4 permitting physician ownership and invest-  
5 ment interests in a hospital under this sec-  
6 tion.

7           “(B) EXCEPTION.—For purposes of this  
8 section, the term ‘specialty hospital’ does not  
9 include any hospital—

10           “(i) determined by the Secretary—

11           “(I) to be in operation before  
12 June 12, 2003; or

13           “(II) under development as of  
14 such date;

15           “(ii) for which the number of beds  
16 and the number of physician investors at  
17 any time on or after such date is no great-  
18 er than the number of such beds or inves-  
19 tors as of such date; and

20           “(iii) that meets such other require-  
21 ments as the Secretary may specify.”.

22           (2) OWNERSHIP AND INVESTMENT INTERESTS  
23 IN A RURAL PROVIDER.—Section 1877(d)(2) (42  
24 U.S.C. 1395nn(d)(2)) is amended to read as follows:

1           “(2) RURAL PROVIDERS.—In the case of des-  
2           ignated health services furnished in a rural area (as  
3           defined in section 1886(d)(2)(D)) by an entity, if—

4                   “(A) substantially all of the designated  
5           health services furnished by the entity are fur-  
6           nished to individuals residing in such a rural  
7           area;

8                   “(B) the entity is not a specialty hospital  
9           (as defined in subsection (h)(7)); and

10                   “(C) the Secretary determines, with re-  
11           spect to such entity, that such services would  
12           not be available in such area but for the owner-  
13           ship or investment interest.”.

14           (b) EFFECTIVE DATE.—Subject to paragraph (2),  
15           the amendments made by this section shall apply to refer-  
16           rals made for designated health services on or after Janu-  
17           ary 1, 2004.

18           (c) APPLICATION OF EXCEPTION FOR HOSPITALS  
19           UNDER DEVELOPMENT.—For purposes of section  
20           1877(h)(7)(B)(i)(II) of the Social Security Act, as added  
21           by subsection (a)(1)(B), in determining whether a hospital  
22           is under development as of June 12, 2003, the Secretary  
23           shall consider—

24                   (1) whether architectural plans have been com-  
25           pleted, funding has been received, zoning require-

1       ments have been met, and necessary approvals from  
2       appropriate State agencies have been received; and

3               (2) any other evidence the Secretary determines  
4       would indicate whether a hospital is under develop-  
5       ment as of such date.

6 **SEC. 454. DEMONSTRATION PROGRAM FOR SUBSTITUTE**  
7                               **ADULT DAY SERVICES.**

8       (a) **ESTABLISHMENT.**—The Secretary shall establish  
9       a demonstration program (in this section referred to as  
10      the “demonstration program”) under which the Secretary  
11      provides eligible medicare beneficiaries with coverage  
12      under the medicare program of substitute adult day serv-  
13      ices furnished by an adult day services facility.

14      (b) **PAYMENT RATE FOR SUBSTITUTE ADULT DAY**  
15      **SERVICES.**—

16               (1) **PAYMENT RATE.**—For purposes of making  
17      payments to an adult day services facility for sub-  
18      stitute adult day services under the demonstration  
19      program, the following rules shall apply:

20                       (A) **ESTIMATION OF PAYMENT AMOUNT.**—

21               The Secretary shall estimate the amount that  
22               would otherwise be payable to a home health  
23               agency under section 1895 of the Social Secu-  
24               rity Act (42 U.S.C. 1395fff) for all home health

1 services described in subsection (i)(4)(B)(i)  
2 under the plan of care.

3 (B) AMOUNT OF PAYMENT.—Subject to  
4 paragraph (3)(B), the total amount payable for  
5 substitute adult day services under the plan of  
6 care is equal to 95 percent of the amount esti-  
7 mated to be payable under subparagraph (A).

8 (2) LIMITATION ON BALANCE BILLING.—Under  
9 the demonstration program, an adult day services  
10 facility shall accept as payment in full for substitute  
11 adult day services (including those services described  
12 in clauses (ii) through (iv) of subsection (i)(4)(B))  
13 furnished by the facility to an eligible medicare ben-  
14 eficiary the amount of payment provided under the  
15 demonstration program for home health services  
16 consisting of substitute adult services.

17 (3) ADJUSTMENT IN CASE OF OVERUTILIZA-  
18 TION OF SUBSTITUTE ADULT DAY SERVICES TO EN-  
19 SURE BUDGET NEUTRALITY.—The Secretary shall  
20 monitor the expenditures under the demonstration  
21 program and under title XVIII of the Social Secu-  
22 rity Act for home health services. If the Secretary  
23 estimates that the total expenditures under the dem-  
24 onstration program and under such title XVIII for  
25 home health services for a period determined by the

1 Secretary exceed expenditures that would have been  
2 made under such title XVIII for home health serv-  
3 ices for such period if the demonstration program  
4 had not been conducted, the Secretary shall adjust  
5 the rate of payment to adult day services facilities  
6 under paragraph (1)(B) in order to eliminate such  
7 excess.

8 (c) DEMONSTRATION PROGRAM SITES.—The dem-  
9 onstration program shall be conducted in not more than  
10 3 sites selected by the Secretary.

11 (d) DURATION; IMPLEMENTATION.—

12 (1) DURATION.—The Secretary shall conduct  
13 the demonstration program for a period of 3 years.

14 (2) IMPLEMENTATION.—The Secretary may not  
15 implement the demonstration program before Octo-  
16 ber 1, 2004.

17 (e) VOLUNTARY PARTICIPATION.—Participation of  
18 eligible medicare beneficiaries in the demonstration pro-  
19 gram shall be voluntary.

20 (f) WAIVER AUTHORITY.—

21 (1) IN GENERAL.—Except as provided in para-  
22 graph (2), the Secretary may waive such require-  
23 ments of titles XI and XVIII of the Social Security  
24 Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may

1 be necessary for the purposes of carrying out the  
2 demonstration program.

3 (2) MAY NOT WAIVE ELIGIBILITY REQUIRE-  
4 MENTS FOR HOME HEALTH SERVICES.—The Sec-  
5 retary may not waive the beneficiary eligibility re-  
6 quirements for home health services under title  
7 XVIII of the Social Security Act.

8 (g) EVALUATION AND REPORT.—

9 (1) EVALUATION.—The Secretary shall conduct  
10 an evaluation of the clinical and cost effectiveness of  
11 the demonstration program.

12 (2) REPORT.—Not later than 30 months after  
13 the commencement of the demonstration program,  
14 the Secretary shall submit to Congress a report on  
15 the evaluation conducted under paragraph (1) and  
16 shall include in the report the following:

17 (A) An analysis of the patient outcomes  
18 and costs of furnishing care to the eligible  
19 medicare beneficiaries participating in the dem-  
20 onstration program as compared to such out-  
21 comes and costs to such beneficiaries receiving  
22 only home health services under title XVIII of  
23 the Social Security Act for the same health con-  
24 ditions.

1           (B) Such recommendations regarding the  
2           extension, expansion, or termination of the pro-  
3           gram as the Secretary determines appropriate.

4           (i) DEFINITIONS.—In this section:

5           (1) ADULT DAY SERVICES FACILITY.—

6           (A) IN GENERAL.—Except as provided in  
7           subparagraphs (B) and (C), the term “adult  
8           day services facility” means a public agency or  
9           private organization, or a subdivision of such an  
10          agency or organization, that—

11           (i) is engaged in providing skilled  
12           nursing services and other therapeutic  
13           services directly or under arrangement  
14           with a home health agency;

15           (ii) provides the items and services de-  
16           scribed in paragraph (4)(B); and

17           (iii) meets the requirements of para-  
18           graphs (2) through (8) of subsection (o).

19          (B) INCLUSION.—Notwithstanding sub-  
20          paragraph (A), the term “adult day services fa-  
21          cility” shall include a home health agency in  
22          which the items and services described in  
23          clauses (ii) through (iv) of paragraph (4)(B)  
24          are provided—

1 (i) by an adult day services program  
2 that is licensed or certified by a State, or  
3 accredited, to furnish such items and serv-  
4 ices in the State; and

5 (ii) under arrangements with that  
6 program made by such agency.

7 (C) WAIVER OF SURETY BOND.—The Sec-  
8 retary may waive the requirement of a surety  
9 bond under section 1861(o)(7) of the Social Se-  
10 curity Act (42 U.S.C. 1395x(o)(7)) in the case  
11 of an agency or organization that provides a  
12 comparable surety bond under State law.

13 (2) ELIGIBLE MEDICARE BENEFICIARY.—The  
14 term “eligible medicare beneficiary” means an indi-  
15 vidual eligible for home health services under title  
16 XVIII of the Social Security Act.

17 (3) HOME HEALTH AGENCY.—The term “home  
18 health agency” has the meaning given such term in  
19 section 1861(o) of the Social Security Act (42  
20 U.S.C. 1395x(o)).

21 (4) SUBSTITUTE ADULT DAY SERVICES.—

22 (A) IN GENERAL.—The term “substitute  
23 adult day services” means the items and serv-  
24 ices described in subparagraph (B) that are fur-  
25 nished to an individual by an adult day services

1 facility as a part of a plan under section  
2 1861(m) of the Social Security Act (42 U.S.C.  
3 1395x(m)) that substitutes such services for  
4 some or all of the items and services described  
5 in subparagraph (B)(i) furnished by a home  
6 health agency under the plan, as determined by  
7 the physician establishing the plan.

8 (B) ITEMS AND SERVICES DESCRIBED.—

9 The items and services described in this sub-  
10 paragraph are the following items and services:

11 (i) Items and services described in  
12 paragraphs (1) through (7) of such section  
13 1861(m).

14 (ii) Meals.

15 (iii) A program of supervised activities  
16 designed to promote physical and mental  
17 health and furnished to the individual by  
18 the adult day services facility in a group  
19 setting for a period of not fewer than 4  
20 and not greater than 12 hours per day.

21 (iv) A medication management pro-  
22 gram (as defined in subparagraph (C)).

23 (C) MEDICATION MANAGEMENT PRO-  
24 GRAM.—For purposes of subparagraph (B)(iv),  
25 the term “medication management program”

1 means a program of services, including medi-  
2 cine screening and patient and health care pro-  
3 vider education programs, that provides services  
4 to minimize—

5 (i) unnecessary or inappropriate use  
6 of prescription drugs; and

7 (ii) adverse events due to unintended  
8 prescription drug-to-drug interactions.

9 **SEC. 455. MEDICARE SECONDARY PAYOR (MSP) PROVI-**  
10 **SIONS.**

11 (a) TECHNICAL AMENDMENT CONCERNING SEC-  
12 RETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT  
13 WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPT-  
14 LY.—

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

17 (A) in subparagraph (A)(ii), by striking  
18 “promptly (as determined in accordance with  
19 regulations)”;

20 (B) in subparagraph (B)—

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

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

1           “(i) AUTHORITY TO MAKE CONDI-  
2           TIONAL PAYMENT.—The Secretary may  
3           make payment under this title with respect  
4           to an item or service if a primary plan de-  
5           scribed in subparagraph (A)(ii) has not  
6           made or cannot reasonably be expected to  
7           make payment with respect to such item or  
8           service promptly (as determined in accord-  
9           ance with regulations). Any such payment  
10          by the Secretary shall be conditioned on  
11          reimbursement to the appropriate Trust  
12          Fund in accordance with the succeeding  
13          provisions of this subsection.”.

14           (2) EFFECTIVE DATE.—The amendments made  
15          by paragraph (1) shall be effective as if included in  
16          the enactment of title III of the Medicare and Med-  
17          icaid Budget Reconciliation Amendments of 1984  
18          (Public Law 98–369).

19           (b) CLARIFYING AMENDMENTS TO CONDITIONAL  
20          PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.  
21          1395y(b)(2)) is further amended—

22           (1) in subparagraph (A), in the matter fol-  
23          lowing clause (ii), by inserting the following sentence  
24          at the end: “An entity that engages in a business,  
25          trade, or profession shall be deemed to have a self-

1 insured plan if it carries its own risk (whether by a  
2 failure to obtain insurance, or otherwise) in whole or  
3 in part.”;

4 (2) in subparagraph (B)(ii), as redesignated by  
5 subsection (a)(2)(B)—

6 (A) by striking the first sentence and in-  
7 serting the following: “A primary plan, and an  
8 entity that receives payment from a primary  
9 plan, shall reimburse the appropriate Trust  
10 Fund for any payment made by the Secretary  
11 under this title with respect to an item or serv-  
12 ice if it is demonstrated that such primary plan  
13 has or had a responsibility to make payment  
14 with respect to such item or service. A primary  
15 plan’s responsibility for such payment may be  
16 demonstrated by a judgment, a payment condi-  
17 tioned upon the recipient’s compromise, waiver,  
18 or release (whether or not there is a determina-  
19 tion or admission of liability) of payment for  
20 items or services included in a claim against the  
21 primary plan or the primary plan’s insured, or  
22 by other means.”; and

23 (B) in the final sentence, by striking “on  
24 the date such notice or other information is re-  
25 ceived” and inserting “on the date notice of, or

1 information related to, a primary plan’s respon-  
2 sibility for such payment or other information is  
3 received”; and

4 (3) in subparagraph (B)(iii), as redesignated by  
5 subsection (a)(2)(B), by striking the first sentence  
6 and inserting the following: “In order to recover  
7 payment made under this title for an item or service,  
8 the United States may bring an action against any  
9 or all entities that are or were required or respon-  
10 sible (directly, as an insurer or self-insurer, as a  
11 third-party administrator, as an employer that spon-  
12 sors or contributes to a group health plan, or large  
13 group health plan, or otherwise) to make payment  
14 with respect to the same item or service (or any por-  
15 tion thereof) under a primary plan. The United  
16 States may, in accordance with paragraph (3)(A)  
17 collect double damages against any such entity. In  
18 addition, the United States may recover under this  
19 clause from any entity that has received payment  
20 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  
23 U.S.C. 1395y(b)) is amended—

24 (1) in paragraph (1)(A), by moving the indenta-  
25 tion of clauses (ii) through (v) 2 ems to the left; and

1 (2) in paragraph (3)(A), by striking “such” be-  
2 fore “paragraphs”.

3 **TITLE V—MEDICARE APPEALS,**  
4 **REGULATORY, AND CON-**  
5 **TRACTING IMPROVEMENTS**  
6 **Subtitle A—Regulatory Reform**

7 **SEC. 501. RULES FOR THE PUBLICATION OF A FINAL REGU-**  
8 **LATION BASED ON THE PREVIOUS PUBLICA-**  
9 **TION OF AN INTERIM FINAL REGULATION.**

10 (a) IN GENERAL.—Section 1871(a) (42 U.S.C.  
11 1395hh(a)) is amended by adding at the end the following  
12 new paragraph:

13 “(3)(A) With respect to the publication of a final reg-  
14 ulation based on the previous publication of an interim  
15 final regulation—

16 “(i) subject to subparagraph (B), the Secretary  
17 shall publish the final regulation within the 12-  
18 month period that begins on the date of publication  
19 of the interim final regulation;

20 “(ii) if a final regulation is not published by the  
21 deadline established under this paragraph, the in-  
22 terim final regulation shall not continue in effect un-  
23 less the Secretary publishes a notice described in  
24 subparagraph (B) by such deadline; and

1           “(iii) the final regulation shall include responses  
2           to comments submitted in response to the interim  
3           final regulation.

4           “(B) If the Secretary determines before the deadline  
5           otherwise established in this paragraph that there is good  
6           cause, specified in a notice published before such deadline,  
7           for delaying the deadline otherwise applicable under this  
8           paragraph, the deadline otherwise established under this  
9           paragraph shall be extended for such period (not to exceed  
10          12 months) as the Secretary specifies in such notice.”.

11          (b) EFFECTIVE DATE.—The amendment made by  
12          subsection (a) shall take effect on the date of enactment  
13          of this Act and shall apply to interim final regulations  
14          published on or after such date.

15          (c) STATUS OF PENDING INTERIM FINAL REGULA-  
16          TIONS.—Not later than 6 months after the date of enact-  
17          ment of this Act, the Secretary shall publish a notice in  
18          the Federal Register that provides the status of each in-  
19          terim final regulation that was published on or before the  
20          date of enactment of this Act and for which no final regu-  
21          lation has been published. Such notice shall include the  
22          date by which the Secretary plans to publish the final reg-  
23          ulation that is based on the interim final regulation.

1 **SEC. 502. COMPLIANCE WITH CHANGES IN REGULATIONS**  
2 **AND POLICIES.**

3 (a) NO RETROACTIVE APPLICATION OF SUB-  
4 STANTIVE CHANGES.—

5 (1) IN GENERAL.—Section 1871 (42 U.S.C.  
6 1395hh) is amended by adding at the end the fol-  
7 lowing new subsection:

8 “(d)(1)(A) A substantive change in regulations, man-  
9 ual instructions, interpretative rules, statements of policy,  
10 or guidelines of general applicability under this title shall  
11 not be applied (by extrapolation or otherwise) retroactively  
12 to items and services furnished before the effective date  
13 of the change, unless the Secretary determines that—

14 “(i) such retroactive application is necessary to  
15 comply with statutory requirements; or

16 “(ii) failure to apply the change retroactively  
17 would be contrary to the public interest.”.

18 (2) EFFECTIVE DATE.—The amendment made  
19 by paragraph (1) shall apply to substantive changes  
20 issued on or after the date of enactment of this Act.

21 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE  
22 CHANGES AFTER NOTICE.—

23 (1) IN GENERAL.—Section 1871(d)(1), as  
24 added by subsection (a), is amended by adding at  
25 the end the following:

1           “(B) A compliance action may be made against a pro-  
2 vider of services, physician, practitioner, or other supplier  
3 with respect to noncompliance with such a substantive  
4 change only for items and services furnished on or after  
5 the effective date of the change.

6           “(C)(i) Except as provided in clause (ii), a sub-  
7 stantive change may not take effect before the date that  
8 is the end of the 30-day period that begins on the date  
9 that the Secretary has issued or published, as the case  
10 may be, the substantive change.

11           “(ii) The Secretary may provide for a substantive  
12 change to take effect on a date that precedes the end of  
13 the 30-day period under clause (i) if the Secretary finds  
14 that waiver of such 30-day period is necessary to comply  
15 with statutory requirements or that the application of such  
16 30-day period is contrary to the public interest. If the Sec-  
17 retary provides for an earlier effective date pursuant to  
18 this clause, the Secretary shall include in the issuance or  
19 publication of the substantive change a finding described  
20 in the first sentence, and a brief statement of the reasons  
21 for such finding.”.

22           (2) EFFECTIVE DATE.—The amendment made  
23 by paragraph (1) shall apply to compliance actions  
24 undertaken on or after the date of enactment of this  
25 Act.

1 **SEC. 503. REPORT ON LEGAL AND REGULATORY INCON-**  
2 **SISTENCIES.**

3 Section 1871 (42 U.S.C. 1395hh), as amended by  
4 section 502(a)(1), is amended by adding at the end the  
5 following new subsection:

6 “(e)(1) Not later than 2 years after the date of enact-  
7 ment of this subsection, and every 3 years thereafter, the  
8 Secretary shall submit to Congress a report with respect  
9 to the administration of this title and areas of inconsist-  
10 ency or conflict among the various provisions under law  
11 and regulation.

12 “(2) In preparing a report under paragraph (1), the  
13 Secretary shall collect—

14 “(A) information from beneficiaries, providers  
15 of services, physicians, practitioners, and other sup-  
16 pliers with respect to such areas of inconsistency  
17 and conflict; and

18 “(B) information from medicare contractors  
19 that tracks the nature of all communications and  
20 correspondence.

21 “(3) A report under paragraph (1) shall include a de-  
22 scription of efforts by the Secretary to reduce such incon-  
23 sistency or conflicts, and recommendations for legislation  
24 or administrative action that the Secretary determines ap-  
25 propriate to further reduce such inconsistency or con-  
26 flicts.”.

1           **Subtitle B—Appeals Process**  
2                           **Reform**

3   **SEC. 511. SUBMISSION OF PLAN FOR TRANSFER OF RE-**  
4                           **SPONSIBILITY FOR MEDICARE APPEALS.**

5           (a) SUBMISSION OF TRANSITION PLAN.—

6                   (1) IN GENERAL.—Not later than April 1,  
7           2004, the Commissioner of Social Security and the  
8           Secretary shall develop and transmit to Congress  
9           and the Comptroller General of the United States a  
10          plan under which the functions of administrative law  
11          judges responsible for hearing cases under title  
12          XVIII of the Social Security Act (and related provi-  
13          sions in title XI of such Act) are transferred from  
14          the responsibility of the Commissioner and the So-  
15          cial Security Administration to the Secretary and  
16          the Department of Health and Human Services.

17                  (2) CONTENTS.—The plan shall include infor-  
18          mation on the following:

19                       (A) WORKLOAD.—The number of such ad-  
20                       ministrative law judges and support staff re-  
21                       quired now and in the future to hear and decide  
22                       such cases in a timely manner, taking into ac-  
23                       count the current and anticipated claims vol-  
24                       ume, appeals, number of beneficiaries, and stat-  
25                       utory changes.

1 (B) COST PROJECTIONS AND FINANC-  
2 ING.—Funding levels required for fiscal year  
3 2005 and subsequent fiscal years to carry out  
4 the functions transferred under the plan and  
5 how such transfer should be financed.

6 (C) TRANSITION TIMETABLE.—A timetable  
7 for the transition.

8 (D) REGULATIONS.—The establishment of  
9 specific regulations to govern the appeals proc-  
10 ess.

11 (E) CASE TRACKING.—The development of  
12 a unified case tracking system that will facili-  
13 tate the maintenance and transfer of case spe-  
14 cific data across both the fee-for-service and  
15 managed care components of the medicare pro-  
16 gram.

17 (F) FEASIBILITY OF PRECEDENTIAL AU-  
18 THORITY.—The feasibility of developing a proc-  
19 ess to give decisions of the Departmental Ap-  
20 peals Board in the Department of Health and  
21 Human Services addressing broad legal issues  
22 binding, precedential authority.

23 (G) ACCESS TO ADMINISTRATIVE LAW  
24 JUDGES.—The feasibility of—

1 (i) filing appeals with administrative  
2 law judges electronically; and

3 (ii) conducting hearings using tele- or  
4 video-conference technologies.

5 (H) INDEPENDENCE OF ADMINISTRATIVE  
6 LAW JUDGES.—The steps that should be taken  
7 to ensure the independence of administrative  
8 law judges, including ensuring that such judges  
9 are in an office that is functionally and oper-  
10 ationally separate from the Centers for Medi-  
11 care and Medicaid Services and the Center for  
12 Medicare Choices.

13 (I) GEOGRAPHIC DISTRIBUTION.—The  
14 steps that should be taken to provide for an ap-  
15 propriate geographic distribution of administra-  
16 tive law judges throughout the United States to  
17 ensure timely access to such judges.

18 (J) HIRING.—The steps that should be  
19 taken to hire administrative law judges (and  
20 support staff).

21 (K) PERFORMANCE STANDARDS.—The es-  
22 tablishment of performance standards for ad-  
23 ministrative law judges with respect to timelines  
24 for decisions in cases under title XVIII of the  
25 Social Security Act.

1           (L) SHARED RESOURCES.—The feasibility  
2 of the Secretary entering into such arrange-  
3 ments with the Commissioner of Social Security  
4 as may be appropriate with respect to trans-  
5 ferred functions under the plan to share office  
6 space, support staff, and other resources, with  
7 appropriate reimbursement.

8           (M) TRAINING.—The training that should  
9 be provided to administrative law judges with  
10 respect to laws and regulations under title  
11 XVIII of the Social Security Act.

12           (3) ADDITIONAL INFORMATION.—The plan may  
13 also include recommendations for further congres-  
14 sional action, including modifications to the require-  
15 ments and deadlines established under section 1869  
16 of the Social Security Act (as amended by sections  
17 521 and 522 of BIPA (114 Stat. 2763A–534) and  
18 this Act).

19           (b) GAO EVALUATION.—The Comptroller General of  
20 the United States shall—

21           (1) evaluate the plan submitted under sub-  
22 section (a); and

23           (2) not later than 6 months after such submis-  
24 sion, submit to Congress, the Commissioner of So-

1       cial Security, and the Secretary a report on such  
2       evaluation.

3       (c) **SUBMISSION OF GAO REPORT REQUIRED BE-**  
4 **FORE PLAN IMPLEMENTATION.**—The Commissioner of  
5 Social Security and the Secretary may not implement the  
6 plan developed under subsection (a) before the date that  
7 is 6 months after the date the report required under sub-  
8 section (b)(2) is submitted to the Commissioner and the  
9 Secretary.

10 **SEC. 512. EXPEDITED ACCESS TO JUDICIAL REVIEW.**

11       (a) **IN GENERAL.**—Section 1869(b) (42 U.S.C.  
12 1395ff(b)) is amended—

13               (1) in paragraph (1)(A), by inserting “, subject  
14       to paragraph (2),” before “to judicial review of the  
15       Secretary’s final decision”; and

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

18               “(2) **EXPEDITED ACCESS TO JUDICIAL RE-**  
19 **VIEW.**—

20               “(A) **IN GENERAL.**—The Secretary shall  
21       establish a process under which a provider of  
22       services or supplier that furnishes an item or  
23       service or a beneficiary who has filed an appeal  
24       under paragraph (1) (other than an appeal filed  
25       under paragraph (1)(F)(i)) may obtain access

1 to judicial review when a review entity (de-  
2 scribed in subparagraph (D)), on its own mo-  
3 tion or at the request of the appellant, deter-  
4 mines that the Departmental Appeals Board  
5 does not have the authority to decide the ques-  
6 tion of law or regulation relevant to the matters  
7 in controversy and that there is no material  
8 issue of fact in dispute. The appellant may  
9 make such request only once with respect to a  
10 question of law or regulation for a specific mat-  
11 ter in dispute in a case of an appeal.

12 “(B) PROMPT DETERMINATIONS.—If, after  
13 or coincident with appropriately filing a request  
14 for an administrative hearing, the appellant re-  
15 quests a determination by the appropriate re-  
16 view entity that the Departmental Appeals  
17 Board does not have the authority to decide the  
18 question of law or regulations relevant to the  
19 matters in controversy and that there is no ma-  
20 terial issue of fact in dispute, and if such re-  
21 quest is accompanied by the documents and  
22 materials as the appropriate review entity shall  
23 require for purposes of making such determina-  
24 tion, such review entity shall make a determina-  
25 tion on the request in writing within 60 days

1 after the date such review entity receives the re-  
2 quest and such accompanying documents and  
3 materials. Such a determination by such review  
4 entity shall be considered a final decision and  
5 not subject to review by the Secretary.

6 “(C) ACCESS TO JUDICIAL REVIEW.—

7 “(i) IN GENERAL.—If the appropriate  
8 review entity—

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

15 “(II) fails to make such deter-  
16 mination within the period provided  
17 under subparagraph (B);

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

20 “(ii) DEADLINE FOR FILING.—Such  
21 action shall be filed, in the case described  
22 in—

23 “(I) clause (i)(I), within 60 days  
24 of the date of the determination de-  
25 scribed in such clause; or

1                   “(II) clause (i)(II), within 60  
2                   days of the end of the period provided  
3                   under subparagraph (B) for the deter-  
4                   mination.

5                   “(iii) VENUE.—Such action shall be  
6                   brought in the district court of the United  
7                   States for the judicial district in which the  
8                   appellant is located (or, in the case of an  
9                   action brought jointly by more than 1 ap-  
10                  plicant, the judicial district in which the  
11                  greatest number of applicants are located)  
12                  or in the District Court for the District of  
13                  Columbia.

14                  “(iv) INTEREST ON ANY AMOUNTS IN  
15                  CONTROVERSY.—Where a provider of serv-  
16                  ices or supplier is granted judicial review  
17                  pursuant to this paragraph, the amount in  
18                  controversy (if any) shall be subject to an-  
19                  nual interest beginning on the first day of  
20                  the first month beginning after the 60-day  
21                  period as determined pursuant to clause  
22                  (ii) and equal to the rate of interest on ob-  
23                  ligations issued for purchase by the Fed-  
24                  eral Supplementary Medical Insurance  
25                  Trust Fund for the month in which the

1 civil action authorized under this para-  
2 graph is commenced, to be awarded by the  
3 reviewing court in favor of the prevailing  
4 party. No interest awarded pursuant to the  
5 preceding sentence shall be deemed income  
6 or cost for the purposes of determining re-  
7 imbursement due providers of services,  
8 physicians, practitioners, and other sup-  
9 pliers under this Act.

