

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

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.

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 “Essential Medicines
5 Strategic Stockpile Act of 2020”.

1 **SEC. 2. PILOT PROGRAM ON ENSURING MEDICATION SUP-**
2 **PLY STABILITY.**

3 Part D of the Public Health Service Act (42 U.S.C.
4 254b et seq.) is amended by adding at the end the fol-
5 lowing new subpart:

6 **“Subpart XIII—Ensuring Medication Supply Stability**

7 **“SEC. 340J. ENSURING MEDICATION SUPPLY STABILITY.**

8 “(a) AWARD OF CONTRACTS.—Beginning not later
9 than January 1, 2021, the Secretary shall award contracts
10 to eligible entities to each implement and test the effective-
11 ness of acquiring, maintaining, managing, and distrib-
12 uting a stockpile that—

13 “(1) consists of generic drugs at risk of short-
14 age; and

15 “(2) is of sufficient quantity to ensure that cus-
16 tomers in the United States of the respective eligible
17 entity have access to such drugs for at least 6
18 months (as specified by the Secretary based on the
19 historic demand for those drugs).

20 “(b) SELECTION OF DRUGS.—

21 “(1) IN GENERAL.—The Secretary shall—

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

1 “(B) maintain an up-to-date list of such
2 drugs; and

3 “(C) make such list publicly available.

4 “(2) CHOICE OF ELIGIBLE ENTITIES.—A con-
5 tract awarded to an eligible entity under this section
6 need not require the stockpile of the eligible entity
7 to include all 50 types of drugs listed pursuant to
8 paragraph (1).

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

15 “(d) DURATION; LIQUIDATION OF INVENTORY.—

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

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

23 “(e) STOCKPILE REQUIREMENTS.—

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

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

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

6 “(B) to comply with subparagraph (A)—

7 “(i) sell drugs in the stockpile through
8 normal commercial channels and replace
9 those drugs; or

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

14 “(2) MANAGEMENT OF STOCKPILE.—

15 “(A) IN GENERAL.—Each eligible entity
16 with a contract under this section for a stock-
17 pile of generic drugs at risk of shortage shall—

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

1 tity over the previous year for such drug;
2 and

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

7 “(B) INVENTORY MANAGEMENT.—Each el-
8 igible entity with a contract under this section
9 for a stockpile of generic drugs at risk of short-
10 age shall manage inventory to ensure that
11 drugs in the stockpile are efficiently cycled to
12 the commercial market and—

13 “(i) may stockpile inventory at the eli-
14 gible entity’s distribution center with speci-
15 fied inventory amounts virtually reserved
16 for the Federal Government with constant
17 cycling to reduce product expiration; or

18 “(ii) may store stockpiled inventory
19 separately in a different location and re-
20 place drugs in the stockpile inventory with
21 the same drug with newer dating.

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

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

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

6 “(ii) shall submit a report to the Sec-
7 retary identifying—

8 “(I) each such drug; and

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

12 “(D) ANNUAL AUDITS.—Not more than
13 annually, the Secretary may request a physical
14 audit count of the inventories of all eligible enti-
15 ties with a contract under this section to vali-
16 date that each such entity is maintaining the
17 appropriate amount of stockpiled inventory.

18 “(3) PERIODIC PRODUCT REVIEW.—

19 “(A) USE OF PROCEEDS.—An eligible enti-
20 ty with a contract under this section for a
21 stockpile of generic drugs at risk of shortage
22 shall use the proceeds of the sale of any drugs
23 in the stockpile to purchase drugs for the stock-
24 pile in accordance with this section.

1 “(B) MARKET INFLATION OR DEFLA-
2 TION.—In the case of market inflation or defla-
3 tion affecting the price of a drug in the stock-
4 pile of an eligible entity maintained pursuant to
5 a contract under this section, the contract shall
6 ensure that the Federal Government does not
7 profit or suffer loss on items of such drug as
8 a result of such inflation or deflation.

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

13 “(A) current inventory levels of stockpiled
14 drugs at a drug level;

15 “(B) indicators of current inventory levels
16 of stockpiled drugs relative to acceptable mini-
17 mums; and

18 “(C) such other matters as the Secretary
19 determines appropriate.

