118TH CONGRESS
1ST SESSION

S. 2683

To establish requirements for purchasing certain generic drugs from manufacturers who produce the drug domestically.

IN THE SENATE OF THE UNITED STATES

JULY 27, 2023

Mr. SCOTT of Florida introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To establish requirements for purchasing certain generic drugs from manufacturers who produce the drug domestically.

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 ''Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for US Government Services Act'' or the ''AMERICAN DRUGS Act''.

SEC. 2. FDA NOTIFICATION.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of

Food and Drugs (referred to in this section as the ''Commissioner''), shall issue notifications to the Administrator of the Centers for Medicare & Medicaid Services, the Secretary of Defense, and the Secretary of Veterans Affairs upon a determination by the Commissioner that—

(1) there are at least 2 approved generic drugs that are manufactured domestically, as described in subsection (b), each of which—

(A) is approved pursuant to an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); and

(B) references the same listed drug under paragraph (7) of such section 505(j); or

(2) there are fewer than 2 approved generic drugs that are manufactured domestically—

(A) approved pursuant to an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); and

(B) that reference the same listed drug under paragraph (7) of such section 505(j) as another drug approved under such section 505(j);

(3) paragraph (1)(B) may soon apply because the Commissioner has been notified that a holder of an approved application for a generic drug that is manufactured domestically, as described in subsection (b), plans to discontinue manufacturing, or expects an interruption of the manufacture of, such drug at an establishment described in subsection (b)(1)(B); or

(4) a generic drug that is manufactured domestically, as described in subsection (b), is in shortage, as defined in section 506C(h)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(h)(2)).

(b) GENERIC DRUG MANUFACTURED DOMESTICALLY DESCRIBED.—In this section, a generic drug that is manufactured domestically—

(1) is a drug—

(A) that is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); and

(B) for which there is at least one establishment registered under section 510(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)(1)) engaged in the manufacture of the finished dosage form of the drug; and

(2) excludes any authorized generic drug, as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)(3)).

(c) SPECIAL RULE CONCERNING GENERIC DRUGS IN SHORTAGE.—A notification under subsection (a)(4) that a generic drug that is manufactured domestically, as described in subsection (b), is in shortage, shall apply only for—

(1) an initial period of not more than 90 days; and

(2) such additional 30-day renewal periods as the Secretary of Health and Human Services may indicate by—

(A) submitting to Congress a notification of intent to renew the notification under subsection (a)(4); and

(B) publicly posting information about the shortage, the steps the Food and Drug Administration is taking to address the shortage, and an estimated date by which the shortage is expected to be resolved.

SEC. 3. EXPEDITED CONSIDERATION OF CERTAIN ABBREVIATED NEW DRUG APPLICATIONS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506L the following:

"SEC. 506M. EXPEDITED CONSIDERATION OF CERTAIN ABBREVIATED NEW DRUG APPLICATIONS.

''(a) IN GENERAL.—The Secretary may, at the request of a sponsor of an application for an applicable drug, expedite the development and review of an abbreviated new drug application under section 505(j) for such drug.

''(b) APPLICABLE DRUG.—For purposes of this section, an applicable drug is a drug for which there are fewer than 2 drugs approved under section 505(j) that are manufactured domestically, as described in paragraph (2), each of which is approved pursuant to an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) and references the same listed drug under paragraph (7) of such section 505(j).

''(c) ACTIONS.—In expediting the development and review of an application under subsection (a), the Secretary may, as requested by the applicant, take actions including the following:

''(1) Hold meetings with the applicant and the review team throughout the development of the drug

prior to submission of the application for such drug under section 505(j).

''(2) Provide timely advice to, and interactive communication with, the applicant regarding the development of the drug to ensure that the development program to gather the data necessary for approval is as efficient as practicable.

''(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of such application, including with respect to drug-device combination products and other complex products.

''(4) Assign a cross-disciplinary project lead—

''(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

''(B) to serve as a scientific liaison between the review team and the applicant.

''(d) REPORTING REQUIREMENT.—Not later than one year after the date of the approval of an application under section 505(j) with respect to a drug for which the development and review is expedited under this section, the sponsor of such drug shall report to the Secretary on whether the drug has been marketed in interstate commerce since the date of such approval.''.

SEC. 4. PROHIBITION OF PAYMENT UNDER MEDICARE PART B OR COVERAGE UNDER MEDICARE PART D FOR CERTAIN GENERIC DRUGS MANUFACTURED OUTSIDE OF THE UNITED STATES.

(a) MEDICARE PART B.—Section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o)) is amended by adding at the end the following new paragraph:

''(9)(A) Payment shall only be made under this part for a generic drug furnished on or after January 1, 2025, if it is a generic drug manufactured domestically (as described in section 2(b) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act).

''(B) Subparagraph (A) shall not apply, with respect to a drug, during any period for which the Secretary—

''(i) has notified the Administrator of the Centers for Medicare & Medicaid Services pursuant to section 2(a) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act that the circumstances under paragraph (2), (3), or (4) of such section apply; or

''(ii) otherwise determines that access to the drug is essential to the health of beneficiaries under this part.''.