10 “(D) REVIEW ENTITY DEFINED.—For pur-  
11 poses of this subsection, a ‘review entity’ is a  
12 panel of no more than 3 members from the De-  
13 partmental Appeals Board, selected for the pur-  
14 pose of making determinations under this para-  
15 graph.”.

16 (b) APPLICATION TO PROVIDER AGREEMENT DETER-  
17 MINATIONS.—Section 1866(h)(1) (42 U.S.C.  
18 1395cc(h)(1)) is amended—

19 (1) by inserting “(A)” after “(h)(1)”; and

20 (2) by adding at the end the following new sub-  
21 paragraph:

22 “(B) An institution or agency described in subpara-  
23 graph (A) that has filed for a hearing under subparagraph  
24 (A) shall have expedited access to judicial review under  
25 this subparagraph in the same manner as providers of

1 services, suppliers, and beneficiaries may obtain expedited  
2 access to judicial review under the process established  
3 under section 1869(b)(2). Nothing in this subparagraph  
4 shall be construed to affect the application of any remedy  
5 imposed under section 1819 during the pendency of an  
6 appeal under this subparagraph.”.

7 (c) GAO STUDY AND REPORT ON ACCESS TO JUDI-  
8 CIAL REVIEW.—

9 (1) STUDY.—The Comptroller General of the  
10 United States shall conduct a study on the access of  
11 medicare beneficiaries and health care providers to  
12 judicial review of actions of the Secretary and the  
13 Department of Health and Human Services with re-  
14 spect to items and services under title XVIII of the  
15 Social Security Act subsequent to February 29,  
16 2000, the date of the decision of Shalala, Secretary  
17 of Health and Human Services, et al. v. Illinois  
18 Council on Long Term Care, Inc. (529 U.S. 1  
19 (2000)).

20 (2) REPORT.—Not later than 1 year after the  
21 date of enactment of this Act, the Comptroller Gen-  
22 eral shall submit to Congress a report on the study  
23 conducted under paragraph (1) together with such  
24 recommendations as the Comptroller General deter-  
25 mines to be appropriate.

1 (d) CONFORMING AMENDMENT.—Section  
2 1869(b)(1)(F)(ii) (42 U.S.C. 1395ff(b)(1)(F)(ii)) is  
3 amended to read as follows:

4 “(ii) REFERENCE TO EXPEDITED AC-  
5 CESS TO JUDICIAL REVIEW.—For the pro-  
6 vision relating to expedited access to judi-  
7 cial review, see paragraph (2).”.

8 (e) EFFECTIVE DATE.—The amendments made by  
9 this section shall apply to appeals filed on or after October  
10 1, 2004.

11 **SEC. 513. EXPEDITED REVIEW OF CERTAIN PROVIDER**  
12 **AGREEMENT DETERMINATIONS.**

13 (a) TERMINATION AND CERTAIN OTHER IMMEDIATE  
14 REMEDIES.—

15 (1) IN GENERAL.—The Secretary shall develop  
16 and implement a process to expedite proceedings  
17 under sections 1866(h) of the Social Security Act  
18 (42 U.S.C. 1395cc(h)) in which—

19 (A) the remedy of termination of participa-  
20 tion has been imposed;

21 (B) a sanction described in clause (i) or  
22 (iii) of section 1819(h)(2)(B) of such Act (42  
23 U.S.C. 1395i–3(h)(2)(B)) has been imposed,  
24 but only if such sanction has been imposed on  
25 an immediate basis; or

1 (C) the Secretary has required a skilled  
2 nursing facility to suspend operations of a  
3 nurse aide training program.

4 (2) PRIORITY FOR CASES OF TERMINATION.—  
5 Under the process described in paragraph (1), pri-  
6 ority shall be provided in cases of termination de-  
7 scribed in subparagraph (A) of such paragraph.

8 (b) INCREASED FINANCIAL SUPPORT.—In addition  
9 to any amounts otherwise appropriated, to reduce by 50  
10 percent the average time for administrative determina-  
11 tions on appeals under section 1866(h) of the Social Secu-  
12 rity Act (42 U.S.C. 1395cc(h)), there are authorized to  
13 be appropriated (in appropriate part from the Federal  
14 Hospital Insurance Trust Fund and the Federal Supple-  
15 mentary Medical Insurance Trust Fund) to the Secretary  
16 such sums for fiscal year 2004 and each subsequent fiscal  
17 year as may be necessary to increase the number of ad-  
18 ministrative law judges (and their staffs) at the Depart-  
19 mental Appeals Board of the Department of Health and  
20 Human Services and to educate such judges and staff on  
21 long-term care issues.

22 **SEC. 514. REVISIONS TO MEDICARE APPEALS PROCESS.**

23 (a) TIMEFRAMES FOR THE COMPLETION OF THE  
24 RECORD.—Section 1869(b) (42 U.S.C. 1395ff(b)), as

1 amended by section 512(a)(2), is amended by adding at  
2 the end the following new paragraph:

3 “(3) TIMELY COMPLETION OF THE RECORD.—

4 “(A) DEADLINE.—Subject to subpara-  
5 graph (B), the deadline to complete the record  
6 in a hearing before an administrative law judge  
7 or a review by the Departmental Appeals Board  
8 is 90 days after the date the request for the re-  
9 view or hearing is filed.

10 “(B) EXTENSIONS FOR GOOD CAUSE.—

11 The person filing a request under subparagraph  
12 (A) may request an extension of such deadline  
13 for good cause. The administrative law judge,  
14 in the case of a hearing, and the Departmental  
15 Appeals Board, in the case of a review, may ex-  
16 tend such deadline based upon a finding of  
17 good cause to a date specified by the judge or  
18 Board, as the case may be.

19 “(C) DELAY IN DECISION DEADLINES

20 UNTIL COMPLETION OF RECORD.—Notwith-  
21 standing any other provision of this section, the  
22 deadlines otherwise established under sub-  
23 section (d) for the making of determinations in  
24 hearings or review under this section are 90

1 days after the date on which the record is com-  
2 plete.

3 “(D) COMPLETE RECORD DESCRIBED.—  
4 For purposes of this paragraph, a record is  
5 complete when the administrative law judge, in  
6 the case of a hearing, or the Departmental Ap-  
7 peals Board, in the case of a review, has re-  
8 ceived—

9 “(i) written or testimonial evidence, or  
10 both, submitted by the person filing the re-  
11 quest,

12 “(ii) written or oral argument, or  
13 both,

14 “(iii) the decision of, and the record  
15 for, the prior level of appeal, and

16 “(iv) such other evidence as such  
17 judge or Board, as the case may be, deter-  
18 mines is required to make a determination  
19 on the request.”.

20 (b) USE OF PATIENTS’ MEDICAL RECORDS.—Section  
21 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)) is amend-  
22 ed by inserting “(including the medical records of the indi-  
23 vidual involved)” after “clinical experience”.

24 (c) NOTICE REQUIREMENTS FOR MEDICARE AP-  
25 PEALS.—

1           (1) INITIAL DETERMINATIONS AND REDETER-  
2           MINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a))  
3           is amended by adding at the end the following new  
4           paragraph:

5           “(4) REQUIREMENTS OF NOTICE OF DETER-  
6           MINATIONS AND REDETERMINATIONS.—A written  
7           notice of a determination on an initial determination  
8           or on a redetermination, insofar as such determina-  
9           tion or redetermination results in a denial of a claim  
10          for benefits, shall be provided in printed form and  
11          written in a manner to be understood by the bene-  
12          ficiary and shall include—

13               “(A) the reasons for the determination, in-  
14               cluding, as appropriate—

15                       “(i) upon request in the case of an  
16                       initial determination, the provision of the  
17                       policy, manual, or regulation that resulted  
18                       in the denial; and

19                       “(ii) in the case of a redetermination,  
20                       a summary of the clinical or scientific evi-  
21                       dence used in making the determination  
22                       (as appropriate);

23               “(B) the procedures for obtaining addi-  
24               tional information concerning the determination  
25               or redetermination; and

1           “(C) notification of the right to seek a re-  
2           determination or otherwise appeal the deter-  
3           mination and instructions on how to initiate  
4           such a redetermination or appeal under this  
5           section.”.

6           (2)                   RECONSIDERATIONS.—Section  
7           1869(e)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)) is  
8           amended to read as follows:

9           “(E) EXPLANATION OF DECISION.—Any  
10          decision with respect to a reconsideration of a  
11          qualified independent contractor shall be in  
12          writing in a manner to be understood by the  
13          beneficiary and shall include—

14                 “(i) to the extent appropriate, a de-  
15                 tailed explanation of the decision as well as  
16                 a discussion of the pertinent facts and ap-  
17                 plicable regulations applied in making such  
18                 decision;

19                 “(ii) a notification of the right to ap-  
20                 peal such determination and instructions  
21                 on how to initiate such appeal under this  
22                 section; and

23                 “(iii) in the case of a determination of  
24                 whether an item or service is reasonable  
25                 and necessary for the diagnosis or treat-

1           ment of illness or injury (under section  
2           1862(a)(1)(A)) an explanation of the med-  
3           ical or scientific rationale for the deci-  
4           sion.”.

5           (3) APPEALS.—Section 1869(d) (42 U.S.C.  
6           1395ff(d)) is amended—

7           (A) in the heading, by inserting “; NO-  
8           TICE” after “SECRETARY”; and

9           (B) by adding at the end the following new  
10          paragraph:

11          “(4) NOTICE.—Notice of the decision of an ad-  
12          ministrative law judge shall be in writing in a man-  
13          ner to be understood by the beneficiary and shall in-  
14          clude—

15                 “(A) the specific reasons for the deter-  
16                 mination (including, to the extent appropriate,  
17                 a summary of the clinical or scientific evidence  
18                 used in making the determination);

19                 “(B) the procedures for obtaining addi-  
20                 tional information concerning the decision; and

21                 “(C) notification of the right to appeal the  
22                 decision and instructions on how to initiate  
23                 such an appeal under this section.”.

24          (4) PREPARATION OF RECORD FOR APPEAL.—  
25          Section 1869(c)(3)(J) (42 U.S.C. 1395ff(c)(3)(J)) is

1 amended by striking “such information as is re-  
2 quired for an appeal” and inserting “the record for  
3 the appeal”.

4 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

5 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED  
6 INDEPENDENT CONTRACTORS.—Section 1869(c) (42  
7 U.S.C. 1395ff(c)) is amended—

8 (A) in paragraph (2)—

9 (i) by inserting “(except in the case of  
10 a utilization and quality control peer re-  
11 view organization, as defined in section  
12 1152)” after “means an entity or organi-  
13 zation that”; and

14 (ii) by striking the period at the end  
15 and inserting the following: “and meets the  
16 following requirements:

17 “(A) GENERAL REQUIREMENTS.—

18 “(i) The entity or organization has  
19 (directly or through contracts or other ar-  
20 rangements) sufficient medical, legal, and  
21 other expertise (including knowledge of the  
22 program under this title) and sufficient  
23 staffing to carry out duties of a qualified  
24 independent contractor under this section  
25 on a timely basis.

1           “(ii) The entity or organization has  
2 provided assurances that it will conduct ac-  
3 tivities consistent with the applicable re-  
4 quirements of this section, including that it  
5 will not conduct any activities in a case un-  
6 less the independence requirements of sub-  
7 paragraph (B) are met with respect to the  
8 case.

9           “(iii) The entity or organization meets  
10 such other requirements as the Secretary  
11 provides by regulation.

12           “(B) INDEPENDENCE REQUIREMENTS.—

13           “(i) IN GENERAL.—Subject to clause  
14 (ii), an entity or organization meets the  
15 independence requirements of this sub-  
16 paragraph with respect to any case if the  
17 entity—

18                   “(I) is not a related party (as de-  
19 fined in subsection (g)(5));

20                   “(II) does not have a material fa-  
21 milial, financial, or professional rela-  
22 tionship with such a party in relation  
23 to such case; and

1                   “(III) does not otherwise have a  
2                   conflict of interest with such a party  
3                   (as determined under regulations).

4                   “(ii) EXCEPTION FOR COMPENSA-  
5                   TION.—Nothing in clause (i) shall be con-  
6                   strued to prohibit receipt by a qualified  
7                   independent contractor of compensation  
8                   from the Secretary for the conduct of ac-  
9                   tivities under this section if the compensa-  
10                  tion is provided consistent with clause (iii).

11                  “(iii) LIMITATIONS ON ENTITY COM-  
12                  PENSATION.—Compensation provided by  
13                  the Secretary to a qualified independent  
14                  contractor in connection with reviews  
15                  under this section shall not be contingent  
16                  on any decision rendered by the contractor  
17                  or by any reviewing professional.”; and

18                  (B) in paragraph (3)(A), by striking “,  
19                  and shall have sufficient training and expertise  
20                  in medical science and legal matters to make  
21                  reconsiderations under this subsection”.

22                  (2) ELIGIBILITY REQUIREMENTS FOR REVIEW-  
23                  ERS.—Section 1869 (42 U.S.C. 1395ff) is amend-  
24                  ed—

1 (A) by amending subsection (c)(3)(D) to  
2 read as follows:

3 “(D) QUALIFICATIONS OF REVIEWERS.—  
4 The requirements of subsection (g) shall be met  
5 (relating to qualifications of reviewing profes-  
6 sionals).”; and

7 (B) by adding at the end the following new  
8 subsection:

9 “(g) QUALIFICATIONS OF REVIEWERS.—

10 “(1) IN GENERAL.—In reviewing determina-  
11 tions under this section, a qualified independent con-  
12 tractor shall assure that—

13 “(A) each individual conducting a review  
14 shall meet the qualifications of paragraph (2);

15 “(B) compensation provided by the con-  
16 tractor to each such reviewer is consistent with  
17 paragraph (3); and

18 “(C) in the case of a review by a panel de-  
19 scribed in subsection (c)(3)(B) composed of  
20 physicians or other health care professionals  
21 (each in this subsection referred to as a ‘review-  
22 ing professional’), each reviewing professional  
23 meets the qualifications described in paragraph  
24 (4).

25 “(2) INDEPENDENCE.—

1           “(A) IN GENERAL.—Subject to subpara-  
2 graph (B), each individual conducting a review  
3 in a case shall—

4                   “(i) not be a related party (as defined  
5 in paragraph (5));

6                   “(ii) not have a material familial, fi-  
7 nancial, or professional relationship with  
8 such a party in the case under review; and

9                   “(iii) not otherwise have a conflict of  
10 interest with such a party (as determined  
11 under regulations).

12           “(B) EXCEPTION.—Nothing in subpara-  
13 graph (A) shall be construed to—

14                   “(i) prohibit an individual, solely on  
15 the basis of affiliation with a fiscal inter-  
16 mediary, carrier, or other contractor, from  
17 serving as a reviewing professional if—

18                           “(I) a nonaffiliated individual is  
19 not reasonably available;

20                           “(II) the affiliated individual is  
21 not involved in the provision of items  
22 or services in the case under review;

23                           “(III) the fact of such an affili-  
24 ation is disclosed to the Secretary and  
25 the beneficiary (or authorized rep-

1           representative) and neither party objects;  
2           and

3                   “(IV) the affiliated individual is  
4           not an employee of the intermediary,  
5           carrier, or contractor and does not  
6           provide services exclusively or pri-  
7           marily to or on behalf of such inter-  
8           mediary, carrier, or contractor;

9                   “(ii) prohibit an individual who has  
10          staff privileges at the institution where the  
11          treatment involved takes place from serv-  
12          ing as a reviewer merely on the basis of  
13          such affiliation if the affiliation is disclosed  
14          to the Secretary and the beneficiary (or  
15          authorized representative), and neither  
16          party objects; or

17                   “(iii) prohibit receipt of compensation  
18          by a reviewing professional from a con-  
19          tractor if the compensation is provided  
20          consistent with paragraph (3).

21                   “(3) LIMITATIONS ON REVIEWER COMPENSA-  
22          TION.—Compensation provided by a qualified inde-  
23          pendent contractor to a reviewer in connection with  
24          a review under this section shall not be contingent  
25          on the decision rendered by the reviewer.

1           “(4) LICENSURE AND EXPERTISE.—Each re-  
2           viewing professional shall be a physician (allopathic  
3           or osteopathic) or health care professional who—

4                   “(A) is appropriately credentialed or li-  
5                   censed in 1 or more States to deliver health  
6                   care services; and

7                   “(B) has medical expertise in the field of  
8                   practice that is appropriate for the items or  
9                   services at issue.

10           “(5) RELATED PARTY DEFINED.—For purposes  
11           of this section, the term ‘related party’ means, with  
12           respect to a case under this title involving an indi-  
13           vidual beneficiary, any of the following:

14                   “(A) The Secretary, the medicare adminis-  
15                   trative contractor involved, or any fiduciary, of-  
16                   ficer, director, or employee of the Department  
17                   of Health and Human Services, or of such con-  
18                   tractor.

19                   “(B) The individual (or authorized rep-  
20                   resentative).

21                   “(C) The health care professional that pro-  
22                   vides the items or services involved in the case.

23                   “(D) The institution at which the items or  
24                   services (or treatment) involved in the case are  
25                   provided.

1           “(E) The manufacturer of any drug or  
2           other item that is included in the items or serv-  
3           ices involved in the case.

4           “(F) Any other party determined under  
5           any regulations to have a substantial interest in  
6           the case involved.”.

7           (3) NUMBER OF QUALIFIED INDEPENDENT  
8           CONTRACTORS.—Section 1869(c)(4) (42 U.S.C.  
9           1395ff(c)(4)) is amended by striking “12” and in-  
10          serting “4”.

11          (e) IMPLEMENTATION OF CERTAIN BIPA RE-  
12          FORMS.—

13           (1) DELAY IN CERTAIN BIPA REFORMS.—Sec-  
14           tion 521(d) of BIPA (114 Stat. 2763A–543) is  
15           amended to read as follows:

16          “(d) EFFECTIVE DATE.—

17           “(1) IN GENERAL.—Except as specified in  
18           paragraph (2), the amendments made by this section  
19           shall apply with respect to initial determinations  
20           made on or after December 1, 2004.

21           “(2) EXPEDITED PROCEEDINGS AND RECONSID-  
22           ERATION REQUIREMENTS.—For the following provi-  
23           sions, the amendments made by subsection (a) shall  
24           apply with respect to initial determinations made on  
25           or after October 1, 2003:

1           “(A) Subsection (b)(1)(F)(i) of section  
2           1869 of the Social Security Act.

3           “(B) Subsection (c)(3)(C)(iii) of such sec-  
4           tion.

5           “(C) Subsection (c)(3)(C)(iv) of such sec-  
6           tion to the extent that it applies to expedited  
7           reconsiderations under subsection (c)(3)(C)(iii)  
8           of such section.

9           “(3) TRANSITIONAL USE OF PEER REVIEW OR-  
10          GANIZATIONS TO CONDUCT EXPEDITED RECONSID-  
11          ERATIONS UNTIL QICS ARE OPERATIONAL.—Expe-  
12          dited reconsiderations of initial determinations under  
13          section 1869(c)(3)(C)(iii) of the Social Security Act  
14          shall be made by peer review organizations until  
15          qualified independent contractors are available for  
16          such expedited reconsiderations.”.

17          (2) CONFORMING AMENDMENTS.—Section  
18          521(c) of BIPA (114 Stat. 2763A–543) and section  
19          1869(c)(3)(C)(iii)(III) of the Social Security Act (42  
20          U.S.C. 1395ff(c)(3)(C)(iii)(III)), as added by section  
21          521 of BIPA, are repealed.

22          (f) EFFECTIVE DATE.—The amendments made by  
23          this section shall be effective as if included in the enact-  
24          ment of the respective provisions of subtitle C of title V  
25          of BIPA, 114 Stat. 2763A–534.

1 (g) TRANSITION.—In applying section 1869(g) of the  
2 Social Security Act (as added by subsection (d)(2)), any  
3 reference to a medicare administrative contractor shall be  
4 deemed to include a reference to a fiscal intermediary  
5 under section 1816 of the Social Security Act (42 U.S.C.  
6 1395h) and a carrier under section 1842 of such Act (42  
7 U.S.C. 1395u).

8 **SEC. 515. HEARING RIGHTS RELATED TO DECISIONS BY**  
9 **THE SECRETARY TO DENY OR NOT RENEW A**  
10 **MEDICARE ENROLLMENT AGREEMENT; CON-**  
11 **SULTATION BEFORE CHANGING PROVIDER**  
12 **ENROLLMENT FORMS.**

13 (a) HEARING RIGHTS.—

14 (1) IN GENERAL.—Section 1866 (42 U.S.C.  
15 1395cc) is amended by adding at the end the fol-  
16 lowing new subsection:

17 “(j) HEARING RIGHTS IN CASES OF DENIAL OR  
18 NONRENEWAL.—The Secretary shall establish by regula-  
19 tion procedures under which—

20 “(1) there are deadlines for actions on applica-  
21 tions for enrollment (and, if applicable, renewal of  
22 enrollment); and

23 “(2) providers of services, physicians, practi-  
24 tioners, and suppliers whose application to enroll  
25 (or, if applicable, to renew enrollment) are denied

1 are provided a mechanism to appeal such denial and  
2 a deadline for consideration of such appeals.”.

3 (2) EFFECTIVE DATE.—The Secretary shall  
4 provide for the establishment of the procedures  
5 under the amendment made by paragraph (1) within  
6 18 months after the date of enactment of this Act.

7 (b) CONSULTATION BEFORE CHANGING PROVIDER  
8 ENROLLMENT FORMS.—Section 1871 (42 U.S.C.  
9 1395hh), as amended by sections 502 and 503, is amend-  
10 ed by adding at the end the following new subsection:

11 “(f) The Secretary shall consult with providers of  
12 services, physicians, practitioners, and suppliers before  
13 making changes in the provider enrollment forms required  
14 of such providers, physicians, practitioners, and suppliers  
15 to be eligible to submit claims for which payment may be  
16 made under this title.”.

17 **SEC. 516. APPEALS BY PROVIDERS WHEN THERE IS NO**  
18 **OTHER PARTY AVAILABLE.**

19 (a) IN GENERAL.—Section 1870 (42 U.S.C. 1395gg)  
20 is amended by adding at the end the following new sub-  
21 section:

22 “(h) Notwithstanding subsection (f) or any other pro-  
23 vision of law, the Secretary shall permit a provider of serv-  
24 ices, physician, practitioner, or other supplier to appeal  
25 any determination of the Secretary under this title relating

1 to services rendered under this title to an individual who  
 2 subsequently dies if there is no other party available to  
 3 appeal such determination.”.

4 (b) EFFECTIVE DATE.—The amendment made by  
 5 subsection (a) shall take effect on the date of enactment  
 6 of this Act and shall apply to items and services furnished  
 7 on or after such date.

8 **SEC. 517. PROVIDER ACCESS TO REVIEW OF LOCAL COV-**  
 9 **ERAGE DETERMINATIONS.**

10 (a) PROVIDER ACCESS TO REVIEW OF LOCAL COV-  
 11 ERAGE DETERMINATIONS.—Section 1869(f)(5) (42  
 12 U.S.C. 1395ff(f)(5)) is amended to read as follows:

13 “(5) AGGRIEVED PARTY DEFINED.—In this sec-  
 14 tion, the term ‘aggrieved party’ means—

15 “(A) with respect to a national coverage  
 16 determination, an individual entitled to benefits  
 17 under part A, or enrolled under part B, or both,  
 18 who is in need of the items or services that are  
 19 the subject of the coverage determination; and

20 “(B) with respect to a local coverage deter-  
 21 mination—

22 “(i) an individual who is entitled to  
 23 benefits under part A, or enrolled under  
 24 part B, or both, who is adversely affected  
 25 by such a determination; or

1                   “(ii) a provider of services, physician,  
2                   practitioner, or supplier that is adversely  
3                   affected by such a determination.”.

4           (b) CLARIFICATION OF LOCAL COVERAGE DETER-  
5 MINATION DEFINITION.—Section 1869(f)(2)(B) (42  
6 U.S.C. 1395ff(f)(2)(B)) is amended by inserting “, includ-  
7 ing, where appropriate, the specific requirements and clin-  
8 ical indications relating to the medical necessity of an item  
9 or service” before the period at the end.

10          (c) REQUEST FOR LOCAL COVERAGE DETERMINA-  
11 TIONS BY PROVIDERS.—Section 1869 (42 U.S.C. 1395ff),  
12 as amended by section 514(d)(2)(B), is amended by add-  
13 ing at the end the following new subsection:

14          “(h) REQUEST FOR LOCAL COVERAGE DETERMINA-  
15 TIONS BY PROVIDERS.—

16               “(1) ESTABLISHMENT OF PROCESS.—The Sec-  
17 retary shall establish a process under which a pro-  
18 vider of services, physician, practitioner, or supplier  
19 who certifies that they meet the requirements estab-  
20 lished in paragraph (3) may request a local coverage  
21 determination in accordance with the succeeding  
22 provisions of this subsection.

23               “(2) PROVIDER LOCAL COVERAGE DETERMINA-  
24 TION REQUEST DEFINED.—In this subsection, the  
25 term ‘provider local coverage determination request’

1 means a request, filed with the Secretary, at such  
2 time and in such form and manner as the Secretary  
3 may specify, that the Secretary, pursuant to para-  
4 graph (4)(A), require a fiscal intermediary, carrier,  
5 or program safeguard contractor to make or revise  
6 a local coverage determination under this section  
7 with respect to an item or service.

8 “(3) REQUEST REQUIREMENTS.—Under the  
9 process established under paragraph (1), by not  
10 later than 30 days after the date on which a pro-  
11 vider local coverage determination request is filed  
12 under paragraph (1), the Secretary shall determine  
13 whether such request establishes that—

14 “(A) there have been at least 5 reversals of  
15 redeterminations made by a fiscal intermediary  
16 or carrier after a hearing before an administra-  
17 tive law judge on claims submitted by the pro-  
18 vider in at least 2 different cases before an ad-  
19 ministrative law judge;

20 “(B) each reversal described in subpara-  
21 graph (A) involves substantially similar mate-  
22 rial facts;

23 “(C) each reversal described in subpara-  
24 graph (A) involves the same medical necessity  
25 issue; and

1           “(D) at least 50 percent of the total num-  
2 ber of claims submitted by such provider within  
3 the past year involving the substantially similar  
4 material facts described in subparagraph (B)  
5 and the same medical necessity issue described  
6 in subparagraph (C) have been denied and have  
7 been reversed by an administrative law judge.

8           “(4) APPROVAL OR REJECTION OF REQUEST.—

9           “(A) APPROVAL OF REQUEST.—If the Sec-  
10 retary determines that subparagraphs (A)  
11 through (D) of paragraph (3) have been satis-  
12 fied, the Secretary shall require the fiscal inter-  
13 mediary, carrier, or program safeguard con-  
14 tractor identified in the provider local coverage  
15 determination request, to make or revise a local  
16 coverage determination with respect to the item  
17 or service that is the subject of the request not  
18 later than the date that is 210 days after the  
19 date on which the Secretary makes the deter-  
20 mination. Such fiscal intermediary, carrier, or  
21 program safeguard contractor shall retain the  
22 discretion to determine whether or not, and/or  
23 the circumstances under which, to cover the  
24 item or service for which a local coverage deter-  
25 mination is requested. Nothing in this sub-

1 section shall be construed to require a fiscal  
2 intermediary, carrier or program safeguard con-  
3 tractor to develop a local coverage determina-  
4 tion that is inconsistent with any national cov-  
5 erage determination, or any coverage provision  
6 in this title or in regulation, manual, or inter-  
7 pretive guidance of the Secretary.

8 “(B) REJECTION OF REQUEST.—If the  
9 Secretary determines that subparagraphs (A)  
10 through (D) of paragraph (3) have not been  
11 satisfied, the Secretary shall reject the provider  
12 local coverage determination request and shall  
13 notify the provider of services, physician, practi-  
14 tioner, or supplier that filed the request of the  
15 reason for such rejection and no further pro-  
16 ceedings in relation to such request shall be  
17 conducted.”.

