ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions as follows:

H.R. 58: Mr. ANDREWS, Mr. FLETCHER, and Mr. CUMMINGS.

H.R. 97: Mrs. CAPITO, Mr. VITTER, Mr. COSTELLO, and Mr. WEINER.

H.R. 111: Mr. FATTAH.

H.R. 220: Mr. PEARCE.

H.R. 227: Mr. MCDERMOTT and Mr. OWENS.

H.R. 235: Mr. HASTINGS of Washington, Mr. CRENSHAW, Mr. RYAN of Wisconsin, and Mr. ISAKSON.

H.R. 236: Ms. HARMAN, Mr. BOUCHER, and Mr. ORTIZ.

H.R. 303: Mr. PRICE of North Carolina.

H.R. 369: Mr. EHLERS.

H.R. 438: Mr. JENKINS.

H.R. 439: Mr. OWENS.

H.R. 528: Mr. MCHUGH.

H.R. 531: Mr. WEINER.

H.R. 627: Mr. LARSON of Connecticut.

H.R. 668: Mr. OWENS.

H.R. 687: Mr. JANKLOW and Mr. BOOZMAN.

H.R. 709: Mrs. KELLY.

H.R. 737: Mr. DAVIS of Illinois.

H.R. 785: Mr. MICHAUD.

H.R. 792: Mr. HILL, Mr. JEFFERSON, Mrs. NAPOLITANO, and Ms. ROS-LEHTINEN.

H.R. 817: Mr. GINGREY.

H.R. 832: Mr. GEPHARDT and Ms. BERKLEY.

H.R. 852: Mr. VAN HOLLEN, Mr. SANDERS, and Mr. BLUMENAUER.

H.R. 869: Mr. EVANS.

H.R. 873: Mrs. JO ANN DAVIS of Virginia.

H.R. 898: Mr. STRICKLAND, Mr. GORDON, and Mr. LANTOS.

H.R. 996: Mr. REYES, Mr. DAVIS of Tennessee, Mr. RYUN of Kansas, Ms. HART, Mr. JEFFERSON, Mr. WILSON of South Carolina, Mrs. BLACKBURN, Mr. JENKINS, and Mr. LARSON of Connecticut.

H.R. 1099: Mr. GUTKNECHT.

H.R. 1125: Mr. REHBERG, Mr. BARRETT of South Carolina, and Mr. WELDON of Pennsylvania.

H.R. 1157: Mr. GILCHREST.

H.R. 1167: Mr. UDALL of New Mexico, Mr. MOORE, and Mr. CARTER.

H.R. 1177: Mr. BISHOP of Utah, Mr. PLATTS, and Mr. OWENS.

H.R. 1214: Mr. TERRY, Mr. PALLONE, Mr. PICKERING, Mr. KNOLLENBERG, Mr. GRIJALVA, Mr. RUSH, Mr. MARKEY, and Mr. CLAY.

H.R. 1215: Mr. FROST, Mr. JEFFERSON, Mr. VAN HOLLEN, Mr. RANGEL, and Mr. OWENS.

H.R. 1216: Mr. FROST, Mr. SKELTON, Mr. CASE, Mr. RANGEL, Mr. SANDERS, Mr. RYAN of Ohio, and Mr. OWENS.

H.R. 1217: Mr. CASE, Mr. SANDERS, Mr. RYAN of Ohio, and Mr. OWENS.

H.R. 1218: Mr. DUNCAN, Mr. EVANS, Ms. WOOLSEY, and Mr. OWENS.

H.R. 1238: Mr. MCDERMOTT.

H.R. 1285: Ms. DEGETTE.

H.R. 1296: Ms. WATSON and Mr. OWENS.

H.R. 1310: Mr. WU, Mr. SAM JOHNSON of Texas, Mr. BEAUPREZ, and Mr. BOEHLERT.

H.R. 1323: Mr. JANKLOW.

H.R. 1377: Mr. UDALL of Colorado.

H.R. 1388: Mr. FOLEY.

H.R. 1411: Mr. FROST, Mr. RAHALL, Ms. CORRINE BROWN of Florida, Mr. TAYLOR of Mississippi, Mr. GRIJALVA, Mr. DOYLE, Mr. RANGEL, and Mr. OWENS.

H.R. 1473: Mr. CLYBURN.

H.R. 1479: Mr. SIMMONS and Mr. HOUGHTON.

H.R. 1489: Mr. LUCAS of Kentucky and Mr. SHAW.

H.R. 1499: Ms. BERKLEY and Mrs. CHRISTENSEN.

H.R. 1516: Mr. WILSON of South Carolina.

H.R. 1551: Mr. PAYNE, Mr. PALLONE, and Mrs. CAPPS.

H.R. 1568: Mr. VAN HOLLEN.

H.R. 1585: Ms. HOOLEY of Oregon.

H.R. 1660: Mr. SENSENBRENNER.

H.R. 1671: Mr. NUNES.

H.R. 1677: Mr. LIPINSKI.

H.R. 1693: Mr. LIPINSKI.

H.R. 1695: Ms. CORRINE BROWN of Florida, Mr. CARDIN, Mr. FRANK of Massachusetts, Mr. HINCHEY, Ms. JACKSON-LEE of Texas, Mr. MCGOVERN, Ms. MILLENDER-MCDONALD, Mr. OWENS, and Ms. WOOLSEY.

H.R. 1730: Mr. BLUMENAUER.

H.R. 1751: Mr. CLYBURN.

H.R. 1755: Mr. TURNER of Ohio.

H.R. 1767: Mr. CARTER.

H.R. 1769: Mr. HUNTER and Mr. LIPINSKI.

H.R. 1784: Mr. ISSA, Mr. FLETCHER, and Ms. JACKSON-LEE of Texas.

H.R. 1793: Mr. BARRETT of South Carolina and Mrs. BLACKBURN.

H.R. 1812: Mr. CROWLEY, Mr. GREENWOOD, Mr. BELL, Mr. HONDA, Ms. DEGETTE, Mr. WU, Ms. SOLIS, Mr. MICHAUD, and Mr. PRICE of North Carolina.

H.R. 1813: Mrs. NAPOLITANO, Mr. MCNULTY, Mr. LEWIS of Georgia, Mr. UDALL of Colorado, and Ms. LOFGREN.

H.R. 1838: Mr. UDALL of New Mexico.

H.R. 1871: Ms. WOOLSEY and Mr. OWENS.

H.R. 1873: Mrs. KELLY.

H.R. 1933: Mr. GRIJALVA and Ms. DELAURO.

H.R. 1964: Mr. FRANK of Massachusetts.

H.R. 1991: Mr. OWENS.

H.R. 1998: Ms. BALDWIN, Ms. DEGETTE, Mr. GREEN of Texas, Ms. ESHOO, Mr. FLETCHER, Mr. WALSH, and Mr. COSTELLO.

H.R. 2032: Mr. STUPAK, Ms. KAPTUR, Mr. SULLIVAN, and Mr. CARSON of Oklahoma.

H.R. 2065: Mr. PAUL.

H.R. 2081: Mr. OWENS.

H.R. 2124: Mr. OWENS and Mr. FROST.

H.R. 2127: Mr. KOLBE.

H.R. 2137: Mr. FROST, Mr. GREEN of Texas, Ms. ROS-LEHTINEN, and Mr. OWENS.

H.R. 2163: Mr. EVANS.

H.R. 2164: Mr. GUTIERREZ, Ms. CORRINE BROWN of Florida, Mr. RODRIGUEZ, Mr. STRICKLAND, Mr. EVANS, Mr. FILNER, and Mr. UDALL of New Mexico.

H.R. 2173: Mr. OWENS.

H.R. 2174: Mr. FROST.

H.R. 2176: Mrs. JO ANN DAVIS of Virginia, Mr. OWENS, Mr. JANKLOW, and Mr. BROWN of Ohio.

H.R. 2182: Mr. BELL, Mr. DOYLE, Ms. JACKSON-LEE of Texas, Mr. SANDERS, and Mrs. CHRISTENSEN.

H.R. 2183: Mr. WILSON of South Carolina, Mr. OWENS, Mr. PICKERING, and Mr. CLAY.

H.R. 2198: Mr. CASE.

H.R. 2208: Ms. PRYCE of Ohio.

H.R. 2214: Mr. SMITH of Texas, Mr. BLUMENAUER, Mr. GREEN of Wisconsin, Mr. FOLEY, Mr. CASE, and Mr. MCHUGH.

H.R. 2216: Mrs. CHRISTENSEN, Mr. FROST, and Mr. JANKLOW.

H.R. 2249: Mr. CARSON of Oklahoma and Mr. BEREUTER.

H.R. 2260: Mr. WALSH, Mr. LATHAM, Mr. BOYD, Mr. LAMPSON, Mr. BAKER, Mr. TOWNS, Mr. PLATTS, Mr. LEACH, Mr. FROST, Mr. BURNS, Mr. MOLLOHAN, Mr. GEORGE MILLER of California, Ms. CARSON of Indiana, Mr. GREEN of Texas, Mr. DELAURO, Mr. HOEFFEL, Ms. JACKSON-LEE of Texas, Mr. DELAHUNT, Mr. MENENDEZ, Mr. STUPAK, Mr. MORAN of Virginia, and Mr. WU.

H.R. 2301: Mr. OWENS.

H.R. 2316: Mr. FROST, Mr. LATOURETTE, Ms. SLAUGHTER, Mr. FRANK of Massachusetts, Mr. OWENS, and Mr. LANTOS.

H.R. 2318: Mr. PLATTS.

H.R. 2321: Mr. KILDEE.

H.R. 2323: Ms. KILPATRICK.

H.R. 2329: Ms. SLAUGHTER and Ms. JACKSON-LEE of Texas.

H.R. 2340: Mr. ENGLISH, Mr. MCHUGH, Mr. BARRETT of South Carolina, and Mr. PAUL.

H.R. 2357: Mr. JONES of North Carolina, Ms. BORDALLO, Mrs. BLACKBURN, Mr. FROST, and Mr. DEAL of Georgia.

H.R. 2361: Mr. LEWIS of Kentucky.

