I

108TH CONGRESS
2D SESSION

H. R. 4512

To amend part D of title XVIII of the Social Security Act to authorize the Secretary of Health and Human Services to negotiate for lower prices for Medicare prescription drugs and to eliminate the gap in coverage of Medicare prescription drug benefits, to authorize the Secretary of Health and Human Services to promulgate regulations for the reimportation of prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 3, 2004

Mr. WU introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend part D of title XVIII of the Social Security Act to authorize the Secretary of Health and Human Services to negotiate for lower prices for Medicare prescription drugs and to eliminate the gap in coverage of Medicare prescription drug benefits, to authorize the Secretary of Health and Human Services to promulgate regulations for the reimportation of prescription drugs, 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.

This Act may be cited as the ''Medicare Prescription Drug Improvement Act''.

TITLE I—IMPROVEMENT OF MEDICARE PRESCRIPTION DRUG BENEFITS

SEC. 101. PERMITTING THE NEGOTIATION OF FAIR PRICES FOR MEDICARE PRESCRIPTION DRUGS ON BEHALF OF MEDICARE BENEFICIARIES.

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 (Public Law 108–173), 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, MA–PD plans, and qualified retiree prescription drug plans pay the lowest possible price, the Secretary shall have authority similar to that of the Secretary of Veterans Affairs, Secretary of Defense, and the heads of other Federal agencies and departments that purchase prescription drugs in bulk to negotiate contracts with manufacturers of covered part D drugs, consistent with the requirements and in further-

ance of the goals of providing quality care and containing costs under this part.''.

SEC. 102. ELIMINATION OF GAP IN COVERAGE OF PRESCRIPTION DRUG BENEFITS.

(a) IN GENERAL.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)), as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is amended by striking paragraph (3) and inserting the following:

''(3) Repealed.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(A) in subsection (a)(2)(A)(i)(I), by striking '', or an increase in the initial coverage limit with respect to covered part D drugs'';

(B) in subsection (b)(2)(A), by striking ''and up to the initial coverage limit under paragraph (3)'';

(C) in subsection (b)(4)(C)(i)—

(i) by striking the comma after ''paragraph (1)'' and inserting ''and''; and

(ii) by striking '', and for amounts for which benefits are not provided because of

the application of the initial coverage limit described in paragraph (3)'';

(D) in subsection (c)(1), by striking subparagraph (C); and

(E) in subsection (d)(1)(A), by striking ''or an initial coverage limit (described in subsection (b)(3))''.

(2) Section 1860D–4(a)(4)(B) of such Act (42 U.S.C. 1395w–104(a)(4)(B)) is amended to read as follows:

''(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to the annual out-of-pocket threshold for the current year.''.

(3)(A) Section 1860D–14(a) of such Act (42 U.S.C. 1395w–114(a)) is amended—

(i) in paragraph (1), by striking subparagraph (C) and redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively;

(ii) in paragraph (2), by striking subparagraph (C) and redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively; and

(iii) in paragraph (4)(A) in the matter preceding clause (i), by striking ''paragraph (1)(D)(ii)'' and inserting ''paragraph (1)(C)(ii)''.

(B) Section 1860D–14(c)(1) of such Act (42 U.S.C. 1395w–114(c)(1)) is amended in the second sentence by striking ''subsections (a)(1)(D) and (a)(2)(E)'' and inserting ''subsections (a)(1)(C) and (a)(2)(D)''.

(C) Section 1860D–15(e)(1)(B) of such Act (42 U.S.C. 1395w–115(e)(1)(B)) is amended by striking ''paragraphs (1)(D) and (2)(E)'' and inserting ''paragraphs (1)(C) and (2)(D)''.

(4)(A) Section 1860D–41(a)(6) of such Act (42 U.S.C. 1395w–151(a)(6)) is amended by striking paragraph (6) and redesignating paragraphs (7) through (18) as paragraphs (6) through (17), respectively.

(B) Section 1860D–1(a)(1)(A) of such Act (42 U.S.C. 1395w–101(a)(1)(A)) is amended by striking ''1860D–41(a)(14)'' and inserting ''1860D–41(a)(13)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect as if included in the enact-

ment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public law 108–173).

TITLE II—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 201. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access Act of 2004''.

SEC. 202. IMPORTATION OF PRESCRIPTION DRUGS.

(a) NULLIFICATION OF CERTAIN AMENDMENTS MADE BY PUBLIC LAW 108–173.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 804 (21 U.S.C. 384), by amending the section to read as if section 1121(a) of Public Law 108–173 had not been enacted;

(2) in section 301 (21 U.S.C. 331), by amending the section to read as if section 1121(b)(1) of Public Law 108–173 had not been enacted; and

(3) in section 303 (21 U.S.C. 333), by amending the section to read as if section 1121(b)(2) of Public Law 108–173 had not been enacted.

