(5) USE OF OTHER ENTITIES FOR COVERED OUTPATIENT DRUGS.—Section 1842(f) (42 U.S.C. 1395u(f)) is amended—

(A) by striking "and" at the end of paragraph (1),

(B) by striking the period at the end of paragraph (2) and inserting "; and", and

(C) by adding at the end the following:

"(3) with respect to activities related to covered outpatient drugs, any other private entity which the Secretary determines is qualified to conduct such activities.".

(6) DESIGNATED CARRIERS TO PROCESS CLAIMS OF RAILROAD RETIREES.—Section 1842(g) (42 U.S.C. 1395u(g)) is amended by inserting "(other than functions related to covered outpatient drugs)" after "functions".

(e) CONFORMING AMENDMENTS.—

(1)(A) Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(i) by striking "and" at the end of clause (O), and

(ii) by inserting before the semicolon at the end the following: ", and (Q) with respect to

covered outpatient drugs, the amounts paid shall be as prescribed by section 1834(d)".

(B) Section 1833(a)(2) (42 U.S.C. 1395l(a)(2)) is amended in the matter preceding subparagraph (A) by inserting ", except for covered outpatient drugs," after "and (I) of such section".

(2) Section 1833(b)(2) (42 U.S.C. 1395l(b)(2)) is amended by inserting "or with respect to covered outpatient drugs" before the comma.

(3) Section 1834(j)(3)(F) (42 U.S.C. 1395m(j)(4)(F)), as added by section 8421(a)(1) and as redesignated by section 8423(a), is amended—

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

(B) by striking clauses (ii), (iv), and (v) and redesignating clause (iii) as clause (ii); and

(C) in clause (ii) (as so redesignated), by striking the comma at the end and inserting a period.

(4) The first sentence of section 1842(h)(2) (42 U.S.C. 1395u(h)(2)) is amended by inserting "(other than a carrier described in subsection (f)(3))" after "Each carrier".

(5) The first sentence of section 1866(a)(2)(A) (42 U.S.C. 1395cc(a)(2)(A)) is amended—

(A) in clause (i), by inserting "section 1834(d)," after "section 1833(b),", and

(B) in clause (ii), by inserting ", other than for covered outpatient drugs," after "provider)".

SEC. 2003. MEDICARE REBATES FOR COVERED OUTPATIENT DRUGS.

(a) IN GENERAL.—Part B of title XVIII is amended by adding at the end the following new section:

"REBATES FOR COVERED OUTPATIENT DRUGS

"Sec. 1850. (a) REQUIREMENT FOR REBATE AGREEMENT.—In order for payment to be available under this part for covered outpatient drugs of a manufacturer dispensed or provided on or after January 1, 1998, the manufacturer must have entered into and have in effect a rebate agreement with the Secretary meeting the requirements of subsection (b), and an agreement to give equal access to discounts in accordance with subsection (e).

"(b) TERMS, IMPLEMENTATION, AND ENFORCEMENT OF REBATE AGREEMENT.—

"(1) PERIODIC REBATES.—

"(A) IN GENERAL.—A rebate agreement under this section shall require the manufacturer to pay to the Secretary for each calendar

quarter, not later than 30 days after the date of receipt of the information described in paragraph (2) for such quarter, a rebate in an amount determined under subsection (c) for all covered outpatient drugs of the manufacturer described in subparagraph (B).

"(B) DRUGS INCLUDED IN QUARTERLY REBATE CALCULATION.—Drugs subject to rebate with respect to a calendar quarter are drugs which are dispensed by a pharmacy during such quarter to [individuals (other than individuals enrolled with an entity with a contract under section 1876) or a medicare drug benefit plan with a contract under section 1851] eligible for benefits under this part, as reported by such pharmacies to the Secretary.

"(2) INFORMATION FURNISHED TO MANUFACTURERS.—

"(A) IN GENERAL.—The Secretary shall report to each manufacturer, not later than 60 days after the end of each calendar quarter, information on the total number, for each covered outpatient drug, of units of each dosage form, strength, and package size dispensed under the plan during the quarter, on the basis of the

data reported to the Secretary described in paragraph (1)(B).

"(B) AUDIT.—The Comptroller General may audit the records of the Secretary to the extent necessary to determine the accuracy of reports by the Secretary pursuant to subparagraph (A). Adjustments to rebates shall be made to the extent determined necessary by the audit to reflect actual units of drugs dispensed.

"(3) PROVISION OF PRICE INFORMATION BY MANUFACTURER.—

"(A) QUARTERLY PRICING INFORMATION.—Each manufacturer with an agreement in effect under this section shall report to the Secretary, not later than 30 days after the last day of each calendar quarter, on the average manufacturer retail price and the average manufacturer non-retail price for each dosage form and strength of each covered outpatient drug for the quarter.

"(B) BASE QUARTER PRICES.—Each manufacturer of a covered outpatient drug with an agreement under this section shall report to the Secretary, by not later than 30 days after the effective date of such agreement (or, if later, 30

days after the end of the base quarter), the average manufacturer retail price, for such base quarter, for each dosage form and strength of each such covered drug.

"(C) VERIFICATION OF AVERAGE MANUFACTURER PRICE.—The Secretary may inspect the records of manufacturers, and survey wholesalers, pharmacies, and institutional purchasers of drugs, as necessary to verify prices reported under subparagraph (A).

