

107TH CONGRESS
2D SESSION

H. R. 5019

To amend titles XVIII and XIX of the Social Security Act to provide for a voluntary Medicare prescription medicine benefit, to provide greater access to affordable pharmaceuticals, to revise and improve payments to providers of services under the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 26, 2002

Mr. RANGEL (for himself, Mr. DINGELL, Mr. HOLDEN, Mr. MALONEY of Connecticut, Mr. ROSS, Mr. SHOWS, Mr. BROWN of Ohio, Mr. STARK, Mr. WAXMAN, Mr. PALLONE, Mr. ABERCROMBIE, Mr. ACKERMAN, Mr. ALLEN, Mr. ANDREWS, Mr. BACA, Mr. BAIRD, Mr. BALDACCI, Ms. BALDWIN, Mr. BARCIA, Mr. BARRETT of Wisconsin, Mr. BECERRA, Ms. BERKLEY, Mr. BERRY, Mr. BLUMENAUER, Mr. BONIOR, Mr. BORSKI, Mr. BOSWELL, Mr. BOUCHER, Mrs. CAPPS, Mr. CAPUANO, Mr. CARDIN, Ms. CARSON of Indiana, Mrs. CHRISTENSEN, Mr. CLAY, Mr. CONYERS, Mr. COYNE, Mr. CROWLEY, Mr. CUMMINGS, Mr. DAVIS of Illinois, Ms. DEGETTE, Mr. DELAHUNT, Ms. DELAURO, Mr. DEUTSCH, Mr. DOYLE, Mr. ENGEL, Ms. ESHOO, Mr. EVANS, Mr. FILNER, Mr. FRANK, Mr. FROST, Mr. GEPHARDT, Mr. GONZALEZ, Mr. GORDON, Mr. GREEN of Texas, Mr. HASTINGS of Florida, Mr. HILLIARD, Mr. HINCHEY, Mr. HINOJOSA, Mr. HONDA, Mr. HOYER, Mr. ISRAEL, Ms. JACKSON-LEE of Texas, Mr. JEFFERSON, Mr. JOHN, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. KANJORSKI, Ms. KAPTUR, Mr. KENNEDY of Rhode Island, Mr. KILDEE, Ms. KILPATRICK, Mr. KLECZKA, Mr. LaFALCE, Mr. LAMPSON, Mr. LANGEVIN, Mr. LANTOS, Mr. LARSON of Connecticut, Ms. LEE, Mr. LEVIN, Mr. LEWIS of Georgia, Mrs. LOWEY, Mr. LYNCH, Mrs. MALONEY of New York, Mr. MARKEY, Mr. MASCARA, Mr. MATSUI, Mrs. MCCARTHY of New York, Ms. MCCARTHY of Missouri, Ms. MCCOLLUM, Mr. McDERMOTT, Mr. McGOVERN, Ms. MCKINNEY, Mr. McNULTY, Mr. MEEHAN, Mrs. MEEK of Florida, Mr. MEEKS of New York, Mr. GEORGE MILLER of California, Mr. MURTHA, Mr. NADLER, Mr. NEAL of Massachusetts, Ms. NORTON, Mr. OBERSTAR, Mr. OLVER, Mr. ORTIZ, Mr. OWENS, Mr. PASTOR, Ms. PELOSI, Mr. PHELPS, Mr. RAHALL, Mr. REYES, Ms. RIVERS, Mr. RODRIGUEZ, Ms. ROYBAL-ALLARD, Mr. RUSH, Mr. SANDLIN, Mr. SAWYER, Ms. SCHAKOWSKY, Mr. SCHIFF, Mr. SCOTT, Mr. SERRANO, Ms. SLAUGHTER, Ms. SOLIS, Mr. STRICKLAND, Mr. STUPAK, Mr. THOMPSON of Mississippi, Mrs. THURMAN, Mrs. JONES of

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

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

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

TITLE I—PRESCRIPTION DRUG PROVISIONS

SUBTITLE A—MEDICARE PRESCRIPTION MEDICINE BENEFIT

Sec. 101. Voluntary medicare outpatient prescription medicine program.

“PART D—VOLUNTARY PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND DISABLED

“Sec. 1859. Medicare outpatient prescription medicine benefit.

“Sec. 1859A. Negotiating fair prices with pharmaceutical manufacturers.

“Sec. 1859B. Contract authority.

“Sec. 1859C. Eligibility; voluntary enrollment; coverage.

“Sec. 1859D. Provision of, and entitlement to, benefits.

“Sec. 1859E. Administration; quality assurance.

“Sec. 1859F. Federal Medicare Prescription Medicine Trust Fund.

“Sec. 1859G. Compensation for employers covering retiree medicine costs.

“Sec. 1859H. Medicare Prescription Medicine Advisory Committee.

Sec. 102. Provision of medicare outpatient prescription medicine coverage
under the Medicare+Choice program.

Sec. 103. Medigap revisions.

Sec. 104. Transitional assistance for low income beneficiaries.

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

SUBTITLE B—AFFORDABLE PHARMACEUTICALS

PART I—GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

Sec. 111. Accelerated generic drug competition.

Sec. 112. Patent certification.

Sec. 113. Additional uses.

PART II—NOTIFICATION OF AGREEMENTS AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS

Sec. 121. Definitions.

Sec. 122. Notification of agreements affecting the sale or marketing of generic
drugs.

- Sec. 123. Filing deadlines.
- Sec. 124. Enforcement.
- Sec. 125. Rulemaking.
- Sec. 126. Effective dates.

TITLE II—MEDICARE+CHOICE REVITALIZATION AND MEDICARE+CHOICE COMPETITION PROGRAM

- Sec. 201. Medicare+Choice improvements.
- Sec. 202. Making permanent change in Medicare+Choice reporting deadlines and annual, coordinated election period.
- Sec. 203. Specialized Medicare+Choice plans for special needs beneficiaries.
- Sec. 204. Extension of reasonable cost and SHMO contracts.
- Sec. 205. Continuous open enrollment and disenrollment.
- Sec. 206. Limitation on Medicare+Choice cost-sharing.
- Sec. 207. Extension of municipal health service demonstration projects.

TITLE III—RURAL HEALTH CARE IMPROVEMENTS

- Sec. 301. Reference to full market basket increase for sole community hospitals.
- Sec. 302. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.
- Sec. 303. 2-year phased-in increase in the standardized amount in rural and small urban areas to achieve a single, uniform standardized amount.
- Sec. 304. More frequent update in weights used in hospital market basket.
- Sec. 305. Improvements to critical access hospital program.
- Sec. 306. Extension of temporary increase for home health services furnished in a rural area.
- Sec. 307. Reference to 10 percent increase in payment for hospice care furnished in a frontier area and rural hospice demonstration project.
- Sec. 308. Reference to priority for hospitals located in rural or small urban areas in redistribution of unused graduate medical education residencies.
- Sec. 309. GAO study of geographic differences in payments for physicians' services.
- Sec. 310. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
- Sec. 311. Relief for certain non-teaching hospitals.

TITLE IV—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

- Sec. 401. Revision of acute care hospital payment updates.
- Sec. 402. Freeze in level of adjustment for indirect costs of medical education (IME) through fiscal year 2007.
- Sec. 403. Recognition of new medical technologies under inpatient hospital PPS.
- Sec. 404. Phase-in of Federal rate for hospitals in Puerto Rico.
- Sec. 405. Reference to provision relating to enhanced disproportionate share hospital (DSH) payments for rural hospitals and urban hospitals with fewer than 100 beds.

- Sec. 406. Reference to provision relating to 2-year phased-in increase in the standardized amount in rural and small urban areas to achieve a single, uniform standardized amount.
- Sec. 407. Reference to provision for more frequent updates in the weights used in hospital market basket.
- Sec. 408. Reference to provision making improvements to critical access hospital program.

Subtitle B—Skilled Nursing Facility Services

- Sec. 411. Payment for covered skilled nursing facility services.

Subtitle C—Hospice

- Sec. 421. Coverage of hospice consultation services.
- Sec. 422. 10 percent increase in payment for hospice care furnished in a frontier area.
- Sec. 423. Rural hospice demonstration project.

Subtitle D—Other Provisions

- Sec. 431. Demonstration project for use of recovery audit contractors for part A services.

TITLE V—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

- Sec. 501. Revision of updates for physicians' services.
- Sec. 502. Studies on access to physicians' services.
- Sec. 503. MedPAC report on payment for physicians' services.
- Sec. 504. 1-year extension of treatment of certain physician pathology services under medicare.
- Sec. 505. Physician fee schedule wage index revision.

Subtitle B—Other Services

- Sec. 511. Competitive acquisition of certain items and services.
- Sec. 512. Payment for ambulance services.
- Sec. 513. 5-year extension of moratorium on therapy caps; provisions relating to reports.
- Sec. 514. Accelerated implementation of 20 percent coinsurance for hospital outpatient department (OPD) services; other OPD provisions.
- Sec. 515. Coverage of an initial preventive physical examination.
- Sec. 516. Renal dialysis services.
- Sec. 517. Improved payment for certain mammography services.
- Sec. 518. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 519. Coverage of cholesterol and blood lipid screening.

TITLE VI—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 601. Elimination of 15 percent reduction in payment rates under the prospective payment system.
- Sec. 602. Update in home health services.

- Sec. 603. OASIS Task Force; suspension of certain OASIS data collection requirements pending Task Force submittal of report.
- Sec. 604. MedPAC study on medicare margins of home health agencies.

Subtitle B—Direct Graduate Medical Education

- Sec. 611. Redistribution of unused resident positions.
- Sec. 612. Increasing for 5 years to 100 percent of the locality adjusted national average per resident amount the payment floor for direct graduate medical education payments under the medicare program.

Subtitle C—Other Provisions

- Sec. 621. Modifications to Medicare Payment Advisory Commission (MedPAC).
- Sec. 622. Demonstration project for disease management for certain medicare beneficiaries with diabetes.
- Sec. 623. Demonstration project for medical adult day care services.
- Sec. 624. Publication on final written guidance concerning prohibitions against discrimination by national origin with respect to health care services.

TITLE VII—MEDICAID PROVISIONS

Subtitle A—Medicaid Provisions

- Sec. 701. DSH provisions.
- Sec. 702. 1-year extension of Q-I1 program.

Subtitle B—Internet Pharmacies

- Sec. 711. Internet sales of prescription drugs. Findings.
- Sec. 712. Internet sales of prescription drugs; consideration by secretary of practices and procedures for certification of legitimate businesses.
- Sec. 713. Effective date.

Subtitle C—Treatment of Rare Diseases

- Sec. 721. NIH Office of Rare Diseases at National Institutes of Health.
- Sec. 722. Rare disease regional centers of excellence.

Subtitle D—Other Provisions Relating to Drugs

- Sec. 731. GAO study regarding direct-to-consumer advertising of prescription drugs.
- Sec. 732. Certain health professions programs regarding practice of pharmacy.

“SUBPART 3—PHARMACIST WORKFORCE PROGRAMS

- “Sec. 771. Public service announcements.
- “Sec. 772. Demonstration project.
- “Sec. 773. Information technology.
- “Sec. 774. Authorization of appropriations.

1 **TITLE I—PRESCRIPTION**
 2 **MEDICINE PROVISIONS**
 3 **Subtitle A—MEDICARE PRE-**
 4 **SCRIPTION MEDICINE BEN-**
 5 **EFIT**

6 **SEC. 101. VOLUNTARY MEDICARE OUTPATIENT PRESCRIP-**
 7 **TION MEDICINE PROGRAM.**

8 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et
 9 seq.) is amended—

10 (1) by redesignating section 1859 and part D
 11 as section 1858 and part E, respectively; and

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

14 “PART D—VOLUNTARY PRESCRIPTION MEDICINE
 15 BENEFIT FOR THE AGED AND DISABLED

16 “MEDICARE OUTPATIENT PRESCRIPTION MEDICINE
 17 BENEFIT

18 “SEC. 1859. Subject to the succeeding provisions of
 19 this part, the voluntary prescription medicine benefit pro-
 20 gram under this part provides the following:

21 “(1) PREMIUM.—The monthly premium is \$25.

22 “(2) DEDUCTIBLE.—The annual deductible is
 23 \$100.

24 “(3) COINSURANCE.—The coinsurance is 20
 25 percent.

1 “(2) PROCEDURES.—The Secretary shall estab-
2 lish procedures under which the Secretary—

3 “(A) accepts bids submitted by entities to
4 serve as pharmacy contractors under this part
5 in a region or on a national basis;

6 “(B) awards contracts to such contractors
7 to administer benefits under this part to eligible
8 beneficiaries in the region or on a national
9 basis; and

10 “(C) provides for the termination (and
11 nonrenewal) of a contract in the case of a con-
12 tractor’s failure to meet the requirements of the
13 contract and this part.

14 “(3) COMPETITIVE PROCEDURES.—Competitive
15 procedures (as defined in section 4(5) of the Office
16 of Federal Procurement Policy Act (41 U.S.C.
17 403(5))) shall be used to enter into contracts under
18 this part.

19 “(4) TERMS AND CONDITIONS.—Such contracts
20 shall have such terms and conditions as the Sec-
21 retary shall specify and shall be for such terms (of
22 at least 2 years, but not to exceed 5 years) as the
23 Secretary shall specify consistent with this part.

24 “(5) USE OF PHARMACY CONTRACTORS IN
25 PRICE NEGOTIATIONS.—Such contracts shall require

1 the contractor involved to negotiate contracts with
2 manufacturers that provide for maximum prices for
3 covered outpatient prescription medicines that are
4 lower than the maximum prices negotiated under
5 section 1859A(a), if applicable. The price reductions
6 shall be passed on to eligible beneficiaries and the
7 Secretary shall hold the contractor accountable for
8 meeting performance requirements with respect to
9 price reductions and limiting price increases.

10 “(6) AREA FOR CONTRACTS.—

11 “(A) REGIONAL BASIS.—

12 “(i) IN GENERAL.—Except as pro-
13 vided in clause (ii) and subject to subpara-
14 graph (B), the contract entered into be-
15 tween the Secretary and a pharmacy con-
16 tractor shall require the contractor to ad-
17 minister the benefits under this part in a
18 region determined by the Secretary under
19 subparagraph (B) or on a national basis.

20 “(ii) PARTIAL REGIONAL BASIS.—

21 “(I) IN GENERAL.—If deter-
22 mined appropriate by the Secretary,
23 the Secretary may permit the benefits
24 to be administered in a partial region

1 determined appropriate by the Sec-
2 retary.

3 “(II) REQUIREMENTS.—If the
4 Secretary permits administration pur-
5 suant to subclause (I), the Secretary
6 shall ensure that the partial region in
7 which administration is effected is no
8 smaller than a State and is at least
9 the size of the commercial service area
10 of the contractor for that area.

11 “(B) DETERMINATION.—

12 “(i) IN GENERAL.—In determining re-
13 gions for contracts under this part, the
14 Secretary shall—

15 “(I) take into account the num-
16 ber of individuals enrolled under this
17 part in an area in order to encourage
18 participation by pharmacy contrac-
19 tors; and

20 “(II) ensure that there are at
21 least 10 different regions in the
22 United States.

23 “(ii) NO ADMINISTRATIVE OR JUDI-
24 CIAL REVIEW.—The determination of ad-
25 ministrative areas under this paragraph

1 shall not be subject to administrative or ju-
2 dicial review.

3 “(7) SUBMISSION OF BIDS.—

4 “(A) SUBMISSION.—

5 “(i) IN GENERAL.—Subject to sub-
6 paragraph (B), each entity desiring to
7 serve as a pharmacy contractor under this
8 part in an area shall submit a bid with re-
9 spect to such area to the Secretary at such
10 time, in such manner, and accompanied by
11 such information as the Secretary may rea-
12 sonably require.

13 “(ii) BID THAT COVERS MULTIPLE
14 AREAS.—The Secretary shall permit an en-
15 tity to submit a single bid for multiple
16 areas if the bid is applicable to all such
17 areas.

18 “(B) REQUIRED INFORMATION.—The bids
19 described in subparagraph (A) shall include—

20 “(i) a proposal for the estimated
21 prices of covered outpatient prescription
22 medicines and the projected annual in-
23 creases in such prices, including the addi-
24 tional reduction in price negotiated below
25 the Secretary’s maximum price and dif-

1 ferentials between preferred and nonpre-
2 ferred prices, if applicable;

3 “(ii) a statement regarding the
4 amount that the entity will charge the Sec-
5 retary for administering the benefits under
6 the contract;

7 “(iii) a statement regarding whether
8 the entity will reduce the applicable coin-
9 surance percentage pursuant to section
10 1859E(a)(1)(A)(ii) and if so, the amount
11 of such reduction and how such reduction
12 is tied to the performance requirements de-
13 scribed in subsection (c)(4)(A)(ii);

14 “(iv) a detailed description of the per-
15 formance requirements for which the ad-
16 ministrative fee of the entity will be subject
17 to risk pursuant to subsection (c)(4)(A)(ii);

18 “(v) a detailed description of access to
19 pharmacy services provided by the entity,
20 including information regarding whether
21 the pharmacy contractor will use a pre-
22 ferred pharmacy network, and, if so, how
23 the pharmacy contractor will ensure access
24 to pharmacies that choose to be outside of
25 that network, and whether there will be in-

1 creased cost-sharing for beneficiaries if
2 they obtain medicines at such pharmacies;

3 “(vi) a detailed description of the pro-
4 cedures and standards the entity will use
5 for—

6 “(I) selecting preferred prescrip-
7 tion medicines; and

8 “(II) determining when and how
9 often the list of preferred prescription
10 medicines should be modified;

11 “(vii) a detailed description of any
12 ownership or shared financial interests
13 with pharmaceutical manufacturers, phar-
14 macies, and other entities involved in the
15 administration or delivery of benefits under
16 this part as proposed in the bid;

17 “(viii) a detailed description of the en-
18 tity’s estimated marketing and advertising
19 expenditures related to enrolling and re-
20 taining eligible beneficiaries; and

21 “(ix) such other information that the
22 Secretary determines is necessary in order
23 to carry out this part, including informa-
24 tion relating to the bidding process under
25 this part.

1 The procedures under clause (vi) shall include
2 the use of a pharmaceutical and therapeutics
3 committee the members of which include prac-
4 ticing pharmacists.

5 “(8) AWARDING OF CONTRACTS.—

6 “(A) NUMBER OF CONTRACTS.—The Sec-
7 retary shall, consistent with the requirements of
8 this part and the goals of providing quality care
9 and of containing costs under this part, award
10 in a competitive manner at least 2 contracts to
11 administer benefits under this part in each area
12 specified under paragraph (6), unless only 1
13 pharmacy contractor submitting a bid meets the
14 minimum standards specified under this part
15 and by the Secretary.

16 “(B) DETERMINATION.—In determining
17 which of the pharmacy contractors that sub-
18 mitted bids that meet the minimum standards
19 specified under this part and by the Secretary
20 to award a contract, the Secretary shall con-
21 sider the comparative merits of each bid, as de-
22 termined on the basis of relevant factors, with
23 respect to—

24 “(i) how well the contractor meets
25 such minimum standards;

1 “(ii) the amount that the contractor
2 will charge the Secretary for administering
3 the benefits under the contract;

4 “(iii) the performance standards es-
5 tablished under subsection (c)(2) and per-
6 formance requirements for which the ad-
7 ministrative fee of the entity will be subject
8 to risk pursuant to subsection (c)(4)(A)(ii);

9 “(iv) the proposed negotiated prices of
10 covered outpatient medicines and annual
11 increases in such prices;

12 “(v) factors relating to benefits, qual-
13 ity and performance, beneficiary cost-shar-
14 ing, and consumer satisfaction;

15 “(vi) past performance and prior ex-
16 perience of the contractor in administering
17 a prescription medicine benefit program;

18 “(vii) effectiveness of the contractor
19 in containing costs through pricing incen-
20 tives and utilization management; and

21 “(viii) such other factors as the Sec-
22 retary deems necessary to evaluate the
23 merits of each bid.

24 “(C) EXCEPTION TO CONFLICT OF INTER-
25 EST RULES.—In awarding contracts with phar-

1 macy contractors under this part, the Secretary
2 may waive conflict of interest laws generally ap-
3 plicable to Federal acquisitions (subject to such
4 safeguards as the Secretary may find necessary
5 to impose) in circumstances where the Sec-
6 retary finds that such waiver—

7 “(i) is not inconsistent with the—

8 “(I) purposes of the programs
9 under this part; or

10 “(II) best interests of bene-
11 ficiaries enrolled under this part; and

12 “(ii) permits a sufficient level of com-
13 petition for such contracts, promotes effi-
14 ciency of benefits administration, or other-
15 wise serves the objectives of the program
16 under this part.

17 “(D) NO ADMINISTRATIVE OR JUDICIAL
18 REVIEW.—The determination of the Secretary
19 to award or not award a contract to a phar-
20 macy contractor under this part shall not be
21 subject to administrative or judicial review.

22 “(9) ACCESS TO BENEFITS IN CERTAIN
23 AREAS.—

24 “(A) AREAS NOT COVERED BY CON-
25 TRACTS.—The Secretary shall develop proce-

1 dures for the provision of covered outpatient
2 prescription medicines under this part to each
3 eligible beneficiary enrolled under this part that
4 resides in an area that is not covered by any
5 contract under this part.

6 “(B) BENEFICIARIES RESIDING IN DIF-
7 FERENT LOCATIONS.—The Secretary shall de-
8 velop procedures to ensure that each eligible
9 beneficiary enrolled under this part that resides
10 in different areas in a year is provided the ben-
11 efits under this part throughout the entire year.

12 “(b) QUALITY, FINANCIAL, AND OTHER STANDARDS
13 AND PROGRAMS.—In consultation with appropriate phar-
14 macy contractors, pharmacists, and health care profes-
15 sionals with expertise in prescribing, dispensing, and the
16 appropriate use of prescription medicines, the Secretary
17 shall establish standards and programs for the administra-
18 tion of this part to ensure appropriate prescribing, dis-
19 pensing, and utilization of outpatient medicines under this
20 part, to avoid adverse medicine reactions, and to contin-
21 ually reduce errors in the delivery of medically appropriate
22 covered benefits. The Secretary shall not award a contract
23 to a pharmacy contractor under this part unless the Sec-
24 retary finds that the contractor agrees to comply with
25 such standards and programs and other terms and condi-

1 tions as the Secretary shall specify. The standards and
2 programs under this subsection shall be applied to any ad-
3 ministrative agreements described in subsection (a) the
4 Secretary enters into. Such standards and programs shall
5 include the following:

6 “(1) ACCESS.—

7 “(A) IN GENERAL.—The pharmacy con-
8 tractor shall ensure that covered outpatient pre-
9 scription medicines are accessible and conven-
10 nient to eligible beneficiaries enrolled under this
11 part for whom benefits are administered by the
12 pharmacy contractor, including by offering the
13 services 24 hours a day and 7 days a week for
14 emergencies.

15 “(B) ON-LINE REVIEW.—The pharmacy
16 contractor shall provide for on-line prospective
17 review available 24 hours a day and 7 days a
18 week in order to evaluate each prescription for
19 medicine therapy problems due to duplication,
20 interaction, or incorrect dosage or duration of
21 therapy.

22 “(C) GUARANTEED ACCESS TO MEDICINES
23 IN RURAL AND HARD-TO-SERVE AREAS.—The
24 Secretary shall ensure that all beneficiaries
25 have guaranteed access to the full range of

1 pharmaceuticals under this part, and shall give
2 special attention to access, pharmacist coun-
3 seling, and delivery in rural and hard-to-serve
4 areas, including through the use of incentives
5 such as bonus payments to retail pharmacists
6 in rural areas and extra payments to the phar-
7 macy contractor for the cost of rapid delivery of
8 pharmaceuticals and any other actions nec-
9 essary.

10 “(D) PREFERRED PHARMACY NET-
11 WORKS.—

12 “(i) IN GENERAL.—If a pharmacy
13 contractor uses a preferred pharmacy net-
14 work to deliver benefits under this part,
15 such network shall meet minimum access
16 standards established by the Secretary.

17 “(ii) STANDARDS.—In establishing
18 standards under clause (i), the Secretary
19 shall take into account reasonable dis-
20 tances to pharmacy services in both urban
21 and rural areas.

22 “(E) ADHERENCE TO NEGOTIATED
23 PRICES.—The pharmacy contractor shall have
24 in place procedures to assure compliance of
25 pharmacies with the requirements of subsection

1 (d)(3)(C) (relating to adherence to negotiated
2 prices).

3 “(F) CONTINUITY OF CARE.—

4 “(i) IN GENERAL.—The pharmacy
5 contractor shall ensure that, in the case of
6 an eligible beneficiary who loses coverage
7 under this part with such entity under cir-
8 cumstances that would permit a special
9 election period (as established by the Sec-
10 retary under section 1859C(b)(3)), the
11 contractor will continue to provide cov-
12 erage under this part to such beneficiary
13 until the beneficiary enrolls and receives
14 such coverage with another pharmacy con-
15 tractor under this part or, if eligible, with
16 a Medicare+Choice organization.

17 “(ii) LIMITED PERIOD.—In no event
18 shall a pharmacy contractor be required to
19 provide the extended coverage required
20 under clause (i) beyond the date which is
21 30 days after the coverage with such con-
22 tractor would have terminated but for this
23 subparagraph.

1 “(2) ENROLLEE GUIDELINES.—The pharmacy
2 contractor shall, consistent with State law, apply
3 guidelines for counseling enrollees regarding—

4 “(A) the proper use of covered outpatient
5 prescription medicine: and

6 “(B) interactions and contra-indications.

7 “(3) EDUCATION.—The pharmacy contractor
8 shall apply methods to identify and educate pro-
9 viders, pharmacists, and enrollees regarding—

10 “(A) instances or patterns concerning the
11 unnecessary or inappropriate prescribing or dis-
12 pensing of covered outpatient prescription medi-
13 cines;

14 “(B) instances or patterns of substandard
15 care;

16 “(C) potential adverse reactions to covered
17 outpatient prescription medicines;

18 “(D) inappropriate use of antibiotics;

19 “(E) appropriate use of generic products;
20 and

21 “(F) the importance of using covered out-
22 patient prescription medicines in accordance
23 with the instruction of prescribing providers.

24 “(4) COORDINATION.—The pharmacy con-
25 tractor shall coordinate with State prescription med-

1 icine programs, other pharmacy contractors, phar-
2 macies, and other relevant entities as necessary to
3 ensure appropriate coordination of benefits with re-
4 spect to enrolled individuals when such individual is
5 traveling outside the home service area, and under
6 such other circumstances as the Secretary may
7 specify.

8 “(5) COST DATA.—

9 “(A) The pharmacy contractor shall make
10 data on prescription medicine negotiated prices
11 (including data on discounts) available to the
12 Secretary.

13 “(B) The Secretary shall require, either di-
14 rectly or through a pharmacy contractor, that
15 participating pharmacists, physicians, and
16 manufacturers—

17 “(i) maintain their prescription medi-
18 cine cost data (including data on dis-
19 counts) in a form and manner specified by
20 the Secretary;

21 “(ii) make such prescription medicine
22 cost data available for review and audit by
23 the Secretary; and

24 “(iii) certify that the prescription
25 medicine cost data are current, accurate,

1 and complete, and reflect all discounts ob-
2 tained by the pharmacist or physician in
3 the purchasing of covered outpatient pre-
4 scription medicines.

5 Discounts referred to in subparagraphs (A) and (B)
6 shall include all volume discounts, manufacturer re-
7 bates, prompt payment discounts, free goods, in-kind
8 services, or any other thing of financial value pro-
9 vided explicitly or implicitly in exchange for the pur-
10 chase of a covered outpatient prescription medicine.

11 “(6) REPORTING.—The pharmacy contractor
12 shall provide the Secretary with periodic reports
13 on—

14 “(A) the contractor’s costs of admin-
15 istering this part;

16 “(B) utilization of benefits under this part;

17 “(C) marketing and advertising expendi-
18 tures related to enrolling and retaining individ-
19 uals under this part; and

20 “(D) grievances and appeals.

21 “(7) RECORDS AND AUDITS.—The pharmacy
22 contractor shall maintain adequate records related to
23 the administration of benefits under this part and
24 afford the Secretary access to such records for au-
25 diting purposes.

1 “(8) APPROVAL OF MARKETING MATERIAL AND
2 APPLICATION FORMS.—The pharmacy contractor
3 shall comply with requirements of section 1851(h)
4 (relating to marketing material and application
5 forms) with respect to this part in the same manner
6 as such requirements apply under part C, except
7 that the provisions of paragraph (4)(A) of such sec-
8 tion shall not apply with respect to discounts or re-
9 bates provided in accordance with this part.

10 “(c) INCENTIVES FOR COST AND UTILIZATION MAN-
11 AGEMENT AND QUALITY IMPROVEMENT.—

12 “(1) IN GENERAL.—The Secretary shall include
13 in a contract awarded under subsection (b) with a
14 pharmacy contractor such incentives for cost and
15 utilization management and quality improvement as
16 the Secretary may deem appropriate. The contract
17 may provide financial or other incentives to encour-
18 age greater savings to the program under this part.

19 “(2) PERFORMANCE STANDARDS.—The Sec-
20 retary shall provide for performance standards
21 (which may include monetary bonuses if the stand-
22 ards are met and penalties if the standards are not
23 met), including standards relating to the time taken
24 to answer member and pharmacy inquiries (written
25 or by telephone), the accuracy of responses, claims

1 processing accuracy, online system availability, ap-
2 peal procedure turnaround time, system availability,
3 the accuracy and timeliness of reports, and level of
4 beneficiary satisfaction.

5 “(3) OTHER INCENTIVES.—Such incentives
6 under this subsection may also include—

7 “(A) financial incentives under which sav-
8 ings derived from the substitution of generic
9 and other preferred multi-source medicines in
10 lieu of nongeneric and nonpreferred medicines
11 are made available to pharmacy contractors,
12 pharmacies, beneficiaries, and the Federal
13 Medicare Prescription Medicine Trust Fund;
14 and

15 “(B) any other incentive that the Secretary
16 deems appropriate and likely to be effective in
17 managing costs or utilization or improving qual-
18 ity that does not reduce the access of bene-
19 ficiaries to medically necessary covered out-
20 patient medicines.

21 “(4) REQUIREMENTS FOR PROCEDURES.—

22 “(A) IN GENERAL.—The Secretary shall
23 establish procedures for making payments to
24 each pharmacy contractor with a contract under
25 this part for the administration of the benefits

1 under this part. The procedures shall provide
2 for the following:

3 “(i) ADMINISTRATIVE PAYMENT.—

4 Payment of administrative fees for such
5 administration.

6 “(ii) RISK REQUIREMENT.—An ad-

7 justment of a percentage (determined
8 under subparagraph (B)) of the adminis-
9 trative fee payments made to a pharmacy
10 contractor to ensure that the contractor, in
11 administering the benefits under this part,
12 pursues performance requirements estab-
13 lished by the Secretary, including the fol-
14 lowing:

15 “(I) QUALITY SERVICE.—The

16 contractor provides eligible bene-
17 ficiaries for whom it administers bene-
18 fits with quality services, as measured
19 by such factors as sustained pharmacy
20 network access, timeliness and accu-
21 racy of service delivery in claims proc-
22 essing and card production, pharmacy
23 and member service support access,
24 and timely action with regard to ap-

1 peals and current beneficiary service
2 surveys.

3 “(II) QUALITY CLINICAL CARE.—

4 The contractor provides such bene-
5 ficiaries with quality clinical care, as
6 measured by such factors as providing
7 notification to such beneficiaries and
8 to providers in order to prevent ad-
9 verse drug reactions and reduce medi-
10 cation errors and specific clinical sug-
11 gestions to improve health and patient
12 and prescriber education as appro-
13 priate.

14 “(III) CONTROL OF MEDICARE

15 COSTS.—The contractor contains costs
16 under this part to the Federal Medi-
17 care Prescription Medicine Trust
18 Fund and enrollees, as measured by
19 generic substitution rates, price dis-
20 counts, and other factors determined
21 appropriate by the Secretary that do
22 not reduce the access of beneficiaries
23 to medically necessary covered out-
24 patient prescription medicines.

1 “(B) PERCENTAGE OF PAYMENT TIED TO
2 RISK.—

3 “(i) IN GENERAL.—Subject to clause
4 (ii), the Secretary shall determine the per-
5 centage of the administrative payments to
6 a pharmacy contractor that will be tied to
7 the performance requirements described in
8 subparagraph (A)(ii).