(b) MEDICARE PART D.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

''(e) PROHIBITION OF COVERAGE FOR CERTAIN GENERIC DRUGS MANUFACTURED OUTSIDE OF THE UNITED STATES.—

''(1) IN GENERAL.—Coverage shall only be available under this part for a covered part D drug that is a generic drug dispensed on or after January 1, 2025, if it is a generic drug manufactured domestically (as described in section 2(b) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act).

''(2) EXCEPTIONS.—Paragraph (1) shall not apply, with respect to a covered part D drug, during any period for which the Secretary—

''(A) has notified the Administrator of the Centers for Medicare & Medicaid Services pursuant to section 2(a) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act that the circumstances under paragraph (2), (3), or (4) of such section apply; or

''(B) otherwise determines that access to the drug is essential to the health of beneficiaries under this part.''.

SEC. 5. PROHIBITION OF PAYMENT UNDER MEDICAID AND CHIP FOR CERTAIN GENERIC DRUGS MANUFACTURED OUTSIDE OF THE UNITED STATES.

(a) MEDICAID.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended—

(1) in section 1903(i)(10)—

(A) in subparagraph (D), by striking ''; and'' and inserting a semicolon;

(B) in subparagraph (E), by striking ''; or'' and inserting ''; and''; and

(C) by inserting after subparagraph (E) the following new subparagraph:

''(F) with respect to any amount expended for a covered outpatient drug which the State is required to exclude from coverage under section 1927(d)(8); or''; and

(2) in section 1927(d), by adding at the end the following new paragraph:

''(8) RESTRICTION ON COVERAGE OF FOREIGN-MADE GENERIC DRUGS.—

''(A) IN GENERAL.—Beginning January 1, 2025, a State shall exclude coverage of a for-

eign-made generic covered outpatient drug if there is a generic drug that is manufactured domestically (as described in section 2(b) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act) that references the same listed drug under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act as the foreign-made generic covered outpatient drug.

''(B) DEFINITION OF FOREIGN-MADE GENERIC COVERED OUTPATIENT DRUG.—For purposes of this paragraph, the term 'foreign-made generic covered outpatient drug' means a covered outpatient drug that—

''(i) is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) is not a generic drug that is manufactured domestically (as described in section 2(b) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act).

''(C) EXCEPTIONS.—Subparagraph (A) shall not apply to a foreign-made generic covered outpatient drug during any period for which the Secretary—

''(i) has notified the Administrator of the Centers for Medicare & Medicaid Services pursuant to section 2(a) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act that the circumstances under paragraph (2), (3), or (4) of such section apply with respect to such drug; or

''(ii) otherwise determines that access to the foreign-made generic covered outpatient drug is essential to the health of individuals enrolled for medical assistance under this title.

''(D) NOTICE TO STATES.—The Secretary shall provide notice to States if a foreign-made generic covered outpatient drug is subject to exclusion from coverage under this paragraph.''.

(b) CHIP.—Section 2107(e)(1)(M) of the Social Security Act (42 U.S.C. 1397gg(e)(1)(M)) is amended by inserting ''(10)(F),'' after ''(2),''.

SEC. 6. PROCUREMENT BY DEPARTMENT OF VETERANS AFFAIRS OF GENERIC DRUGS MANUFACTURED DOMESTICALLY.

(a) IN GENERAL.—Subchapter II of chapter 81 of title 38, United States Code, is amended by inserting after section 8126 the following new section:

"§ 8126A. Procurement of generic drugs manufactured domestically

''(a) IN GENERAL.—Subject to subsection (b), the Secretary may only procure a generic drug if it is a generic drug manufactured domestically, as described in section 2(b) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act.

''(b) EXCEPTIONS.—Subsection (a) shall not apply with respect to a drug during any period for which—

''(1) the Secretary of Health and Human Services has notified the Secretary of Veterans Affairs pursuant to section 2(a) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act that the circumstances under paragraph (2), (3), or (4) of such section apply; or

''(2) the Secretary of Veterans Affairs determines that access to the drug is essential to the

health of beneficiaries under the laws administered by the Secretary.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such subchapter is amended by inserting after the item relating to section 8126 the following new item:

''8126A. Procurement of generic drugs manufactured domestically.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2025.

SEC. 7. PROCUREMENT BY DEPARTMENT OF DEFENSE OF GENERIC DRUGS MANUFACTURED DOMESTICALLY.

(a) IN GENERAL.—Chapter 55 of title 10, United States Code, is amended by inserting after section 1074g the following new section:

''§ 1074g–1. Procurement of generic drugs manufactured domestically

''(a) IN GENERAL.—Subject to subsection (b), the Secretary of Defense may only procure a generic drug if it is a generic drug manufactured domestically, as described in section 2(b) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act.

''(b) EXCEPTIONS.—Subsection (a) shall not apply with respect to a drug during any period for which—

''(1) the Secretary of Health and Human Services has notified the Secretary of Defense pursuant to section 2(a) of the Accelerating Movement of Essential Rx Items to Create Access to National Drug Resources for U.S. Government Services Act that the circumstances under paragraph (2), (3), or (4) of such section apply; or

''(2) the Secretary of Defense determines that access to the drug is essential to the health of beneficiaries under the TRICARE program.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 1074g the following new item:

''1074g–1. Procurement of generic drugs manufactured domestically.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2025.

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