"(D) PENALTIES.—

"(i) CIVIL MONEY PENALTIES.—The Secretary may impose a civil money penalty on a manufacturer with an agreement under this section—

"(I) for failure to provide information required under subparagraph (A) on a timely basis, in an amount up to $10,000 per day of delay;

"(II) for refusal to provide information about charges or prices requested by the Secretary for purposes of verification pursuant to subparagraph (C), in an amount up to $100,000; and

"(III) for provision, pursuant to subparagraph (A) or (B), of information that the manufacturer knows or should know is false, in an amount up to $100,000 per item of information. Such civil money penalties are in addition to any other penalties prescribed by law. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(ii) TERMINATION OF AGREEMENT.—If a manufacturer with an agreement under this section has not provided information required under subparagraph (A) or (B) within 90 days of the deadline imposed, the Secretary may suspend the agreement with respect to covered outpatient drugs dispensed after the end of such 90-day period and until the date such information is reported (but in no case

shall a suspension be for less than 30 days).

"(4) LENGTH OF AGREEMENT.—

"(A) IN GENERAL.—A rebate agreement shall be effective for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

"(B) TERMINATION.—

"(i) BY THE SECRETARY.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall afford a manufacturer an opportunity for a hearing concerning such termination, but such hearing shall not delay the effective date of the termination.

"(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at

least 60 days after the date the manufacturer provides notice to the Secretary.

"(iii) EFFECTIVE DATE OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

"(iv) NOTICE TO PHARMACIES.—In the case of a termination under this subparagraph, the Secretary shall notify pharmacies and physician organizations not less than 30 days before the effective date of such termination.

"(c) AMOUNT OF REBATE.—

"(1) BASE REBATE.—Each manufacturer shall remit a basic rebate to the Secretary for each calendar quarter in an amount, with respect to each dosage form and strength of a covered outpatient drug equal to the product of—

"(A) the total number of units subject to rebate for such quarter, as described in subsection (b)(1)(B); and

"(B)(i) in the case of a single-source drug or an innovator-multiple source drug, 15 per-

cent of the average manufacturer retail price, or

"(ii) in the case of a noninnovator-multiple source drug, insulin furnished over-the-counter, or an enteral nutrient, 6 percent or the applicable percent (if the Secretary implements the sliding scale developed in accordance with paragraph (4)) of the average manufacturer retail price.

"(2) ADDITIONAL REBATE.—Each manufacturer shall remit to the Secretary, for each calendar quarter, an additional rebate for each dosage form and strength of a single-source or innovator-multiple-source drug, in an amount equal to—

"(A) the total number of units subject to rebate for such quarter, as described in subsection (b)(1)(B), multiplied by

"(B) the amount, if any, by which the average manufacturer retail price for such drugs of the manufacturer exceeds the average manufacturer retail price for the base quarter, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from the end of such base quar-

ter to the month before the beginning of such calendar quarter.

"(3) DEPOSIT OF REBATES.—The Secretary shall deposit rebates under this section in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

"(4) APPLICABLE PERCENT.—

"(A) IN GENERAL.—For purposes of this paragraph, the Secretary may develop and implement a sliding scale for rebates based on the relationship between the average manufacturer retail price of the drug [insulin, or enteral nutrient] and the average manufacturer retail price of [the equivalent] innovator drug [insulin, or enteral nutrient].

"(B) SLIDING SCALE DESCRIBED.—The sliding scale developed by the Secretary under subparagraph (A) shall—

"(i) require that the applicable percent be not less than 2 percent and not be greater than 15 percent; and

"(ii) ensure that the total level of rebates collected under such a sliding scale would be equivalent to a flat 6 percent re-

bate on such drugs, [insulin, and enteral nutrients.]

"(d) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by a manufacturer under this section is confidential and shall not be disclosed by the Secretary (or a carrier), except—

"(A) as the Secretary determines to be necessary to carry out this section,

"(B) to permit the Comptroller General to review the information provided, and

"(C) to permit the Director of the Congressional Budget Office to review the information provided.

"(e) AGREEMENT TO GIVE EQUAL ACCESS TO DISCOUNTS.—An agreement under this subsection by a manufacturer of covered outpatient drugs shall guarantee that the manufacturer will offer, to each wholesaler or retailer (or other purchaser representing a group of such wholesalers or retailers) that purchases such drugs on substantially the same terms (including such terms as prompt payment, cash payment, volume purchase, single-site delivery, the use of formularies by purchasers, and any other terms effectively reducing the manufacturer's costs) as any other purchaser (including any institutional pur-

chaser) the same price for such drugs as is offered to such other purchaser. In determining a manufacturer's compliance with the previous sentence, there shall not be taken into account terms offered to the Department of Veterans Affairs, the Department of Defense, or any public program.

"(f) DEFINITIONS.—For purposes of this section—

"(1) AVERAGE MANUFACTURER RETAIL PRICE.—The term 'average manufacturer retail price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price (inclusive of discounts for cash payment, prompt payment, volume purchases, and rebates (other than rebates under this section), but exclusive of nominal prices) paid to the manufacturer for the drug in the United States for drugs distributed to the retail pharmacy class of trade.

