

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

A BILL

To establish requirements for purchasing certain generic
drugs from manufacturers who produce the drug domes-
tically.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Accelerating Movement
5 of Essential Rx Items to Create Access to National Drug
6 Resources for US Government Services Act” or the
7 “AMERICAN DRUGS Act”.

8 **SEC. 2. FDA NOTIFICATION.**

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

1 Food and Drugs (referred to in this section as the “Com-
2 missioner”), shall issue notifications to the Administrator
3 of the Centers for Medicare & Medicaid Services, the Sec-
4 retary of Defense, and the Secretary of Veterans Affairs
5 upon a determination by the Commissioner that—

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

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

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

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

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

21 (B) that reference the same listed drug
22 under paragraph (7) of such section 505(j) as
23 another drug approved under such section
24 505(j);

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

9 (4) a generic drug that is manufactured domes-
10 tically, as described in subsection (b), is in shortage,
11 as defined in section 506C(h)(2) of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C.
13 356c(h)(2)).

14 (b) GENERIC DRUG MANUFACTURED DOMESTICALLY
15 DESCRIBED.—In this section, a generic drug that is man-
16 ufactured domestically—

17 (1) is a drug—

18 (A) that is approved under section 505(j)
19 of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 355(j)); and

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

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

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

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

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

14 (A) submitting to Congress a notification
15 of intent to renew the notification under sub-
16 section (a)(4); and

17 (B) publicly posting information about the
18 shortage, the steps the Food and Drug Admin-
19 istration is taking to address the shortage, and
20 an estimated date by which the shortage is ex-
21 pected to be resolved.

1 **SEC. 3. EXPEDITED CONSIDERATION OF CERTAIN ABBRE-**
2 **VIATED NEW DRUG APPLICATIONS.**

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

6 **“SEC. 506M. EXPEDITED CONSIDERATION OF CERTAIN AB-**
7 **BREVIATED NEW DRUG APPLICATIONS.**

8 “(a) IN GENERAL.—The Secretary may, at the re-
9 quest of a sponsor of an application for an applicable drug,
10 expedite the development and review of an abbreviated
11 new drug application under section 505(j) for such drug.

12 “(b) APPLICABLE DRUG.—For purposes of this sec-
13 tion, an applicable drug is a drug for which there are fewer
14 than 2 drugs approved under section 505(j) that are man-
15 ufactured domestically, as described in paragraph (2),
16 each of which is approved pursuant to an application
17 under section 505(j) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355(j)) and references the same list-
19 ed drug under paragraph (7) of such section 505(j).

20 “(c) ACTIONS.—In expediting the development and
21 review of an application under subsection (a), the Sec-
22 retary may, as requested by the applicant, take actions
23 including the following:

24 “(1) Hold meetings with the applicant and the
25 review team throughout the development of the drug

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

3 “(2) Provide timely advice to, and interactive
4 communication with, the applicant regarding the de-
5 velopment of the drug to ensure that the develop-
6 ment program to gather the data necessary for ap-
7 proval is as efficient as practicable.

8 “(3) Involve senior managers and experienced
9 review staff, as appropriate, in a collaborative, co-
10 ordinated review of such application, including with
11 respect to drug-device combination products and
12 other complex products.

13 “(4) Assign a cross-disciplinary project lead—

14 “(A) to facilitate an efficient review of the
15 development program and application, including
16 manufacturing inspections; and

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

19 “(d) REPORTING REQUIREMENT.—Not later than
20 one year after the date of the approval of an application
21 under section 505(j) with respect to a drug for which the
22 development and review is expedited under this section,
23 the sponsor of such drug shall report to the Secretary on
24 whether the drug has been marketed in interstate com-
25 merce since the date of such approval.”.

1 **SEC. 4. PROHIBITION OF PAYMENT UNDER MEDICARE**
2 **PART B OR COVERAGE UNDER MEDICARE**
3 **PART D FOR CERTAIN GENERIC DRUGS MAN-**
4 **UFACTURED OUTSIDE OF THE UNITED**
5 **STATES.**

6 (a) MEDICARE PART B.—Section 1842(o) of the So-
7 cial Security Act (42 U.S.C. 1395u(o)) is amended by add-
8 ing at the end the following new paragraph:

9 “(9)(A) Payment shall only be made under this part
10 for a generic drug furnished on or after January 1, 2025,
11 if it is a generic drug manufactured domestically (as de-
12 scribed in section 2(b) of the Accelerating Movement of
13 Essential Rx Items to Create Access to National Drug Re-
14 sources for U.S. Government Services Act).

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

17 “(i) has notified the Administrator of the Cen-
18 ters for Medicare & Medicaid Services pursuant to
19 section 2(a) of the Accelerating Movement of Essen-
20 tial Rx Items to Create Access to National Drug Re-
21 sources for U.S. Government Services Act that the
22 circumstances under paragraph (2), (3), or (4) of
23 such section apply; or

24 “(ii) otherwise determines that access to the
25 drug is essential to the health of beneficiaries under
26 this part.”.

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

4 “(e) PROHIBITION OF COVERAGE FOR CERTAIN GE-
5 NERIC DRUGS MANUFACTURED OUTSIDE OF THE UNITED
6 STATES.—

7 “(1) IN GENERAL.—Coverage shall only be
8 available under this part for a covered part D drug
9 that is a generic drug dispensed on or after January
10 1, 2025, if it is a generic drug manufactured domes-
11 tically (as described in section 2(b) of the Accel-
12 erating Movement of Essential Rx Items to Create
13 Access to National Drug Resources for U.S. Govern-
14 ment Services Act).