9 “(ii) LIMITATION ON RISK TO ENSURE
10 PROGRAM STABILITY.—In order to provide
11 for program stability, the Secretary may
12 not establish a percentage to be adjusted
13 under this paragraph at a level that jeop-
14 ardizes the ability of a pharmacy con-
15 tractor to administer the benefits under
16 this part or administer such benefits in a
17 quality manner.

18 “(C) RISK ADJUSTMENT OF PAYMENTS
19 BASED ON ENROLLEES IN PLAN.—To the extent
20 that a pharmacy contractor is at risk under this
21 paragraph, the procedures established under
22 this paragraph may include a methodology for
23 risk adjusting the payments made to such con-
24 tractor based on the differences in actuarial
25 risk of different enrollees being served if the

1 Secretary determines such adjustments to be
2 necessary and appropriate.

3 “(d) AUTHORITY RELATING TO PHARMACY PARTICI-
4 PATION.—

5 “(1) IN GENERAL.—Subject to the succeeding
6 provisions of this subsection, a pharmacy contractor
7 may establish consistent with this part conditions for
8 the participation of pharmacies, including conditions
9 relating to quality (including reduction of medical
10 errors) and technology.

11 “(2) AGREEMENTS WITH PHARMACIES.—Each
12 pharmacy contractor shall enter into a participation
13 agreement with any pharmacy that meets the re-
14 quirements of this subsection and section 1859E to
15 furnish covered outpatient prescription medicines to
16 individuals enrolled under this part.

17 “(3) TERMS OF AGREEMENT.—An agreement
18 under this subsection shall include the following
19 terms and conditions:

20 “(A) APPLICABLE REQUIREMENTS.—The
21 pharmacy shall meet (and throughout the con-
22 tract period continue to meet) all applicable
23 Federal requirements and State and local li-
24 censing requirements.

1 “(B) ACCESS AND QUALITY STANDARDS.—
2 The pharmacy shall comply with such standards
3 as the Secretary (and such a pharmacy con-
4 tractor) shall establish concerning the quality
5 of, and enrolled individuals’ access to, phar-
6 macy services under this part. Such standards
7 shall require the pharmacy—

8 “(i) not to refuse to dispense covered
9 outpatient prescription medicines to any
10 individual enrolled under this part;

11 “(ii) to keep patient records (includ-
12 ing records on expenses) for all covered
13 outpatient prescription medicines dispensed
14 to such enrolled individuals;

15 “(iii) to submit information (in a
16 manner specified by the Secretary to be
17 necessary to administer this part) on all
18 purchases of such medicines dispensed to
19 such enrolled individuals; and

20 “(iv) to comply with periodic audits to
21 assure compliance with the requirements of
22 this part and the accuracy of information
23 submitted.

24 “(C) ADHERENCE TO NEGOTIATED
25 PRICES.—(i) The total charge for each medicine

1 dispensed by the pharmacy to an enrolled indi-
2 vidual under this part, without regard to wheth-
3 er the individual is financially responsible for
4 any or all of such charge, shall not exceed the
5 price negotiated under section 1859A(a) or, if
6 lower, negotiated under subsection (a)(5) (or, if
7 less, the retail price for the medicine involved)
8 with respect to such medicine plus a reasonable
9 dispensing fee determined contractually with
10 the pharmacy contractor.

11 “(ii) The pharmacy does not charge (or
12 collect from) an enrolled individual an amount
13 that exceeds the individual’s obligation (as de-
14 termined in accordance with the provisions of
15 this part) of the applicable price described in
16 clause (i).

17 “(D) ADDITIONAL REQUIREMENTS.—The
18 pharmacy shall meet such additional contract
19 requirements as the applicable pharmacy con-
20 tractor specifies under this section.

21 “(4) APPLICABILITY OF FRAUD AND ABUSE
22 PROVISIONS.—The provisions of section 1128
23 through 1128C (relating to fraud and abuse) apply
24 to pharmacies participating in the program under
25 this part.

1 “ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

2 “SEC. 1859C. (a) ELIGIBILITY.—Each individual
3 who is entitled to hospital insurance benefits under part
4 A or is eligible to be enrolled in the medical insurance pro-
5 gram under part B is eligible to enroll in accordance with
6 this section for outpatient prescription medicine benefits
7 under this part.

8 “(b) VOLUNTARY ENROLLMENT.—

9 “(1) IN GENERAL.—An individual may enroll
10 under this part only in such manner and form as
11 may be prescribed by regulations, and only during
12 an enrollment period prescribed in or under this sub-
13 section.

14 “(2) INITIAL ENROLLMENT PERIOD.—

15 “(A) INDIVIDUALS CURRENTLY COV-
16 ERED.—In the case of an individual who satis-
17 fies subsection (a) as of November 1, 2004, the
18 initial general enrollment period shall begin on
19 August 1, 2004, and shall end on March 1,
20 2005.

21 “(B) INDIVIDUAL COVERED IN FUTURE.—

22 In the case of an individual who first satisfies
23 subsection (a) on or after November 1, 2004,
24 the individual’s initial enrollment period shall
25 begin on the first day of the third month before

1 the month in which such individual first satis-
2 fies such paragraph and shall end seven months
3 later. The Secretary shall apply rules similar to
4 the rule described in the second sentence of sec-
5 tion 1837(d).

6 “(3) SPECIAL ENROLLMENT PERIODS (WITHOUT
7 PREMIUM PENALTY).—

8 “(A) EMPLOYER COVERAGE AT TIME OF
9 INITIAL GENERAL ENROLLMENT PERIOD.—In
10 the case of an individual who—

11 “(i) at the time the individual first
12 satisfies subsection (a) is enrolled in a
13 group health plan (including continuation
14 coverage) that provides outpatient pre-
15 scription medicine coverage by reason of
16 the individual’s (or the individual’s
17 spouse’s) current (or, in the case of con-
18 tinuation coverage, former) employment
19 status, and

20 “(ii) has elected not to enroll (or to be
21 deemed enrolled) under this subsection
22 during the individual’s initial enrollment
23 period,

24 there shall be a special enrollment period of 6
25 months beginning with the first month that in-

1 includes the date of the individual's (or individ-
2 ual's spouse's) retirement from or termination
3 of current employment status with the employer
4 that sponsors the plan, or, in the case of con-
5 tinuation coverage, that includes the date of
6 termination of such coverage, or that includes
7 the date the plan substantially terminates out-
8 patient prescription medicine coverage.

9 “(B) DROPPING OF RETIREE PRESCRIP-
10 TION MEDICINE COVERAGE.—In the case of an
11 individual who—

12 “(i) at the time the individual first
13 satisfies subsection (a) is enrolled in a
14 group health plan that provides outpatient
15 prescription medicine coverage other than
16 by reason of the individual's (or the indi-
17 vidual's spouse's) current employment; and

18 “(ii) has elected not to enroll (or to be
19 deemed enrolled) under this subsection
20 during the individual's initial enrollment
21 period,

22 there shall be a special enrollment period of 6
23 months beginning with the first month that in-
24 cludes the date that the plan substantially ter-

1 minates outpatient prescription medicine cov-
2 erage and ending 6 months later.

3 “(C) LOSS OF MEDICARE+CHOICE PRE-
4 SCRIPTION MEDICINE COVERAGE.—In the case
5 of an individual who is enrolled under part C in
6 a Medicare+Choice plan that provides prescrip-
7 tion medicine benefits, if such enrollment is ter-
8 minated because of the termination or reduction
9 in service area of the plan, there shall be a spe-
10 cial enrollment period of 6 months beginning
11 with the first month that includes the date that
12 such plan is terminated or such reduction oc-
13 curs and ending 6 months later.

14 “(D) LOSS OF MEDICAID PRESCRIPTION
15 MEDICINE COVERAGE.—In the case of an indi-
16 vidual who—

17 “(i) satisfies subsection (a);

18 “(ii) loses eligibility for benefits (that
19 include benefits for prescription medicine)
20 under a State plan after having been en-
21 rolled (or determined to be eligible) for
22 such benefits under such plan; and

23 “(iii) is not otherwise enrolled under
24 this subsection at the time of such loss of
25 eligibility,

1 there shall be a special enrollment period speci-
2 fied by the Secretary of not less than 6 months
3 beginning with the first month that includes the
4 date that the individual loses such eligibility.

5 “(4) LATE ENROLLMENT WITH PREMIUM PEN-
6 ALTY.—The Secretary shall permit an individual
7 who satisfies subsection (a) to enroll other than dur-
8 ing the initial enrollment period under paragraph (2)
9 or a special enrollment period under paragraph (3).
10 But, in the case of such an enrollment, the amount
11 of the monthly premium of the individual is subject
12 to an increase under section 1859C(e)(1).

13 “(5) INFORMATION.—

14 “(A) IN GENERAL.—The Secretary shall
15 broadly distribute information to individuals
16 who satisfy subsection (a) on the benefits pro-
17 vided under this part. The Secretary shall peri-
18 odically make available information on the cost
19 differentials to enrollees for the use of generic
20 medicines and other medicines.

21 “(B) TOLL-FREE HOTLINE.—The Sec-
22 retary shall maintain a toll-free telephone hot-
23 line (which may be a hotline already used by
24 the Secretary under this title) for purposes of
25 providing assistance to beneficiaries in the pro-

1 gram under this part, including responding to
2 questions concerning coverage, enrollment, ben-
3 efits, grievances and appeals procedures, and
4 other aspects of such program.

5 “(6) ENROLLEE DEFINED.—For purposes of
6 this part, the term ‘enrollee’ means an individual en-
7 rolled for benefits under this part.

8 “(c) COVERAGE PERIOD.—

9 “(1) IN GENERAL.—The period during which
10 an individual is entitled to benefits under this part
11 (in this subsection referred to as the individual’s
12 ‘coverage period’) shall begin on such a date as the
13 Secretary shall establish consistent with the type of
14 coverage rules described in subsections (a) and (e)
15 of section 1838, except that in no case shall a cov-
16 erage period begin before January 1, 2005. No pay-
17 ments may be made under this part with respect to
18 the expenses of an individual unless such expenses
19 were incurred by such individual during a period
20 which, with respect to the individual, is a coverage
21 period.

22 “(2) TERMINATION.—The Secretary shall pro-
23 vide for the application of provisions under this sub-
24 section similar to the provisions in section 1838(b).

1 “(d) PROVISION OF BENEFITS TO
2 MEDICARE+CHOICE ENROLLEES.—In the case of an indi-
3 vidual who is enrolled under this part and is enrolled in
4 a Medicare+Choice plan under part C, the individual shall
5 be provided the benefits under this part through such plan
6 and not through payment under this part.

7 “(e) LATE ENROLLMENT PENALTIES; PAYMENT OF
8 PREMIUMS.—

9 “(1) LATE ENROLLMENT PENALTY.—

10 “(A) IN GENERAL.—In the case of a late
11 enrollment described in subsection (b)(4), sub-
12 ject to the succeeding provisions of this para-
13 graph, the Secretary shall establish procedures
14 for increasing the amount of the monthly pre-
15 mium under this part applicable to such en-
16 rollee by an amount that the Secretary deter-
17 mines is actuarially sound for each such period.

18 “(B) PERIODS TAKEN INTO ACCOUNT.—
19 For purposes of calculating any 12-month pe-
20 riod under subparagraph (A), there shall be
21 taken into account months of lapsed coverage in
22 a manner comparable to that applicable under
23 the second sentence of section 1839(b).

24 “(C) PERIODS NOT TAKEN INTO AC-
25 COUNT.—

1 “(i) IN GENERAL.—For purposes of
2 calculating any 12-month period under
3 subparagraph (A), subject to clause (ii),
4 there shall not be taken into account
5 months for which the enrollee can dem-
6 onstrate that the enrollee was covered
7 under a group health plan that provides
8 coverage of the cost of prescription medi-
9 cines whose actuarial value (as defined by
10 the Secretary) to the enrollee equals or ex-
11 ceeds the actuarial value of the benefits
12 provided to an individual enrolled in the
13 outpatient prescription medicine benefit
14 program under this part.

15 “(ii) APPLICATION.—This subpara-
16 graph shall only apply with respect to a
17 coverage period the enrollment for which
18 occurs before the end of the 60-day period
19 that begins on the first day of the month
20 which includes the date on which the plan
21 terminates or reduces its service area (in a
22 manner that results in termination of en-
23 rollment), ceases to provide, or reduces the
24 value of the prescription medicine coverage
25 under such plan to below the value of the

1 coverage provided under the program
2 under this part.

3 “(2) INCORPORATION OF PREMIUM PAYMENT
4 AND GOVERNMENT CONTRIBUTIONS PROVISIONS.—
5 The provisions of sections 1840 and 1844(a)(1) shall
6 apply to enrollees under this part in the same man-
7 ner as they apply to individuals 65 years of age or
8 older enrolled under part B. For purposes of this
9 subsection, any reference in a section referred to in
10 a previous subsection to the Federal Supplementary
11 Medical Insurance Trust Fund is deemed a reference
12 to the Federal Medicare Prescription Medicine Trust
13 Fund.

14 “(f) ELECTION OF PHARMACY CONTRACTOR TO AD-
15 MINISTER BENEFITS.—The Secretary shall establish a
16 process whereby each individual enrolled under this part
17 and residing in a region may elect the pharmacy con-
18 tractor that will administer the benefits under this part
19 with respect to the individual. Such process shall permit
20 the individual to make an initial election and to change
21 such an election on at least an annual basis and under
22 such other circumstances as the Secretary shall specify.

23 “PROVISION OF, AND ENTITLEMENT TO, BENEFITS

24 “SEC. 1859D. (a) BENEFITS.—Subject to the suc-
25 ceeding provisions of this section, the benefits provided to

1 an enrollee by the program under this part shall consist
2 of the following:

3 “(1) COVERED OUTPATIENT PRESCRIPTION
4 MEDICINE BENEFITS.—Entitlement to have payment
5 made on the individual’s behalf for covered out-
6 patient prescription medicines.

7 “(2) LIMITATION ON COST-SHARING FOR PART
8 B OUTPATIENT PRESCRIPTION MEDICINES.—

9 “(A) IN GENERAL.—Once an enrollee has
10 incurred aggregate countable cost-sharing (as
11 defined in subparagraph (B)) equal to the stop-
12 loss limit specified in subsection (c)(4) for ex-
13 penses in a year, entitlement to the elimination
14 of cost-sharing otherwise applicable under part
15 B for additional expenses incurred in the year
16 for outpatient prescription medicines or
17 biologicals for which payment is made under
18 part B.

19 “(B) COUNTABLE COST-SHARING DE-
20 FINED.—For purposes of this part, the term
21 ‘countable cost-sharing’ means—

22 “(i) out-of-pocket expenses for out-
23 patient prescription medicines with respect
24 to which benefits are payable under part
25 B, and

1 “(ii) cost-sharing under subsections
2 (c)(3)(B) and (c)(3)(C)(i).

3 “(b) COVERED OUTPATIENT PRESCRIPTION MEDI-
4 CINE DEFINED.—

5 “(1) IN GENERAL.—Except as provided in para-
6 graph (2), for purposes of this part the term ‘cov-
7 ered outpatient prescription medicine’ means any of
8 the following products:

9 “(A) A medicine which may be dispensed
10 only upon prescription, and—

11 “(i) which is approved for safety and
12 effectiveness as a prescription medicine
13 under section 505 of the Federal Food,
14 Drug, and Cosmetic Act;

15 “(ii)(I) which was commercially used
16 or sold in the United States before the
17 date of enactment of the Drug Amend-
18 ments of 1962 or which is identical, simi-
19 lar, or related (within the meaning of sec-
20 tion 310.6(b)(1) of title 21 of the Code of
21 Federal Regulations) to such a medicine,
22 and (II) which has not been the subject of
23 a final determination by the Secretary that
24 it is a ‘new drug’ (within the meaning of
25 section 201(p) of the Federal Food, Drug,

1 and Cosmetic Act) or an action brought by
2 the Secretary under section 301, 302(a),
3 or 304(a) of such Act to enforce section
4 502(f) or 505(a) of such Act; or

5 “(iii)(I) which is described in section
6 107(e)(3) of the Drug Amendments of
7 1962 and for which the Secretary has de-
8 termined there is a compelling justification
9 for its medical need, or is identical, simi-
10 lar, or related (within the meaning of sec-
11 tion 310.6(b)(1) of title 21 of the Code of
12 Federal Regulations) to such a medicine,
13 and (II) for which the Secretary has not
14 issued a notice of an opportunity for a
15 hearing under section 505(e) of the Fed-
16 eral Food, Drug, and Cosmetic Act on a
17 proposed order of the Secretary to with-
18 draw approval of an application for such
19 medicine under such section because the
20 Secretary has determined that the medi-
21 cine is less than effective for all conditions
22 of use prescribed, recommended, or sug-
23 gested in its labeling.

24 “(B) A biological product which—

1 “(i) may only be dispensed upon pre-
2 scription;

3 “(ii) is licensed under section 351 of
4 the Public Health Service Act; and

5 “(iii) is produced at an establishment
6 licensed under such section to produce
7 such product.

8 “(C) Insulin approved under appropriate
9 Federal law, and needles, syringes, and dispos-
10 able pumps for the administration of such insu-
11 lin.

12 “(D) A prescribed medicine or biological
13 product that would meet the requirements of
14 subparagraph (A) or (B) but that is available
15 over-the-counter in addition to being available
16 upon prescription, but only if the particular
17 dosage form or strength prescribed and re-
18 quired for the individual is not available over-
19 the-counter.

20 “(E) Smoking cessation agents (as speci-
21 fied by the Secretary).

22 “(2) EXCLUSION.—The term ‘covered out-
23 patient prescription medicine’ does not include—

24 “(A) medicines or classes of medicines, or
25 their medical uses, which may be excluded from

1 coverage or otherwise restricted under section
2 1927(d)(2), other than subparagraph (E) there-
3 of (relating to smoking cessation agents), as the
4 Secretary may specify and does not include
5 such other medicines, classes, and uses as the
6 Secretary may specify consistent with the goals
7 of providing quality care and containing costs
8 under this part;

9 “(B) except as provided in paragraphs
10 (1)(D) and (1)(E), any product which may be
11 distributed to individuals without a prescrip-
12 tion;

13 “(C) any product when furnished as part
14 of, or as incident to, a diagnostic service or any
15 other item or service for which payment may be
16 made under this title; or

17 “(D) any product that is covered under
18 part B of this title.

19 “(c) PAYMENT OF BENEFITS.—

20 “(1) COVERED OUTPATIENT PRESCRIPTION
21 MEDICINES.—There shall be paid from the Federal
22 Medicare Prescription Medicine Trust Fund, in the
23 case of each enrollee who incurs expenses for medi-
24 cines with respect to which benefits are payable

1 under this part under subsection (a)(1), amounts
2 equal to the sum of—

3 “(A) the price for which the medicine is
4 made available under this part (consistent with
5 sections 1859A and 1859B), reduced by any
6 applicable cost-sharing under paragraphs (2)
7 and (3); and

8 “(B) a reasonable dispensing fee.

9 The price under subparagraph (A) shall in no case
10 exceed the retail price for the medicine involved.

11 “(2) DEDUCTIBLE.—The amount of payment
12 under paragraph (1) for expenses incurred in a year,
13 beginning with 2005, shall be reduced by an annual
14 deductible equal to the amount specified in section
15 1859(2) (subject to adjustment under paragraph
16 (8)). Only expenses for countable cost-sharing (as
17 defined in subsection (a)(2)(B)) shall be taken into
18 account in applying this paragraph.

19 “(3) COINSURANCE.—

20 “(A) IN GENERAL.—The amount of pay-
21 ment under paragraph (1) for expenses in-
22 curred in a year shall be further reduced (sub-
23 ject to the stop-loss limit under paragraph (4))
24 by coinsurance as provided under this para-
25 graph.

1 “(B) PREFERRED MEDICINES.—The coin-
2 surance under this paragraph in the case of a
3 preferred medicine (including a medicine treat-
4 ed as a preferred medicine under paragraph
5 (5)), is equal to 20 percent of the price applica-
6 ble under paragraph (1)(A) (or such lower per-
7 centage as may be provided for under section
8 1859E(a)(1)(A)(ii)). In this part, the term ‘pre-
9 ferred medicine’ means, with respect to medi-
10 cines classified within a therapeutic class, those
11 medicines which have been designated as a pre-
12 ferred medicine by the Secretary or the phar-
13 macy contractor involved with respect to that
14 class and (in the case of a nongeneric medicine)
15 with respect to which a contract has been nego-
16 tiated under this part.

17 “(C) NONPREFERRED MEDICINES.—The
18 coinsurance under this paragraph in the case of
19 a nonpreferred medicine that is not treated as
20 a preferred medicine under paragraph (5) is
21 equal to the sum of—

22 “(i) 20 percent of the price for lowest
23 price preferred medicine that is within the
24 same therapeutic class; and

25 “(ii) the amount by which—

1 “(I) the price at which the non-
2 preferred medicine is made available
3 to the enrollee; exceeds

4 “(II) the price of such lowest
5 price preferred medicine.

6 “(4) NO COINSURANCE ONCE OUT-OF-POCKET
7 EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an
8 enrollee has incurred aggregate countable cost-shar-
9 ing under paragraph (3) (including cost-sharing
10 under part B attributable to outpatient prescription
11 drugs or biologicals) equal to the amount specified
12 in section 1859(4) (subject to adjustment under
13 paragraph (8)) for expenses in a year—

14 “(A) there shall be no coinsurance under
15 paragraph (3) for additional expenses incurred
16 in the year involved; and

17 “(B) there shall be no coinsurance under
18 part B for additional expenses incurred in the
19 year involved for outpatient prescription drugs
20 and biologicals.

21 “(5) APPEALS RIGHTS RELATING TO COVERAGE
22 OF NONPREFERRED MEDICINES.—

23 “(A) PROCEDURES REGARDING THE DE-
24 TERMINATION OF MEDICINES THAT ARE MEDI-
25 CALLY NECESSARY.—Each pharmacy contractor

1 shall have in place procedures on a case-by-case
2 basis to treat a nonpreferred medicine as a pre-
3 ferred medicine under this part if the preferred
4 medicine is determined to be not as effective for
5 the enrollee or to have significant adverse effect
6 on the enrollee. Such procedures shall require
7 that such determinations are based on profes-
8 sional medical judgment, the medical condition
9 of the enrollee, and other medical evidence.

10 “(B) PROCEDURES REGARDING DENIALS
11 OF CARE.—Such contractor shall have in place
12 procedures to ensure—

13 “(i) a timely internal review for reso-
14 lution of denials of coverage (in whole or
15 in part and including those regarding the
16 coverage of nonpreferred medicines) in ac-
17 cordance with the medical exigencies of the
18 case and a timely resolution of complaints,
19 by enrollees in the plan, or by providers,
20 pharmacists, and other individuals acting
21 on behalf of each such enrollee (with the
22 enrollee’s consent) in accordance with re-
23 quirements (as established by the Sec-
24 retary) that are comparable to such re-

1 requirements for Medicare+Choice organiza-
2 tions under part C;

3 “(ii) that the entity complies in a
4 timely manner with requirements estab-
5 lished by the Secretary that (I) provide for
6 an external review by an independent enti-
7 ty selected by the Secretary of denials of
8 coverage described in clause (i) not re-
9 solved in the favor of the beneficiary (or
10 other complainant) under the process de-
11 scribed in such clause and (II) are com-
12 parable to the external review requirements
13 established for Medicare+Choice organiza-
14 tions under part C; and

15 “(iii) that enrollees are provided with
16 information regarding the appeals proce-
17 dures under this part at the time of enroll-
18 ment with a pharmacy contractor under
19 this part and upon request thereafter.

20 “(6) TRANSFER OF FUNDS TO COVER COSTS OF
21 PART B PRESCRIPTION MEDICINE CATASTROPHIC
22 BENEFIT.—With respect to benefits described in
23 subsection (a)(2), there shall transferred from the
24 Federal Medicare Prescription Medicine Trust Fund
25 to the Federal Supplementary Medical Insurance

1 Trust Fund amounts equivalent to the elimination of
2 cost-sharing described in such subsection.

3 “(7) PERMITTING APPLICATION UNDER PART B
4 OF NEGOTIATED PRICES.—For purposes of making
5 payment under part B for medicines that would be
6 covered outpatient prescription medicines but for the
7 exclusion under subparagraph (B) or (C) of sub-
8 section (b)(2), the Secretary may elect to apply the
9 payment basis used for payment of covered out-
10 patient prescription medicines under this part in-
11 stead of the payment basis otherwise used under
12 such part, if it results in a lower cost to the pro-
13 gram.

14 “(8) INFLATION ADJUSTMENT.—

15 “(A) IN GENERAL.—With respect to ex-
16 penses incurred in a year after 2005—

17 “(i) the deductible under paragraph
18 (2) is equal to the deductible determined
19 under such paragraph (or this subpara-
20 graph) for the previous year increased by
21 the percentage increase in per capita pro-
22 gram expenditures (as estimated in ad-
23 vance for the year involved under subpara-
24 graph (B)); and

1 “(ii) the stop-loss limit under para-
2 graph (3) is equal to the stop-loss limit de-
3 termined under such paragraph (or this
4 subparagraph) for the previous year in-
5 creased by such percentage increase.

6 The Secretary shall adjust such percentage in-
7 crease in subsequent years to take into account
8 misestimations made of the per capita program
9 expenditures under clauses (i) and (ii) in pre-
10 vious years. Any increase under this subpara-
11 graph that is not a multiple of \$10 shall be
12 rounded to the nearest multiple of \$10.

13 “(B) ESTIMATION OF INCREASE IN PER
14 CAPITA PROGRAM EXPENDITURES.—The Sec-
15 retary shall before the beginning of each year
16 (beginning with 2006) estimate the percentage
17 increase in average per capita aggregate ex-
18 penditures from the Federal Medicare Prescrip-
19 tion Medicine Trust Fund for the year involved
20 compared to the previous year.

21 “(C) RECONCILIATION.—The Secretary
22 shall also compute (beginning with 2007) the
23 actual percentage increase in such aggregate
24 expenditures in order to provide for reconcili-
25 ation of deductibles, stop-loss limits, and pre-

1 miums under the second sentence of subpara-
2 graph (A) and under section 1859D(d)(2).

3 “(d) AMOUNT OF PREMIUMS.—

4 “(1) MONTHLY PREMIUM RATE IN 2005.—The
5 monthly premium rate in 2005 for prescription med-
6 icine benefits under this part is the amount specified
7 in section 1859(1).

8 “(2) INFLATION ADJUSTMENT FOR SUBSE-
9 QUENT YEARS.—The monthly premium rate for a
10 year after 2005 for prescription medicine benefits
11 under this part is equal to the monthly premium
12 rate for the previous year under this subsection in-
13 creased by the percentage increase in per capita pro-
14 gram expenditures (as estimated in advance for the
15 year involved under subsection (c)(8)(B)). The Sec-
16 retary shall adjust such percentage in subsequent
17 years to take into account misestimations made of
18 the per capita program expenditures under the pre-
19 vious sentence in previous years. Any increase under
20 this paragraph that is not a multiple of \$1 shall be
21 rounded to the nearest multiple of \$1.

22 “ADMINISTRATION; QUALITY ASSURANCE

23 “SEC. 1859E. (a) RULES RELATING TO PROVISION
24 OF BENEFITS.—

25 “(1) PROVISION OF BENEFITS.—

1 “(A) IN GENERAL.—In providing benefits
2 under this part, the Secretary (directly or
3 through the contracts with pharmacy contrac-
4 tors) shall employ mechanisms to provide bene-
5 fits appropriately and efficiently, and those
6 mechanisms may include—

7 “(i) the use of—

8 “(I) price negotiations (con-
9 sistent with subsection (b));

10 “(II) reduced coinsurance (below
11 20 percent) to encourage the utiliza-
12 tion of appropriate preferred medi-
13 cines; and

14 “(III) methods to reduce medica-
15 tion errors and encourage appropriate
16 use of medications; and

17 “(ii) permitting pharmacy contractors,
18 as approved by the Secretary, to make ex-
19 ceptions to section 1859D(c)(3)(C) (relat-
20 ing to cost-sharing for non-preferred medi-
21 cines) to secure best prices for enrollees so
22 long as the payment amount under section
23 1859D(e)(1) does not equal zero.

24 “(B) CONSTRUCTION.—Nothing in this
25 subsection shall be construed to prevent the

1 Secretary (directly or through the contracts
2 with pharmacy contractors) from using incen-
3 tives to encourage enrollees to select generic or
4 other cost-effective medicines, so long as—

5 “(i) such incentives are designed not
6 to result in any increase in the aggregate
7 expenditures under the Federal Medicare
8 Prescription Medicine Trust Fund; and

9 “(ii) a beneficiary’s coinsurance shall
10 be no greater than 20 percent in the case
11 of a preferred medicine (including a non-
12 preferred medicine treated as a preferred
13 medicine under section 1859D(c)(5)).

14 “(2) CONSTRUCTION.—Nothing in this part
15 shall preclude the Secretary or a pharmacy con-
16 tractor from—

17 “(A) educating prescribing providers, phar-
18 macists, and enrollees about medical and cost
19 benefits of preferred medicines;

20 “(B) requesting prescribing providers to
21 consider a preferred medicine prior to dis-
22 pensing of a nonpreferred medicine, as long as
23 such request does not unduly delay the provi-
24 sion of the medicine;

1 “(C) using mechanisms to encourage en-
2 rollees under this part to select cost-effective
3 medicines or less costly means of receiving or
4 administering medicines, including the use of
5 therapeutic interchange programs, disease man-
6 agement programs, and notification to the bene-
7 ficiary that a more affordable generic medicine
8 equivalent was not selected by the prescribing
9 provider and a statement of the lost cost sav-
10 ings to the beneficiary;

11 “(D) using price negotiations to achieve re-
12 duced prices on covered outpatient prescription
13 medicines, including new medicines, medicines
14 for which there are few therapeutic alternatives,
15 and medicines of particular clinical importance
16 to individuals enrolled under this part; and

17 “(E) utilizing information on medicine
18 prices of OECD countries and of other payors
19 in the United States in the negotiation of prices
20 under this part.

21 “(b) PRICE NEGOTIATIONS PROCESS.—

22 “(1) REQUIREMENTS WITH RESPECT TO PRE-
23 FERRED MEDICINES.—Negotiations of contracts with
24 manufacturers with respect to covered outpatient

1 prescription medicines under this part shall be con-
2 ducted in a manner so that—

3 “(A) there is at least a contract for a med-
4 icine within each therapeutic class (as defined
5 by the Secretary in consultation with such
6 Medicare Prescription Medicine Advisory Com-
7 mittee);

8 “(B) if there is more than 1 medicine
9 available in a therapeutic class, there are con-
10 tracts for at least 2 medicines within such class
11 unless determined clinically inappropriate in ac-
12 cordance with standards established by the Sec-
13 retary; and

14 “(C) if there are more than 2 medicines
15 available in a therapeutic class, there is a con-
16 tract for at least 2 medicines within such class
17 and a contract for generic medicine substitute
18 if available unless determined clinically inappro-
19 priate in accordance with standards established
20 by the Secretary.

21 “(2) ESTABLISHMENT OF THERAPEUTIC CLASS-
22 ES.—The Secretary, in consultation with the Medi-
23 care Prescription Medicine Advisory Committee (es-
24 tablished under section 1859H), shall establish for
25 purposes of this part therapeutic classes and assign

1 to such classes covered outpatient prescription medi-
2 cines.

3 “(3) DISCLOSURE CONCERNING PREFERRED
4 MEDICINES.—The Secretary shall provide, through
5 pharmacy contractors or otherwise, for—

6 “(A) disclosure to current and prospective
7 enrollees and to participating providers and
8 pharmacies in each service area a list of the
9 preferred medicines and differences in applica-
10 ble cost-sharing between such medicines and
11 nonpreferred medicines; and

12 “(B) advance disclosure to current enroll-
13 ees and to participating providers and phar-
14 macies in each service area of changes to any
15 such list of preferred medicines and differences
16 in applicable cost-sharing.

17 “(4) NO REVIEW.—The Secretary’s establish-
18 ment of therapeutic classes and the assignment of
19 medicines to such classes and the Secretary’s deter-
20 mination of what is a breakthrough medicine are not
21 subject to administrative or judicial review.

