

116TH CONGRESS  
1ST SESSION

# H. R. 1845

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

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 21, 2019

Ms. KUSTER of New Hampshire (for herself and Mr. MULLIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

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

1 **SEC. 2. PRESCRIPTION SAFETY ALERT SYSTEM TO HELP**  
2 **PREVENT ABUSE AND MISUSE OF PRESCRIP-**  
3 **TION DRUGS.**

4 The Federal Food, Drug, and Cosmetic Act is amend-  
5 ed by inserting after section 505–1 of such Act (21 U.S.C.  
6 355–1) the following new section:

7 **“SEC. 505–2. PRESCRIPTION SAFETY ALERT SYSTEM TO**  
8 **PREVENT ABUSE AND MISUSE.**

9 “(a) IN GENERAL.—For the purpose of combating  
10 the national prescription drug abuse epidemic, the Sec-  
11 retary shall, with respect to covered drug products, estab-  
12 lish and maintain an electronic system, to be known as  
13 the Prescription Safety Alert System, that—

14 “(1) reviews patient prescription and dispensing  
15 history through pharmaceutical claims data trans-  
16 actions described in section 1173(a)(2) of the Social  
17 Security Act and developed by a standard setting or-  
18 ganization;

19 “(2) collects, maintains, and is capable of pro-  
20 viding to dispensers, within a dispenser’s ordinary  
21 clinical workflow, information about a patient’s pre-  
22 scription and dispensing history;

23 “(3) delivers information about a patient’s pre-  
24 scription and dispensing history in summary form,  
25 that allows the dispenser to evaluate the risk of mis-  
26 use, abuse, addiction, overdose, and drug-drug inter-

1 actions associated with filling the prescription  
2 sought by a patient based upon such patient's pre-  
3 scription and dispensing history for covered drug  
4 products;

5 “(4) provides to dispensers the information de-  
6 scribed in paragraphs (2) and (3) in real-time;

7 “(5) allows dispensers to obtain access to a pa-  
8 tient's prescription and dispensing history; and

9 “(6) requires dispensers as a condition on using  
10 such System to have a written use agreement with  
11 such System to—

12 “(A) allow such System to access required  
13 data elements about the dispenser's patients to  
14 ensure that the prescribing and dispensing his-  
15 tory of such patients is updated on a real-time  
16 basis in such System; and

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

20 “(b) IMPLEMENTATION.—Beginning not later than  
21 12 months after the date of enactment of this Act, the  
22 Secretary shall require, pursuant to section 505–1, that  
23 covered drug products be dispensed using the Prescription  
24 Safety Alert System to help combat the national prescrip-  
25 tion drug abuse epidemic.

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

5           “(1) Providing dispensers with information to  
6 evaluate the risk of misuse, abuse, addiction, over-  
7 dose, and drug-drug interactions associated with a  
8 covered drug product based upon a patient’s pre-  
9 scription and dispensing history.

10          “(2) Providing the Secretary with aggregate in-  
11 formation on an annualized basis regarding the  
12 number of patients or prescriptions flagged by such  
13 System or a dispenser as potentially presenting a  
14 risk of misuse, abuse, addiction, overdose, or drug-  
15 drug interactions, and other aggregate information,  
16 where the Secretary deems the provision of such in-  
17 formation to be appropriate.

18       “(d) RULE OF CONSTRUCTION ON LIABILITY.—  
19 Nothing in this section shall be construed to create or  
20 serve as the basis for additional liability for any entity con-  
21 necting to the System, beyond existing applicable State  
22 and Federal laws and regulations.

23       “(e) WAIVERS.—

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

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

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

6 “(B) a natural disaster, a power disrup-  
7 tion, or other extenuating circumstances.

8 “(2) GUIDANCE.—Not later than 12 months  
9 after the date of enactment of this section, the Sec-  
10 retary shall issue guidance to clarify the cir-  
11 cumstances under which waivers will be granted  
12 under paragraph (1).

13 “(f) RELATION TO PRIVACY LAW.—

14 “(1) APPROPRIATE SAFEGUARDS.—The Sec-  
15 retary shall take appropriate measures to safeguard  
16 the privacy and cybersecurity of the data in the Pre-  
17 scription Safety Alert System.

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

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

3           “(3) DISCLOSURE BY PRESCRIPTION SAFETY  
4       ALERT SYSTEM.—The use of protected health infor-  
5       mation, or the disclosure to a dispenser of protected  
6       health information, by the Prescription Safety Alert  
7       System pursuant to requirements prescribed under  
8       this section is deemed to be a use or disclosure, as  
9       applicable, required by law and therefore permitted,  
10      without authorization of the individual, under sec-  
11      tion 164.512(a) of title 45 of the Code of Federal  
12      Regulations (or any successor regulations).

13           “(4) DEFINITIONS.—In this subsection:

14           “(A) The term ‘protected health informa-  
15      tion’ has the meaning given to that term in sec-  
16      tion 160.103 of title 45, Code of Federal Regu-  
17      lations (or any successor regulations).

18           “(B) The term ‘required by law’ has the  
19      meaning given to that term in section 164.103  
20      of title 45 of the Code of Federal Regulations  
21      (or any successor regulations).

22           “(g) DEFINITIONS.—In this section:

23           “(1) The term ‘covered drug product’ means  
24      any drug product that—

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

4           “(B) has been included in a list of drugs  
5           published by the Secretary in the Federal Reg-  
6           ister as presenting a risk of misuse, abuse, ad-  
7           diction, overdose, or drug-drug interactions ne-  
8           cessitating inclusion in the Prescription Safety  
9           Alert System, so long as the Secretary provided  
10          no less than 30 days for public comment before  
11          finalizing the inclusion of such drug product in  
12          such list.

13          “(2) The term ‘dispenser’ means a person who  
14          is licensed in accordance with State law to engage  
15          in the practice of pharmacy to dispense covered drug  
16          products directly to patients or their caregivers, ex-  
17          cept such term does not include a closed-system  
18          pharmacy.

19          “(3) The term ‘closed-system pharmacy’ means  
20          any facility, including a nursing home, correctional  
21          facility, adult congregate living facility, or other cus-  
22          todial care facility, that is licensed by law to engage  
23          in the practice of pharmacy that distributes or dis-  
24          penses covered drug products utilizing a closed deliv-

1       ery system where prescriptions are individually pre-  
2       pared for a custodial consumer.

3               “(4) The term ‘prescription and dispensing his-  
4       tory’ means a patient’s history, dating back a min-  
5       imum of 12 months, or such period as the Secretary  
6       deems appropriate, of receiving, filling, or attempt-  
7       ing to receive or fill, prescriptions for covered drug  
8       products, including specific data elements, as appli-  
9       cable to any particular patient or prescription, in-  
10      cluding—

11               “(A) a description of the drug dispensed or  
12              attempted to be filled;

13               “(B) pharmacy national provider identifier  
14              (NPI);

15               “(C) prescription (Rx) number;

16               “(D) fill number;

17               “(E) other applicable coverage code;

18               “(F) date or dates of service;

19               “(G) prescriber identifiers;

20               “(H) patient information;

21               “(I) third party identifiers; and

22               “(J) such other information the Secretary  
23              deems appropriate by guidance.



1           “(5) The term ‘standard setting organization’  
2           has the meaning given to such term in section  
3           1171(8) of the Social Security Act.”.

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