20 “(f) CONTRACT TERMS.—

21 “(1) PAYMENT OF MONTHLY FEES FOR MAN-
22 AGEMENT.—Subject to paragraph (2), the Secretary
23 shall pay to each eligible entity with a contract
24 under this section for a stockpile of generic drugs at

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

3 “(2) PAYMENT CONDITIONED ON STOCKPILE
4 ADEQUACY.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (B), each contract with an eligi-
7 ble entity under this section shall provide that
8 no payment under the contract may be made
9 until the entity demonstrates to the Secretary
10 that the entity has stockpiled such portion of
11 the total quantity of drugs to be stockpiled
12 under the contract as the Secretary determines
13 to be acceptable for payment.

14 “(B) EXCEPTIONS FOR ADVANCE PAY-
15 MENTS.—

16 “(i) IN GENERAL.—A contract under
17 this section may provide that, if the Sec-
18 retary determines (in the Secretary’s dis-
19 cretion) that an advance payment, partial
20 payment for significant milestones, or pay-
21 ment to increase capacity is necessary to
22 ensure success of the terms of the con-
23 tract, the Secretary shall pay, in advance
24 of delivery, an amount not to exceed 10
25 percent of the total contract amount to be

1 paid to the eligible entity by the Secretary
2 pursuant to the contract over the full pe-
3 riod of the contract.

4 “(ii) COST OF CAPITAL.—A contract
5 under this section may provide for pay-
6 ments to compensate the contracting eligi-
7 ble entity for additional capital require-
8 ments related to the additional inventory
9 to be maintained.

10 “(iii) TIMING.—The Secretary shall,
11 to the extent practicable, make any deter-
12 mination under clause (i) to make an ad-
13 vance payment at the same time as the
14 issuance of a solicitation.

15 “(iv) REPAYMENT.—If the Secretary
16 makes an advance payment pursuant to
17 clause (i), the Secretary shall require the
18 eligible entity receiving such advance pay-
19 ment to repay it if there is a failure to per-
20 form by the eligible entity.

21 “(3) TERMINATION.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), nothing in this section shall be con-
24 strued as affecting the rights of eligible entities
25 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

1 that does not incorporate perpetual inventory
2 cycling.

3 “(B) Identification of drawdowns from the
4 stockpile, as evidence of market shortage avoid-
5 ance.

6 “(C) The allocation of drugs included in
7 the stockpiles funded pursuant to this section to
8 the customers of the eligible entities with con-
9 tracts under this section.

10 “(D) The degree to which eligible entities
11 with contracts under this section fulfilled their
12 obligations under such contracts.

13 “(h) DEFINITIONS.—In this section:

14 “(1) The term ‘eligible entity’ means an entity
15 that meets each of the following criteria:

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

20 “(B) The entity agrees—

21 “(i) to purchase all drugs to be main-
22 tained in its stockpile funded under this
23 section directly from the manufacturers of
24 the drugs or the exclusive distributors of
25 such manufacturers; or

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

3 “(I) to purchase drugs to be
4 maintained in its stockpile funded
5 under this section from an authorized
6 distributor; and

7 “(II) distribute those drugs only
8 to its member pharmacies.

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

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

14 “(E) The entity agrees to distribute inven-
15 tory from its stockpile funded under this section
16 only to dispensers that are customers of the en-
17 tity.

18 “(2) The term ‘generic drug at risk of shortage’
19 means a drug (as defined in section 201 of the Fed-
20 eral Food, Drug, and Cosmetic Act) that—

21 “(A) is approved pursuant to section
22 505(j) of such Act;

23 “(B) is included in the World Health Or-
24 ganization’s most recent Model List of Essen-
25 tial Medicines;

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

5 “(D) is manufactured by 3 or fewer per-
6 sons that are registered under section 510 of
7 the Federal Food, Drug, and Cosmetic Act for
8 purposes of such manufacture.

9 “(i) AUTHORIZATION OF APPROPRIATIONS.—To
10 carry out this section, there is authorized to be appro-
11 priated \$120,000,000 for fiscal years 2021 through 2023,
12 to remain available until expended.”.

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