22 “(c) CONFIDENTIALITY.—The Secretary shall ensure
23 that the confidentiality of individually identifiable health
24 information relating to the provision of benefits under this
25 part is protected, consistent with the standards for the

1 privacy of such information promulgated by the Secretary
2 under the Health Insurance Portability and Accountability
3 Act of 1996, or any subsequent comprehensive and more
4 protective set of confidentiality standards enacted into law
5 or promulgated by the Secretary. Nothing in this sub-
6 section shall be construed as preventing the coordination
7 of data with a State prescription medicine program so long
8 as such program has in place confidentiality standards
9 that are equal to or exceed the standards used by the Sec-
10 retary.

11 “(d) FRAUD AND ABUSE SAFEGUARDS.—The Sec-
12 retary, through the Office of the Inspector General, is au-
13 thorized and directed to issue regulations establishing ap-
14 propriate safeguards to prevent fraud and abuse under
15 this part. Such safeguards, at a minimum, should include
16 compliance programs, certification data, audits, and rec-
17 ordkeeping practices. In developing such regulations, the
18 Secretary shall consult with the Attorney General and
19 other law enforcement and regulatory agencies.

20 “FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST
21 FUND

22 “SEC. 1859F. (a) ESTABLISHMENT.—There is here-
23 by created on the books of the Treasury of the United
24 States a trust fund to be known as the ‘Federal Medicare
25 Prescription Medicine Trust Fund’ (in this section re-
26 ferred to as the ‘Trust Fund’). The Trust Fund shall con-

1 sist of such gifts and bequests as may be made as provided
2 in section 201(i)(1), and such amounts as may be depos-
3 ited in, or appropriated to, such fund as provided in this
4 part.

5 “(b) APPLICATION OF SMI TRUST FUND PROVI-
6 SIONS.—The provisions of subsections (b) through (i) of
7 section 1841 shall apply to this part and the Trust Fund
8 in the same manner as they apply to part B and the Fed-
9 eral Supplementary Medical Insurance Trust Fund, re-
10 spectively.

11 “COMPENSATION FOR EMPLOYERS COVERING RETIREE
12 MEDICINE COSTS

13 “SEC. 1859G. (a) IN GENERAL.—In the case of an
14 individual who is eligible to be enrolled under this part
15 and is a participant or beneficiary under a group health
16 plan that provides outpatient prescription medicine cov-
17 erage to retirees the actuarial value of which is not less
18 than the actuarial value of the coverage provided under
19 this part, the Secretary shall make payments to such plan
20 subject to the provisions of this section. Such payments
21 shall be treated as payments under this part for purposes
22 of sections 1859F and 1859C(e)(2). In applying the pre-
23 vious sentence with respect to section 1859C(e)(2), the
24 amount of the Government contribution referred to in sec-
25 tion 1844(a)(1)(A) is deemed to be equal to the aggregate
26 amount of the payments made under this section.

1 “(b) REQUIREMENTS.—To receive payment under
2 this section, a group health plan shall comply with the fol-
3 lowing requirements:

4 “(1) COMPLIANCE WITH REQUIREMENTS.—The
5 group health plan shall comply with the require-
6 ments of this Act and other reasonable, necessary,
7 and related requirements that are needed to admin-
8 ister this section, as determined by the Secretary.

9 “(2) ANNUAL ASSURANCES AND NOTICE BE-
10 FORE TERMINATION.—The sponsor of the plan
11 shall—

12 “(A) annually attest, and provide such as-
13 surances as the Secretary may require, that the
14 coverage offered under the group health plan
15 meets the requirements of this section and will
16 continue to meet such requirements for the du-
17 ration of the sponsor’s participation in the pro-
18 gram under this section; and

19 “(B) guarantee that it will give notice to
20 the Secretary and covered enrollees—

21 “(i) at least 120 days before termi-
22 nating its plan, and

23 “(ii) immediately upon determining
24 that the actuarial value of the prescription
25 medicine benefit under the plan falls below

1 the actuarial value required under sub-
2 section (a).

3 “(3) BENEFICIARY INFORMATION.—The spon-
4 sor of the plan shall report to the Secretary, for
5 each calendar quarter for which it seeks a payment
6 under this section, the names and social security
7 numbers of all enrollees described in subsection (a)
8 covered under such plan during such quarter and
9 the dates (if less than the full quarter) during which
10 each such individual was covered.

11 “(4) AUDITS.—The sponsor or plan seeking
12 payment under this section shall agree to maintain,
13 and to afford the Secretary access to, such records
14 as the Secretary may require for purposes of audits
15 and other oversight activities necessary to ensure the
16 adequacy of prescription medicine coverage, the ac-
17 curacy of payments made, and such other matters as
18 may be appropriate.

19 “(c) PAYMENT.—

20 “(1) IN GENERAL.—The sponsor of a group
21 health plan that meets the requirements of sub-
22 section (b) with respect to a quarter in a calendar
23 year shall be entitled to have payment made on a
24 quarterly basis of the amount specified in paragraph
25 (2) for each individual described in subsection (a)

1 who during the quarter is covered under the plan
2 and was not enrolled in the insurance program
3 under this part.

4 “(2) AMOUNT OF PAYMENT.—

5 “(A) IN GENERAL.—The amount of the
6 payment for a quarter shall approximate, for
7 each such covered individual, $\frac{2}{3}$ of the sum of
8 the monthly Government contribution amounts
9 (computed under subparagraph (B)) for each of
10 the 3 months in the quarter.

11 “(B) COMPUTATION OF MONTHLY GOV-
12 ERNMENT CONTRIBUTION AMOUNT.—For pur-
13 poses of subparagraph (A), the monthly Gov-
14 ernment contribution amount for a month in a
15 year is equal to the amount by which—

16 “(i) $\frac{1}{12}$ of the average per capita ag-
17 gregate expenditures, as estimated under
18 section 1859D(c)(8) for the year involved;
19 exceeds

20 “(ii) the monthly premium rate under
21 section 1859D(d) for the month involved.

22 “MEDICARE PRESCRIPTION MEDICINE ADVISORY

23 COMMITTEE

24 “SEC. 1859H. (a) ESTABLISHMENT OF COM-
25 MITTEE.—There is established a Medicare Prescription

1 Medicine Advisory Committee (in this section referred to
2 as the ‘Committee’).

3 “(b) FUNCTIONS OF COMMITTEE.—The Committee
4 shall advise the Secretary on policies related to—

5 “(1) the development of guidelines for the im-
6 plementation and administration of the outpatient
7 prescription medicine benefit program under this
8 part; and

9 “(2) the development of—

10 “(A) standards required of pharmacy con-
11 tractors under section 1859D(e)(5) for deter-
12 mining if a medicine is as effective for an en-
13 rollee or has a significant adverse effect on an
14 enrollee under this part;

15 “(B) standards for—

16 “(i) defining therapeutic classes;

17 “(ii) adding new therapeutic classes;

18 “(iii) assigning to such classes covered
19 outpatient prescription medicines; and

20 “(iv) identifying breakthrough medi-
21 cines;

22 “(C) procedures to evaluate the bids sub-
23 mitted by pharmacy contractors under this
24 part;

1 “(D) procedures for negotiations, and
2 standards for entering into contracts, with
3 manufacturers, including identifying medicines
4 or classes of medicines where Secretarial nego-
5 tiation is most likely to yield savings under this
6 part significantly above those that which could
7 be achieved by a pharmacy contractor; and

8 “(E) procedures to ensure that pharmacy
9 contractors with a contract under this part are
10 in compliance with the requirements under this
11 part.

12 For purposes of this part, a medicine is a ‘breakthrough
13 medicine’ if the Secretary, in consultation with the Com-
14 mittee, determines it is a new product that will make a
15 significant and major improvement by reducing physical
16 or mental illness, reducing mortality, or reducing dis-
17 ability, and that no other product is available to bene-
18 ficiaries that achieves similar results for the same condi-
19 tion. The Committee may consider cost-effectiveness in es-
20 tablishing standards for defining therapeutic classes and
21 assigning drugs to such classes under subparagraph (B).

22 “(c) STRUCTURE AND MEMBERSHIP OF THE COM-
23 MITTEE.—

1 “(1) STRUCTURE.—The Committee shall be
2 composed of 19 members who shall be appointed by
3 the Secretary.

4 “(2) MEMBERSHIP.—

5 “(A) IN GENERAL.—The members of the
6 Committee shall be chosen on the basis of their
7 integrity, impartiality, and good judgment, and
8 shall be individuals who are, by reason of their
9 education, experience, and attainments, excep-
10 tionally qualified to perform the duties of mem-
11 bers of the Committee.

12 “(B) SPECIFIC MEMBERS.—Of the mem-
13 bers appointed under paragraph (1)—

14 “(i) 5 shall be chosen to represent
15 practicing physicians, 2 of whom shall be
16 gerontologists;

17 “(ii) 2 shall be chosen to represent
18 practicing nurse practitioners;

19 “(iii) 4 shall be chosen to represent
20 practicing pharmacists;

21 “(iv) 1 shall be chosen to represent
22 the Centers for Medicare & Medicaid Serv-
23 ices;

1 “(v) 4 shall be chosen to represent ac-
2 tuaries, pharmacoeconomists, researchers,
3 and other appropriate experts;

4 “(vi) 1 shall be chosen to represent
5 emerging medicine technologies;

6 “(vii) 1 shall be chosen to represent
7 the Food and Drug Administration; and

8 “(viii) 1 shall be chosen to represent
9 individuals enrolled under this part.

10 “(d) TERMS OF APPOINTMENT.—Each member of
11 the Committee shall serve for a term determined appro-
12 priate by the Secretary. The terms of service of the mem-
13 bers initially appointed shall begin on January 1, 2004.

14 “(e) CHAIRPERSON.—The Secretary shall designate
15 a member of the Committee as Chairperson. The term as
16 Chairperson shall be for a 1-year period.

17 “(f) COMMITTEE PERSONNEL MATTERS.—

18 “(1) MEMBERS.—

19 “(A) COMPENSATION.—Each member of
20 the Committee who is not an officer or em-
21 ployee of the Federal Government shall be com-
22 pensated at a rate equal to the daily equivalent
23 of the annual rate of basic pay prescribed for
24 level IV of the Executive Schedule under section
25 5315 of title 5, United States Code, for each

1 day (including travel time) during which such
2 member is engaged in the performance of the
3 duties of the Committee. All members of the
4 Committee who are officers or employees of the
5 United States shall serve without compensation
6 in addition to that received for their services as
7 officers or employees of the United States.

8 “(B) TRAVEL EXPENSES.—The members
9 of the Committee shall be allowed travel ex-
10 penses, including per diem in lieu of subsist-
11 ence, at rates authorized for employees of agen-
12 cies under subchapter I of chapter 57 of title 5,
13 United States Code, while away from their
14 homes or regular places of business in the per-
15 formance of services for the Committee.

16 “(2) STAFF.—The Committee may appoint
17 such personnel as the Committee considers appro-
18 priate.

19 “(g) OPERATION OF THE COMMITTEE.—

20 “(1) MEETINGS.—The Committee shall meet at
21 the call of the Chairperson (after consultation with
22 the other members of the Committee) not less often
23 than quarterly to consider a specific agenda of
24 issues, as determined by the Chairperson after such
25 consultation.

1 “(2) QUORUM.—Ten members of the Com-
2 mittee shall constitute a quorum for purposes of
3 conducting business.

4 “(h) FEDERAL ADVISORY COMMITTEE ACT.—Section
5 14 of the Federal Advisory Committee Act (5 U.S.C.
6 App.) shall not apply to the Committee.

7 “(i) TRANSFER OF PERSONNEL, RESOURCES, AND
8 ASSETS.—For purposes of carrying out its duties, the Sec-
9 retary and the Committee may provide for the transfer
10 to the Committee of such civil service personnel in the em-
11 ploy of the Department of Health and Human Services
12 (including the Centers for Medicare & Medicaid Services),
13 and such resources and assets of the Department used in
14 carrying out this title, as the Committee requires.

15 “(j) AUTHORIZATION OF APPROPRIATIONS.—There
16 are authorized to be appropriated such sums as may be
17 necessary to carry out the purposes of this section.”.

18 (b) APPLICATION OF GENERAL EXCLUSIONS FROM
19 COVERAGE.—

20 (1) APPLICATION TO PART D.—Section 1862(a)
21 (42 U.S.C. 1395y(a)) is amended in the matter pre-
22 ceding paragraph (1) by striking “part A or part B”
23 and inserting “part A, B, or D”.

24 (2) PRESCRIPTION MEDICINES NOT EXCLUDED
25 FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—

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

3 (A) in subparagraph (H), by striking
4 “and” at the end;

5 (B) in subparagraph (I), by striking the
6 semicolon at the end and inserting “, and”; and

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

9 “(J) in the case of prescription medicines
10 covered under part D, which are not prescribed
11 in accordance with such part;”.

12 (c) CONFORMING AMENDMENTS.—(1) Part C of title
13 XVIII is amended—

14 (A) in section 1851(a)(2)(B) (42 U.S.C.
15 1395w-21(a)(2)(B)), by striking “1859(b)(3)” and
16 inserting “1858(b)(3)”;

17 (B) in section 1851(a)(2)(C) (42 U.S.C.
18 1395w-21(a)(2)(C)), by striking “1859(b)(2)” and
19 inserting “1858(b)(2)”;

20 (C) in section 1852(a)(1) (42 U.S.C. 1395w-
21 22(a)(1)), by striking “1859(b)(3)” and inserting
22 “1858(b)(3)”;

23 (D) in section 1852(a)(3)(B)(ii) (42 U.S.C.
24 1395w-22(a)(3)(B)(ii)), by striking
25 “1859(b)(2)(B)” and inserting “1858(b)(2)(B)”;

1 (E) in section 1853(a)(1)(A) (42 U.S.C.
2 1395w-23(a)(1)(A)), by striking “1859(e)(4)” and
3 inserting “1858(e)(4)”; and

4 (F) in section 1853(a)(3)(D) (42 U.S.C.
5 1395w-23(a)(3)(D)), by striking “1859(e)(4)” and
6 inserting “1858(e)(4)”.

7 (2) Section 1171(a)(5)(D) (42 U.S.C.
8 1320d(a)(5)(D)) is amended by striking “or (C)” and in-
9 serting “(C), or (D)”.

10 **SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRE-**
11 **SCRIPTION MEDICINE COVERAGE UNDER**
12 **THE MEDICARE+CHOICE PROGRAM.**

13 (a) REQUIRING AVAILABILITY OF AN ACTUARIALLY
14 EQUIVALENT PRESCRIPTION MEDICINE BENEFIT.—Sec-
15 tion 1851 (42 U.S.C. 1395w-21) is amended by adding
16 at the end the following new subsection:

17 “(j) AVAILABILITY OF PRESCRIPTION MEDICINE
18 BENEFITS.—

19 “(1) IN GENERAL.—Notwithstanding any other
20 provision of this part, each Medicare+Choice organi-
21 zation that makes available a Medicare+Choice plan
22 described in section 1851(a)(2)(A) shall make avail-
23 able such a plan that offers coverage of covered out-
24 patient prescription medicines that is at least actu-
25 arially equivalent to the benefits provided under part

1 D. Information respecting such benefits shall be
2 made available in the same manner as information
3 on other benefits provided under this part is made
4 available. Nothing in this paragraph shall be con-
5 strued as requiring the offering of such coverage
6 separate from coverage that includes benefits under
7 parts A and B.

8 “(2) TREATMENT OF PRESCRIPTION MEDICINE
9 ENROLLEES.—In the case of a Medicare+Choice eli-
10 gible individual who is enrolled under part D, the
11 benefits described in paragraph (1) shall be treated
12 in the same manner as benefits described in part B
13 for purposes of coverage and payment and any ref-
14 erence in this part to the Federal Supplementary
15 Medical Insurance Trust Fund shall be deemed, with
16 respect to such benefits, to be a reference to the
17 Federal Medicare Prescription Medicine Trust
18 Fund.”.

19 (b) APPLICATION OF QUALITY STANDARDS.—Section
20 1852(e)(2)(A) (42 U.S.C. 1395w-22(e)(2)(A)) is
21 amended—

22 (1) by striking “and” at the end of clause (xi);

23 (2) by striking the period at the end of clause

24 (xii) and inserting “, and”; and

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

3 “(xiii) comply with the standards, and
4 apply the programs, under section
5 1859B(b) for covered outpatient prescrip-
6 tion medicines under the plan.”.

7 (c) PAYMENT SEPARATE FROM PAYMENT FOR PART
8 A AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w-
9 23) is amended—

10 (1) in subsection (a)(1)(A), by striking “and
11 (i)” and inserting “(i), and (j)”; and

12 (2) by adding at the end the following new sub-
13 section:

14 “(j) PAYMENT FOR PRESCRIPTION MEDICINE COV-
15 ERAGE OPTION.—

16 “(1) IN GENERAL.—In the case of a
17 Medicare+Choice plan that provides prescription
18 medicine benefits described in section 1851(j)(1),
19 the amount of payment otherwise made to the
20 Medicare+Choice organization offering the plan
21 shall be increased by the amount described in para-
22 graph (2). Such payments shall be made in the same
23 manner and time as the amount otherwise paid, but
24 such amount shall be payable from the Federal
25 Medicare Prescription Medicine Trust Fund.

1 “(2) AMOUNT.—The amount described in this
2 paragraph is the monthly Government contribution
3 amount computed under section 1859G(c)(2)(B),
4 but subject to adjustment under paragraph (3).
5 Such amount shall be uniform geographically and
6 shall not vary based on the Medicare+Choice pay-
7 ment area involved.

8 “(3) RISK ADJUSTMENT.—The Secretary shall
9 establish a methodology for the adjustment of the
10 payment amount under this subsection in a manner
11 that takes into account the relative risks for use of
12 outpatient prescription medicines by
13 Medicare+Choice enrollees. Such methodology shall
14 be designed in a manner so that the total payments
15 under this title (including part D) are not changed
16 as a result of the application of such methodology.”.

17 (d) SEPARATE APPLICATION OF ADJUSTED COMMU-
18 NITY RATE (ACR).—Section 1854 (42 U.S.C. 1395w–24)
19 is amended by adding at the end the following:

20 “(i) APPLICATION TO PRESCRIPTION MEDICINE COV-
21 ERAGE.—The Secretary shall apply the previous provisions
22 of this section (including the computation of the adjusted
23 community rate) separately with respect to prescription
24 medicine benefits described in section 1851(j)(1).”.

25 (f) CONFORMING AMENDMENTS.—

1 (1) Section 1851 (42 U.S.C. 1395w-21) is
2 amended—

3 (A) in subsection (a)(1)(A), by striking
4 “parts A and B” and inserting “parts A, B,
5 and D”; and

6 (B) in subsection (i) by inserting “(and, if
7 applicable, part D)” after “parts A and B”.

8 (2) Section 1852(a)(1)(A) (42 U.S.C. 1395w-
9 22(a)(1)(A)) is amended by inserting “(and under
10 part D to individuals also enrolled under such part)”
11 after “parts A and B”.

12 (3) Section 1852(d)(1) (42 U.S.C. 1395w-
13 22(d)(1)) is amended—

14 (A) by striking “and” at the end of sub-
15 paragraph (D);

16 (B) by striking the period at the end of
17 subparagraph (E) and inserting “; and”; and

18 (C) by adding at the end the following:

19 “(F) the plan for part D benefits guaran-
20 tees coverage of any specifically named pre-
21 scription medicine for an enrollee to the extent
22 that it would be required to be covered under
23 part D.

24 In carrying out subparagraph (F), a
25 Medicare+Choice organization has the same author-

1 ity to enter into contracts with respect to coverage
2 of preferred medicines as the Secretary has under
3 part D, but subject to an independent contractor ap-
4 peal or other appeal process that would be applicable
5 to determinations by such a pharmacy contractor
6 consistent with section 1859D(e)(5).”.

7 (e) LIMITATION ON COST-SHARING.—Section
8 1854(e) (42 U.S.C. 1395w–24(e)) is amended by adding
9 at the end the following new paragraph:

10 “(5) LIMITATION ON COST-SHARING.—In no
11 event may a Medicare+Choice organization include
12 a requirement that an enrollee pay cost-sharing in
13 excess of the cost-sharing otherwise permitted under
14 part D.”.

15 **SEC. 103. MEDIGAP REVISIONS.**

16 (a) REQUIRED COVERAGE OF COVERED OUTPATIENT
17 PRESCRIPTION MEDICINES.—Section 1882(p)(2)(B) (42
18 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before
19 “and” at the end the following: “including a requirement
20 that an appropriate number of policies provide coverage
21 of medicines which complements but does not duplicate
22 the medicine benefits that beneficiaries are otherwise eligi-
23 ble for benefits under part D of this title (with the Sec-
24 retary and the National Association of Insurance Commis-
25 sioners determining the appropriate level of medicine ben-

1 efits that each benefit package must provide and ensuring
2 that policies providing such coverage are affordable for
3 beneficiaries;”.

4 (b) EFFECTIVE DATE.—The amendment made by
5 subsection (a) shall take effect on January 1, 2005.

6 (c) TRANSITION PROVISIONS.—

7 (1) IN GENERAL.—If the Secretary of Health
8 and Human Services identifies a State as requiring
9 a change to its statutes or regulations to conform its
10 regulatory program to the amendments made by this
11 section, the State regulatory program shall not be
12 considered to be out of compliance with the require-
13 ments of section 1882 of the Social Security Act due
14 solely to failure to make such change until the date
15 specified in paragraph (4).

16 (2) NAIC STANDARDS.—If, within 9 months
17 after the date of enactment of this Act, the National
18 Association of Insurance Commissioners (in this
19 subsection referred to as the “NAIC”) modifies its
20 NAIC Model Regulation relating to section 1882 of
21 the Social Security Act (referred to in such section
22 as the 1991 NAIC Model Regulation, as subse-
23 quently modified) to conform to the amendments
24 made by this section, such revised regulation incor-
25 porating the modifications shall be considered to be

1 the applicable NAIC model regulation (including the
2 revised NAIC model regulation and the 1991 NAIC
3 Model Regulation) for the purposes of such section.

4 (3) SECRETARY STANDARDS.—If the NAIC
5 does not make the modifications described in para-
6 graph (2) within the period specified in such para-
7 graph, the Secretary of Health and Human Services
8 shall make the modifications described in such para-
9 graph and such revised regulation incorporating the
10 modifications shall be considered to be the appro-
11 priate regulation for the purposes of such section.

12 (4) DATE SPECIFIED.—

13 (A) IN GENERAL.—Subject to subpara-
14 graph (B), the date specified in this paragraph
15 for a State is the earlier of—

16 (i) the date the State changes its stat-
17 utes or regulations to conform its regu-
18 latory program to the changes made by
19 this section; or

20 (ii) 1 year after the date the NAIC or
21 the Secretary first makes the modifications
22 under paragraph (2) or (3), respectively.

23 (B) ADDITIONAL LEGISLATIVE ACTION RE-
24 QUIRED.—In the case of a State which the Sec-
25 retary identifies as—

1 (i) requiring State legislation (other
2 than legislation appropriating funds) to
3 conform its regulatory program to the
4 changes made in this section; but

5 (ii) having a legislature which is not
6 scheduled to meet in 2003 in a legislative
7 session in which such legislation may be
8 considered;

9 the date specified in this paragraph is the first
10 day of the first calendar quarter beginning after
11 the close of the first legislative session of the
12 State legislature that begins on or after Janu-
13 ary 1, 2003. For purposes of the previous sen-
14 tence, in the case of a State that has a 2-year
15 legislative session, each year of such session
16 shall be deemed to be a separate regular session
17 of the State legislature.

18 **SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME**

19 **BENEFICIARIES.**

20 (a) QMB COVERAGE OF PREMIUMS AND COST-SHAR-
21 ING.—Section 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is
22 amended—

23 (1) in subparagraph (A)—

24 (A) by striking “and” at the end of clause

25 (i),

1 (B) by adding “and” at the end of clause
2 (ii), and

3 (C) by adding at the end the following new
4 clause:

5 “(iii) premiums under section 1859D(d).”;

6 (2) in subparagraph (B), by inserting “and sec-
7 tion 1859D(c)(3)(B) and 1859D(c)(3)(C)(i)” after
8 “1813”; and

9 (3) in subparagraph (C), by striking “and sec-
10 tion 1833(b)” and inserting “, section 1833(b), and
11 section 1859D(c)(2)”.

12 (b) EXPANDED SLMB ELIGIBILITY.—Section
13 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is
14 amended—

15 (1) by striking “and” at the end of clause (iii);

16 (2) by adding “and” at the end of clause (iv);

17 and

18 (3) by adding at the end the following new
19 clause:

20 “(v)(I) for making medical assistance
21 available for medicare cost-sharing described in
22 section 1905(p)(3)(A)(iii) and medicare cost-
23 sharing described in section 1905(p)(3)(B) and
24 section 1905(p)(3)(C) but only insofar as it re-
25 lates to benefits provided under part D of title

1 XVIII, subject to section 1905(p)(4), for indi-
2 viduals (other than qualified medicare bene-
3 ficiaries) who are enrolled under part D of title
4 XVIII and are described in section
5 1905(p)(1)(B) or would be so described but for
6 the fact that their income exceeds 100 percent,
7 but is less than 150 percent, of the official pov-
8 erty line (referred to in such section) for a fam-
9 ily of the size involved;

10 “(II) subject to section 1905(p)(4), for in-
11 dividuals (other than qualified medicare bene-
12 ficiaries and individuals described in subclause
13 (I)) who are enrolled under part D of title
14 XVIII and would be described in section
15 1905(p)(1)(B) but for the fact that their in-
16 come exceeds 150 percent, but is less than 175
17 percent, of the official poverty line (referred to
18 in such section) for a family of the size in-
19 volved, for making medical assistance available
20 for medicare cost-sharing described in section
21 1905(p)(3)(A)(iii) and medicare cost-sharing
22 described in section 1905(p)(3)(B) and section
23 1905(p)(3)(C) but only insofar as it relates to
24 benefits provided under part D of title XVIII,
25 and the assistance for medicare cost-sharing de-

1 scribed in section 1905(p)(3)(A)(iii) is reduced
2 (on a sliding scale based on income) from 100
3 percent to 0 percent as the income increases
4 from 150 percent to 175 percent of such pov-
5 erty line;”.

6 (c) FEDERAL FINANCING.—The third sentence of
7 section 1905(b) (42 U.S.C. 1396d(b)) is amended by in-
8 serting before the period at the end the following: “and
9 with respect to amounts expended that are attributable to
10 section 1902(a)(10)(E)(v) (other than for individuals de-
11 scribed in section 1905(p)(1)(B))”.

12 (d) TREATMENT OF TERRITORIES.—

13 (1) IN GENERAL.—Section 1905(p) (42 U.S.C.
14 1396d(p)) is amended—

15 (A) by redesignating paragraphs (5) and
16 (6) as paragraphs (6) and (7), respectively; and

17 (B) by inserting after paragraph (4) the
18 following new paragraph:

19 “(5)(A) In the case of a State, other than the 50
20 States and the District of Columbia—

21 “(i) the provisions of paragraph (3) insofar as
22 they relate to section 1859D and the provisions of
23 section 1902(a)(10)(E)(v) shall not apply to resi-
24 dents of such State; and

1 “(ii) if the State establishes a plan described in
2 subparagraph (B) (for providing medical assistance
3 with respect to the provision of prescription medi-
4 cines to medicare beneficiaries), the amount other-
5 wise determined under section 1108(f) (as increased
6 under section 1108(g)) for the State shall be in-
7 creased by the amount specified in subparagraph
8 (C).

9 “(B) The plan described in this subparagraph is a
10 plan that—

11 “(i) provides medical assistance with respect to
12 the provision of covered outpatient medicines (as de-
13 fined in section 1859D(b)) to low-income medicare
14 beneficiaries; and

15 “(ii) assures that additional amounts received
16 by the State that are attributable to the operation
17 of this paragraph are used only for such assistance.

18 “(C)(i) The amount specified in this subparagraph
19 for a State for a year is equal to the product of—

20 “(I) the aggregate amount specified in clause
21 (ii); and

22 “(II) the amount specified in section 1108(g)(1)
23 for that State, divided by the sum of the amounts
24 specified in such section for all such States.

1 “(ii) The aggregate amount specified in this clause
2 for—

3 “(I) 2005, is equal to \$25,000,000; or

4 “(II) a subsequent year, is equal to the aggre-
5 gate amount specified in this clause for the previous
6 year increased by annual percentage increase speci-
7 fied in section 1859D(c)(8)(B) for the year involved.

8 “(D) The Secretary shall submit to Congress a report
9 on the application of this paragraph and may include in
10 the report such recommendations as the Secretary deems
11 appropriate.”.

12 (2) CONFORMING AMENDMENT.—Section
13 1108(f) (42 U.S.C. 1308(f)) is amended by inserting
14 “and section 1905(p)(5)(A)(ii)” after “Subject to
15 subsection (g)”.

16 (e) APPLICATION OF COST-SHARING.—Section
17 1902(n)(2) (42 U.S.C. 1396a(n)(2)) is amended by add-
18 ing at the end the following: “The previous sentence shall
19 not apply to medicare cost-sharing relating to benefits
20 under part D of title XVIII.”.

21 (f) EFFECTIVE DATE.—The amendments made by
22 this section apply to medical assistance for premiums and
23 cost-sharing incurred on or after January 1, 2005, with
24 regard to whether regulations to implement such amend-
25 ments are promulgated by such date.

1 **SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF**
2 **MEDICARE PAYMENT ADVISORY COMMISSION**
3 **(MEDPAC).**

4 (a) EXPANSION OF MEMBERSHIP.—

5 (1) IN GENERAL.—Section 1805(c) (42 U.S.C.
6 1395b–6(c)) is amended—

7 (A) in paragraph (1), by striking “17” and
8 inserting “19”; and

9 (B) in paragraph (2)(B), by inserting “ex-
10 perts in the area of pharmacology and prescrip-
11 tion medicine benefit programs,” after “other
12 health professionals,”.

13 (2) INITIAL TERMS OF ADDITIONAL MEM-
14 BERS.—

15 (A) IN GENERAL.—For purposes of stag-
16 gering the initial terms of members of the
17 Medicare Payment Advisory Commission under
18 section 1805(c)(3) of the Social Security Act
19 (42 U.S.C. 1395b–6(c)(3)), the initial terms of
20 the 2 additional members of the Commission
21 provided for by the amendment under para-
22 graph (1)(A) are as follows:

23 (i) One member shall be appointed for
24 1 year.

25 (ii) One member shall be appointed
26 for 2 years.

1 (B) COMMENCEMENT OF TERMS.—Such
2 terms shall begin on January 1, 2003.

3 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42
4 U.S.C. 1395b–6(b)(2)) is amended by adding at the end
5 the following new subparagraph:

6 “(D) PRESCRIPTION MEDICINE BENEFIT
7 PROGRAM.—Specifically, the Commission shall
8 review, with respect to the prescription medicine
9 benefit program under part D, the following:

10 “(i) The methodologies used for the
11 management of costs and utilization of
12 prescription medicines.

13 “(ii) The prices negotiated and paid,
14 including trends in such prices and appli-
15 cable discounts and comparisons with
16 prices under section 1859E(a)(2)(E).

17 “(iii) The relationship of pharmacy
18 acquisition costs to the prices so negotiated
19 and paid.

20 “(iv) The methodologies used to en-
21 sure access to covered outpatient prescrip-
22 tion medicines and to ensure quality in the
23 appropriate dispensing and utilization of
24 such medicines.

1 “(v) The impact of the program on
2 promoting the development of break-
3 through medicines.”.