H.R. 2379: Mr. UDALL of New Mexico and Mr. BEREUTER.

H.R. 2394: Mr. SPRATT, Mr. ABERCROMBIE, Mr. OWENS, and Mrs. DAVIS of California.

H.R. 2433: Mr. MILLER of Florida and Mr. RYUN of Kansas.

H.R. 2444: Mr. BROWN of South Carolina, Mr. MILLER of Florida, Mr. BURTON of Indiana, and Mr. HENSARLING.

H.R. 2455: Mr. CASE, Ms. KAPTUR, Mr. STARK, Mrs. MALONEY, and Mr. OWENS.

H.R. 2462: Mr. WEXLER, Mr. PRICE of North Carolina, Mr. MCNULTY, and Mr. SPRATT.

H.R. 2474: Ms. MCCARTHY of Missouri.

H.R. 2475: Mr. LEWIS of Kentucky.

H.R. 2490: Mr. ENGEL.

H.R. 2497: Mr. BLUMENAUER.

H.R. 2514: Mr. STUPAK.

H.R. 2524: Ms. CARSON of Indiana.

H.R. 2532: Mrs. CHRISTENSEN.

H.R. 2546: Mr. STARK and Mr. OWENS.

H.R. 2556: Mr. BEAUPREZ, Mr. FRANKS of Arizona, Mr. MCKEON, Mr. TIBERI, and Mrs. MUSGRAVE.

H.R. 2569: Ms. PELOSI, Mr. MICHAUD, Mr. RAHALL, Mrs. MCCARTHY of New York, Mr. TIERNEY, Mr. RYAN of Ohio, Mr. STRICKLAND, Mr. MCNULTY, Mrs. MALONEY, Mr. GRIJALVA, Mr. TURNER of Texas, Mr. SANDLIN, Mr. PALLONE, Mr. HOLDEN, Mr. KIND, Mr. JOHN, Mr. CUMMINGS, Mr. FARR, Mr. WYNN, Ms. WATERS, and Ms. SLAUGHTER.

H.J. Res. 56: Mr. MILLER of Florida and Mr. LEWIS of Kentucky.

H. Con. Res. 30: Mr. WU.

H. Con. Res. 60: Mr. MCINTYRE, Mr. LATOURETTE, Mr. SOUDER, Mr. CHABOT, Mr. WILSON of South Carolina, and Mr. SAXTON.

H. Con. Res. 175: Ms. LINDA T. SANCHEZ of California.

H. Con. Res. 212: Mr. CAPUANO.

H. Con. Res. 215: Mr. CONYERS, Mr. KILDEE, Mr. LEVIN, Mr. MCCOTTER, Mrs. MILLER of Michigan, and Mr. UPTON.

H. Res. 137: Mr. DOYLE and Mr. ALLEN.

H. Res. 144: Ms. WATSON, Mr. BELL, Mr. HOLDEN, Mr. WAXMAN, Ms. WOOLSEY, Mr. MCDERMOTT, and Mr. OWENS.

H. Res. 228: Ms. SOLIS.

H. Res. 234: Mr. CROWLEY and Ms. CARSON of Indiana.

H. Res. 254: Mr. KING of New York and Mr. OWENS.

H. Res. 290: Mr. LANTOS, Mr. SMITH of New Jersey, Mr. HOEFFEL, Mr. DOYLE, Mr. GREEN of Wisconsin, Mr. BELL, Ms. LINDA T. SANCHEZ of California, Ms. WATSON, Mr. BROWN of Ohio, Mr. SHERMAN, Mr. BERMAN, Mr. ENGEL, Mrs. MCCARTHY of New York, Mr. PAYNE, Ms. LEE, Mr. CROWLEY, Mr. SMITH of Michigan, Mr. MEEKS of New York, Mr. WEXLER, Mr. HASTINGS of Florida, and Mr. BURTON of Indiana.

H. Res. 294: Mr. CROWLEY, Ms. BERKLEY, Mr. CARDOZA, Mr. ROTHMAN, Mr. BERMAN, Mr. ACKERMAN, Mr. RAMSTAD, Mr. DEUTSCH, Ms. SCHAKOWSKY, Mr. BURNS, Mr. SCHIFF, Mr. WEINER, Mr. KENNEDY of Minnesota, Mrs. MCCARTHY of New York, Mr. CARDIN, Mr. WEXLER, and Mr. ENGEL.

AMENDMENTS

Under clause 8 of rule XVIII, proposed amendments were submitted as follows:

H.R. 1

OFFERED BY: MR. KING of Iowa

AMENDMENT NO. 1: At the end of title VII add the following new section:

SEC. 735. ENCOURAGEMENT OF PROVISION OF HIGH-QUALITY, COST-EFFECTIVE INPATIENT HOSPITAL SERVICES.

(a) PURPOSE.—The purpose under this section is to encourage the provision of high-

quality, cost-effective health care to beneficiaries under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) by providing incentive payments to hospitals located in States in which high-quality and cost-effective services are being provided in order to finance further quality improvements.

(b) INTENT.—It is the intent of Congress to provide incentives for States to deliver high quality health care and to create incentives that assures medicare recognizes value in the products and services that the program purchases on behalf of medicare beneficiaries.

(c) MECHANISM.—

(1) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this Act, the Secretary shall establish a mechanism under which—

(A) the Secretary provides economic incentives to providers of inpatient hospital services that deliver high-quality health care at low costs in accordance with the methodology established by the Agency for Healthcare Research and Quality under paragraph (2) with a 5 percent add-on bonus payment to providers of inpatient hospital services within the top ten performing States; and

(B) the Secretary necessarily recognizes and includes measurements that factor both the quality of care delivered in a medicare purchasing region or in the event that purchasing regions are not developed, then in a State, to medicare beneficiaries and consumption of resources, including but not limited to labor, technology, capital infrastructure and pharmaceuticals in the delivery of services to medicare beneficiaries under the medicare program under title XVIII of the Social Security Act.

(2) VALUE AND QUALITY RANKING METHODOLOGY.—

(A) IN GENERAL.—The Agency for Healthcare Research and Quality shall establish a value and quality ranking methodology under which the Secretary awards bonus payments to providers of inpatient hospital services located in those States that demonstrate that such providers in the State are providing high value because of the high-quality, cost-effective health care services being provided to medicare beneficiaries.

(B) BASIS.—The methodology established under subparagraph (A) shall be based on the rank and performance on medicare quality indicators published annually in the Journal of the American Medical Association (JAMA) that uses Medicare's current quality of care measures. Cost rankings will be based on the Centers for Medicare and Medicaid Services (CMS) annual report ranking States based on average Medicare spending per recipient for each State.

(d) DEFINITIONS.—In this section:

(1) PROVIDER OF INPATIENT HOSPITAL SERVICES.—The term ''provider of inpatient hospital services'' means any individual or entity that receives payment under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for providing an inpatient hospital services (as defined in section 1861(b) of such Act (42 U.S.C. 1395x(b))).

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

H.R. 1

OFFERED BY: MR. SANDERS

AMENDMENT NO. 2: Amend title I to read as follows:

TITLE I—MEDICARE EXTENSION OF DRUGS TO SENIORS (MEDS)

SEC. 101. FINDINGS.

Congress makes the following findings:

(1) Prescription medicine coverage was not a standard part of health insurance when the medicare program under title XVIII of the Social Security Act was enacted in 1965. Since 1965, however, medicine coverage has become a key component of most private and public health insurance coverage, except for the medicare program.

(2) At least ⅔ of medicare beneficiaries have unreliable, inadequate, or no medicine coverage at all.

(3) Seniors who do not have medicine coverage typically pay, at a minimum, 15 percent more than people with coverage.

(4) Medicare beneficiaries at all income levels lack prescription medicine coverage, with more than ½ of such beneficiaries having incomes greater than 150 percent of the poverty line.

(5) The number of private firms offering retiree health coverage is declining.

(6) Medigap premiums for medicines are too expensive for most beneficiaries and are highest for older senior citizens, who need prescription medicine coverage the most and typically have the lowest incomes.

(7) All medicare beneficiaries should have access to a voluntary, reliable, affordable, and defined outpatient medicine benefit as part of the medicare program that assists with the high cost of prescription medicines and protects them against excessive out-of-pocket costs.

SEC. 102. PRESCRIPTION MEDICINE BENEFIT PROGRAM.

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended—

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

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

''PART D—PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND DISABLED

''ESTABLISHMENT OF PRESCRIPTION MEDICINE BENEFIT PROGRAM FOR THE AGED AND DISABLED

''SEC. 1860. (a) IN GENERAL.—There is established a voluntary insurance program to provide prescription medicine benefits, including pharmacy services, in accordance with the provisions of this part for individuals who are aged or disabled or have end-stage renal disease and who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

''(b) SUNSET FOR EXCESSIVE COSTS.—Notwithstanding any other provision of law, the Secretary shall determine the net amount of expenditures resulting from the enactment of the Medicare Prescription Drug and Modernization Act of 2003 during the period beginning with fiscal year 2004 and ending with fiscal year 2013, including the provisions of this part. If the Secretary determines that such net expenditures during such period (without regard to this subsection) will exceed $400,000,000,000, then the Secretary shall provide for the termination of the program under this part as of such date as will assure that such net expenditures do not exceed $400,000,000,000 during such period.

''SCOPE OF BENEFITS

''SEC. 1860A. (a) IN GENERAL.—The benefits provided to an individual enrolled in the insurance program under this part shall consist of—

''(1) payments made, in accordance with the provisions of this part, for covered prescription medicines (as specified in subsection (b)) dispensed by any pharmacy participating in the program under this part (and, in circumstances designated by the Secretary, by a nonparticipating pharmacy), including any specifically named medicine prescribed for the individual by a qualified health care professional regardless of whether the medicine is included in any formulary established under this part if such medicine is certified as medically necessary by such health care professional (except that the Secretary shall encourage to the maximum extent possible the substitution and use of lower-cost generics), up to the benefit limits specified in section 1860B; and

''(2) charging by pharmacies of the negotiated price—

''(A) for all covered prescription medicines, without regard to such benefit limit; and

''(B) established with respect to any drugs or classes of drugs described in subparagraphs (A), (B), (D), (E), or (F) of section 1927(d)(2) that are available to individuals receiving benefits under this title.

