

117TH CONGRESS
2D SESSION

S. 3991

To direct the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States.

IN THE SENATE OF THE UNITED STATES

APRIL 5, 2022

Ms. SMITH (for herself and Mr. COTTON) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To direct the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States.

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 “American Made Phar-
5 maceuticals Act of 2022”.

1 **SEC. 2. DEMONSTRATION PROGRAM TO TEST PROVIDING**
2 **PREFERENTIAL TREATMENT UNDER THE**
3 **MEDICARE, MEDICAID, AND CHIP PROGRAMS**
4 **FOR CERTAIN DRUGS AND BIOLOGICALS**
5 **MANUFACTURED IN THE UNITED STATES.**

6 Part A of title XI of the Social Security Act (42
7 U.S.C. 1301 et seq.) is amended by inserting after section
8 1150C the following:

9 **“SEC. 1150D. DEMONSTRATION PROGRAM TO TEST PRO-**
10 **VIDING PREFERENTIAL TREATMENT UNDER**
11 **THE MEDICARE, MEDICAID, AND CHIP PRO-**
12 **GRAMS FOR CERTAIN DRUGS AND**
13 **BIOLOGICALS MANUFACTURED IN THE**
14 **UNITED STATES.**

15 “(a) IN GENERAL.—Not later than 1 year after the
16 date of enactment of this section, the Secretary shall con-
17 duct a demonstration program (in this section referred to
18 as the ‘Program’) under which U.S. manufactured drugs
19 are given preference under titles XVIII, XIX, and XXI
20 compared to drugs that are not U.S. manufactured drugs
21 through the use of applicable tools.

22 “(b) SITES.—The Program shall be conducted in at
23 least 8 States.

24 “(c) DURATION.—The Secretary shall conduct the
25 Program for a period of not less than 7 years.

26 “(d) DEFINITIONS.—In this section:

1 “(1) APPLICABLE DRUG.—The term ‘applicable
2 drug’ means—

3 “(A) a drug that is approved and marketed
4 under section 505(j) of the Federal Food,
5 Drug, and Cosmetic Act;

6 “(B) a biological product that is licensed
7 and marketed under section 351(k) of the Pub-
8 lic Health Service Act; or

9 “(C) a critical drug.

10 “(2) APPLICABLE U.S.-BASED PHARMA-
11 CEUTICAL COMPANY.—The term ‘applicable U.S.-
12 based pharmaceutical company’ means a manufac-
13 turer (as defined in section 1860D–14A(g)(5))—

14 “(A) that has a manufacturing location in
15 the United States for an applicable drug;

16 “(B) beginning 3 years after the date of
17 the implementation of the Program, for which
18 at least 50 percent of the starter products, by
19 weight, for the applicable drugs manufactured
20 by manufacturer are derived from countries
21 other than covered nations (as defined in sec-
22 tion 4871(d)(2) of title 10, United States
23 Code); and

24 “(C) that, as determined by the Sec-
25 retary—

1 “(i) maintains an appropriate level of
 2 transparency on locations of manufac-
 3 turing;

4 “(ii) maintains an appropriate level of
 5 diversity in sourcing;

6 “(iii) maintains appropriate levels of
 7 inventory and emergency reserves;

8 “(iv) has in place an appropriate ac-
 9 tion plan for increases in demand and for
 10 when links in the supply chain break down;
 11 and

12 “(v) meets any other characteristics
 13 the Secretary determines appropriate.

14 “(3) APPLICABLE TOOLS.—The term ‘applica-
 15 ble tools’ means tools determined appropriate by the
 16 Secretary, such as—

17 “(A) preferential treatment on a for-
 18 mulary;

19 “(B) providing lower cost-sharing;

20 “(C) waiving rebates under the Medicaid
 21 program under title XIX;

22 “(D) establishing a Medicare Star Rating
 23 under part D of title XVIII; or

1 “(E) providing bonus payments to pro-
2 viders of services and suppliers under part B of
3 title XVIII.

4 “(4) CRITICAL DRUG.—In this section, the term
5 ‘critical drug’ includes the following:

6 “(A) A medicine, medical countermeasure,
7 or critical input identified on the list under sec-
8 tion 3(c) of Executive Order 13944 of August
9 6, 2020 (85 Red. Reg 49929; relating to essen-
10 tial medicines, medical Countermeasures, and
11 critical inputs).

12 “(B) A drug or biological that—

13 “(i) is not described in subparagraph
14 (A);

15 “(ii) is approved and marketed under
16 section 505(c) of the Federal Food, Drug,
17 and Cosmetic Act or is licensed and mar-
18 keted under section 351(a) of the Public
19 Health Service Act (or is an active phar-
20 maceutical ingredient of such a drug or bi-
21 ological);

22 “(iii) the Secretary determines—

23 “(I) is—

1 “(aa) likely to be needed for
2 use in a public health emergency;
3 or

4 “(bb) at high risk of short
5 supply; and

6 “(II) has a vulnerable global sup-
7 ply chain.

8 “(5) U.S. MANUFACTURED DRUG.—The term
9 ‘U.S. manufactured drug’ means an applicable drug
10 that is manufactured in the United States by an ap-
11 plicable U.S.-based pharmaceutical company.

12 “(e) ANNUAL REPORT TO CONGRESS.—Not later
13 than 1 year after the date the Secretary implements the
14 Program, and annually thereafter for as long as the Pro-
15 gram is being conducted, the Secretary shall submit to
16 Congress a report on activities under the Program, to-
17 gether with recommendations for such legislation and ad-
18 ministrative action as the Secretary determines to be ap-
19 propriate.

20 “(f) WAIVERS.—The Secretary may waive such provi-
21 sions of this title and titles XVIII, XIX, and XXI as the
22 Secretary determines necessary in order to implement the
23 Program

24 “(g) ADMINISTRATIVE FUNDING.—There is author-
25 ized to be appropriated to the Secretary such sums as may

- 1 be necessary for the administrative expenses of carrying
- 2 out the Program, to remain available until expended.”.