4 **Subtitle B—Affordable**
5 **Pharmaceuticals**

6 **PART I—GREATER ACCESS TO AFFORDABLE**

7 **PHARMACEUTICALS**

8 **SEC. 111. ACCELERATED GENERIC DRUG COMPETITION.**

9 (a) IN GENERAL.—Section 505(j)(5) of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is
11 amended—

12 (1) in subparagraph (B)(iv), by striking sub-
13 clause (II) and inserting the following:

14 “(II) the earlier of—

15 “(aa) the date of a final decision of a
16 court in an action described in clause
17 (iii)(II) (from which no appeal can or has
18 been taken, other than a petition to the
19 Supreme Court for a writ of certiorari)
20 holding the patent that is the subject of
21 the certification to be invalid or not in-
22 fringed; or

23 “(bb) the date of a settlement order
24 or consent decree in such an action signed
25 by a Federal judge that enters a final

1 judgment and includes a finding that the
2 patent that is the subject of the certifi-
3 cation is invalid or not infringed;”;

4 (2) by redesignating subparagraphs (C) and
5 (D) as subparagraphs (E) and (F), respectively; and

6 (3) by inserting before subparagraph (E) (as so
7 redesignated) the following subparagraph:

8 “(D)(i) The 180-day period described in subpara-
9 graph (B)(iv) shall be forfeited by the previous applicant
10 if—

11 “(I) the previous applicant fails to market the
12 drug by the later of the date 60 days after the date
13 on which the approval of the application for the drug
14 is made effective under subparagraph (B)(iii) or, if
15 such approval has been made effective, and if an ac-
16 tion has been brought against the previous applicant
17 for infringement of a patent subject to a certifi-
18 cation under paragraph (2)(A)(vii)(IV), or an action
19 has been brought by the previous applicant for a de-
20 claratory judgment that such a patent is invalid or
21 not infringed, the date 60 days after the date of a
22 final decision in such action, if there is no other
23 such action pending by or against the previous appli-
24 cant; except, however, that either of such dates may

1 be extended due to extraordinary or unusual cir-
2 cumstances, as determined by the Secretary;

3 “(II) the previous applicant withdraws the ap-
4 plication;

5 “(III) the previous applicant amends the certifi-
6 cation from a certification under subclause (IV) of
7 paragraph (2)(A)(vii) to a certification under sub-
8 clause (III) of such paragraph, either voluntarily or
9 as a result of a settlement or defeat in patent litiga-
10 tion;

11 “(IV) the previous applicant fails to obtain ten-
12 tative approval of the application within 30 months
13 after the date on which the application is filed, un-
14 less the failure is caused by—

15 “(aa) a change in the requirements for
16 tentative approval of the application imposed
17 after the date on which the application was
18 filed; or

19 “(bb) other extraordinary or unusual cir-
20 cumstances, as determined by the Secretary;

21 “(V) in a case in which, after the date on which
22 the previous application was submitted under this
23 subsection, new patent information is submitted
24 under subsection (c)(2) for the listed drug for a pat-
25 ent for which certification or a method of use state-

1 ment is required under paragraph (2)(A), the pre-
2 vious applicant fails to submit no later than 60 days
3 from the date the applicant receives notice from the
4 Secretary under paragraph (7)(A)(iii) of the submis-
5 sion of the new patent information either a certifi-
6 cation described in paragraph (2)(A)(vii)(IV) or a
7 statement that the method of use patent does not
8 claim a use for which the applicant is seeking ap-
9 proval under this subsection in accordance with
10 paragraph (2)(A)(viii); except, however, that such
11 date may be extended due to extraordinary or un-
12 usual circumstances, as determined by the Secretary;
13 or

14 “(VI) the previous applicant is determined by
15 the Secretary, after a fair and sufficient hearing and
16 in consultation with the Federal Trade Commission,
17 to have engaged in anticompetitive or collusive con-
18 duct, or any other conduct intended to unfairly mo-
19 nopolize the commercial manufacturing of the drug
20 of the application.

21 “(ii) If under clause (i) the previous applicant re-
22 ferred to in subparagraph (B)(iv) forfeits the 180-day pe-
23 riod described in such subparagraph, such period shall be-
24 come available to the next applicant submitting an appli-

1 cation containing a certification under paragraph
2 (2)(A)(vii)(IV) if—

3 “(I) no action described in subparagraph
4 (B)(iii)(II) was brought against or by the previous
5 applicant, or such an action was brought but did not
6 result in a final judgment that included a finding
7 that the patent involved is invalid; and

8 “(II) an action described in subparagraph
9 (B)(iii)(II) is brought against or by the next appli-
10 cant, and such action results in a final judgment
11 that includes a finding that the patent involved is in-
12 valid.

13 “(iii) The 180-day period described in subparagraph
14 (B)(iv) shall be available only to—

15 “(I) the previous applicant submitting an appli-
16 cation for a drug under this subsection containing a
17 certification described in paragraph (2)(A)(vii)(IV)
18 with respect to any patent; or

19 “(II) under clause (ii), the next applicant sub-
20 mitting an application for a drug under this sub-
21 section containing such a certification with respect
22 to any patent;

23 even if an application has been submitted for the drug
24 under this subsection containing such a certification with
25 respect to a different patent.

1 “(iv) The 180-day period described in subparagraph
2 (B)(iv) for an application containing a certification de-
3 scribed in paragraph (2)(A)(vii)(IV) shall apply only if an
4 action is brought for infringement of a patent that is the
5 subject of the certification or the applicant brings an ac-
6 tion (not later than 60 days after the date on which the
7 notice provided under paragraph (2)(B)(ii) was received)
8 against the holder of the approved application for the list-
9 ed drug.”.

10 (b) EFFECTIVE DATE.—The amendment made by
11 this section shall be effective only with respect to an appli-
12 cation filed under section 505(j) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 355(j)) for a listed
14 drug for which no certification under section
15 505(j)(2)(A)(vii)(IV) of that Act was made before June
16 7, 2002.

17 **SEC. 112. PATENT CERTIFICATION.**

18 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
19 tion 505(j)(5) of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 355(j)(5)) is amended—

21 (1) in subparagraph (B), by striking clause (iii)
22 and inserting the following:

23 “(iii)(I) If the applicant made a certification de-
24 scribed in paragraph (2)(A)(vii)(IV) and—

1 “(aa) no action is brought for infringement
2 of a patent that is the subject of the certifi-
3 cation before the expiration of the 45-day pe-
4 riod beginning on the date on which the notice
5 provided under paragraph (2)(B)(ii) was re-
6 ceived; and

7 “(bb) the applicant does not bring an ac-
8 tion for declaratory judgment authorized in
9 subclause (II) before the expiration of the 60-
10 day period beginning on the date on which the
11 notice provided under paragraph (2)(B)(ii) was
12 received;

13 the approval shall be made effective on the expira-
14 tion of 60 days after the date on which the notice
15 provided under paragraph (2)(B)(ii) was received,
16 provided none of the conditions for denial of ap-
17 proval in paragraph (4) apply.

18 “(II) With respect to an applicant who made a
19 certification described in paragraph (2)(A)(vii)(IV),
20 if an action referred to in item (aa) of subclause (I)
21 is brought before the expiration of the period de-
22 scribed in such item, or if the applicant brings an
23 action for declaratory judgment of invalidity or non-
24 infringement of such patent (which action is hereby
25 authorized) before the expiration of the period de-

1 scribed in item (bb) of such subclause, the approval
2 shall, provided none of the conditions for denial of
3 approval in paragraph (4) apply, be made effective
4 in accordance with the following:

5 “(aa) If the action is an action referred to
6 in subclause (I)(aa), and neither the holder of
7 the approved application nor the owner of the
8 patent seek a preliminary injunction prohibiting
9 the applicant from engaging in the commercial
10 manufacture or sale (or both) of the drug, the
11 approval shall be made effective on the expira-
12 tion of 60 days after the date on which the no-
13 tice provided under paragraph (2)(B)(ii) was
14 received.

15 “(bb) If the action is an action referred to
16 in subclause (I)(aa), and such a preliminary in-
17 junction is sought and the court denies the mo-
18 tion, the approval shall be made effective on the
19 date on which the court denies the injunction.

20 “(cc) If neither item (aa) nor (bb) applies,
21 and the holding of the court in the decision in
22 the action is that the patent is invalid or was
23 not infringed, the approval shall be made effec-
24 tive on the date of the decision of the court.

1 “(dd) If neither item (aa) nor (bb) applies,
2 and the holding of the court in the decision in
3 the action is that the patent was infringed, the
4 approval shall be made effective on such date as
5 the court orders under section 271(e)(4)(A) of
6 title 35, United States Code.”; and

7 (2) by inserting before subparagraph (D) (as
8 added by section 111(a)(3)) the following subpara-
9 graph:

10 “(C) With respect to a civil action described in sub-
11 paragraph (B)(iii)(II):

12 “(i) Each of the parties shall reasonably cooper-
13 ate in expediting the action.

14 “(ii) If the notice under paragraph (2)(B)(ii)
15 contains an address for the receipt of expedited noti-
16 fication of such an action, the plaintiff shall, on the
17 date the complaint is filed in the court, simulta-
18 neously cause a notification of such action to be de-
19 livered to such address by the next business day.

20 “(iii) An action for a declaratory judgment au-
21 thorized in such subparagraph may not be brought
22 by the applicant until the expiration of 45 days after
23 the date the notice provided under paragraph
24 (2)(B)(ii) was received, except that if information on
25 the patent involved has been published under sub-

1 section (c)(2) for at least one year after the date on
2 which the application under this subsection was filed
3 in relation to the listed drug involved, the applicant
4 may immediately bring such an action for declara-
5 tory judgment.

6 “(iv) Any such action shall be brought in the
7 judicial district in which the defendant has its prin-
8 cipal place of business or a regular and established
9 place of business.”.

10 (b) NEW DRUG APPLICATIONS.—Section 505(c)(3)
11 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 355(c)(3)) is amended by striking subparagraph (C) and
13 inserting the following:

14 “(C)(i)(I) If the applicant made a certification
15 described in subsection (b)(2)(A)(iv) and—

16 “(aa) no action is brought for infringement
17 of a patent that is the subject of the certifi-
18 cation before the expiration of the 45-day pe-
19 riod beginning on the date on which the notice
20 provided under subsection (b)(3)(B) was re-
21 ceived; and

22 “(bb) the applicant does not bring an ac-
23 tion for declaratory judgment authorized in
24 subclause (II) before the expiration of the 60-
25 day period beginning on the date on which the

1 notice provided under subsection (b)(3)(B) was
2 received;

3 the approval shall be made effective on the expira-
4 tion of 60 days after the date on which the notice
5 provided under subsection (b)(3)(B) was received,
6 provided that none of the conditions for refusal of
7 approval in subsection (d) apply.

8 “(II) With respect to an applicant who made a
9 certification described in subsection (b)(2)(A)(iv), if
10 an action referred to in item (aa) of subclause (I)
11 is brought before the expiration of the period de-
12 scribed in such item, or if the applicant brings an
13 action for declaratory judgment of invalidity or non-
14 infringement of such patent (which action is hereby
15 authorized) before the expiration of the period de-
16 scribed in item (bb) of such subclause, the approval
17 shall, provided none of the conditions for refusal of
18 approval in subsection (d) apply, be made effective
19 in accordance with the following:

20 “(aa) If the action is an action referred to
21 in subclause (I)(aa), and neither the holder of
22 the approved application nor the owner of the
23 patent seek a preliminary injunction prohibiting
24 the applicant from engaging in the commercial
25 manufacture or sale (or both) of the drug, the

1 approval shall be made effective on the expira-
2 tion of 60 days after the date on which the no-
3 tice provided under subsection (b)(3)(B) was re-
4 ceived.

5 “(bb) If the action is an action referred to
6 in subclause (I)(aa), and such a preliminary in-
7 junction is sought and the court denies the mo-
8 tion, the approval shall be made effective on the
9 date on which the court denies the injunction.

10 “(cc) If neither item (aa) nor (bb) applies,
11 and the holding of the court in the decision in
12 the action is that the patent is invalid or was
13 not infringed, the approval shall be made effec-
14 tive on the date of the decision of the court.

15 “(dd) If neither item (aa) nor (bb) applies,
16 and the holding of the court in the decision in
17 the action is that the patent was infringed, the
18 approval shall be made effective on such date as
19 the court orders under section 271(e)(4)(A) of
20 title 35, United States Code.

21 “(ii) With respect to a civil action described in
22 clause (i)(II):

23 “(I) Each of the parties shall reasonably
24 cooperate in expediting the action.

1 “(II) If the notice under subsection
2 (b)(3)(B) contains an address for the receipt of
3 expedited notification of such an action, the
4 plaintiff shall, on the date the complaint is filed
5 in the court, simultaneously cause a notification
6 of such action to be delivered to such address
7 by the next business day.

8 “(III) An action for a declaratory judgment
9 authorized in such clause may not be
10 brought by the applicant until the expiration of
11 45 days after the date the notice provided
12 under subsection (b)(3)(B) was received, except
13 that if information on the patent involved has
14 been published under paragraph (2) for at least
15 one year after the date on which the application
16 was filed in relation to the drug involved, the
17 applicant may immediately bring such an action
18 for declaratory judgment.

19 “(IV) Any such action shall be brought in
20 the judicial district in which the defendant has
21 its principal place of business or a regular and
22 established place of business.”.

23 (c) EFFECTIVE DATE.—The amendments made by
24 this section shall not apply to an application submitted
25 under section 505(b)(1) or 505(j) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355) before June 7,
2 2002.

3 **SEC. 113. ADDITIONAL USES.**

4 Section 505(j) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(j)) is amended by adding at the
6 end the following paragraph:”

7 “(10)(A) A drug for which an application has been
8 submitted or approved under this subsection shall not be
9 considered ineligible for approval under this subsection or
10 misbranded under section 502 on the basis that the label-
11 ing of the drug omits a use or any other aspect of labeling
12 when the omitted use or other aspect is protected by pat-
13 ent or by exclusivity under clause (iii) or (iv) of paragraph
14 (5)(D).

15 “(B) Notwithstanding clauses (iii) and (iv) of para-
16 graph (5)(D), the Secretary may require that the labeling
17 of a drug approved under this subsection that omits a use
18 or other aspect of labeling as described in subparagraph
19 (A) include—

20 “(i) any statement that the Secretary considers
21 necessary for the safe use of the drug, such as ap-
22 propriate contraindications, warnings, or pre-
23 cautions; and

1 “(ii) a statement that, because of marketing ex-
2 clusivity for a manufacturer, the drug is not labeled
3 for the use.”.

4 **PART II—NOTIFICATION OF AGREEMENTS AF-**
5 **FECTING THE SALE OR MARKETING OF GE-**
6 **NERIC DRUGS**

7 **SEC. 121. DEFINITIONS.**

8 In this part:

9 (1) **AGREEMENT.**—The term “agreement”
10 means an agreement under section 1 of the Sherman
11 Act (15 U.S.C. 1) or section 5 of the Federal Trade
12 Commission Act (15 U.S.C. 45).

13 (2) **ANTITRUST LAWS.**—The term “antitrust
14 laws” has the same meaning as in section 1 of the
15 Clayton Act (15 U.S.C. 12), except that such term
16 includes section 5 of the Federal Trade Commission
17 Act (15 U.S.C. 45) to the extent that such section
18 applies to unfair methods of competition.

19 (3) **ANDA.**—The term “ANDA” means an Ab-
20 breviated New Drug Application, as defined under
21 section 505(j) of the Federal Food, Drug and Cos-
22 metic Act.

23 (4) **BRAND NAME DRUG COMPANY.**—The term
24 “brand name drug company” means a person en-
25 gaged in the manufacture or marketing of a drug

1 approved under section 505(b) of the Federal Food,
2 Drug and Cosmetic Act.

3 (5) COMMISSION.—The term “Commission”
4 means the Federal Trade Commission.

5 (6) FDA.—The term “FDA” means the United
6 States Food and Drug Administration.

7 (7) GENERIC DRUG.—The term “generic drug”
8 means a product that is the subject of an ANDA.

9 (8) GENERIC DRUG APPLICANT.—The term
10 “generic drug applicant” means a person who has
11 filed or received approval for an ANDA under sec-
12 tion 505(j) of the Federal Food, Drug and Cosmetic
13 Act.

14 (9) SECRETARY.—The term “Secretary” means
15 the Secretary of Health and Human Services.

16 **SEC. 122. NOTIFICATION OF AGREEMENTS AFFECTING THE**
17 **SALE OR MARKETING OF GENERIC DRUGS.**

18 A brand name drug company and a generic drug ap-
19 plicant that enter into an agreement regarding the sale
20 or manufacture of a generic drug that the Secretary has
21 determined is the therapeutic equivalent of a brand name
22 drug that is manufactured or marketed by that brand
23 name drug company, or for which the generic drug appli-
24 cant seeks such a determination of therapeutic equiva-
25 lence, and which agreement could have the effect of lim-

1 iting the research, development, manufacture, marketing,
2 or selling of a generic drug that has been or could be ap-
3 proved for sale by the FDA pursuant to an ANDA, shall
4 file with the Commission and the Secretary the text of
5 the agreement, an explanation of the purpose and scope
6 of the agreement, and an explanation of whether the
7 agreement could delay, restrain, limit, or in any way inter-
8 fere with the production, manufacture, or sale of the ge-
9 neric version of the drug in question.

10 **SEC. 123. FILING DEADLINES.**

11 Any notice, agreement, or other material required to
12 be filed under section 122 shall be filed with the Commis-
13 sion and the Secretary not later than 10 business days
14 after the date the agreement is executed.

15 **SEC. 124. ENFORCEMENT.**

16 (a) CIVIL FINE.—Any person, or any officer, direc-
17 tor, or partner thereof, who fails to comply with any provi-
18 sion of this part shall be liable for a civil penalty of not
19 more than \$20,000 for each day during which such person
20 is in violation of this part. Such penalty may be recovered
21 in a civil action brought by the United States, or brought
22 by the Commission in accordance with the procedures es-
23 tablished in section 16(a)(1) of the Federal Trade Com-
24 mission Act (15 U.S.C. 56(a)).

1 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any
2 person, or any officer, director, partner, agent, or em-
3 ployee thereof, fails to comply with the notification re-
4 quirement under section 122 of this part, the United
5 States district court may order compliance, and may grant
6 such other equitable relief as the court in its discretion
7 determines necessary or appropriate, upon application of
8 the Commission or the Assistant Attorney General.

9 **SEC. 125. RULEMAKING.**

10 The Commission, in consultation with the Secretary,
11 and with the concurrence of the Assistant Attorney Gen-
12 eral and by rule in accordance with section 553 of title
13 5, United States Code, consistent with the purposes of this
14 part—

15 (1) may require that the notice described in sec-
16 tion 122 of this part be in such form and contain
17 such documentary material and information relevant
18 to the agreement as is necessary and appropriate to
19 enable the Commission and the Assistant Attorney
20 General to determine whether such agreement may
21 violate the antitrust laws;

22 (2) may define the terms used in this part;

23 (3) may exempt classes of persons or agree-
24 ments from the requirements of this part; and

1 (4) may prescribe such other rules as may be
2 necessary and appropriate to carry out the purposes
3 of this part.

4 **SEC. 126. EFFECTIVE DATES.**

5 This part shall take effect 90 days after the date of
6 enactment of this Act.

7 **TITLE II—MEDICARE+CHOICE**
8 **REVITALIZATION AND**
9 **MEDICARE+CHOICE COM-**
10 **PETITION PROGRAM**

11 **SEC. 201. MEDICARE+CHOICE IMPROVEMENTS.**

12 (a) **EQUALIZING PAYMENTS BETWEEN FEE-FOR-**
13 **SERVICE AND MEDICARE+CHOICE.—**

14 (1) **IN GENERAL.—**Section 1853(c)(1) (42
15 U.S.C. 1395w-23(c)(1)) is amended by adding at
16 the end the following:

17 “(D) **BASED ON 100 PERCENT OF FEE-**
18 **FOR-SERVICE COSTS.—**

19 “(i) **IN GENERAL.—**For 2003 and
20 2004, the adjusted average per capita cost
21 for the year involved, determined under
22 section 1876(a)(4) for the
23 Medicare+Choice payment area for serv-
24 ices covered under parts A and B for indi-
25 viduals entitled to benefits under part A

1 and enrolled under part B who are not en-
2 rolled in a Medicare+Choice plan under
3 this part for the year, but adjusted to ex-
4 clude costs attributable to payments under
5 section 1886(h).

6 “(ii) INCLUSION OF COSTS OF VA AND
7 DOD MILITARY FACILITY SERVICES TO
8 MEDICARE-ELIGIBLE BENEFICIARIES.—In
9 determining the adjusted average per cap-
10 ita cost under clause (i) for a year, such
11 cost shall be adjusted to include the Sec-
12 retary’s estimate, on a per capita basis, of
13 the amount of additional payments that
14 would have been made in the area involved
15 under this title if individuals entitled to
16 benefits under this title had not received
17 services from facilities of the Department
18 of Veterans Affairs or the Department of
19 Defense.”.

20 (2) CONFORMING AMENDMENT.—Such section
21 is further amended, in the matter before subpara-
22 graph (A), by striking “or (C)” and inserting “(C),
23 or (D)”.

24 (b) REVISION OF BLEND.—

1 (1) REVISION OF NATIONAL AVERAGE USED IN
2 CALCULATION OF BLEND.—Section
3 1853(c)(4)(B)(i)(II) (42 U.S.C. 1395w–
4 23(c)(4)(B)(i)(II)) is amended by inserting “who
5 (with respect to determinations for 2003 and for
6 2004) are enrolled in a Medicare+Choice plan”
7 after “the average number of medicare bene-
8 ficiaries”.

9 (2) CHANGE IN BUDGET NEUTRALITY.—Section
10 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

11 (A) in paragraph (1)(A), by inserting “(for
12 a year before 2003)” after “multiplied”; and

13 (B) in paragraph (5), by inserting “(before
14 2003)” after “for each year”.

15 (c) REVISION IN MINIMUM PERCENTAGE INCREASE
16 FOR 2003 AND 2004.—Section 1853(c)(1)(C) (42 U.S.C.
17 1395w–23(c)(1)(C)) is amended by striking clause (iv)
18 and inserting the following:

19 “(iv) For 2002, 102 percent of the
20 annual Medicare+Choice capitation rate
21 under this paragraph for the area for
22 2001.

23 “(v) For 2003 and 2004, 103 percent
24 of the annual Medicare+Choice capitation

1 rate under this paragraph for the area for
2 the previous year.

3 “(iv) For 2005 and each succeeding
4 year, 102 percent of the annual
5 Medicare+Choice capitation rate under
6 this paragraph for the area for the pre-
7 vious year.”.

8 (d) INCLUSION OF COSTS OF DOD AND VA MILI-
9 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENE-
10 FICIARIES IN CALCULATION OF MEDICARE+CHOICE PAY-
11 MENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w-
12 23(c)(3)) is amended—

13 (1) in subparagraph (A), by striking “subpara-
14 graph (B)” and inserting “subparagraphs (B) and
15 (E)”, and

16 (2) by adding at the end the following new sub-
17 paragraph:

18 “(E) INCLUSION OF COSTS OF DOD AND
19 VA MILITARY FACILITY SERVICES TO MEDICARE-
20 ELIGIBLE BENEFICIARIES.—In determining the
21 area-specific Medicare+Choice capitation rate
22 under subparagraph (A) for a year (beginning
23 with 2003), the annual per capita rate of pay-
24 ment for 1997 determined under section
25 1876(a)(1)(C) shall be adjusted to include in

1 the rate the Secretary's estimate, on a per cap-
2 ita basis, of the amount of additional payments
3 that would have been made in the area involved
4 under this title if individuals entitled to benefits
5 under this title had not received services from
6 facilities of the Department of Defense or the
7 Department of Veterans Affairs.".

8 (e) ANNOUNCEMENT OF REVISED
9 MEDICARE+CHOICE PAYMENT RATES.—Within 2 weeks
10 after the date of the enactment of this Act, the Secretary
11 shall determine, and shall announce (in a manner intended
12 to provide notice to interested parties) Medicare+Choice
13 capitation rates under section 1853 of the Social Security
14 Act (42 U.S.C. 1395w-23) for 2003, revised in accordance
15 with the provisions of this section.

16 (f) MEDPAC STUDY OF AAPCC.—

17 (1) STUDY.—The Medicare Payment Advisory
18 Commission shall conduct a study that assesses the
19 method used for determining the adjusted average
20 per capita cost (AAPCC) under section 1876(a)(4)
21 of the Social Security Act (42 U.S.C.
22 1395mm(a)(4)). Such study shall examine—

23 (A) the bases for variation in such costs
24 between different areas, including differences in
25 input prices, utilization, and practice patterns;

1 (B) the appropriate geographic area for
2 payment under the Medicare+Choice program
3 under part C of title XVIII of such Act; and

4 (C) the accuracy of risk adjustment meth-
5 ods in reflecting differences in costs of pro-
6 viding care to different groups of beneficiaries
7 served under such program.

8 (2) REPORT.—Not later than 9 months after
9 the date of the enactment of this Act, the Commis-
10 sion shall submit to Congress a report on the study
11 conducted under paragraph (1). Such report shall
12 include recommendations regarding changes in the
13 methods for computing the adjusted average per
14 capita cost among different areas.

15 (g) APPLYING LIMITATIONS ON BALANCE BILLING
16 TO MEDICARE MSAs.—Section 1852(k)(1) (42 U.S.C.
17 1395w–22(k)(1)) is amended by inserting “or with an or-
18 ganization offering a MSA plan” after “section
19 1851(a)(2)(A)”.

20 (h) REPORT ON IMPACT OF INCREASED FINANCIAL
21 ASSISTANCE TO MEDICARE+CHOICE PLANS.—Not later
22 than July 1, 2003, the Secretary shall submit to Congress
23 a report that describes the impact of additional financing
24 provided under this Act and other Acts (including the
25 Medicare, Medicaid, and SCHIP Balanced Budget Refine-

1 ment Act of 1999 and BIPA) on the availability of
2 Medicare+Choice plans in different areas and its impact
3 on lowering premiums and increasing benefits under such
4 plans.

5 **SEC. 202. MAKING PERMANENT CHANGE IN**
6 **MEDICARE+CHOICE REPORTING DEADLINES**
7 **AND ANNUAL, COORDINATED ELECTION PE-**
8 **RIOD.**

9 (a) CHANGE IN REPORTING DEADLINE.—Section
10 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by
11 section 532(b)(1) of the Public Health Security and Bio-
12 terrorism Preparedness and Response Act of 2002, is
13 amended by striking “2002, 2003, and 2004 (or July 1
14 of each other year)” and inserting “2002 and each subse-
15 quent year (or July 1 of each year before 2002)”.

16 (b) DELAY IN ANNUAL, COORDINATED ELECTION
17 PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–
18 21(e)(3)(B)), as amended by section 532(c)(1)(A) of the
19 Public Health Security and Bioterrorism Preparedness
20 and Response Act of 2002, is amended by striking “and
21 after 2005, the month of November before such year and
22 with respect to 2003, 2004, and 2005” and inserting “,
23 the month of November before such year and with respect
24 to 2003 and any subsequent year”.

1 (c) ANNUAL ANNOUNCEMENT OF PAYMENT
 2 RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–
 3 23(b)(1)), as amended by section 532(d)(1) of the Public
 4 Health Security and Bioterrorism Preparedness and Re-
 5 sponse Act of 2002, is amended by striking “and after
 6 2005 not later than March 1 before the calendar year con-
 7 cerned and for 2004 and 2005” and inserting “not later
 8 than March 1 before the calendar year concerned and for
 9 2004 and each subsequent year”.

10 (d) REQUIRING PROVISION OF AVAILABLE INFORMA-
 11 TION COMPARING PLAN OPTIONS.—The first sentence of
 12 section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w–
 13 21(d)(2)(A)(ii)) is amended by inserting before the period
 14 the following: “to the extent such information is available
 15 at the time of preparation of materials for the mailing”.

16 **SEC. 203. SPECIALIZED MEDICARE+CHOICE PLANS FOR**
 17 **SPECIAL NEEDS BENEFICIARIES.**

18 (a) TREATMENT AS COORDINATED CARE PLAN.—
 19 Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is
 20 amended by adding at the end the following new sentence:
 21 “Specialized Medicare+Choice plans for special needs
 22 beneficiaries (as defined in section 1859(b)(4)) may be
 23 any type of coordinated care plan.”.

24 (b) SPECIALIZED MEDICARE+CHOICE PLAN FOR
 25 SPECIAL NEEDS BENEFICIARIES DEFINED.—Section

1 1859(b) (42 U.S.C. 1395w-29(b)) is amended by adding
2 at the end the following new paragraph:

3 “(4) SPECIALIZED MEDICARE+CHOICE PLANS
4 FOR SPECIAL NEEDS BENEFICIARIES.—

5 “(A) IN GENERAL.—The term ‘specialized
6 Medicare+Choice plan for special needs bene-
7 ficiaries’ means a Medicare+Choice plan that
8 exclusively serves special needs beneficiaries (as
9 defined in subparagraph (B)).

10 “(B) SPECIAL NEEDS BENEFICIARY.—The
11 term ‘special needs beneficiary’ means a
12 Medicare+Choice eligible individual who—

13 “(i) is institutionalized (as defined by
14 the Secretary);

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

17 “(iii) meets such requirements as the
18 Secretary may determine would benefit
19 from enrollment in such a specialized
20 Medicare+Choice plan described in sub-
21 paragraph (A) for individuals with severe
22 or disabling chronic conditions.”.

23 (c) RESTRICTION ON ENROLLMENT PERMITTED.—
24 Section 1859 (42 U.S.C. 1395w-29) is amended by add-
25 ing at the end the following new subsection:

1 “(f) RESTRICTION ON ENROLLMENT FOR SPECIAL-
2 IZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS
3 BENEFICIARIES.—In the case of a specialized
4 Medicare+Choice plan (as defined in subsection (b)(4)),
5 notwithstanding any other provision of this part and in
6 accordance with regulations of the Secretary and for peri-
7 ods before January 1, 2007, the plan may restrict the en-
8 rollment of individuals under the plan to individuals who
9 are within one or more classes of special needs bene-
10 ficiaries.”.

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

19 (e) EFFECTIVE DATES.—

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

23 (2) DEADLINE FOR ISSUANCE OF REQUIRE-
24 MENTS FOR SPECIAL NEEDS BENEFICIARIES; TRAN-
25 SITION.—No later than 6 months after the date of

1 the enactment of this Act, the Secretary of Health
2 and Human Services shall issue final regulations to
3 establish requirements for special needs beneficiaries
4 under section 1859(b)(4)(B)(iii) of the Social Secu-
5 rity Act, as added by subsection (b).

6 **SEC. 204. EXTENSION OF REASONABLE COST AND SHMO**
7 **CONTRACTS.**

8 (a) REASONABLE COST CONTRACTS.—

9 (1) IN GENERAL.—Section 1876(h)(5)(C) (42
10 U.S.C. 1395mm(h)(5)(C)) is amended—

11 (A) by inserting “(i)” after “(C)”;

12 (B) by inserting before the period the fol-
13 lowing: “, except (subject to clause (ii)) in the
14 case of a contract for an area which is not cov-
15 ered in the service area of 1 or more coordi-
16 nated care Medicare+Choice plans under part
17 C”; and

18 (C) by adding at the end the following new
19 clause:

20 “(ii) In the case in which—

21 “(I) a reasonable cost reimbursement contract
22 includes an area in its service area as of a date that
23 is after December 31, 2003;

24 “(II) such area is no longer included in such
25 service area after such date by reason of the oper-

1 ation of clause (i) because of the inclusion of such
2 area within the service area of a Medicare+Choice
3 plan; and

4 “(III) all Medicare+Choice plans subsequently
5 terminate coverage in such area;

6 such reasonable cost reimbursement contract may be ex-
7 tended and renewed to cover such area (so long as it is
8 not included in the service area of any Medicare+Choice
9 plan).”.

10 (2) STUDY.—The Secretary shall conduct a
11 study of an appropriate transition for plans offered
12 under reasonable cost contracts under section 1876
13 of the Social Security Act on and after January 1,
14 2005. Such a transition may take into account
15 whether there are one or more coordinated care
16 Medicare+Choice plans being offered in the areas
17 involved. Not later than February 1, 2004, the Sec-
18 retary shall submit to Congress a report on such
19 study and shall include recommendations regarding
20 any changes in the amendment made by paragraph
21 (1) as the Secretary determines to be appropriate.

22 (b) EXTENSION OF SOCIAL HEALTH MAINTENANCE
23 ORGANIZATION (SHMO) DEMONSTRATION PROJECT.—

24 (1) IN GENERAL.—Section 4018(b)(1) of the
25 Omnibus Budget Reconciliation Act of 1987 is

1 amended by striking “the date that is 30 months
2 after the date that the Secretary submits to Con-
3 gress the report described in section 4014(c) of the
4 Balanced Budget Act of 1997” and inserting “De-
5 cember 31, 2004”.

6 (2) SHMOS OFFERING MEDICARE+CHOICE
7 PLANS.—Nothing in such section 4018 shall be con-
8 strued as preventing a social health maintenance or-
9 ganization from offering a Medicare+Choice plan
10 under part C of title XVIII of the Social Security
11 Act.

