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112TH CONGRESS
2D SESSION

H. R. 6611

To amend title XVIII of the Social Security Act to promote public notification and provide incentives to reduce drug shortages, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 29, 2012

Mr. CASSIDY (for himself, Mr. ROONEY, Mr. ROGERS of Michigan, Mr. HARRIS, and Mr. BENISHEK) 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 title XVIII of the Social Security Act to promote public notification and provide incentives to reduce drug shortages, 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 ''Patient Access to Drugs in Shortage Act of 2012''.

SEC. 2. MARKET STABILITY INCENTIVES.

(a) MEDICARE.—

(1) IN GENERAL.—Section 1847A(b) of the Social Security Act (42 U.S.C. 1395w–3a(b)) is amended—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (9)''; and

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

''(9) STERILE INJECTABLE PRODUCTS WITH 3 OR FEWER ACTIVE MANUFACTURERS.—

''(A) IN GENERAL.—The payment amount for a drug described in subparagraph (B) that is furnished on or after July 1, 2013, and before January 1, 2020, shall be equal to—

''(i) in the case of a drug described in subparagraph (B)(i), the volume-weighted wholesale acquisition cost determined under subparagraph (C) for the drug; and

''(ii) in the case of a drug described in subparagraph (B)(ii), the wholesale acquisition cost (as defined in subsection (c)) of the drug.

''(B) DRUG DESCRIBED.—

"(i) IN GENERAL.—A drug described in this subparagraph is a sterile injectable drug product that is manufactured by 3 or fewer active manufacturers (as determined by the Secretary) and is—

"(I) a multiple source drug (as described in subsection (c)(6)(C)) for which there is no period of exclusivity in effect or available under section 505(j), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act; or

"(II) a single source drug (as described in subsection (c)(6)(D)(ii)) for which there is no period of exclusivity in effect or available under section 505(c), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act.

"(ii) STERILE INJECTABLE DRUG DEFINED.—In this paragraph, the term 'sterile injectable drug' means a drug approved by the Food & Drug Administration that is injected into the body.

"(C) USE OF VOLUME-WEIGHTED AVERAGE WHOLESALE ACQUISITION COSTS FOR MULTIPLE SOURCE DRUGS.—The volume-weighted

average wholesale acquisition costs under this paragraph shall be determined under this subparagraph in the same manner as the volume-weighted average of the average sales prices is determined under paragraph (6) except that, for purposes of this paragraph, any reference in such paragraph (6) to the average sale prices for a drug is deemed a reference to wholesale acquisition cost (as defined in subsection (c)(6)(B)) for the drug.''.

(2) HOPD PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(14) of the Social Security Act (42 U.S.C. 1395l(t)(14)) is amended—

(A) in subparagraph (A)(iii), in the matter preceding subclause (I), by striking ''subparagraph (E)'' and inserting ''subparagraphs (E) and (I)''; and

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

''(I) STERILE INJECTABLE PRODUCTS WITH 3 OR FEWER ACTIVE MANUFACTURERS.—The amount of payment for a drug described in section 1847A(b)(9)(B) that is furnished on or after July 1, 2013, and before January 1, 2020, shall be equal to—

"(i) in the case of a drug described in clause (i) of such section, the volume-weighted wholesale acquisition costs amount determined under section 1847A(b)(9)(C) for the drug; and

"(ii) in the case of a drug described in clause (ii) of section 1847A(b)(9)(B), the wholesale acquisition cost (as defined in section 1847A(c)) of the drug.".

(b) MEDICAID.—

(1) IN GENERAL.—Section 1927(a) of the Social Security Act (42 U.S.C. 1396r–8(a)) is amended by adding at the end the following new paragraph:

"(8) STERILE INJECTABLE PRODUCTS WITH 3 OR FEWER ACTIVE MANUFACTURERS.—

"(A) IN GENERAL.—Paragraph (1) of this subsection and section 1903(i)(10)(A) shall not apply to a drug that is described in section 1847A(b)(9)(C), that is furnished on or after July 1, 2013, and before January 1, 2020, and for which payment may be made under part B of title XVIII.

"(B) GUIDANCE.—Not later than July 1, 2013, the Secretary shall publish guidance on

the exclusion of certain sterile injectable products under subparagraph (A).''.

(2) CONFORMING AMENDMENT.—Section 1903(i)(10)(A) of the Social Security Act (42 U.S.C. 1396b(i)(10)(A)) is amended by striking ''unless section 1927(a)(3) applies'' and inserting ''unless paragraph (3) or (9) of section 1927(a) applies''.

(c) 340B PROGRAM.—

(1) IN GENERAL.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by inserting after subsection (e) the following:

''(f) EXCLUSION OF CERTAIN STERILE INJECTABLE PRODUCTS.—

''(1) IN GENERAL.—For purposes of this section (including with respect to the prohibition described in subsection (a)(5)(L)(iii)), the term 'covered outpatient drug' shall not include a drug that is described in section 1847A(b)(9)(C) of the Social Security Act, that is furnished on or after July 1, 2013, and before January 1, 2020, and for which payment may be made under part B of title XVIII of such Act.

''(2) GUIDANCE.—Not later than July 1, 2013, the Secretary shall publish guidance on the exclusion

of certain sterile injectable products under paragraph (1).''.

(d) STUDY AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall contract with an independent entity to study the effects of the amendments made by this section on patient access to sterile injectable products.

(2) REPORT.—As a condition of the contract described under paragraph (1), the independent entity shall agree to submit to Congress and such Secretary, not later than 3 years after the date of enactment of this Act, a report that describes the results of the study conducted under paragraph (1).

SEC. 3. EXCLUSION OF BRANDED PRESCRIPTION DRUGS FROM ANNUAL FEE DURING PERIODS OF SHORTAGE.

(a) IN GENERAL.—Subsection (e) of section 9008 of the Patient Protection and Affordable Care Act is amended by redesignating paragraph (4) as paragraph (5) and by inserting after paragraph (3) the following new paragraph:

''(4) EXCLUSION DURING SHORTAGE.—The term 'branded prescription drug sales' shall not include sales of any branded prescription drug that—

"(A) is on the drug shortage list maintained under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), and

"(B)(i) is the listed drug (as defined in section 505(j)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)(i)) for a drug for which the approval of an application under section 505(j) of such Act (21 U.S.C. 355(j)) is in effect, or

"(ii) is the reference product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) for a biological product for which the approval of an application under section 351(k) of such Act (42 U.S.C. 262(j)) is in effect.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to sales after the date of the enactment of this Act.

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