18 (d) STUDY AND REPORT ON THE USE OF CONTRAC-  
19 TORS TO MONITOR MEDICARE APPEALS.—

20 (1) STUDY.—The Secretary shall conduct a  
21 study on the feasibility and advisability of requiring  
22 fiscal intermediaries and carriers to monitor and  
23 track—

24 (A) the subject matter and status of claims  
25 denied by the fiscal intermediary or carrier (as

1 applicable) that are appealed under section  
2 1869 of the Social Security Act (42 U.S.C.  
3 1395ff), as added by section 522 of BIPA (114  
4 Stat. 2763A–543) and amended by this Act;  
5 and

6 (B) any final determination made with re-  
7 spect to such claims.

8 (2) REPORT.—Not later than the date that is  
9 1 year after the date of enactment of this Act, the  
10 Secretary shall submit to Congress a report on the  
11 study conducted under paragraph (1) together with  
12 such recommendations for legislation and adminis-  
13 trative action as the Commission determines appro-  
14 priate.

15 (e) AUTHORIZATION OF APPROPRIATIONS.—There  
16 are authorized to be appropriated such sums as are nec-  
17 essary to carry out the amendments made by subsections  
18 (a), (b), and (c).

19 (f) EFFECTIVE DATES.—

20 (1) PROVIDER ACCESS TO REVIEW OF LOCAL  
21 COVERAGE DETERMINATIONS.—The amendments  
22 made by subsections (a) and (b) shall apply to—

23 (A) any review of any local coverage deter-  
24 mination filed on or after October 1, 2003;

1 (B) any request to make such a determina-  
2 tion made on or after such date; or

3 (C) any local coverage determination made  
4 on or after such date.

5 (2) PROVIDER LOCAL COVERAGE DETERMINA-  
6 TION REQUESTS.—The amendment made by sub-  
7 section (c) shall apply with respect to provider local  
8 coverage determination requests (as defined in sec-  
9 tion 1869(h)(2) of the Social Security Act, as added  
10 by subsection (c)) filed on or after the date of enact-  
11 ment of this Act.

## 12 **Subtitle C—Contracting Reform**

### 13 **SEC. 521. INCREASED FLEXIBILITY IN MEDICARE ADMINIS-** 14 **TRATION.**

15 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE  
16 ADMINISTRATION.—

17 (1) IN GENERAL.—Title XVIII is amended by  
18 inserting after section 1874 the following new sec-  
19 tion:

20 “CONTRACTS WITH MEDICARE ADMINISTRATIVE  
21 CONTRACTORS

22 “SEC. 1874A. (a) AUTHORITY.—

23 “(1) AUTHORITY TO ENTER INTO CON-  
24 TRACTS.—The Secretary may enter into contracts  
25 with any eligible entity to serve as a medicare ad-  
26 ministrative contractor with respect to the perform-

1       ance of any or all of the functions described in para-  
2       graph (4) or parts of those functions (or, to the ex-  
3       tent provided in a contract, to secure performance  
4       thereof by other entities).

5           “(2) ELIGIBILITY OF ENTITIES.—An entity is  
6       eligible to enter into a contract with respect to the  
7       performance of a particular function described in  
8       paragraph (4) only if—

9           “(A) the entity has demonstrated capa-  
10       bility to carry out such function;

11          “(B) the entity complies with such conflict  
12       of interest standards as are generally applicable  
13       to Federal acquisition and procurement;

14          “(C) the entity has sufficient assets to fi-  
15       nancially support the performance of such func-  
16       tion; and

17          “(D) the entity meets such other require-  
18       ments as the Secretary may impose.

19           “(3) MEDICARE ADMINISTRATIVE CONTRACTOR  
20       DEFINED.—For purposes of this title and title XI—

21          “(A) IN GENERAL.—The term ‘medicare  
22       administrative contractor’ means an agency, or-  
23       ganization, or other person with a contract  
24       under this section.

1           “(B) APPROPRIATE MEDICARE ADMINIS-  
2           TRATIVE CONTRACTOR.—With respect to the  
3           performance of a particular function in relation  
4           to an individual entitled to benefits under part  
5           A or enrolled under part B, or both, a specific  
6           provider of services, physician, practitioner, fa-  
7           cility, or supplier (or class of such providers of  
8           services, physicians, practitioners, facilities, or  
9           suppliers), the ‘appropriate’ medicare adminis-  
10          trative contractor is the medicare administra-  
11          tive contractor that has a contract under this  
12          section with respect to the performance of that  
13          function in relation to that individual, provider  
14          of services, physician, practitioner, facility, or  
15          supplier or class of provider of services, physi-  
16          cian, practitioner, facility, or supplier.

17          “(4) FUNCTIONS DESCRIBED.—The functions  
18          referred to in paragraphs (1) and (2) are payment  
19          functions (including the function of developing local  
20          coverage determinations, as defined in section  
21          1869(f)(2)(B)), provider services functions, and ben-  
22          eficiary services functions as follows:

23                 “(A) DETERMINATION OF PAYMENT  
24                 AMOUNTS.—Determining (subject to the provi-  
25                 sions of section 1878 and to such review by the

1 Secretary as may be provided for by the con-  
2 tracts) the amount of the payments required  
3 pursuant to this title to be made to providers  
4 of services, physicians, practitioners, facilities,  
5 suppliers, and individuals.

6 “(B) MAKING PAYMENTS.—Making pay-  
7 ments described in subparagraph (A) (including  
8 receipt, disbursement, and accounting for funds  
9 in making such payments).

10 “(C) BENEFICIARY EDUCATION AND AS-  
11 SISTANCE.—Serving as a center for, and com-  
12 municating to individuals entitled to benefits  
13 under part A or enrolled under part B, or both,  
14 with respect to education and outreach for  
15 those individuals, and assistance with specific  
16 issues, concerns, or problems of those individ-  
17 uals.

18 “(D) PROVIDER CONSULTATIVE SERV-  
19 ICES.—Providing consultative services to insti-  
20 tutions, agencies, and other persons to enable  
21 them to establish and maintain fiscal records  
22 necessary for purposes of this title and other-  
23 wise to qualify as providers of services, physi-  
24 cians, practitioners, facilities, or suppliers.

1           “(E) COMMUNICATION WITH PRO-  
2           VIDERS.—Serving as a center for, and commu-  
3           nicating to providers of services, physicians,  
4           practitioners, facilities, and suppliers, any infor-  
5           mation or instructions furnished to the medi-  
6           care administrative contractor by the Secretary,  
7           and serving as a channel of communication  
8           from such providers, physicians, practitioners,  
9           facilities, and suppliers to the Secretary.

10           “(F) PROVIDER EDUCATION AND TECH-  
11           NICAL ASSISTANCE.—Performing the functions  
12           described in subsections (e) and (f), relating to  
13           education, training, and technical assistance to  
14           providers of services, physicians, practitioners,  
15           facilities, and suppliers.

16           “(G) ADDITIONAL FUNCTIONS.—Per-  
17           forming such other functions, including (subject  
18           to paragraph (5)) functions under the Medicare  
19           Integrity Program under section 1893, as are  
20           necessary to carry out the purposes of this title.

21           “(5) RELATIONSHIP TO MIP CONTRACTS.—

22           “(A) NONDUPLICATION OF ACTIVITIES.—  
23           In entering into contracts under this section,  
24           the Secretary shall assure that activities of  
25           medicare administrative contractors do not du-

1            plicate activities carried out under contracts en-  
2            tered into under the Medicare Integrity Pro-  
3            gram under section 1893. The previous sen-  
4            tence shall not apply with respect to the activity  
5            described in section 1893(b)(5) (relating to  
6            prior authorization of certain items of durable  
7            medical equipment under section 1834(a)(15)).

8            “(B) CONSTRUCTION.—An entity shall not  
9            be treated as a medicare administrative con-  
10           tractor merely by reason of having entered into  
11           a contract with the Secretary under section  
12           1893.

13           “(6) APPLICATION OF FEDERAL ACQUISITION  
14           REGULATION.—Except to the extent inconsistent  
15           with a specific requirement of this title, the Federal  
16           Acquisition Regulation applies to contracts under  
17           this title.

18           “(b) CONTRACTING REQUIREMENTS.—

19           “(1) USE OF COMPETITIVE PROCEDURES.—

20           “(A) IN GENERAL.—Except as provided in  
21           laws with general applicability to Federal acqui-  
22           sition and procurement, the Federal Acquisition  
23           Regulation, or in subparagraph (B), the Sec-  
24           retary shall use competitive procedures when

1 entering into contracts with medicare adminis-  
2 trative contractors under this section.

3 “(B) RENEWAL OF CONTRACTS.—The Sec-  
4 retary may renew a contract with a medicare  
5 administrative contractor under this section  
6 from term to term without regard to section 5  
7 of title 41, United States Code, or any other  
8 provision of law requiring competition, if the  
9 medicare administrative contractor has met or  
10 exceeded the performance requirements applica-  
11 ble with respect to the contract and contractor,  
12 except that the Secretary shall provide for the  
13 application of competitive procedures under  
14 such a contract not less frequently than once  
15 every 6 years.

16 “(C) TRANSFER OF FUNCTIONS.—The  
17 Secretary may transfer functions among medi-  
18 care administrative contractors without regard  
19 to any provision of law requiring competition.  
20 The Secretary shall ensure that performance  
21 quality is considered in such transfers. The Sec-  
22 retary shall provide notice (whether in the Fed-  
23 eral Register or otherwise) of any such transfer  
24 (including a description of the functions so  
25 transferred and contact information for the

1 contractors involved) to providers of services,  
2 physicians, practitioners, facilities, and sup-  
3 pliers affected by the transfer.

4 “(D) INCENTIVES FOR QUALITY.—The  
5 Secretary may provide incentives for medicare  
6 administrative contractors to provide quality  
7 service and to promote efficiency.

8 “(2) COMPLIANCE WITH REQUIREMENTS.—No  
9 contract under this section shall be entered into with  
10 any medicare administrative contractor unless the  
11 Secretary finds that such medicare administrative  
12 contractor will perform its obligations under the con-  
13 tract efficiently and effectively and will meet such  
14 requirements as to financial responsibility, legal au-  
15 thority, and other matters as the Secretary finds  
16 pertinent.

17 “(3) PERFORMANCE REQUIREMENTS.—

18 “(A) DEVELOPMENT OF SPECIFIC PER-  
19 FORMANCE REQUIREMENTS.—The Secretary  
20 shall develop contract performance require-  
21 ments to carry out the specific requirements ap-  
22 plicable under this title to a function described  
23 in subsection (a)(4) and shall develop standards  
24 for measuring the extent to which a contractor  
25 has met such requirements. In developing such

1 performance requirements and standards for  
2 measurement, the Secretary shall consult with  
3 providers of services, organizations representa-  
4 tive of beneficiaries under this title, and organi-  
5 zations and agencies performing functions nec-  
6 essary to carry out the purposes of this section  
7 with respect to such performance requirements.  
8 The Secretary shall make such performance re-  
9 quirements and measurement standards avail-  
10 able to the public.

11 “(B) CONSIDERATIONS.—The Secretary  
12 shall include, as 1 of the standards, provider  
13 and beneficiary satisfaction levels.

14 “(C) INCLUSION IN CONTRACTS.—All con-  
15 tractor performance requirements shall be set  
16 forth in the contract between the Secretary and  
17 the appropriate medicare administrative con-  
18 tractor. Such performance requirements—

19 “(i) shall reflect the performance re-  
20 quirements published under subparagraph  
21 (A), but may include additional perform-  
22 ance requirements;

23 “(ii) shall be used for evaluating con-  
24 tractor performance under the contract;  
25 and

1                   “(iii) shall be consistent with the writ-  
2                   ten statement of work provided under the  
3                   contract.

4                   “(4) INFORMATION REQUIREMENTS.—The Sec-  
5                   retary shall not enter into a contract with a medi-  
6                   care administrative contractor under this section un-  
7                   less the contractor agrees—

8                   “(A) to furnish to the Secretary such time-  
9                   ly information and reports as the Secretary may  
10                  find necessary in performing his functions  
11                  under this title; and

12                  “(B) to maintain such records and afford  
13                  such access thereto as the Secretary finds nec-  
14                  essary to assure the correctness and verification  
15                  of the information and reports under subpara-  
16                  graph (A) and otherwise to carry out the pur-  
17                  poses of this title.

18                  “(5) SURETY BOND.—A contract with a medi-  
19                  care administrative contractor under this section  
20                  may require the medicare administrative contractor,  
21                  and any of its officers or employees certifying pay-  
22                  ments or disbursing funds pursuant to the contract,  
23                  or otherwise participating in carrying out the con-  
24                  tract, to give surety bond to the United States in

1 such amount as the Secretary may deem appro-  
2 priate.

3 “(6) RETAINING DIVERSITY OF LOCAL COV-  
4 ERAGE DETERMINATIONS.—A contract with a medi-  
5 care administrative contractor under this section to  
6 perform the function of developing local coverage de-  
7 terminations (as defined in section 1869(f)(2)(B))  
8 shall provide that the contractor shall—

9 “(A) designate at least 1 different indi-  
10 vidual to serve as medical director for each  
11 State for which such contract performs such  
12 function;

13 “(B) utilize such medical director in the  
14 performance of such function; and

15 “(C) appoint a contractor advisory com-  
16 mittee with respect to each such State to pro-  
17 vide a formal mechanism for physicians in the  
18 State to be informed of, and participate in, the  
19 development of a local coverage determination  
20 in an advisory capacity.

21 “(c) TERMS AND CONDITIONS.—

22 “(1) IN GENERAL.—Subject to subsection  
23 (a)(6), a contract with any medicare administrative  
24 contractor under this section may contain such  
25 terms and conditions as the Secretary finds nec-

1        essary or appropriate and may provide for advances  
2        of funds to the medicare administrative contractor  
3        for the making of payments by it under subsection  
4        (a)(4)(B).

5           “(2) PROHIBITION ON MANDATES FOR CERTAIN  
6        DATA COLLECTION.—The Secretary may not require,  
7        as a condition of entering into, or renewing, a con-  
8        tract under this section, that the medicare adminis-  
9        trative contractor match data obtained other than in  
10       its activities under this title with data used in the  
11       administration of this title for purposes of identi-  
12       fying situations in which the provisions of section  
13       1862(b) may apply.

14       “(d) LIMITATION ON LIABILITY OF MEDICARE AD-  
15       MINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

16           “(1) CERTIFYING OFFICER.—No individual des-  
17        ignated pursuant to a contract under this section as  
18        a certifying officer shall, in the absence of the reck-  
19        less disregard of the individual’s obligations or the  
20        intent by that individual to defraud the United  
21        States, be liable with respect to any payments cer-  
22        tified by the individual under this section.

23           “(2) DISBURSING OFFICER.—No disbursing of-  
24        ficer shall, in the absence of the reckless disregard  
25        of the officer’s obligations or the intent by that offi-

1 cer to defraud the United States, be liable with re-  
2 spect to any payment by such officer under this sec-  
3 tion if it was based upon an authorization (which  
4 meets the applicable requirements for such internal  
5 controls established by the Comptroller General) of  
6 a certifying officer designated as provided in para-  
7 graph (1) of this subsection.

8 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE  
9 CONTRACTOR.—No medicare administrative con-  
10 tractor shall be liable to the United States for a pay-  
11 ment by a certifying or disbursing officer unless, in  
12 connection with such a payment, the medicare ad-  
13 ministrative contractor acted with reckless disregard  
14 of its obligations under its medicare administrative  
15 contract or with intent to defraud the United States.

16 “(4) RELATIONSHIP TO FALSE CLAIMS ACT.—  
17 Nothing in this subsection shall be construed to limit  
18 liability for conduct that would constitute a violation  
19 of sections 3729 through 3731 of title 31, United  
20 States Code (commonly known as the “False Claims  
21 Act”).

22 “(5) INDEMNIFICATION BY SECRETARY.—

23 “(A) IN GENERAL.—Notwithstanding any  
24 other provision of law and subject to the suc-  
25 ceeding provisions of this paragraph, in the case

1 of a medicare administrative contractor (or a  
2 person who is a director, officer, or employee of  
3 such a contractor or who is engaged by the con-  
4 tractor to participate directly in the claims ad-  
5 ministration process) who is made a party to  
6 any judicial or administrative proceeding aris-  
7 ing from, or relating directly to, the claims ad-  
8 ministration process under this title, the Sec-  
9 retary may, to the extent specified in the con-  
10 tract with the contractor, indemnify the con-  
11 tractor (and such persons).

12 “(B) CONDITIONS.—The Secretary may  
13 not provide indemnification under subparagraph  
14 (A) insofar as the liability for such costs arises  
15 directly from conduct that is determined by the  
16 Secretary to be criminal in nature, fraudulent,  
17 or grossly negligent.

18 “(C) SCOPE OF INDEMNIFICATION.—In-  
19 demnification by the Secretary under subpara-  
20 graph (A) may include payment of judgments,  
21 settlements (subject to subparagraph (D)),  
22 awards, and costs (including reasonable legal  
23 expenses).

24 “(D) WRITTEN APPROVAL FOR SETTLE-  
25 MENTS.—A contractor or other person de-

1           scribed in subparagraph (A) may not propose to  
2           negotiate a settlement or compromise of a pro-  
3           ceeding described in such subparagraph without  
4           the prior written approval of the Secretary to  
5           negotiate a settlement. Any indemnification  
6           under subparagraph (A) with respect to  
7           amounts paid under a settlement are condi-  
8           tioned upon the Secretary's prior written ap-  
9           proval of the final settlement.

10           “(E) CONSTRUCTION.—Nothing in this  
11           paragraph shall be construed—

12                   “(i) to change any common law immu-  
13                   nity that may be available to a medicare  
14                   administrative contractor or person de-  
15                   scribed in subparagraph (A); or

16                   “(ii) to permit the payment of costs  
17                   not otherwise allowable, reasonable, or allo-  
18                   cable under the Federal Acquisition Regu-  
19                   lations.”.

20           (2) CONSIDERATION OF INCORPORATION OF  
21           CURRENT LAW STANDARDS.—In developing contract  
22           performance requirements under section 1874A(b)  
23           of the Social Security Act (as added by paragraph  
24           (1)) the Secretary shall consider inclusion of the per-  
25           formance standards described in sections 1816(f)(2)

1 of such Act (relating to timely processing of recon-  
2 siderations and applications for exemptions) and sec-  
3 tion 1842(b)(2)(B) of such Act (relating to timely  
4 review of determinations and fair hearing requests),  
5 as such sections were in effect before the date of en-  
6 actment of this Act.

7 (b) CONFORMING AMENDMENTS TO SECTION 1816  
8 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816  
9 (42 U.S.C. 1395h) is amended as follows:

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

11 “PROVISIONS RELATING TO THE ADMINISTRATION OF  
12 PART A”.

13 (2) Subsection (a) is amended to read as fol-  
14 lows:

15 “(a) The administration of this part shall be con-  
16 ducted through contracts with medicare administrative  
17 contractors under section 1874A.”.

18 (3) Subsection (b) is repealed.

19 (4) Subsection (c) is amended—

20 (A) by striking paragraph (1); and

21 (B) in each of paragraphs (2)(A) and  
22 (3)(A), by striking “agreement under this sec-  
23 tion” and inserting “contract under section  
24 1874A that provides for making payments  
25 under this part”.

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

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

2 (A) by striking “An agreement with an  
3 agency or organization under this section” and  
4 inserting “A contract with a medicare adminis-  
5 trative contractor under section 1874A with re-  
6 spect to the administration of this part”; and

7 (B) by striking “such agency or organiza-  
8 tion” and inserting “such medicare administra-  
9 tive contractor” each place it appears.

10 (7) Subsection (l) is repealed.

11 (c) CONFORMING AMENDMENTS TO SECTION 1842  
12 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C.  
13 1395u) is amended as follows:

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

15 “PROVISIONS RELATING TO THE ADMINISTRATION OF  
16 PART B”.

17 (2) Subsection (a) is amended to read as fol-  
18 lows:

19 “(a) The administration of this part shall be con-  
20 ducted through contracts with medicare administrative  
21 contractors under section 1874A.”.

22 (3) Subsection (b) is amended—

23 (A) by striking paragraph (1);

24 (B) in paragraph (2)—

25 (i) by striking subparagraphs (A) and

26 (B);

- 1           (ii) in subparagraph (C), by striking  
2           “carriers” and inserting “medicare admin-  
3           istrative contractors”; and
- 4           (iii) by striking subparagraphs (D)  
5           and (E);  
6           (C) in paragraph (3)—
- 7           (i) in the matter before subparagraph  
8           (A), by striking “Each such contract shall  
9           provide that the carrier” and inserting  
10          “The Secretary”;
- 11          (ii) by striking “will” the first place it  
12          appears in each of subparagraphs (A), (B),  
13          (F), (G), (H), and (L) and inserting  
14          “shall”;
- 15          (iii) in subparagraph (B), in the mat-  
16          ter before clause (i), by striking “to the  
17          policyholders and subscribers of the car-  
18          rier” and inserting “to the policyholders  
19          and subscribers of the medicare adminis-  
20          trative contractor”;
- 21          (iv) by striking subparagraphs (C),  
22          (D), and (E);
- 23          (v) in subparagraph (H)—

1 (I) by striking “if it makes deter-  
2 minations or payments with respect to  
3 physicians’ services,”; and

4 (II) by striking “carrier” and in-  
5 serting “medicare administrative con-  
6 tractor”;

7 (vi) by striking subparagraph (I);

8 (vii) in subparagraph (L), by striking  
9 the semicolon and inserting a period;

10 (viii) in the first sentence, after sub-  
11 subparagraph (L), by striking “and shall con-  
12 tain” and all that follows through the pe-  
13 riod; and

14 (ix) in the seventh sentence, by insert-  
15 ing “medicare administrative contractor,”  
16 after “carrier,”;

17 (D) by striking paragraph (5);

18 (E) in paragraph (6)(D)(iv), by striking  
19 “carrier” and inserting “medicare administra-  
20 tive contractor”; and

21 (F) in paragraph (7), by striking “the car-  
22 rier” and inserting “the Secretary” each place  
23 it appears.

24 (4) Subsection (c) is amended—

25 (A) by striking paragraph (1);

1 (B) in paragraph (2), by striking “contract  
2 under this section which provides for the dis-  
3 bursement of funds, as described in subsection  
4 (a)(1)(B),” and inserting “contract under sec-  
5 tion 1874A that provides for making payments  
6 under this part”;

7 (C) in paragraph (3)(A), by striking “sub-  
8 section (a)(1)(B)” and inserting “section  
9 1874A(a)(3)(B)”;

10 (D) in paragraph (4), by striking “carrier”  
11 and inserting “medicare administrative con-  
12 tractor”;

13 (E) in paragraph (5), by striking “contract  
14 under this section which provides for the dis-  
15 bursement of funds, as described in subsection  
16 (a)(1)(B), shall require the carrier” and “car-  
17 rier responses” and inserting “contract under  
18 section 1874A that provides for making pay-  
19 ments under this part shall require the medi-  
20 care administrative contractor” and “contractor  
21 responses”, respectively; and

22 (F) by striking paragraph (6).

23 (5) Subsections (d), (e), and (f) are repealed.

1           (6) Subsection (g) is amended by striking “car-  
2           rier or carriers” and inserting “medicare administra-  
3           tive contractor or contractors”.

4           (7) Subsection (h) is amended—

5                 (A) in paragraph (2)—

6                     (i) by striking “Each carrier having  
7                     an agreement with the Secretary under  
8                     subsection (a)” and inserting “The Sec-  
9                     retary”; and

10                    (ii) by striking “Each such carrier”  
11                    and inserting “The Secretary”;

12                 (B) in paragraph (3)(A)—

13                     (i) by striking “a carrier having an  
14                     agreement with the Secretary under sub-  
15                     section (a)” and inserting “medicare ad-  
16                     ministrative contractor having a contract  
17                     under section 1874A that provides for  
18                     making payments under this part”; and

19                     (ii) by striking “such carrier” and in-  
20                     serting “such contractor”;

21                 (C) in paragraph (3)(B)—

22                     (i) by striking “a carrier” and insert-  
23                     ing “a medicare administrative contractor”  
24                     each place it appears; and

1 (ii) by striking “the carrier” and in-  
2 sserting “the contractor” each place it ap-  
3 pears; and

4 (D) in paragraphs (5)(A) and (5)(B)(iii),  
5 by striking “carriers” and inserting “medicare  
6 administrative contractors” each place it ap-  
7 pears.

8 (8) Subsection (l) is amended—

9 (A) in paragraph (1)(A)(iii), by striking  
10 “carrier” and inserting “medicare administra-  
11 tive contractor”; and

12 (B) in paragraph (2), by striking “carrier”  
13 and inserting “medicare administrative con-  
14 tractor”.

15 (9) Subsection (p)(3)(A) is amended by striking  
16 “carrier” and inserting “medicare administrative  
17 contractor”.

18 (10) Subsection (q)(1)(A) is amended by strik-  
19 ing “carrier”.

20 (d) EFFECTIVE DATE; TRANSITION RULE.—

21 (1) EFFECTIVE DATE.—

22 (A) IN GENERAL.—Except as otherwise  
23 provided in this subsection, the amendments  
24 made by this section shall take effect on Octo-  
25 ber 1, 2005, and the Secretary is authorized to

1 take such steps before such date as may be nec-  
2 essary to implement such amendments on a  
3 timely basis.

4 (B) CONSTRUCTION FOR CURRENT CON-  
5 TRACTS.—Such amendments shall not apply to  
6 contracts in effect before the date specified  
7 under subparagraph (A) that continue to retain  
8 the terms and conditions in effect on such date  
9 (except as otherwise provided under this title,  
10 other than under this section) until such date  
11 as the contract is let out for competitive bid-  
12 ding under such amendments.

13 (C) DEADLINE FOR COMPETITIVE BID-  
14 DING.—The Secretary shall provide for the let-  
15 ting by competitive bidding of all contracts for  
16 functions of medicare administrative contrac-  
17 tors for annual contract periods that begin on  
18 or after October 1, 2011.

19 (2) GENERAL TRANSITION RULES.—

20 (A) AUTHORITY TO CONTINUE TO ENTER  
21 INTO NEW AGREEMENTS AND CONTRACTS AND  
22 WAIVER OF PROVIDER NOMINATION PROVISIONS  
23 DURING TRANSITION.—Prior to the date speci-  
24 fied in paragraph (1)(A), the Secretary may,  
25 consistent with subparagraph (B), continue to

1 enter into agreements under section 1816 and  
2 contracts under section 1842 of the Social Se-  
3 curity Act (42 U.S.C. 1395h, 1395u). The Sec-  
4 retary may enter into new agreements under  
5 section 1816 during the time period without re-  
6 gard to any of the provider nomination provi-  
7 sions of such section.

8 (B) APPROPRIATE TRANSITION.—The Sec-  
9 retary shall take such steps as are necessary to  
10 provide for an appropriate transition from  
11 agreements under section 1816 and contracts  
12 under section 1842 of the Social Security Act  
13 (42 U.S.C. 1395h, 1395u) to contracts under  
14 section 1874A, as added by subsection (a)(1).

15 (3) AUTHORIZING CONTINUATION OF MIP AC-  
16 TIVITIES UNDER CURRENT CONTRACTS AND AGREE-  
17 MENTS AND UNDER TRANSITION CONTRACTS.—The  
18 provisions contained in the exception in section  
19 1893(d)(2) of the Social Security Act (42 U.S.C.  
20 1395ddd(d)(2)) shall continue to apply notwith-  
21 standing the amendments made by this section, and  
22 any reference in such provisions to an agreement or  
23 contract shall be deemed to include agreements and  
24 contracts entered into pursuant to paragraph (2)(A).

1           (e) REFERENCES.—On and after the effective date  
2 provided under subsection (d)(1), any reference to a fiscal  
3 intermediary or carrier under title XI or XVIII of the So-  
4 cial Security Act (or any regulation, manual instruction,  
5 interpretative rule, statement of policy, or guideline issued  
6 to carry out such titles) shall be deemed a reference to  
7 an appropriate medicare administrative contractor (as  
8 provided under section 1874A of the Social Security Act).

9           (f) SECRETARIAL SUBMISSION OF LEGISLATIVE PRO-  
10 POSAL.—Not later than 6 months after the date of enact-  
11 ment of this Act, the Secretary shall submit to the appro-  
12 priate committees of Congress a legislative proposal pro-  
13 viding for such technical and conforming amendments in  
14 the law as are required by the provisions of this section.