''(b) COVERED PRESCRIPTION MEDICINES.—

''(1) IN GENERAL.—Covered prescription medicines, for purposes of this part, include all prescription medicines (as defined in section 1860K(1)), including smoking cessation agents, except as otherwise provided in this subsection.

''(2) EXCLUSIONS FROM COVERAGE.—Covered prescription medicines shall not include drugs or classes of drugs described in subparagraphs (A) through (D) and (F) through (H) of section 1927(d)(2) unless—

''(A) specifically provided otherwise by the Secretary with respect to a drug in any of such classes; or

''(B) a drug in any of such classes is certified to be medically necessary by a health care professional.

''(3) EXCLUSION OF PRESCRIPTION MEDICINES TO THE EXTENT COVERED UNDER PART A OR B.—A medicine prescribed for an individual that would otherwise be a covered prescription medicine under this part shall not be so considered to the extent that payment for such medicine is available under part A or B, including all injectable drugs and biologicals for which payment was made or should have been made by a carrier under section 1861(s)(2) (A) or (B) as of the date of enactment of the Medicare Extension of Drugs to Seniors (MEDS) Act of 2003. Medicines otherwise covered under part A or B shall be covered under this part to the extent that benefits under part A or B are exhausted.

''(4) STUDY ON INCLUSION OF HOME INFUSION THERAPY SERVICES.—Not later than one year after the date of the enactment of the Medicare Extension of Drugs to Seniors (MEDS) Act of 2003, the Secretary shall submit to Congress a legislative proposal for the delivery of home infusion therapy services under this title and for a system of payment for such a benefit that coordinates items and services furnished under part B and under this part.

''PAYMENT OF BENEFITS; BENEFIT LIMITS

''SEC. 1860B. (a) PAYMENT OF BENEFITS.—

''(1) IN GENERAL.—There shall be paid from the Prescription Medicine Insurance Account within the Supplementary Medical Insurance Trust Fund, in the case of each individual who is enrolled in the insurance program under this part and who purchases covered prescription medicines in a calendar year—

''(A) with respect to costs incurred for covered prescription medicine furnished during a year, before the individual has incurred out-of-pocket expenses under this subsection equal to the catastrophic out-of-pocket limit specified in subsection (b), an amount equal to the applicable percentage (specified in paragraph (2)) of the negotiated price for each such covered prescription medicine or such higher percentage as is proposed under section 1860G(b)(7); and

''(B) with respect to costs incurred for covered prescription medicine furnished during

a year, after the individual has incurred out-of-pocket expenses under this subsection equal to the catastrophic out-of-pocket limit specified in subsection (b), an amount equal to 100 percent of the negotiated price for each such covered prescription medicine.

''(2) APPLICABLE PERCENTAGE.—The applicable percentage specified in this paragraph is 80 percent or such higher percentage as is proposed under section 1860G(b)(7), if the Secretary finds that such higher percentage will not increase aggregate costs to the Prescription Medicine Insurance Account.

''(b) CATASTROPHIC LIMIT ON OUT-OF-POCKET EXPENSES.—

''(1) IN GENERAL.—The catastrophic limit on out-of-pocket expenses specified in this subsection for—

''(A) for each of calendar years 2005 and 2006, $2,000; and

''(B) subject to paragraph (2), for calendar year 2007 and each subsequent calendar year is equal the limit for the preceding year under this paragraph adjusted by the sustainable growth rate percentage (determined under section 1861I(b)) for the year involved.

''(2) ROUNDING.—Any amount determined under paragraph (1)(E) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''ELIGIBILITY AND ENROLLMENT

''SEC. 1860C. (a) ELIGIBILITY.—Every individual who, in or after 2005, is entitled to hospital insurance benefits under part A or enrolled in the medical insurance program under part B is eligible to enroll, in accordance with the provisions of this section, in the insurance program under this part, during an enrollment period prescribed in or under this section, in such manner and form as may be prescribed by regulations.

''(b) ENROLLMENT.—

''(1) IN GENERAL.—Each individual who satisfies subsection (a) shall be enrolled (or eligible to enroll) in the program under this part in accordance with the provisions of section 1837, as if that section applied to this part, except as otherwise explicitly provided in this part.

''(2) SINGLE ENROLLMENT PERIOD.—Except as provided in section 1837(i) (as such section applies to this part), 1860E, or 1860H(e), or as otherwise explicitly provided, no individual shall be entitled to enroll in the program under this part at any time after the initial enrollment period without penalty, and in the case of all other late enrollments, the Secretary shall develop a late enrollment penalty for the individual that fully recovers the additional actuarial risk involved providing coverage for the individual.

''(3) SPECIAL ENROLLMENT PERIOD FOR 2005.—

''(A) IN GENERAL.—An individual who first satisfies subsection (a) in 2005 may, at any time on or before December 31, 2005—

''(i) enroll in the program under this part; and

''(ii) enroll or reenroll in such program after having previously declined or terminated enrollment in such program.

''(B) EFFECTIVE DATE OF COVERAGE.—An individual who enrolls under the program under this part pursuant to subparagraph (A) shall be entitled to benefits under this part beginning on the first day of the month following the month in which such enrollment occurs.

''(c) PERIOD OF COVERAGE.—

''(1) IN GENERAL.—Except as otherwise provided in this part, an individual's coverage under the program under this part shall be effective for the period provided in section 1838, as if that section applied to the program under this part.

''(2) PART D COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PARTS A AND B.—In addition to the causes of termination specified in section 1838, an individual's coverage under this part shall be terminated when the individual retains coverage under neither the program under part A nor the program under part B, effective on the effective date of termination of coverage under part A or (if later) under part B.

''PREMIUMS

''SEC. 1860D. (a) ANNUAL ESTABLISHMENT OF MONTHLY PREMIUM RATES.—

''(1) IN GENERAL.—The Secretary shall, during September of 2004 and of each succeeding year, determine and promulgate a monthly premium rate for the succeeding year in accordance with the provisions of this subsection.

''(2) INITIAL PREMIUMS.—For months in 2005, the monthly premium rate under this subsection shall be—

''(A) $24, in the case of premiums paid by an individual enrolled in the program under this part; and

''(B) $32, in the case of premiums paid for such an individual by a former employer (as defined in section 1860H(f)(2)).

''(3) SUBSEQUENT YEARS.—

''(A) IN GENERAL.—For months in a year after 2005, the monthly premium under this subsection shall be (subject to subparagraph (B)) the monthly premium (computed under this subsection without regard to subparagraph (B)) for the previous year increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient medicines in the United States for medicare beneficiaries, as estimated and published by the Secretary in September before the year and for the year involved.

''(B) ROUNDING.—The monthly premium determined under subparagraph (A) shall be rounded to the nearest multiple of 10 cents if it is not a multiple of 10 cents.

''(C) PUBLICATION OF ASSUMPTIONS.—The Secretary shall publish, together with the promulgation of the monthly premium rates under this paragraph, a statement setting forth the actuarial assumptions and bases employed in arriving at the monthly premium under subparagraph (A).

''(b) PAYMENT OF PREMIUMS.—

''(1) PAYMENTS BY DEDUCTION FROM SOCIAL SECURITY, RAILROAD RETIREMENT BENEFITS, OR BENEFITS ADMINISTERED BY OPM.—

''(A) DEDUCTION FROM BENEFITS.—In the case of an individual who is entitled to or receiving benefits as described in subsection (a), (b), or (d) of section 1840, premiums payable under this part shall be collected by deduction from such benefits at the same time and in the same manner as premiums payable under part B are collected pursuant to section 1840.

''(B) TRANSFERS TO PRESCRIPTION MEDICINE INSURANCE ACCOUNT.—The Secretary of the Treasury shall, from time to time, but not less often than quarterly, transfer premiums collected pursuant to subparagraph (A) to the Prescription Medicine Insurance Account from the appropriate funds and accounts described in subsections (a)(2), (b)(2), and (d)(2) of section 1840, on the basis of the certifications described in such subsections. The amounts of such transfers shall be appropriately adjusted to the extent that prior transfers were too great or too small.

''(2) DIRECT PAYMENTS TO SECRETARY.—

''(A) ADDITIONAL PAYMENT BY ENROLLEE.—An individual to whom paragraph (1) applies (other than an individual receiving benefits as described in section 1840(d)) and who estimates that the amount that will be available for deduction under such paragraph for any premium payment period will be less than the amount of the monthly premiums for such period may (under regulations) pay to the Secretary the estimated balance, or such greater portion of the monthly premium as the individual chooses.

''(B) PAYMENTS BY OTHER ENROLLEES.—An individual enrolled in the insurance program under this part with respect to whom none of the preceding provisions of this subsection applies (or to whom section 1840(c) applies) shall pay premiums to the Secretary at such times and in such manner as the Secretary shall by regulations prescribe.

''(C) DEPOSIT OF PREMIUMS.—Amounts paid to the Secretary under this paragraph shall be deposited in the Treasury to the credit of the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund.

''(c) CERTAIN LOW-INCOME INDIVIDUALS.—For rules concerning premiums for certain low-income individuals, see section 1860E.

''SPECIAL ELIGIBILITY, ENROLLMENT, AND COPAYMENT RULES FOR LOW-INCOME INDIVIDUALS

''SEC. 1860E. (a) STATE AGREEMENTS FOR COVERAGE.—

''(1) IN GENERAL.—The Secretary shall, at the request of a State, enter into an agreement with the State under which all individuals described in paragraph (2) are enrolled in the program under this part, without regard to whether any such individual has previously declined the opportunity to enroll in such program.

''(2) ELIGIBILITY GROUPS.—The individuals described in this paragraph, for purposes of paragraph (1), are individuals who satisfy section 1860C(a) and who are—

''(A)(i) eligible individuals within the meaning of section 1843; and

''(ii) in a coverage group or groups permitted under section 1843 (as selected by the State and specified in the agreement); or

''(B) qualified medicare medicine beneficiaries (as defined in subsection (e)(1)).