"(2) AVERAGE MANUFACTURER NON-RETAIL PRICE.—The term 'average manufacturer non-retail price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the weighted average price (inclusive of discounts for cash payment, prompt payment, volume purchases, and rebates (other than rebates under this section), but exclusive of nominal prices) paid to the manu-

facturer for the drug in the United States by hospitals and other institutional purchasers that purchase drugs for institutional use and not for resale.

"(3) BASE QUARTER.—The term 'base quarter' means, with respect to a covered outpatient drug of a manufacturer, the calendar quarter beginning April 1, 1993, or (if later) the first full calendar quarter during which the drug was marketed in the United States.

"(4) DRUG.—The terms 'innovator multiple source drug', 'noninnovator multiple source drug', and 'single source drug' have the meanings of those terms under section 1927(k)(7), except that the reference in such section to a 'covered outpatient drug' shall be considered a reference to a covered outpatient drug under this part.

"(5) MANUFACTURER.—The term 'manufacturer' means, with respect to a covered outpatient drug—

"(A) the entity whose National Drug Code number (as issued pursuant to section 510(e) of the Federal Food, Drug, and Cosmetic Act) appears on the labeling of the drug; or

"(B) if the number described in subparagraph (A) does not appear on the labeling of

the drug, the person named as the applicant in a human drug application (in the case of a new drug) or the product license application (in the case of a biological product) for such drug approved by the Food and Drug Administration.".

(b) EXCLUSIONS FROM COVERAGE.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

(1) by striking "and" at the end of paragraph (15),

(2) by striking the period at the end of paragraph (16) and inserting "; or", and

(3) by inserting after paragraph (16) the following new paragraph:

"(17) consisting of a covered outpatient drug (as described in section 1861(t)) furnished during a year for which the drug's manufacturer does not have in effect a rebate agreement with the Secretary that meets the requirements of section 1850 for the year.".

SEC. 2004. PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION.

Part B of title XVIII is amended by inserting after section 1846 the following new section:

"PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION

"SEC. 1847. (a)(1) The Director of the Congressional Office of Technology Assessment (in this section referred

to as the 'Director' and the 'Office', respectively) shall provide for the appointment of a Prescription Drug Payment Review Commission (in this section referred to as the 'Commission'), to be composed of individuals with expertise in the provision and financing of covered outpatient drugs appointed by the Director (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service).

"(2) The Commission shall consist of 11 individuals. Members of the Commission shall first be appointed by no later than January 1, 1996, for a term of 3 years, except that the Director may provide initially for such shorter terms as will insure that (on a continuing basis) the terms of no more than 4 members expire in any one year.

"(3) The membership of the Commission shall include recognized experts in the fields of health care economics, medicine, pharmacology, pharmacy, and prescription drug reimbursement, as well as at least one individual who is a medicare beneficiary and one individual representing a research-based pharmaceutical and biotechnology company.

"(b)(1) The Commission shall submit to Congress an annual report no later than May 1 of each year, beginning with 1997—

"(A) concerning the implementation and the operation of the coverage of covered outpatient drugs under this part, including recommendations to Congress on changes to the program to improve access to prescription drugs, the quality of prescription drug care, and program efficiencies;

"(B) reviewing the process of contracting with medicare drug benefits plans under section 1851;

"(C) the fiscal soundness of the furnishing of covered outpatient drugs under this part;

"(D) the appropriateness, fairness and effectiveness of the rebate structure under section 1850; and

"(E) the advisability of developing a review process to exempt small manufacturers of single source or innovator multiple source drugs from rebates under section 1850 based on the manufacturer's size and the historic pricing of the manufacturer's products.

"(c) Section 1845(c)(1) shall apply to the Commission in the same manner as it applies to the Physician Payment Review Commission.

"(d) There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section. Such sums shall be payable from the Federal Supplementary Medical Insurance Trust Fund and the Medicare Part C Trust Fund under section 2324, in an allocation that reasonably reflects the proportion of expenditures for outpatient prescription drugs under this part and under part A of title XXIII.".

SEC. 2005. COVERAGE OF HOME INFUSION DRUG THERAPY SERVICES.

(a) IN GENERAL.—Section 1832(a)(2)(A) (42 U.S.C. 1395k(a)(2)(A)) is amended by inserting "and home infusion drug therapy services" before the semicolon.

(b) HOME INFUSION DRUG THERAPY SERVICES DEFINED.—Section 1861 (42 U.S.C. 1395x) is amended—

(1) by redesignating the subsection (jj) inserted by section 4156(a)(2) of the Omnibus Budget Reconciliation Act of 1990 as subsection (kk); and

(2) by inserting after such subsection the following new subsection:

"Home Infusion Drug Therapy Services

"(ll)(1) The term 'home infusion drug therapy services' means the items and services described in paragraph (2) furnished to an individual who is under the care of a physician—

"(A) in a setting described in section 1861(t)(5)(A)(ii),

"(B) by a qualified home infusion drug therapy provider (as defined in paragraph (3)) or by others under arrangements with them made by that provider, and

"(C) under a plan established and periodically reviewed by a physician.

"(2) The items and services described in this paragraph are such nursing, pharmacy, and related services (including medical supplies, intravenous fluids, delivery, and equipment) as are necessary to conduct safely and effectively a drug regimen through use of a covered home infusion drug (as defined in subsection (t)(5)), but do not include such covered home infusion drugs.