12 **SEC. 205. CONTINUOUS OPEN ENROLLMENT AND**
13 **DISENROLLMENT.**

14 (a) IN GENERAL.—Section 1851(e)(2) (42 U.S.C.
15 1395w–21(e)(2)) is amended to read as follows:

16 “(2) CONTINUOUS OPEN ENROLLMENT AND
17 DISENROLLMENT.—Subject to paragraph (5), a
18 Medicare+Choice eligible individual may change the
19 election under subsection (a)(1) at any time.”.

20 (b) CONFORMING AMENDMENTS.—

21 (1) MEDICARE+CHOICE.—Section 1851(e) (42
22 U.S.C. 1395w–21(e)) is amended—

23 (A) in paragraph (4)—

24 (i) by striking “Effective as of Janu-
25 ary 1, 2002, an” and inserting “An”;

1 (ii) by striking “other than during an
2 annual, coordinated election period”;

3 (iii) by inserting “in a special election
4 period for such purpose” after “make a
5 new election under this section”; and

6 (iv) by striking the second sentence;

7 and

8 (B) in paragraphs (5)(B) and (6)(A), by
9 striking “the first sentence of”.

10 (2) PERMITTING ENROLLMENT IN MEDIGAP
11 WHEN M+C PLANS REDUCE BENEFITS OR WHEN
12 PROVIDER LEAVES A M+C PLAN.—

13 (A) IN GENERAL.—Clause (ii) of section
14 1882(s)(3)(B) (42 U.S.C. 1395ss(s)(3)(B)) is
15 amended—

16 (i) by inserting “(I)” after “(ii)”;

17 (ii) by striking “under the first sen-
18 tence of” each place it appears and insert-
19 ing “during a special election period pro-
20 vided for under”;

21 (iii) by inserting “the circumstances
22 described in subclause (II) are present or”
23 before “there are circumstances”; and

24 (iv) by adding at the end the following
25 new subclause:

1 “(II) The circumstances described in this sub-
2 clause are, with respect to an individual enrolled in
3 a Medicare+Choice plan, a reduction in benefits (in-
4 cluding an increase in cost-sharing) offered under
5 the Medicare+Choice plan from the previous year or
6 a provider of services or physician who serves the in-
7 dividual no longer participating in the plan (other
8 than because of good cause relating to quality of
9 care under the plan).”.

10 (B) CONFORMING AMENDMENT.—Clause

11 (iii) of such section is amended—

12 (i) by inserting “the circumstances de-
13 scribed in clause (ii)(II) are met or” after
14 “policy described in subsection (t), and”;
15 and

16 (ii) by striking “under the first sen-
17 tence of” and inserting “during a special
18 election period provided for under”.

19 (c) EFFECTIVE DATE.—The amendments made by
20 this section shall take effect on January 1, 2003, and shall
21 apply to reductions in benefits and changes in provider
22 participation occurring on or after such date.

1 **SEC. 206. LIMITATION ON MEDICARE+CHOICE COST-SHAR-**
2 **ING.**

3 (a) IN GENERAL.—Section 1852(a) (42 U.S.C.
4 1395w–22(a)) is amended by adding at the end the fol-
5 lowing new paragraph:

6 “(6) LIMITATION ON COST-SHARING.—

7 “(A) IN GENERAL.—Subject to subpara-
8 graph (B), in no case shall the cost-sharing
9 with respect to an item or service under a
10 Medicare+Choice plan exceed the cost-sharing
11 otherwise applicable under parts A and B to an
12 individual who is not enrolled in a
13 Medicare+Choice plan under this part.

14 “(B) PERMITTING FLAT COPAYMENTS.—
15 Subparagraph (A) shall not be construed as
16 preventing the application of flat dollar copay-
17 ment amounts (in place of a percentage coin-
18 surance), such as a fixed copayment for a doc-
19 tor’s visit, so long as such amounts are reason-
20 able and appropriate and do not adversely af-
21 fect access to items and services (as determined
22 by the Secretary).”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall apply as of January 1, 2003.

1 **SEC. 207. EXTENSION OF MUNICIPAL HEALTH SERVICE**
2 **DEMONSTRATION PROJECTS.**

3 The last sentence of section 9215(a) of the Consoli-
4 dated Omnibus Budget Reconciliation Act of 1985 (42
5 U.S.C. 1395b–1 note), as previously amended, is amended
6 by striking “December 31, 2004, but only with respect
7 to” and all that follows and inserting “December 31,
8 2009, but only with respect to individuals who reside in
9 the city in which the project is operated and so long as
10 the total number of individuals participating in the project
11 does not exceed the number of such individuals partici-
12 pating as of January 1, 1996.”.

13 **TITLE III—RURAL HEALTH CARE**
14 **IMPROVEMENTS**

15 **SEC. 301. REFERENCE TO FULL MARKET BASKET INCREASE**
16 **FOR SOLE COMMUNITY HOSPITALS.**

17 For provision eliminating any reduction from full
18 market basket in the update for inpatient hospital services
19 for sole community hospitals, see section 401.

20 **SEC. 302. ENHANCED DISPROPORTIONATE SHARE HOS-**
21 **PITAL (DSH) TREATMENT FOR RURAL HOS-**
22 **PITALS AND URBAN HOSPITALS WITH FEWER**
23 **THAN 100 BEDS.**

24 (a) **BLENDING OF PAYMENT AMOUNTS.—**

1 (1) IN GENERAL.—Section 1886(d)(5)(F) (42
2 U.S.C. 1395ww(d)(5)(F)) is amended by adding at
3 the end the following new clause:

4 “(xiv)(I) In the case of discharges in a fiscal year
5 beginning on or after October 1, 2002, subject to sub-
6 clause (II), there shall be substituted for the dispropor-
7 tionate share adjustment percentage otherwise determined
8 under clause (iv) (other than subclause (I)) or under
9 clause (viii), (x), (xi), (xii), or (xiii), the old blend propor-
10 tion (specified under subclause (III)) of the dispropor-
11 tionate share adjustment percentage otherwise determined
12 under the respective clause and 100 percent minus such
13 old blend proportion of the disproportionate share adjust-
14 ment percentage determined under clause (vii) (relating
15 to large, urban hospitals).

16 “(II) Under subclause (I), the disproportionate share
17 adjustment percentage shall not exceed 10 percent for a
18 hospital that is not classified as a rural referral center
19 under subparagraph (C).

20 “(III) For purposes of subclause (I), the old blend
21 proportion for fiscal year 2003 is $66\frac{2}{3}$ percent, for fiscal
22 year 2004 is $33\frac{1}{3}$ percent subsequent year, and for each
23 fiscal year beginning with 2005 is 0 percent.”.

1 (2) CONFORMING AMENDMENTS.—Section
 2 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is
 3 amended—

4 (A) in each of subclauses (II), (III), (IV),
 5 (V), and (VI) of clause (iv), by inserting “sub-
 6 ject to clause (xiv) and” before “for discharges
 7 occurring”;

8 (B) in clause (viii), by striking “The for-
 9 mula” and inserting “Subject to clause (xiv),
 10 the formula”; and

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

14 (b) EFFECTIVE DATE.—The amendments made by
 15 this section shall apply with respect to discharges occur-
 16 ring on or after October 1, 2002.

17 **SEC. 303. 2-YEAR PHASED-IN INCREASE IN THE STANDARD-**
 18 **IZED AMOUNT IN RURAL AND SMALL URBAN**
 19 **AREAS TO ACHIEVE A SINGLE, UNIFORM**
 20 **STANDARDIZED AMOUNT.**

21 Section 1886(d)(3)(A)(iv) (42 U.S.C.
 22 1395ww(d)(3)(A)(iv)) is amended—

23 (1) by striking “(iv) For discharges” and in-
 24 serting “(iv)(I) Subject to the succeeding provisions
 25 of this clause, for discharges”; and

1 (2) by adding at the end the following new sub-
2 clauses:

3 “(II) For discharges occurring during fiscal
4 year 2003, the average standardized amount for hos-
5 pitals located other than in a large urban area shall
6 be increased by $\frac{1}{2}$ of the difference between the av-
7 erage standardized amount determined under sub-
8 clause (I) for hospitals located in large urban areas
9 for such fiscal year and such amount determined
10 (without regard to this subclause) for other hospitals
11 for such fiscal year.

12 “(III) For discharges occurring in a fiscal year
13 beginning with fiscal year 2004, the Secretary shall
14 compute an average standardized amount for hos-
15 pitals located in any area within the United States
16 and within each region equal to the average stand-
17 arized amount computed for the previous fiscal
18 year under this subparagraph for hospitals located
19 in a large urban area (or, beginning with fiscal year
20 2005, for hospitals located in any area) increased by
21 the applicable percentage increase under subsection
22 (b)(3)(B)(i).”.

1 **SEC. 304. MORE FREQUENT UPDATE IN WEIGHTS USED IN**
2 **HOSPITAL MARKET BASKET.**

3 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After
4 revising the weights used in the hospital market basket
5 under section 1886(b)(3)(B)(iii) of the Social Security Act
6 (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most cur-
7 rent data available, the Secretary shall establish a fre-
8 quency for revising such weights in such market basket
9 to reflect the most current data available more frequently
10 than once every 5 years.

11 (b) REPORT.—Not later than October 1, 2003, the
12 Secretary shall submit a report to Congress on the fre-
13 quency established under subsection (a), including an ex-
14 planation of the reasons for, and options considered, in
15 determining such frequency.

16 **SEC. 305. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL**
17 **PROGRAM.**

18 (a) REINSTATEMENT OF PERIODIC INTERIM PAY-
19 MENT (PIP).—Section 1815(e)(2) (42 U.S.C.
20 1395g(e)(2)) is amended—

21 (1) by striking “and” at the end of subpara-
22 graph (C);

23 (2) by adding “and” at the end of subpara-
24 graph (D); and

25 (3) by inserting after subparagraph (D) the fol-
26 lowing new subparagraph:

1 “(E) inpatient critical access hospital services;”.

2 (b) CONDITION FOR APPLICATION OF SPECIAL PHY-
3 SICIAN PAYMENT ADJUSTMENT.—Section 1834(g)(2) (42
4 U.S.C. 1395m(g)(2)) is amended by adding after and
5 below subparagraph (B) the following:

6 “The Secretary may not require, as a condition for
7 applying subparagraph (B) with respect to a critical
8 access hospital, that each physician providing profes-
9 sional services in the hospital must assign billing
10 rights with respect to such services, except that such
11 subparagraph shall not apply to those physicians
12 who have not assigned such billing rights.”.

13 (c) FLEXIBILITY IN BED LIMITATION FOR HOS-
14 PITALS WITH STRONG SEASONAL CENSUS FLUCTUA-
15 TIONS.—Section 1820 (42 U.S.C. 1395i–4) is amended—

16 (1) in subsection (c)(2)(B)(iii), by inserting
17 “subject to paragraph (3)” after “(iii) provides”;

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

20 “(3) INCREASE IN MAXIMUM NUMBER OF BEDS
21 FOR HOSPITALS WITH STRONG SEASONAL CENSUS
22 FLUCTUATIONS.—

23 “(A) IN GENERAL.—In the case of a hos-
24 pital that demonstrates that it meets the stand-
25 ards established under subparagraph (B), the

1 bed limitations otherwise applicable under para-
2 graph (2)(B)(iii) and subsection (f) shall be in-
3 creased by 5 beds.

4 “(B) STANDARDS.—The Secretary shall
5 specify standards for determining whether a
6 critical access hospital has sufficiently strong
7 seasonal variations in patient admissions to jus-
8 tify the increase in bed limitation provided
9 under subparagraph (A).”; and

10 (3) in subsection (f), by adding at the end the
11 following new sentence: “The limitations in numbers
12 of beds under the first sentence are subject to ad-
13 justment under subsection (c)(3).”.

14 (d) 5-YEAR EXTENSION OF THE AUTHORIZATION
15 FOR APPROPRIATIONS FOR GRANT PROGRAM.—Section
16 1820(j) (42 U.S.C. 1395i–4(j)) is amended by striking
17 “through 2002” and inserting “through 2007”.

18 (e) PROHIBITION OF RETROACTIVE RECOUPMENT.—
19 The Secretary shall not recoup (or otherwise seek to re-
20 cover) overpayments made for outpatient critical access
21 hospital services under part B of title XVIII of the Social
22 Security Act, for services furnished in cost reporting peri-
23 ods that began before October 1, 2002, insofar as such
24 overpayments are attributable to payment being based on

1 80 percent of reasonable costs (instead of 100 percent of
2 reasonable costs minus 20 percent of charges).

3 (f) EFFECTIVE DATES.—

4 (1) REINSTATEMENT OF PIP.—The amend-
5 ments made by subsection (a) shall apply to pay-
6 ments made on or after January 1, 2003.

7 (2) PHYSICIAN PAYMENT ADJUSTMENT CONDI-
8 TION.—The amendment made by subsection (b)
9 shall be effective as if included in the enactment of
10 section 403(d) of the Medicare, Medicaid, and
11 SCHIP Balanced Budget Refinement Act of 1999
12 (113 Stat. 1501A–371).

13 (3) FLEXIBILITY IN BED LIMITATION.—The
14 amendments made by subsection (c) shall apply to
15 designations made on or after January 1, 2003, but
16 shall not apply to critical access hospitals that were
17 designated as of such date.

18 **SEC. 306. EXTENSION OF TEMPORARY INCREASE FOR**
19 **HOME HEALTH SERVICES FURNISHED IN A**
20 **RURAL AREA.**

21 (a) IN GENERAL.—Section 508(a) of BIPA (114
22 Stat. 2763A–533) is amended—

23 (1) by striking “24-MONTH INCREASE BEGIN-
24 NING APRIL 1, 2001” and inserting “IN GENERAL”;
25 and

1 (2) by striking “April 1, 2003” and inserting
2 “January 1, 2005”.

3 (b) CONFORMING AMENDMENT.—Section 547(c)(2)
4 of BIPA (114 Stat. 2763A–553) is amended by striking
5 “the period beginning on April 1, 2001, and ending on
6 September 30, 2002,” and inserting “a period under such
7 section”.

8 **SEC. 307. REFERENCE TO 10 PERCENT INCREASE IN PAY-**
9 **MENT FOR HOSPICE CARE FURNISHED IN A**
10 **FRONTIER AREA AND RURAL HOSPICE DEM-**
11 **ONSTRATION PROJECT.**

12 For—

13 (1) provision of 10 percent increase in payment
14 for hospice care furnished in a frontier area, see sec-
15 tion 422; and

16 (2) provision of a rural hospice demonstration
17 project, see section 423.

18 **SEC. 308. REFERENCE TO PRIORITY FOR HOSPITALS LO-**
19 **CATED IN RURAL OR SMALL URBAN AREAS IN**
20 **REDISTRIBUTION OF UNUSED GRADUATE**
21 **MEDICAL EDUCATION RESIDENCIES.**

22 For provision providing priority for hospitals located
23 in rural or small urban areas in redistribution of unused
24 graduate medical education residencies, see section 611.

1 **SEC. 309. 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; and

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 (b) REPORT.—Not later than 1 year after the date
23 of the enactment of this Act, the Comptroller General shall
24 submit to Congress a report on the study conducted under
25 subsection (a). The report shall include recommendations
26 regarding the use of more current data in computing geo-

1 graphic cost of practice indices as well as the use of data
2 directly representative of physicians' costs (rather than
3 proxy measures of such costs).

4 **SEC. 310. PROVIDING SAFE HARBOR FOR CERTAIN COL-**
5 **LABORATIVE EFFORTS THAT BENEFIT MEDI-**
6 **CALLY UNDERSERVED POPULATIONS.**

7 (a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C.
8 1320a–7(b)(3)), as amended by section 101(b)(2), is
9 amended—

10 (1) in subparagraph (F), by striking “and”
11 after the semicolon at the end;

12 (2) in subparagraph (G), by striking the period
13 at the end and inserting “; and”; and

14 (3) by adding at the end the following new sub-
15 paragraph:

16 “(H) any remuneration between a public
17 or nonprofit private health center entity de-
18 scribed under clause (i) or (ii) of section
19 1905(l)(2)(B) and any individual or entity pro-
20 viding goods, items, services, donations or
21 loans, or a combination thereof, to such health
22 center entity pursuant to a contract, lease,
23 grant, loan, or other agreement, if such agree-
24 ment contributes to the ability of the health
25 center entity to maintain or increase the avail-

1 ability, or enhance the quality, of services pro-
2 vided to a medically underserved population
3 served by the health center entity.”.

4 (b) RULEMAKING FOR EXCEPTION FOR HEALTH
5 CENTER ENTITY ARRANGEMENTS.—

6 (1) ESTABLISHMENT.—

7 (A) IN GENERAL.—The Secretary of
8 Health and Human Services (in this subsection
9 referred to as the “Secretary”) shall establish,
10 on an expedited basis, standards relating to the
11 exception described in section 1128B(b)(3)(H)
12 of the Social Security Act, as added by sub-
13 section (a), for health center entity arrange-
14 ments to the antikickback penalties.

15 (B) FACTORS TO CONSIDER.—The Sec-
16 retary shall consider the following factors,
17 among others, in establishing standards relating
18 to the exception for health center entity ar-
19 rangements under subparagraph (A):

20 (i) Whether the arrangement between
21 the health center entity and the other
22 party results in savings of Federal grant
23 funds or increased revenues to the health
24 center entity.

1 (ii) Whether the arrangement between
2 the health center entity and the other
3 party restricts or limits a patient's freedom
4 of choice.

5 (iii) Whether the arrangement be-
6 tween the health center entity and the
7 other party protects a health care profes-
8 sional's independent medical judgment re-
9 garding medically appropriate treatment.

10 The Secretary may also include other standards
11 and criteria that are consistent with the intent
12 of Congress in enacting the exception estab-
13 lished under this section.

14 (2) INTERIM FINAL EFFECT.—No later than
15 180 days after the date of enactment of this Act, the
16 Secretary shall publish a rule in the Federal Reg-
17 ister consistent with the factors under paragraph
18 (1)(B). Such rule shall be effective and final imme-
19 diately on an interim basis, subject to such change
20 and revision, after public notice and opportunity (for
21 a period of not more than 60 days) for public com-
22 ment, as is consistent with this subsection.

1 **SEC. 311. RELIEF FOR CERTAIN NON-TEACHING HOS-**
2 **PITALS.**

3 (a) IN GENERAL.—In the case of a non-teaching hos-
4 pital that meets the condition of subsection (b), for its
5 cost reporting period beginning in each of fiscal years
6 2003, 2004, and 2005 the amount of payment made to
7 the hospital under section 1886(d) of the Social Security
8 Act for discharges occurring during such fiscal year only
9 shall be increased as though the applicable percentage in-
10 crease (otherwise applicable to discharges occurring dur-
11 ing such fiscal year under section 1886(b)(3)(B)(i) of the
12 Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(i)) had
13 been increased by 5 percentage points. The previous sen-
14 tence shall be applied for each such fiscal year separately
15 without regard to its application in a previous fiscal year
16 and shall not affect payment for discharges for any hos-
17 pital occurring during a fiscal year after fiscal year 2005.

18 (b) CONDITION.—A non-teaching hospital meets the
19 condition of this paragraph if—

20 (1) it is located in a rural area and the amount
21 of the aggregate payments under subsection (d) of
22 such section for non-teaching hospitals located in
23 rural areas in the State for their cost reporting peri-
24 ods beginning during fiscal year 1999 is less than
25 the aggregate allowable operating costs of inpatient
26 hospital services (as defined in section 1886(a)(4) of

1 such Act) for all such hospitals in such areas in such
2 State with respect to such cost reporting periods; or
3 (2) it is located in an urban area and the
4 amount of the aggregate payments under subsection
5 (d) of such section for non-teaching hospitals located
6 in urban areas in the State for their cost reporting
7 periods beginning during fiscal year 1999 is less
8 than 103 percent of the aggregate allowable oper-
9 ating costs of inpatient hospital services (as defined
10 in section 1886(a)(4) of such Act) for all such hos-
11 pitals in such areas in such State with respect to
12 such cost reporting periods.

13 The amounts under paragraphs (1) and (2) shall be deter-
14 mined by the Secretary of Health and Human Services
15 based on data of the Medicare Payment Advisory Commis-
16 sion.

17 (c) DEFINITIONS.—For purposes of this section:

18 (1) NON-TEACHING HOSPITAL.—The term
19 “non-teaching hospital” means, for a cost reporting
20 period, a subsection (d) hospital (as defined in sec-
21 tion 1886(d)(1)(B) of the Social Security Act, 42
22 U.S.C. 1395ww(d)(1)(B))) that is not receiving any
23 additional payment under section 1886(d)(5)(B) of
24 such Act (42 U.S.C. 1395ww(d)(5)(B)) or a pay-
25 ment under section 1886(h) of such Act (42 U.S.C.

1 1395ww(h)) for discharges occurring during the pe-
 2 riod.

3 (2) RURAL; URBAN.—The terms “rural” and
 4 “urban” have the meanings given such terms for
 5 purposes of section 1886(d) of the Social Security
 6 Act (42 U.S.C. 1395ww(d)).

7 **TITLE IV—PROVISIONS**
 8 **RELATING TO PART A**
 9 **Subtitle A—Inpatient Hospital**
 10 **Services**

11 **SEC. 401. REVISION OF ACUTE CARE HOSPITAL PAYMENT**
 12 **UPDATES.**

13 Subclause (XVIII) of section 1886(b)(3)(B)(i) (42
 14 U.S.C. 1395ww(b)(3)(B)(i)) is amended to read as fol-
 15 lows:

16 “(XVIII) for fiscal year 2003, the market bas-
 17 ket percentage increase for sole community hospitals
 18 and such increase minus 0.25 percentage points for
 19 other hospitals, and”.

20 **SEC. 402. FREEZE IN LEVEL OF ADJUSTMENT FOR INDI-**
 21 **RECT COSTS OF MEDICAL EDUCATION (IME)**
 22 **THROUGH FISCAL YEAR 2007.**

23 Section 1886(d)(5)(B)(ii) (42 U.S.C.
 24 1395ww(d)(5)(B)(ii)) is amended—

1 (1) in subclause (VI), by inserting “and each
2 succeeding fiscal year through fiscal year 2007”
3 after “2002”; and

4 (2) in subclause (VII), by striking “2002” and
5 inserting “2007”.

6 **SEC. 403. RECOGNITION OF NEW MEDICAL TECHNOLOGIES**

7 **UNDER INPATIENT HOSPITAL PPS.**

8 (a) **IMPROVING TIMELINESS OF DATA COLLEC-**
9 **TION.**—Section 1886(d)(5)(K) (42 U.S.C.
10 1395ww(d)(5)(K)) is amended by adding at the end the
11 following new clause:

12 “(vii) Under the mechanism under this subpara-
13 graph, the Secretary shall provide for the addition of new
14 diagnosis and procedure codes in April 1 of each year, but
15 the addition of such codes shall not require the Secretary
16 to adjust the payment (or diagnosis-related group classi-
17 fication) under this subsection until the fiscal year that
18 begins after such date.”.

19 (b) **ELIGIBILITY STANDARD.**—

20 (1) **MINIMUM PERIOD FOR RECOGNITION OF**
21 **NEW TECHNOLOGIES.**—Section 1886(d)(5)(K)(vi)
22 (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

23 (A) by inserting “(I)” after “(vi)”; and

24 (B) by adding at the end the following new
25 subclause:

1 “(II) Under such criteria, a service or technology
2 shall not be denied treatment as a new service or tech-
3 nology on the basis of the period of time in which the serv-
4 ice or technology has been in use if such period ends before
5 the end of the 2-to-3-year period that begins on the effec-
6 tive date of implementation of a code under ICD–9–CM
7 (or a successor coding methodology) that enables the iden-
8 tification of a significant sample of specific discharges in
9 which the service or technology has been used.”.

10 (2) ADJUSTMENT OF THRESHOLD.—Section
11 1886(d)(5)(K)(ii)(I) (42 U.S.C.
12 1395ww(d)(5)(K)(ii)(I)) is amended by inserting
13 “(applying a threshold specified by the Secretary
14 that is the lesser of 50 percent of the national aver-
15 age standardized amount for operating costs of inpa-
16 tient hospital services for all hospitals and all diag-
17 nosis-related groups or one standard deviation for
18 the diagnosis-related group involved)” after “is inad-
19 equate”.

20 (3) CRITERION FOR SUBSTANTIAL IMPROVE-
21 MENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C.
22 1395ww(d)(5)(K)(vi)), as amended by paragraph
23 (1), is further amended by adding at the end the fol-
24 lowing subclause:

1 “(III) The Secretary shall by regulation provide for
2 further clarification of the criteria applied to determine
3 whether a new service or technology represents an advance
4 in medical technology that substantially improves the diag-
5 nosis or treatment of beneficiaries. Under such criteria,
6 in determining whether a new service or technology rep-
7 resents an advance in medical technology that substan-
8 tially improves the diagnosis or treatment of beneficiaries,
9 the Secretary shall deem a service or technology as meet-
10 ing such requirement if the service or technology is a drug
11 or biological that is designated under section 506 or 526
12 of the Federal Food, Drug, and Cosmetic Act, approved
13 under section 314.510 or 601.41 of title 21, Code of Fed-
14 eral Regulations, or designated for priority review when
15 the marketing application for such drug or biological was
16 filed or is a medical device for which an exemption has
17 been granted under section 520(m) of such Act, or for
18 which priority review has been provided under section
19 515(d)(5) of such Act.”.

20 (4) PROCESS FOR PUBLIC INPUT.—Section
21 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as
22 amended by paragraph (1), is amended—

23 (A) in clause (i), by adding at the end the
24 following: “Such mechanism shall be modified
25 to meet the requirements of clause (viii).”; and

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

3 “(viii) The mechanism established pursuant to clause
4 (i) shall be adjusted to provide, before publication of a
5 proposed rule, for public input regarding whether a new
6 service or technology not described in the second sentence
7 of clause (vi)(III) represents an advance in medical tech-
8 nology that substantially improves the diagnosis or treat-
9 ment of beneficiaries as follows:

10 “(I) The Secretary shall make public and peri-
11 odically update a list of all the services and tech-
12 nologies for which an application for additional pay-
13 ment under this subparagraph is pending.

14 “(II) The Secretary shall accept comments, rec-
15 ommendations, and data from the public regarding
16 whether the service or technology represents a sub-
17 stantial improvement.

18 “(III) The Secretary shall provide for a meeting
19 at which organizations representing hospitals, physi-
20 cians, medicare beneficiaries, manufacturers, and
21 any other interested party may present comments,
22 recommendations, and data to the clinical staff of
23 the Centers for Medicare & Medicaid Services before
24 publication of a notice of proposed rulemaking re-

1 garding whether service or technology represents a
2 substantial improvement.”.

3 (c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—
4 Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is
5 further amended by adding at the end the following new
6 clause:

7 “(ix) Before establishing any add-on payment under
8 this subparagraph with respect to a new technology, the
9 Secretary shall seek to identify one or more diagnosis-re-
10 lated groups associated with such technology, based on
11 similar clinical or anatomical characteristics and the cost
12 of the technology. Within such groups the Secretary shall
13 assign an eligible new technology into a diagnosis-related
14 group where the average costs of care most closely approx-
15 imate the costs of care of using the new technology. In
16 such case, no add-on payment under this subparagraph
17 shall be made with respect to such new technology and
18 this clause shall not affect the application of paragraph
19 (4)(C)(iii).”.

20 (d) IMPROVEMENT IN PAYMENT FOR NEW TECH-
21 NOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C.
22 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after
23 “the estimated average cost of such service or technology”
24 the following: “(based on the marginal rate applied to
25 costs under subparagraph (A))”.

1 (e) EFFECTIVE DATE.—

2 (1) IN GENERAL.—The Secretary shall imple-
3 ment the amendments made by this section so that
4 they apply to classification for fiscal years beginning
5 with fiscal year 2004.

6 (2) RECONSIDERATIONS OF APPLICATIONS FOR
7 FISCAL YEAR 2003 THAT ARE DENIED.—In the case
8 of an application for a classification of a medical
9 service or technology as a new medical service or
10 technology under section 1886(d)(5)(K) of the Social
11 Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was
12 filed for fiscal year 2003 and that is denied—

13 (A) the Secretary shall automatically re-
14 consider the application as an application for
15 fiscal year 2004 under the amendments made
16 by this section; and

17 (B) the maximum time period otherwise
18 permitted for such classification of the service
19 or technology shall be extended by 12 months.

20 **SEC. 404. PHASE-IN OF FEDERAL RATE FOR HOSPITALS IN**
21 **PUERTO RICO.**

22 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is
23 amended—

24 (1) in subparagraph (A)—

1 (A) in clause (i), by striking “for dis-
2 charges beginning on or after October 1, 1997,
3 50 percent (and for discharges between October
4 1, 1987, and September 30, 1997, 75 percent)”
5 and inserting “the applicable Puerto Rico per-
6 centage (specified in subparagraph (E))”; and

7 (B) in clause (ii), by striking “for dis-
8 charges beginning in a fiscal year beginning on
9 or after October 1, 1997, 50 percent (and for
10 discharges between October 1, 1987, and Sep-
11 tember 30, 1997, 25 percent)” and inserting
12 “the applicable Federal percentage (specified in
13 subparagraph (E))”; and

14 (2) by adding at the end the following new sub-
15 paragraph:

16 “(E) For purposes of subparagraph (A), for dis-
17 charges occurring—

18 “(i) between October 1, 1987, and September
19 30, 1997, the applicable Puerto Rico percentage is
20 75 percent and the applicable Federal percentage is
21 25 percent;

22 “(ii) on or after October 1, 1997, and before
23 October 1, 2003, the applicable Puerto Rico percent-
24 age is 50 percent and the applicable Federal per-
25 centage is 50 percent;

1 “(iii) during fiscal year 2004, the applicable
2 Puerto Rico percentage is 45 percent and the appli-
3 cable Federal percentage is 55 percent;

4 “(iv) during fiscal year 2005, the applicable
5 Puerto Rico percentage is 40 percent and the appli-
6 cable Federal percentage is 60 percent;

7 “(v) during fiscal year 2006, the applicable
8 Puerto Rico percentage is 35 percent and the appli-
9 cable Federal percentage is 65 percent;

10 “(vi) during fiscal year 2007, the applicable
11 Puerto Rico percentage is 30 percent and the appli-
12 cable Federal percentage is 70 percent; and

13 “(vii) on or after October 1, 2007, the applica-
14 ble Puerto Rico percentage is 25 percent and the ap-
15 plicable Federal percentage is 75 percent.”.

16 **SEC. 405. REFERENCE TO PROVISION RELATING TO EN-**
17 **HANCED DISPROPORTIONATE SHARE HOS-**
18 **PITAL (DSH) PAYMENTS FOR RURAL HOS-**
19 **PITALS AND URBAN HOSPITALS WITH FEWER**
20 **THAN 100 BEDS.**

21 For provision enhancing disproportionate share hos-
22 pital (DSH) treatment for rural hospitals and urban hos-
23 pitals with fewer than 100 beds, see section 302.

1 **SEC. 406. REFERENCE TO PROVISION RELATING TO 2-YEAR**
 2 **PHASED-IN INCREASE IN THE STANDARDIZED**
 3 **AMOUNT IN RURAL AND SMALL URBAN**
 4 **AREAS TO ACHIEVE A SINGLE, UNIFORM**
 5 **STANDARDIZED AMOUNT.**

6 For provision phasing in over a 2-year period an in-
 7 crease in the standardized amount for rural and small
 8 urban areas to achieve a single, uniform, standardized
 9 amount, see section 303.

10 **SEC. 407. REFERENCE TO PROVISION FOR MORE FRE-**
 11 **QUENT UPDATES IN THE WEIGHTS USED IN**
 12 **HOSPITAL MARKET BASKET.**

13 For provision providing for more frequent updates in
 14 the weights used in hospital market basket, see section
 15 304.

16 **SEC. 408. REFERENCE TO PROVISION MAKING IMPROVE-**
 17 **MENTS TO CRITICAL ACCESS HOSPITAL PRO-**
 18 **GRAM.**

19 For provision providing making improvements to crit-
 20 ical access hospital program, see section 305.

21 **Subtitle B—Skilled Nursing**

22 **Facility Services**

23 **SEC. 411. PAYMENT FOR COVERED SKILLED NURSING FA-**
 24 **CILITY SERVICES.**

25 (a) 5-YEAR EXTENSION OF TEMPORARY INCREASE
 26 IN NURSING COMPONENT OF PPS FEDERAL RATE.—Sec-

1 tion 312(a) of BIPA is amended by striking “, and before
2 October 1, 2002” and inserting “and before October 1,
3 2007”.