''(3) COVERAGE PERIOD.—The period of coverage under this part of an individual enrolled under an agreement under this subsection shall be as follows:

''(A) INDIVIDUALS ELIGIBLE (AT STATE OPTION) FOR PART B BUY-IN.—In the case of an individual described in subsection (a)(2)(A), the coverage period shall be the same period that applies (or would apply) pursuant to section 1843(d).

''(B) QUALIFIED MEDICARE MEDICINE BENEFICIARIES.—In the case of an individual described in subsection (a)(2)(B)—

''(i) the coverage period shall begin on the latest of—

''(I) January 1, 2005;

''(II) the first day of the third month following the month in which the State agreement is entered into; or

''(III) the first day of the first month following the month in which the individual satisfies section 1860C(a); and

''(ii) the coverage period shall end on the last day of the month in which the individual is determined by the State to have become ineligible for medicare medicine cost-sharing.

''(4) ALTERNATIVE ENROLLMENT METHODS.—In the process of enrolling low-income individuals under this part, the Secretary shall use the system provided under section 154 of the Social Security Act Amendments of 1994 for newly eligible medicare beneficiaries and shall apply a similar system for other medicare beneficiaries. Such system shall use existing Federal government databases to identify eligibility. Such system shall not require that beneficiaries apply for, or enroll through, State medicaid systems in order to obtain low-income assistance described in this section.

''(b) SPECIAL PART D ENROLLMENT OPPORTUNITY FOR INDIVIDUALS LOSING MEDICAID ELIGIBILITY.—In the case of an individual who—

''(1) satisfies section 1860C(a); and

''(2) loses eligibility for benefits under the State plan under title XIX after having been enrolled under such plan or having been determined eligible for such benefits;

the Secretary shall provide an opportunity for enrollment under the program under this part during the period that begins on the date that such individual loses such eligibility and ends on the date specified by the Secretary.

''(c) STATE OPTION TO BUY-IN DUALLY ELIGIBLE INDIVIDUALS.—

''(1) COVERAGE OF PREMIUMS AS MEDICAL ASSISTANCE.—For purposes of applying the second sentence of section 1905(a), any reference to premiums under part B shall be considered to include a reference to premiums under this part.

''(2) STATE COMMITMENT TO CONTINUE PARTICIPATION IN PART D AFTER BENEFIT LIMIT REACHED.—As a condition of additional funding to a State under subsection (d), the State, in its State plan under title XIX, shall provide that in the case of any individual whose eligibility for medical assistance under title XIX is not limited to medicare cost-sharing and for whom the State elects to pay premiums under this part pursuant to this section, the State will purchase all prescription medicines for such individual in accordance with the provisions of this part without regard to whether the benefit limit for such individual under section 1860B(b) has been reached.

''(3) MEDICARE COST-SHARING REQUIRED FOR QUALIFIED MEDICARE BENEFICIARIES.—In applying title XIX, the term 'medicare cost-sharing' (as defined in section 1905(p)(3)) is deemed to include—

''(A) premiums under section 1860D; and

''(B) the difference between the amount that is paid under section 1860B and the amount that would be paid under such section if any reference to '80 percent' in subsection (a)(2) of such section were deemed a reference to '100 percent' (or, if the Secretary approves a higher percentage under such section, if such percentage were deemed to be 100 percent).

''(d) PAYMENT TO STATES FOR COVERAGE OF CERTAIN MEDICARE COST-SHARING.—

''(1) IN GENERAL.—The Secretary shall provide for payment under this subsection to each State that provides for—

''(A) medicare cost-sharing described in section 1905(p)(3)(A)(ii) for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) and is at least 120 percent, but less than 135 percent, of the official poverty line (referred to in such section) for a family of the size involved and who are not otherwise eligible for medical assistance under the State plan; and

''(B) medicare medicine cost-sharing (as defined in subsection (e)(2)) for qualified medicare medicine beneficiaries described in subsection (e)(1).

''(2) AMOUNT OF PAYMENT.—The amount of payment under paragraph (1) shall equal 100 percent of the cost-sharing described in such paragraph, except that, in the case of an individual whose eligibility for medical assistance under title XIX is not limited to medicare cost-sharing or medicare medicine cost-sharing, the amount of payment under paragraph (1)(B) shall be equal to the Federal medical assistance percentage described in section 1905(b)) of amounts as expended for such cost-sharing.

''(3) METHOD OF PAYMENT; RELATION TO OTHER PAYMENTS.—Amounts shall be paid to States under this subsection in a manner similar to that provided under section 1903(d). Payments under this subsection shall be made in lieu of any payments that otherwise may be made for medical assistance provided under section 1902(a)(10)(E)(iv).

''(4) TREATMENT OF TERRITORIES.—

''(A) IN GENERAL.—Subject to subparagraph (B), this subsection shall not apply to States other than the 50 States and the District of Columbia.

''(B) PAYMENTS.—In the case of a State (other than the 50 States and the District of Columbia) that develops and implements a plan of assistance for pharmaceuticals provided to low-income medicare beneficiaries, the Secretary shall provide for payment to the State in an amount that is reasonable in relation to the payment levels provided to other States under paragraph (2).

''(e) DEFINITIONS; SPECIAL RULES.—For purposes of this section:

''(1) QUALIFIED MEDICARE MEDICINE BENEFICIARY.—The term 'qualified medicare medicine beneficiary' means an individual—

''(A) who is entitled to hospital insurance benefits under part A (including an individual entitled to such benefits pursuant to an enrollment under section 1818, but not including an individual entitled to such benefits only pursuant to an enrollment under section 1818A);

''(B) whose income (as determined under section 1612 for purposes of the supplemental security income program, except as provided in section 1905(p)(2)(D)) is above 100 percent but below 150 percent of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; and

''(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual may have and obtain benefits under that program.

''(2) MEDICARE MEDICINE COST-SHARING.—The term 'medicare medicine cost-sharing' means the following costs incurred with respect to a qualified medicare medicine beneficiary, without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under a State plan under title XIX:

''(A) In the case of a qualified medicare medicine beneficiary whose income (as determined under paragraph (1)) is less than 135 percent of the official poverty line—

''(i) premiums under section 1860D; and

''(ii) the difference between the amount that is paid under section 1860B and the amount that would be paid under such section if any reference to '50 percent' therein were deemed a reference to '100 percent' (or, if the Secretary approves a higher percentage under such section, if such percentage were deemed to be 100 percent).

''(B) In the case of a qualified medicare medicine beneficiary whose income (as determined under paragraph (1)) is at least 135 percent but less than 150 percent of the official poverty line, a percentage of premiums under section 1860D, determined on a linear sliding scale ranging from 100 percent for individuals with incomes at 135 percent of such line to 0 percent for individuals with incomes at 150 percent of such line.

''(3) STATE.—The term 'State' has the meaning given such term under section 1101(a) for purposes of title XIX.

''(4) TREATMENT OF DRUGS PURCHASED.—The provisions of section 1927 shall not apply to prescription drugs purchased under this part pursuant to an agreement with the Secretary under this section (including any drugs so purchased after the limit under section 1860B(b) has been exceeded).

''PRESCRIPTION MEDICINE INSURANCE ACCOUNT

''SEC. 1860F. (a) ESTABLISHMENT.—There is created within the Federal Supplemental Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Prescription Medicine Insurance Account' (in this section referred to as the 'Account').

''(b) AMOUNTS IN ACCOUNT.—

''(1) IN GENERAL.—The Account shall consist of—

''(A) such amounts as may be deposited in, or appropriated to, such fund as provided in this part; and

''(B) such gifts and bequests as may be made as provided in section 201(i)(1).

''(2) SEPARATION OF FUNDS.—Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplemental Medical Insurance Trust Fund.

''(c) PAYMENTS FROM ACCOUNT.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make the payments provided for by this part, and the payments with respect to administrative expenses in accordance with section 201(g).

''ADMINISTRATION OF BENEFITS

''SEC. 1860G. (a) THROUGH CMS.—The Secretary shall provide for administration of the benefits under this part through the Centers for Medicare & Medicaid Services in accordance with the provisions of this section. The Administrator of such Centers may enter into contracts with carriers to administer this part in the same manner as the Administrator enters into such contracts to administer part B. Any such contract shall be separate from any contract under section 1842.

''(b) ADMINISTRATION FUNCTIONS.—In carrying out this part, the Administrator (or a carrier under a contract with the Administrator) shall (or in the case of the function described in paragraph (9), may) perform the following functions:

''(1) PARTICIPATION AGREEMENTS, PRICES, AND FEES.—

''(A) NEGOTIATED PRICES.—Establish, through negotiations with medicine manufacturers and wholesalers and pharmacies, a schedule of prices for covered prescription medicines.

''(B) AGREEMENTS WITH PHARMACIES.—Enter into participation agreements under subsection (c) with pharmacies, that include terms that—

''(i) secure the participation of sufficient numbers of pharmacies to ensure convenient access (including adequate emergency access);

''(ii) permit the participation of any pharmacy in the service area that meets the participation requirements described in subsection (c); and

''(iii) allow for reasonable dispensing and consultation fees for pharmacies.

''(C) LISTS OF PRICES AND PARTICIPATING PHARMACIES.—Ensure that the negotiated prices established under subparagraph (A) and the list of pharmacies with agreements under subsection (c) are regularly updated and readily available to health care professionals authorized to prescribe medicines, participating pharmacies, and enrolled individuals.

''(2) TRACKING OF COVERED ENROLLED INDIVIDUALS.—Maintain accurate, updated records of all enrolled individuals (other than individuals enrolled in a plan under part C).

''(3) PAYMENT AND COORDINATION OF BENEFITS.—

''(A) PAYMENT.—

''(i) Administer claims for payment of benefits under this part and encourage, to the maximum extent possible, use of electronic means for the submissions of claims.

''(ii) Determine amounts of benefit payments to be made.

''(iii) Receive, disburse, and account for funds used in making such payments, including through the activities specified in the provisions of this paragraph.

