AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4421

OFFERED BY M__. _____

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Page 26, after line 12, add the following:

SEC. 114. IMPROVING NOTIFICATION PROCEDURES IN CASE OF INCREASED DEMAND FOR CRITICAL ESSENTIAL MEDICINES.

(a) NOTIFICATION REQUIRED.—

(1) IN GENERAL.—Subject to paragraph (2), a manufacturer of a critical essential medicine shall notify the Secretary, in accordance with subsection (b), of—

(A) an increased demand (other than an anticipated seasonal surge) for such drug or an active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug that is likely to lead to a shortage of the drug or the active pharmaceutical ingredient, an excipient, or any other input in the final dosage form of such drug; and

(B) the reasons for such increased demand.

(2) DETERMINATION.—The requirement under subsection (a) shall begin to apply upon a determination by the Secretary that requiring the provision of notifications under this section will support public health security and all-hazards preparedness and response for emergency periods (as defined in section 1135(g)(1) of the Social Security Act (42 U.S.C. 1320b-5(g)(1))).

(3) CONTENTS.—Notification under this subsection with respect to a critical essential medicine shall include—

(A) the expected duration of the increased demand; and

(B) such other information as the Secretary may require.

(b) TIMING.—

(1) IN GENERAL.—A notice required under subsection (a) shall be submitted to the Secretary—

(A) not later than 30 days after the submission of the initial notification under paragraph (2); or

(B) if compliance with such deadline is not possible, as soon as practicable.

(2) INITIAL NOTIFICATION WITH RESPECT TO INCREASED DEMAND.—The manufacturer of the

critical essential medicine involved shall submit to the Secretary an initial notification not later than 48 hours after the date on which there has been increased demand for the critical essential medicine for a period of at least 6 consecutive weeks.

(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary deems appropriate, information on the increased demand for critical essential medicines to appropriate organizations, including physician, health provider, and patient organizations.

(d) REGULATIONS.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement this section.

(e) GUIDANCE.—

(1) IN GENERAL.—The Secretary shall issue guidance on the requirements for notifications required under this section. Such guidance shall specifically address—

(A) the ways in which manufacturers of critical essential medicines can improve demand predictability;

(B) what information manufacturers of critical essential medicines should send to the Secretary; and

(C) what communications from the manufacturer the Secretary would request with respect to increases in demand following such notifications.

(2) CONSULTATION.—In developing such guidance, the Secretary shall consult with relevant stakeholders, including manufacturers of critical essential medicines and local, State, or Federal public health officials.

(3) TIMING.—The Secretary shall issue—

(A) draft guidance under paragraph (1) not later than 120 days after the date of the enactment of this Act; and

(B) final guidance under such paragraph not later than 180 days after the date of the enactment of this Act.

(f) DEFINITIONS.—In this section:

(1) The term ''critical essential medicine'' means a drug that—

(A) is—

(i) life-supporting;

(ii) life-sustaining; or

(iii) intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in

emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

(B) is not a radio pharmaceutical drug product or any other product as designated by the Secretary.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.