(b) IMPORTATION OF PRESCRIPTION DRUGS.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by subsection (a)(1) of this section, is amended—

(1) in subsection (a)—

(A) by striking ''The Secretary'' and inserting ''Not later than 180 days after the date of the enactment of the Pharmaceutical Market Access Act of 2003, the Secretary''; and

(B) by striking ''pharmacists and wholesalers'' and inserting ''pharmacists, wholesalers, and qualifying individuals'';

(2) in subsection (b)—

(A) by amending paragraph (1) to read as follows:

''(1) require that each covered product imported pursuant to such subsection complies with sections 501, 502, and 505, and other applicable requirements of this Act; and'';

(B) in paragraph (2), by striking '', including subsection (d); and'' and inserting a period; and

(C) by striking paragraph (3);

(3) in subsection (c), by inserting ''by pharmacists and wholesalers (but not qualifying individuals)'' after ''importation of covered products'';

(4) in subsection (d)—

(A) by striking paragraphs (3) and (10);

(B) in paragraph (5), by striking ", including the professional license number of the importer, if any";

(C) in paragraph (6)—

(i) in subparagraph (C), by inserting "(if required under subsection (e))" before the period;

(ii) in subparagraph (D), by inserting "(if required under subsection (e))" before the period; and

(iii) in subparagraph (E), by striking "labeling";

(D) in paragraph (7)—

(i) in subparagraph (A), by inserting "(if required under subsection (e))" before the period; and

(ii) by amending subparagraph (B) to read as follows:

"(B) Certification from the importer or manufacturer of such product that the product meets all requirements of this Act."; and

(E) by redesignating paragraphs (4) through (9) as paragraphs (3) through (8), respectively;

(5) by amending subsection (e) to read as follows:

''(e) TESTING.—

''(1) IN GENERAL.—Subject to paragraph (2), regulations under subsection (a) shall require that testing referred to in paragraphs (5) through (7) of subsection (d) be conducted by the importer of the covered product, unless the covered product is a prescription drug subject to the requirements of section 505C for counterfeit-resistant technologies.

''(2) EXCEPTION.—The testing requirements of paragraphs (5) through (7) of subsection (d) shall not apply to an importer unless the importer is a wholesaler.'';

(6) in subsection (f), by striking ''or designated by the Secretary, subject to such limitations as the Secretary determines to be appropriate to protect the public health'';

(7) in subsection (g)—

(A) by striking ''counterfeit or''; and

(B) by striking ''and the Secretary determines that the public is adequately protected from counterfeit and violative covered products being imported pursuant to subsection (a)'';

(8) in subsection (i)(1)—

(A) by amending subparagraph (A) to read as follows:

''(A) IN GENERAL.—The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted pursuant to subsection (a), including consideration of the information received under subsection (d). In conducting such study, the Secretary or entity shall evaluate the compliance of importers with regulations under subsection (a), and the incidence of shipments pursuant to such subsection, if any, that have been determined to be misbranded or adulterated, and determine how such compliance contrasts with the incidence of shipments of prescription drugs transported within the United States that have been determined to be misbranded or adulterated.''; and

(B) in subparagraph (B), by striking ''Not later than 2 years after the effective date of final regulations under subsection (a),'' and inserting ''Not later than 18 months after the date of the enactment of the Pharmaceutical Market Access Act of 2003,'';

(9) in subsection (k)(2)—

(A) by redesignating subparagraphs (D) and (E) as subparagraphs (E) and (F), respectively; and

(B) by inserting after subparagraph (C) the following:

''(D) The term 'qualifying individual' means an individual who is not a pharmacist or a wholesaler.''; and

(10) by striking subsections (l) and (m).

SEC. 203. USE OF COUNTERFEIT-RESISTANT TECHNOLOGIES TO PREVENT COUNTERFEITING.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming drugs and devices to be misbranded) is amended by adding at the end the following:

''(w) If it is a drug subject to section 503(b), unless the packaging of such drug complies with the requirements of section 505C for counterfeit-resistant technologies.''.

(b) REQUIREMENTS.—Title V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

''SEC. 505C. COUNTERFEIT-RESISTANT TECHNOLOGIES.

''(a) INCORPORATION OF COUNTERFEIT-RESISTANT TECHNOLOGIES INTO PRESCRIPTION DRUG PACK-

AGING.—The Secretary shall require that the packaging of any drug subject to section 503(b) incorporate—

''(1) overt optically variable counterfeit-resistant technologies that are described in subsection (b) and comply with the standards of subsection (c); or

''(2) technologies that have an equivalent function of security, as determined by the Secretary.

''(b) ELIGIBLE TECHNOLOGIES.—Technologies described in this subsection—

''(1) shall be visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

''(2) shall be similar to that used by the Bureau of Engraving and Printing to secure United States currency;

''(3) shall be manufactured and distributed in a highly secure, tightly controlled environment; and

''(4) should incorporate additional layers of non-visible covert security features up to and including forensic capability.

''(c) STANDARDS FOR PACKAGING.—

''(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to section 503(b), manufac-

turers of the drugs shall incorporate the technologies described in subsection (b) into multiple elements of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

''(2) LABELING OF SHIPPING CONTAINER.—Shipments of drugs described in subsection (a) shall include a label on the shipping container that incorporates the technologies described in subsection (b), so that officials inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.''.

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