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116TH CONGRESS
2D SESSION

H. R. 8479

To amend the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 1, 2020

Mr. CARTER of Georgia (for himself and Ms. BLUNT ROCHESTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, 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 ''Essential Medicines Strategic Stockpile Act of 2020''.

SEC. 2. PILOT PROGRAM ON ENSURING MEDICATION SUPPLY STABILITY.

Part D of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following new subpart:

"Subpart XIII—Ensuring Medication Supply Stability

"SEC. 340J. ENSURING MEDICATION SUPPLY STABILITY.

''(a) AWARD OF CONTRACTS.—Beginning not later than January 1, 2021, the Secretary shall award contracts to eligible entities to each implement and test the effectiveness of acquiring, maintaining, managing, and distributing a stockpile that—

''(1) consists of generic drugs at risk of shortage; and

''(2) is of sufficient quantity to ensure that customers in the United States of the respective eligible entity have access to such drugs for at least 6 months (as specified by the Secretary based on the historic demand for those drugs).

''(b) SELECTION OF DRUGS.—

''(1) IN GENERAL.—The Secretary shall—

''(A) select not more than 50 types of drugs that may be included by eligible entities in a stockpile pursuant to a contract under this section; and

''(B) maintain an up-to-date list of such drugs; and

''(C) make such list publicly available.

''(2) CHOICE OF ELIGIBLE ENTITIES.—A contract awarded to an eligible entity under this section need not require the stockpile of the eligible entity to include all 50 types of drugs listed pursuant to paragraph (1).

''(c) SUFFICIENT QUANTITY.—For each generic drug in a stockpile maintained pursuant to subsection (a), the Secretary shall specify the quantity of such drug that is sufficient for purposes of such subsection to ensure that consumers in the United States of the respective eligible entity have access to such drug for at least 6 months.

''(d) DURATION; LIQUIDATION OF INVENTORY.—

''(1) DURATION.—A contract awarded under this section shall be for a term of no more than 3 years.

''(2) LIQUIDATION OF INVENTORY.—A drug held in a stockpile pursuant to a contract under this section may be liquidated by the eligible entity at the end of the period of the contract.

''(e) STOCKPILE REQUIREMENTS.—

''(1) ENSURING AVAILABILITY OF UNEXPIRED PRODUCTS.—Each eligible entity with a contract

under this section for a stockpile of generic drugs at risk of shortage shall—

''(A) ensure that each drug maintained in the stockpile has an expiration date at least 1 year beyond the current date; and

''(B) to comply with subparagraph (A)—

''(i) sell drugs in the stockpile through normal commercial channels and replace those drugs; or

''(ii) if there is no commercial market for a drug in the stockpile, dispose of the drug, report such disposal to the Secretary, and replace the drug.

''(2) MANAGEMENT OF STOCKPILE.—

''(A) IN GENERAL.—Each eligible entity with a contract under this section for a stockpile of generic drugs at risk of shortage shall—

''(i) acquire not later than 6 months following the date the contract is awarded, and maintain thereafter, a 6-month supply of each type of drug the eligible entity has contracted to stockpile, which 6-month supply shall be in addition to the average levels of inventory held by such eligible en-

tity over the previous year for such drug; and

"(ii) if it is not possible to comply with clause (i), notify the Secretary, citing the reason why it is not possible and the expected time of acquisition of the drug.

"(B) INVENTORY MANAGEMENT.—Each eligible entity with a contract under this section for a stockpile of generic drugs at risk of shortage shall manage inventory to ensure that drugs in the stockpile are efficiently cycled to the commercial market and—

"(i) may stockpile inventory at the eligible entity's distribution center with specified inventory amounts virtually reserved for the Federal Government with constant cycling to reduce product expiration; or

"(ii) may store stockpiled inventory separately in a different location and replace drugs in the stockpile inventory with the same drug with newer dating.

"(C) INSUFFICIENT FUNDS.—If amounts available to an eligible entity through contracts under this section are not sufficient to acquire or maintain a 6-month supply of any drug in

the stockpile of the eligible entity funded under this section, the eligible entity—

"(i) may acquire and maintain less than a 6-month supply, but in no case less than a 3-month supply; and

"(ii) shall submit a report to the Secretary identifying—

"(I) each such drug; and

"(II) the reasons why such amounts are not sufficient to acquire or maintain a 6-month supply.

"(D) ANNUAL AUDITS.—Not more than annually, the Secretary may request a physical audit count of the inventories of all eligible entities with a contract under this section to validate that each such entity is maintaining the appropriate amount of stockpiled inventory.

"(3) PERIODIC PRODUCT REVIEW.—

"(A) USE OF PROCEEDS.—An eligible entity with a contract under this section for a stockpile of generic drugs at risk of shortage shall use the proceeds of the sale of any drugs in the stockpile to purchase drugs for the stockpile in accordance with this section.