"(3) The term 'qualified home infusion drug therapy provider' means any entity that the Secretary determines meets the following requirements (or, in the case of a home health agency or an entity with respect to which the only items and services described in paragraph (2) furnished by the entity are enteral nutrition therapy services, meets any of the following requirements which the Secretary considers appropriate):

"(A) The entity is capable of providing or arranging for the items and services described in paragraph (2) and covered home infusion drugs.

"(B) The entity maintains clinical records on all patients.

"(C) The entity adheres to written protocols and policies with respect to the provision of items and services.

"(D) The entity makes services available (as needed) seven days a week on a 24-hour basis.

"(E) The entity coordinates all service with the patient's physician.

"(F) The entity conducts a quality assessment and assurance program, including drug regimen review and coordination of patient care.

"(G) The entity assures that only trained personnel provide covered home infusion drugs (and any other service for which training is required to provide the service safely).

"(H) The entity assumes responsibility for the quality of services provided by others under arrangements with the entity.

"(I) In the case of an entity in any State in which State or applicable local law provides for the licensing of entities of this nature, the entity (i) is

licensed pursuant to such law, or (ii) is approved, by the agency of such State or locality responsible for licensing entities of this nature, as meeting the standards established for such licensing.

"(J) The entity meets such other requirements as the Secretary may determine are necessary to assure the safe and effective provision of home infusion drug therapy services and the efficient administration of the home infusion drug therapy benefit.".

(c) PAYMENT.—

(1) IN GENERAL.—Section 1833 (42 U.S.C. 1395l) is amended—

(A) in subsection (a)(2)(B), by striking "or (E)" and inserting "(E), or (F)",

(B) in subsection (a)(2)(D), by striking "and" at the end,

(C) in subsection (a)(2)(E), by striking the semicolon and inserting "; and",

(D) by inserting after subsection (a)(2)(E) the following new subparagraph:

"(F) with respect to home infusion drug therapy services, the amounts described in section 1834(j);", and

(E) in the first sentence of subsection (b), by striking "services, (3)" and inserting "serv-

ices and home infusion drug therapy services, (3)".

(2) AMOUNT DESCRIBED.—Section 1834 is amended by adding at the end the following new subsection:

"(j) HOME INFUSION DRUG THERAPY SERVICES.—

"(1) IN GENERAL.—With respect to home infusion drug therapy services, payment under this part shall be made in an amount equal to the lesser of the actual charges for such services or the fee schedule established under paragraph (2).

"(2) ESTABLISHMENT OF FEE SCHEDULE.—

"(A) IN GENERAL.—The Secretary shall establish by regulation before the beginning of 1998 and each succeeding year a fee schedule for home infusion drug therapy services for which payment is made under this part. A fee schedule established under this subsection shall be on a per diem basis.

"(B) ADJUSTMENT FOR SERVICES FURNISHED BY INSTITUTIONS.—The fee schedule established by the Secretary under subparagraph (A) shall provide for adjustments in the case of home infusion drug therapy services for which payment is made under this part that are

furnished by a provider of services to avoid duplicative payments under this title for the service costs associated with such services.".

(d) CERTIFICATION.—Section 1835(a)(2) (42 U.S.C. 1395n(a)(2)) is amended—

(1) by striking "and" at the end of subparagraph (E),

(2) by striking the period at the end of subparagraph (F) and inserting "; and", and

(3) by inserting after subparagraph (F) the following:

"(G) in the case of home infusion drug therapy services, (i) such services are or were required because the individual needed such services for the administration of a covered home infusion drug, (ii) a plan for furnishing such services has been established and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.".

(e) CERTIFICATION OF HOME INFUSION DRUG THERAPY PROVIDERS; INTERMEDIATE SANCTIONS FOR NONCOMPLIANCE.—

(1) TREATMENT AS PROVIDER OF SERVICES.—Section 1861(u) (42 U.S.C. 1395x(u)) is amended by inserting "home infusion drug therapy provider," after "hospice program,".

(2) CONSULTATION WITH STATE AGENCIES AND OTHER ORGANIZATIONS.—Section 1863 (42 U.S.C. 1395z) is amended by striking "and (dd)(2)" and inserting "(dd)(2), and (ll)(3)".

(3) USE OF STATE AGENCIES IN DETERMINING COMPLIANCE.—Section 1864(a) (42 U.S.C. 1395aa(a)) is amended—

(A) in the first sentence, by striking "an agency is a hospice program" and inserting "an agency or entity is a hospice program or a home infusion drug therapy provider,"; and

(B) in the second sentence—

(i) by striking "institution or agency" and inserting "institution, agency, or entity", and

(ii) by striking "or hospice program" and inserting "hospice program, or home infusion drug therapy provider".

(4) APPLICATION OF INTERMEDIATE SANCTIONS.—Section 1846 (42 U.S.C. 1395w–2) is amended—

(A) in the heading, by adding "AND FOR QUALIFIED HOME INFUSION DRUG THERAPY PROVIDERS" at the end,

(B) in subsection (a), by inserting "or that a qualified home infusion drug therapy provider that is certified for participation under this title no longer substantially meets the requirements of section 1861(ll)(3)" after "under this part", and

(C) in subsection (b)(2)(A)(iv), by inserting "or home infusion drug therapy services" after "clinical diagnostic laboratory tests".