4 (b) ADJUSTMENT TO RUGS FOR AIDS RESI-
5 DENTS.—

6 (1) IN GENERAL.—Paragraph (12) of section
7 1888(e) (42 U.S.C. 1395yy(e)) is amended to read
8 as follows:

9 “(12) ADJUSTMENT FOR RESIDENTS WITH
10 AIDS.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (B), in the case of a resident of a skilled
13 nursing facility who is afflicted with acquired
14 immune deficiency syndrome (AIDS), the per
15 diem amount of payment otherwise applicable
16 shall be increased by 128 percent to reflect in-
17 creased costs associated with such residents.

18 “(B) SUNSET.—Subparagraph (A) shall
19 not apply on and after such date as the Sec-
20 retary certifies that there is an appropriate ad-
21 justment in the case mix under paragraph
22 (4)(G)(i) to compensate for the increased costs
23 associated with residents described in such sub-
24 paragraph.”.

1 “(C) advising the individual regarding ad-
2 vanced care planning.”.

3 (b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i))
4 is amended by adding at the end the following new para-
5 graph:

6 “(4) The amount paid to a hospice program with re-
7 spect to the services under section 1812(a)(5) for which
8 payment may be made under this part shall be equal to
9 an amount equivalent to the amount established for an
10 office or other outpatient visit for evaluation and manage-
11 ment associated with presenting problems of moderate se-
12 verity under the fee schedule established under section
13 1848(b), other than the portion of such amount attrib-
14 utable to the practice expense component.”.

15 (c) CONFORMING AMENDMENT.—Section
16 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is
17 amended by inserting before the comma at the end the
18 following: “and services described in section 1812(a)(5)”.

19 (d) EFFECTIVE DATE.—The amendments made by
20 this section shall apply to services provided by a hospice
21 program on or after January 1, 2004.

1 **SEC. 422. 10 PERCENT INCREASE IN PAYMENT FOR HOS-**
2 **PICE CARE FURNISHED IN A FRONTIER AREA.**

3 (a) IN GENERAL.—Section 1814(i)(1) (42 U.S.C.
4 1395f(i)(1)) is amended by adding at the end the following
5 new subparagraph:

6 “(D) With respect to hospice care furnished in a fron-
7 tier area on or after January 1, 2003, and before January
8 1, 2008, the payment rates otherwise established for such
9 care shall be increased by 10 percent. For purposes of this
10 subparagraph, the term ‘frontier area’ means a county in
11 which the population density is less than 7 persons per
12 square mile.”.

13 (b) REPORT ON COSTS.—Not later than January 1,
14 2007, the Comptroller General of the United States shall
15 submit to Congress a report on the costs of furnishing
16 hospice care in frontier areas. Such report shall include
17 recommendations regarding the appropriateness of extend-
18 ing, and modifying, the payment increase provided under
19 the amendment made by subsection (a).

20 **SEC. 423. RURAL HOSPICE DEMONSTRATION PROJECT.**

21 (a) IN GENERAL.—The Secretary shall conduct a
22 demonstration project for the delivery of hospice care to
23 medicare beneficiaries in rural areas. Under the project
24 medicare beneficiaries who are unable to receive hospice
25 care in the home for lack of an appropriate caregiver are
26 provided such care in a facility of 20 or fewer beds which

1 offers, within its walls, the full range of services provided
2 by hospice programs under section 1861(dd) of the Social
3 Security Act (42 U.S.C. 1395x(dd)).

4 (b) SCOPE OF PROJECT.—The Secretary shall con-
5 duct the project under this section with respect to no more
6 than 3 hospice programs over a period of not longer than
7 5 years each.

8 (c) COMPLIANCE WITH CONDITIONS.—Under the
9 demonstration project—

10 (1) the hospice program shall comply with oth-
11 erwise applicable requirements, except that it shall
12 not be required to offer services outside of the home
13 or to meet the requirements of section
14 1861(dd)(2)(A)(iii) of the Social Security Act; and

15 (2) payments for hospice care shall be made at
16 the rates otherwise applicable to such care under
17 title XVIII of such Act.

18 The Secretary may require the program to comply with
19 such additional quality assurance standards for its provi-
20 sion of services in its facility as the Secretary deems ap-
21 propriate.

22 (d) REPORT.—Upon completion of the project, the
23 Secretary shall submit a report to Congress on the project
24 and shall include in the report recommendations regarding

1 extension of such project to hospice programs serving
2 rural areas.

3 **Subtitle D—Other Provisions**

4 **SEC. 431. DEMONSTRATION PROJECT FOR USE OF RECOV-** 5 **ERY AUDIT CONTRACTORS.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services shall conduct a demonstration project
8 under this section (in this section referred to as the
9 “project”) to demonstrate the use of recovery audit con-
10 tractors under the Medicare Integrity Program in identi-
11 fying and recouping overpayments under the medicare
12 program for services for which payment is made under
13 part A of title XVIII of the Social Security Act. Under
14 the project—

15 (1) payment may be made to such a contractor
16 on a contingent basis;

17 (2) a percentage of the amount recovered may
18 be retained by the Secretary and shall be available
19 to the program management account of the Centers
20 for Medicare & Medicaid Services; and

21 (3) the Secretary shall examine the efficacy of
22 such use with respect to duplicative payments, accu-
23 racy of coding, and other payment policies in which
24 inaccurate payments arise.

1 (b) SCOPE AND DURATION.—The project shall cover
2 at least 2 States and at least 3 contractors and shall last
3 for not longer than 3 years.

4 (c) WAIVER.—The Secretary of Health and Human
5 Services shall waive such provisions of title XVIII of the
6 Social Security Act as may be necessary to provide for
7 payment for services under the project in accordance with
8 subsection (a).

9 (d) QUALIFICATIONS OF CONTRACTORS.—

10 (1) IN GENERAL.—The Secretary shall enter
11 into a recovery audit contract under this section
12 with an entity only if the entity has staff that has
13 knowledge of and experience with the payment rules
14 and regulations under the medicare program or the
15 entity has or will contract with another entity that
16 has such knowledgeable and experienced staff.

17 (2) INELIGIBILITY OF CERTAIN CONTRAC-
18 TORS.—The Secretary may not enter into a recovery
19 audit contract under this section with an entity to
20 the extent that the entity is a fiscal intermediary
21 under section 1816 of the Social Security Act (42
22 U.S.C. 1395h), a carrier under section 1842 of such
23 Act (42 U.S.C. 1395u), or a Medicare Administra-
24 tive Contractor under section 1874A of such Act, or
25 any other entity that carries out the type of activi-

1 ties with respect to providers of services under part
2 A that would constitute a conflict of interest, as de-
3 termined by the Secretary.

4 (3) PREFERENCE FOR ENTITIES WITH DEM-
5 ONSTRATED PROFICIENCY WITH PRIVATE INSUR-
6 ERS.—In awarding contracts to recovery audit con-
7 tractors under this section, the Secretary shall give
8 preference to those entities that the Secretary deter-
9 mines have demonstrated proficiency in recovery au-
10 dits with private insurers or under the medicaid pro-
11 gram under title XIX of such Act.

12 (e) REPORT.—The Secretary of Health and Human
13 Services shall submit to Congress a report on the project
14 not later than 6 months after the date of its completion.
15 Such reports shall include information on the impact of
16 the project on savings to the medicare program and rec-
17 ommendations on the cost-effectiveness of extending or ex-
18 panding the project.

19 **TITLE V—PROVISIONS**
20 **RELATING TO PART B**

21 **Subtitle A—Physicians’ Services**

22 **SEC. 501. REVISION OF UPDATES FOR PHYSICIANS’ SERV-**
23 **ICES.**

24 (a) UPDATE FOR 2003 THROUGH 2006.—

1 (1) IN GENERAL.—Section 1848(d) (42 U.S.C.
2 1395w-4(d)) is amended by adding at the end the
3 following new paragraphs:

4 “(5) UPDATE FOR 2003.—The update to the
5 single conversion factor established in paragraph
6 (1)(C) for 2003 is 2 percent.

7 “(6) SPECIAL RULES FOR UPDATE FOR 2004,
8 2005, AND 2006.—The following rules apply in deter-
9 mining the update adjustment factors under para-
10 graph (4)(B) for 2004, 2005, and 2006:

11 “(A) USE OF 2002 DATA IN DETERMINING
12 ALLOWABLE COSTS.—

13 “(i) The reference in clause (ii)(I) of
14 such paragraph to April 1, 1996, is
15 deemed to be a reference to January 1,
16 2002.

17 “(ii) The allowed expenditures for
18 2002 is deemed to be equal to the actual
19 expenditures for physicians’ services fur-
20 nished during 2002, as estimated by the
21 Secretary.

22 “(B) 1 PERCENTAGE POINT INCREASE IN
23 GDP UNDER SGR.—The annual average percent-
24 age growth in real gross domestic product per
25 capita under subsection (f)(2)(C) for each of

1 2003, 2004, 2005, and 2006 is deemed to be
2 increased by 1 percentage point.”.

3 (2) CONFORMING AMENDMENT.—Paragraph
4 (4)(B) of such section is amended, in the matter be-
5 fore clause (i), by inserting “and paragraph (6)”
6 after “subparagraph (D)”.

7 (3) NOT TREATED AS CHANGE IN LAW AND
8 REGULATION IN SUSTAINABLE GROWTH RATE DE-
9 TERMINATION.—The amendments made by this sub-
10 section shall not be treated as a change in law for
11 purposes of applying section 1848(f)(2)(D) of the
12 Social Security Act (42 U.S.C. 1395w-4(f)(2)(D)).

13 (b) USE OF 10-YEAR ROLLING AVERAGE IN COM-
14 PUTING GROSS DOMESTIC PRODUCT.—

15 (1) IN GENERAL.—Section 1848(f)(2)(C) (42
16 U.S.C. 1395w-4(f)(2)(C)) is amended—

17 (A) by striking “projected” and inserting
18 “annual average”; and

19 (B) by striking “from the previous applica-
20 ble period to the applicable period involved”
21 and inserting “during the 10-year period ending
22 with the applicable period involved”.

23 (2) EFFECTIVE DATE.—The amendment made
24 by paragraph (1) shall apply to computations of the

1 sustainable growth rate for years beginning with
2 2002.

3 (c) ELIMINATION OF TRANSITIONAL ADJUSTMENT.—
4 Section 1848(d)(4)(F) (42 U.S.C. 1395w-4(d)(4)(F)) is
5 amended by striking “subparagraph (A)” and all that fol-
6 lows and inserting “subparagraph (A), for each of 2001
7 and 2002, of – 0.2 percent.”

8 **SEC. 502. STUDIES ON ACCESS TO PHYSICIANS’ SERVICES.**

9 (a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSI-
10 CIANS’ SERVICES.—

11 (1) STUDY.—The Comptroller General of the
12 United States shall conduct a study on access of
13 medicare beneficiaries to physicians’ services under
14 the medicare program. The study shall include—

15 (A) an assessment of the use by bene-
16 ficiaries of such services through an analysis of
17 claims submitted by physicians for such services
18 under part B of the medicare program;

19 (B) an examination of changes in the use
20 by beneficiaries of physicians’ services over
21 time;

22 (C) an examination of the extent to which
23 physicians are not accepting new medicare
24 beneficiaries as patients.

1 (2) REPORT.—Not later than 18 months after
2 the date of the enactment of this Act, the Comp-
3 troller General shall submit to Congress a report on
4 the study conducted under paragraph (1). The re-
5 port shall include a determination whether—

6 (A) data from claims submitted by physi-
7 cians under part B of the medicare program in-
8 dicate potential access problems for medicare
9 beneficiaries in certain geographic areas; and

10 (B) access by medicare beneficiaries to
11 physicians' services may have improved, re-
12 mained constant, or deteriorated over time.

13 (b) STUDY AND REPORT ON SUPPLY OF PHYSI-
14 CIANS.—

15 (1) STUDY.—The Secretary shall request the
16 Institute of Medicine of the National Academy of
17 Sciences to conduct a study on the adequacy of the
18 supply of physicians (including specialists) in the
19 United States and the factors that affect such sup-
20 ply.

21 (2) REPORT TO CONGRESS.—Not later than 2
22 years after the date of enactment of this section, the
23 Secretary shall submit to Congress a report on the
24 results of the study described in paragraph (1), in-
25 cluding any recommendations for legislation.

1 **SEC. 503. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS'**
2 **SERVICES.**

3 Not later than 1 year after the date of the enactment
4 of this Act, the Medicare Payment Advisory Commission
5 shall submit to Congress a report on the effect of refine-
6 ments to the practice expense component of payments for
7 physicians' services in the case of services for which there
8 are no physician work relative value units, after the transi-
9 tion to a full resource-based payment system in 2002,
10 under section 1848 of the Social Security Act (42 U.S.C.
11 1395w-4). Such report shall examine the following mat-
12 ters by physician specialty:

13 (1) The effect of such refinements on payment
14 for physicians' services.

15 (2) The interaction of the practice expense com-
16 ponent with other components of and adjustments to
17 payment for physicians' services under such section.

18 (3) The appropriateness of the amount of com-
19 pensation by reason of such refinements.

20 (4) The effect of such refinements on access to
21 care by medicare beneficiaries to physicians' serv-
22 ices.

23 (5) The effect of such refinements on physician
24 participation under the medicare program.

1 **SEC. 504. 1-YEAR EXTENSION OF TREATMENT OF CERTAIN**
2 **PHYSICIAN PATHOLOGY SERVICES UNDER**
3 **MEDICARE.**

4 Section 542(c) of BIPA is amended by striking “2-
5 year period” and inserting “3-year period”.

6 **SEC. 505. PHYSICIAN FEE SCHEDULE WAGE INDEX REVI-**
7 **SION.**

8 (a) IN GENERAL.—Notwithstanding any other provi-
9 sion of law, for purposes of payment under the physician
10 fee schedule under section 1848 of the Social Security Act
11 (42 U.S.C. 1395w–4) for physicians’ services furnished
12 during 2004, in no case may the work geographic index
13 otherwise calculated under section 1848(e)(1)(A)(iii) of
14 such Act (42 U.S.C. 1395w–4(e)(1)(A)(iii)) be less than
15 0.985.

16 (b) EXEMPTION FROM LIMITATION ON ANNUAL AD-
17 JUSTMENTS.—The increase in expenditures attributable to
18 subsection (a) during 2004 shall not be taken into account
19 in applying section 1848(c)(2)(B)(ii)(II) of such Act (42
20 U.S.C. 1395w–4(c)(2)(B)(ii)(II)) for that year.

21 (c) GAO REPORT.—

22 (1) STUDY.—The Comptroller General of the
23 United States shall conduct a study to evaluate the
24 following:

25 (A) The economic basis of the current
26 methodology for geographic adjustment of the

1 work component of the physician payment rate
2 under the physician fee schedule under section
3 1848 of the Social Security Act (42 U.S.C.
4 1395w-4).

5 (B) Whether the adjustment under sub-
6 section (a) should be continued, and whether
7 there is an economic basis for the continuation
8 of such adjustment, in those areas in which the
9 adjustment applies.

10 (C) The effect of the methodology on phy-
11 sician location and retention in areas affected
12 by such adjustment.

13 (D) The differences in recruitment costs
14 and retention rates for physicians, including
15 specialists, between large urban areas and other
16 areas.

17 (E) The mobility of physicians, including
18 specialists, over the last decade.

19 (F) The effect of raising the floor of the
20 geographic index to a value of 1.0 for adjust-
21 ment of the work component.

22 (2) REPORT.—The Comptroller General shall
23 submit to Congress a report on the study conducted
24 under paragraph (1) by not later than 1 year after
25 the date of the enactment of this Act.

Subtitle B—Other Services**SEC. 511. COMPETITIVE ACQUISITION OF CERTAIN ITEMS
AND SERVICES.**

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

“COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND
SERVICES

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

“(1) IMPLEMENTATION OF PROGRAMS.—

“(A) IN GENERAL.—The Secretary shall establish and implement programs under which, beginning in 2008, competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

“(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

1 “(i) at least $\frac{1}{3}$ of such areas in 2008;

2 and

3 “(ii) at least $\frac{2}{3}$ of such areas in
4 2009.

5 “(C) WAIVER OF CERTAIN PROVISIONS.—

6 In carrying out the programs, the Secretary
7 may waive such provisions of the Federal Ac-
8 quisition Regulation as are necessary for the ef-
9 ficient implementation of this section, other
10 than provisions relating to confidentiality of in-
11 formation and such other provisions as the Sec-
12 retary determines appropriate.

13 “(2) ITEMS AND SERVICES DESCRIBED.—The
14 items and services referred to in paragraph (1) are
15 the following:

16 “(A) DURABLE MEDICAL EQUIPMENT AND
17 INHALATION DRUGS USED IN CONNECTION
18 WITH DURABLE MEDICAL EQUIPMENT.—Cov-
19 ered items (as defined in section 1834(a)(13))
20 for which payment is otherwise made under sec-
21 tion 1834(a), other than items used in infusion,
22 and inhalation drugs used in conjunction with
23 durable medical equipment.

24 “(B) OFF-THE-SHELF ORTHOTICS.—

25 Orthotics (described in section 1861(s)(9)) for

1 which payment is otherwise made under section
2 1834(h) which require minimal self-adjustment
3 for appropriate use and does not require exper-
4 tise in trimming, bending, molding, assembling,
5 or customizing to fit to the patient.

6 “(3) EXEMPTION AUTHORITY.—In carrying out
7 the programs under this section, the Secretary may
8 exempt—

9 “(A) areas that are not competitive due to
10 low population density; and

11 “(B) items and services for which the ap-
12 plication of competitive acquisition is not likely
13 to result in significant savings.

14 “(b) PROGRAM REQUIREMENTS.—

15 “(1) IN GENERAL.—The Secretary shall con-
16 duct a competition among entities supplying items
17 and services described in subsection (a)(2) for each
18 competitive acquisition area in which the program is
19 implemented under subsection (a) with respect to
20 such items and services.

21 “(2) CONDITIONS FOR AWARDING CONTRACT.—

22 “(A) IN GENERAL.—The Secretary may
23 not award a contract to any entity under the
24 competition conducted in an competitive acqui-
25 sition area pursuant to paragraph (1) to fur-

1 nish such items or services unless the Secretary
2 finds all of the following:

3 “(i) The entity meets quality and fi-
4 nancial standards specified by the Sec-
5 retary or developed by accreditation enti-
6 ties or organizations recognized by the Sec-
7 retary.

8 “(ii) The total amounts to be paid
9 under the contract (including costs associ-
10 ated with the administration of the con-
11 tract) are expected to be less than the total
12 amounts that would otherwise be paid.

13 “(iii) Beneficiary access to a choice of
14 multiple suppliers in the area is main-
15 tained.

16 “(iv) Beneficiary liability is limited to
17 the applicable percentage of contract
18 award price.

19 “(B) QUALITY STANDARDS.—The quality
20 standards specified under subparagraph (A)(i)
21 shall not be less than the quality standards that
22 would otherwise apply if this section did not
23 apply and shall include consumer services
24 standards. The Secretary shall consult with an
25 expert outside advisory panel composed of an

1 appropriate selection of representatives of phy-
2 sicians, practitioners, and suppliers to review
3 (and advise the Secretary concerning) such
4 quality standards.

5 “(3) CONTENTS OF CONTRACT.—

6 “(A) IN GENERAL.—A contract entered
7 into with an entity under the competition con-
8 ducted pursuant to paragraph (1) is subject to
9 terms and conditions that the Secretary may
10 specify.

11 “(B) TERM OF CONTRACTS.—The Sec-
12 retary shall rebid contracts under this section
13 not less often than once every 3 years.

14 “(4) LIMIT ON NUMBER OF CONTRACTORS.—

15 “(A) IN GENERAL.—The Secretary may
16 limit the number of contractors in a competitive
17 acquisition area to the number needed to meet
18 projected demand for items and services covered
19 under the contracts. In awarding contracts, the
20 Secretary shall take into account the ability of
21 bidding entities to furnish items or services in
22 sufficient quantities to meet the anticipated
23 needs of beneficiaries for such items or services
24 in the geographic area covered under the con-
25 tract on a timely basis.

1 “(B) MULTIPLE WINNERS.—The Secretary
2 shall award contracts to more than one entity
3 submitting a bid in each area for an item or
4 service.

5 “(5) PARTICIPATING CONTRACTORS.—Payment
6 shall not be made for items and services described
7 in subsection (a)(2) furnished by a contractor and
8 for which competition is conducted under this sec-
9 tion unless—

10 “(A) the contractor has submitted a bid
11 for such items and services under this section;
12 and

13 “(B) the Secretary has awarded a contract
14 to the contractor for such items and services
15 under this section.

16 “(6) AUTHORITY TO CONTRACT FOR EDU-
17 CATION, OUTREACH AND COMPLAINT SERVICES.—
18 The Secretary may enter into a contract with an ap-
19 propriate entity to address complaints from bene-
20 ficiaries who receive items and services from an enti-
21 ty with a contract under this section and to conduct
22 appropriate education of and outreach to such bene-
23 ficiaries with respect to the program.

24 “(c) ANNUAL REPORTS.—The Secretary shall submit
25 to Congress an annual management report on the pro-

1 grams under this section. Each such report shall include
2 information on savings, reductions in cost-sharing, access
3 to items and services, and beneficiary satisfaction.

4 “(d) DEMONSTRATION PROJECT FOR CLINICAL LAB-
5 ORATORY SERVICES.—

6 “(1) IN GENERAL.—The Secretary shall, begin-
7 ning in 2008, conduct a demonstration project on
8 the application of competitive acquisition under this
9 section to clinical diagnostic laboratory tests—

10 “(A) for which payment is otherwise made
11 under section 1833(h) or 1834(d)(1) (relating
12 to colorectal cancer screening tests); and

13 “(B) which are furnished without a face-
14 to-face encounter between the individual and
15 the hospital or physician ordering the tests.

16 “(2) TERMS AND CONDITIONS.—Such project
17 shall be under the same conditions as are applicable
18 to items and services described in subsection (a)(2).

19 “(3) REPORT.—The Secretary shall submit to
20 Congress—

21 “(A) an initial report on the project not
22 later than December 31, 2009; and

23 “(B) such progress and final reports on
24 the project after such date as the Secretary de-
25 termines appropriate.”.

1 (b) CONTINUATION OF CERTAIN DEMONSTRATION
2 PROJECTS.—Notwithstanding the amendment made by
3 subsection (a), with respect to demonstration projects im-
4 plemented by the Secretary under section 1847 of the So-
5 cial Security Act (42 U.S.C. 1395w–3) (relating to the es-
6 tablishment of competitive acquisition areas) that was in
7 effect on the day before the date of the enactment of this
8 Act, each such demonstration project may continue under
9 the same terms and conditions applicable under that sec-
10 tion as in effect on that date.

11 (c) REPORT ON DIFFERENCES IN PAYMENT FOR
12 LABORATORY SERVICES.—Not later than 18 months after
13 the date of the enactment of this Act, the Comptroller
14 General of the United States shall submit to Congress a
15 report that analyzes differences in reimbursement between
16 public and private payors for clinical diagnostic laboratory
17 services.

18 (d) MEDPAC REPORT ON IMPACT OF DEMONSTRA-
19 TION PROJECTS ON BENEFICIARY ACCESS TO SERV-
20 ICES.—Not later than 1 year after the date of the enact-
21 ment of this Act, the Medicare Payment Advisory Com-
22 mission shall submit to Congress a report that analyzes
23 the impact of demonstration projects carried out under
24 section 1847 of the Social Security Act, as in effect on
25 June 1, 2002, on access by medicare beneficiaries to dura-

1 ble medical equipment for which payment was made under
2 the demonstration project.

3 **SEC. 512. PAYMENT FOR AMBULANCE SERVICES.**

4 (a) PHASE-IN PROVIDING FLOOR USING BLEND OF
5 FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Sec-
6 tion 1834(l) (42 U.S.C. 1395m(l)) is amended—

7 (1) in paragraph (2)(E), by inserting “con-
8 sistent with paragraph (10)” after “in an efficient
9 and fair manner”;

10 (2) by redesignating the paragraph (8) added
11 by section 221(a) of BIPA as paragraph (9); and

12 (3) by adding at the end the following new
13 paragraph:

14 “(10) PHASE-IN PROVIDING FLOOR USING
15 BLEND OF FEE SCHEDULE AND REGIONAL FEE
16 SCHEDULES.—In carrying out the phase-in under
17 paragraph (2)(E) for each level of service furnished
18 in a year before January 1, 2007, the portion of the
19 payment amount that is based on the fee schedule
20 shall not be less than the following blended rate of
21 the fee schedule under paragraph (1) and of a re-
22 gional fee schedule for the region involved:

23 “(A) For 2003, the blended rate shall be
24 based 20 percent on the fee schedule under

1 paragraph (1) and 80 percent on the regional
2 fee schedule.

3 “(B) For 2004, the blended rate shall be
4 based 40 percent on the fee schedule under
5 paragraph (1) and 60 percent on the regional
6 fee schedule.

7 “(C) For 2005, the blended rate shall be
8 based 60 percent on the fee schedule under
9 paragraph (1) and 40 percent on the regional
10 fee schedule.

11 “(D) For 2006, the blended rate shall be
12 based 80 percent on the fee schedule under
13 paragraph (1) and 20 percent on the regional
14 fee schedule.

15 For purposes of this paragraph, the Secretary shall
16 establish a regional fee schedule for each of the 9
17 Census divisions using the methodology (used in es-
18 tablishing the fee schedule under paragraph (1)) to
19 calculate a regional conversion factor and a regional
20 mileage payment rate and using the same payment
21 adjustments and the same relative value units as
22 used in the fee schedule under such paragraph.”.

23 (b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
24 TRIPS.—Section 1834(l), as amended by subsection (a),

1 is further amended by adding at the end the following new
2 paragraph:

3 “(11) ADJUSTMENT IN PAYMENT FOR CERTAIN
4 LONG TRIPS.—In the case of ground ambulance
5 services furnished on or after January 1, 2003, and
6 before January 1, 2008, regardless of where the
7 transportation originates, the fee schedule estab-
8 lished under this subsection shall provide that, with
9 respect to the payment rate for mileage for a trip
10 above 50 miles the per mile rate otherwise estab-
11 lished shall be increased by $\frac{1}{4}$ of the payment per
12 mile otherwise applicable to such miles.”.

13 (c) EFFECTIVE DATE.—The amendments made by
14 this section shall apply to ambulance services furnished
15 on or after January 1, 2003.

16 **SEC. 513. 5-YEAR EXTENSION OF MORATORIUM ON THER-**
17 **APY CAPS; PROVISIONS RELATING TO RE-**
18 **PORTS.**

19 (a) 5-YEAR EXTENSION OF MORATORIUM ON THER-
20 APY CAPS.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4))
21 is amended by striking “and 2002” and inserting “2002,
22 2003, 2004, 2005, 2006, and 2007”.

23 (b) PROMPT SUBMISSION OF OVERDUE REPORTS ON
24 PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY
25 SERVICES.—Not later than December 31, 2002, the Sec-

1 retary shall submit to Congress the reports required under
2 section 4541(d)(2) of the Balanced Budget Act of 1997
3 (relating to alternatives to a single annual dollar cap on
4 outpatient therapy) and under section 221(d) of the Medi-
5 care, Medicaid, and SCHIP Balanced Budget Refinement
6 Act of 1999 (relating to utilization patterns for outpatient
7 therapy).

8 (c) IDENTIFICATION OF CONDITIONS AND DISEASES
9 JUSTIFYING WAIVER OF THERAPY CAP.—

10 (1) STUDY.—The Secretary shall request the
11 Institute of Medicine of the National Academy of
12 Sciences to identify conditions or diseases that
13 should justify conducting an assessment of the need
14 to waive the therapy caps under section 1833(g)(4)
15 of the Social Security Act (42 U.S.C. 1395l(g)(4)).

16 (2) REPORTS TO CONGRESS.—Not later than
17 July 1, 2003, the Secretary shall submit to Congress
18 a preliminary report on the conditions and diseases
19 identified under paragraph (1) and not later than
20 September 1, 2003, a final report on the conditions
21 and diseases so identified.

22 (d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL
23 THERAPIST SERVICES.—

24 (1) STUDY.—The Comptroller General of the
25 United States shall conduct a study on access to

1 physical therapist services in States authorizing such
2 services without a physician referral and in States
3 that require such a physician referral. The study
4 shall—

5 (A) examine the use of and referral pat-
6 terns for physical therapist services for patients
7 age 50 and older in States that authorize such
8 services without a physician referral and in
9 States that require such a physician referral;

10 (B) examine the use of and referral pat-
11 terns for physical therapist services for patients
12 who are medicare beneficiaries;

13 (C) examine the potential effect of prohib-
14 iting a physician from referring patients to
15 physical therapy services owned by the physi-
16 cian and provided in the physician's office;

17 (D) examine the delivery of physical thera-
18 pists' services within the facilities of Depart-
19 ment of Defense; and

20 (E) analyze the potential impact on medi-
21 care beneficiaries and on expenditures under
22 the medicare program of eliminating the need
23 for a physician referral and physician certifi-
24 cation for physical therapist services under the
25 medicare program.

1 (2) REPORT.—The Comptroller General shall
2 submit to Congress a report on the study conducted
3 under paragraph (1) by not later than 1 year after
4 the date of the enactment of this Act.

5 **SEC. 514. ACCELERATED IMPLEMENTATION OF 20 PERCENT**
6 **COINSURANCE FOR HOSPITAL OUTPATIENT**
7 **DEPARTMENT (OPD) SERVICES; OTHER OPD**
8 **PROVISIONS.**

9 (a) ACCELERATED IMPLEMENTATION OF COINSUR-
10 ANCE REDUCTIONS.—Section 1833(t)(8)(C)(ii) (42
11 U.S.C. 1395l(t)(8)(C)(ii)) is amended by striking sub-
12 clauses (III) through (V) and inserting the following:

13 “(III) For procedures performed
14 in 2004, 45 percent.

15 “(IV) For procedures performed
16 in 2005, 40 percent.

17 “(V) For procedures performed
18 in 2006, 2007, 2008 and 2009, 35
19 percent.

20 “(VI) For procedures performed
21 in 2010, 30 percent.

22 “(VII) For procedures performed
23 in 2011, 25 percent.

1 “(VIII) For procedures per-
2 formed in 2012 and thereafter, 20
3 percent.”.

4 (b) TREATMENT OF TEMPERATURE MONITORED
5 CRYOABLATION.—

6 (1) IN GENERAL.—Section 1833(t)(6)(A)(ii)
7 (42 U.S.C. 1395l(t)(6)(A)(ii)) is amended by strik-
8 ing “or temperature monitored cryoablation”.

9 (2) EFFECTIVE DATE.—The amendment made
10 by paragraph (1) applies to payment for services
11 furnished on or after January 1, 2003.

12 **SEC. 515. COVERAGE OF AN INITIAL PREVENTIVE PHYS-**
13 **ICAL EXAMINATION.**

14 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
15 1395x(s)(2)), is amended—

16 (1) in subparagraph (U), by striking “and” at
17 the end;

18 (2) in subparagraph (V), by inserting “and” at
19 the end; and

20 (3) by adding at the end the following new sub-
21 paragraph:

22 “(W) an initial preventive physical exam-
23 ination (as defined in subsection (ww));”.

1 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
2 1395x) is amended by adding at the end the following new
3 subsection:

4 “Initial Preventive Physical Examination
5 “(ww) The term ‘initial preventive physical examina-
6 tion’ means physicians’ services consisting of a physical
7 examination with the goal of health promotion and disease
8 detection and includes items and services specified by the
9 Secretary in regulations.”.

10 (c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

11 (1) DEDUCTIBLE.—The first sentence of sec-
12 tion 1833(b) (42 U.S.C. 1395l(b)) is amended—

13 (A) by striking “and” before “(6)”, and

14 (B) by inserting before the period at the
15 end the following: “, and (7) such deductible
16 shall not apply with respect to an initial preven-
17 tive physical examination (as defined in section
18 1861(ww))”.

19 (2) COINSURANCE.—Section 1833(a)(1) (42
20 U.S.C. 1395l(a)(1)) is amended—

21 (A) in clause (N), by inserting “(or 100
22 percent in the case of an initial preventive phys-
23 ical examination, as defined in section
24 1861(ww))” after “80 percent”; and

1 (B) in clause (O), by inserting “(or 100
2 percent in the case of an initial preventive phys-
3 ical examination, as defined in section
4 1861(ww))” after “80 percent”.