15           (g) REPORTS ON IMPLEMENTATION.—

16           (1) PROPOSAL FOR IMPLEMENTATION.—At  
17 least 1 year before the date specified in subsection  
18 (d)(1)(A), the Secretary shall submit a report to  
19 Congress and the Comptroller General of the United  
20 States that describes a plan for an appropriate tran-  
21 sition. The Comptroller General shall conduct an  
22 evaluation of such plan and shall submit to Con-  
23 gress, not later than 6 months after the date the re-  
24 port is received, a report on such evaluation and

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

3 (2) STATUS OF IMPLEMENTATION.—The Sec-  
4 retary shall submit a report to Congress not later  
5 than October 1, 2008, that describes the status of  
6 implementation of such amendments and that in-  
7 cludes a description of the following:

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

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

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

14 (D) A detailed description of how the Sec-  
15 retary has modified oversight and management  
16 of medicare contractors to adapt to full com-  
17 petition.

## 18 **Subtitle D—Education and** 19 **Outreach Improvements**

### 20 **SEC. 531. PROVIDER EDUCATION AND TECHNICAL ASSIST-** 21 **ANCE.**

22 (a) COORDINATION OF EDUCATION FUNDING.—

23 (1) IN GENERAL.—The Social Security Act is  
24 amended by inserting after section 1888 the fol-  
25 lowing new section:

1 “PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

2 “SEC. 1889. (a) COORDINATION OF EDUCATION  
3 FUNDING.—The Secretary shall coordinate the edu-  
4 cational activities provided through medicare contractors  
5 (as defined in subsection (e), including under section  
6 1893) in order to maximize the effectiveness of Federal  
7 education efforts for providers of services, physicians,  
8 practitioners, and suppliers.”.

9 (2) EFFECTIVE DATE.—The amendment made  
10 by paragraph (1) shall take effect on the date of en-  
11 actment of this Act.

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

18 (b) INCENTIVES TO IMPROVE CONTRACTOR PER-  
19 FORMANCE.—

20 (1) IN GENERAL.—Section 1874A, as added by  
21 section 521(a)(1), is amended by adding at the end  
22 the following new subsection:

23 “(e) INCENTIVES TO IMPROVE CONTRACTOR PER-  
24 FORMANCE IN PROVIDER EDUCATION AND OUTREACH.—

1           “(1) METHODOLOGY TO MEASURE CONTRACTOR  
2           ERROR RATES.—In order to give medicare contrac-  
3           tors (as defined in paragraph (3)) an incentive to  
4           implement effective education and outreach pro-  
5           grams for providers of services, physicians, practi-  
6           tioners, and suppliers, the Secretary shall develop  
7           and implement by October 1, 2004, a methodology  
8           to measure the specific claims payment error rates  
9           of such contractors in the processing or reviewing of  
10          medicare claims.

11          “(2) GAO REVIEW OF METHODOLOGY.—The  
12          Comptroller General of the United States shall re-  
13          view, and make recommendations to the Secretary,  
14          regarding the adequacy of such methodology.

15          “(3) MEDICARE CONTRACTOR DEFINED.—For  
16          purposes of this subsection, the term ‘medicare con-  
17          tractor’ includes a medicare administrative con-  
18          tractor, a fiscal intermediary with a contract under  
19          section 1816, and a carrier with a contract under  
20          section 1842.”.

21          (2) REPORT.—The Secretary shall submit to  
22          Congress a report that describes how the Secretary  
23          intends to use the methodology developed under sec-  
24          tion 1874A(e)(1) of the Social Security Act, as  
25          added by paragraph (1), in assessing medicare con-

1 tractor performance in implementing effective edu-  
2 cation and outreach programs, including whether to  
3 use such methodology as a basis for performance bo-  
4 nuses.

5 (c) IMPROVED PROVIDER EDUCATION AND TRAIN-  
6 ING.—

7 (1) INCREASED FUNDING FOR ENHANCED EDU-  
8 CATION AND TRAINING THROUGH MEDICARE INTEG-  
9 RITY PROGRAM.—Section 1817(k)(4) (42 U.S.C.  
10 1395i(k)(4)) is amended—

11 (A) in subparagraph (A), by striking “sub-  
12 subparagraph (B)” and inserting “subparagraphs  
13 (B) and (C)”;

14 (B) in subparagraph (B), by striking “The  
15 amount appropriated” and inserting “Subject  
16 to subparagraph (C), the amount appro-  
17 priated”; and

18 (C) by adding at the end the following new  
19 subparagraph:

20 “(C) ENHANCED PROVIDER EDUCATION  
21 AND TRAINING.—

22 “(i) IN GENERAL.—In addition to the  
23 amount appropriated under subparagraph  
24 (B), the amount appropriated under sub-  
25 paragraph (A) for a fiscal year (beginning

1 with fiscal year 2004) is increased by  
2 \$35,000,000.

3 “(ii) USE.—The funds made available  
4 under this subparagraph shall be used only  
5 to increase the conduct by medicare con-  
6 tractors of education and training of pro-  
7 viders of services, physicians, practitioners,  
8 and suppliers regarding billing, coding, and  
9 other appropriate items and may also be  
10 used to improve the accuracy, consistency,  
11 and timeliness of contractor responses to  
12 written and phone inquiries from providers  
13 of services, physicians, practitioners, and  
14 suppliers.”.

15 (2) TAILORING EDUCATION AND TRAINING FOR  
16 SMALL PROVIDERS OR SUPPLIERS.—

17 (A) IN GENERAL.—Section 1889, as added  
18 by subsection (a), is amended by adding at the  
19 end the following new subsection:

20 “(b) TAILORING EDUCATION AND TRAINING ACTIVI-  
21 TIES FOR SMALL PROVIDERS OR SUPPLIERS.—

22 “(1) IN GENERAL.—Insofar as a medicare con-  
23 tractor conducts education and training activities, it  
24 shall take into consideration the special needs of  
25 small providers of services or suppliers (as defined in

1 paragraph (2)). Such education and training activi-  
2 ties for small providers of services and suppliers may  
3 include the provision of technical assistance (such as  
4 review of billing systems and internal controls to de-  
5 termine program compliance and to suggest more ef-  
6 ficient and effective means of achieving such compli-  
7 ance).

8 “(2) SMALL PROVIDER OF SERVICES OR SUP-  
9 PLIER.—In this subsection, the term ‘small provider  
10 of services or supplier’ means—

11 “(A) an institutional provider of services  
12 with fewer than 25 full-time-equivalent employ-  
13 ees; or

14 “(B) a physician, practitioner, or supplier  
15 with fewer than 10 full-time-equivalent employ-  
16 ees.”.

17 (B) EFFECTIVE DATE.—The amendment  
18 made by subparagraph (A) shall take effect on  
19 January 1, 2004.

20 (d) ADDITIONAL PROVIDER EDUCATION PROVI-  
21 SIONS.—

22 (1) IN GENERAL.—Section 1889, as added by  
23 subsection (a) and as amended by subsection (c)(2),  
24 is amended by adding at the end the following new  
25 subsections:

1       “(c) ENCOURAGEMENT OF PARTICIPATION IN EDU-  
2       CATION PROGRAM ACTIVITIES.—A medicare contractor  
3       may not use a record of attendance at (or failure to at-  
4       tend) educational activities or other information gathered  
5       during an educational program conducted under this sec-  
6       tion or otherwise by the Secretary to select or track pro-  
7       viders of services, physicians, practitioners, or suppliers  
8       for the purpose of conducting any type of audit or prepay-  
9       ment review.

10       “(d) CONSTRUCTION.—Nothing in this section or sec-  
11       tion 1893(g) shall be construed as providing for disclosure  
12       by a medicare contractor—

13               “(1) of the screens used for identifying claims  
14       that will be subject to medical review; or

15               “(2) of information that would compromise  
16       pending law enforcement activities or reveal findings  
17       of law enforcement-related audits.

18       “(e) DEFINITIONS.—For purposes of this section and  
19       section 1817(k)(4)(C), the term ‘medicare contractor’ in-  
20       cludes the following:

21               “(1) A medicare administrative contractor with  
22       a contract under section 1874A, a fiscal inter-  
23       mediary with a contract under section 1816, and a  
24       carrier with a contract under section 1842.

1           “(2) An eligible entity with a contract under  
2           section 1893.

3 Such term does not include, with respect to activities of  
4 a specific provider of services, physician, practitioner, or  
5 supplier an entity that has no authority under this title  
6 or title XI with respect to such activities and such provider  
7 of services, physician, practitioner, or supplier.”.

8           (2) EFFECTIVE DATE.—The amendment made  
9           by paragraph (1) shall take effect on the date of en-  
10          actment of this Act.

11 **SEC. 532. ACCESS TO AND PROMPT RESPONSES FROM**  
12                                   **MEDICARE CONTRACTORS.**

13          (a) IN GENERAL.—Section 1874A, as added by sec-  
14 tion 521(a)(1) and as amended by section 531(b)(1), is  
15 amended by adding at the end the following new sub-  
16 section:

17          “(f) COMMUNICATING WITH BENEFICIARIES AND  
18 PROVIDERS.—

19               “(1) COMMUNICATION PROCESS.—The Sec-  
20 retary shall develop a process for medicare contrac-  
21 tors to communicate with beneficiaries and with pro-  
22 viders of services, physicians, practitioners, and sup-  
23 pliers under this title.

24               “(2) RESPONSE TO WRITTEN INQUIRIES.—Each  
25 medicare contractor (as defined in paragraph (5))

1 shall provide general written responses (which may  
2 be through electronic transmission) in a clear, con-  
3 cise, and accurate manner to inquiries by bene-  
4 ficiaries, providers of services, physicians, practi-  
5 tioners, and suppliers concerning the programs  
6 under this title within 45 business days of the date  
7 of receipt of such inquiries.

8 “(3) RESPONSE TO TOLL-FREE LINES.—The  
9 Secretary shall ensure that medicare contractors  
10 provide a toll-free telephone number at which bene-  
11 ficiaries, providers, physicians, practitioners, and  
12 suppliers may obtain information regarding billing,  
13 coding, claims, coverage, and other appropriate in-  
14 formation under this title.

15 “(4) MONITORING OF CONTRACTOR RE-  
16 SPONSES.—

17 “(A) IN GENERAL.—Each medicare con-  
18 tractor shall, consistent with standards devel-  
19 oped by the Secretary under subparagraph  
20 (B)—

21 “(i) maintain a system for identifying  
22 who provides the information referred to in  
23 paragraphs (2) and (3); and

1           “(ii) monitor the accuracy, consist-  
2           ency, and timeliness of the information so  
3           provided.

4           “(B) DEVELOPMENT OF STANDARDS.—

5           “(i) IN GENERAL.—The Secretary  
6           shall establish (and publish in the Federal  
7           Register) standards regarding the accu-  
8           racy, consistency, and timeliness of the in-  
9           formation provided in response to inquiries  
10          under this subsection. Such standards shall  
11          be consistent with the performance require-  
12          ments established under subsection (b)(3).

13          “(ii) EVALUATION.—In conducting  
14          evaluations of individual medicare contrac-  
15          tors, the Secretary shall consider the re-  
16          sults of the monitoring conducted under  
17          subparagraph (A) taking into account as  
18          performance requirements the standards  
19          established under clause (i). The Secretary  
20          shall, in consultation with organizations  
21          representing providers of services, sup-  
22          pliers, and individuals entitled to benefits  
23          under part A or enrolled under part B, or  
24          both, establish standards relating to the

1 accuracy, consistency, and timeliness of the  
2 information so provided.

3 “(C) DIRECT MONITORING.—Nothing in  
4 this paragraph shall be construed as preventing  
5 the Secretary from directly monitoring the ac-  
6 curacy, consistency, and timeliness of the infor-  
7 mation so provided.

8 “(5) MEDICARE CONTRACTOR DEFINED.—For  
9 purposes of this subsection, the term ‘medicare con-  
10 tractor’ has the meaning given such term in sub-  
11 section (e)(3).”.

12 (b) EFFECTIVE DATE.—The amendment made by  
13 subsection (a) shall take effect October 1, 2004.

14 **SEC. 533. RELIANCE ON GUIDANCE.**

15 (a) IN GENERAL.—Section 1871(d), as added by sec-  
16 tion 502(a), is amended by adding at the end the following  
17 new paragraph:

18 “(2) If—

19 “(A) a provider of services, physician, practi-  
20 tioner, or other supplier follows written guidance  
21 provided—

22 “(i) by the Secretary; or

23 “(ii) by a medicare contractor (as defined  
24 in section 1889(e) and whether in the form of  
25 a written response to a written inquiry under

1 section 1874A(f)(1) or otherwise) acting within  
2 the scope of the contractor's contract authority,  
3 in response to a written inquiry with respect to the  
4 furnishing of items or services or the submission of  
5 a claim for benefits for such items or services;

6 “(B) the Secretary determines that—

7 “(i) the provider of services, physician,  
8 practitioner, or supplier has accurately pre-  
9 sented the circumstances relating to such items,  
10 services, and claim to the Secretary or the con-  
11 tractor in the written guidance; and

12 “(ii) there is no indication of fraud or  
13 abuse committed by the provider of services,  
14 physician, practitioner, or supplier against the  
15 program under this title; and

16 “(C) the guidance was in error;

17 the provider of services, physician, practitioner, or supplier  
18 shall not be subject to any penalty or interest under this  
19 title (or the provisions of title XI insofar as they relate  
20 to this title) relating to the provision of such items or serv-  
21 ice or such claim if the provider of services, physician,  
22 practitioner, or supplier reasonably relied on such guid-  
23 ance. In applying this paragraph with respect to guidance  
24 in the form of general responses to frequently asked ques-  
25 tions, the Secretary retains authority to determine the ex-

1 tent to which such general responses apply to the par-  
2 ticular circumstances of individual claims.”.

3 (b) EFFECTIVE DATE.—The amendment made by  
4 subsection (a) shall apply to penalties imposed on or after  
5 the date of enactment of this Act.

6 **SEC. 534. MEDICARE PROVIDER OMBUDSMAN.**

7 (a) MEDICARE PROVIDER OMBUDSMAN.—Section  
8 1868 (42 U.S.C. 1395ee) is amended—

9 (1) by adding at the end of the heading the fol-  
10 lowing: “; MEDICARE PROVIDER OMBUDSMAN”;

11 (2) by inserting “PRACTICING PHYSICIANS AD-  
12 VISORY COUNCIL.—(1)” after “(a)”;

13 (3) in paragraph (1), as so redesignated under  
14 paragraph (2), by striking “in this section” and in-  
15 serting “in this subsection”;

16 (4) by redesignating subsections (b) and (c) as  
17 paragraphs (2) and (3), respectively; and

18 (5) by adding at the end the following new sub-  
19 section:

20 “(b) MEDICARE PROVIDER OMBUDSMAN.—

21 “(1) IN GENERAL.—By not later than 1 year  
22 after the date of enactment of the Prescription Drug  
23 and Medicare Improvement Act of 2003, the Sec-  
24 retary shall appoint a Medicare Provider Ombuds-  
25 man.

1           “(2) DUTIES.—The Medicare Provider Om-  
2           budsman shall—

3                   “(A) provide assistance, on a confidential  
4           basis, to entities and individuals providing items  
5           and services, including covered drugs under  
6           part D, under this title with respect to com-  
7           plaints, grievances, and requests for informa-  
8           tion concerning the programs under this title  
9           (including provisions of title XI insofar as they  
10          relate to this title and are not administered by  
11          the Office of the Inspector General of the De-  
12          partment of Health and Human Services) and  
13          in the resolution of unclear or conflicting guid-  
14          ance given by the Secretary and medicare con-  
15          tractors to such providers of services and sup-  
16          pliers regarding such programs and provisions  
17          and requirements under this title and such pro-  
18          visions; and

19                   “(B) submit recommendations to the Sec-  
20          retary for improvement in the administration of  
21          this title and such provisions, including—

22                           “(i) recommendations to respond to  
23                           recurring patterns of confusion in this title  
24                           and such provisions (including rec-  
25                           ommendations regarding suspending impo-

1 sition of sanctions where there is wide-  
2 spread confusion in program administra-  
3 tion), and

4 “(ii) recommendations to provide for  
5 an appropriate and consistent response (in-  
6 cluding not providing for audits) in cases  
7 of self-identified overpayments by providers  
8 of services and suppliers.

9 “(3) STAFF.—The Secretary shall provide the  
10 Medicare Provider Ombudsman with appropriate  
11 staff.”.

12 (b) FUNDING.—There are authorized to be appro-  
13 priated to the Secretary (in appropriate part from the  
14 Federal Hospital Insurance Trust Fund and the Federal  
15 Supplementary Medical Insurance Trust Fund (including  
16 the Prescription Drug Account)) to carry out the provi-  
17 sions of subsection (b) of section 1868 of the Social Secu-  
18 rity Act (42 U.S.C. 1395ee) (relating to the Medicare Pro-  
19 vider Ombudsman), as added by subsection (a)(5), such  
20 sums as are necessary for fiscal year 2004 and each suc-  
21 ceeding fiscal year.

22 **SEC. 535. BENEFICIARY OUTREACH DEMONSTRATION PRO-**  
23 **GRAMS.**

24 (a) DEMONSTRATION ON THE PROVISION OF ADVICE  
25 AND ASSISTANCE TO MEDICARE BENEFICIARIES AT

1 LOCAL OFFICES OF THE SOCIAL SECURITY ADMINISTRA-  
2 TION.—

3 (1) ESTABLISHMENT.—The Secretary shall es-  
4 tablish a demonstration program (in this subsection  
5 referred to as the “demonstration program”) under  
6 which medicare specialists employed by the Depart-  
7 ment of Health and Human Services provide advice  
8 and assistance to medicare beneficiaries at the loca-  
9 tion of existing local offices of the Social Security  
10 Administration.

11 (2) LOCATIONS.—

12 (A) IN GENERAL.—The demonstration pro-  
13 gram shall be conducted in at least 6 offices or  
14 areas. Subject to subparagraph (B), in selecting  
15 such offices and areas, the Secretary shall pro-  
16 vide preference for offices with a high volume of  
17 visits by medicare beneficiaries.

18 (B) ASSISTANCE FOR RURAL BENE-  
19 FICIARIES.—The Secretary shall provide for the  
20 selection of at least 2 rural areas to participate  
21 in the demonstration program. In conducting  
22 the demonstration program in such rural areas,  
23 the Secretary shall provide for medicare special-  
24 ists to travel among local offices in a rural area  
25 on a scheduled basis.

1           (3) DURATION.—The demonstration program  
2 shall be conducted over a 3-year period.

3           (4) EVALUATION AND REPORT.—

4           (A) EVALUATION.—The Secretary shall  
5 provide for an evaluation of the demonstration  
6 program. Such evaluation shall include an anal-  
7 ysis of—

8                   (i) utilization of, and beneficiary satis-  
9 faction with, the assistance provided under  
10 the program; and

11                   (ii) the cost-effectiveness of providing  
12 beneficiary assistance through out-sta-  
13 tioning medicare specialists at local social  
14 security offices.

15           (B) REPORT.—The Secretary shall submit  
16 to Congress a report on such evaluation and  
17 shall include in such report recommendations  
18 regarding the feasibility of permanently out-sta-  
19 tioning Medicare specialists at local social secu-  
20 rity offices.

21           (b) DEMONSTRATION ON PROVIDING PRIOR DETER-  
22 MINATIONS.—

23           (1) ESTABLISHMENT.—By not later than 1  
24 year after the date of enactment of this Act, the  
25 Secretary shall establish a demonstration project to

1 test the administrative feasibility of providing a  
2 process for medicare beneficiaries and entities and  
3 individuals furnishing such beneficiaries with items  
4 and services under title XVIII of the Social Security  
5 Act program to make a request for, and receive, a  
6 determination (after an advance beneficiary notice is  
7 issued with respect to the item or service involved  
8 but before such item or service is furnished to the  
9 beneficiary) as to whether the item or service is cov-  
10 ered under such title consistent with the applicable  
11 requirements of section 1862(a)(1)(A) of such Act  
12 (42 U.S.C. 1395y(a)(1)(A)) (relating to medical ne-  
13 cessity).

14 (2) EVALUATION AND REPORT.—

15 (A) EVALUATION.—The Secretary shall  
16 provide for an evaluation of the demonstration  
17 program conducted under paragraph (1).

18 (B) REPORT.—By not later than January  
19 1, 2006, the Secretary shall submit to Congress  
20 a report on such evaluation together with rec-  
21 ommendations for such legislation and adminis-  
22 trative actions as the Secretary considers appro-  
23 priate.

1     **Subtitle E—Review, Recovery, and**  
2                     **Enforcement Reform**

3     **SEC. 541. PREPAYMENT REVIEW.**

4             (a) IN GENERAL.—Section 1874A, as added by sec-  
5     tion 521(a)(1) and as amended by sections 531(b)(1) and  
6     532(a), is amended by adding at the end the following new  
7     subsection:

8             “(g) CONDUCT OF PREPAYMENT REVIEW.—

9                     “(1) STANDARDIZATION OF RANDOM PREPAY-  
10             MENT REVIEW.—A medicare administrative con-  
11             tractor shall conduct random prepayment review  
12             only in accordance with a standard protocol for ran-  
13             dom prepayment audits developed by the Secretary.

14                     “(2) LIMITATIONS ON INITIATION OF NON-  
15             RANDOM PREPAYMENT REVIEW.—A medicare admin-  
16             istrative contractor may not initiate nonrandom pre-  
17             payment review of a provider of services, physician,  
18             practitioner, or supplier based on the initial identi-  
19             fication by that provider of services, physician, prac-  
20             titioner, or supplier of an improper billing practice  
21             unless there is a likelihood of sustained or high level  
22             of payment error (as defined by the Secretary).

23                     “(3) TERMINATION OF NONRANDOM PREPAY-  
24             MENT REVIEW.—The Secretary shall establish proto-  
25             cols or standards relating to the termination, includ-

1       ing termination dates, of nonrandom prepayment re-  
2       view. Such regulations may vary such a termination  
3       date based upon the differences in the circumstances  
4       triggering prepayment review.

5           “(4) CONSTRUCTION.—Nothing in this sub-  
6       section shall be construed as preventing the denial of  
7       payments for claims actually reviewed under a ran-  
8       dom prepayment review. In the case of a provider of  
9       services, physician, practitioner, or supplier with re-  
10      spect to which amounts were previously overpaid,  
11      nothing in this subsection shall be construed as lim-  
12      iting the ability of a medicare administrative con-  
13      tractor to request the periodic production of records  
14      or supporting documentation for a limited sample of  
15      submitted claims to ensure that the previous prac-  
16      tice is not continuing.

17           “(5) RANDOM PREPAYMENT REVIEW DE-  
18      FINED.—For purposes of this subsection, the term  
19      ‘random prepayment review’ means a demand for  
20      the production of records or documentation absent  
21      cause with respect to a claim.”.

22      (b) EFFECTIVE DATE.—

23           (1) IN GENERAL.—Except as provided in this  
24      subsection, the amendment made by subsection (a)

1 shall take effect on the date of enactment of this  
2 Act.

3 (2) DEADLINE FOR PROMULGATION OF CER-  
4 TAIN REGULATIONS.—The Secretary shall first issue  
5 regulations under section 1874A(g) of the Social Se-  
6 curity Act, as added by subsection (a), by not later  
7 than 1 year after the date of enactment of this Act.

8 (3) APPLICATION OF STANDARD PROTOCOLS  
9 FOR RANDOM PREPAYMENT REVIEW.—Section  
10 1874A(g)(1) of the Social Security Act, as added by  
11 subsection (a), shall apply to random prepayment re-  
12 views conducted on or after such date (not later  
13 than 1 year after the date of enactment of this Act)  
14 as the Secretary shall specify. The Secretary shall  
15 develop and publish the standard protocol under  
16 such section by not later than 1 year after the date  
17 of enactment of this Act.

18 **SEC. 542. RECOVERY OF OVERPAYMENTS.**

19 (a) IN GENERAL.—Section 1874A, as added by sec-  
20 tion 521(a)(1) and as amended by sections 531(b)(1),  
21 532(a), and 541(a), is amended by adding at the end the  
22 following new subsection:

23 “(h) RECOVERY OF OVERPAYMENTS.—

24 “(1) USE OF REPAYMENT PLANS.—

1           “(A) IN GENERAL.—If the repayment,  
2           within the period otherwise permitted by a pro-  
3           vider of services, physician, practitioner, or  
4           other supplier, of an overpayment under this  
5           title meets the standards developed under sub-  
6           paragraph (B), subject to subparagraph (C),  
7           and the provider, physician, practitioner, or  
8           supplier requests the Secretary to enter into a  
9           repayment plan with respect to such overpay-  
10          ment, the Secretary shall enter into a plan with  
11          the provider, physician, practitioner, or supplier  
12          for the offset or repayment (at the election of  
13          the provider, physician, practitioner, or sup-  
14          plier) of such overpayment over a period of at  
15          least 1 year, but not longer than 3 years. Inter-  
16          est shall accrue on the balance through the pe-  
17          riod of repayment. The repayment plan shall  
18          meet terms and conditions determined to be ap-  
19          propriate by the Secretary.

20          “(B) DEVELOPMENT OF STANDARDS.—  
21          The Secretary shall develop standards for the  
22          recovery of overpayments. Such standards  
23          shall—

24                  “(i) include a requirement that the  
25                  Secretary take into account (and weigh in

1 favor of the use of a repayment plan) the  
2 reliance (as described in section  
3 1871(d)(2)) by a provider of services, phy-  
4 sician, practitioner, and supplier on guid-  
5 ance when determining whether a repay-  
6 ment plan should be offered; and

7 “(ii) provide for consideration of the  
8 financial hardship imposed on a provider of  
9 services, physician, practitioner, or supplier  
10 in considering such a repayment plan.

11 In developing standards with regard to financial  
12 hardship with respect to a provider of services,  
13 physician, practitioner, or supplier, the Sec-  
14 retary shall take into account the amount of the  
15 proposed recovery as a proportion of payments  
16 made to that provider, physician, practitioner,  
17 or supplier.

18 “(C) EXCEPTIONS.—Subparagraph (A)  
19 shall not apply if—

20 “(i) the Secretary has reason to sus-  
21 pect that the provider of services, physi-  
22 cian, practitioner, or supplier may file for  
23 bankruptcy or otherwise cease to do busi-  
24 ness or discontinue participation in the  
25 program under this title; or

1                   “(ii) there is an indication of fraud or  
2                   abuse committed against the program.

3                   “(D) IMMEDIATE COLLECTION IF VIOLA-  
4                   TION OF REPAYMENT PLAN.—If a provider of  
5                   services, physician, practitioner, or supplier fails  
6                   to make a payment in accordance with a repay-  
7                   ment plan under this paragraph, the Secretary  
8                   may immediately seek to offset or otherwise re-  
9                   cover the total balance outstanding (including  
10                  applicable interest) under the repayment plan.

11                  “(E) RELATION TO NO FAULT PROVI-  
12                  SION.—Nothing in this paragraph shall be con-  
13                  strued as affecting the application of section  
14                  1870(c) (relating to no adjustment in the cases  
15                  of certain overpayments).

16                  “(2) LIMITATION ON RECOUPMENT.—

17                  “(A) NO RECOUPMENT UNTIL RECONSID-  
18                  ERATION EXERCISED.—In the case of a pro-  
19                  vider of services, physician, practitioner, or sup-  
20                  plier that is determined to have received an  
21                  overpayment under this title and that seeks a  
22                  reconsideration of such determination by a  
23                  qualified independent contractor under section  
24                  1869(c), the Secretary may not take any action  
25                  (or authorize any other person, including any

1 Medicare contractor, as defined in subpara-  
2 graph (C)) to recoup the overpayment until the  
3 date the decision on the reconsideration has  
4 been rendered.

5 “(B) PAYMENT OF INTEREST.—

6 “(i) RETURN OF RECOUPED AMOUNT  
7 WITH INTEREST IN CASE OF REVERSAL.—

8 Insofar as such determination on appeal  
9 against the provider of services, physician,  
10 practitioner, or supplier is later reversed,  
11 the Secretary shall provide for repayment  
12 of the amount recouped plus interest for  
13 the period in which the amount was re-  
14 couped.