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

18 “(A) has notified the Administrator of the
19 Centers for Medicare & Medicaid Services pur-
20 suant to section 2(a) of the Accelerating Move-
21 ment of Essential Rx Items to Create Access to
22 National Drug Resources for U.S. Government
23 Services Act that the circumstances under para-
24 graph (2), (3), or (4) of such section apply; or

1 “(B) otherwise determines that access to
2 the drug is essential to the health of bene-
3 ficiaries under this part.”.

4 **SEC. 5. PROHIBITION OF PAYMENT UNDER MEDICAID AND**
5 **CHIP FOR CERTAIN GENERIC DRUGS MANU-**
6 **FACTURED OUTSIDE OF THE UNITED STATES.**

7 (a) MEDICAID.—Title XIX of the Social Security Act
8 (42 U.S.C. 1396 et seq.) is amended—

9 (1) in section 1903(i)(10)—

10 (A) in subparagraph (D), by striking “;
11 and” and inserting a semicolon;

12 (B) in subparagraph (E), by striking “;
13 or” and inserting “; and”; and

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

16 “(F) with respect to any amount expended for
17 a covered outpatient drug which the State is re-
18 quired to exclude from coverage under section
19 1927(d)(8); or”; and

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

22 “(8) RESTRICTION ON COVERAGE OF FOREIGN-
23 MADE GENERIC DRUGS.—

24 “(A) IN GENERAL.—Beginning January 1,
25 2025, a State shall exclude coverage of a for-

1 eign-made generic covered outpatient drug if
2 there is a generic drug that is manufactured
3 domestically (as described in section 2(b) of the
4 Accelerating Movement of Essential Rx Items
5 to Create Access to National Drug Resources
6 for U.S. Government Services Act) that ref-
7 erences the same listed drug under section
8 505(j)(7) of the Federal Food, Drug, and Cos-
9 metic Act as the foreign-made generic covered
10 outpatient drug.

11 “(B) DEFINITION OF FOREIGN-MADE GE-
12 NERIC COVERED OUTPATIENT DRUG.—For pur-
13 poses of this paragraph, the term ‘foreign-made
14 generic covered outpatient drug’ means a cov-
15 ered outpatient drug that—

16 “(i) is approved under section 505(j)
17 of the Federal Food, Drug, and Cosmetic
18 Act; and

19 “(ii) is not a generic drug that is
20 manufactured domestically (as described in
21 section 2(b) of the Accelerating Movement
22 of Essential Rx Items to Create Access to
23 National Drug Resources for U.S. Govern-
24 ment Services Act).

1 “(C) EXCEPTIONS.—Subparagraph (A)
2 shall not apply to a foreign-made generic cov-
3 ered outpatient drug during any period for
4 which the Secretary—

5 “(i) has notified the Administrator of
6 the Centers for Medicare & Medicaid Serv-
7 ices pursuant to section 2(a) of the Accel-
8 erating Movement of Essential Rx Items to
9 Create Access to National Drug Resources
10 for U.S. Government Services Act that the
11 circumstances under paragraph (2), (3), or
12 (4) of such section apply with respect to
13 such drug; or

14 “(ii) otherwise determines that access
15 to the foreign-made generic covered out-
16 patient drug is essential to the health of
17 individuals enrolled for medical assistance
18 under this title.

19 “(D) NOTICE TO STATES.—The Secretary
20 shall provide notice to States if a foreign-made
21 generic covered outpatient drug is subject to ex-
22 clusion from coverage under this paragraph.”.

23 (b) CHIP.—Section 2107(e)(1)(M) of the Social Se-
24 curity Act (42 U.S.C. 1397gg(e)(1)(M)) is amended by in-
25 serting “(10)(F),” after “(2),”.

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

3
4 (a) IN GENERAL.—Subchapter II of chapter 81 of
5 title 38, United States Code, is amended by inserting after
6 section 8126 the following new section:

7 **“§ 8126A. Procurement of generic drugs manufactured**
8 **domestically**

9 “(a) IN GENERAL.—Subject to subsection (b), the
10 Secretary may only procure a generic drug if it is a generic
11 drug manufactured domestically, as described in section
12 2(b) of the Accelerating Movement of Essential Rx Items
13 to Create Access to National Drug Resources for U.S.
14 Government Services Act.

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

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

24 “(2) the Secretary of Veterans Affairs deter-
25 mines that access to the drug is essential to the

1 health of beneficiaries under the laws administered
2 by the Secretary.”.

3 (b) CLERICAL AMENDMENT.—The table of sections
4 at the beginning of such subchapter is amended by insert-
5 ing after the item relating to section 8126 the following
6 new item:

“8126A. Procurement of generic drugs manufactured domestically.”.

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

9 **SEC. 7. PROCUREMENT BY DEPARTMENT OF DEFENSE OF**
10 **GENERIC DRUGS MANUFACTURED DOMESTI-**
11 **CALLY.**

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

15 **“§ 1074g–1. Procurement of generic drugs manufac-**
16 **tured domestically**

17 “(a) IN GENERAL.—Subject to subsection (b), the
18 Secretary of Defense may only procure a generic drug if
19 it is a generic drug manufactured domestically, as de-
20 scribed in section 2(b) of the Accelerating Movement of
21 Essential Rx Items to Create Access to National Drug Re-
22 sources for U.S. Government Services Act.

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

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

8 “(2) the Secretary of Defense determines that
9 access to the drug is essential to the health of bene-
10 ficiaries under the TRICARE program.”.

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

 “1074g-1. Procurement of generic drugs manufactured domestically.”.

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

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