5 (d) PAYMENT AS PHYSICIANS’ SERVICES.—Section
6 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by in-
7 serting “(2)(W),” after “(2)(S),”.

8 (e) OTHER CONFORMING AMENDMENTS.—Section
9 1862(a) (42 U.S.C. 1395y(a)) is amended—

10 (1) in paragraph (1)—

11 (A) by striking “and” at the end of sub-
12 paragraph (H);

13 (B) by striking the semicolon at the end of
14 subparagraph (I) and inserting “, and”; and

15 (C) by adding at the end the following new
16 subparagraph:

17 “(J) in the case of an initial preventive physical
18 examination, which is performed not later than 6
19 months after the date the individual’s first coverage
20 period begins under part B;” and

21 (2) in paragraph (7), by striking “or (H)” and
22 inserting “(H), or (J)”.

23 (f) EFFECTIVE DATE.—The amendments made by
24 this section shall apply to services furnished on or after

1 January 1, 2004, but only for individuals whose coverage
2 period begins on or after such date.

3 **SEC. 516. RENAL DIALYSIS SERVICES.**

4 (a) REPORT ON DIFFERENCES IN COSTS IN DIF-
5 FERENT SETTINGS.—Not later than 1 year after the date
6 of the enactment of this Act, the Comptroller General of
7 the United States shall submit to Congress a report
8 containing—

9 (1) an analysis of the differences in costs of
10 providing renal dialysis services under the medicare
11 program in home settings and in facility settings;

12 (2) an assessment of the percentage of overhead
13 costs in home settings and in facility settings; and

14 (3) an evaluation of whether the charges for
15 home dialysis supplies and equipment are reasonable
16 and necessary.

17 (b) RESTORING COMPOSITE RATE EXCEPTIONS FOR
18 PEDIATRIC FACILITIES.—

19 (1) IN GENERAL.—Section 422(a)(2) of BIPA
20 is amended—

21 (A) in subparagraph (A), by striking “and
22 (C)” and inserting “, (C), and (D)”;

23 (B) in subparagraph (B), by striking “In
24 the case” and inserting “Subject to subpara-
25 graph (D), in the case”; and

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

3 “(D) INAPPLICABILITY TO PEDIATRIC FA-
4 CILITIES.—Subparagraphs (A) and (B) shall
5 not apply, as of October 1, 2002, to pediatric
6 facilities that do not have an exception rate de-
7 scribed in subparagraph (C) in effect on such
8 date. For purposes of this subparagraph, the
9 term ‘pediatric facility’ means a renal facility at
10 least 50 percent of whose patients are individ-
11 uals under 18 years of age.”.

12 (2) CONFORMING AMENDMENT.—The fourth
13 sentence of section 1881(b)(7) (42 U.S.C.
14 1395rr(b)(7)) is amended by striking “The Sec-
15 retary” and inserting “Subject to section 422(a)(2)
16 of the Medicare, Medicaid, and SCHIP Benefits Im-
17 provement and Protection Act of 2000, the Sec-
18 retary”.

19 (c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE
20 FOR SERVICES FURNISHED IN 2004.—Notwithstanding
21 any other provision of law, with respect to payment under
22 part B of title XVIII of the Social Security Act for renal
23 dialysis services furnished in 2004, the composite payment
24 rate otherwise established under section 1881(b)(7) of

1 such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by
2 1.2 percent.

3 **SEC. 517. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
4 **RAPHY SERVICES.**

5 (a) EXCLUSION FROM OPD FEE SCHEDULE.—Sec-
6 tion 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is
7 amended by inserting before the period at the end the fol-
8 lowing: “and does not include screening mammography (as
9 defined in section 1861(jj)) and unilateral and bilateral
10 diagnostic mammography”.

11 (b) ADJUSTMENT TO TECHNICAL COMPONENT.—For
12 diagnostic mammography performed on or after January
13 1, 2004, for which payment is made under the physician
14 fee schedule under section 1848 of the Social Security Act
15 (42 U.S.C. 1395w-4), the Secretary, based on the most
16 recent cost data available, shall provide for an appropriate
17 adjustment in the payment amount for the technical com-
18 ponent of the diagnostic mammography.

19 (c) EFFECTIVE DATE.—The amendment made by
20 subsection (a) shall apply to mammography performed on
21 or after January 1, 2004.

22 **SEC. 518. WAIVER OF PART B LATE ENROLLMENT PENALTY**
23 **FOR CERTAIN MILITARY RETIREES; SPECIAL**
24 **ENROLLMENT PERIOD.**

25 (a) WAIVER OF PENALTY.—

1 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.
2 1395r(b)) is amended by adding at the end the fol-
3 lowing new sentence: “No increase in the premium
4 shall be effected for a month in the case of an indi-
5 vidual who is 65 years of age or older, who enrolls
6 under this part during 2001, 2002, or 2003, and
7 who demonstrates to the Secretary before December
8 31, 2003, that the individual is a covered beneficiary
9 (as defined in section 1072(5) of title 10, United
10 States Code). The Secretary of Health and Human
11 Services shall consult with the Secretary of Defense
12 in identifying individuals described in the previous
13 sentence.”.

14 (2) EFFECTIVE DATE.—The amendment made
15 by paragraph (1) shall apply to premiums for
16 months beginning with January 2003. The Secretary
17 of Health and Human Services shall establish a
18 method for providing rebates of premium penalties
19 paid for months on or after January 2003 for which
20 a penalty does not apply under such amendment but
21 for which a penalty was previously collected.

22 (b) MEDICARE PART B SPECIAL ENROLLMENT PE-
23 RIOD.—

24 (1) IN GENERAL.—In the case of any individual
25 who, as of the date of the enactment of this Act, is

1 65 years of age or older, is eligible to enroll but is
2 not enrolled under part B of title XVIII of the So-
3 cial Security Act, and is a covered beneficiary (as
4 defined in section 1072(5) of title 10, United States
5 Code), the Secretary of Health and Human Services
6 shall provide for a special enrollment period during
7 which the individual may enroll under such part.
8 Such period shall begin as soon as possible after the
9 date of the enactment of this Act and shall end on
10 December 31, 2003.

11 (2) COVERAGE PERIOD.—In the case of an indi-
12 vidual who enrolls during the special enrollment pe-
13 riod provided under paragraph (1), the coverage pe-
14 riod under part B of title XVIII of the Social Secu-
15 rity Act shall begin on the first day of the month
16 following the month in which the individual enrolls.

17 **SEC. 519. COVERAGE OF CHOLESTEROL AND BLOOD LIPID**
18 **SCREENING.**

19 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
20 1395x(s)(2)), as amended by section 515(a), is amended—

21 (1) in subparagraph (V), by striking “and” at
22 the end;

23 (2) in subparagraph (W), by inserting “and” at
24 the end; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(X) cholesterol and other blood lipid
4 screening tests (as defined in subsection (xx));”.

5 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
6 1395x), as amended by section 515(b), is amended by add-
7 ing at the end the following new subsection:

8 “Cholesterol and Other Blood Lipid Screening Test

9 “(xx)(1) The term ‘cholesterol and other blood lipid
10 screening test’ means diagnostic testing of cholesterol and
11 other lipid levels of the blood for the purpose of early de-
12 tection of abnormal cholesterol and other lipid levels.

13 “(2) The Secretary shall establish standards, in con-
14 sultation with appropriate organizations, regarding the
15 frequency and type of cholesterol and other blood lipid
16 screening tests, except that such frequency may not be
17 more often than once every 2 years.”.

18 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
19 1395y(a)(1)), as amended by section 515(e), is amended

20 (1) by striking “and” at the end of subpara-
21 graph (I);

22 (2) by striking the semicolon at the end of sub-
23 paragraph (J) and inserting “; and”; and

24 (3) by adding at the end the following new sub-
25 paragraph:

1 “(K) in the case of a cholesterol and other
2 blood lipid screening test (as defined in section
3 1861(xx)(1)), which is performed more frequently
4 than is covered under section 1861(xx)(2).”.

5 (d) EFFECTIVE DATE.—The amendments made by
6 this section shall apply to tests furnished on or after Janu-
7 ary 1, 2004.

8 **TITLE VI—PROVISIONS**
9 **RELATING TO PARTS A AND B**
10 **Subtitle A—Home Health Services**

11 **SEC. 601. ELIMINATION OF 15 PERCENT REDUCTION IN**
12 **PAYMENT RATES UNDER THE PROSPECTIVE**
13 **PAYMENT SYSTEM.**

14 (a) IN GENERAL.—Section 1895(b)(3)(A) (42 U.S.C.
15 1395fff(b)(3)(A)) is amended to read as follows:

16 “(A) INITIAL BASIS.—Under such system
17 the Secretary shall provide for computation of
18 a standard prospective payment amount (or
19 amounts) as follows:

20 “(i) Such amount (or amounts) shall
21 initially be based on the most current au-
22 dited cost report data available to the Sec-
23 retary and shall be computed in a manner
24 so that the total amounts payable under
25 the system for fiscal year 2001 shall be

1 equal to the total amount that would have
2 been made if the system had not been in
3 effect and if section 1861(v)(1)(L)(ix) had
4 not been enacted.

5 “(ii) For fiscal year 2002 and for the
6 first quarter of fiscal year 2003, such
7 amount (or amounts) shall be equal to the
8 amount (or amounts) determined under
9 this paragraph for the previous fiscal year,
10 updated under subparagraph (B).

11 “(iii) For 2003, such amount (or
12 amounts) shall be equal to the amount (or
13 amounts) determined under this paragraph
14 for fiscal year 2002, updated under sub-
15 paragraph (B) for 2003.

16 “(iv) For 2004 and each subsequent
17 year, such amount (or amounts) shall be
18 equal to the amount (or amounts) deter-
19 mined under this paragraph for the pre-
20 vious year, updated under subparagraph
21 (B).

22 Each such amount shall be standardized in a
23 manner that eliminates the effect of variations
24 in relative case mix and area wage adjustments
25 among different home health agencies in a

1 budget neutral manner consistent with the case
2 mix and wage level adjustments provided under
3 paragraph (4)(A). Under the system, the Sec-
4 retary may recognize regional differences or dif-
5 ferences based upon whether or not the services
6 or agency are in an urbanized area.”.

7 (b) EFFECTIVE DATE.—The amendment made by
8 subsection (a) shall take effect as if included in the
9 amendments made by section 501 of the Medicare, Med-
10 icaid, and SCHIP Benefits Improvement and Protection
11 Act of 2000 (as enacted into law by section 1(a)(6) of
12 Public Law 106–554).

13 **SEC. 602. UPDATE IN HOME HEALTH SERVICES.**

14 (a) CHANGE TO CALENDAR YEAR UPDATE.—

15 (1) IN GENERAL.—Section 1895(b) (42 U.S.C.
16 1395fff(b)(3)) is amended—

17 (A) in paragraph (3)(B)(i)—

18 (i) by striking “each fiscal year (be-
19 ginning with fiscal year 2002)” and insert-
20 ing “fiscal year 2002 and for each subse-
21 quent year (beginning with 2003)”; and

22 (ii) by inserting “or year” after “the
23 fiscal year”;

24 (B) in paragraph (3)(B)(ii)—

1 (i) in subclause (II), by striking “fis-
2 cal year” and inserting “year” and by re-
3 designating such subclause as subclause
4 (III); and

5 (ii) in subclause (I), by striking “each
6 of fiscal years 2002 and 2003” and insert-
7 ing the following: “fiscal year 2002, the
8 home health market basket percentage in-
9 crease (as defined in clause (iii)) minus 1.1
10 percentage points;

11 “(II) 2003”;

12 (C) in paragraph (3)(B)(iii), by inserting
13 “or year” after “fiscal year” each place it ap-
14 pears;

15 (D) in paragraph (3)(B)(iv)—

16 (i) by inserting “or year” after “fiscal
17 year” each place it appears; and

18 (ii) by inserting “or years” after “fis-
19 cal years”; and

20 (E) in paragraph (5), by inserting “or
21 year” after “fiscal year”.

22 (2) TRANSITION RULE.—The standard prospec-
23 tive payment amount (or amounts) under section
24 1895(b)(3) of the Social Security Act for the cal-
25 endar quarter beginning on October 1, 2002, shall

1 be such amount (or amounts) for the previous cal-
2 endar quarter.

3 (b) CHANGES IN UPDATES FOR 2003, 2004, AND
4 2005.—Section 1895(b)(3)(B)(ii) (42 U.S.C.
5 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B),
6 is amended—

7 (1) in subclause (II), by striking “the home
8 health market basket percentage increase (as defined
9 in clause (iii)) minus 1.1 percentage points” and in-
10 sserting “2.0 percentage points”;

11 (2) by striking “or” at the end of subclause
12 (II);

13 (3) by redesignating subclause (III) as sub-
14 clause (V); and

15 (4) by inserting after subclause (II) the fol-
16 lowing new subclause:

17 “(III) 2004, 1.1 percentage
18 points;

19 “(IV) 2005, 2.7 percentage
20 points; or”.

21 (c) PAYMENT ADJUSTMENT.—

22 (1) IN GENERAL.—Section 1895(b)(5) (42
23 U.S.C. 1395fff(b)(5)) is amended by striking “5 per-
24 cent” and inserting “3 percent”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by paragraph (1) shall apply to years beginning with
3 2003.

4 **SEC. 603. OASIS TASK FORCE; SUSPENSION OF CERTAIN**
5 **OASIS DATA COLLECTION REQUIREMENTS**
6 **PENDING TASK FORCE SUBMITTAL OF RE-**
7 **PORT.**

8 (a) ESTABLISHMENT.—The Secretary of Health and
9 Human Services shall establish and appoint a task force
10 (to be known as the “OASIS Task Force”) to examine
11 the data collection and reporting requirements under
12 OASIS. For purposes of this section, the term “OASIS”
13 means the Outcome and Assessment Information Set re-
14 quired by reason of section 4602(e) of Balanced Budget
15 Act of 1997 (42 U.S.C. 1395fff note).

16 (b) COMPOSITION.—The OASIS Task Force shall be
17 composed of the following:

18 (1) Staff of the Centers for Medicare & Med-
19 icaid Services with expertise in post-acute care.

20 (2) Representatives of home health agencies.

21 (3) Health care professionals and research and
22 health care quality experts outside the Federal Gov-
23 ernment with expertise in post-acute care.

24 (4) Advocates for individuals requiring home
25 health services.

1 (c) DUTIES.—

2 (1) REVIEW AND RECOMMENDATIONS.—The
3 OASIS Task Force shall review and make rec-
4 ommendations to the Secretary regarding changes in
5 OASIS to improve and simplify data collection for
6 purposes of—

7 (A) assessing the quality of home health
8 services; and

9 (B) providing consistency in classification
10 of patients into home health resource groups
11 (HHRGs) for payment under section 1895 of
12 the Social Security Act (42 U.S.C. 1395fff).

13 (2) SPECIFIC ITEMS.—In conducting the review
14 under paragraph (1), the OASIS Task Force shall
15 specifically examine—

16 (A) the 41 outcome measures currently in
17 use;

18 (B) the timing and frequency of data col-
19 lection; and

20 (C) the collection of information on
21 comorbidities and clinical indicators.

22 (3) REPORT.—The OASIS Task Force shall
23 submit a report to the Secretary containing its find-
24 ings and recommendations for changes in OASIS by

1 not later than 18 months after the date of the enact-
2 ment of this Act.

3 (d) SUNSET.—The OASIS Task Force shall termi-
4 nate 60 days after the date on which the report is sub-
5 mitted under subsection (c)(2).

6 (e) NONAPPLICATION OF FACCA.—The provisions of
7 the Federal Advisory Committee Act shall not apply to
8 the OASIS Task Force.

9 (f) SUSPENSION OF OASIS REQUIREMENT FOR COL-
10 LECTION OF DATA ON NON-MEDICARE AND NON-MED-
11 ICAID PATIENTS PENDING TASK FORCE REPORT.—

12 (1) IN GENERAL.—During the period described
13 in paragraph (2), the Secretary of Health and
14 Human Services may not require, under section
15 4602(e) of the Balanced Budget Act of 1997 or oth-
16 erwise under OASIS, a home health agency to gath-
17 er or submit information that relates to an indi-
18 vidual who is not eligible for benefits under either
19 title XVIII or title XIX of the Social Security Act.

20 (2) PERIOD OF SUSPENSION.—The period de-
21 scribed in this paragraph—

22 (A) begins on January 1, 2003, and

23 (B) ends on the last day of the 2nd month
24 beginning after the date the report is submitted
25 under subsection (c)(2).

1 **SEC. 604. MEDPAC STUDY ON MEDICARE MARGINS OF**
2 **HOME HEALTH AGENCIES.**

3 (a) **STUDY.**—The Medicare Payment Advisory Com-
4 mission shall conduct a study of payment margins of home
5 health agencies under the home health prospective pay-
6 ment system under section 1895 of the Social Security Act
7 (42 U.S.C. 1395fff). Such study shall examine whether
8 systematic differences in payment margins are related to
9 differences in case mix (as measured by home health re-
10 source groups (HHRGs)) among such agencies. The study
11 shall use the partial or full-year cost reports filed by home
12 health agencies.

13 (b) **REPORT.**—Not later than 2 years after the date
14 of the enactment of this Act, the Commission shall submit
15 to Congress a report on the study under subsection (a).

16 **Subtitle B—Direct Graduate**
17 **Medical Education**

18 **SEC. 611. REDISTRIBUTION OF UNUSED RESIDENT POSI-**
19 **TIONS.**

20 (a) **IN GENERAL.**—Section 1886(h)(4) (42 U.S.C.
21 1395ww(h)(4)) is amended—

22 (1) in subparagraph (F)(i), by inserting “sub-
23 ject to subparagraph (I),” after “October 1, 1997,”;

24 (2) in subparagraph (H)(i), by inserting “sub-
25 ject to subparagraph (I),” after “subparagraphs (F)
26 and (G),”; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(I) REDISTRIBUTION OF UNUSED RESI-
4 DENT POSITIONS.—

5 “(i) REDUCTION IN LIMIT BASED ON
6 UNUSED POSITIONS.—

7 “(I) IN GENERAL.—If a hos-
8 pital’s resident level (as defined in
9 clause (iii)(I)) is less than the other-
10 wise applicable resident limit (as de-
11 fined in clause (iii)(II)) for each of
12 the reference periods (as defined in
13 subclause (II)), effective for cost re-
14 porting periods beginning on or after
15 January 1, 2003, the otherwise appli-
16 cable resident limit shall be reduced
17 by 75 percent of the difference be-
18 tween such limit and the reference
19 resident level specified in subclause
20 (III) (or subclause (IV) if applicable).

21 “(II) REFERENCE PERIODS DE-
22 FINED.—In this clause, the term ‘ref-
23 erence periods’ means, for a hospital,
24 the 3 most recent consecutive cost re-
25 porting periods of the hospital for

1 which cost reports have been settled
2 (or, if not, submitted) on or before
3 September 30, 2001.

4 “(III) REFERENCE RESIDENT
5 LEVEL.—Subject to subclause (IV),
6 the reference resident level specified in
7 this subclause for a hospital is the
8 highest resident level for the hospital
9 during any of the reference periods.

10 “(IV) ADJUSTMENT PROCESS.—
11 Upon the timely request of a hospital,
12 the Secretary may adjust the ref-
13 erence resident level for a hospital to
14 be the resident level for the hospital
15 for the cost reporting period that in-
16 cludes July 1, 2002.

17 “(ii) REDISTRIBUTION.—

18 “(I) IN GENERAL.—The Sec-
19 retary is authorized to increase the
20 otherwise applicable resident limits for
21 hospitals by an aggregate number es-
22 timated by the Secretary that does
23 not exceed the aggregate reduction in
24 such limits attributable to clause (i)
25 (without taking into account any ad-

1 justment under subclause (IV) of such
2 clause).

3 “(II) EFFECTIVE DATE.—No in-
4 crease under subclause (I) shall be
5 permitted or taken into account for a
6 hospital for any portion of a cost re-
7 porting period that occurs before July
8 1, 2003, or before the date of the hos-
9 pital’s application for an increase
10 under this clause. No such increase
11 shall be permitted for a hospital un-
12 less the hospital has applied to the
13 Secretary for such increase by Decem-
14 ber 31, 2004.

15 “(III) CONSIDERATIONS IN RE-
16 DISTRIBUTION.—In determining for
17 which hospitals the increase in the
18 otherwise applicable resident limit is
19 provided under subclause (I), the Sec-
20 retary shall take into account the
21 need for such an increase by specialty
22 and location involved, consistent with
23 subclause (IV).

24 “(IV) PRIORITY FOR RURAL AND
25 SMALL URBAN AREAS.—In deter-

1 mining for which hospitals and resi-
2 dency training programs an increase
3 in the otherwise applicable resident
4 limit is provided under subclause (I),
5 the Secretary shall first distribute the
6 increase to programs of hospitals lo-
7 cated in rural areas or in urban areas
8 that are not large urban areas (as de-
9 fined for purposes of subsection (d))
10 on a first-come-first-served basis (as
11 determined by the Secretary) based on
12 a demonstration that the hospital will
13 fill the positions made available under
14 this clause and not to exceed an in-
15 crease of 25 full-time equivalent posi-
16 tions with respect to any hospital.

17 “(V) APPLICATION OF LOCALITY
18 ADJUSTED NATIONAL AVERAGE PER
19 RESIDENT AMOUNT.—With respect to
20 additional residency positions in a
21 hospital attributable to the increase
22 provided under this clause, notwith-
23 standing any other provision of this
24 subsection, the approved FTE resi-
25 dent amount is deemed to be equal to

1 the locality adjusted national average
2 per resident amount computed under
3 subparagraph (E) for that hospital.

4 “(VI) CONSTRUCTION.—Nothing
5 in this clause shall be construed as
6 permitting the redistribution of reduc-
7 tions in residency positions attrib-
8 utable to voluntary reduction pro-
9 grams under paragraph (6) or as af-
10 fecting the ability of a hospital to es-
11 tablish new medical residency training
12 programs under subparagraph (H).

13 “(iii) RESIDENT LEVEL AND LIMIT
14 DEFINED.—In this subparagraph:

15 “(I) RESIDENT LEVEL.—The
16 term ‘resident level’ means, with re-
17 spect to a hospital, the total number
18 of full-time equivalent residents, be-
19 fore the application of weighting fac-
20 tors (as determined under this para-
21 graph), in the fields of allopathic and
22 osteopathic medicine for the hospital.

23 “(II) OTHERWISE APPLICABLE
24 RESIDENT LIMIT.—The term ‘other-
25 wise applicable resident limit’ means,

1 with respect to a hospital, the limit
2 otherwise applicable under subpara-
3 graphs (F)(i) and (H) on the resident
4 level for the hospital determined with-
5 out regard to this subparagraph.”.

6 (b) NO APPLICATION OF INCREASE TO IME.—Sec-
7 tion 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is
8 amended by adding at the end the following: “The provi-
9 sions of clause (i) of subparagraph (I) of subsection (h)(4)
10 shall apply with respect to the first sentence of this clause
11 in the same manner as it applies with respect to subpara-
12 graph (F) of such subsection, but the provisions of clause
13 (ii) of such subparagraph shall not apply.”.

14 (c) REPORT ON EXTENSION OF APPLICATIONS
15 UNDER REDISTRIBUTION PROGRAM.—Not later than July
16 1, 2004, the Secretary shall submit to Congress a report
17 containing recommendations regarding whether to extend
18 the deadline for applications for an increase in resident
19 limits under section 1886(h)(4)(I)(ii)(II) of the Social Se-
20 curity Act (as added by subsection (a)).

1 **SEC. 612. INCREASING FOR 5 YEARS TO 100 PERCENT OF**
2 **THE LOCALITY ADJUSTED NATIONAL AVER-**
3 **AGE PER RESIDENT AMOUNT THE PAYMENT**
4 **FLOOR FOR DIRECT GRADUATE MEDICAL**
5 **EDUCATION PAYMENTS UNDER THE MEDI-**
6 **CARE PROGRAM.**

7 Section 1886(h)(2)(D)(iii) (42 U.S.C.
8 1395ww(h)(2)(D)(iii)), as amended by section 511 of
9 BIPA, is amended—

10 (1) by striking “and” after “70 percent,”; and

11 (2) by inserting after “85 percent,” the fol-
12 lowing: “and for cost reporting periods beginning
13 during the period beginning on October 1, 2002, and
14 ending on September 31, 2007, shall not be less
15 than 100 percent.”.

16 **Subtitle C—Other Provisions**

17 **SEC. 621. MODIFICATIONS TO MEDICARE PAYMENT ADVI-**
18 **SORY COMMISSION (MEDPAC).**

19 (a) EXAMINATION OF BUDGET CONSEQUENCES.—
20 Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by
21 adding at the end the following new paragraph:

22 “(8) EXAMINATION OF BUDGET CON-
23 SEQUENCES.—Before making any recommendations,
24 the Commission shall examine the budget con-
25 sequences of such recommendations, directly or

1 through consultation with appropriate expert enti-
2 ties.”.

3 (b) CONSIDERATION OF EFFICIENT PROVISION OF
4 SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b-
5 6(b)(2)(B)(i)) is amended by inserting “the efficient provi-
6 sion of” after “expenditures for”.

7 (c) ADDITIONAL REPORTS.—

8 (1) DATA NEEDS AND SOURCES.—The Medicare
9 Payment Advisory Commission shall conduct a
10 study, and submit a report to Congress by not later
11 than June 1, 2003, on the need for current data,
12 and sources of current data available, to determine
13 the solvency and financial circumstances of hospitals
14 and other medicare providers of services. The Com-
15 mission shall examine data on uncompensated care,
16 as well as the sahere of uncompensated care ac-
17 counted for by the expenses for treating illegal
18 aliens.

19 (2) USE OF TAX-RELATED RETURNS.—Using
20 return information provided under Form 990 of the
21 Internal Revenue Service, the Commission shall sub-
22 mit to Congress, by not later than June 1, 2003, a
23 report on the following:

1 (A) Investments and capital financing of
2 hospitals participating under the medicare pro-
3 gram and related foundations.

4 (B) Access to capital financing for private
5 and for not-for-profit hospitals.

6 **SEC. 622. DEMONSTRATION PROJECT FOR DISEASE MAN-**
7 **AGEMENT FOR CERTAIN MEDICARE BENE-**
8 **FICIARIES WITH DIABETES.**

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services shall conduct a demonstration project
11 under this section (in this section referred to as the
12 “project”) to demonstrate the impact on costs and health
13 outcomes of applying disease management to certain medi-
14 care beneficiaries with diagnosed diabetes. In no case may
15 the number of participants in the project exceed 30,000
16 at any time.

17 (b) VOLUNTARY PARTICIPATION.—

18 (1) ELIGIBILITY.—Medicare beneficiaries are
19 eligible to participate in the project only if—

20 (a) they are Hispanic, as determined by
21 the Secretary;

22 (A) they meet specific medical criteria
23 demonstrating the appropriate diagnosis and
24 the advanced nature of their disease;

1 (B) their physicians approve of participa-
2 tion in the project; and

3 (C) they are not enrolled in a
4 Medicare+Choice plan.

5 (2) BENEFITS.—A medicare beneficiary who is
6 enrolled in the project shall be eligible—

7 (A) for disease management services re-
8 lated to their diabetes; and

9 (B) for payment for all costs for prescrip-
10 tion drugs without regard to whether or not
11 they relate to the diabetes, except that the
12 project may provide for modest cost-sharing
13 with respect to prescription drug coverage.

14 (c) CONTRACTS WITH DISEASE MANAGEMENT ORGA-
15 NIZATIONS.—

16 (1) IN GENERAL.—The Secretary of Health and
17 Human Services shall carry out the project through
18 contracts with up to three disease management orga-
19 nizations. The Secretary shall not enter into such a
20 contract with an organization unless the organiza-
21 tion demonstrates that it can produce improved
22 health outcomes and reduce aggregate medicare ex-
23 penditures consistent with paragraph (2).

24 (2) CONTRACT PROVISIONS.—Under such
25 contracts—

1 (A) such an organization shall be required
2 to provide for prescription drug coverage de-
3 scribed in subsection (b)(2)(B);

4 (B) such an organization shall be paid a
5 fee negotiated and established by the Secretary
6 in a manner so that (taking into account sav-
7 ings in expenditures under parts A and B of
8 the medicare program under title XVIII of the
9 Social Security Act) there will be no net in-
10 crease, and to the extent practicable, there will
11 be a net reduction in expenditures under the
12 medicare program as a result of the project;
13 and

14 (C) such an organization shall guarantee,
15 through an appropriate arrangement with a re-
16 insurance company or otherwise, the prohibition
17 on net increases in expenditures described in
18 subparagraph (B).

19 (3) PAYMENTS.—Payments to such organiza-
20 tions shall be made in appropriate proportion from
21 the Trust Funds established under title XVIII of the
22 Social Security Act.

23 (4) WORKING GROUP.—The Secretary shall es-
24 tablish within the Department of Health and
25 Human Services a working group consisting of em-

1 employees of the Department to carry out the fol-
2 lowing:

3 (A) To oversee the project.

4 (B) To establish policy and criteria for
5 medicare disease management programs within
6 the Department, including the establishment of
7 policy and criteria for such programs.

8 (C) To identify targeted medical conditions
9 and targeted individuals.

10 (D) To select areas in which such pro-
11 grams are carried out.

12 (E) To monitor health outcomes under
13 such programs.

14 (F) To measure the effectiveness of such
15 programs in meeting any budget neutrality re-
16 quirements.

17 (G) Otherwise to serve as a central focal
18 point within the Department for dissemination
19 of information on medicare disease management
20 programs.

21 (d) APPLICATION OF MEDIGAP PROTECTIONS TO
22 DEMONSTRATION PROJECT ENROLLEES.—(1) Subject to
23 paragraph (2), the provisions of section 1882(s)(3) (other
24 than clauses (i) through (iv) of subparagraph (B)) and
25 1882(s)(4) of the Social Security Act shall apply to enroll-

1 ment (and termination of enrollment) in the demonstra-
2 tion project under this section, in the same manner as they
3 apply to enrollment (and termination of enrollment) with
4 a Medicare+Choice organization in a Medicare+Choice
5 plan.

6 (2) In applying paragraph (1)—

7 (A) any reference in clause (v) or (vi) of section
8 1882(s)(3)(B) of such Act to 12 months is deemed
9 a reference to the period of the demonstration
10 project; and

11 (B) the notification required under section
12 1882(s)(3)(D) of such Act shall be provided in a
13 manner specified by the Secretary of Health and
14 Human Services.

15 (e) DURATION.—The project shall last for not longer
16 than 3 years.

17 (f) WAIVER.—The Secretary of Health and Human
18 Services shall waive such provisions of title XVIII of the
19 Social Security Act as may be necessary to provide for
20 payment for services under the project in accordance with
21 subsection (c)(3).

22 (g) REPORT.—The Secretary of Health and Human
23 Services shall submit to Congress an interim report on the
24 project not later than 2 years after the date it is first im-
25 plemented and a final report on the project not later than

1 6 months after the date of its completion. Such reports
2 shall include information on the impact of the project on
3 costs and health outcomes and recommendations on the
4 cost-effectiveness of extending or expanding the project.

5 (h) GAO STUDY ON DISEASE MANAGEMENT PRO-
6 GRAMS.—The Comptroller General of the United States
7 shall conduct a study that compares disease management
8 programs under title XVIII of the Social Security Act with
9 such programs conducted in the private sector, including
10 the prevalence of such programs and programs for case
11 management. The study shall identify the cost-effective-
12 ness of such programs and any savings achieved by such
13 programs. The Comptroller General shall submit a report
14 on such study to Congress by not later than 18 months
15 after the date of the enactment of this Act.

16 **SEC. 623. DEMONSTRATION PROJECT FOR MEDICAL ADULT**
17 **DAY CARE SERVICES.**

18 (a) ESTABLISHMENT.—Subject to the succeeding
19 provisions of this section, the Secretary of Health and
20 Human Services shall establish a demonstration project
21 (in this section referred to as the “demonstration project”)
22 under which the Secretary shall, as part of a plan of an
23 episode of care for home health services established for
24 a medicare beneficiary, permit a medical adult day care
25 facility or a home health agency, directly or under ar-

1 rangements with a medical adult day care facility, to pro-
2 vide medical adult day care services as a substitute for
3 a portion of home health services that would otherwise be
4 provided in the beneficiary's home.