(f) USE OF REGIONAL INTERMEDIARIES IN ADMINISTRATION OF BENEFIT.—Section 1816 (42 U.S.C. 1395h) is amended by adding at the end the following new subsection:

"(k) With respect to carrying out functions relating to payment for home infusion drug therapy services and covered home infusion drugs, the Secretary may enter into contracts with agencies or organizations under this section to perform such functions on a regional basis.".

(g) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(B) (42 U.S.C. 1395m(h)(4)(B)) is amended by striking ", except that" and all that follows through "equipment".

(2) Section 1861(n) (42 U.S.C. 1395x(n)) is amended by adding at the end the following: "Such term does not include any home infusion drug therapy services described in section 1861(ll) or any covered outpatient drug used as a supply related to the furnishing of an item of durable medical equipment.".

(3) Section 1861(s)(8) (42 U.S.C. 1395x(s)(8)) is amended by inserting after "dental" the following: "devices or enteral and parenteral nutrients, supplies, and equipment".

(h) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 1998.

SEC. 2006. MEDICARE DRUG BENEFIT PLANS.

(a) IN GENERAL.—Part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.), as amended by section 2203, is amended by adding at the end the following new section:

"SEC. 1851. MEDICARE DRUG BENEFIT PLANS.

"(a) CONTRACTS WITH MEDICARE DRUG BENEFIT PLANS.—

"(1) IN GENERAL.—

"(A) 3 PLANS PER STATE.—Beginning January 1, 1998, the Secretary shall enter into contracts with 3 medicare drug benefit plans

that have submitted bids in accordance with subsection (b) in each State, but only if the Secretary determines that such plans meet the certification requirements of subsection (d). If more than 3 medicare drug benefit plans per State submit bids that meet such certification requirements, the Secretary shall enter into contracts with 3 such plans in such State on the basis of the bids submitted under such subsection and the quality of the plans.

"(B) INSUFFICIENT NUMBER OF BIDS.—If the Secretary determines that less than 3 medicare drug benefit plans have submitted bids in accordance with subsection (d) that meet the certification requirements of subsection (c), the Secretary [shall] enter into a contract with each such plan that has submitted a bid and meets such requirements. If no medicare drug benefit plans submit bids in a State that meet such certification requirements, [Please supply].

"(2) ENTITIES ELIGIBLE TO ENTER INTO CONTRACTS.—The Secretary may enter into a contract under this section with a medicare drug benefit plan that is—

"(A) [a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Act [but only if such organization has not entered into a risk contract with the Secretary under section 1876;

"(B) [a health plan];

"(C) [a network of preferred providers];

"(D) a network of chain and independent pharmacy providers;

"(E) a pharmacy benefit management company; or

"(F) any other entity that meets selection requirements developed by the Secretary.

"(b) BIDS.—

"(1) IN GENERAL.—Each medicare drug benefit plan that desires to enter into a contract with the Secretary under this section shall, not later than August 1 of 1997, and August 1 on each succeeding third year, submit to the Secretary a bid for the uniform monthly premium amount that the plan intends to charge over the next 3 years for furnishing covered outpatient drugs (as defined in section 1861(t)(2)), except as provided in subsection (d)(1)(B)(viii)), to an individual enrolled in part B. Such bid amount shall not take into account cost-

sharing requirements in excess of the cost sharing requirements described in subsection (d)(1)(A)(iii).

"(2) NOTICE BEFORE BID SUBMISSIONS.—At least 45 days before the date for submitting bids under paragraph (1), the Secretary shall provide for notice to medicare drug benefit plans that desire to submit bids under this section of the fee-for-service amount determined under subsection (c)(1)(B) and the proposed changes to be made in the methodology or benefit coverage assumptions from the methodology and assumptions used in the previous three year period and shall provide such plans an opportunity to comment on such proposed changes.

"(3) BID AMOUNT IN EXCESS OF FEE-FOR-SERVICE AMOUNT.—The Secretary shall not enter into a contract under this section with any medicare drug benefit plan that submits a bid amount in excess of the fee-for-service amount determined under subsection (c)(1)(B).

"(c) PAYMENTS.—

"(1) IN GENERAL.—

"(A) PAYMENTS IN LIEU OF NORMAL PAYMENTS.—Payments under a contract to a medicare drug benefit plan under this section shall be instead of the amounts which (in the absence

of the contract) would be otherwise payable, pursuant to section 1834(d), for covered outpatient drugs furnished by or through the plan to individuals enrolled with the plan under this section.

"(B) SOURCE OF PAYMENT.—The payment to a medicare outpatient drug coverage plan under this section shall be made from the Supplementary Insurance Trust Fund.

"(2) PAYMENT RULES UNDER MEDICARE DRUG BENEFIT PLANS.—

"(A) IN GENERAL.—

"(i) PAYMENT AMOUNT.—Each medicare drug benefit plan with a contract under this section shall receive a monthly payment in advance under this title for each individual enrolled with the plan for a month in an amount equal to the lesser of the bid amount submitted under subsection (b), [adjusted by the rate factor determined under subparagraph (C) for the class of such individual,] or the fee-for-service amount determined in accordance with subparagraph (B), [as so adjusted.]

