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118TH CONGRESS
2D SESSION

H. R. 6992

To require the Secretary of Health and Human Services to establish a list of essential medicines, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 12, 2024

Ms. MATSUI (for herself and Mr. BUCSHON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the Secretary of Health and Human Services to establish a list of essential medicines, 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 ''Mapping America's Pharmaceutical Supply Act'' or the ''MAPS Act''.

SEC. 2. ESSENTIAL MEDICINES LIST UPDATE.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish and maintain a list of essential medicines.

(b) CRITERIA.— The list under subsection (a) shall consist of drugs and active pharmaceutical ingredients that—

(1) are reasonably likely to be required to respond to a public health emergency or to a chemical, biological, radiological, or nuclear threat; or

(2) the shortage of which would pose a significant threat to the United States health care system or at-risk populations.

(c) SELECTION.—The Secretary shall select drugs and active pharmaceutical ingredients for inclusion on the list under subsection (a)—

(1) based on the criteria specified in subsection (b); and

(2) from the list of essential medicines, medical countermeasures, and critical inputs developed by the Food and Drug Administration in response to Executive Order 13944 (85 Fed. Reg. 49929) and other relevant assessments or lists.

(d) PROCESS.—

(1) IN GENERAL.—Before finalizing the list under subsection (a) or any update to such list, the Secretary shall—

(A) publish a proposed list or update, as applicable; and

(B) provide an opportunity for public comment on the proposed list or update.

(2) INITIAL LIST.—The Secretary shall—

(A) publish the proposed initial list under subsection (a) not later than 6 months after the date of enactment of this Act; and

(B) publish the final initial list under subsection (a) not later than 1 year after such date of enactment.

(3) REGULAR REVIEW.—The Secretary shall regularly review the list under subsection (a) to determine whether any updates should be made pursuant to paragraph (1).

(e) RELATION TO EXECUTIVE ORDER.—The participation of the Secretary in establishing, maintaining, and updating the list under subsection (a) shall be deemed to be full satisfaction of the requirements applicable to the Secretary under section 3 of Executive Order 13944 (85 Fed. Reg. 49929).

SEC. 3. FEDERAL UNITED STATES PHARMACEUTICAL SUPPLY CHAIN MAPPING.

(a) IN GENERAL.—The Secretary of Health and Human Services, in coordination with the heads of other relevant agencies, shall support efforts, including through public-private partnerships, to map the entire United

States pharmaceutical supply chain, from inception to distribution, and use data analytics to identify supply chain vulnerabilities and other national security threats. Such activities shall include, at a minimum—

(1) defining agency roles in monitoring the pharmaceutical supply chain and communicating supply chain vulnerabilities; and

(2) with respect to drugs and active pharmaceutical ingredients on the list of essential medicines under section 2(a), establishing a database that shall include—

(A) the location of establishments registered under subsection (b), (c), or (i) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) involved in the production of—

(i) the finished dosage forms of the drugs on such list;

(ii) the active pharmaceutical ingredients of such drugs; or

(iii) active pharmaceutical ingredients on such list;

(B) the amount of such finished dosage forms and active pharmaceutical ingredients produced at each such establishment;

(C) to the extent available—

(i) the location of establishments involved in the production of the key starting materials and excipients used to produce the finished dosage forms and active pharmaceutical ingredients referred to in subparagraph (A); and

(ii) the amount of such materials and excipients produced at each such establishment; and

(D) any regulatory actions with respect to the establishments referred to in subparagraph (A) or (C), including with respect to—

(i) labeling requirements;

(ii) registration and listing information required to be submitted under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360);

(iii) inspections and related regulatory activities conducted under section 704 of such Act (21 U.S.C. 374);

(iv) the seizure of such a drug or active pharmaceutical ingredient pursuant to section 304 of such Act (21 U.S.C. 334);

(v) any recalls of a drug or active pharmaceutical ingredient on the list of essential medicines under section 2(a), or a drug containing an active pharmaceutical ingredient on such list;

(vi) inclusion of such a drug or active pharmaceutical ingredient on the drug shortage list under section 506E of such Act (21 U.S.C. 356e); or

(vii) prior reports of a discontinuance or interruption in the production of such a drug or active pharmaceutical ingredient under 506C of such Act (21 U.S.C. 356c).

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services, in consultation with the heads of agencies with which such Secretary coordinates under subsection (a), shall submit a report to Congress on—

(1) progress on implementing subsection (a), including any timelines for full implementation;

(2) gaps in data needed for full implementation of such subsection;

(3) how the database established pursuant to subsection (a) increases Federal visibility into the pharmaceutical supply chain;

(4) how Federal agencies are able to use data analytics to conduct predictive modeling of anticipated drug shortages or national security threats; and

(5) the extent to which industry has cooperated in mapping the pharmaceutical supply chain.

(c) CONFIDENTIAL COMMERCIAL INFORMATION.—The exchange of information among the Secretary of Health and Human Services and the heads of other relevant agencies for purposes of carrying out this section shall not be a violation of section 1905 of title 18, United States Code.

(d) CLARIFICATION.—The information in the database established pursuant to subsection (a) shall not be publicly disclosed. Nothing in this subsection shall be construed to relieve the Secretary of Health and Human Services from the Secretary's obligation to provide information to Congress.

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