

115TH CONGRESS  
2D SESSION

# H. R. 6600

To amend the Controlled Substances Act to require that orders subject to review be submitted through a clearinghouse, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2018

Mr. LANCE (for himself and Ms. MATSUI) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Controlled Substances Act to require that orders subject to review be submitted through a clearinghouse, 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 “DEA Order Clearing-  
5 house Act of 2018”.

1   **SEC. 2. REQUIRED CLEARINGHOUSE FOR REGISTRANT OR-**

2                   **DERS.**

3               (a) IN GENERAL.—The Controlled Substances Act

4 (21 U.S.C. 801 et seq.) is amended—

5                   (1) in section 303(f), in the matter preceding  
6 paragraph (1), by striking “The Attorney General”  
7 and inserting “Subject to section 303A, the Attorney  
8 General”; and

9                   (2) by inserting after section 303 the following:

10   **“SEC. 303A. REQUIRED CLEARINGHOUSE FOR REGISTRANT**

11                   **ORDERS.**

12               “(a) IN GENERAL.—Not later than 2 years after the  
13 date of enactment of this section, the Attorney General  
14 shall—

15                   “(1) establish a clearinghouse that would sub-  
16 ject all orders of controlled substances and listed  
17 chemicals to the clearinghouse for recording and re-  
18 view, prior to final review by the registrant;

19                   “(2) amend the regulations relative to con-  
20 trolled substances in schedule II ordering require-  
21 ments that would allow for uniform electronic order-  
22 ing of controlled substances in schedule II, III, IV,  
23 and V electronically to the clearinghouse; and

24                   “(3) may deny, suspend, or revoke a registra-  
25 tion issued under section 303(f), or the registration  
26 of a distributor under section 303(b) or 303(e), if

1       the practitioner or distributor, as applicable, is not  
2       substantially in compliance with the requirements of  
3       this section.

4       **“(b) CLEARINGHOUSE.—”**

5           **“(1) IN GENERAL.”**—An order for a controlled  
6       substance may not be filled by the registrant un-  
7       less—

8               **“(A)** the order is first transmitted elec-  
9       tronically to the Attorney General, acting  
10      through the Administrator of the Drug En-  
11      forcement Administration (referred to in this  
12      section as the ‘Administrator’);

13               **“(B)** the Administrator uses the algorithm  
14      described in paragraph (2) to determine if the  
15      order is an outlier and is potentially suspicious;

16               **“(C)** the Administrator relays the order to  
17      the registrant with whom the order is placed,  
18      regardless of whether the algorithm was exceed-  
19      ed, for further analysis of the order under sec-  
20      tion 1301.74(b) of title 21, Code of Federal  
21      Regulations; and

22               **“(D)** the registrant has received a waiver  
23      from the Administrator exempting the reg-  
24      istrant from this section.

25       **“(2) ALGORITHM.—”**

1                 “(A) IN GENERAL.—The clearinghouse es-  
2                 tablished under this section shall use an input-  
3                 based algorithm, including techniques such as  
4                 artificial intelligence, machine learning, and  
5                 other methods of analyzing large data, that—

6                         “(i) automatically identifies orders  
7                 that exceed the metrics of the algorithm;

8                         “(ii) notifies the registrant if the  
9                 order is an outlier and is potentially sus-  
10                 picious;

11                         “(iii) is informed by all data available  
12                 to the Administrator and uses pharmacy  
13                 best practices;

14                         “(iv) takes into consideration existing  
15                 State and Federal law; and

16                         “(v) establishes different parameters  
17                 for different registrants using relevant in-  
18                 formation based on pharmacy type, loca-  
19                 tion, and size.

20                 “(B) REFINEMENT.—The Administrator of  
21                 the Drug Enforcement Administration (referred  
22                 to in this section as the ‘Administrator’) shall  
23                 review, update, and revise the algorithm bian-  
24                 nually based on feedback from industry and rel-  
25                 evant stakeholders to ensure functionality.

1           “(3) CONSULTATION.—The Administrator shall  
2       consult with the Director of the National Institute of  
3       Standards and Technology for technical assistance  
4       in establishing the clearinghouse.