"(ii) RETROACTIVE ADJUSTMENT.—The amount of payment under this subparagraph may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in the plan under this section and the number of individuals estimated to be so enrolled in determining the amount of the advance payment.

"(B) FEE-FOR-SERVICE AMOUNT.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the term 'fee-for-service amount' means the amount, prorated to be expressed as a monthly amount, representing 95 percent of the national average per capita amount that the Secretary estimates in advance would be payable in any [contract year during the 3 year period for which a contract is in effect under this section] for furnishing covered outpatient drugs to individuals enrolled in part B, if the covered outpatient drugs were to be furnished by other than a medicare drug benefit plan with a contract under this sec-

tion or [an entity with a contract under section 1876].

["(ii) BASIS FOR ESTIMATES.—The estimate made by the Secretary under subparagraph (A) shall be made on the basis of actual experience, or the retrospective actuarial equivalent based upon an adequate sample and other information and data with appropriate adjustments to assure actuarial equivalence, including adjustments the Secretary may determine appropriate to adjust for demographics, health status, and the presence of specific medical conditions.]

"(C) DETERMINATION OF CLASSES OF INDIVIDUALS AND RATE FACTORS FOR SUCH CLASSES.—

"(i) DETERMINATION OF CLASSES.—For purposes of this subparagraph, the Secretary shall define appropriate classes of individuals, based on age, disability status, and such other factors as the Secretary determines to be appropriate.

"(ii) RATE FACTORS.—The Secretary shall annually determine the rate factors

for each class of individuals defined in clause (i) reflecting the differences in the average per capita spending for covered outpatient drugs under part B among individuals in such classes. The Secretary shall announce such rate factors (in a manner intended to provide notice to interested parties) not later than August 1 before the year in which bids are submitted under subsection (b).

"(d) CERTIFICATION REQUIREMENTS.—

"(1) MEDICARE DRUG BENEFIT PLAN.—

"(A) IN GENERAL.—Each medicare drug benefit plan that has entered into a contract under this section must—

"(i) except as provided in subparagraph (B)(viii), furnish covered outpatient drugs (as defined in section 1861(t)(2)) for a uniform monthly premium in accordance with the plans's bid under subsection (b)(1);

"(ii) meet or exceed the standards established under subparagraph (B);

"(iii) not provide for cost-sharing in excess of 95 percent of the actuarial value

of the cost-sharing requirements described in section 1834(d);

"(iv) permit enrollment and termination in accordance with the enrollment periods and termination provisions under subsection (e);

"(v) collect and provide such standard information as the Secretary shall prescribe by regulation as necessary to evaluate the performance and quality of such plan, including enrollee satisfaction, to compare such performance and quality with competing plans, and to prepare comparative materials for distribution to beneficiaries under subsection (e)(2);

"(vi) not discriminate against beneficiaries based on their health status, claims experience, medical history, or other factors that are generally related to utilization of health care services; and

"(vii) be guaranteed renewable and—

"(I) may not be canceled or nonrenewed solely on the ground of health status of an individual; and

"(II) may not be canceled or nonrenewed for any reason other than nonpayment of premium or material misrepresentation.

"(B) DEVELOPMENT OF STANDARDS.—Not later then January 1, 1997, the Secretary shall establish standards for medicare drug benefit plans with contracts under this section, [that to the extent possible are consistent with the standards relating to entities that have entered into contracts under section 1876], and which provide that a medicare drug benefit plan—

"(i) demonstrate financial solvency;

"(ii) demonstrate the ability to provide benefits to all potential enrollees throughout the State;

"(iii) shall not engage in marketing or other practices designed to discourage or limit the issuance of a medicare outpatient drug coverage plan to any potential enrollee on the basis of health status, claims experience, medical history, or other factors that are generally related to utilization of health services;

"(iv) may inform individuals eligible to enroll with the plan about the plan only in accordance with procedures and conditions designed to ensure fair marketing practices and may not distribute brochures, application forms, or other promotional or informational material unless—

"(I) at least 45 days before its distribution, the plan has submitted the material to the Secretary for review,

"(II) the material is made available to all individuals eligible to enroll in the plan in the market area, and

"(III) the Secretary has not disapproved the distribution of the material due to a determination that in the Secretary's discretion, the material is materially inaccurate or misleading or otherwise makes a material misrepresentation; and

"(v) estimate the mechanisms through which the medicare drug benefit plan will achieve program savings and efficiencies,

assuring that such savings are achieved in relative proportion to plan outlays and expenditures;

"(vi) provide convenient access to pharmacies for individuals in each zip code region of the State taking into account the special needs of individuals who are enrolled in part B;

"(vii) in addition to the access described in clause (vi), may provide enrollees with a mail-order pharmacy option;

"(viii) may establish a formulary system which ensures that—

"(I) the formulary shall cover at least one covered outpatient drug in each therapeutic class of drugs representing a unique mechanism of action;

"(II) that any covered outpatient drug excluded by the formulary is subject to a prior authorization process similar to the process established under section 1834(d)(7)(C); and

