108TH CONGRESS
1ST SESSION

S. 1992

To amend the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to eliminate privatization of the medicare program, to improve the medicare prescription drug benefit, to repeal health savings accounts, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 9, 2003

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To amend the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to eliminate privatization of the medicare program, to improve the medicare prescription drug benefit, to repeal health savings accounts, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as ''Defense of Medicare and Real Medicare Prescription Drug Benefit Act''.

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

TITLE I—DEFENSE OF MEDICARE

SEC. 101. APPLICATION OF RISK ADJUSTMENT REFLECTING CHARACTERISTICS FOR THE ENTIRE MEDICARE POPULATION.

Effective January 1, 2005, in applying risk adjustment factors to payment to organizations under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) in a budget neutral manner, the Secretary of Health and

Human Services shall assure that such factors, in the aggregate, take into account the actuarial characteristics of the entire medicare population, and not merely the population of individuals enrolled under a plan under part C of title XVIII of such Act.

SEC. 102. PHASE-IN TO PAYMENT AT 100 PERCENT OF FEE-FOR-SERVICE RATE.

Notwithstanding any other provision of law, the Secretary of Health and Human Services shall provide, in a phased-in manner over a 5-year period beginning with 2005, for adjustment of payment rates to organizations under section 1853 of the Social Security Act so that, at the end of such phase-in period, such payment rates reflect only the payment rate described in subsection (c)(1)(D) of such section (relating to 100 percent fee-for-service payment).

SEC. 103. ELIMINATION OF MA REGIONAL PLAN STABILIZATION FUND (SLUSH FUND).

Subsection (e) of section 1858 of the Social Security Act, as added by section 221(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is repealed.

SEC. 104. REPEAL OF PREMIUM SUPPORT PROGRAM.

Effective as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization

Act of 2003, subtitle E of title I of such Act is repealed and any provisions of law amended by such subtitle are restored as if such subtitle had not been enacted.

SEC. 105. REPEAL OF MEDICARE EXPENDITURE CAP.

Subtitle A of title VIII of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is repealed and any provisions of law amended by such subtitle are restored as if such subtitle had not been enacted.

TITLE II—ESTABLISHMENT OF REAL MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 201. ELIMINATION OF COVERAGE GAP.

(a) IN GENERAL.—Section 1860D–2(b) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is amended—

(1) in paragraph (3)(A), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (5)'';

(2) by redesignating paragraph (5) as paragraph (7) and by moving such paragraph to follow paragraph (6); and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) PHASED-IN ELIMINATION OF COVERAGE GAP.—The coverage provides continuation of bene-

fits from the initial coverage limit (under paragraph (3)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4), subject to coinsurance of the following:

"(A) 2006, 2007, AND 2008.—During the years 2006 through 2008, 75 percent (or actuarially equivalent, using processes and methods established under section 1860D–11(c)) to an average expected payment of 75 percent of such costs.

"(B) 2009, 2010, AND 2011.—During the years 2009 through 2011, 50 percent (or actuarially equivalent, using processes and methods established under section 1860D–11(c)) to an average expected payment of 50 percent of such costs.

"(C) 2012 AND SUBSEQUENT YEARS.—During 2012 and each subsequent year, 25 percent (or actuarially equivalent, using processes and methods established under section 1860D–11(c)) to an average expected payment of 25 percent of such costs.

The provisions of paragraph (2)(B) shall apply under this paragraph in the same manner as they apply with respect to paragraph (2)(A).''.

(b) CONFORMING AMENDMENT.—Section 1860D–14(a) of such Act, as so added, is amended by striking subparagraph (C) of paragraphs (1) and (2).

SEC. 202. ELIMINATION OF DISCRIMINATORY TREATMENT OF EMPLOYER PLANS.

(a) ELIMINATION OF TRUE OUT-OF-POCKET LIMITATION.—Section 1860D–2(b)(4)(C) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is amended to read as follows:

''(C) APPLICATION.—In applying subparagraph (A), incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary.''.

(b) EQUALIZATION OF SUBSIDIES.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall provide for such increase in the special subsidy payment amounts under section 1860D–22(a)(3) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as may be appropriate to provide for payments in the aggregate equivalent to the payments that would have been made under section 1860D–15 of such Act if the individuals were not enrolled in a qualified retiree prescription drug plan. In making such computation, the Secretary shall not take into account the application of the amendments made by section 1202 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

SEC. 203. ALLOWING MEDICAID WRAP.

Section 1935(d) of the Social Security Act, as added by section 103(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is repealed.

SEC. 204. ELIMINATION OF ASSETS TEST.

(a) IN GENERAL.—Section 1860D–14 of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is amended as follows:

(1) In subsection (a)(1), strike ''and who meets the resource requirements of paragraph (3)(B)''.

(2) In subsection (a)(3)(A), add ''and'' at the end of clause (i), strike ''; and'' at the end of clause (ii) and inserting period, and strike clause (iii).

(3) In subsection (a)(3), strike subparagraphs (D) and (E).

(b) CONFORMING AMENDMENT.—Section 107(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is repealed.

SEC. 205. REQUIRING TWO PRESCRIPTION DRUG PLANS TO AVOID FEDERAL FALLBACK.

Section 1860D–3(a) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is amended—

(1) in paragraph (1), by striking ''qualifying plans (as defined in paragraph (3)'' and inserting ''prescription drug plans'';

(2) in paragraph (2), by striking ''qualifying plans'' and inserting ''prescription drug plans'';

(3) by striking paragraph (3).

SEC. 206. SECRETARY DEFINING CLASSES AND CATEGORIES UNDER ANY FORMULARY.