5           “(c) RESPONSIBILITIES OF DISTRIBUTORS AND MAN-  
6       UFACTURERS REGARDING SUSPICIOUS ORDERS.—This  
7       section may not be construed as relieving any distributor  
8       or manufacturer from the requirements established in sec-  
9       tion 1301.74(b) of title 21, Code of Federal Regulations,  
10      or any successor regulation, with respect to suspicious or-  
11      ders.

12       “(d) CONTRACTOR REGARDING DATA ANALYTICS.—  
13           “(1) IN GENERAL.—The Administrator shall  
14       award a contract to a public or private entity ena-  
15       bling the Administrator to carry out the techno-  
16       logical aspects of tracking, processing and evaluating  
17       orders under this section.

18       “(2) ELIGIBLE ENTITIES.—An entity is eligible  
19       for an award under paragraph (1) if the entity has  
20       significant experience in data analytics and in proc-  
21       essing the volume of electronic data involved in re-  
22       viewing orders under this section within the time-  
23       frame required in subsection (c).

24       “(3) CAPABILITIES.—A contract awarded under  
25       paragraph (1) shall—

1                 “(A) provide a data management and  
2                 configurable visual analytics solution capable of  
3                 ingesting and managing data entities, including  
4                 manufacturers, and distributors, retail dis-  
5                 pensers across relevant data maintained by the  
6                 Administrator;

7                 “(B) standardize the data format, with the  
8                 ability to flexibly model data for analyses and  
9                 link data across sources; and

10                 “(C) provide an environment for analysis  
11                 that is interoperable.

12                 “(4) COMMERCIAL ITEMS.—The Administrator  
13                 shall comply with section 3307 of title 41, United  
14                 States Code, in awarding a contract under para-  
15                 graph (1). The Administrator may not enter into a  
16                 contract for any capabilities sought under paragraph  
17                 (1) that are not for commercial items unless the Ad-  
18                 ministrator first determines in writing that no com-  
19                 mercial items are suitable to meet the needs of the  
20                 Drug Enforcement Administration.

21                 “(5) TIMELINE OF CONTRACT.—Any contract  
22                 awarded under paragraph (1) for a data manage-  
23                 ment and visual analytics solution shall require the  
24                 public or private entity awarded such contract to de-  
25                 liver a functioning solution sufficient to fulfill the

1       purposes of this section not later than 180 days  
2       after the date on which the contract is awarded, un-  
3       less the Administrator grants an extension for  
4       unforseen delays.

5           “(6) FEDERAL ACQUISITION REGULATION.—A  
6       contract awarded under this subsection shall be in  
7       accordance with the Federal Acquisition Regulation.

8           “(7) ACCESS TO DATA.—An entity that is  
9       awarded a contract under this subsection shall have  
10      access to the relevant data to create the system.

11      “(e) WAIVER.—

12           “(1) IN GENERAL.—Beginning on the date on  
13       which the 36-month period described in subsection  
14       (b)(1)(A)(ii) expires, a pharmacy may submit to the  
15       Administrator an application for a waiver from the  
16       requirements of subsection (b)(1)(A) if the phar-  
17       macy is unable to transmit orders electronically.

18           “(2) RESPONSE.—The Administrator shall ap-  
19       prove or deny an application submitted under para-  
20       graph (1) not later than the 90-day period beginning  
21       on the date on which the application is received.

22           “(3) LIABILITY.—No waiver issued under para-  
23       graph (1) shall mitigate the liability of the pharmacy  
24       for any drugs diverted that did not pass through the  
25       clearinghouse.

1       “(f) FUNDING.—

2           “(1) DIVERSION CONTROL FEE ACCOUNT.—The  
3       activities performed under this section shall be con-  
4       sidered to be elements of the diversion control pro-  
5       gram for purposes of this section.

6           “(2) PROHIBITION.—No registrant may pass on  
7       the cost of the clearinghouse to its customers.”.

8       (b) TECHNICAL AND CONFORMING AMENDMENT.—

9       The table of contents for the Controlled Substances Act  
10      (21 U.S.C. 801 et seq.) is amended by inserting after the  
11      item relating to section 303 the following:

“Sec. 303A. Required clearinghouse for registrant orders.”.