''(B) COORDINATION.—Coordinate with other private benefit providers, pharmacies, and other relevant entities as necessary to ensure appropriate coordination of benefits with respect to enrolled individuals, including coordination of access to and payment for covered prescription medicines according to an individual's in-service area plan provisions, when such individual is traveling outside the home service area, and under such other circumstances as the Secretary may specify.

''(C) EXPLANATION OF BENEFITS.—Furnish to enrolled individuals an explanation of benefits in accordance with section 1806(a), and a notice of the balance of benefits remaining for the current year, whenever prescription medicine benefits are provided under this part (except that such notice need not be provided more often than monthly).

''(4) RULES RELATING TO PROVISION OF BENEFITS.—

''(A) IN GENERAL.—In providing benefits under this part, the Secretary (directly or through contracts) shall employ mechanisms to provide benefits economically, including the use of—

''(i) formularies (consistent with subparagraph (B));

''(ii) automatic generic medicine substitution (unless the physician specifies otherwise, in which case a 30-day prescription may be dispensed pending a consultation with the physician on whether a generic substitute can be dispensed in the future);

''(iii) tiered copayments (which may include copayments at a rate lower than 20 percent) to encourage the use of the lowest cost, on-formulary product in cases where there is no restrictive prescription (described in subparagraph (D)(i)); and

''(iv) therapeutic interchange.

''(B) REQUIREMENTS WITH RESPECT TO FORMULARIES.—If a formulary is used to contain costs under this part—

''(i) use an advisory committee (or a therapeutics committee) comprised of licensed practicing physicians, pharmacists, and other health care practitioners to develop and manage the formulary;

''(ii) include in the formulary at least 1 medicine from each therapeutic class and, if available, a generic equivalent thereof; and

''(iii) disclose to current and prospective enrollees and to participating providers and pharmacies, the nature of the formulary restrictions, including information regarding the medicines included in the formulary and any difference in cost-sharing amounts.

''(C) CONSTRUCTION.—Nothing in this subsection shall be construed to prevent the Secretary (directly or through contracts) from using incentives (including a lower beneficiary coinsurance) to encourage enrollees to select generic or other cost-effective medicines, so long as—

''(i) such incentives are designed not to result in any increase in the aggregate expenditures under the Federal Medicare Prescription Medicine Trust Fund;

''(ii) the average coinsurance charged to all beneficiaries by the Secretary (directly or through contractors) shall seek to approximate (but in no case exceed) 20 percent for on-formulary medicines;

''(iii) a beneficiary's coinsurance shall be no greater than 20 percent if the prescription is a restrictive prescription; and

''(iv) the reimbursement for a prescribed nonformulary medicine without a restrictive prescription in no case shall be more than the lowest reimbursement for a formulary medicine in the therapeutic class of the prescribed medicine.

''(D) RESTRICTIVE PRESCRIPTION.—For purposes of this section:

''(i) WRITTEN PRESCRIPTIONS.—In the case of a written prescription for a medicine, it is a restrictive prescription only if the prescription indicates, in the writing of the physician or other qualified person prescribing the medicine and with an appropriate phrase (such as 'brand medically necessary') recognized by the Secretary, that a particular medicine product must be dispensed based upon a belief by the physician or person prescribing the medicine that the particular medicine will provide even marginally superior therapeutic benefits to the individual for whom the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual.

''(ii) TELEPHONE PRESCRIPTIONS.—In the case of a prescription issued by telephone for a medicine, it is a restrictive prescription only if the prescription cannot be longer than 30 days and the physician or other qualified person prescribing the medicine (through use of such an appropriate phrase) states that a particular medicine product must be dispensed, and the physician or other qualified person submits to the pharmacy involved, within 30 days after the date of the telephone prescription, a written confirmation from the physician or other qualified person prescribing the medicine and which indicates with such appropriate phrase that the particular medicine product was required to have been dispensed based upon a belief by the physician or person prescribing the medicine that the particular medicine will provide even marginally superior therapeutic benefits to the individual for whom the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual. Such written confirmation is required to refill the prescription.

''(iii) REVIEW OF RESTRICTIVE PRESCRIPTIONS.—The advisory committee (established under subparagraph (B)(i)) may decide to review a restrictive prescription and, if so, it may approve or disapprove such restrictive prescription. It may not disapprove such restrictive prescription unless it finds that there is no literature approved by the Food and Drug Administration that supports a determination that the particular medicine provides even marginally superior therapeutic benefits to the individual for whom the medicine is prescribed or would have marginally fewer adverse reactions with respect to such individual. If it disapproves, upon request of the prescribing physician or the enrollee, the committee must provide for a review by an independent contractor of such decision within 48 hours of the time of submission of the prescription, to determine whether the prescription is an eligible benefit under this part. The Secretary shall ensure that independent contractors so used are completely independent of the contractor or its advisory committee.

''(5) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE.—Have in place effective cost and utilization management, drug utilization review, quality assurance measures, and systems to reduce medical errors, including at least the following, together with such additional measures as the Administrator may specify:

''(A) DRUG UTILIZATION REVIEW.—A drug utilization review program conforming to the standards provided in section 1927(g)(2) (with such modifications as the Administrator finds appropriate).

''(B) FRAUD AND ABUSE CONTROL.—Activities to control fraud, abuse, and waste, including prevention of diversion of pharmaceuticals to the illegal market.

''(C) MEDICATION THERAPY MANAGEMENT.—

''(i) IN GENERAL.—A program of medicine therapy management and medication administration that is designed to assure that covered outpatient medicines are appropriately used to achieve therapeutic goals and reduce the risk of adverse events, including adverse drug interactions.

''(ii) ELEMENTS.—Such program may include—

''(I) enhanced beneficiary understanding of such appropriate use through beneficiary education, counseling, and other appropriate means; and

''(II) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other appropriate means.

''(iii) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed pharmacists and physicians.

''(iv) CONSIDERATIONS IN PHARMACY FEES.—There shall be taken into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program.

''(6) EDUCATION AND INFORMATION ACTIVITIES.—Have in place mechanisms for disseminating educational and informational materials to enrolled individuals and health care providers designed to encourage effective and cost-effective use of prescription medicine benefits and to ensure that enrolled individuals understand their rights and obligations under the program.

''(7) BENEFICIARY PROTECTIONS.—

''(A) CONFIDENTIALITY OF HEALTH INFORMATION.—Have in effect systems to safeguard the confidentiality of health care information on enrolled individuals, which comply with section 1106 and with section 552a of title 5, United States Code, and meet such additional standards as the Administrator may prescribe.

''(B) GRIEVANCE AND APPEAL PROCEDURES.—Have in place such procedures as the Administrator may specify for hearing and resolving grievances and appeals, including expedited appeals, brought by enrolled individuals against the Administrator or a pharmacy concerning benefits under this part, which shall include procedures equivalent to those specified in subsections (f) and (g) of section 1852.

''(8) RECORDS, REPORTS, AND AUDITS.—

''(A) RECORDS AND AUDITS.—Maintain adequate records, and afford the Administrator access to such records (including for audit purposes).

''(B) REPORTS.—Make such reports and submissions of financial and utilization data as the Administrator may require taking into account standard commercial practices.

''(9) PROPOSAL FOR ALTERNATIVE COINSURANCE AMOUNT.—

''(A) SUBMISSION.—The Administrator may provide for increased Government cost-sharing for generic prescription medicines, prescription medicines on a formulary, or prescription medicines obtained through mail order pharmacies.

''(B) CONTENTS.—The proposal submitted under subparagraph (A) shall contain evidence that such increased cost-sharing would not result in an increase in aggregate costs to the Account, including an analysis of differences in projected drug utilization patterns by beneficiaries whose cost-sharing would be reduced under the proposal and those making the cost-sharing payments that would otherwise apply.

''(10) OTHER REQUIREMENTS.—Meet such other requirements as the Secretary may specify.

The Administrator shall negotiate a schedule of prices under paragraph (1)(A), except that nothing in this sentence shall prevent a carrier under a contract with the Administrator from negotiating a lower schedule of prices for covered prescription medicines.

''(c) PHARMACY PARTICIPATION AGREEMENTS.—

''(1) IN GENERAL.—A pharmacy that meets the requirements of this subsection shall be eligible to enter an agreement with the Administrator to furnish covered prescription medicines and pharmacists' services to enrolled individuals.

''(2) TERMS OF AGREEMENT.—An agreement under this subsection shall include the following terms and requirements:

''(A) LICENSING.—The pharmacy and pharmacists shall meet (and throughout the contract period will continue to meet) all applicable State and local licensing requirements.

''(B) LIMITATION ON CHARGES.—Pharmacies participating under this part shall not charge an enrolled individual more than the negotiated price for an individual medicine as established under subsection (b)(1), regardless of whether such individual has attained the benefit limit under section 1860B(b), and shall not charge an enrolled individual more than the individual's share of the negotiated price as determined under the provisions of this part.

''(C) PERFORMANCE STANDARDS.—The pharmacy and the pharmacist shall comply with performance standards relating to—

''(i) measures for quality assurance, reduction of medical errors, and participation in the drug utilization review program described in subsection (b)(3)(A);

''(ii) systems to ensure compliance with the confidentiality standards applicable under subsection (b)(5)(A); and

''(iii) other requirements as the Secretary may impose to ensure integrity, efficiency, and the quality of the program.

''(D) DISCLOSURE OF PRICE OF GENERIC MEDICINE.—A pharmacy participating under this part shall inform an enrollee of the difference in price between generic and non-generic equivalents.

''(d) SPECIAL ATTENTION TO RURAL AND HARD-TO-SERVE AREAS.—

''(1) IN GENERAL.—The Secretary shall ensure that all beneficiaries have access to the full range of pharmaceuticals under this part, and shall give special attention to access, pharmacist counseling, and delivery in rural and hard-to-serve areas (as the Secretary may define by regulation).

''(2) SPECIAL ATTENTION DEFINED.—For purposes of paragraph (1), the term 'special attention' may include bonus payments to retail pharmacists in rural areas and any other actions the Secretary determines are necessary to ensure full access to rural and hard-to-serve beneficiaries.

