[115H6688]

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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

To provide for the establishment of the Prescription Safety Alert System with respect to covered drug products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. KUSTER of New Hampshire introduced the following bill; which was referred to the Committee on _____

A BILL

To provide for the establishment of the Prescription Safety Alert System with respect to covered drug products, 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 ''Analyzing and Leveraging Existing Rx Transactions Act of 2019'' or the ''ALERT Act of 2019''.

SEC. 2. PRESCRIPTION SAFETY ALERT SYSTEM TO HELP PREVENT ABUSE AND MISUSE OF PRESCRIPTION DRUGS.

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505–1 of such Act (21 U.S.C. 355–1) the following new section:

"SEC. 505–2. PRESCRIPTION SAFETY ALERT SYSTEM TO PREVENT ABUSE AND MISUSE.

"(a) IN GENERAL.—For the purpose of combating the national prescription drug abuse epidemic, the Secretary shall, with respect to covered drug products, establish and maintain an electronic system, to be known as the Prescription Safety Alert System, that—

"(1) reviews patient prescription and dispensing history through pharmaceutical claims data transactions described in section 1173(a)(2) of the Social Security Act and developed by a standard setting organization;

"(2) collects, maintains, and is capable of providing to dispensers, within a dispenser's ordinary clinical workflow, information about a patient's prescription and dispensing history;

"(3) delivers information about a patient's prescription and dispensing history in summary form, that allows the dispenser to evaluate the risk of misuse, abuse, addiction, overdose, and drug-drug inter-

actions associated with filling the prescription sought by a patient based upon such patient's prescription and dispensing history for covered drug products;

''(4) provides to dispensers the information described in paragraphs (2) and (3) in real-time;

''(5) allows dispensers to obtain access to a patient's prescription and dispensing history; and

''(6) requires dispensers as a condition on using such System to have a written use agreement with such System to—

''(A) allow such System to access required data elements about the dispenser's patients to ensure that the prescribing and dispensing history of such patients is updated on a real-time basis in such System; and

''(B) receive information about a patient's prescription and dispensing history in summary form from such System.

''(b) IMPLEMENTATION.—Beginning not later than 12 months after the date of enactment of this Act, the Secretary shall require, pursuant to section 505–1, that covered drug products be dispensed using the Prescription Safety Alert System to help combat the national prescription drug abuse epidemic.

''(c) PURPOSES OF COLLECTING AND MAKING AVAILABLE INFORMATION.—The Prescription Safety Alert System shall collect and make available information only for the following purposes:

''(1) Providing dispensers with information to evaluate the risk of misuse, abuse, addiction, overdose, and drug-drug interactions associated with a covered drug product based upon a patient's prescription and dispensing history.

''(2) Providing the Secretary with aggregate information on an annualized basis regarding the number of patients or prescriptions flagged by such System or a dispenser as potentially presenting a risk of misuse, abuse, addiction, overdose, or drug-drug interactions, and other aggregate information, where the Secretary deems the provision of such information to be appropriate.

''(d) RULE OF CONSTRUCTION ON LIABILITY.—Nothing in this section shall be construed to create or serve as the basis for additional liability for any entity connecting to the System, beyond existing applicable State and Federal laws and regulations.

''(e) WAIVERS.—

''(1) IN GENERAL.—The Secretary may waive the requirements of this section in whole or in part

if the Secretary determines that compliance with such requirements is not feasible due to—

''(A) a public health emergency declared pursuant to a section 319 of the Public Health Service Act; or

''(B) a natural disaster, a power disruption, or other extenuating circumstances.

''(2) GUIDANCE.—Not later than 12 months after the date of enactment of this section, the Secretary shall issue guidance to clarify the circumstances under which waivers will be granted under paragraph (1).

''(f) RELATION TO PRIVACY LAW.—

''(1) APPROPRIATE SAFEGUARDS.—The Secretary shall take appropriate measures to safeguard the privacy and cybersecurity of the data in the Prescription Safety Alert System.

''(2) DISPENSERS.—The use of protected health information, or the disclosure to the Prescription Safety Alert System of protected health information, by a dispenser pursuant to requirements prescribed under this section is deemed to be a use or disclosure, as applicable, required by law and therefore permitted, without the authorization of the indi-

vidual, under section 164.512(a) of title 45, Code of Federal Regulations (or any successor regulations).

''(3) DISCLOSURE BY PRESCRIPTION SAFETY ALERT SYSTEM.—The use of protected health information, or the disclosure to a dispenser of protected health information, by the Prescription Safety Alert System pursuant to requirements prescribed under this section is deemed to be a use or disclosure, as applicable, required by law and therefore permitted, without authorization of the individual, under section 164.512(a) of title 45 of the Code of Federal Regulations (or any successor regulations).

''(4) DEFINITIONS.—In this subsection:

''(A) The term 'protected health information' has the meaning given to that term in section 160.103 of title 45, Code of Federal Regulations (or any successor regulations).

''(B) The term 'required by law' has the meaning given to that term in section 164.103 of title 45 of the Code of Federal Regulations (or any successor regulations).

''(g) DEFINITIONS.—In this section:

''(1) The term 'covered drug product' means any drug product that—

''(A) has been approved for any use under section 505 of this Act or section 351 of the Public Health Service Act; and

''(B) has been included in a list of drugs published by the Secretary in the Federal Register as presenting a risk of misuse, abuse, addiction, overdose, or drug-drug interactions necessitating inclusion in the Prescription Safety Alert System, so long as the Secretary provided no less than 30 days for public comment before finalizing the inclusion of such drug product in such list.

''(2) The term 'dispenser' means a person who is licensed in accordance with State law to engage in the practice of pharmacy to dispense covered drug products directly to patients or their caregivers, except such term does not include a closed-system pharmacy.

''(3) The term 'closed system pharmacy' means any facility, including a nursing home, correctional facility, adult congregate living facility, or other custodial care facility, that is licensed by law to engage in the practice of pharmacy that distributes or dispenses covered drug products utilizing a closed deliv-

ery system where prescriptions are individually prepared for a custodial consumer.

''(4) The term 'prescription and dispensing history' means a patient's history, dating back a minimum of 12 months, or such period as the Secretary deems appropriate, of receiving, filling, or attempting to receive or fill, prescriptions for covered drug products, including specific data elements, as applicable to any particular patient or prescription, including—

''(A) a description of the drug dispensed or attempted to be filled;

''(B) pharmacy national provider identifier (NPI);

''(C) prescription (Rx) number;

''(D) fill number;

''(E) other applicable coverage code;

''(F) date or dates of service;

''(G) prescriber identifiers;

''(H) patient information;

''(I) third party identifiers; and

''(J) such other information the Secretary deems appropriate by guidance.

''(5) The term 'standard setting organization' has the meaning given to such term in section 1171(8) of the Social Security Act.''.