"(III) new drugs which represent a significant therapeutic advance as

defined in section 1927(d)(5) shall be included in the formulary, except that the plan may develop treatment protocols for the use of the drug among individuals enrolled in the plan and shall indicate the treatment protocols to the Secretary;

"(ix) disclose any special relationships or arrangements with drug manufacturers, including ownership arrangements, distribution arrangements, or alliances;

"(x) has standards to assure the appropriate use of outpatient prescription medications, including a program of prospective and retrospective drug use review, consistent with standards under the drug use review program developed by the Secretary under section 1834(d)(7), including for any mail order services operated or used by the plan;

"(xi) has established an appeals process allowing enrollees, physicians and pharmacists a timely and efficient right of appeal on decisions concerning coverage and

payment for covered outpatient prescription drugs under the plan;

"(xii) is able to process claims for outpatient prescription drugs under the program through an on-line real time point of sale system, and has developed a process for processing out-of-area claims;

"(xiii) provides for reasonable payment to the pharmacists for pharmaceuticals, administrative procedures, and pharmacy services provided under the program, including payment for medication management services and other cognitive services; and

"(xiv) considers the special needs of certain populations in taking generic prescription medications, where scientific evidence demonstrates that such generic medications may not be pharmaceutically and therapeutically equivalent to brand name innovator medications.

"(e) ENROLLMENT AND TERMINATION.—

"(1) MEDICARE DRUG BENEFIT PLANS.—During the annual open enrollment period established under subsection (f), any individual who is enrolled

under part B residing in a State may choose enrollment for the next calendar year in a medicare drug benefit plan with which the Secretary has contracted under this section in such State.

"(2) INFORMATION REGARDING COVERED OUTPATIENT DRUG OPTIONS IN THE STATE.—The Secretary shall provide each individual making an enrollment decision during any enrollment period described in subsection (f) with the following information, in comparative form, regarding the medicare drug benefit plans available in the State in which such individual resides, the availability of payment for covered outpatient drugs under section 1834, and the availability of covered outpatient drugs to enrollees of entities with contracts under section 1876:

"(A) The individual's premiums, deductibles, and copayments for coverage of covered outpatient drugs.

"(B) Enrollee restrictions.

"(C) Quality information, including enrollee satisfaction and health outcomes.

"(D) Out-of-area coverage provided in any plan that restricts coverage for covered outpatient drugs to designated pharmacies.

"(E) Coverage of covered outpatient drugs in emergency circumstances in which an enrollee is unable to comply with a plan restriction.

"(F) Appeal rights of enrollees.

"(G) Any other necessary information as determined by the Secretary.

"(f) ENROLLMENT PERIODS.—

"(1) IN GENERAL.—The Secretary shall provide for a 30-day annual open enrollment period, during which all individuals enrolled under part B residing in a State may choose enrollment for the next calendar year in a medicare drug benefit plan in such State.

"(2) PERIOD OF ENROLLMENT.—

"(A) IN GENERAL.—Except as provided in subparagraphs (B), (C), (D), and (E), an individual may not choose another enrollment until the next annual period provided under paragraph (1).

"(B) ENROLLMENT UPON ELIGIBILITY.—The Secretary shall provide an enrollment period of not less than 30 days to any individual beginning 30 days before the date such individual first becomes eligible for benefits under part

A or enrolled under part B only. Such enrollment shall be effective on the date of such eligibility.

"(C) TERMINATION OF PLAN.—If a contract for a medicare drug benefit plan under this section is terminated during any calendar year for any reason (including the financial insolvency of the plan), the Secretary shall provide for an enrollment period of not less than 30 days to any individual enrolled in such plan beginning on the date of such termination.

"(D) INDIVIDUAL NO LONGER IN AREA.—An individual terminating residence in a State may terminate enrollment with the medicare drug benefit plan of such area as of the beginning of the first calendar month following the date on which the request is made for such termination, and the Secretary shall provide for an open enrollment period of 30 days to such individual for enrollment in the new State in which such individual resides beginning on the date of such termination. In the case of an individual's termination of enrollment, the plan shall provide the individual with a copy of the written request for termination of enrollment and a

written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the plan and may not receive medicare covered outpatient drug coverage under this title other than through such plan.

"(E) APPEALS PROCESS.—An enrollee shall have the right to appeal the Secretary for permission to terminate enrollment in the enrollee's medicare drug benefit plan and enroll in another plan available in the State prior to the next annual enrollment period.

"(F) EFFECTIVE DATE OF NEW ENROLLMENT.—Enrollment under subparagraphs (C) or (D) shall be effective 30 days after the end of the enrollment period, or, if the Secretary determines that such date is not feasible, such other date as the Secretary specifies.

["(G) NOTICE OF RIGHT OF TERMINATION.—

"(i) IN GENERAL.—Each medicare drug benefit plan with a contract under this section shall notify individuals eligible to enroll with the plan under this section

and individuals enrolled with the plan under this section that—

"(I) the plan is authorized by law to terminate or refuse to renew the contract, and

"(II) termination or nonrenewal of the contract may result in termination of the enrollments of individuals enrolled with the plan under this section.

"(ii) PLACEMENT OF NOTICE.—The notice required by clause (i) shall be included in any marketing materials described in subsection (d)(1)(B)(iv) that are distributed by a plan to individuals eligible to enroll under this section with the plan.]

