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117TH CONGRESS
2D SESSION

H. R. 7400

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 HOUSE OF REPRESENTATIVES

APRIL 5, 2022

Ms. CRAIG (for herself and Mr. MULLIN) 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 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.

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 ''American Made Pharmaceuticals Act of 2022''.

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

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

"SEC. 1150D. DEMONSTRATION PROGRAM TO TEST PROVIDING PREFERENTIAL TREATMENT UNDER THE MEDICARE, MEDICAID, AND CHIP PROGRAMS FOR CERTAIN DRUGS AND BIOLOGICALS MANUFACTURED IN THE UNITED STATES.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall conduct a demonstration program (in this section referred to as the 'Program') under which U.S. manufactured drugs are given preference under titles XVIII, XIX, and XXI compared to drugs that are not U.S. manufactured drugs through the use of applicable tools.

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

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

''(d) DEFINITIONS.—In this section:

"(1) APPLICABLE DRUG.—The term 'applicable drug' means—

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

"(B) a biological product that is licensed and marketed under section 351(k) of the Public Health Service Act; or

"(C) a critical drug.

"(2) APPLICABLE U.S.-BASED PHARMACEUTICAL COMPANY.—The term 'applicable U.S.-based pharmaceutical company' means a manufacturer (as defined in section 1860D–14A(g)(5))—

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

"(B) beginning 3 years after the date of the implementation of the Program, for which at least 50 percent of the starter products, by weight, for the applicable drugs manufactured by manufacturer are derived from countries other than covered nations (as defined in section 4871(d)(2) of title 10, United States Code); and

"(C) that, as determined by the Secretary—

"(i) maintains an appropriate level of transparency on locations of manufacturing;

"(ii) maintains an appropriate level of diversity in sourcing;

"(iii) maintains appropriate levels of inventory and emergency reserves;

"(iv) has in place an appropriate action plan for increases in demand and for when links in the supply chain break down; and

"(v) meets any other characteristics the Secretary determines appropriate.

"(3) APPLICABLE TOOLS.—The term 'applicable tools' means tools determined appropriate by the Secretary, such as—

"(A) preferential treatment on a formulary;

"(B) providing lower cost-sharing;

"(C) waiving rebates under the Medicaid program under title XIX;

"(D) establishing a Medicare Star Rating under part D of title XVIII; or

''(E) providing bonus payments to providers of services and suppliers under part B of title XVIII.

''(4) CRITICAL DRUG.—In this section, the term 'critical drug' includes the following:

''(A) A medicine, medical countermeasure, or critical input identified on the list under section 3(c) of Executive Order 13944 of August 6, 2020 (85 Red. Reg 49929; relating to essential medicines, medical Countermeasures, and critical inputs).

''(B) A drug or biological that—

''(i) is not described in subparagraph (A);

''(ii) is approved and marketed under section 505(c) of the Federal Food, Drug, and Cosmetic Act or is licensed and marketed under section 351(a) of the Public Health Service Act (or is an active pharmaceutical ingredient of such a drug or biological); and

''(iii) the Secretary determines—

''(I) is—

"(aa) likely to be needed for use in a public health emergency; or

"(bb) at high risk of short supply; and

"(II) has a vulnerable global supply chain.

"(5) U.S. MANUFACTURED DRUG.—The term 'U.S. manufactured drug' means an applicable drug that is manufactured in the United States by an applicable U.S.-based pharmaceutical company.

"(e) ANNUAL REPORT TO CONGRESS.—Not later than 1 year after the date the Secretary implements the Program, and annually thereafter for as long as the Program is being conducted, the Secretary shall submit to Congress a report on activities under the Program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

"(f) WAIVERS.—The Secretary may waive such provisions of this title and titles XVIII, XIX, and XXI as the Secretary determines necessary in order to implement the Program.

"(g) ADMINISTRATIVE FUNDING.—There is authorized to be appropriated to the Secretary such sums as may

be necessary for the administrative expenses of carrying out the Program, to remain available until expended.''.

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