15 “(ii) INTEREST IN CASE OF AFFIRMA-  
16 TION.—Insofar as the determination on  
17 such appeal is against the provider of serv-  
18 ices, physician, practitioner, or supplier, in-  
19 terest on the overpayment shall accrue on  
20 and after the date of the original notice of  
21 overpayment.

22 “(iii) RATE OF INTEREST.—The rate  
23 of interest under this subparagraph shall  
24 be the rate otherwise applicable under this  
25 title in the case of overpayments.

1           “(C) MEDICARE CONTRACTOR DEFINED.—

2           For purposes of this subsection, the term ‘medi-  
3           care contractor’ has the meaning given such  
4           term in section 1889(e).

5           “(3) PAYMENT AUDITS.—

6           “(A) WRITTEN NOTICE FOR POST-PAY-  
7           MENT AUDITS.—Subject to subparagraph (C), if  
8           a medicare contractor decides to conduct a  
9           post-payment audit of a provider of services,  
10          physician, practitioner, or supplier under this  
11          title, the contractor shall provide the provider of  
12          services, physician, practitioner, or supplier  
13          with written notice (which may be in electronic  
14          form) of the intent to conduct such an audit.

15          “(B) EXPLANATION OF FINDINGS FOR ALL  
16          AUDITS.—Subject to subparagraph (C), if a  
17          medicare contractor audits a provider of serv-  
18          ices, physician, practitioner, or supplier under  
19          this title, the contractor shall—

20                 “(i) give the provider of services, phy-  
21                 sician, practitioner, or supplier a full re-  
22                 view and explanation of the findings of the  
23                 audit in a manner that is understandable  
24                 to the provider of services, physician, prac-  
25                 titioner, or supplier and permits the devel-

1           opment of an appropriate corrective action  
2           plan;

3           “(ii) inform the provider of services,  
4           physician, practitioner, or supplier of the  
5           appeal rights under this title as well as  
6           consent settlement options (which are at  
7           the discretion of the Secretary); and

8           “(iii) give the provider of services,  
9           physician, practitioner, or supplier an op-  
10          portunity to provide additional information  
11          to the contractor.

12          “(C) EXCEPTION.—Subparagraphs (A)  
13          and (B) shall not apply if the provision of no-  
14          tice or findings would compromise pending law  
15          enforcement activities, whether civil or criminal,  
16          or reveal findings of law enforcement-related  
17          audits.

18          “(4) NOTICE OF OVER-UTILIZATION OF  
19          CODES.—The Secretary shall establish, in consulta-  
20          tion with organizations representing the classes of  
21          providers of services, physicians, practitioners, and  
22          suppliers, a process under which the Secretary pro-  
23          vides for notice to classes of providers of services,  
24          physicians, practitioners, and suppliers served by a  
25          medicare contractor in cases in which the contractor

1 has identified that particular billing codes may be  
2 overutilized by that class of providers of services,  
3 physicians, practitioners, or suppliers under the pro-  
4 grams under this title (or provisions of title XI inso-  
5 far as they relate to such programs).

6 “(5) STANDARD METHODOLOGY FOR PROBE  
7 SAMPLING.—The Secretary shall establish a stand-  
8 ard methodology for medicare administrative con-  
9 tractors to use in selecting a sample of claims for re-  
10 view in the case of an abnormal billing pattern.

11 “(6) CONSENT SETTLEMENT REFORMS.—

12 “(A) IN GENERAL.—The Secretary may  
13 use a consent settlement (as defined in sub-  
14 paragraph (D)) to settle a projected overpay-  
15 ment.

16 “(B) OPPORTUNITY TO SUBMIT ADDI-  
17 TIONAL INFORMATION BEFORE CONSENT SET-  
18 TLEMENT OFFER.—Before offering a provider  
19 of services, physician, practitioner, or supplier a  
20 consent settlement, the Secretary shall—

21 “(i) communicate to the provider of  
22 services, physician, practitioner, or supplier  
23 in a nonthreatening manner that, based on  
24 a review of the medical records requested  
25 by the Secretary, a preliminary evaluation

1 of those records indicates that there would  
2 be an overpayment; and

3 “(ii) provide for a 45-day period dur-  
4 ing which the provider of services, physi-  
5 cian, practitioner, or supplier may furnish  
6 additional information concerning the med-  
7 ical records for the claims that had been  
8 reviewed.

9 “(C) CONSENT SETTLEMENT OFFER.—The  
10 Secretary shall review any additional informa-  
11 tion furnished by the provider of services, physi-  
12 cian, practitioner, or supplier under subpara-  
13 graph (B)(ii). Taking into consideration such  
14 information, the Secretary shall determine if  
15 there still appears to be an overpayment. If so,  
16 the Secretary—

17 “(i) shall provide notice of such deter-  
18 mination to the provider of services, physi-  
19 cian, practitioner, or supplier, including an  
20 explanation of the reason for such deter-  
21 mination; and

22 “(ii) in order to resolve the overpay-  
23 ment, may offer the provider of services,  
24 physician, practitioner, or supplier—

1                   “(I) the opportunity for a statis-  
2                   tically valid random sample; or

3                   “(II) a consent settlement.

4                   The opportunity provided under clause (ii)(I)  
5                   does not waive any appeal rights with respect to  
6                   the alleged overpayment involved.

7                   “(D) CONSENT SETTLEMENT DEFINED.—

8                   For purposes of this paragraph, the term ‘con-  
9                   sent settlement’ means an agreement between  
10                  the Secretary and a provider of services, physi-  
11                  cian, practitioner, or supplier whereby both par-  
12                  ties agree to settle a projected overpayment  
13                  based on less than a statistically valid sample of  
14                  claims and the provider of services, physician,  
15                  practitioner, or supplier agrees not to appeal  
16                  the claims involved.”.

17                  (b) EFFECTIVE DATES AND DEADLINES.—

18                   (1) Not later than 1 year after the date of en-  
19                  actment of this Act, the Secretary shall first—

20                   (A) develop standards for the recovery of  
21                   overpayments under section 1874A(h)(1)(B) of  
22                   the Social Security Act, as added by subsection  
23                   (a);

24                   (B) establish the process for notice of over-  
25                  utilization of billing codes under section

1 1874A(h)(4) of the Social Security Act, as  
2 added by subsection (a); and

3 (C) establish a standard methodology for  
4 selection of sample claims for abnormal billing  
5 patterns under section 1874A(h)(5) of the So-  
6 cial Security Act, as added by subsection (a).

7 (2) Section 1874A(h)(2) of the Social Security  
8 Act, as added by subsection (a), shall apply to ac-  
9 tions taken after the date that is 1 year after the  
10 date of enactment of this Act.

11 (3) Section 1874A(h)(3) of the Social Security  
12 Act, as added by subsection (a), shall apply to audits  
13 initiated after the date of enactment of this Act.

14 (4) Section 1874A(h)(6) of the Social Security  
15 Act, as added by subsection (a), shall apply to con-  
16 sent settlements entered into after the date of enact-  
17 ment of this Act.

18 **SEC. 543. PROCESS FOR CORRECTION OF MINOR ERRORS**  
19 **AND OMISSIONS ON CLAIMS WITHOUT PUR-**  
20 **SUING APPEALS PROCESS.**

21 (a) IN GENERAL.—The Secretary shall develop, in  
22 consultation with appropriate medicare contractors (as de-  
23 fined in section 1889(e) of the Social Security Act, as  
24 added by section 531(d)(1)) and representatives of pro-  
25 viders of services, physicians, practitioners, facilities, and

1 suppliers, a process whereby, in the case of minor errors  
2 or omissions (as defined by the Secretary) that are de-  
3 tected in the submission of claims under the programs  
4 under title XVIII of such Act, a provider of services, phy-  
5 sician, practitioner, facility, or supplier is given an oppor-  
6 tunity to correct such an error or omission without the  
7 need to initiate an appeal. Such process shall include the  
8 ability to resubmit corrected claims.

9 (b) DEADLINE.—Not later than 1 year after the date  
10 of enactment of this Act, the Secretary shall first develop  
11 the process under subsection (a).

12 **SEC. 544. AUTHORITY TO WAIVE A PROGRAM EXCLUSION.**

13 The first sentence of section 1128(c)(3)(B) (42  
14 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows:  
15 “Subject to subparagraph (G), in the case of an exclusion  
16 under subsection (a), the minimum period of exclusion  
17 shall be not less than 5 years, except that, upon the re-  
18 quest of an administrator of a Federal health care pro-  
19 gram (as defined in section 1128B(f)) who determines  
20 that the exclusion would impose a hardship on bene-  
21 ficiaries of that program, the Secretary may, after con-  
22 sulting with the Inspector General of the Department of  
23 Health and Human Services, waive the exclusion under  
24 subsection (a)(1), (a)(3), or (a)(4) with respect to that  
25 program in the case of an individual or entity that is the

1 sole community physician or sole source of essential spe-  
 2 cialized services in a community.”.

### 3 **TITLE VI—OTHER PROVISIONS**

#### 4 **SEC. 601. INCREASE IN MEDICAID DSH ALLOTMENTS FOR** 5 **FISCAL YEARS 2004 AND 2005.**

6 (a) IN GENERAL.—Section 1923(f)(4) (42 U.S.C.  
 7 1396r-4(f)(4)) is amended—

8 (1) in the paragraph heading, by striking “FIS-  
 9 CAL YEARS 2001 AND 2002” and inserting “CERTAIN  
 10 FISCAL YEARS”;

11 (2) in subparagraph (A)—

12 (A) in clause (i)—

13 (i) by striking “paragraph (2)” and  
 14 inserting “paragraphs (2) and (3)”; and

15 (ii) by striking “and” at the end;

16 (B) in clause (ii), by striking the period  
 17 and inserting a semicolon; and

18 (C) by adding at the end the following:

19 “(iii) for fiscal year 2004, shall be the  
 20 DSH allotment determined under para-  
 21 graph (3) for that fiscal year increased by  
 22 the amount equal to the product of 0.50  
 23 and the difference between—

24 “(I) the amount that the DSH  
 25 allotment would be if the DSH allot-

1                   ment for the State determined under  
2                   clause (ii) were increased, subject to  
3                   subparagraph (B) and paragraph (5),  
4                   by the percentage change in the Con-  
5                   sumer Price Index for all urban con-  
6                   sumers (all items; U.S. city average)  
7                   for each of fiscal years 2002 and  
8                   2003; and

9                   “(II) the DSH allotment deter-  
10                  mined under paragraph (3) for the  
11                  State for fiscal year 2004; and

12                  “(iv) for fiscal year 2005, shall be the  
13                  DSH allotment determined under para-  
14                  graph (3) for that fiscal year increased by  
15                  the amount equal to the product of 0.50  
16                  and the difference between—

17                  “(I) the amount that the DSH  
18                  allotment would be if the DSH allot-  
19                  ment for the State determined under  
20                  clause (ii) were increased, subject to  
21                  subparagraph (B) and paragraph (5),  
22                  by the percentage change in the Con-  
23                  sumer Price Index for all urban con-  
24                  sumers (all items; U.S. city average)

1 for each of fiscal years 2002, 2003,  
2 and 2004; and

3 “(II) the DSH allotment deter-  
4 mined under paragraph (3) for the  
5 State for fiscal year 2005.”; and

6 (3) in subparagraph (C)—

7 (A) in the subparagraph heading, by strik-  
8 ing “AFTER FISCAL YEAR 2002” and inserting  
9 “FOR OTHER FISCAL YEARS”; and

10 (B) by striking “2003 or” and inserting  
11 “2003, fiscal year 2006, or”.

12 (b) DSH ALLOTMENT FOR THE DISTRICT OF CO-  
13 LUMBIA.—Section 1923(f)(4) (42 U.S.C. 1396r-4(f)(4)),  
14 as amended by paragraph (1), is amended—

15 (1) in subparagraph (A), by inserting “and ex-  
16 cept as provided in subparagraph (C)” after “para-  
17 graph (2)”;

18 (2) by redesignating subparagraph (C) as sub-  
19 paragraph (D); and

20 (3) by inserting after subparagraph (B) the fol-  
21 lowing:

22 “(C) DSH ALLOTMENT FOR THE DISTRICT  
23 OF COLUMBIA.—

24 “(i) IN GENERAL.—Notwithstanding  
25 subparagraph (A), the DSH allotment for

1 the District of Columbia for fiscal year  
2 2004, shall be determined by substituting  
3 “49” for “32” in the item in the table con-  
4 tained in paragraph (2) with respect to the  
5 DSH allotment for FY 00 (fiscal year  
6 2000) for the District of Columbia, and  
7 then increasing such allotment, subject to  
8 subparagraph (B) and paragraph (5), by  
9 the percentage change in the Consumer  
10 Price Index for all urban consumers (all  
11 items; U.S. city average) for each of fiscal  
12 years 2000, 2001, 2002, and 2003.

13 “(ii) NO APPLICATION TO ALLOT-  
14 MENTS AFTER FISCAL YEAR 2004.—The  
15 DSH allotment for the District of Colum-  
16 bia for fiscal year 2003, fiscal year 2005,  
17 or any succeeding fiscal year shall be de-  
18 termined under paragraph (3) without re-  
19 gard to the DSH allotment determined  
20 under clause (i).”.

21 (c) CONFORMING AMENDMENT.—Section 1923(f)(3)  
22 of such Act (42 U.S.C. 1396r-4(f)(3)) is amended by in-  
23 serting “, paragraph (4),” after “subparagraph (B)”.

1 **SEC. 602. INCREASE IN FLOOR FOR TREATMENT AS AN EX-**  
2 **TREMELY LOW DSH STATE UNDER THE MED-**  
3 **ICAID PROGRAM FOR FISCAL YEARS 2004 AND**  
4 **2005.**

5 (a) IN GENERAL.—Section 1923(f)(5) (42 U.S.C.  
6 1396r-4(f)(5)) is amended—

7 (1) by striking “In the case of” and inserting  
8 the following:

9 “(A) IN GENERAL.—In the case of”; and

10 (2) by adding at the end the following:

11 “(B) INCREASE IN FLOOR FOR FISCAL  
12 YEARS 2004 AND 2005.—

13 “(i) FISCAL YEAR 2004.—In the case  
14 of a State in which the total expenditures  
15 under the State plan (including Federal  
16 and State shares) for disproportionate  
17 share hospital adjustments under this sec-  
18 tion for fiscal year 2000, as reported to the  
19 Administrator of the Centers for Medicare  
20 and Medicaid Services as of August 31,  
21 2003, is greater than 0 but less than 3  
22 percent of the State’s total amount of ex-  
23 penditures under the State plan for med-  
24 ical assistance during the fiscal year, the  
25 DSH allotment for fiscal year 2004 shall  
26 be increased to 3 percent of the State’s

1 total amount of expenditures under such  
2 plan for such assistance during such fiscal  
3 year.

4 “(ii) FISCAL YEAR 2005.—In the case  
5 of a State in which the total expenditures  
6 under the State plan (including Federal  
7 and State shares) for disproportionate  
8 share hospital adjustments under this sec-  
9 tion for fiscal year 2001, as reported to the  
10 Administrator of the Centers for Medicare  
11 and Medicaid Services as of August 31,  
12 2004, is greater than 0 but less than 3  
13 percent of the State’s total amount of ex-  
14 penditures under the State plan for med-  
15 ical assistance during the fiscal year, the  
16 DSH allotment for fiscal year 2005 shall  
17 be the DSH allotment determined for the  
18 State for fiscal year 2004 (under clause (i)  
19 or paragraph (4) (as applicable)), in-  
20 creased by the percentage change in the  
21 consumer price index for all urban con-  
22 sumers (all items; U.S. city average) for  
23 fiscal year 2004.

24 “(iii) NO APPLICATION TO ALLOT-  
25 MENTS AFTER FISCAL YEAR 2005.—The

1 DSH allotment for any State for fiscal  
2 year 2006 or any succeeding fiscal year  
3 shall be determined under this subsection  
4 without regard to the DSH allotments de-  
5 termined under this subparagraph.”.

6 (b) ALLOTMENT ADJUSTMENT.—

7 (1) IN GENERAL.—Section 1923(f) of the Social  
8 Security Act (42 U.S.C. 1396r-4(f)) is amended—

9 (A) by redesignating paragraph (6) as  
10 paragraph (7); and

11 (B) by inserting after paragraph (5) the  
12 following:

13 “(6) ALLOTMENT ADJUSTMENT.—Only with re-  
14 spect to fiscal year 2004 or 2005, if a statewide  
15 waiver under section 1115 that was implemented on  
16 January 1, 1994, is revoked or terminated before  
17 the end of either such fiscal year, the Secretary  
18 shall—

19 “(A) permit the State whose waiver was  
20 revoked or terminated to submit an amendment  
21 to its State plan that would describe the meth-  
22 odology to be used by the State (after the effec-  
23 tive date of such revocation or termination) to  
24 identify and make payments to disproportionate  
25 share hospitals, including children’s hospitals

1 and institutions for mental diseases or other  
2 mental health facilities (other than State-owned  
3 institutions or facilities), on the basis of the  
4 proportion of patients served by such hospitals  
5 that are low-income patients with special needs;  
6 and

7 “(B) provide for purposes of this sub-  
8 section for computation of an appropriate DSH  
9 allotment for the State for fiscal year 2004 or  
10 2005 (or both) that provides for the maximum  
11 amount (permitted consistent with paragraph  
12 (3)(B)(ii)) that does not result in greater ex-  
13 penditures under this title than would have  
14 been made if such waiver had not been revoked  
15 or terminated.”.

16 (2) TREATMENT OF INSTITUTIONS FOR MENTAL  
17 DISEASES.—Section 1923(h)(1) of the Social Secu-  
18 rity Act (42 U.S.C. 1396r-4(h)(1)) is amended—

19 (A) in paragraph (1), in the matter pre-  
20 ceeding subparagraph (A), by inserting “(subject  
21 to paragraph (3))” after “the lesser of the fol-  
22 lowing”; and

23 (B) by adding at the end the following new  
24 paragraph:

1           “(3) SPECIAL RULE.—The limitation of para-  
2           graph (1) shall not apply in the case of a State to  
3           which subsection (f)(6) applies.”.

4 **SEC. 603. INCREASED REPORTING REQUIREMENTS TO EN-**  
5 **SURE THE APPROPRIATENESS OF PAYMENT**  
6 **ADJUSTMENTS TO DISPROPORTIONATE**  
7 **SHARE HOSPITALS UNDER THE MEDICAID**  
8 **PROGRAM.**

9           Section 1923 (42 U.S.C. 1396r-4) is amended by  
10 adding at the end the following new subsection:

11           “(j) ANNUAL REPORTS REGARDING PAYMENT AD-  
12 JUSTMENTS.—With respect to fiscal year 2004 and each  
13 fiscal year thereafter, the Secretary shall require a State,  
14 as a condition of receiving a payment under section  
15 1903(a)(1) with respect to a payment adjustment made  
16 under this section, to submit an annual report that—

17           “(1) identifies each disproportionate share hos-  
18 pital that received a payment adjustment under this  
19 section for the preceding fiscal year and the amount  
20 of the payment adjustment made to such hospital  
21 for the preceding fiscal year; and

22           “(2) includes such other information as the  
23 Secretary determines necessary to ensure the appro-  
24 priateness of the payment adjustments made under  
25 this section for the preceding fiscal year.”.

1 **SEC. 604. CLARIFICATION OF INCLUSION OF INPATIENT**  
2 **DRUG PRICES CHARGED TO CERTAIN PUBLIC**  
3 **HOSPITALS IN THE BEST PRICE EXEMPTIONS**  
4 **FOR THE MEDICAID DRUG REBATE PRO-**  
5 **GRAM.**

6 (a) **IN GENERAL.**—Section 1927(c)(1)(C)(i)(I) of the  
7 Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is  
8 amended by inserting before the semicolon the following:  
9 “(including inpatient prices charged to hospitals described  
10 in section 340B(a)(4)(L) of the Public Health Service  
11 Act)”.

12 (b) **ANTI-DIVERSION PROTECTION.**—Section  
13 1927(c)(1)(C) of the Social Security Act (42 U.S.C.  
14 1396r–8(c)(1)(C)) is amended by adding at the end the  
15 following:

16 “(iii) **APPLICATION OF AUDITING AND**  
17 **RECORDKEEPING REQUIREMENTS.**—With  
18 respect to a covered entity described in  
19 section 340B(a)(4)(L) of the Public Health  
20 Service Act, any drug purchased for inpa-  
21 tient use shall be subject to the auditing  
22 and recordkeeping requirements described  
23 in section 340B(a)(5)(C) of the Public  
24 Health Service Act.”.

25 (c) **EFFECTIVE DATE.**—The amendments made by  
26 this section take effect on October 1, 2003.

1 **SEC. 605. ASSISTANCE WITH COVERAGE OF LEGAL IMMI-**  
2 **GRANTS UNDER THE MEDICAID PROGRAM**  
3 **AND SCHIP.**

4 (a) MEDICAID PROGRAM.—Section 1903(v) (42  
5 U.S.C. 1396b(v)) is amended—

6 (1) in paragraph (1), by striking “paragraph  
7 (2)” and inserting “paragraphs (2) and (4)”; and

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

10 “(4)(A) With respect to any or all of fiscal years 2005  
11 through 2007, a State may elect (in a plan amendment  
12 under this title) to provide medical assistance under this  
13 title (including under a waiver authorized by the Sec-  
14 retary) for aliens who are lawfully residing in the United  
15 States (including battered aliens described in section  
16 431(c) of such Act) and who are otherwise eligible for such  
17 assistance, within either or both of the following eligibility  
18 categories:

19 “(i) PREGNANT WOMEN.—Women during preg-  
20 nancy (and during the 60-day period beginning on  
21 the last day of the pregnancy).

22 “(ii) CHILDREN.—Children (as defined under  
23 such plan), including optional targeted low-income  
24 children described in section 1905(u)(2)(B).

25 “(B)(i) In the case of a State that has elected to pro-  
26 vide medical assistance to a category of aliens under sub-

1 paragraph (A), no debt shall accrue under an affidavit of  
2 support against any sponsor of such an alien on the basis  
3 of provision of assistance to such category and the cost  
4 of such assistance shall not be considered as an unreim-  
5 bursed cost.

6 “(ii) The provisions of sections 401(a), 402(b), 403,  
7 and 421 of the Personal Responsibility and Work Oppor-  
8 tunity Reconciliation Act of 1996 shall not apply to a  
9 State that makes an election under subparagraph (A).”.

10 (b) SCHIP.—Section 2107(e)(1) (42 U.S.C.  
11 1397gg(e)(1)) is amended by redesignating subparagraphs  
12 (C) and (D) as subparagraph (D) and (E), respectively,  
13 and by inserting after subparagraph (B) the following new  
14 subparagraph:

15 “(C) Section 1903(v)(4) (relating to op-  
16 tional coverage of categories of permanent resi-  
17 dent alien children), but only if the State has  
18 elected to apply such section to the category of  
19 children under title XIX and only with respect  
20 to any or all of fiscal years 2005 through  
21 2007.”.

1 **SEC. 606. ESTABLISHMENT OF CONSUMER OMBUDSMAN AC-**  
2 **COUNT.**

3 (a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i)  
4 is amended by adding at the end the following new sub-  
5 section:

6 “(i) CONSUMER OMBUDSMAN ACCOUNT.—

7 “(1) ESTABLISHMENT.—There is hereby estab-  
8 lished in the Trust Fund an expenditure account to  
9 be known as the ‘Consumer Ombudsman Account’  
10 (in this subsection referred to as the ‘Account’).

11 “(2) APPROPRIATED AMOUNTS TO ACCOUNT  
12 FOR HEALTH INSURANCE INFORMATION, COUN-  
13 SELING, AND ASSISTANCE GRANTS.—

14 “(A) IN GENERAL.—There are hereby ap-  
15 propriated to the Account from the Trust Fund  
16 for each fiscal year beginning with fiscal year  
17 2005, the amount described in subparagraph  
18 (B) for such fiscal year for the purpose of mak-  
19 ing grants under section 4360 of the Omnibus  
20 Budget Reconciliation Act of 1990.

21 “(B) AMOUNT DESCRIBED.—For purposes  
22 of subparagraph (A), the amount described in  
23 this subparagraph for a fiscal year is the  
24 amount equal to the product of—

25 “(i) \$1; and

1                   “(ii) the total number of individuals  
2                   receiving benefits under this title for the  
3                   calendar year ending on December 31 of  
4                   the preceding fiscal year.”.

5           (b) CONFORMING AMENDMENT.—Section 4360(g) of  
6 the Omnibus Budget Reconciliation Act of 1990 (42  
7 U.S.C. 1395b–4(g)) is amended to read as follows:

8           “(g) FUNDING.—The Secretary shall use amounts  
9 appropriated to the Consumer Ombudsman Account in ac-  
10 cordance with section 1817(i) of the Social Security Act  
11 for a fiscal year for making grants under this section for  
12 that fiscal year.”.

13 **SEC. 607. GAO STUDY REGARDING IMPACT OF ASSETS TEST**  
14 **FOR LOW-INCOME BENEFICIARIES.**

15           (a) STUDY.—The Comptroller General of the United  
16 States shall conduct a study to determine the extent to  
17 which drug utilization and access to covered drugs for an  
18 individual described in subsection (b) differs from the drug  
19 utilization and access to covered drugs of an individual  
20 who qualifies for the transitional assistance prescription  
21 drug card program under section 1807A of the Social Se-  
22 curity Act (as added by section 111) or for the premiums  
23 and cost-sharing subsidies applicable to a qualified medi-  
24 care beneficiary, a specified low-income medicare bene-

1 ficiary, or a qualifying individual under section 1860D–  
2 19 of the Social Security Act (as added by section 101).

3 (b) INDIVIDUAL DESCRIBED.—An individual is de-  
4 scribed in this subsection if the individual does not qualify  
5 for the transitional assistance prescription drug card pro-  
6 gram under section 1807A of the Social Security Act or  
7 for the premiums and cost-sharing subsidies applicable to  
8 a qualified medicare beneficiary, a specified low-income  
9 medicare beneficiary, or a qualifying individual under sec-  
10 tion 1860D–19 of the Social Security Act solely as a result  
11 of the application of an assets test to the individual.

12 (c) REPORT.—Not later than September 30, 2007,  
13 the Comptroller General shall submit a report to Congress  
14 on the study conducted under subsection (a) that includes  
15 such recommendations for legislation as the Comptroller  
16 General determines are appropriate.

17 (d) DEFINITIONS.—In this section:

18 (1) COVERED DRUGS.—The term “covered  
19 drugs” has the meaning given that term in section  
20 1860D(a)(D) of the Social Security Act.

21 (2) QUALIFIED MEDICARE BENEFICIARY; SPECI-  
22 FIED LOW-INCOME MEDICARE BENEFICIARY; QUALI-  
23 FYING INDIVIDUAL.—The terms “qualified medicare  
24 beneficiary”, “specified low-income medicare bene-  
25 ficiary” and “qualifying individual” have the mean-

1       ing given those terms under section 1860D–19 of  
2       the Social Security Act.

3 **SEC. 608. HEALTH CARE INFRASTRUCTURE IMPROVEMENT.**

4       At the end of the Social Security Act, add the fol-  
5       lowing new title:

6 **“TITLE XXII—HEALTH CARE IN-**  
7 **FRAS**TRUCTURE       **IMPROVE-**  
8 **MENT**

9 **“SEC. 2201. DEFINITIONS.**

10       “In this title, the following definitions apply:

11               “(1) ELIGIBLE PROJECT COSTS.—The term ‘eli-  
12       gible project costs’ means amounts substantially all  
13       of which are paid by, or for the account of, an obli-  
14       gator in connection with a project, including the cost  
15       of—

16                       “(A) development phase activities, includ-  
17       ing planning, feasibility analysis, revenue fore-  
18       casting, environmental study and review, per-  
19       mitting, architectural engineering and design  
20       work, and other preconstruction activities;

21                       “(B) construction, reconstruction, rehabili-  
22       tation, replacement, and acquisition of facilities  
23       and real property (including land related to the  
24       project and improvements to land), environ-

1           mental mitigation, construction contingencies,  
2           and acquisition of equipment;

3           “(C) capitalized interest necessary to meet  
4           market requirements, reasonably required re-  
5           serve funds, capital issuance expenses, and  
6           other carrying costs during construction;

7           “(D) major medical equipment determined  
8           to be appropriate by the Secretary; and

9           “(E) refinancing projects or activities that  
10          are otherwise eligible for financial assistance  
11          under subparagraphs (A) through (D).