''(3) GAO REPORT.—Not later than 2 years after the implementation of this part the Comptroller General of the United States shall submit to Congress a report on the access of medicare beneficiaries to pharmaceuticals and pharmacists' services in rural and hard-to-serve areas under this part together with any recommendations of the Comptroller General regarding any additional steps the Secretary may need to take to ensure the access of medicare beneficiaries to pharmaceuticals and pharmacists' services in such areas under this part.

''(e) INCENTIVES FOR COST AND UTILIZATION MANAGEMENT AND QUALITY IMPROVEMENT.—The Secretary is authorized to include in a contract awarded under subsection (b) with a carrier such incentives for cost and utilization management and quality improvement as the Secretary may deem appropriate, including—

''(1) bonus and penalty incentives to encourage administrative efficiency;

''(2) incentives under which carriers share in any benefit savings achieved;

''(3) risk-sharing arrangements related to initiatives to encourage savings in benefit payments;

''(4) financial incentives under which savings derived from the substitution of generic medicines in lieu of non-generic medicines are made available to carriers, pharmacies, and the Prescription Medicine Insurance Account; and

''(5) any other incentive that the Secretary deems appropriate and likely to be effective in managing costs or utilization.

''EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-BASED RETIREE MEDICINE COVERAGE

''SEC. 1860H. (a) PROGRAM AUTHORITY.—The Secretary shall develop and implement a program under this section called the 'Employer Incentive Program' that encourages employers and other sponsors of employment-based health care coverage to provide adequate prescription medicine benefits to retired individuals and to maintain such existing benefit programs, by subsidizing, in part, the sponsor's cost of providing coverage under qualifying plans.

''(b) SPONSOR REQUIREMENTS.—In order to be eligible to receive an incentive payment under this section with respect to coverage of an individual under a qualified retiree prescription medicine plan (as defined in subsection (f)(3)), a sponsor shall meet the following requirements:

''(1) ASSURANCES.—The sponsor shall—

''(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered by the sponsor is a qualified retiree prescription medicine plan, and will remain such a plan for the duration of the sponsor's participation in the program under this section; and

''(B) guarantee that it will give notice to the Secretary and covered retirees—

''(i) at least 120 days before terminating its plan; and

''(ii) immediately upon determining that the actuarial value of the prescription medicine benefit under the plan falls below the actuarial value of the insurance benefit under this part.

''(2) OTHER REQUIREMENTS.—The sponsor shall provide such information, and comply with such requirements, including information requirements to ensure the integrity of the program, as the Secretary may find necessary to administer the program under this section.

''(c) INCENTIVE PAYMENT.—

''(1) IN GENERAL.—A sponsor that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall have payment made by the Secretary on a quarterly basis (to the sponsor or, at the sponsor's direction, to the appropriate employment-based health plan) of an incentive payment, in the amount determined as described in paragraph (2), for each retired individual (or spouse) who—

''(A) was covered under the sponsor's qualified retiree prescription medicine plan during such quarter; and

''(B) was eligible for but was not enrolled in the insurance program under this part.

''(2) AMOUNT OF INCENTIVE.—The payment under this section with respect to each individual described in paragraph (1) for a month shall be equal to ⅔ of the monthly premium amount payable from the Prescription Medicine Insurance Account for an enrolled individual, as set for the calendar year pursuant to section 1860D(a)(2).

''(3) PAYMENT DATE.—The incentive under this section with respect to a calendar quarter shall be payable as of the end of the next succeeding calendar quarter.

''(d) CIVIL MONEY PENALTIES.—A sponsor, health plan, or other entity that the Secretary determines has, directly or through its agent, provided information in connection with a request for an incentive payment under this section that the entity knew or should have known to be false shall be subject to a civil monetary penalty in an amount equal to $2,000 for each false representation plus an amount not to exceed 3 times the total incentive amounts under subsection (c) that were paid (or would have been payable) on the basis of such information.

''(e) PART D ENROLLMENT FOR CERTAIN INDIVIDUALS COVERED BY EMPLOYMENT-BASED RETIREE HEALTH COVERAGE PLANS.—

''(1) ELIGIBLE INDIVIDUALS.—An individual shall be given the opportunity to enroll in the program under this part during the period specified in paragraph (2) if—

''(A) the individual declined enrollment in the program under this part at the time the individual first satisfied section 1860C(a);

''(B) at that time, the individual was covered under a qualified retiree prescription medicine plan for which an incentive payment was paid under this section; and

''(C)(i) the sponsor subsequently ceased to offer such plan; or

''(ii) the value of prescription medicine coverage under such plan is reduced below the value of the coverage provided at the time the individual first became eligible to participate in the program under this part.

''(2) SPECIAL ENROLLMENT PERIOD.—An individual described in paragraph (1) shall be eligible to enroll in the program under this part during the 6-month period beginning on the first day of the month in which—

''(A) the individual receives a notice that coverage under such plan has terminated (in the circumstance described in paragraph (1)(C)(i)) or notice that a claim has been denied because of such a termination; or

''(B) the individual received notice of the change in benefits (in the circumstance described in paragraph (1)(C)(ii)).

''(f) DEFINITIONS.—In this section:

''(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs for retired individuals (or for such individuals and their spouses and dependents) based on their status as former employees or labor union members.

''(2) EMPLOYER.—The term 'employer' has the meaning given to such term by section 3(5) of the Employee Retirement Income Security Act of 1974 (except that such term shall include only employers of 2 or more employees).

''(3) QUALIFIED RETIREE PRESCRIPTION MEDICINE PLAN.—The term 'qualified retiree prescription medicine plan' means health insurance coverage included in employment-based retiree health coverage that—

''(A) provides coverage of the cost of prescription medicines whose actuarial value to each retired beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the program under this part; and

''(B) does not deny, limit, or condition the coverage or provision of prescription medicine benefits for retired individuals based on age or any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

''(4) SPONSOR.—The term 'sponsor' has the meaning given the term 'plan sponsor' by section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

''PROMOTION OF PHARMACEUTICAL RESEARCH ON BREAK-THROUGH MEDICINES WHILE PROVIDING PROGRAM COST CONTAINMENT

''SEC. 1860I. (a) MONITORING EXPENDITURES.—The Secretary shall monitor expenditures under this part. On October 1, 2005, Secretary shall estimate total expenditures under this part for 2005.

''(b) ESTABLISHMENT OF SUSTAINABLE GROWTH RATE.—

''(1) IN GENERAL.—The Secretary shall establish a sustainable growth rate prescription medicine target system for expenditures under this part for each year after 2005.

''(2) INITIAL COMPUTATION.—Such target shall equal the amount of total expenditures estimated for 2005 adjusted by the Secretary's estimate of a sustainable growth rate (in this section referred to as an 'SGR') percentage between 2005 and 2006. Such SGR shall be estimated based on the following:

''(A) Reasonable changes in the cost of production or price of covered pharmaceuticals, but in no event more than the rate of increase in the consumer price index for all urban consumers for the period involved.

''(B) Population enrolled in this part, both in numbers and in average age and severity of chronic and acute illnesses.

''(C) Appropriate changes in utilization of pharmaceuticals, as determined by the Drug Review Board (established under subsection (c)(3)) and based on best estimates of utilization change if there were no direct-to-consumer advertising or promotions to providers.

''(D) Productivity index of manufacturers and distributors.

''(E) Percentage of products with patent and market exclusivity protection versus products without patent protection and changes in the availability of generic substitutes.

''(F) Such other factors as the Secretary may determine are appropriate.

In no event may the sustainable growth rate exceed 120 percent of the estimated per capita growth in total spending under this title.

''(3) COMPUTATION FOR SUBSEQUENT YEARS.—In October of 2006 and each year thereafter, for purposes of setting the SGRs for the succeeding year, the Secretary shall adjust each current year's estimated expenditures by the estimated SGR for the succeeding year, further adjusted for corrections in earlier estimates and the receipt of additional data on previous years spending as follows:

''(A) ERROR ESTIMATES.—An adjustment (up or down) for errors in the estimate of total expenditures under this part for the previous year.

''(B) COSTS.—An adjustment (up or down) for corrections in the cost of production of prescriptions covered under this part between the current calendar year and the previous year.

''(C) TARGET.—An adjustment for any amount (over or under) that expenditures in the current year under this part are estimated to differ from the target amount set for the year. If expenditures in the current year are estimated to be—

''(i) less than the target amount, future target amounts will be adjusted downward; or

''(ii) more than the target amount, the Secretary shall notify all pharmaceutical manufacturers with sales of pharmaceutical prescription medicine products to medicare beneficiaries under this part, of a rebate requirement (except as provided in this subparagraph) to be deposited in the Federal Medicare Prescription Medicine Trust Fund.

''(D) REBATE DETERMINATION.—The amount of the rebate described in subparagraph (C)(ii) may vary among manufacturers and shall be based on the manufacturer's estimated contribution to the expenditure above the target amount, taking into consideration such factors as—

''(i) above average increases in the cost of the manufacturer's product;

''(ii) increases in utilization due to promotion activities of the manufacturer, wholesaler, or retailer;

''(iii) launch prices of new drugs at the same or higher prices as similar drugs already in the marketplace (so-called 'me too' or 'copy-cat' drugs);

''(iv) the role of the manufacturer in delaying the entry of generic products into the market; and

''(v) such other actions by the manufacturer that the Secretary may determine has contributed to the failure to meet the SGR target.

The rebates shall be established under such subparagraph so that the total amount of the rebates is estimated to ensure that the amount the target for the current year is estimated to be exceeded is recovered in lower spending in the subsequent year; except that, no rebate shall be made in any manufacturer's product which the Food and Drug Administration has determined is a breakthrough medicine (as determined under subsection (c)) or an orphan medicine.

''(c) BREAKTHROUGH MEDICINES.—

''(1) DETERMINATION.—For purposes of this section, a medicine is a 'breakthrough medicine' if the Drug Review Board (established under paragraph (3)) determines—

''(A) it is a new product that will make a significant and major improvement by reducing physical or mental illness, reducing mortality, or reducing disability; and

''(B) that no other product is available to beneficiaries that achieves similar results for the same condition at a lower cost.