[**"(g) PROMPT PAYMENT REQUIREMENT.—**

"(1) IN GENERAL.—A contract under this section shall require the medicare drug benefit plan to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2)) of claims submitted for covered outpatient drugs furnished to individuals pursuant to such contract, if the services or supplies are not furnished under a contract between the plan and the [supplier].

"(2) FAILURE.—In the case of a plan which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with subparagraph (A), the Secretary may provide for direct payment of the amounts owed to suppliers for such covered outpatient drugs furnished to individuals enrolled under this section under the contract. If the Secretary provides for such direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the plan under this section to reflect the amount of the Secretary's payments (and costs incurred by the Secretary in making such payments).]

[THE FOLLOWING SUBSECTION WAS TAKEN FROM A REWRITE OF SECTION 1876 THAT WILL PROBABLY BE GOING INTO THE BILL. DO YOU WANT TO TAKE ANY OF THIS? WHAT IS APPROPRIATE HERE?]

[''(h) DURATION, TERMINATION, EFFECTIVE DATE, AND TERMS OF CONTRACT; POWERS AND DUTIES OF SECRETARY.—

"(1) DURATION AND TERMINATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each contract under this section shall be for a term of 3 years.

"(B) EXCEPTION.—The Secretary may terminate a contract at any time (after such reasonable notice and opportunity for hearing to the medicare drug benefit plan involved as the Secretary may provide in regulations), if the Secretary finds that the plan—

"(i) has failed substantially to carry out the contract,

"(ii) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this section, or

"(iii) no longer substantially complies with the requirements of this section.

"(2) EFFECTIVE DATE.—The effective date of any contract executed pursuant to this section shall be specified in the contract.

"(3) TERMS.—Each contract under this section—

"(A) shall provide that the Secretary, or any person or organization designated by the Secretary—

"(i) shall have the right to inspect or otherwise evaluate—

"(I) the quality, appropriateness, and timeliness of services performed under the contract, and

"(II) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

"(ii) shall have the right to audit and inspect any books and records of the medicare drug benefit plan that pertain—

"(I) to the ability of the plan to bear the risk of potential financial losses, or

"(II) to services performed or determinations of amounts payable under the contract;

"(B) shall require the plan with a contract to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining coverage of covered outpatient drugs under this title, to each individual enrolled under this section with the plan; and

"(C)(i) shall require the plan to comply with subsections (a) and (c) of section 1318 of the Public Health Service Act (relating to disclosure of certain financial information) and with the requirement of section 1301(c)(8) of such Act (relating to liability arrangements to protect members);

"(ii) shall require the plan to provide and supply information determined appropriate by the Secretary in the manner determined appropriate by the Secretary;

"(iii) shall require the plan to notify the Secretary of loans and other special financial arrangements which are made between the plan and subcontractors, affiliates, and related parties; and

"(D) shall contain such other terms and conditions not inconsistent with this section (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

"(4) PERIOD OF DISQUALIFICATION.—The Secretary may not enter into a contract with a medicare drug benefit plan if a previous contract with that plan under this section was terminated at the re-

quest of the plan within the preceding five-year period, except in circumstances which warrant special consideration, as determined by the Secretary.

"(5) DISREGARD OF CERTAIN INCONSISTENT LAWS, ETC.—The authority vested in the Secretary by this section may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

"(6) FINDINGS OF FAILURE.—

"(A) IN GENERAL.—If the Secretary determines that a medicare drug benefit plan with a contract under this section—

"(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

"(ii) imposes premiums on individuals enrolled under this section in excess of the premiums permitted;

"(iii) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this section;

"(iv) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this section) by eligible individuals with the plan whose medical condition or history indicates a need for substantial future medical services;

"(v) misrepresents or falsifies information that is furnished—

"(I) to the Secretary under this section, or

"(II) to an individual or to any other entity under this section;

"(vi) fails to comply with the requirements of subsection (g)(1);

"(vii) in the case of a contract under this section, employs or contracts with any individual or entity that is excluded from

participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services; or

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in subparagraph (B).

"(B) REMEDIES.—The remedies described in this subparagraph are—

"(i) civil money penalties of not more than $ 25,000 for each determination under subparagraph (A) or, with respect to a determination under clause (iv) or (v)(I) of such subparagraph, of not more than $ 100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and

plus, with respect to a determination under subparagraph (A)(iv), $ 15,000 for each individual not enrolled as a result of the practice involved,

"(ii) suspension of enrollment of individuals under this section after the date the Secretary notifies the plan of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

"(iii) suspension of payment to the plan under this section for individuals enrolled after the date the Secretary notifies the plan of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).".]

SEC. 2007. SECONDARY PAYER.

[(a) MAINTENANCE OF EFFORT WITH RESPECT TO PRESCRIPTION DRUGS.—Section 1862(b)(1)(A) (42 U.S.C. 1395y(b)(1)(A)) is amended by adding at the end the following new clause:

"(vi) PRESCRIPTION DRUGS FOR WORKING AGED AND RETIREES.—A group health plan may—

"(I) not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status or with an employer may be eligible to receive covered outpatient drugs under part B, and

"(II) shall provide that any individual age 65 or over (and the individual's spouse age 65 or older) who is covered under the plan by virtue of the individual's current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65,