12          “(2) FEDERAL CREDIT INSTRUMENT.—The  
13          term ‘Federal credit instrument’ means a secured  
14          loan, loan guarantee, or line of credit authorized to  
15          be made available under this title with respect to a  
16          project.

17          “(3) INVESTMENT-GRADE RATING.—The term  
18          ‘investment-grade rating’ means a rating category of  
19          BBB minus, Baa3, or higher assigned by a rating  
20          agency to project obligations offered into the capital  
21          markets.

22          “(4) LENDER.—The term ‘lender’ means any  
23          non-Federal qualified institutional buyer (as defined  
24          in section 230.144A(a) of title 17, Code of Federal  
25          Regulations (or any successor regulation), known as

1 Rule 144A(a) of the Securities and Exchange Com-  
2 mission and issued under the Securities Act of 1933  
3 (15 U.S.C. 77a et seq.), including—

4 “(A) a qualified retirement plan (as de-  
5 fined in section 4974(c) of the Internal Revenue  
6 Code of 1986) that is a qualified institutional  
7 buyer; and

8 “(B) a governmental plan (as defined in  
9 section 414(d) of the Internal Revenue Code of  
10 1986) that is a qualified institutional buyer.

11 “(5) LINE OF CREDIT.—The term ‘line of cred-  
12 it’ means an agreement entered into by the Sec-  
13 retary with an obligor under section 2204 to provide  
14 a direct loan at a future date upon the occurrence  
15 of certain events.

16 “(6) LOAN GUARANTEE.—The term ‘loan guar-  
17 antee’ means any guarantee or other pledge by the  
18 Secretary to pay all or part of the principal of and  
19 interest on a loan or other debt obligation issued by  
20 an obligor and funded by a lender.

21 “(7) LOCAL SERVICER.—The term ‘local  
22 servicer’ means a State or local government or any  
23 agency of a State or local government that is re-  
24 sponsible for servicing a Federal credit instrument  
25 on behalf of the Secretary.

1           “(8) OBLIGOR.—The term ‘obligor’ means a  
2 party primarily liable for payment of the principal of  
3 or interest on a Federal credit instrument, which  
4 party may be a corporation, partnership, joint ven-  
5 ture, trust, or governmental entity, agency, or in-  
6 strumentality.

7           “(9) PROJECT.—The term ‘project’ means any  
8 project that is designed to improve the health care  
9 infrastructure, including the construction, renova-  
10 tion, or other capital improvement of any hospital,  
11 medical research facility, or other medical facility or  
12 the purchase of any equipment to be used in a hos-  
13 pital, research facility, or other medical research fa-  
14 cility.

15           “(10) PROJECT OBLIGATION.—The term  
16 ‘project obligation’ means any note, bond, debenture,  
17 lease, installment sale agreement, or other debt obli-  
18 gation issued or entered into by an obligor in con-  
19 nection with the financing of a project, other than  
20 a Federal credit instrument.

21           “(11) RATING AGENCY.—The term ‘rating  
22 agency’ means a bond rating agency identified by  
23 the Securities and Exchange Commission as a Na-  
24 tionally Recognized Statistical Rating Organization.

1           “(12) SECURED LOAN.—The term ‘secured  
2 loan’ means a direct loan or other debt obligation  
3 issued by an obligor and funded by the Secretary in  
4 connection with the financing of a project under sec-  
5 tion 2203.

6           “(13) STATE.—The term ‘State’ has the mean-  
7 ing given the term in section 101 of title 23, United  
8 States Code.

9           “(14) SUBSIDY AMOUNT.—The term ‘subsidy  
10 amount’ means the amount of budget authority suf-  
11 ficient to cover the estimated long-term cost to the  
12 Federal Government of a Federal credit instrument,  
13 calculated on a net present value basis, excluding  
14 administrative costs and any incidental effects on  
15 governmental receipts or outlays in accordance with  
16 the provisions of the Federal Credit Reform Act of  
17 1990 (2 U.S.C. 661 et seq.).

18           “(15) SUBSTANTIAL COMPLETION.—The term  
19 ‘substantial completion’ means the opening of a  
20 project to patients or for research purposes.

21 **“SEC. 2202. DETERMINATION OF ELIGIBILITY AND PROJECT**  
22 **SELECTION.**

23           “(a) ELIGIBILITY.—To be eligible to receive financial  
24 assistance under this title, a project shall meet the fol-  
25 lowing criteria:

1           “(1) APPLICATION.—A State, a local servicer  
2 identified under section 2205(a), or the entity un-  
3 dertaking a project shall submit a project application  
4 to the Secretary.

5           “(2) ELIGIBLE PROJECT COSTS.—To be eligible  
6 for assistance under this title, a project shall have  
7 total eligible project costs that are reasonably antici-  
8 pated to equal or exceed \$40,000,000.

9           “(3) SOURCES OF REPAYMENTS.—Project fi-  
10 nancing shall be repayable, in whole or in part, from  
11 reliable revenue sources as described in the applica-  
12 tion submitted under paragraph (1).

13           “(4) PUBLIC SPONSORSHIP OF PRIVATE ENTI-  
14 TIES.—In the case of a project that is undertaken  
15 by an entity that is not a State or local government  
16 or an agency or instrumentality of a State or local  
17 government, the project that the entity is under-  
18 taking shall be publicly sponsored or sponsored by  
19 an entity that is described in section 501(c)(3) of  
20 the Internal Revenue Code of 1986 and exempt from  
21 tax under section 501(a) of such Code.

22           “(b) SELECTION AMONG ELIGIBLE PROJECTS.—

23           “(1) ESTABLISHMENT.—The Secretary shall es-  
24 tablish criteria for selecting among projects that

1 meet the eligibility criteria specified in subsection  
2 (a).

3 “(2) SELECTION CRITERIA.—

4 “(A) IN GENERAL.—The selection criteria  
5 shall include the following:

6 “(i) The extent to which the project is  
7 nationally or regionally significant, in  
8 terms of expanding or improving the  
9 health care infrastructure of the United  
10 States or the region or in terms of the  
11 medical benefit that the project will have.

12 “(ii) The creditworthiness of the  
13 project, including a determination by the  
14 Secretary that any financing for the  
15 project has appropriate security features,  
16 such as a rate covenant, credit enhance-  
17 ment requirements, or debt services cov-  
18 erages, to ensure repayment.

19 “(iii) The extent to which assistance  
20 under this title would foster innovative  
21 public-private partnerships and attract pri-  
22 vate debt or equity investment.

23 “(iv) The likelihood that assistance  
24 under this title would enable the project to

1 proceed at an earlier date than the project  
2 would otherwise be able to proceed.

3 “(v) The extent to which the project  
4 uses or results in new technologies.

5 “(vi) The amount of budget authority  
6 required to fund the Federal credit instru-  
7 ment made available under this title.

8 “(vii) The extent to which the project  
9 helps maintain or protect the environment.

10 “(B) SPECIFIC REQUIREMENTS.—The se-  
11 lection criteria shall require that a project ap-  
12 plicant—

13 “(i) be engaged in research in the  
14 causes, prevention, and treatment of can-  
15 cer;

16 “(ii) be designated as a cancer center  
17 for the National Cancer Institute or be  
18 designated by the State as the official can-  
19 cer institute of the State; and

20 “(iii) be located in a State that, on  
21 the date of enactment of this title, has a  
22 population of less than 3,000,000 individ-  
23 uals.

24 “(C) RATING LETTER.—For purposes of  
25 subparagraph (A)(ii), the Secretary shall re-

1           quire each project applicant to provide a rating  
2           letter from at least 1 rating agency indicating  
3           that the project’s senior obligations have the  
4           potential to achieve an investment-grade rating  
5           with or without credit enhancement.

6 **“SEC. 2203. SECURED LOANS.**

7           “(a) IN GENERAL.—

8                   “(1) AGREEMENTS.—Subject to paragraphs (2)  
9           through (4), the Secretary may enter into agree-  
10          ments with 1 or more obligors to make secured  
11          loans, the proceeds of which shall be used—

12                           “(A) to finance eligible project costs;

13                           “(B) to refinance interim construction fi-  
14           nancing of eligible project costs; or

15                           “(C) to refinance existing debt or prior  
16           project obligations;

17          of any project selected under section 2202.

18                   “(2) LIMITATION ON REFINANCING OF INTERIM  
19          CONSTRUCTION FINANCING.—A loan under para-  
20          graph (1) shall not refinance interim construction fi-  
21          nancing under paragraph (1)(B) later than 1 year  
22          after the date of substantial completion of the  
23          project.

24                   “(3) RISK ASSESSMENT.—Before entering into  
25          an agreement for a secured loan under this sub-

1 section, the Secretary, in consultation with each rat-  
2 ing agency providing a rating letter under section  
3 2202(b)(2)(B), shall determine an appropriate cap-  
4 ital reserve subsidy amount for each secured loan,  
5 taking into account such letter.

6 “(4) INVESTMENT-GRADE RATING REQUIRE-  
7 MENT.—The funding of a secured loan under this  
8 section shall be contingent on the project’s senior  
9 obligations receiving an investment-grade rating, ex-  
10 cept that—

11 “(A) the Secretary may fund an amount of  
12 the secured loan not to exceed the capital re-  
13 serve subsidy amount determined under para-  
14 graph (3) prior to the obligations receiving an  
15 investment-grade rating; and

16 “(B) the Secretary may fund the remain-  
17 ing portion of the secured loan only after the  
18 obligations have received an investment-grade  
19 rating by at least 1 rating agency.

20 “(b) TERMS AND LIMITATIONS.—

21 “(1) IN GENERAL.—A secured loan under this  
22 section with respect to a project shall be on such  
23 terms and conditions and contain such covenants,  
24 representations, warranties, and requirements (in-

1 including requirements for audits) as the Secretary de-  
2 termines appropriate.

3 “(2) MAXIMUM AMOUNT.—The amount of the  
4 secured loan shall not exceed 100 percent of the rea-  
5 sonably anticipated eligible project costs.

6 “(3) PAYMENT.—The secured loan—

7 “(A) shall—

8 “(i) be payable, in whole or in part,  
9 from reliable revenue sources; and

10 “(ii) include a rate covenant, coverage  
11 requirement, or similar security feature  
12 supporting the project obligations; and

13 “(B) may have a lien on revenues de-  
14 scribed in subparagraph (A) subject to any lien  
15 securing project obligations.

16 “(4) INTEREST RATE.—The interest rate on the  
17 secured loan shall be not less than the yield on mar-  
18 ketable United States Treasury securities of a simi-  
19 lar maturity to the maturity of the secured loan on  
20 the date of execution of the loan agreement.

21 “(5) MATURITY DATE.—The final maturity  
22 date of the secured loan shall be not later than 30  
23 years after the date of substantial completion of the  
24 project.

1           “(6) NONSUBORDINATION.—The secured loan  
2 shall not be subordinated to the claims of any holder  
3 of project obligations in the event of bankruptcy, in-  
4 solvency, or liquidation of the obligor.

5           “(7) FEES.—The Secretary may establish fees  
6 at a level sufficient to cover all or a portion of the  
7 costs to the Federal Government of making a se-  
8 cured loan under this section.

9           “(c) REPAYMENT.—

10           “(1) SCHEDULE.—The Secretary shall establish  
11 a repayment schedule for each secured loan under  
12 this section based on the projected cash flow from  
13 project revenues and other repayment sources.

14           “(2) COMMENCEMENT.—Scheduled loan repay-  
15 ments of principal or interest on a secured loan  
16 under this section shall commence not later than 5  
17 years after the date of substantial completion of the  
18 project.

19           “(3) SOURCES OF REPAYMENT FUNDS.—The  
20 sources of funds for scheduled loan repayments  
21 under this section shall include any revenue gen-  
22 erated by the project.

23           “(4) DEFERRED PAYMENTS.—

24           “(A) AUTHORIZATION.—If, at any time  
25 during the 10 years after the date of substan-

1           tial completion of the project, the project is un-  
2           able to generate sufficient revenues to pay the  
3           scheduled loan repayments of principal and in-  
4           terest on the secured loan, the Secretary may,  
5           subject to subparagraph (C), allow the obligor  
6           to add unpaid principal and interest to the out-  
7           standing balance of the secured loan.

8           “(B) INTEREST.—Any payment deferred  
9           under subparagraph (A) shall—

10           “(i) continue to accrue interest in ac-  
11           cordance with subsection (b)(4) until fully  
12           repaid; and

13           “(ii) be scheduled to be amortized  
14           over the remaining term of the loan begin-  
15           ning not later than 10 years after the date  
16           of substantial completion of the project in  
17           accordance with paragraph (1).

18           “(C) CRITERIA.—

19           “(i) IN GENERAL.—Any payment de-  
20           ferral under subparagraph (A) shall be  
21           contingent on the project meeting criteria  
22           established by the Secretary.

23           “(ii) REPAYMENT STANDARDS.—The  
24           criteria established under clause (i) shall

1 include standards for reasonable assurance  
2 of repayment.

3 “(5) PREPAYMENT.—

4 “(A) USE OF EXCESS REVENUES.—Any  
5 excess revenues that remain after satisfying  
6 scheduled debt service requirements on the  
7 project obligations and secured loan and all de-  
8 posit requirements under the terms of any trust  
9 agreement, bond resolution, reimbursement  
10 agreement, credit agreement, loan agreement,  
11 or similar agreement securing project obliga-  
12 tions may be applied annually to prepay the se-  
13 cured loan without penalty.

14 “(B) USE OF PROCEEDS OF REFI-  
15 NANCING.—The secured loan may be prepaid at  
16 any time without penalty, regardless of whether  
17 such repayment is from the proceeds of refi-  
18 nancing from non-Federal funding sources.

19 “(6) FORGIVENESS OF INDEBTEDNESS.—The  
20 Secretary may forgive a loan secured under this title  
21 under terms and conditions that are analogous to  
22 the loan forgiveness provision for student loans  
23 under part D of title IV of the Higher Education  
24 Act of 1965 (20 U.S.C. 1087a et seq.), except that

1 the Secretary shall condition such forgiveness on the  
2 establishment by the project of—

3 “(A) an outreach program for cancer pre-  
4 vention, early diagnosis, and treatment that  
5 provides services to a substantial majority of  
6 the residents of a State or region, including  
7 residents of rural areas;

8 “(B) an outreach program for cancer pre-  
9 vention, early diagnosis, and treatment that  
10 provides services to multiple Indian tribes; and

11 “(C)(i) unique research resources (such as  
12 population databases); or

13 “(ii) an affiliation with an entity that has  
14 unique research resources.

15 “(d) SALE OF SECURED LOANS.—

16 “(1) IN GENERAL.—Subject to paragraph (2),  
17 as soon as practicable after substantial completion of  
18 a project and after notifying the obligor, the Sec-  
19 retary may sell to another entity or reoffer into the  
20 capital markets a secured loan for the project if the  
21 Secretary determines that the sale or reoffering can  
22 be made on favorable terms.

23 “(2) CONSENT OF OBLIGOR.—In making a sale  
24 or reoffering under paragraph (1), the Secretary  
25 may not change the original terms and conditions of

1 the secured loan without the written consent of the  
2 obligor.

3 “(e) LOAN GUARANTEES.—

4 “(1) IN GENERAL.—The Secretary may provide  
5 a loan guarantee to a lender in lieu of making a se-  
6 cured loan if the Secretary determines that the  
7 budgetary cost of the loan guarantee is substantially  
8 the same as that of a secured loan.

9 “(2) TERMS.—The terms of a guaranteed loan  
10 shall be consistent with the terms set forth in this  
11 section for a secured loan, except that the rate on  
12 the guaranteed loan and any prepayment features  
13 shall be negotiated between the obligor and the lend-  
14 er, with the consent of the Secretary.

15 **“SEC. 2204. LINES OF CREDIT.**

16 “(a) IN GENERAL.—

17 “(1) AGREEMENTS.—Subject to paragraphs (2)  
18 through (4), the Secretary may enter into agree-  
19 ments to make available lines of credit to 1 or more  
20 obligors in the form of direct loans to be made by  
21 the Secretary at future dates on the occurrence of  
22 certain events for any project selected under section  
23 2202.

24 “(2) USE OF PROCEEDS.—The proceeds of a  
25 line of credit made available under this section shall

1 be available to pay debt service on project obliga-  
2 tions issued to finance eligible project costs, extraor-  
3 dinary repair and replacement costs, operation and  
4 maintenance expenses, and costs associated with un-  
5 expected Federal or State environmental restrictions.

6 “(3) RISK ASSESSMENT.—Before entering into  
7 an agreement for a secured loan under this sub-  
8 section, the Secretary, in consultation with each rat-  
9 ing agency providing a rating letter under section  
10 2202(b)(2)(B), shall determine an appropriate sub-  
11 sidy amount for each secured loan, taking into ac-  
12 count such letter.

13 “(4) INVESTMENT-GRADE RATING REQUIRE-  
14 MENT.—The funding of a line of credit under this  
15 section shall be contingent on the project’s senior  
16 obligations receiving an investment-grade rating  
17 from at least 1 rating agency.

18 “(b) TERMS AND LIMITATIONS.—

19 “(1) IN GENERAL.—A line of credit under this  
20 section with respect to a project shall be on such  
21 terms and conditions and contain such covenants,  
22 representations, warranties, and requirements (in-  
23 cluding requirements for audits) as the Secretary de-  
24 termines appropriate.

25 “(2) MAXIMUM AMOUNTS.—

1           “(A) TOTAL AMOUNT.—The total amount  
2           of the line of credit shall not exceed 33 percent  
3           of the reasonably anticipated eligible project  
4           costs.

5           “(B) 1-YEAR DRAWS.—The amount drawn  
6           in any 1 year shall not exceed 20 percent of the  
7           total amount of the line of credit.

8           “(3) DRAWS.—Any draw on the line of credit  
9           shall represent a direct loan and shall be made only  
10          if net revenues from the project (including capital-  
11          ized interest, any debt service reserve fund, and any  
12          other available reserve) are insufficient to pay the  
13          costs specified in subsection (a)(2).

14          “(4) INTEREST RATE.—The interest rate on a  
15          direct loan resulting from a draw on the line of cred-  
16          it shall be not less than the yield on 30-year market-  
17          able United States Treasury securities as of the date  
18          on which the line of credit is obligated.

19          “(5) SECURITY.—The line of credit—

20                 “(A) shall—

21                         “(i) be payable, in whole or in part,  
22                         from reliable revenue sources; and

23                         “(ii) include a rate covenant, coverage  
24                         requirement, or similar security feature  
25                         supporting the project obligations; and

1           “(B) may have a lien on revenues de-  
2           scribed in subparagraph (A) subject to any lien  
3           securing project obligations.

4           “(6) PERIOD OF AVAILABILITY.—The line of  
5           credit shall be available during the period beginning  
6           on the date of substantial completion of the project  
7           and ending not later than 10 years after that date.

8           “(7) RIGHTS OF THIRD-PARTY CREDITORS.—

9           “(A) AGAINST FEDERAL GOVERNMENT.—A  
10          third-party creditor of the obligor shall not have  
11          any right against the Federal Government with  
12          respect to any draw on the line of credit.

13          “(B) ASSIGNMENT.—An obligor may as-  
14          sign the line of credit to 1 or more lenders or  
15          to a trustee on the lenders’ behalf.

16          “(8) NONSUBORDINATION.—A direct loan  
17          under this section shall not be subordinated to the  
18          claims of any holder of project obligations in the  
19          event of bankruptcy, insolvency, or liquidation of the  
20          obligor.

21          “(9) FEES.—The Secretary may establish fees  
22          at a level sufficient to cover all or a portion of the  
23          costs to the Federal Government of providing a line  
24          of credit under this section.

1           “(10) RELATIONSHIP TO OTHER CREDIT IN-  
2           STRUMENTS.—A project that receives a line of credit  
3           under this section also shall not receive a secured  
4           loan or loan guarantee under section 2203 of an  
5           amount that, combined with the amount of the line  
6           of credit, exceeds 100 percent of eligible project  
7           costs.

8           “(c) REPAYMENT.—

9           “(1) TERMS AND CONDITIONS.—The Secretary  
10          shall establish repayment terms and conditions for  
11          each direct loan under this section based on the pro-  
12          jected cash flow from project revenues and other re-  
13          payment sources.

14          “(2) TIMING.—All scheduled repayments of  
15          principal or interest on a direct loan under this sec-  
16          tion shall commence not later than 5 years after the  
17          end of the period of availability specified in sub-  
18          section (b)(6) and be fully repaid, with interest, by  
19          the date that is 25 years after the end of the period  
20          of availability specified in subsection (b)(6).

21          “(3) SOURCES OF REPAYMENT FUNDS.—The  
22          sources of funds for scheduled loan repayments  
23          under this section shall include reliable revenue  
24          sources.

1 **“SEC. 2205. PROJECT SERVICING.**

2       “(a) REQUIREMENT.—The State in which a project  
3 that receives financial assistance under this title is located  
4 may identify a local servicer to assist the Secretary in  
5 servicing the Federal credit instrument made available  
6 under this title.

7       “(b) AGENCY; FEES.—If a State identifies a local  
8 servicer under subsection (a), the local servicer—

9               “(1) shall act as the agent for the Secretary;  
10       and

11               “(2) may receive a servicing fee, subject to ap-  
12       proval by the Secretary.

13       “(c) LIABILITY.—A local servicer identified under  
14 subsection (a) shall not be liable for the obligations of the  
15 obligor to the Secretary or any lender.

16       “(d) ASSISTANCE FROM EXPERT FIRMS.—The Sec-  
17 retary may retain the services of expert firms in the field  
18 of project finance to assist in the underwriting and serv-  
19 icing of Federal credit instruments.

20 **“SEC. 2206. STATE AND LOCAL PERMITS.**

21       ““The provision of financial assistance under this title  
22 with respect to a project shall not—

23               “(1) relieve any recipient of the assistance of  
24       any obligation to obtain any required State or local  
25       permit or approval with respect to the project;

1           “(2) limit the right of any unit of State or local  
2 government to approve or regulate any rate of re-  
3 turn on private equity invested in the project; or

4           “(3) otherwise supersede any State or local law  
5 (including any regulation) applicable to the construc-  
6 tion or operation of the project.

7 **“SEC. 2207. REGULATIONS.**

8           “The Secretary may issue such regulations as the  
9 Secretary determines appropriate to carry out this title.

10 **“SEC. 2208. FUNDING.**

11           “(a) FUNDING.—

12           “(1) IN GENERAL.—There are authorized to be  
13 appropriated to carry out this title, \$49,000,000 to  
14 remain available during the period beginning on July  
15 1, 2004 and ending on September 30, 2008.

16           “(2) ADMINISTRATIVE COSTS.—From funds  
17 made available under paragraph (1), the Secretary  
18 may use, for the administration of this title, not  
19 more than \$2,000,000 for each of fiscal years 2004  
20 through 2008.

21           “(b) CONTRACT AUTHORITY.—Notwithstanding any  
22 other provision of law, approval by the Secretary of a Fed-  
23 eral credit instrument that uses funds made available  
24 under this title shall be deemed to be acceptance by the

1 United States of a contractual obligation to fund the Fed-  
2 eral credit instrument.

3 “(c) AVAILABILITY.—Amounts appropriated under  
4 this section shall be available for obligation on July 1,  
5 2004.

6 **“SEC. 2209. REPORT TO CONGRESS.**

7 “Not later than 4 years after the date of enactment  
8 of this title, the Secretary shall submit to Congress a re-  
9 port summarizing the financial performance of the  
10 projects that are receiving, or have received, assistance  
11 under this title, including a recommendation as to whether  
12 the objectives of this title are best served—

13 “(1) by continuing the program under the au-  
14 thority of the Secretary;

15 “(2) by establishing a Government corporation  
16 or Government-sponsored enterprise to administer  
17 the program; or

18 “(3) by phasing out the program and relying on  
19 the capital markets to fund the types of infrastruc-  
20 ture investments assisted by this title without Fed-  
21 eral participation.”.

1 **SEC. 609. CAPITAL INFRASTRUCTURE REVOLVING LOAN**  
2 **PROGRAM.**

3 (a) IN GENERAL.—Part A of title XVI of the Public  
4 Health Service Act (42 U.S.C. 300q et seq.) is amended  
5 by adding at the end the following new section:

6 “CAPITAL INFRASTRUCTURE REVOLVING LOAN PROGRAM  
7 “SEC. 1603. (a) AUTHORITY TO MAKE AND GUAR-  
8 ANTEE LOANS.—

9 “(1) AUTHORITY TO MAKE LOANS.—The Sec-  
10 retary may make loans from the fund established  
11 under section 1602(d) to any rural entity for  
12 projects for capital improvements, including—

13 “(A) the acquisition of land necessary for  
14 the capital improvements;

15 “(B) the renovation or modernization of  
16 any building;

17 “(C) the acquisition or repair of fixed or  
18 major movable equipment; and

19 “(D) such other project expenses as the  
20 Secretary determines appropriate.

21 “(2) AUTHORITY TO GUARANTEE LOANS.—

22 “(A) IN GENERAL.—The Secretary may  
23 guarantee the payment of principal and interest  
24 for loans made to rural entities for projects for  
25 any capital improvement described in paragraph  
26 (1) to any non-Federal lender.

1           “(B) INTEREST SUBSIDIES.—In the case  
2           of a guarantee of any loan made to a rural enti-  
3           ty under subparagraph (A), the Secretary may  
4           pay to the holder of such loan, for and on be-  
5           half of the project for which the loan was made,  
6           amounts sufficient to reduce (by not more than  
7           3 percent) the net effective interest rate other-  
8           wise payable on such loan.

9           “(b) AMOUNT OF LOAN.—The principal amount of  
10          a loan directly made or guaranteed under subsection (a)  
11          for a project for capital improvement may not exceed  
12          \$5,000,000.

13          “(c) FUNDING LIMITATIONS.—

14               “(1) GOVERNMENT CREDIT SUBSIDY EXPO-  
15               SURE.—The total of the Government credit subsidy  
16               exposure under the Credit Reform Act of 1990 scor-  
17               ing protocol with respect to the loans outstanding at  
18               any time with respect to which guarantees have been  
19               issued, or which have been directly made, under sub-  
20               section (a) may not exceed \$50,000,000 per year.

21               “(2) TOTAL AMOUNTS.—Subject to paragraph  
22               (1), the total of the principal amount of all loans di-  
23               rectly made or guaranteed under subsection (a) may  
24               not exceed \$250,000,000 per year.

1       “(d) CAPITAL ASSESSMENT AND PLANNING  
2 GRANTS.—

3           “(1) NONREPAYABLE GRANTS.—Subject to  
4 paragraph (2), the Secretary may make a grant to  
5 a rural entity, in an amount not to exceed \$50,000,  
6 for purposes of capital assessment and business  
7 planning.

8           “(2) LIMITATION.—The cumulative total of  
9 grants awarded under this subsection may not ex-  
10 ceed \$2,500,000 per year.

11       “(e) TERMINATION OF AUTHORITY.—The Secretary  
12 may not directly make or guarantee any loan under sub-  
13 section (a) or make a grant under subsection (d) after  
14 September 30, 2008.”.

15       (b) RURAL ENTITY DEFINED.—Section 1624 of the  
16 Public Health Service Act (42 U.S.C. 300s–3) is amended  
17 by adding at the end the following new paragraph:

18           “(14)(A) The term ‘rural entity’ includes—

19               “(i) a rural health clinic, as defined in sec-  
20 tion 1861(aa)(2) of the Social Security Act;

21               “(ii) any medical facility with at least 1  
22 bed, but with less than 50 beds, that is located  
23 in—

24                   “(I) a county that is not part of a  
25 metropolitan statistical area; or

1           “(II) a rural census tract of a metro-  
2           politan statistical area (as determined  
3           under the most recent modification of the  
4           Goldsmith Modification, originally pub-  
5           lished in the Federal Register on February  
6           27, 1992 (57 Fed. Reg. 6725));

7           “(iii) a hospital that is classified as a  
8           rural, regional, or national referral center under  
9           section 1886(d)(5)(C) of the Social Security  
10          Act; and

11          “(iv) a hospital that is a sole community  
12          hospital (as defined in section  
13          1886(d)(5)(D)(iii) of the Social Security Act).