Notwithstanding any other provision of law, no formulary may be established or applied under part D of title XVIII of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, unless the classes and categories used under such formulary are such classes and categories as the Secretary of Health and Human Services shall specify.

SEC. 207. PROVISION OF WRAP-AROUND PRESCRIPTION DRUG COVERAGE THROUGH MEDIGAP.

Section 1882(v) of the Social Security Act (42 U.S.C. 1395ss(v)), as added by section 104(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is amended as follows:

(1) In paragraph (1)(A), by inserting ", other than such a policy that provides wrap-around prescription drug coverage included within a range of such coverage approved under subparagraph (D)(ii)," after "paragraph (6)(A))".

(2) Add at the end of paragraph (1) the following new subparagraph:

"(D) WRAP-AROUND PRESCRIPTION DRUG COVERAGE.—

''(i) IN GENERAL.—Notwithstanding any other provision of this subsection, a medigap Rx policy that provides wrap-around prescription drug coverage included within a range of such coverage approved by the Secretary under clause (ii) may be offered to part D enrollees.

''(ii) DEVELOPMENT OF STANDARDS.—The Secretary shall approve a range of wrap-around prescription drug coverage that may be offered under this subparagraph to part D enrollees.''.

SEC. 208. NO ADDITIONAL BENEFICIARY PREMIUM.

Notwithstanding any other provision of law, the Secretary of Health and Human Services shall provide for such adjustment in payments to PDP sponsors under part D of title XVIII of the Social Security Act, and to MA organizations offering MA–PD plans under part C of such title, as may be appropriate to assure that premiums of part D eligible individuals under prescription drug plans and under MA–PD plans are not increased as a result of this Act (and the amendments made by this Act).

SEC. 209. ELIMINATION OF STATE MAINTENANCE OF EFFORT.

Section 1935(c)(5) of the Social Security Act, as added by section 103(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is amended—

(1) by striking ''or'' at the end of subparagraph (I); and

(2) by striking subparagraph (J) and inserting the following new subparagraphs:

''(J) in each of 2014 and 2015 is 75 percent;

''(K) in 2016 is 67.5 percent;

''(L) in 2017 is 60 percent;

''(M) in 2018 is 52.5 percent;

''(N) in 2019 is 45 percent;

''(O) in 2020 is 37.5 percent;

''(P) in 2021 is 30 percent;

''(Q) in 2022 is 22.5 percent;

''(R) in 2023 is 15 percent;

''(S) in 2024 is 7.5 percent; or

''(T) after December 2024, is 0 percent.''.

TITLE III—REDUCTION IN PRESCRIPTION DRUG PRICES

SEC. 301. 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) CANADIAN PHARMACIST.—The term 'Canadian pharmacist' means a person licensed in Canada to practice pharmacy, including the dispensing and selling of prescription drugs.

''(2) CANADIAN WHOLESALER.—The term 'Canadian wholesaler' means a person licensed in Canada to distribute within Canada prescription drugs that have been approved by Health Canada.

''(3) CANADIAN EXPORTER.—The term 'Canadian exporter' means a Canadian pharmacist or Canadian wholesaler.

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

''(5) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice phar-

macy, including the dispensing and selling of prescription drugs.

''(6) 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.

''(7) 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.

''(8) 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.—No later than 18 months after the date of enactment of this section, 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 a Canadian exporter—

''(A) register with the Secretary the name and place of business of the Canadian exporter (and including the place of business of each warehouse and establishment of the Canadian exporter);

''(B) export only prescription drugs that have been approved by Health Canada and meet all requirements of Canadian law;

''(C) permit inspections by the Secretary (including inspections of all records, including financial records) of each warehouse and establishment of the Canadian exporter; and

''(D) pay an inspection fee to the Secretary on a semiannual basis not to exceed 5 percent of the total price of prescription drugs exported by the Canadian exporter to the United States under the regulations (which fees the Secretary shall use solely to inspect the warehouses and establishments of Canadian exporters and to monitor imports of prescription drugs at ports of entry);

''(2) require that each prescription drug imported under the regulations be imported directly from a Canadian exporter through a limited number of ports of entry (at which the Secretary shall monitor such imports);

''(3) 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;

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

''(5) 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) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer or from a specific Canadian exporter under subsection (b) be immediately suspended on discovery of a pattern of importation

of that specific prescription drug or by that specific importer or Canadian exporter of drugs that are 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).

''(g) 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.

''(h) 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, wholesaler, or Canadian exporter 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, wholesaler, or Canadian exporter 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, wholesalers, or Canadian exporters 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, wholesalers, or Canadian exporters to a prescription drug that is permitted to be imported into the United States under this section.

"(i) 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.

"(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

"(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohi-

bition 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 con-

sistently 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 Canadian exporter 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.

''(k) 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).

''(l) 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.

''(m) 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''; and

(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. 302. NEGOTIATING FAIR PRICES FOR MEDICARE PRESCRIPTION DRUGS.

Section 1860D–11 of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, is

amended by striking subsection (i) (relating to noninterference) and by inserting the following:

''(i) AUTHORITY TO NEGOTIATE PRICES WITH MANUFACTURERS.—In order to ensure that beneficiaries enrolled under prescription drug plans and MA–PD plans pay the lowest possible price, the Secretary shall have authority similar to that of other Federal entities that purchase prescription drugs in bulk to negotiate contracts with manufacturers of covered part D drugs, consistent with the requirements and in furtherance of the goals of providing quality care and containing costs under this part.''.

TITLE IV—REPEAL OF HEALTH SAVINGS ACCOUNTS

SEC. 401. REPEAL OF HEALTH SAVINGS ACCOUNTS.

Section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is repealed and any provisions of law amended by such section are restored as if such section had not been enacted.

○