''(2) CONDITION.—An exemption from rebates under subsection (b)(3) for a breakthrough medicine shall continue as long as the medicine is certified as a breakthrough medicine but shall be limited to 7 calendar years from 2003 or 7 calendar years from the date of the initial determination under paragraph (1), whichever is later.

''(3) DRUG REVIEW BOARD.—The Drug Review Board under this paragraph shall consist of the Commissioner of Food and Drugs, the Directors of the National Institutes of Health, the Director of the National Science Foundation, and 10 experts in pharmaceuticals, medical research, and clinical care, selected by the Commissioner of Food and Drugs from the faculty of academic medical centers, except that no person who has (or who has an immediate family member that has) any conflict of interest with any pharmaceutical manufacturer shall serve on the Board.

''(d) NO REVIEW.—The Secretary's determination of the rebate amounts under this section, and the Drug Review Board's determination of what is a breakthrough drug, are not subject to administrative or judicial review.

''APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS

''SEC. 1860J. (a) IN GENERAL.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Prescription Medicine Insurance Account, a Government contribution equal to—

''(1) the aggregate premiums payable for a month pursuant to section 1860D(a)(2) by individuals enrolled in the program under this part; plus

''(2) one-half the aggregate premiums payable for a month pursuant to such section for such individuals by former employers; plus

''(3) the benefits payable by reason of the application of paragraph (2) of section 1860B(a) (relating to catastrophic benefits).

''(b) APPROPRIATIONS TO COVER INCENTIVES FOR EMPLOYMENT-BASED RETIREE MEDICINE COVERAGE.—There are authorized to be appropriated to the Prescription Medicine Insurance Account from time to time, out of any moneys in the Treasury not otherwise appropriated such sums as may be necessary for payment of incentive payments under section 1860H(c).

''PRESCRIPTION MEDICINE DEFINED

''SEC. 1860K. As used in this part, the term 'prescription medicine' means—

''(1) a drug that may be dispensed only upon a prescription, and that is described in subparagraph (A)(i), (A)(ii), or (B) of section 1927(k)(2); and

''(2) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act, and needles, syringes, and disposable pumps for the administration of such insulin.

''STUDY

''SEC. 1860L. (a) IN GENERAL.—The Secretary shall conduct a study of the efficiency, cost-effectiveness, and impact on health outcomes of the program under this part. The Secretary shall include in such study an analysis of the savings from the cost containment provisions of this part as well as a projection of future costs.

''(b) REPORT.—The Secretary shall submit to Congress a report on the study under subsection (a) by not later than 3 years after the date the program under this part is first implemented.''.

(b) CONFORMING AMENDMENTS.—

(1) AMENDMENTS TO FEDERAL SUPPLEMENTARY HEALTH INSURANCE TRUST FUND.—Section 1841 of the Social Security Act (42 U.S.C. 1395t) is amended—

(A) in the last sentence of subsection (a)—

(i) by striking ''and'' after ''section 201(i)(1)''; and

(ii) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Prescription Medicine Insurance Account established by section 1860F'';

(B) in subsection (g), by inserting after ''by this part,'' the following: ''the payments provided for under part D (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund),'';

(C) in the first sentence of subsection (h), by inserting before the period the following: ''and section 1860D(b)(4) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)''; and

(D) in the first sentence of subsection (i)—

(i) by striking ''and'' after ''section 1840(b)(1)''; and

(ii) by inserting before the period the following: '', section 1860D(b)(2) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)''.

(2) PRESCRIPTION MEDICINE OPTION UNDER MEDICARE+CHOICE PLANS.—

(A) ELIGIBILITY, ELECTION, AND ENROLLMENT.—Section 1851 of the Social Security Act (42 U.S.C. 1395w–21) is amended—

(i) in subsection (a)(1)(A), by striking ''parts A and B'' inserting ''parts A, B, and D''; and

(ii) in subsection (i)(1), by striking ''parts A and B'' and inserting ''parts A, B, and D''.

(B) VOLUNTARY BENEFICIARY ENROLLMENT FOR MEDICINE COVERAGE.—Section 1852(a)(1)(A) of such Act (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting ''(and under part D to individuals also enrolled under that part)'' after ''parts A and B''.

(C) ACCESS TO SERVICES.—Section 1852(d)(1) of such Act (42 U.S.C. 1395w–22(d)(1)) is amended—

(i) in subparagraph (D), by striking ''and'' at the end;

(ii) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

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

''(F) the plan for prescription medicine benefits under part D guarantees coverage of any specifically named covered prescription medicine for an enrollee, when prescribed by a physician in accordance with the provisions of such part, regardless of whether such medicine would otherwise be covered under an applicable formulary or discount arrangement.''.

(D) PAYMENTS TO ORGANIZATIONS.—Section 1853(a)(1)(A) of such Act (42 U.S.C. 1395w–23(a)(1)(A)) is amended—

(i) by inserting ''determined separately for benefits under parts A and B and under part D (for individuals enrolled under that part)'' after ''as calculated under subsection (c)'';

(ii) by striking ''that area, adjusted for such risk factors'' and inserting ''that area. In the case of payment for benefits under parts A and B, such payment shall be adjusted for such risk factors as''; and

(iii) by inserting before the last sentence the following: ''In the case of the payments for benefits under part D, such payment shall initially be adjusted for the risk factors of each enrollee as the Secretary determines to be feasible and appropriate. By 2008, the adjustments would be for the same risk factors applicable for benefits under parts A and B.''.

(E) CALCULATION OF ANNUAL MEDICARE +CHOICE CAPITATION RATES.—Section 1853(c) of such Act (42 U.S.C. 1395w–23(c)) is amended—

(i) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''for benefits under parts A and B'' after ''capitation rate'';

(ii) in paragraph (6)(A), by striking ''rate of growth in expenditures under this title'' and inserting ''rate of growth in expenditures for benefits available under parts A and B''; and

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

''(8) PAYMENT FOR PRESCRIPTION MEDICINES.—The Secretary shall determine a capitation rate for prescription medicines—

''(A) dispensed in 2005, which is based on the projected national per capita costs for prescription medicine benefits under part D and associated claims processing costs for beneficiaries under the original medicare fee-for-service program; and

''(B) dispensed in each subsequent year, which shall be equal to the rate for the previous year updated by the Secretary's estimate of the projected per capita rate of growth in expenditures under this title for an individual enrolled under part D.''.

(F) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) of such Act (42 U.S.C. 1395w–24(e)) is amended by adding at the end the following new paragraph:

''(5) SPECIAL RULE FOR PROVISION OF PART D BENEFITS.—In no event may a Medicare+Choice organization include as part of a plan for prescription medicine benefits under part D a requirement that an enrollee pay a deductible, or a coinsurance percentage that exceeds 20 percent.''.

(G) REQUIREMENT FOR ADDITIONAL BENEFITS.—Section 1854(f)(1) of such Act (42 U.S.C. 1395w–24(f)(1)) is amended by adding at the end the following new sentence: ''Such determination shall be made separately for benefits under parts A and B and for prescription medicine benefits under part D.''.

(3) EXCLUSIONS FROM COVERAGE.—

(A) APPLICATION TO PART D.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended in the matter preceding paragraph (1) by striking ''part A or part B'' and inserting ''part A, B, or D''.

(B) PRESCRIPTION MEDICINES NOT EXCLUDED FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—Section 1862(a)(1) of such Act (42 U.S.C. 1395y(a)(1)) is amended—

(i) in subparagraph (H), by striking ''and'' at the end;

(ii) in subparagraph (I), by striking the semicolon at the end and inserting '', and''; and

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

''(J) in the case of prescription medicines covered under part D, which are not prescribed in accordance with such part;''.

SEC. 103. SUBSTANTIAL REDUCTIONS IN THE PRICE OF PRESCRIPTION DRUGS FOR MEDICARE BENEFICIARIES.

(a) PARTICIPATING MANUFACTURERS.—

(1) IN GENERAL.—Each participating manufacturer of a covered outpatient drug shall make available for purchase by each pharmacy such covered outpatient drug in the amount described in paragraph (2) at the price described in paragraph (3).

(2) DESCRIPTION OF AMOUNT OF DRUGS.—The amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy is an amount equal to the aggregate amount of the covered outpatient drug sold or distributed by the pharmacy to medicare beneficiaries.

(3) DESCRIPTION OF PRICE.—The price at which a participating manufacturer shall make a covered outpatient drug available for purchase by a pharmacy is the price equal to the lowest of the following:

(A) The lowest price paid for the covered outpatient drug by any agency or department of the United States.

(B) The manufacturer's best price for the covered outpatient drug, as defined in section 1927(c)(1)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)).

(C) The lowest price at which the drug is available (as determined by the Secretary) through importation consistent with the provisions of section 804 of the Federal Food, Drug, and Cosmetic Act.

(b) SPECIAL PROVISION WITH RESPECT TO HOSPICE PROGRAMS.—For purposes of determining the amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy under subsection (a), there shall be included in the calculation of such amount the amount of the covered outpatient drug sold or distributed by a pharmacy to a hospice program. In calculating such amount, only amounts of the covered outpatient drug furnished to a medicare beneficiary enrolled in the hospice program shall be included.

(c) ADMINISTRATION.—The Secretary shall issue such regulations as may be necessary to implement this section.

(d) REPORTS TO CONGRESS REGARDING EFFECTIVENESS OF SECTION.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, and annually thereafter, the Secretary shall report to the Congress regarding the effectiveness of this section in—

(A) protecting medicare beneficiaries from discriminatory pricing by drug manufacturers; and

(B) making prescription drugs available to medicare beneficiaries at substantially reduced prices.

(2) CONSULTATION.—In preparing such reports, the Secretary shall consult with public health experts, affected industries, organizations representing consumers and older Americans, and other interested persons.

(3) RECOMMENDATIONS.—The Secretary shall include in such reports any recommendations they consider appropriate for changes in this section to further reduce the cost of covered outpatient drugs to medicare beneficiaries.