14          “(B) For purposes of subparagraph (A), the  
15          fact that a clinic, facility, or hospital has been geo-  
16          graphically reclassified under the medicare program  
17          under title XVIII of the Social Security Act shall not  
18          preclude a hospital from being considered a rural en-  
19          tity under clause (i) or (ii) of subparagraph (A).”.

20          (c) CONFORMING AMENDMENTS.—Section 1602 of  
21          the Public Health Service Act (42 U.S.C. 300q–2) is  
22          amended—

23                 (1) in subsection (b)(2)(D), by inserting “or  
24                 1603(a)(2)(B)” after “1601(a)(2)(B)”; and

25                 (2) in subsection (d)—

1 (A) in paragraph (1)(C), by striking “sec-  
2 tion 1601(a)(2)(B)” and inserting “sections  
3 1601(a)(2)(B) and 1603(a)(2)(B)”;

4 (B) in paragraph (2)(A), by inserting “or  
5 1603(a)(2)(B)” after “1601(a)(2)(B)”.

6 **SEC. 610. FEDERAL REIMBURSEMENT OF EMERGENCY**  
7 **HEALTH SERVICES FURNISHED TO UNDOCU-**  
8 **MENTED ALIENS.**

9 (a) **TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—**

10 There is appropriated, out of any funds in the Treasury  
11 not otherwise appropriated, \$250,000,000 for each of fis-  
12 cal years 2005 through 2008, for the purpose of making  
13 allotments under this section to States described in para-  
14 graph (1) or (2) of subsection (b). Funds appropriated  
15 under the preceding sentence shall remain available until  
16 expended.

17 (b) **STATE ALLOTMENTS.—**

18 (1) **BASED ON PERCENTAGE OF UNDOCU-**  
19 **MENTED ALIENS.—**

20 (A) **IN GENERAL.—**Out of the amount ap-  
21 propriated under subsection (a) for a fiscal  
22 year, the Secretary shall use \$167,000,000 of  
23 such amount to make allotments for such fiscal  
24 year in accordance with subparagraph (B).

1 (B) FORMULA.—The amount of the allot-  
2 ment for each State for a fiscal year shall be  
3 equal to the product of—

4 (i) the total amount available for al-  
5 lotments under this paragraph for the fis-  
6 cal year; and

7 (ii) the percentage of undocumented  
8 aliens residing in the State with respect to  
9 the total number of such aliens residing in  
10 all States, as determined by the Statistics  
11 Division of the Immigration and Natu-  
12 ralization Service, as of January 2003,  
13 based on the 2000 decennial census.

14 (2) BASED ON NUMBER OF UNDOCUMENTED  
15 ALIEN APPREHENSION STATES.—

16 (A) IN GENERAL.—Out of the amount ap-  
17 propriated under subsection (a) for a fiscal  
18 year, the Secretary shall use \$83,000,000 of  
19 such amount to make allotments for such fiscal  
20 year for each of the 6 States with the highest  
21 number of undocumented alien apprehensions  
22 for such fiscal year.

23 (B) DETERMINATION OF ALLOTMENTS.—  
24 The amount of the allotment for each State de-  
25 scribed in subparagraph (A) for a fiscal year

1 shall bear the same ratio to the total amount  
2 available for allotments under this paragraph  
3 for the fiscal year as the ratio of the number  
4 of undocumented alien apprehensions in the  
5 State in that fiscal year bears to the total of  
6 such numbers for all such States for such fiscal  
7 year.

8 (C) DATA.—For purposes of this para-  
9 graph, the highest number of undocumented  
10 alien apprehensions for a fiscal year shall be  
11 based on the 4 most recent quarterly apprehen-  
12 sion rates for undocumented aliens in such  
13 States, as reported by the Immigration and  
14 Naturalization Service.

15 (3) RULE OF CONSTRUCTION.—Nothing in this  
16 section shall be construed as prohibiting a State that  
17 is described in both of paragraphs (1) and (2) from  
18 receiving an allotment under both paragraphs for a  
19 fiscal year.

20 (c) USE OF FUNDS.—

21 (1) AUTHORITY TO MAKE PAYMENTS.—From  
22 the allotments made for a State under subsection (b)  
23 for a fiscal year, the Secretary shall pay directly to  
24 local governments, hospitals, or other providers lo-  
25 cated in the State (including providers of services re-

1       ceived through an Indian Health Service facility  
2       whether operated by the Indian Health Service or by  
3       an Indian tribe or tribal organization) that provide  
4       uncompensated emergency health services furnished  
5       to undocumented aliens during that fiscal year, and  
6       to the State, such amounts (subject to the total  
7       amount available from such allotments) as the local  
8       governments, hospitals, providers, or State dem-  
9       onstrate were incurred for the provision of such  
10      services during that fiscal year.

11           (2) LIMITATION ON STATE USE OF FUNDS.—  
12      Funds paid to a State from allotments made under  
13      subsection (b) for a fiscal year may only be used for  
14      making payments to local governments, hospitals, or  
15      other providers for costs incurred in providing emer-  
16      gency health services to undocumented aliens or for  
17      State costs incurred with respect to the provision of  
18      emergency health services to such aliens.

19           (3) INCLUSION OF COSTS INCURRED WITH RE-  
20      SPECT TO CERTAIN ALIENS.—Uncompensated emer-  
21      gency health services furnished to aliens who have  
22      been allowed to enter the United States for the sole  
23      purpose of receiving emergency health services may  
24      be included in the determination of costs incurred by

1 a State, local government, hospital, or other provider  
2 with respect to the provision of such services.

3 (d) APPLICATIONS; ADVANCE PAYMENTS.—

4 (1) DEADLINE FOR ESTABLISHMENT OF APPLI-  
5 CATION PROCESS.—

6 (A) IN GENERAL.—Not later than Sep-  
7 tember 1, 2004, the Secretary shall establish a  
8 process under which States, local governments,  
9 hospitals, or other providers located in the  
10 State may apply for payments from allotments  
11 made under subsection (b) for a fiscal year for  
12 uncompensated emergency health services fur-  
13 nished to undocumented aliens during that fis-  
14 cal year.

15 (B) INCLUSION OF MEASURES TO COMBAT  
16 FRAUD.—The Secretary shall include in the  
17 process established under subparagraph (A)  
18 measures to ensure that fraudulent payments  
19 are not made from the allotments determined  
20 under subsection (b).

21 (2) ADVANCE PAYMENT; RETROSPECTIVE AD-  
22 JUSTMENT.—The process established under para-  
23 graph (1) shall allow for making payments under  
24 this section for each quarter of a fiscal year on the  
25 basis of advance estimates of expenditures submitted

1 by applicants for such payments and such other in-  
2 vestigation as the Secretary may find necessary, and  
3 for making reductions or increases in the payments  
4 as necessary to adjust for any overpayment or un-  
5 derpayment for prior quarters of such fiscal year.

6 (e) DEFINITIONS.—In this section:

7 (1) HOSPITAL.—The term “hospital” has the  
8 meaning given such term in section 1861(e) of the  
9 Social Security Act (42 U.S.C. 1395x(e)).

10 (2) INDIAN TRIBE; TRIBAL ORGANIZATION.—  
11 The terms “Indian tribe” and “tribal organization”  
12 have the meanings given such terms in section 4 of  
13 the Indian Health Care Improvement Act (25 U.S.C.  
14 1603).

15 (3) PROVIDER.—The term “provider” includes  
16 a physician, any other health care professional li-  
17 censed under State law, and any other entity that  
18 furnishes emergency health services, including ambu-  
19 lance services.

20 (4) SECRETARY.—The term “Secretary” means  
21 the Secretary of Health and Human Services.

22 (5) STATE.—The term “State” means the 50  
23 States and the District of Columbia.

1 **SEC. 611. INCREASE IN APPROPRIATION TO THE HEALTH**  
2 **CARE FRAUD AND ABUSE CONTROL AC-**  
3 **COUNT.**

4 Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is  
5 amended—

6 (1) in clause (i)—

7 (A) in subclause (II), by striking “and” at  
8 the end; and

9 (B) by striking subclause (III), and insert-  
10 ing the following new subclauses:

11 “(III) for fiscal year 2004, the  
12 limit for fiscal year 2003 increased by  
13 \$10,000,000;

14 “(IV) for fiscal year 2005, the  
15 limit for fiscal year 2003 increased by  
16 \$15,000,000;

17 “(V) for fiscal year 2006, the  
18 limit for fiscal year 2003 increased by  
19 \$25,000,000; and

20 “(VI) for each fiscal year after  
21 fiscal year 2006, the limit for fiscal  
22 year 2003.”; and

23 (2) in clause (ii)—

24 (A) in subclause (VI), by striking “and” at  
25 the end;

26 (B) in subclause (VII)—

1 (i) by striking “each fiscal year after  
2 fiscal year 2002” and inserting “fiscal year  
3 2003”; and

4 (ii) by striking the period and insert-  
5 ing a semicolon; and

6 (3) by adding at the end the following:

7 “(VIII) for fiscal year 2004,  
8 \$170,000,000;

9 “(IX) for fiscal year 2005,  
10 \$175,000,000;

11 “(X) for fiscal year 2006,  
12 \$185,000,000; and

13 “(XI) for each fiscal year after  
14 fiscal year 2006, not less than  
15 \$150,000,000 and not more than  
16 \$160,000,000.”.

17 **SEC. 612. INCREASE IN CIVIL PENALTIES UNDER THE**  
18 **FALSE CLAIMS ACT.**

19 (a) IN GENERAL.—Section 3729(a) of title 31,  
20 United States Code, is amended—

21 (1) by striking “\$5,000” and inserting  
22 “\$7,500”; and

23 (2) by striking “\$10,000” and inserting  
24 “\$15,000”.

1 (b) EFFECTIVE DATE.—The amendments made by  
2 subsection (a) shall apply to violations occurring on or  
3 after January 1, 2004.

4 **SEC. 613. INCREASE IN CIVIL MONETARY PENALTIES**  
5 **UNDER THE SOCIAL SECURITY ACT.**

6 (a) IN GENERAL.—Section 1128A(a) (42 U.S.C.  
7 1320a–7a(a)), in the matter following paragraph (7), is  
8 amended—

9 (1) by striking “\$10,000” each place it appears  
10 and inserting “\$12,500”;

11 (2) by striking “\$15,000” and inserting  
12 “\$18,750”; and

13 (3) striking “\$50,000” and inserting  
14 “\$62,500”.

15 (b) EFFECTIVE DATE.—The amendments made by  
16 subsection (a) shall apply to violations occurring on or  
17 after January 1, 2004.

18 **SEC. 614. EXTENSION OF CUSTOMS USER FEES.**

19 Section 13031(j)(3) of the Consolidated Omnibus  
20 Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3))  
21 is amended by striking “September 30, 2003” and insert-  
22 ing “September 30, 2013”.

1 **TITLE VII—ACCESS TO AFFORD-**  
2 **ABLE PHARMACEUTICALS**

3 **SEC. 701. SHORT TITLE.**

4 This title may be cited as the “Greater Access to Af-  
5 fordable Pharmaceuticals Act”.

6 **SEC. 702. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

7 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-  
8 tion 505(j) of the Federal Food, Drug, and Cosmetic Act  
9 (21 U.S.C. 355(j)) is amended—

10 (1) in paragraph (2), by striking subparagraph  
11 (B) and inserting the following:

12 “(B) NOTICE OF OPINION THAT PATENT IS NOT  
13 VALID OR WILL NOT BE INFRINGED.—

14 “(i) AGREEMENT TO GIVE NOTICE.—An appli-  
15 cant that makes a certification described in subpara-  
16 graph (A)(vii)(IV) shall include in the application a  
17 statement that the applicant will give notice as re-  
18 quired by this subparagraph.

19 “(ii) TIMING OF NOTICE.—An applicant that  
20 makes a certification described in subparagraph  
21 (A)(vii)(IV) shall give notice as required under this  
22 subparagraph—

23 “(I) if the certification is in the applica-  
24 tion, not later than 20 days after the date of  
25 the postmark on the notice with which the Sec-

1           retary informs the applicant that the applica-  
2           tion has been filed; or

3           “(II) if the certification is in an amend-  
4           ment or supplement to the application, at the  
5           time at which the applicant submits the amend-  
6           ment or supplement, regardless of whether the  
7           applicant has already given notice with respect  
8           to another such certification contained in the  
9           application or in an amendment or supplement  
10          to the application.

11          “(iii) RECIPIENTS OF NOTICE.—An applicant  
12          required under this subparagraph to give notice shall  
13          give notice to—

14                 “(I) each owner of the patent that is the  
15                 subject of the certification (or a representative  
16                 of the owner designated to receive such a no-  
17                 tice); and

18                 “(II) the holder of the approved applica-  
19                 tion under subsection (b) for the drug that is  
20                 claimed by the patent or a use of which is  
21                 claimed by the patent (or a representative of  
22                 the holder designated to receive such a notice).

23          “(iv) CONTENTS OF NOTICE.—A notice required  
24          under this subparagraph shall—

1           “(I) state that an application that contains  
2 data from bioavailability or bioequivalence stud-  
3 ies has been submitted under this subsection for  
4 the drug with respect to which the certification  
5 is made to obtain approval to engage in the  
6 commercial manufacture, use, or sale of the  
7 drug before the expiration of the patent re-  
8 ferred to in the certification; and

9           “(II) include a detailed statement of the  
10 factual and legal basis of the opinion of the ap-  
11 plicant that the patent is not valid or will not  
12 be infringed.”; and

13 (2) in paragraph (5)—

14           (A) in subparagraph (B)—

15           (i) by striking “under the following”  
16 and inserting “by applying the following to  
17 each certification made under paragraph  
18 (2)(A)(vii)”;

19           (ii) in clause (iii)—

20           (I) in the first sentence, by strik-  
21 ing “unless” and all that follows and  
22 inserting “unless, before the expira-  
23 tion of 45 days after the date on  
24 which the notice described in para-  
25 graph (2)(B) is received, an action is

1 brought for infringement of the patent  
2 that is the subject of the certification  
3 and for which information was sub-  
4 mitted to the Secretary under sub-  
5 section (b)(1) or (c)(2) before the date  
6 on which the application (excluding an  
7 amendment or supplement to the ap-  
8 plication), which the Secretary later  
9 determines is substantially complete,  
10 was submitted.”; and

11 (II) in the second sentence—

12 (aa) by striking subclause

13 (I) and inserting the following:

14 “(I) if before the expiration of such period  
15 the district court decides that the patent is in-  
16 valid or not infringed (including any substantive  
17 determination that there is no cause of action  
18 for patent infringement or invalidity), the ap-  
19 proval shall be made effective on—

20 “(aa) the date on which the court en-  
21 ters judgment reflecting the decision; or

22 “(bb) the date of a settlement order  
23 or consent decree signed and entered by  
24 the court stating that the patent that is

1 the subject of the certification is invalid or  
2 not infringed;”;

3 (bb) by striking subclause  
4 (II) and inserting the following:

5 “(II) if before the expiration of such period  
6 the district court decides that the patent has  
7 been infringed—

8 “(aa) if the judgment of the district  
9 court is appealed, the approval shall be  
10 made effective on—

11 “(AA) the date on which the  
12 court of appeals decides that the pat-  
13 ent is invalid or not infringed (includ-  
14 ing any substantive determination  
15 that there is no cause of action for  
16 patent infringement or invalidity); or

17 “(BB) the date of a settlement  
18 order or consent decree signed and  
19 entered by the court of appeals stat-  
20 ing that the patent that is the subject  
21 of the certification is invalid or not in-  
22 fringed; or

23 “(bb) if the judgment of the district  
24 court is not appealed or is affirmed, the  
25 approval shall be made effective on the

1 date specified by the district court in a  
2 court order under section 271(e)(4)(A) of  
3 title 35, United States Code;”;

4 (cc) in subclause (III), by  
5 striking “on the date of such  
6 court decision.” and inserting “as  
7 provided in subclause (I); or”;  
8 and

9 (dd) by inserting after sub-  
10 clause (III) the following:

11 “(IV) if before the expiration of such pe-  
12 riod the court grants a preliminary injunction  
13 prohibiting the applicant from engaging in the  
14 commercial manufacture or sale of the drug  
15 until the court decides the issues of patent va-  
16 lidity and infringement and if the court decides  
17 that such patent has been infringed, the ap-  
18 proval shall be made effective as provided in  
19 subclause (II).”;

20 (B) by redesignating subparagraphs (C)  
21 and (D) as subparagraphs (E) and (F), respec-  
22 tively; and

23 (C) by inserting after subparagraph (B)  
24 the following:

1           “(C) CIVIL ACTION TO OBTAIN PATENT  
2           CERTAINTY.—

3           “(i) DECLARATORY JUDGMENT AB-  
4           SENT INFRINGEMENT ACTION.—If an  
5           owner of the patent or the holder of the  
6           approved application under subsection (b)  
7           for the drug that is claimed by the patent  
8           or a use of which is claimed by the patent  
9           does not bring a civil action against the  
10          applicant for infringement of the patent on  
11          or before the date that is 45 days after the  
12          date on which the notice given under para-  
13          graph (2)(B) was received, the applicant  
14          may bring a civil action against the owner  
15          or holder (but not against any owner or  
16          holder that has brought such a civil action  
17          against that applicant, unless that civil ac-  
18          tion was dismissed without prejudice) for  
19          a declaratory judgment under section 2201  
20          of title 28, United States Code, that the  
21          patent is invalid or will not be infringed  
22          by the drug for which the applicant seeks  
23          approval.

24          “(ii) COUNTERCLAIM TO INFRINGE-  
25          MENT ACTION.—

1           “(I) IN GENERAL.—If an owner  
2 of the patent or the holder of the ap-  
3 proved application under subsection  
4 (b) for the drug that is claimed by the  
5 patent or a use of which is claimed by  
6 the patent brings a patent infringe-  
7 ment action against the applicant, the  
8 applicant may assert a counterclaim  
9 seeking an order requiring the holder  
10 to correct or delete the patent infor-  
11 mation submitted by the holder under  
12 subsection (b) or (c) on the ground  
13 that the patent does not claim ei-  
14 ther—

15                   “(aa) the drug for which the  
16 application was approved; or

17                   “(bb) an approved method  
18 of using the drug.

19           “(II) NO INDEPENDENT CAUSE  
20 OF ACTION.—Subclause (I) does not  
21 authorize the assertion of a claim de-  
22 scribed in subclause (I) in any civil  
23 action or proceeding other than a  
24 counterclaim described in subclause  
25 (I).

1                   “(iii) NO DAMAGES.—An applicant  
2                   shall not be entitled to damages in a civil  
3                   action under subparagraph (i) or a coun-  
4                   terclaim under subparagraph (ii).”.

5           (b) APPLICATIONS GENERALLY.—Section 505 of the  
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
7 is amended—

8                   (1) in subsection (b), by striking paragraph (3)  
9                   and inserting the following:

10           “(3) NOTICE OF OPINION THAT PATENT IS NOT  
11 VALID OR WILL NOT BE INFRINGED.—

12                   “(A) AGREEMENT TO GIVE NOTICE.—An appli-  
13                   cant that makes a certification described in para-  
14                   graph (2)(A)(iv) shall include in the application a  
15                   statement that the applicant will give notice as re-  
16                   quired by this paragraph.

17                   “(B) TIMING OF NOTICE.—An applicant that  
18                   makes a certification described in paragraph  
19                   (2)(A)(iv) shall give notice as required under this  
20                   paragraph—

21                   “(i) if the certification is in the applica-  
22                   tion, not later than 20 days after the date of  
23                   the postmark on the notice with which the Sec-  
24                   retary informs the applicant that the applica-  
25                   tion has been filed; or

1           “(ii) if the certification is in an amend-  
2           ment or supplement to the application, at the  
3           time at which the applicant submits the amend-  
4           ment or supplement, regardless of whether the  
5           applicant has already given notice with respect  
6           to another such certification contained in the  
7           application or in an amendment or supplement  
8           to the application.

9           “(C) RECIPIENTS OF NOTICE.—An applicant  
10          required under this paragraph to give notice shall  
11          give notice to—

12                 “(i) each owner of the patent that is the  
13                 subject of the certification (or a representative  
14                 of the owner designated to receive such a no-  
15                 tice); and

16                 “(ii) the holder of the approved application  
17                 under this subsection for the drug that is  
18                 claimed by the patent or a use of which is  
19                 claimed by the patent (or a representative of  
20                 the holder designated to receive such a notice).

21           “(D) CONTENTS OF NOTICE.—A notice re-  
22          quired under this paragraph shall—

23                 “(i) state that an application that contains  
24                 data from bioavailability or bioequivalence stud-  
25                 ies has been submitted under this subsection for

1 the drug with respect to which the certification  
2 is made to obtain approval to engage in the  
3 commercial manufacture, use, or sale of the  
4 drug before the expiration of the patent re-  
5 ferred to in the certification; and

6 “(ii) include a detailed statement of the  
7 factual and legal basis of the opinion of the ap-  
8 plicant that the patent is not valid or will not  
9 be infringed.”; and

10 (2) in subsection (c)(3)—

11 (A) in the first sentence, by striking  
12 “under the following” and inserting “by apply-  
13 ing the following to each certification made  
14 under subsection (b)(2)(A)(iv)”;

15 (B) in subparagraph (C)—

16 (i) in the first sentence, by striking  
17 “unless” and all that follows and inserting  
18 “unless, before the expiration of 45 days  
19 after the date on which the notice de-  
20 scribed in subsection (b)(3) is received, an  
21 action is brought for infringement of the  
22 patent that is the subject of the certifi-  
23 cation and for which information was sub-  
24 mitted to the Secretary under paragraph  
25 (2) or subsection (b)(1) before the date on

1 which the application (excluding an amend-  
2 ment or supplement to the application) was  
3 submitted.”;

4 (ii) in the second sentence—

5 (I) by striking “paragraph  
6 (3)(B)” and inserting “subsection  
7 (b)(3)”;

8 (II) by striking clause (i) and in-  
9 serting the following:

10 “(i) if before the expiration of such period  
11 the district court decides that the patent is in-  
12 valid or not infringed (including any substantive  
13 determination that there is no cause of action  
14 for patent infringement or invalidity), the ap-  
15 proval shall be made effective on—

16 “(I) the date on which the court en-  
17 ters judgment reflecting the decision; or

18 “(II) the date of a settlement order or  
19 consent decree signed and entered by the  
20 court stating that the patent that is the  
21 subject of the certification is invalid or not  
22 infringed;”;

23 (III) by striking clause (ii) and  
24 inserting the following:

1           “(ii) if before the expiration of such period  
2 the district court decides that the patent has  
3 been infringed—

4           “(I) if the judgment of the district  
5 court is appealed, the approval shall be  
6 made effective on—

7           “(aa) the date on which the court  
8 of appeals decides that the patent is  
9 invalid or not infringed (including any  
10 substantive determination that there  
11 is no cause of action for patent in-  
12 fringement or invalidity); or

13           “(bb) the date of a settlement  
14 order or consent decree signed and  
15 entered by the court of appeals stat-  
16 ing that the patent that is the subject  
17 of the certification is invalid or not in-  
18 fringed; or

19           “(II) if the judgment of the district  
20 court is not appealed or is affirmed, the  
21 approval shall be made effective on the  
22 date specified by the district court in a  
23 court order under section 271(e)(4)(A) of  
24 title 35, United States Code;”;

1 (IV) in clause (iii), by striking  
2 “on the date of such court decision.”  
3 and inserting “as provided in clause  
4 (i); or”; and

5 (V) by inserting after clause (iii),  
6 the following:

7 “(iv) if before the expiration of such period  
8 the court grants a preliminary injunction pro-  
9 hibiting the applicant from engaging in the  
10 commercial manufacture or sale of the drug  
11 until the court decides the issues of patent va-  
12 lidity and infringement and if the court decides  
13 that such patent has been infringed, the ap-  
14 proval shall be made effective as provided in  
15 clause (ii).”; and

16 (iii) in the third sentence, by striking  
17 “paragraph (3)(B)” and inserting “sub-  
18 section (b)(3)”; and

19 (C) by redesignating subparagraph (D) as  
20 subparagraph (E); and

21 (D) by inserting after subparagraph (C)  
22 the following:

23 “(D) CIVIL ACTION TO OBTAIN PATENT  
24 CERTAINTY.—

1           “(i) DECLARATORY JUDGMENT AB-  
2           SENT INFRINGEMENT ACTION.—If an  
3           owner of the patent or the holder of the  
4           approved application under subsection (b)  
5           for the drug that is claimed by the patent  
6           or a use of which is claimed by the patent  
7           does not bring a civil action against the  
8           applicant for infringement of the patent on  
9           or before the date that is 45 days after the  
10          date on which the notice given under sub-  
11          section (b)(3) was received, the applicant  
12          may bring a civil action against the owner  
13          or holder (but not against any owner or  
14          holder that has brought such a civil action  
15          against that applicant, unless that civil ac-  
16          tion was dismissed without prejudice) for a  
17          declaratory judgment under section 2201  
18          of title 28, United States Code, that the  
19          patent is invalid or will not be infringed by  
20          the drug for which the applicant seeks ap-  
21          proval.

22           “(ii) COUNTERCLAIM TO INFRINGE-  
23          MENT ACTION.—

24                   “(I) IN GENERAL.—If an owner  
25                   of the patent or the holder of the ap-

1 proved application under subsection  
2 (b) for the drug that is claimed by the  
3 patent or a use of which is claimed by  
4 the patent brings a patent infringe-  
5 ment action against the applicant, the  
6 applicant may assert a counterclaim  
7 seeking an order requiring the holder  
8 to correct or delete the patent infor-  
9 mation submitted by the holder under  
10 subsection (b) or this subsection on  
11 the ground that the patent does not  
12 claim either—

13 “(aa) the drug for which the  
14 application was approved; or

15 “(bb) an approved method  
16 of using the drug.

17 “(II) NO INDEPENDENT CAUSE  
18 OF ACTION.—Subclause (I) does not  
19 authorize the assertion of a claim de-  
20 scribed in subclause (I) in any civil  
21 action or proceeding other than a  
22 counterclaim described in subclause  
23 (I).

24 “(iii) NO DAMAGES.—An applicant  
25 shall not be entitled to damages in a civil

1                   action under clause (i) or a counterclaim  
2                   under clause (ii).”.

3           (c) INFRINGEMENT ACTIONS.—Section 271(e) of title  
4 35, United States Code, is amended by adding at the end  
5 the following:

6                   “(5) The filing of an application described in  
7 paragraph (2) that includes a certification under  
8 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-  
9 tion 505 of the Federal Food, Drug, and Cosmetic  
10 Act (21 U.S.C. 355), and the failure of the owner  
11 of the patent to bring an action for infringement of  
12 a patent that is the subject of the certification be-  
13 fore the expiration of 45 days after the date on  
14 which the notice given under subsection (b)(3) or  
15 (j)(2)(B) of that section is received, shall establish  
16 an actual controversy between the applicant and the  
17 patent owner sufficient to confer subject matter ju-  
18 risdiction in the courts of the United States in any  
19 action brought by the applicant under section 2201  
20 of title 28 for a declaratory judgment that any pat-  
21 ent that is the subject of the certification is invalid  
22 or not infringed.”.

23           (d) APPLICABILITY.—

24                   (1) IN GENERAL.—Except as provided in para-  
25 graphs (2) and (3), the amendments made by sub-

1 sections (a), (b), and (c) apply to any proceeding  
2 under section 505 of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 355) that is pending on  
4 or after the date of enactment of this Act regardless  
5 of the date on which the proceeding was commenced  
6 or is commenced.

7 (2) NOTICE OF OPINION THAT PATENT IS IN-  
8 VALID OR WILL NOT BE INFRINGED.—The amend-  
9 ments made by subsections (a)(1) and (b)(1) apply  
10 with respect to any certification under subsection  
11 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of  
12 the Federal Food, Drug, and Cosmetic Act (21  
13 U.S.C. 355) after the date of enactment of this Act  
14 in an application filed under subsection (b)(2) or (j)  
15 of that section or in an amendment or supplement  
16 to an application filed under subsection (b)(2) or (j)  
17 of that section.