5 (b) PAYMENT.—

6 (1) IN GENERAL.—The amount of payment for
7 an episode of care for home health services, a por-
8 tion of which consists of substitute medical adult
9 day care services, under the demonstration project
10 shall be made at a rate equal to 95 percent of the
11 amount that would otherwise apply for such home
12 health services under section 1895 of the Social Se-
13 curity Act (42 u.s.c. 1395fff). In no case may a a
14 medical adult day care facility or home health agen-
15 cy, or a medical adult day care facility under ar-
16 rangements with a home health agency, separately
17 charge a beneficiary for medical adult day care serv-
18 ices furnished under the plan of care.

19 (2) BUDGET NEUTRALITY FOR DEMONSTRA-
20 TION PROJECT.—Notwithstanding any other provi-
21 sion of law, the Secretary shall provide for an appro-
22 priate reduction in the aggregate amount of addi-
23 tional payments made under section 1895 of the So-
24 cial Security Act (42 U.S.C. 1395fff) to reflect any
25 increase in amounts expended from the Trust Funds

1 as a result of the demonstration project conducted
2 under this section.

3 (c) DEMONSTRATION PROJECT SITES.—The project
4 established under this section shall be conducted in not
5 more than 5 sites in States selected by the Secretary that
6 license or certify providers of services that furnish medical
7 adult day care services.

8 (d) DURATION.—The Secretary shall conduct the
9 demonstration project for a period of 3 years.

10 (e) VOLUNTARY PARTICIPATION.—Participation of
11 medicare beneficiaries in the demonstration project shall
12 be voluntary. The total number of such beneficiaries that
13 may participate in the project at any given time may not
14 exceed 15,000.

15 (f) PREFERENCE IN SELECTING AGENCIES.—In se-
16 lecting medical adult day care facilities and home health
17 agencies to participate under the demonstration project,
18 the Secretary shall give preference to those facilities and
19 agencies that—

20 (1) are currently licensed or certified to furnish
21 medical adult day care services; and

22 (2) have furnished medical adult day care serv-
23 ices to medicare beneficiaries for a continuous 2-year
24 period before the beginning of the demonstration
25 project.

1 (g) WAIVER AUTHORITY.—The Secretary may waive
2 such requirements of title XVIII of the Social Security Act
3 as may be necessary for the purposes of carrying out the
4 demonstration project, other than waiving the requirement
5 that an individual be homebound in order to be eligible
6 for benefits for home health services.

7 (h) EVALUATION AND REPORT.—The Secretary shall
8 conduct an evaluation of the clinical and cost effectiveness
9 of the demonstration project. Not later 30 months after
10 the commencement of the project, the Secretary shall sub-
11 mit to Congress a report on the evaluation, and shall in-
12 clude in the report the following:

13 (1) An analysis of the patient outcomes and
14 costs of furnishing care to the medicare beneficiaries
15 participating in the project as compared to such out-
16 comes and costs to beneficiaries receiving only home
17 health services for the same health conditions.

18 (2) Such recommendations regarding the exten-
19 sion, expansion, or termination of the project as the
20 Secretary determines appropriate.

21 (i) DEFINITIONS.—In this section:

22 (1) HOME HEALTH AGENCY.—The term “home
23 health agency” has the meaning given such term in
24 section 1861(o) of the Social Security Act (42
25 U.S.C. 1395x(o)).

1 (2) MEDICAL ADULT DAY CARE FACILITY.—The
2 term “medical adult day care facility” means a facil-
3 ity that—

4 (A) has been licensed or certified by a
5 State to furnish medical adult day care services
6 in the State for a continuous 2-year period;

7 (B) is engaged in providing skilled nursing
8 services and other therapeutic services directly
9 or under arrangement with a home health agen-
10 cy;

11 (C) meets such standards established by
12 the Secretary to assure quality of care and such
13 other requirements as the Secretary finds nec-
14 essary in the interest of the health and safety
15 of individuals who are furnished services in the
16 facility; and

17 (D) provides medical adult day care serv-
18 ices.

19 (3) MEDICAL ADULT DAY CARE SERVICES.—
20 The term “medical adult day care services” means—

21 (A) home health service items and services
22 described in paragraphs (1) through (7) of sec-
23 tion 1861(m) furnished in a medical adult day
24 care facility;

1 (B) a program of supervised activities fur-
2 nished in a group setting in the facility that—

3 (i) meet such criteria as the Secretary
4 determines appropriate; and

5 (ii) is designed to promote physical
6 and mental health of the individuals; and

7 (C) such other services as the Secretary
8 may specify.

9 (4) **MEDICARE BENEFICIARY.**—The term
10 “medicare beneficiary” means an individual entitled
11 to benefits under part A of this title, enrolled under
12 part B of this title, or both.

13 **SEC. 624. PUBLICATION ON FINAL WRITTEN GUIDANCE**
14 **CONCERNING PROHIBITIONS AGAINST DIS-**
15 **CRIMINATION BY NATIONAL ORIGIN WITH**
16 **RESPECT TO HEALTH CARE SERVICES.**

17 Not later than January 1, 2003, the Secretary shall
18 issue final written guidance concerning the application of
19 the prohibition in title VI of the Civil Rights Act of 1964
20 against national origin discrimination as it affects persons
21 with limited English proficiency with respect to access to
22 health care services under the medicare program.

1 **TITLE VII—MEDICAID AND**
2 **OTHER HEALTH PROVISIONS**
3 **Subtitle A—Medicaid Provisions**

4 **SEC. 701. DSH PROVISIONS.**

5 (a) CONTINUATION OF MEDICAID DSH ALLOTMENT
6 ADJUSTMENTS UNDER BIPA2000.—

7 (1) IN GENERAL.—Section 1923(f) (42 U.S.C.
8 1396r-4(f))—

9 (A) in paragraph (2)—

10 (i) in the heading, by striking
11 “THROUGH 2002” and inserting “THROUGH
12 2000”;

13 (ii) by striking “ending with fiscal
14 year 2002” and inserting “ending with fis-
15 cal year 2000”; and

16 (iii) in the table in such paragraph, by
17 striking the columns labeled “FY 01” and
18 “FY02”;

19 (B) in paragraph (3)(A), by striking
20 “paragraph (2)” and inserting “paragraph
21 (4)”; and

22 (C) in paragraph (4), as added by section
23 701(a)(1) of BIPA—

24 (i) by striking “FOR FISCAL YEARS
25 2001 AND 2002” in the heading;

1 (ii) in subparagraph (A), by striking
2 “Notwithstanding paragraph (2), the” and
3 inserting “The”;

4 (iii) in subparagraph (C)—

5 (I) by striking “NO APPLICA-
6 TION” and inserting “APPLICATION”;
7 and

8 (II) by striking “without regard
9 to” and inserting “taking into ac-
10 count”.

11 (2) INCREASE IN MEDICAID DSH ALLOTMENT
12 FOR THE DISTRICT OF COLUMBIA.—

13 (A) IN GENERAL.—Effective for DSH al-
14 lotments beginning with fiscal year 2002, the
15 item in the table contained in section
16 1923(f)(2) of the Social Security Act (42
17 U.S.C. 1396r-4(f)(2)) for the District of Co-
18 lumbia for the DSH allotment for FY 00 (fiscal
19 year 2000) is amended by striking “32” and in-
20 serting “49”.

21 (B) CONSTRUCTION.—Nothing in subpara-
22 graph (A) shall be construed as preventing the
23 application of section 1923(f)(4) of the Social
24 Security Act (as amended by subsection (a)) to

1 the District of Columbia for fiscal year 2002
2 and subsequent fiscal years.

3 (b) INCREASE IN FLOOR FOR TREATMENT AS AN EX-
4 TREMELY LOW DSH STATE TO 3 PERCENT IN FISCAL
5 YEAR 2002.—

6 (1) INCREASE IN DSH FLOOR.—Section
7 1923(f)(5) (42 U.S.C. 1396r-4(f)(5)) is amended—

8 (A) by striking “fiscal year 1999” and in-
9 serting “fiscal year 2001”;

10 (B) by striking “August 31, 2000” and in-
11 serting “August 31, 2002”;

12 (C) by striking “1 percent” each place it
13 appears and inserting “3 percent”; and

14 (D) by striking “fiscal year 2001” and in-
15 serting “fiscal year 2003”.

16 (2) EFFECTIVE DATE.—The amendments made
17 by paragraph (1) take effect on October 1, 2002,
18 and apply to DSH allotments under title XIX of the
19 Social Security Act for fiscal year 2003 and each fis-
20 cal year thereafter.

21 **SEC. 702. 1-YEAR EXTENSION OF Q-I1 PROGRAM.**

22 Section 1902(a)(10)(E)(E)(iv) (42 U.S.C.
23 1396a(a)(10)(E)(E)(iv)) is amended by striking “2002”
24 and inserting “2003”.

1 **Subtitle B—Internet Pharmacies**

2 **SEC. 711. INTERNET SALES OF PRESCRIPTION DRUGS.**

3 (a) IN GENERAL.—Chapter 5 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
5 ed by inserting after section 503A the following section:

6 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

7 “(a) REQUIREMENTS REGARDING INFORMATION ON
8 INTERNET SITE.—

9 “(1) IN GENERAL.—A person may not dispense
10 a prescription drug pursuant to a sale of the drug
11 by such person if—

12 “(A) the purchaser of the drug submitted
13 the purchase order for the drug, or conducted
14 any other part of the sales transaction for the
15 drug, through an Internet site; and

16 “(B) such site, or any other Internet site
17 used by such person for purposes of sales of a
18 prescription drug, fails to meet each of the re-
19 quirements specified in paragraph (2) (other
20 than a site or pages on a site that are not in-
21 tended to be accessed by purchasers or prospec-
22 tive purchasers).

23 “(2) REQUIREMENTS.—With respect to an
24 Internet site, the requirements referred to in sub-

1 paragraph (B) of paragraph (1) for a person to
2 whom such paragraph applies are as follows:

3 “(A) Each page of the site shall include ei-
4 ther the following information or a link to a
5 page that provides the following information:

6 “(i) The name of such person; the ad-
7 dress of the principal place of business of
8 the person with respect to sales of pre-
9 scription drugs through the Internet; and
10 the telephone number for such place of
11 business.

12 “(ii) Each State in which the person
13 is authorized by law to dispense prescrip-
14 tion drugs.

15 “(iii) The name of each individual
16 who serves as a pharmacist for purposes of
17 the site, and each State in which the indi-
18 vidual is authorized by law to dispense pre-
19 scription drugs.

20 “(iv) If the person provides for med-
21 ical consultations through the site for pur-
22 poses of providing prescriptions, the name
23 of each individual who provides such con-
24 sultations; each State in which the indi-
25 vidual is licensed or otherwise authorized

1 by law to provide such consultations; and
2 the type or types of health professions for
3 which the individual holds such licenses or
4 other authorizations.

5 “(B) A link to which paragraph (1) applies
6 shall be clearly visible on the page involved,
7 shall not be of a size smaller than other links
8 on the page (if any), and shall include in the
9 caption for the link the words ‘licensing and
10 contact information’.

11 “(b) INTERNET SALES WITHOUT APPROPRIATE
12 MEDICAL RELATIONSHIPS.—

13 “(1) IN GENERAL.—A person may not dispense
14 a prescription drug, or arrange the dispensing of
15 such a drug, pursuant to a sale of the drug if—

16 “(A) for purposes of such sale, the pur-
17 chaser communicated with the person through
18 the Internet;

19 “(B) the patient for whom the drug was
20 purchased did not, when such communications
21 began, have a prescription for the drug;

22 “(C) pursuant to such communications, the
23 person provided for the involvement of a practi-
24 tioner and the practitioner issued a prescription
25 for the drug that was purchased;

1 “(D) the person knew, or had reason to
2 know, that the practitioner did not, when
3 issuing the prescription, have a qualifying med-
4 ical relationship with the patient; and

5 “(E)(i) the person received payment for
6 the drug from the purchaser; or

7 “(ii) in the case of arranging the dis-
8 pensing of the drug, the person received pay-
9 ment for doing so from the person who dis-
10 pensed the drug.

11 For purposes of subparagraph (E), payment is re-
12 ceived if money or other valuable consideration is re-
13 ceived.

14 “(2) QUALIFYING MEDICAL RELATIONSHIP.—

15 “(A) IN GENERAL.—With respect to
16 issuing a prescription for a drug for a patient,
17 a practitioner has a qualifying medical relation-
18 ship with the patient for purposes of this sec-
19 tion if at least one in-person medical evaluation
20 of the patient has been conducted by the practi-
21 tioner. This subparagraph and subparagraph
22 (B) may not be construed as having any appli-
23 cability beyond this section.

24 “(B) IN-PERSON MEDICAL EVALUATION.—

25 A medical evaluation by a practitioner is an in-

1 person medical evaluation for purposes of this
2 section if the practitioner is in the physical
3 presence of the patient as part of conducting
4 the evaluation, without regard to whether por-
5 tions of the evaluation are conducted by other
6 health professionals.

7 “(c) ACTIONS BY STATES.—

8 “(1) IN GENERAL.—Whenever an attorney gen-
9 eral of any State has reason to believe that the in-
10 terests of the residents of that State have been or
11 are being threatened or adversely affected because
12 any person has engaged or is engaging in a pattern
13 or practice that violates section 301(l), the State
14 may bring a civil action on behalf of its residents in
15 an appropriate district court of the United States to
16 enjoin such practice, to enforce compliance with such
17 section (including a nationwide injunction), to obtain
18 damages, restitution, or other compensation on be-
19 half of residents of such State, to obtain reasonable
20 attorneys fees and costs if the State prevails in the
21 civil action, or to obtain such further and other relief
22 as the court may deem appropriate.

23 “(2) NOTICE.—The State shall serve prior writ-
24 ten notice of any civil action under paragraph (1) or
25 (5)(B) upon the Secretary and provide the Secretary

1 with a copy of its complaint, except that if it is not
2 feasible for the State to provide such prior notice,
3 the State shall serve such notice immediately upon
4 instituting such action. Upon receiving a notice re-
5 specting a civil action, the Secretary shall have the
6 right—

7 “(A) to intervene in such action;

8 “(B) upon so intervening, to be heard on
9 all matters arising therein; and

10 “(C) to file petitions for appeal.

11 “(3) CONSTRUCTION.—For purposes of bring-
12 ing any civil action under paragraph (1), nothing in
13 this chapter shall prevent an attorney general of a
14 State from exercising the powers conferred on the
15 attorney general by the laws of such State to con-
16 duct investigations or to administer oaths or affir-
17 mations or to compel the attendance of witnesses or
18 the production of documentary and other evidence.

19 “(4) VENUE; SERVICE OF PROCESS.—Any civil
20 action brought under paragraph (1) in a district
21 court of the United States may be brought in the
22 district in which the defendant is found, is an inhab-
23 itant, or transacts business or wherever venue is
24 proper under section 1391 of title 28, United States
25 Code. Process in such an action may be served in

1 any district in which the defendant is an inhabitant
2 or in which the defendant may be found.

3 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

4 “(A) Nothing contained in this section
5 shall prohibit an authorized State official from
6 proceeding in State court on the basis of an al-
7 leged violation of any civil or criminal statute of
8 such State.

9 “(B) In addition to actions brought by an
10 attorney general of a State under paragraph
11 (1), such an action may be brought by officers
12 of such State who are authorized by the State
13 to bring actions in such State on behalf of its
14 residents.

15 “(d) DEFINITIONS.—

16 “(1) INTERNET-RELATED DEFINITIONS.—For
17 purposes of this section:

18 “(A) The term ‘Internet’ means collectively
19 the myriad of computer and telecommunications
20 facilities, including equipment and operating
21 software, which comprise the interconnected
22 world-wide network of networks that employ the
23 transmission control protocol/internet protocol,
24 or any predecessor or successor protocols to

1 such protocol, to communicate information of
2 all kinds by wire or radio.

3 “(B) The term ‘link’, with respect to the
4 Internet, means one or more letters, words,
5 numbers, symbols, or graphic items that appear
6 on a page of an Internet site for the purpose
7 of serving, when activated, as a method for exe-
8 cuting an electronic command—

9 “(i) to move from viewing one portion
10 of a page on such site to another portion
11 of the page;

12 “(ii) to move from viewing one page
13 on such site to another page on such site;
14 or

15 “(iii) to move from viewing a page on
16 one Internet site to a page on another
17 Internet site.

18 “(C) The term ‘page’, with respect to the
19 Internet, means a document or other file
20 accessed at an Internet site.

21 “(D)(i) The terms ‘site’ and ‘address’, with
22 respect to the Internet, mean a specific location
23 on the Internet that is determined by Internet
24 Protocol numbers. Such term includes the do-
25 main name, if any.

1 “(ii) The term ‘domain name’ means a
2 method of representing an Internet address
3 without direct reference to the Internet Protocol
4 numbers for the address, including methods
5 that use designations such as ‘.com’, ‘.edu’,
6 ‘.gov’, ‘.net’, or ‘.org’.

7 “(iii) The term ‘Internet Protocol num-
8 bers’ includes any successor protocol for deter-
9 mining a specific location on the Internet.

10 “(2) OTHER DEFINITIONS.—For purposes of
11 this section:

12 “(A) The term ‘practitioner’, with respect
13 to the issuance of a prescription for a drug for
14 a patient, means—

15 “(i) an individual authorized by law to
16 administer the drug; or

17 “(ii) an individual who is not so au-
18 thorized but represents himself or herself
19 as an individual who is so authorized.

20 “(B) The term ‘prescription drug’ means a
21 drug that is subject to section 503(b).

22 “(C) The term ‘qualifying medical relation-
23 ship’, with respect to a practitioner and a pa-
24 tient, has the meaning indicated for such term
25 in subsection (b).”.

1 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 331) is amended by inserting after paragraph (k) the fol-
4 lowing:

5 “(l) The dispensing of a prescription drug in violation
6 of section 503B, or arranging for the dispensing of such
7 a drug in violation of such section.”.

8 **SEC. 712. INTERNET SALES OF PRESCRIPTION DRUGS; CON-**
9 **SIDERATION BY SECRETARY OF PRACTICES**
10 **AND PROCEDURES FOR CERTIFICATION OF**
11 **LEGITIMATE BUSINESSES.**

12 In carrying out section 503B of the Federal Food,
13 Drug, and Cosmetic Act (as added by section 711 of this
14 Act), the Secretary of Health and Human Services shall
15 take into consideration the practices and procedures of
16 public or private entities that certify that businesses sell-
17 ing prescription drugs through Internet sites are legiti-
18 mate businesses, including practices and procedures re-
19 garding disclosure formats and verification programs.

20 **SEC. 713. EFFECTIVE DATE.**

21 The amendments made by section 711 take effect
22 upon the expiration of the 60-day period beginning on the
23 date of the enactment of this Act, without regard to
24 whether a final rule to implement such amendments has
25 been promulgated by the Secretary of Health and Human

1 Services under section 701(a) of the Federal Food, Drug,
2 and Cosmetic Act. The preceding sentence may not be con-
3 strued as affecting the authority of such Secretary to pro-
4 mulgate such a final rule.

5 **Subtitle C—Treatment of Rare**
6 **Diseases**

7 **SEC. 721. NIH OFFICE OF RARE DISEASES AT NATIONAL IN-**
8 **STITUTES OF HEALTH.**

9 Title IV of the Public Health Service Act (42 U.S.C.
10 281 et seq.), as amended by Public Law 107–84, is
11 amended by inserting after section 404E the following:

12 “OFFICE OF RARE DISEASES

13 “SEC. 404F. (a) ESTABLISHMENT.—There is estab-
14 lished within the Office of the Director of NIH an office
15 to be known as the Office of Rare Diseases (in this section
16 referred to as the ‘Office’), which shall be headed by a
17 Director (in this section referred to as the ‘Director’), ap-
18 pointed by the Director of NIH.

19 “(b) DUTIES.—

20 “(1) IN GENERAL.—The Director of the Office
21 shall carry out the following:

22 “(A) The Director shall recommend an
23 agenda for conducting and supporting research
24 on rare diseases through the national research
25 institutes and centers. The agenda shall provide
26 for a broad range of research and education ac-

1 activities, including scientific workshops and
2 symposia to identify research opportunities for
3 rare diseases.

4 “(B) The Director shall, with respect to
5 rare diseases, promote coordination and co-
6 operation among the national research insti-
7 tutes and centers and entities whose research is
8 supported by such institutes.

9 “(C) The Director, in collaboration with
10 the directors of the other relevant institutes and
11 centers of the National Institutes of Health,
12 may enter into cooperative agreements with and
13 make grants for regional centers of excellence
14 on rare diseases in accordance with section
15 404G.

16 “(D) The Director shall promote the suffi-
17 cient allocation of the resources of the National
18 Institutes of Health for conducting and sup-
19 porting research on rare diseases.

20 “(E) The Director shall promote and en-
21 courage the establishment of a centralized
22 clearinghouse for rare and genetic disease infor-
23 mation that will provide understandable infor-
24 mation about these diseases to the public, med-
25 ical professionals, patients and families.

1 “(F) The Director shall biennially prepare
2 a report that describes the research and edu-
3 cation activities on rare diseases being con-
4 ducted or supported through the national re-
5 search institutes and centers, and that identi-
6 fies particular projects or types of projects that
7 should in the future be conducted or supported
8 by the national research institutes and centers
9 or other entities in the field of research on rare
10 diseases.

11 “(G) The Director shall prepare the NIH
12 Director’s annual report to Congress on rare
13 disease research conducted by or supported
14 through the national research institutes and
15 centers.

16 “(2) PRINCIPAL ADVISOR REGARDING ORPHAN
17 DISEASES.—With respect to rare diseases, the Direc-
18 tor shall serve as the principal advisor to the Direc-
19 tor of NIH and shall provide advice to other relevant
20 agencies. The Director shall provide liaison with na-
21 tional and international patient, health and scientific
22 organizations concerned with rare diseases.

23 “(c) DEFINITION.—For purposes of this section, the
24 term ‘rare disease’ means any disease or condition that
25 affects less than 200,000 persons in the United States.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated such sums as already have been appro-
4 priated for fiscal year 2002, and \$4,000,000 for each of
5 the fiscal years 2003 through 2006.”.

6 **SEC. 722. RARE DISEASE REGIONAL CENTERS OF EXCEL-**
7 **LENCE.**

8 Title IV of the Public Health Service Act (42 U.S.C.
9 281 et seq.), as amended by section 721, is further amend-
10 ed by inserting after section 404F the following:

11 “RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

12 “SEC. 404G. (a) COOPERATIVE AGREEMENTS AND
13 GRANTS.—

14 “(1) IN GENERAL.—The Director of the Office
15 of Rare Diseases (in this section referred to as the
16 ‘Director’), in collaboration with the directors of the
17 other relevant institutes and centers of the National
18 Institutes of Health, may enter into cooperative
19 agreements with and make grants to public or pri-
20 vate nonprofit entities to pay all or part of the cost
21 of planning, establishing, or strengthening, and pro-
22 viding basic operating support for regional centers of
23 excellence for clinical research into, training in, and
24 demonstration of diagnostic, prevention, control, and
25 treatment methods for rare diseases.

1 “(2) POLICIES.—A cooperative agreement or
2 grant under paragraph (1) shall be entered into in
3 accordance with policies established by the Director
4 of NIH.

5 “(b) COORDINATION WITH OTHER INSTITUTES.—
6 The Director shall coordinate the activities under this sec-
7 tion with similar activities conducted by other national re-
8 search institutes, centers and agencies of the National In-
9 stitutes of Health and by the Food and Drug Administra-
10 tion to the extent that such institutes, centers and agen-
11 cies have responsibilities that are related to rare diseases.

12 “(c) USES FOR FEDERAL PAYMENTS UNDER COOP-
13 ERATIVE AGREEMENTS OR GRANTS.—Federal payments
14 made under a cooperative agreement or grant under sub-
15 section (a) may be used for—

16 “(1) staffing, administrative, and other basic
17 operating costs, including such patient care costs as
18 are required for research;

19 “(2) clinical training, including training for al-
20 lied health professionals, continuing education for
21 health professionals and allied health professions
22 personnel, and information programs for the public
23 with respect to rare diseases; and

24 “(3) clinical research and demonstration pro-
25 grams.

1 “(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—
2 Support of a center under subsection (a) may be for a
3 period of not to exceed 5 years. Such period may be ex-
4 tended by the Director for additional periods of not more
5 than 5 years if the operations of such center have been
6 reviewed by an appropriate technical and scientific peer
7 review group established by the Director and if such group
8 has recommended to the Director that such period should
9 be extended.

10 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
11 purpose of carrying out this section, there are authorized
12 to be appropriated such sums as already have been appro-
13 priated for fiscal year 2002, and \$20,000,000 for each of
14 the fiscal years 2003 through 2006.”.

15 **Subtitle D—Other Provisions**
16 **Relating to Drugs**

17 **SEC. 731. GAO STUDY REGARDING DIRECT-TO-CONSUMER**
18 **ADVERTISING OF PRESCRIPTION DRUGS.**

19 (a) IN GENERAL.—The Comptroller General of the
20 United States shall conduct a study for the purpose of
21 determining—

22 (1) whether and to what extent there have been
23 increases in utilization rates of prescription drugs
24 that are attributable to guidance regarding direct-to-
25 consumer advertising of such drugs that has been

1 issued by the Food and Drug Administration under
2 section 502(n) of the Federal Food, Drug, and Cos-
3 metic Act; and

4 (2) if so, whether and to what extent such in-
5 creased utilization rates have resulted in increases in
6 the costs of public or private health plans, health in-
7 surance, or other health programs.

8 (b) CERTAIN DETERMINATIONS.—The study under
9 subsection (a) shall include determinations of the fol-
10 lowing:

11 (1) The extent to which advertisements referred
12 to in such subsection have resulted in effective con-
13 sumer education about the prescription drugs in-
14 volved, including an understanding of the risks of
15 the drugs relative to the benefits.

16 (2) The extent of consumer satisfaction with
17 such advertisements.

18 (3) The extent of physician satisfaction with the
19 advertisements, including determining whether phy-
20 sicians believe that the advertisements interfere with
21 the exercise of their medical judgment by influencing
22 consumers to prefer advertised drugs over alter-
23 native therapies.

24 (4) The extent to which the advertisements
25 have resulted in increases in health care costs for

1 taxpayers, for employers, or for consumers due to
2 consumer decisions to seek advertised drugs rather
3 than lower-costs alternative therapies.

4 (5) The extent to which the advertisements
5 have resulted in decreases in health care costs for
6 taxpayers, for employers, or for consumers due to
7 decreased hospitalization rates, fewer physician visits
8 (not related to hospitalization), lower treatment
9 costs, or reduced instances of employee absences to
10 care for family members with diseases or disorders.

11 (c) REPORT.—Not later than two years after the date
12 of the enactment of this Act, the Comptroller General of
13 the United States shall submit to the Congress a report
14 providing the findings of the study under subsection (a).

15 **SEC. 732. CERTAIN HEALTH PROFESSIONS PROGRAMS RE-**
16 **GARDING PRACTICE OF PHARMACY.**

17 Part E of title VII of the Public Health Service Act
18 (42 U.S.C. 294n et seq.) is amended by adding at the end
19 the following subpart:

20 **“Subpart 3—Pharmacist Workforce Programs**

21 **“SEC. 771. PUBLIC SERVICE ANNOUNCEMENTS.**

22 “(a) PUBLIC SERVICE ANNOUNCEMENTS.—

23 “(1) IN GENERAL.—The Secretary shall develop
24 and issue public service announcements that adver-
25 tise and promote the pharmacist profession, high-

1 light the advantages and rewards of being a phar-
2 macist, and encourage individuals to enter the phar-
3 macist profession.

4 “(2) METHOD.—The public service announce-
5 ments described in subsection (a) shall be broadcast
6 through appropriate media outlets, including tele-
7 vision or radio, in a manner intended to reach as
8 wide and diverse an audience as possible.

9 “(b) STATE AND LOCAL PUBLIC SERVICE AN-
10 NOUNCEMENTS.—

11 “(1) IN GENERAL.—The Secretary shall award
12 grants to entities to support State and local adver-
13 tising campaigns through appropriate media outlets
14 to promote the pharmacist profession, highlight the
15 advantages and rewards of being a pharmacist, and
16 encourage individuals from disadvantaged back-
17 grounds to enter the pharmacist profession.

18 “(2) USE OF FUNDS.—An entity that receives
19 a grant under subsection (a) shall use funds received
20 through such grant to acquire local television and
21 radio time, place advertisements in local newspapers,
22 and post information on billboards or on the Inter-
23 net, in order to—

24 “(A) advertise and promote the pharmacist
25 profession;

1 “(B) promote pharmacist education pro-
2 grams;

3 “(C) inform the public of public assistance
4 regarding such education programs;

5 “(D) highlight individuals in the commu-
6 nity that are presently practicing as phar-
7 macists to recruit new pharmacists; and

8 “(E) provide any other information to re-
9 cruit individuals for the pharmacist profession.

10 “(3) METHOD.—The campaigns described in
11 subsection (a) shall be broadcast on television or
12 radio, placed in newspapers as advertisements, or
13 posted on billboards or the Internet, in a manner in-
14 tended to reach as wide and diverse an audience as
15 possible.

16 **“SEC. 772. DEMONSTRATION PROJECT.**

17 “(a) IN GENERAL.—The Secretary shall establish a
18 demonstration project to enhance the participation of indi-
19 viduals who are pharmacists in the National Health Serv-
20 ice Corps Loan Repayment Program described in section
21 338B.

22 “(b) SERVICES.—Services that may be provided by
23 pharmacists pursuant to the demonstration project estab-
24 lished under this section include medication therapy man-
25 agement services to assure that medications are used ap-

1 appropriately by patients, to enhance patients' under-
2 standing of the appropriate use of medications, to increase
3 patients' adherence to prescription medication regimens,
4 to reduce the risk of adverse events associated with medi-
5 cations, and to reduce the need for other costly medical
6 services through better management of medication ther-
7 apy. Such services may include case management, disease
8 management, drug therapy management, patient training
9 and education, counseling, drug therapy problem resolu-
10 tion, medication administration, the provision of special
11 packaging, or other services that enhance the use of pre-
12 scription medications.

13 “(c) PROCEDURE.—The Secretary may not provide
14 assistance to an individual under this section unless the
15 individual agrees to comply with all requirements de-
16 scribed in sections 338B and 338E.

17 “(d) LIMITATIONS.—The demonstration project de-
18 scribed in this section shall provide for the participation
19 of—

20 “(1) individuals to provide services in rural and
21 urban areas; and

22 “(2) enough individuals to allow the Secretary
23 to properly analyze the effectiveness of such project.

24 “(e) DESIGNATIONS.—The demonstration project de-
25 scribed in this section, and any pharmacists who are se-

1 lected to participate in such project, shall not be consid-
2 ered by the Secretary in the designation of a health profes-
3 sional shortage area under section 332 during fiscal years
4 2003 through 2005.

5 “(f) RULE OF CONSTRUCTION.—This section shall
6 not be construed to require any State to participate in the
7 project described in this section.

8 “(g) REPORT.—The Secretary shall prepare and sub-
9 mit a report on the project to—

10 “(1) the Committee on Health, Education,
11 Labor, and Pensions of the Senate;

12 “(2) the Subcommittee on Labor, Health and
13 Human Services, and Education of the Committee
14 on Appropriations of the Senate;

15 “(3) the Committee on Energy and Commerce
16 of the House of Representatives; and

17 “(4) the Subcommittee on Labor, Health and
18 Human Services, and Education of the Committee
19 on Appropriations of the House of Representatives.

20 **“SEC. 773. INFORMATION TECHNOLOGY.**

21 “(a) GRANTS AND CONTRACTS.—The Secretary may
22 make awards of grants or contracts to qualifying schools
23 of pharmacy for the purpose of assisting such schools in
24 acquiring and installing computer-based systems to pro-
25 vide pharmaceutical education. Education provided

1 through such systems may be graduate education, profes-
2 sional education, or continuing education. The computer-
3 based systems may be designed to provide on-site edu-
4 cation, or education at remote sites (commonly referred
5 to as distance learning), or both.

6 “(b) QUALIFYING SCHOOL OF PHARMACY.—For pur-
7 poses of this section, the term ‘qualifying school of phar-
8 macy’ means a school of pharmacy (as defined in section
9 799B) that requires students to serve in a clinical rotation
10 in which pharmacist services are part of the curriculum.

11 **“SEC. 774. AUTHORIZATION OF APPROPRIATIONS.**

12 “For the purpose of carrying out this subpart, there
13 are authorized to be appropriated such sums as may be
14 necessary for each of the fiscal years 2003 through
15 2006.”.

○