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

(1) PARTICIPATING MANUFACTURER.—The term ''participating manufacturer'' means any manufacturer of drugs or biologicals that, on or after the date of the enactment of this Act, enters into a contract or agreement with the United States for the sale or distribution of covered outpatient drugs to the United States.

(2) COVERED OUTPATIENT DRUG.—The term ''covered outpatient drug'' has the meaning given that term in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)).

(3) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title, or both.

(4) HOSPICE PROGRAM.—The term ''hospice program'' has the meaning given that term under section 1861(dd)(2) of the Social Security Act (42 U.S.C. 1395x(dd)(2)).

(5) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(f) EFFECTIVE DATE.—The Secretary shall implement this section as expeditiously as practicable and in a manner consistent with the obligations of the United States.

SEC. 104. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

''SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug; or

''(E) a drug that is inhaled during surgery.

''(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(5) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that safeguards be in place to ensure that each prescription drug imported

under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

''(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

''(d) INFORMATION AND RECORDS.—

''(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

''(A) The name and quantity of the active ingredient of the prescription drug.

''(B) A description of the dosage form of the prescription drug.

''(C) The date on which the prescription drug is shipped.

''(D) The quantity of the prescription drug that is shipped.

''(E) The point of origin and destination of the prescription drug.

''(F) The price paid by the importer for the prescription drug.

''(G) Documentation from the foreign seller specifying—

''(i) the original source of the prescription drug; and

''(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

''(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

''(I) The name, address, telephone number, and professional license number (if any) of the importer.

''(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

''(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

''(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

''(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States; and

''(ii) meets all labeling requirements under this Act.

''(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

''(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

''(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

''(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

''(e) TESTING.—The regulations under subsection (b) shall require—

''(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of the prescription drugs or by the importer that is counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

''(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

''(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

''(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

''(B) exercise discretion to permit individuals to make such importations in circumstances in which—

''(i) the importation is clearly for personal use; and

''(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

''(2) WAIVER AUTHORITY.—

''(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

''(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

''(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(l) STUDIES; REPORTS.—

''(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

''(I) importations of prescription drugs made under the regulations under subsection (b); and

''(II) information and documentation submitted under subsection (d).

''(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

''(I) evaluate the compliance of importers with the regulations under subsection (b);

''(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

''(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

''(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(2) BY THE COMPTROLLER GENERAL.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(n) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804'';

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

SEC. 105. REASONABLE PRICE AGREEMENT FOR FEDERALLY FUNDED RESEARCH.

(a) IN GENERAL.—If any Federal agency or any non-profit entity undertakes federally funded health care research and development and is to convey or provide a patent or other exclusive right to use such research and development for a drug or other health care technology, such agency or entity shall not make such conveyance or provide such patent or other right until the person who will receive such conveyance or patent or other right first agrees to a reasonable pricing agreement with the Secretary of Health and Human Services or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (c).

(b) CONSIDERATION OF COMPETITIVE BIDDING.—In cases where the Federal Government conveys or licenses exclusive rights to federally funded research under subsection (a), consideration shall be given to mechanisms for determining reasonable prices which are based upon a competitive bidding process. When appropriate, the mechanisms should be considered where—

(1) qualified bidders compete on the basis of the lowest prices that will be charged to consumers;

(2) qualified bidders compete on the basis of the least sales revenues before prices are adjusted in accordance with a cost based reasonable pricing formula;

(3) qualified bidders compete on the basis of the least period of time before prices are adjusted in accordance with a cost based reasonable pricing formula;

(4) qualified bidders compete on the basis of the shortest period of exclusivity; or

(5) qualified bidders compete under other competitive bidding systems.

Such competitive bidding process may incorporate requirements for minimum levels of expenditures on research, marketing, maximum price, or other factors.

(c) WAIVER.—No waiver shall take effect under subsection (a) before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.

SEC. 106. GAO ONGOING STUDIES AND REPORTS ON PROGRAM; MISCELLANEOUS REPORTS.

(a) ONGOING STUDY.—The Comptroller General of the United States shall conduct an ongoing study and analysis of the prescription medicine benefit program under part D of the medicare program under title XVIII of the Social Security Act (as added by section 102 of this Act), including an analysis of each of the following:

(1) The extent to which the administering entities have achieved volume-based discounts similar to the favored price paid by other large purchasers.

(2) Whether access to the benefits under such program are in fact available to all beneficiaries, with special attention given to access for beneficiaries living in rural and hard-to-serve areas.

(3) The success of such program in reducing medication error and adverse medicine reactions and improving quality of care, and whether it is probable that the program has resulted in savings through reduced hospitalizations and morbidity due to medication errors and adverse medicine reactions.

(4) Whether patient medical record confidentiality is being maintained and safeguarded.

(5) Such other issues as the Comptroller General may consider.

(b) REPORTS.—The Comptroller General shall issue such reports on the results of the ongoing study described in (a) as the Comptroller General shall deem appropriate and shall notify Congress on a timely basis of significant problems in the operation of the part D prescription medicine program and the need for legislative adjustments and improvements.

(c) MISCELLANEOUS STUDIES AND REPORTS.—

(1) STUDY ON METHODS TO ENCOURAGE ADDITIONAL RESEARCH ON BREAKTHROUGH PHARMACEUTICALS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall seek the advice of the Secretary of the Treasury on possible tax and trade law changes to encourage increased original research on new pharmaceutical breakthrough products designed to address disease and illness.

(B) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on such study. The report shall include recommended methods to encourage the pharmaceutical industry to devote more resources to research and development of new covered products than it devotes to overhead expenses.

(2) STUDY ON PHARMACEUTICAL SALES PRACTICES AND IMPACT ON COSTS AND QUALITY OF CARE.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study on the methods used by the pharmaceutical industry to advertise and sell to consumers and educate and sell to providers.

(B) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on such study. The report shall include the estimated direct and indirect costs of the sales methods used, the quality of the information conveyed, and whether such sales efforts leads (or could lead) to inappropriate prescribing. Such report may include legislative and regulatory recommendations to encourage more appropriate education and prescribing practices.

(3) STUDY ON COST OF PHARMACEUTICAL RESEARCH.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study on the costs of, and needs for, the pharmaceutical research and the role that the taxpayer provides in encouraging such research.

(B) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on such study. The report shall include a description of the full-range of taxpayer-assisted programs impacting pharmaceutical research, including tax, trade, government research, and regulatory assistance. The report may also include legislative and regulatory recommendations that are designed to ensure that the taxpayer's investment in pharmaceutical research results in the availability of pharmaceuticals at reasonable prices.

(4) REPORT ON PHARMACEUTICAL PRICES IN MAJOR FOREIGN NATIONS.—Not later than January 1, 2005, the Secretary of Health and Human Services shall submit to Congress a report on the retail price of major pharmaceutical products in various developed nations, compared to prices for the same or similar products in the United States. The report shall include a description of the principal reasons for any price differences that may exist.

SEC. 107. MEDIGAP TRANSITION PROVISIONS.

(a) IN GENERAL.—Notwithstanding any other provision of law, no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under section 1882 of the Social Security Act on or after January 1, 2005, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs.

(b) ISSUANCE OF SUBSTITUTE POLICIES IF OBTAINING PRESCRIPTION DRUG COVERAGE THROUGH MEDICARE.—

(1) IN GENERAL.—The issuer of a medicare supplemental policy—

(A) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as ''A'', ''B'', ''C'', ''D'', ''E'', ''F'', or ''G'' (under the standards established under subsection (p)(2) of section 1882 of the Social Security Act, 42 U.S.C. 1395ss) and that is offered and is available for issuance to new enrollees by such issuer;

(B) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

(C) may not impose an exclusion of benefits based on a pre-existing condition under such policy,

in the case of an individual described in paragraph (2) who seeks to enroll under the policy not later than 63 days after the date of the termination of enrollment described in such paragraph and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

(2) INDIVIDUAL COVERED.—An individual described in this paragraph is an individual who—

(A) enrolls in a prescription drug plan under part D of title XVIII of the Social Security Act; and

(B) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as ''H'', ''I'', or ''J'' under the standards referred to in paragraph (1)(A) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

(3) ENFORCEMENT.—The provisions of paragraph (1) shall be enforced as though they were included in section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)).

(4) DEFINITIONS.—For purposes of this subsection, the term ''medicare supplemental policy'' has the meaning given such term in section 1882(g) of the Social Security Act (42 U.S.C. 1395ss(g)).

H.R. 1

OFFERED BY: MR. SANDERS

AMENDMENT NO. 3: Add at the end of title I the following new section:

SEC. 108. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

''SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug; or

''(E) a drug that is inhaled during surgery.

''(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(5) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

''(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

''(d) INFORMATION AND RECORDS.—

''(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

''(A) The name and quantity of the active ingredient of the prescription drug.

''(B) A description of the dosage form of the prescription drug.

''(C) The date on which the prescription drug is shipped.

''(D) The quantity of the prescription drug that is shipped.

''(E) The point of origin and destination of the prescription drug.

''(F) The price paid by the importer for the prescription drug.

''(G) Documentation from the foreign seller specifying—

''(i) the original source of the prescription drug; and

''(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

''(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

''(I) The name, address, telephone number, and professional license number (if any) of the importer.

''(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

''(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

''(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

''(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States; and

''(ii) meets all labeling requirements under this Act.

''(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

''(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

''(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

''(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

''(e) TESTING.—The regulations under subsection (b) shall require—

''(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of the prescription drugs or by the importer that is counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

''(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

''(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise

supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

''(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

''(B) exercise discretion to permit individuals to make such importations in circumstances in which—

''(i) the importation is clearly for personal use; and

''(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

''(2) WAIVER AUTHORITY.—

''(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

''(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

''(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(l) STUDIES; REPORTS.—

''(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

''(I) importations of prescription drugs made under the regulations under subsection (b); and

''(II) information and documentation submitted under subsection (d).

''(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

''(I) evaluate the compliance of importers with the regulations under subsection (b);

''(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

''(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

''(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(2) BY THE COMPTROLLER GENERAL.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(n) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804'';

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.