18 (3) EFFECTIVE DATE OF APPROVAL.—The  
19 amendments made by subsections (a)(2)(A)(ii)(I)  
20 and (b)(2)(B)(i) apply with respect to any patent in-  
21 formation submitted under subsection (b)(1) or  
22 (c)(2) of section 505 of the Federal Food, Drug, and  
23 Cosmetic Act (21 U.S.C. 355) made after the date  
24 of enactment of this Act.

1 **SEC. 703. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

2 (a) IN GENERAL.—Section 505(j)(5) of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as  
4 amended by section \_\_\_\_02) is amended—

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

7 “(iv) 180-DAY EXCLUSIVITY PERIOD.—

8 “(I) DEFINITIONS.—In this paragraph:

9 “(aa) 180-DAY EXCLUSIVITY PE-  
10 RIOD.—The term ‘180-day exclusivity pe-  
11 riod’ means the 180-day period ending on  
12 the day before the date on which an appli-  
13 cation submitted by an applicant other  
14 than a first applicant could become effec-  
15 tive under this clause.

16 “(bb) FIRST APPLICANT.—The term  
17 ‘first applicant’ means an applicant that,  
18 on the first day on which a substantially  
19 complete application containing a certifi-  
20 cation described in paragraph  
21 (2)(A)(vii)(IV) is submitted for approval of  
22 a drug, submits a substantially complete  
23 application containing a certification de-  
24 scribed in paragraph (2)(A)(vii)(IV) for  
25 the drug.

1           “(cc) SUBSTANTIALLY COMPLETE AP-  
2           PLICATION.—The term ‘substantially com-  
3           plete application’ means an application  
4           under this subsection that on its face is  
5           sufficiently complete to permit a sub-  
6           stantive review and contains all the infor-  
7           mation required by paragraph (2)(A).

8           “(dd) TENTATIVE APPROVAL.—

9           “(AA) IN GENERAL.—The term  
10          ‘tentative approval’ means notification  
11          to an applicant by the Secretary that  
12          an application under this subsection  
13          meets the requirements of paragraph  
14          (2)(A), but cannot receive effective  
15          approval because the application does  
16          not meet the requirements of this sub-  
17          paragraph, there is a period of exclu-  
18          sivity for the listed drug under sub-  
19          paragraph (E) or section 505A, or  
20          there is a 7-year period of exclusivity  
21          for the listed drug under section 527.

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

1                   proval until the Secretary issues an  
2                   approval after any necessary addi-  
3                   tional review of the application.

4                   “(II) EFFECTIVENESS OF APPLICATION.—

5                   Subject to subparagraph (D), if the application  
6                   contains a certification described in paragraph  
7                   (2)(A)(vii)(IV) and is for a drug for which a  
8                   first applicant has submitted an application  
9                   containing such a certification, the application  
10                  shall be made effective on the date that is 180  
11                  days after the date of the first commercial mar-  
12                  keting of the drug (including the commercial  
13                  marketing of the listed drug) by any first appli-  
14                  cant.”; and

15                  (2) by inserting after subparagraph (C) the fol-  
16                  lowing:

17                  “(D) FORFEITURE OF 180-DAY EXCLU-  
18                  SIVITY PERIOD.—

19                  “(i) DEFINITION OF FORFEITURE  
20                  EVENT.—In this subparagraph, the term  
21                  ‘forfeiture event’, with respect to an appli-  
22                  cation under this subsection, means the oc-  
23                  currence of any of the following:

1           “(I) FAILURE TO MARKET.—The  
2 first applicant fails to market the  
3 drug by the later of—

4                   “(aa) the earlier of the date  
5 that is—

6                           “(AA) 75 days after the  
7 date on which the approval  
8 of the application of the first  
9 applicant is made effective  
10 under subparagraph (B)(iii);  
11 or

12                           “(BB) 30 months after  
13 the date of submission of  
14 the application of the first  
15 applicant; or

16                   “(bb) with respect to the  
17 first applicant or any other appli-  
18 cant (which other applicant has  
19 received tentative approval), the  
20 date that is 75 days after the  
21 date as of which, as to each of  
22 the patents with respect to which  
23 the first applicant submitted a  
24 certification qualifying the first  
25 applicant for the 180-day exclu-

1 sivity period under subparagraph  
2 (B)(iv), at least 1 of the fol-  
3 lowing has occurred:

4 “(AA) In an infringe-  
5 ment action brought against  
6 that applicant with respect  
7 to the patent or in a declar-  
8 atory judgment action  
9 brought by that applicant  
10 with respect to the patent, a  
11 court enters a final decision  
12 from which no appeal (other  
13 than a petition to the Su-  
14 preme Court for a writ of  
15 certiorari) has been or can  
16 be taken that the patent is  
17 invalid or not infringed.

18 “(BB) In an infringe-  
19 ment action or a declaratory  
20 judgment action described in  
21 subitem (AA), a court signs  
22 a settlement order or con-  
23 sent decree that enters a  
24 final judgment that includes

1 a finding that the patent is  
2 invalid or not infringed.

3 “(CC) The patent ex-  
4 pires.

5 “(DD) The patent is  
6 withdrawn by the holder of  
7 the application approved  
8 under subsection (b).

9 “(II) WITHDRAWAL OF APPLICA-  
10 TION.—The first applicant withdraws  
11 the application or the Secretary con-  
12 siders the application to have been  
13 withdrawn as a result of a determina-  
14 tion by the Secretary that the applica-  
15 tion does not meet the requirements  
16 for approval under paragraph (4).

17 “(III) AMENDMENT OF CERTIFI-  
18 CATION.—The first applicant amends  
19 or withdraws the certification for all  
20 of the patents with respect to which  
21 that applicant submitted a certifi-  
22 cation qualifying the applicant for the  
23 180-day exclusivity period.

24 “(IV) FAILURE TO OBTAIN TEN-  
25 TATIVE APPROVAL.—The first appli-

1 cant fails to obtain tentative approval  
2 of the application within 30 months  
3 after the date on which the applica-  
4 tion is filed, unless the failure is  
5 caused by a change in or a review of  
6 the requirements for approval of the  
7 application imposed after the date on  
8 which the application is filed.

9 “(V) AGREEMENT WITH AN-  
10 OTHER APPLICANT, THE LISTED DRUG  
11 APPLICATION HOLDER, OR A PATENT  
12 OWNER.—The first applicant enters  
13 into an agreement with another appli-  
14 cant under this subsection for the  
15 drug, the holder of the application for  
16 the listed drug, or an owner of the  
17 patent that is the subject of the cer-  
18 tification under paragraph  
19 (2)(A)(vii)(IV), the Federal Trade  
20 Commission or the Attorney General  
21 files a complaint, and there is a final  
22 decision of the Federal Trade Com-  
23 mission or the court with regard to  
24 the complaint from which no appeal  
25 (other than a petition to the Supreme

1 Court for a writ of certiorari) has  
2 been or can be taken that the agree-  
3 ment has violated the antitrust laws  
4 (as defined in section 1 of the Clayton  
5 Act (15 U.S.C. 12), except that the  
6 term includes section 5 of the Federal  
7 Trade Commission Act (15 U.S.C. 45)  
8 to the extent that that section applies  
9 to unfair methods of competition).

10 “(VI) EXPIRATION OF ALL PAT-  
11 ENTS.—All of the patents as to which  
12 the applicant submitted a certification  
13 qualifying it for the 180-day exclu-  
14 sivity period have expired.

15 “(ii) FORFEITURE.—The 180-day ex-  
16 clusivity period described in subparagraph  
17 (B)(iv) shall be forfeited by a first appli-  
18 cant if a forfeiture event occurs with re-  
19 spect to that first applicant.

20 “(iii) SUBSEQUENT APPLICANT.—If  
21 all first applicants forfeit the 180-day ex-  
22 clusivity period under clause (ii)—

23 “(I) approval of any application  
24 containing a certification described in  
25 paragraph (2)(A)(vii)(IV) shall be

1                   made effective in accordance with sub-  
2                   paragraph (B)(iii); and

3                   “(II) no applicant shall be eligi-  
4                   ble for a 180-day exclusivity period.”.

5           (b) EFFECTIVE DATE.—

6               (1) IN GENERAL.—Except as provided in para-  
7               graph (2), the amendment made by subsection (a)  
8               shall be effective only with respect to an application  
9               filed under section 505(j) of the Federal Food,  
10              Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the  
11              date of enactment of this Act for a listed drug for  
12              which no certification under section  
13              505(j)(2)(A)(vii)(IV) of that Act was made before  
14              the date of enactment of this Act.

15             (2) COLLUSIVE AGREEMENTS.—If a forfeiture  
16             event described in section 505(j)(5)(D)(i)(V) of that  
17             Act occurs in the case of an applicant, the applicant  
18             shall forfeit the 180-day period under section  
19             505(j)(5)(B)(iv) of that Act without regard to when  
20             the first certification under section  
21             505(j)(2)(A)(vii)(IV) of that Act for the listed drug  
22             was made.

23             (3) DECISION OF A COURT WHEN THE 180-DAY  
24             EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.—  
25             With respect to an application filed before, on, or

1 after the date of enactment of this Act for a listed  
2 drug for which a certification under section  
3 505(j)(2)(A)(vii)(IV) of that Act was made before  
4 the date of enactment of this Act and for which nei-  
5 ther of the events described in subclause (I) or (II)  
6 of section 505(j)(5)(B)(iv) of that Act (as in effect  
7 on the day before the date of enactment of this Act)  
8 has occurred on or before the date of enactment of  
9 this Act, the term “decision of a court” as used in  
10 clause (iv) of section 505(j)(5)(B) of that Act means  
11 a final decision of a court from which no appeal  
12 (other than a petition to the Supreme Court for a  
13 writ of certiorari) has been or can be taken.

14 **SEC. 704. BIOAVAILABILITY AND BIOEQUIVALENCE.**

15 (a) IN GENERAL.—Section 505(j)(8) of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is  
17 amended—

18 (1) by striking subparagraph (A) and inserting  
19 the following:

20 “(A)(i) The term ‘bioavailability’ means the  
21 rate and extent to which the active ingredient or  
22 therapeutic ingredient is absorbed from a drug and  
23 becomes available at the site of drug action.

24 “(ii) For a drug that is not intended to be ab-  
25 sorbed into the bloodstream, the Secretary may as-

1       sess bioavailability by scientifically valid measure-  
2       ments intended to reflect the rate and extent to  
3       which the active ingredient or therapeutic ingredient  
4       becomes available at the site of drug action.”; and

5               (2) by adding at the end the following:

6               “(C) For a drug that is not intended to be ab-  
7       sorbed into the bloodstream, the Secretary may es-  
8       tablish alternative, scientifically valid methods to  
9       show bioequivalence if the alternative methods are  
10      expected to detect a significant difference between  
11      the drug and the listed drug in safety and thera-  
12      peutic effect.”.

13      (b) EFFECT OF AMENDMENT.—The amendment  
14      made by subsection (a) does not alter the standards for  
15      approval of drugs under section 505(j) of the Federal  
16      Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

17      **SEC. 705. REMEDIES FOR INFRINGEMENT.**

18      Section 287 of title 35, United States Code, is  
19      amended by adding at the end the following:

20              “(d) CONSIDERATION.—In making a determination  
21      with respect to remedy brought for infringement of a pat-  
22      ent that claims a drug or a method of using a drug, the  
23      court shall consider whether information on the patent  
24      was filed as required under 21 U.S.C. 355 (b) or (c), and,  
25      if such information was required to be filed but was not,

1 the court may refuse to award treble damages under sec-  
2 tion 284.”.

3 **SEC. 706. CONFORMING AMENDMENTS.**

4 Section 505A of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 355a) is amended—

6 (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i),  
7 by striking “(j)(5)(D)(ii)” each place it appears and  
8 inserting “(j)(5)(F)(ii)”;

9 (2) in subsections (b)(1)(A)(ii) and  
10 (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it  
11 appears and inserting “(j)(5)(F)”;

12 (3) in subsections (e) and (l), by striking  
13 “505(j)(5)(D)” each place it appears and inserting  
14 “505(j)(5)(F)”.

15 **TITLE VIII—IMPORTATION OF**  
16 **PRESCRIPTION DRUGS**

17 **SEC. 801. IMPORTATION OF PRESCRIPTION DRUGS.**

18 (a) IN GENERAL.—Chapter VIII of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)  
20 is amended by striking section 804 and inserting the fol-  
21 lowing:

22 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

23 **“(a) DEFINITIONS.—**In this section:

24 **“(1) IMPORTER.—**The term ‘importer’ means a  
25 pharmacist or wholesaler.

1           “(2) PHARMACIST.—The term ‘pharmacist’  
2 means a person licensed by a State to practice phar-  
3 macy, including the dispensing and selling of pre-  
4 scription drugs.

5           “(3) PRESCRIPTION DRUG.—The term ‘pre-  
6 scription drug’ means a drug subject to section  
7 503(b), other than—

8                   “(A) a controlled substance (as defined in  
9 section 102 of the Controlled Substances Act  
10 (21 U.S.C. 802));

11                   “(B) a biological product (as defined in  
12 section 351 of the Public Health Service Act  
13 (42 U.S.C. 262));

14                   “(C) an infused drug (including a peri-  
15 toneal dialysis solution);

16                   “(D) an intravenously injected drug; or

17                   “(E) a drug that is inhaled during surgery.

18           “(4) QUALIFYING LABORATORY.—The term  
19 ‘qualifying laboratory’ means a laboratory in the  
20 United States that has been approved by the Sec-  
21 retary for the purposes of this section.

22           “(5) WHOLESALER.—

23                   “(A) IN GENERAL.—The term ‘wholesaler’  
24 means a person licensed as a wholesaler or dis-

1           tributor of prescription drugs in the United  
2           States under section 503(e)(2)(A).

3           “(B) EXCLUSION.—The term ‘wholesaler’  
4           does not include a person authorized to import  
5           drugs under section 801(d)(1).

6           “(b) REGULATIONS.—The Secretary, after consulta-  
7           tion with the United States Trade Representative and the  
8           Commissioner of Customs, shall promulgate regulations  
9           permitting pharmacists and wholesalers to import pre-  
10          scription drugs from Canada into the United States.

11          “(c) LIMITATION.—The regulations under subsection  
12          (b) shall—

13                 “(1) require that safeguards be in place to en-  
14                 sure that each prescription drug imported under the  
15                 regulations complies with section 505 (including  
16                 with respect to being safe and effective for the in-  
17                 tended use of the prescription drug), with sections  
18                 501 and 502, and with other applicable require-  
19                 ments of this Act;

20                 “(2) require that an importer of a prescription  
21                 drug under the regulations comply with subsections  
22                 (d)(1) and (e); and

23                 “(3) contain any additional provisions deter-  
24                 mined by the Secretary to be appropriate as a safe-

1 guard to protect the public health or as a means to  
2 facilitate the importation of prescription drugs.

3 “(d) INFORMATION AND RECORDS.—

4 “(1) IN GENERAL.—The regulations under sub-  
5 section (b) shall require an importer of a prescrip-  
6 tion drug under subsection (b) to submit to the Sec-  
7 retary the following information and documentation:

8 “(A) The name and quantity of the active  
9 ingredient of the prescription drug.

10 “(B) A description of the dosage form of  
11 the prescription drug.

12 “(C) The date on which the prescription  
13 drug is shipped.

14 “(D) The quantity of the prescription drug  
15 that is shipped.

16 “(E) The point of origin and destination of  
17 the prescription drug.

18 “(F) The price paid by the importer for  
19 the prescription drug.

20 “(G) Documentation from the foreign sell-  
21 er specifying—

22 “(i) the original source of the pre-  
23 scription drug; and

1           “(ii) the quantity of each lot of the  
2           prescription drug originally received by the  
3           seller from that source.

4           “(H) The lot or control number assigned  
5           to the prescription drug by the manufacturer of  
6           the prescription drug.

7           “(I) The name, address, telephone number,  
8           and professional license number (if any) of the  
9           importer.

10          “(J)(i) In the case of a prescription drug  
11          that is shipped directly from the first foreign  
12          recipient of the prescription drug from the  
13          manufacturer:

14               “(I) Documentation demonstrating  
15               that the prescription drug was received by  
16               the recipient from the manufacturer and  
17               subsequently shipped by the first foreign  
18               recipient to the importer.

19               “(II) Documentation of the quantity  
20               of each lot of the prescription drug re-  
21               ceived by the first foreign recipient dem-  
22               onstrating that the quantity being im-  
23               ported into the United States is not more  
24               than the quantity that was received by the  
25               first foreign recipient.

1           “(III)(aa) In the case of an initial im-  
2           ported shipment, documentation dem-  
3           onstrating that each batch of the prescrip-  
4           tion drug in the shipment was statistically  
5           sampled and tested for authenticity and  
6           degradation.

7           “(bb) In the case of any subsequent  
8           shipment, documentation demonstrating  
9           that a statistically valid sample of the ship-  
10          ment was tested for authenticity and deg-  
11          radation.

12          “(ii) In the case of a prescription drug  
13          that is not shipped directly from the first for-  
14          eign recipient of the prescription drug from the  
15          manufacturer, documentation demonstrating  
16          that each batch in each shipment offered for  
17          importation into the United States was statis-  
18          tically sampled and tested for authenticity and  
19          degradation.

20          “(K) Certification from the importer or  
21          manufacturer of the prescription drug that the  
22          prescription drug—

23                  “(i) is approved for marketing in the  
24                  United States; and

1                   “(ii) meets all labeling requirements  
2                   under this Act.

3                   “(L) Laboratory records, including com-  
4                   plete data derived from all tests necessary to  
5                   ensure that the prescription drug is in compli-  
6                   ance with established specifications and stand-  
7                   ards.

8                   “(M) Documentation demonstrating that  
9                   the testing required by subparagraphs (J) and  
10                  (L) was conducted at a qualifying laboratory.

11                  “(N) Any other information that the Sec-  
12                  retary determines is necessary to ensure the  
13                  protection of the public health.

14                  “(2) MAINTENANCE BY THE SECRETARY.—The  
15                  Secretary shall maintain information and docu-  
16                  mentation submitted under paragraph (1) for such  
17                  period of time as the Secretary determines to be nec-  
18                  essary.

19                  “(e) TESTING.—The regulations under subsection (b)  
20 shall require—

21                  “(1) that testing described in subparagraphs  
22                  (J) and (L) of subsection (d)(1) be conducted by the  
23                  importer or by the manufacturer of the prescription  
24                  drug at a qualified laboratory;

1           “(2) if the tests are conducted by the im-  
2           porter—

3                   “(A) that information needed to—

4                           “(i) authenticate the prescription drug  
5                           being tested; and

6                           “(ii) confirm that the labeling of the  
7                           prescription drug complies with labeling re-  
8                           quirements under this Act;

9                   be supplied by the manufacturer of the pre-  
10                  scription drug to the pharmacist or wholesaler;  
11                  and

12                   “(B) that the information supplied under  
13                   subparagraph (A) be kept in strict confidence  
14                   and used only for purposes of testing or other-  
15                   wise complying with this Act; and

16                  “(3) may include such additional provisions as  
17                  the Secretary determines to be appropriate to pro-  
18                  vide for the protection of trade secrets and commer-  
19                  cial or financial information that is privileged or  
20                  confidential.

21                  “(f) REGISTRATION OF FOREIGN SELLERS.—Any es-  
22                  tablishment within Canada engaged in the distribution of  
23                  a prescription drug that is imported or offered for impor-  
24                  tation into the United States shall register with the Sec-

1 retary the name and place of business of the establish-  
2 ment.

3 “(g) SUSPENSION OF IMPORTATION.—The Secretary  
4 shall require that importations of a specific prescription  
5 drug or importations by a specific importer under sub-  
6 section (b) be immediately suspended on discovery of a  
7 pattern of importation of that specific prescription drug  
8 or by that specific importer of drugs that are counterfeit  
9 or in violation of any requirement under this section, until  
10 an investigation is completed and the Secretary deter-  
11 mines that the public is adequately protected from coun-  
12 terfeit and violative prescription drugs being imported  
13 under subsection (b).

14 “(h) APPROVED LABELING.—The manufacturer of a  
15 prescription drug shall provide an importer written au-  
16 thorization for the importer to use, at no cost, the ap-  
17 proved labeling for the prescription drug.

18 “(i) PROHIBITION OF DISCRIMINATION.—

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

1 prescription drug manufactured by the drug manu-  
2 facturer.

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

10 “(A) providing pharmacists or wholesalers  
11 access to prescription drugs on terms or condi-  
12 tions that are less favorable than the terms or  
13 conditions provided to a foreign purchaser  
14 (other than a charitable or humanitarian orga-  
15 nization) of the prescription drug; or

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

20 “(j) CHARITABLE CONTRIBUTIONS.—Notwith-  
21 standing any other provision of this section, section  
22 801(d)(1) continues to apply to a prescription drug that  
23 is donated or otherwise supplied at no charge by the man-  
24 ufacturer of the drug to a charitable or humanitarian or-

1 ganization (including the United Nations and affiliates)  
2 or to a government of a foreign country.

3 “(k) WAIVER AUTHORITY FOR IMPORTATION BY IN-  
4 DIVIDUALS.—

5 “(1) DECLARATIONS.—Congress declares that  
6 in the enforcement against individuals of the prohi-  
7 bition of importation of prescription drugs and de-  
8 vices, the Secretary should—

9 “(A) focus enforcement on cases in which  
10 the importation by an individual poses a signifi-  
11 cant threat to public health; and

12 “(B) exercise discretion to permit individ-  
13 uals to make such importations in cir-  
14 cumstances in which—

15 “(i) the importation is clearly for per-  
16 sonal use; and

17 “(ii) the prescription drug or device  
18 imported does not appear to present an  
19 unreasonable risk to the individual.

20 “(2) WAIVER AUTHORITY.—

21 “(A) IN GENERAL.—The Secretary may  
22 grant to individuals, by regulation or on a case-  
23 by-case basis, a waiver of the prohibition of im-  
24 portation of a prescription drug or device or  
25 class of prescription drugs or devices, under

1 such conditions as the Secretary determines to  
2 be appropriate.

3 “(B) GUIDANCE ON CASE-BY-CASE WAIV-  
4 ERS.—The Secretary shall publish, and update  
5 as necessary, guidance that accurately describes  
6 circumstances in which the Secretary will con-  
7 sistently grant waivers on a case-by-case basis  
8 under subparagraph (A), so that individuals  
9 may know with the greatest practicable degree  
10 of certainty whether a particular importation  
11 for personal use will be permitted.

12 “(3) DRUGS IMPORTED FROM CANADA.—In  
13 particular, the Secretary shall by regulation grant  
14 individuals a waiver to permit individuals to import  
15 into the United States a prescription drug that—

16 “(A) is imported from a licensed pharmacy  
17 for personal use by an individual, not for resale,  
18 in quantities that do not exceed a 90-day sup-  
19 ply;

20 “(B) is accompanied by a copy of a valid  
21 prescription;

22 “(C) is imported from Canada, from a sell-  
23 er registered with the Secretary;

24 “(D) is a prescription drug approved by  
25 the Secretary under chapter V;

1           “(E) is in the form of a final finished dos-  
2           age that was manufactured in an establishment  
3           registered under section 510; and

4           “(F) is imported under such other condi-  
5           tions as the Secretary determines to be nec-  
6           essary to ensure public safety.

7           “(1) STUDIES; REPORTS.—

8           “(1) BY THE INSTITUTE OF MEDICINE OF THE  
9           NATIONAL ACADEMY OF SCIENCES.—

10           “(A) STUDY.—

11           “(i) IN GENERAL.—The Secretary  
12           shall request that the Institute of Medicine  
13           of the National Academy of Sciences con-  
14           duct a study of—

15           “(I) importations of prescription  
16           drugs made under the regulations  
17           under subsection (b); and

18           “(II) information and docu-  
19           mentation submitted under subsection  
20           (d).

21           “(ii) REQUIREMENTS.—In conducting  
22           the study, the Institute of Medicine shall—

23           “(I) evaluate the compliance of  
24           importers with the regulations under  
25           subsection (b);

1           “(II) compare the number of  
2           shipments under the regulations  
3           under subsection (b) during the study  
4           period that are determined to be  
5           counterfeit, misbranded, or adulter-  
6           ated, and compare that number with  
7           the number of shipments made during  
8           the study period within the United  
9           States that are determined to be  
10          counterfeit, misbranded, or adulter-  
11          ated; and

12           “(III) consult with the Secretary,  
13          the United States Trade Representa-  
14          tive, and the Commissioner of Patents  
15          and Trademarks to evaluate the effect  
16          of importations under the regulations  
17          under subsection (b) on trade and  
18          patent rights under Federal law.

19           “(B) REPORT.—Not later than 2 years  
20          after the effective date of the regulations under  
21          subsection (b), the Institute of Medicine shall  
22          submit to Congress a report describing the find-  
23          ings of the study under subparagraph (A).

24           “(2) BY THE COMPTROLLER GENERAL.—

1           “(A) STUDY.—The Comptroller General of  
2           the United States shall conduct a study to de-  
3           termine the effect of this section on the price of  
4           prescription drugs sold to consumers at retail.

5           “(B) REPORT.—Not later than 18 months  
6           after the effective date of the regulations under  
7           subsection (b), the Comptroller General of the  
8           United States shall submit to Congress a report  
9           describing the findings of the study under sub-  
10          paragraph (A).

11          “(m) CONSTRUCTION.—Nothing in this section limits  
12          the authority of the Secretary relating to the importation  
13          of prescription drugs, other than with respect to section  
14          801(d)(1) as provided in this section.

15          “(n) EFFECTIVENESS OF SECTION.—

16                 “(1) IN GENERAL.—If, after the date that is 1  
17                 year after the effective date of the regulations under  
18                 subsection (b) and before the date that is 18 months  
19                 after the effective date, the Secretary submits to  
20                 Congress a certification that, in the opinion of the  
21                 Secretary, based on substantial evidence obtained  
22                 after the effective date, the benefits of implementa-  
23                 tion of this section do not outweigh any detriment  
24                 of implementation of this section, this section shall  
25                 cease to be effective as of the date that is 30 days

1 after the date on which the Secretary submits the  
2 certification.

3 “(2) PROCEDURE.—The Secretary shall not  
4 submit a certification under paragraph (1) unless,  
5 after a hearing on the record under sections 556 and  
6 557 of title 5, United States Code, the Secretary—

7 “(A)(i) determines that it is more likely  
8 than not that implementation of this section  
9 would result in an increase in the risk to the  
10 public health and safety;

11 “(ii) identifies specifically, in qualitative  
12 and quantitative terms, the nature of the in-  
13 creased risk;

14 “(iii) identifies specifically the causes of  
15 the increased risk; and

16 “(iv)(I) considers whether any measures  
17 can be taken to avoid, reduce, or mitigate the  
18 increased risk; and

19 “(II) if the Secretary determines that any  
20 measures described in subclause (I) would re-  
21 quire additional statutory authority, submits to  
22 Congress a report describing the legislation that  
23 would be required;

24 “(B) identifies specifically, in qualitative  
25 and quantitative terms, the benefits that would

1 result from implementation of this section (in-  
2 cluding the benefit of reductions in the cost of  
3 covered products to consumers in the United  
4 States, allowing consumers to procure needed  
5 medication that consumers might not otherwise  
6 be able to procure without foregoing other ne-  
7 cessities of life); and

8 “(C)(i) compares in specific terms the det-  
9 riment identified under subparagraph (A) with  
10 the benefits identified under subparagraph (B);  
11 and

12 “(ii) determines that the benefits do not  
13 outweigh the detriment.

14 “(o) CONDITIONS.—This section shall become effec-  
15 tive only if the Secretary of Health and Human Services  
16 certifies to the Congress that the implementation of this  
17 section will—

18 “(1) pose no additional risk to the public’s  
19 health and safety, and

20 “(2) result in a significant reduction in the cost  
21 of covered products to the American consumer.

22 “(p) AUTHORIZATION OF APPROPRIATIONS.—There  
23 are authorized to be appropriated such sums as are nec-  
24 essary to carry out this section.”.

1 (b) CONFORMING AMENDMENTS.—The Federal  
2 Food, Drug, and Cosmetic Act is amended—

3 (1) in section 301(aa) (21 U.S.C. 331(aa)), by  
4 striking “covered product in violation of section  
5 804” and inserting “prescription drug in violation of  
6 section 804”; and

7 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6),  
8 by striking “covered product pursuant to section  
9 804(a)” and inserting “prescription drug under sec-  
10 tion 804(b)”.

○