"(B) MARKET INFLATION OR DEFLATION.—In the case of market inflation or deflation affecting the price of a drug in the stockpile of an eligible entity maintained pursuant to a contract under this section, the contract shall ensure that the Federal Government does not profit or suffer loss on items of such drug as a result of such inflation or deflation.

"(4) REPORTING.—Each eligible entity with a contract under this section shall submit reports at such time and in such manner as the Secretary may require regarding—

"(A) current inventory levels of stockpiled drugs at a drug level;

"(B) indicators of current inventory levels of stockpiled drugs relative to acceptable minimums; and

"(C) such other matters as the Secretary determines appropriate.

"(f) CONTRACT TERMS.—

"(1) PAYMENT OF MONTHLY FEES FOR MANAGEMENT.—Subject to paragraph (2), the Secretary shall pay to each eligible entity with a contract under this section for a stockpile of generic drugs at

risk of shortage appropriate monthly fees for the management of the stockpile.

''(2) PAYMENT CONDITIONED ON STOCKPILE ADEQUACY.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each contract with an eligible entity under this section shall provide that no payment under the contract may be made until the entity demonstrates to the Secretary that the entity has stockpiled such portion of the total quantity of drugs to be stockpiled under the contract as the Secretary determines to be acceptable for payment.

''(B) EXCEPTIONS FOR ADVANCE PAYMENTS.—

''(i) IN GENERAL.—A contract under this section may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase capacity is necessary to ensure success of the terms of the contract, the Secretary shall pay, in advance of delivery, an amount not to exceed 10 percent of the total contract amount to be

paid to the eligible entity by the Secretary pursuant to the contract over the full period of the contract.

''(ii) COST OF CAPITAL.—A contract under this section may provide for payments to compensate the contracting eligible entity for additional capital requirements related to the additional inventory to be maintained.

''(iii) TIMING.—The Secretary shall, to the extent practicable, make any determination under clause (i) to make an advance payment at the same time as the issuance of a solicitation.

''(iv) REPAYMENT.—If the Secretary makes an advance payment pursuant to clause (i), the Secretary shall require the eligible entity receiving such advance payment to repay it if there is a failure to perform by the eligible entity.

''(3) TERMINATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), nothing in this section shall be construed as affecting the rights of eligible entities under provisions of statute or regulation (in-

cluding the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

''(B) LIQUIDATION OF STOCKPILE.—If a contract under this section is terminated, the eligible entity with the contract shall liquidate the drugs comprising the stockpile funded through the contract and return to the Government any amounts owed in relation to such drugs, but shall collect the management fees associated with such liquidation.

''(g) CONGRESSIONAL OVERSIGHT.—

''(1) INDEPENDENT EVALUATION AND REPORT.—Not later than 1 year after the date of enactment of this section and annually thereafter, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate congressional committees a report, concerning the program under this section.

''(2) CONTENTS OF REPORT.—The report under paragraph (1) shall review, assess, and provide recommendations, as appropriate, on the following:

''(A) Details on likely costs and resultant savings as compared to a stockpiling method

that does not incorporate perpetual inventory cycling.

''(B) Identification of drawdowns from the stockpile, as evidence of market shortage avoidance.

''(C) The allocation of drugs included in the stockpiles funded pursuant to this section to the customers of the eligible entities with contracts under this section.

''(D) The degree to which eligible entities with contracts under this section fulfilled their obligations under such contracts.

''(h) DEFINITIONS.—In this section:

''(1) The term 'eligible entity' means an entity that meets each of the following criteria:

''(A) The entity is licensed or registered in accordance with applicable Federal and State law and in good standing with respect to such licensure or registration.

''(B) The entity agrees—

''(i) to purchase all drugs to be maintained in its stockpile funded under this section directly from the manufacturers of the drugs or the exclusive distributors of such manufacturers; or

"(ii) in the case of an entity that is a co-op or chain pharmacy warehouse—

"(I) to purchase drugs to be maintained in its stockpile funded under this section from an authorized distributor; and

"(II) distribute those drugs only to its member pharmacies.

"(C) The entity holds a verified authorized wholesale distributor certification issued by the National Association of Boards of Pharmacy.

"(D) The entity sells more than 90 percent of its drugs to dispensers.

"(E) The entity agrees to distribute inventory from its stockpile funded under this section only to dispensers that are customers of the entity.

"(2) The term 'generic drug at risk of shortage' means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) that—

"(A) is approved pursuant to section 505(j) of such Act;

"(B) is included in the World Health Organization's most recent Model List of Essential Medicines;

"(C) is included, at any point during the preceding 36 months, on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act; and

"(D) is manufactured by 3 or fewer persons that are registered under section 510 of the Federal Food, Drug, and Cosmetic Act for purposes of such manufacture.

"(i) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $120,000,000 for fiscal years 2021 through 2023, to remain available until expended.".

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