I

116TH CONGRESS
1ST SESSION

H. R. 4814

To improve reporting of the distribution of controlled substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 23, 2019

Ms. MATSUI (for herself and Mr. JOHNSON of Ohio) 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 improve reporting of the distribution of controlled substances, 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 ''Suspicious Order Identification Act of 2019''.

SEC. 2. STRENGTHENING ARCOS.

Section 307(d) of the Controlled Substances Act (21 U.S.C. 827(d)) is amended to read as follows:

''(1)(A) Every registrant under section 303 shall and in such form as the Attorney General may require, make reports in electronic format to the Attorney General of every sale, delivery, or other disposal (other than by dispensing by a practitioner) by the registrant of any controlled substance, identifying by the registration number assigned under this title the person or establishment (unless exempt from registration under section 302(d)) to whom such sale, delivery, or other disposal was made.

''(B) Every registrant shall make each report required under subparagraph (A)—

''(i) not later than 30 days after the sale, delivery, or other disposal; or

''(ii) after the date on which the real-time reporting system is established under section 3(e)(3) of the Suspicious Order Identification Act of 2019 is implemented, in real time.''.

SEC. 3. SUSPICIOUS ORDERS TASK FORCE.

(a) DEFINITIONS.—In this section:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Drug Enforcement Administration.

(2) CONTROLLED SUBSTANCE; DISTRIBUTOR; MANUFACTURER.—The terms ''controlled substance'', ''distributor'', and ''manufacturer'' have the

meanings given those terms in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(3) REAL TIME.—The term ''real time'' means with as little delay as technically and economically feasible, as determined by the Attorney General following the program designed under subsection (e)(1), but not to exceed 24 hours.

(4) REGISTRANT.—The term ''registrant''—

(A) means a person registered under section 303 of the Controlled Substances Act (21 U.S.C. 823); and

(B) does not include practitioner.

(b) ESTABLISHMENT.—The Attorney General, in consultation with the Director of the Office of National Drug Control Policy and the Secretary of Health and Human Services, shall establish a Suspicious Order Monitoring Task Force (referred to in this section as the ''Task Force'').

(c) COMPOSITION.—

(1) IN GENERAL.—The Task Force shall be composed of appropriate personnel from—

(A) the Department of Justice;

(B) the Drug Enforcement Administration;

(C) the Office of National Drug Control Policy;

(D) the National Institute of Standards and Technology; and

(E) other appropriate Federal, State, and local law enforcement and regulatory agencies with experience in investigating and prosecuting illegal transactions of controlled substances as determined by the Attorney General, in consultation with the Secretary of Health and Human Services.

(2) CONSULTANTS.—The Task Force shall consult with—

(A) industry members, including—

(i) data analytic professionals;

(ii) community pharmacies that dispense controlled substances;

(iii) chain pharmacies that dispense controlled substances;

(iv) distributors of controlled substances;

(v) manufacturers of controlled substances;

(vi) State and local public health officials; and

(vii) other relevant industry professionals; and

(B) relevant industry regulators and entities that utilize real-time reporting of transactions, orders, or other activities with the goal of identifying suspicious activity, such as appropriate personnel from the Financial Crimes Enforcement Network and money transfer industry professionals.

(d) MEETINGS.—

(1) IN GENERAL.—The Task Force shall meet not less frequently than 4 times per year and at such other times as may be determined necessary by the Task Force.

(2) INITIAL MEETING.—Not later than 60 days after the date of enactment of this Act, the Task Force shall hold the initial meeting of the Task Force.

(e) PRELIMINARY ORDER EVALUATION PROGRAM.—

(1) IN GENERAL.—

(A) DESIGN.—Not later than 60 days after the date on which the Task Force holds the initial meeting required under subsection (d)(2), the Task Force shall begin to design a program in accordance with paragraph (2).

(B) PURPOSE.—The program described in subparagraph (A) shall be designed to share

necessary data, in a limited capacity, with registrants in order to provide registrants with information to identify suspicious ordering in real time.

(C) DEADLINE FOR COMPLETION.—Not later than 8 months after the date of enactment of this Act, the Task Force shall complete the design required under subparagraph (A).

(2) REQUIREMENTS.—

(A) IN GENERAL.—The program required under paragraph (1) shall establish a process for—

(i) transitioning to a requirement to report in real time to the Attorney General under section 307(d) of the Controlled Substances Act (21 U.S.C. 827(d)) every sale, delivery, or other disposal by a registrant of any controlled substance;

(ii) limited sharing in real time of Automation of Reports and Consolidated Orders System (commonly known as ''ARCOS'') data with registrants to share necessary data, in a limited capacity, with registrants in order to provide registrants

with information to identify suspicious ordering in real time; and

(iii) ensuring data privacy, data de-identification, protection of trade secrets and purchasing history.

(B) OTHER CONSIDERATIONS.—In designing the program under paragraph (1), the Task Force shall take into consideration—

(i) the inclusion of a waiver process for pharmacies and other registrants unable to transmit orders electronically on the date of enactment of this Act;

(ii) a mechanism to ensure that the costs of running the program are not passed through to customers of registrants, unless the registrants are customers of other registrants;

(iii) technical requirements for ensuring that registrants may access all relevant de-identified data, with output provided in a standard database file format; and

(iv) a mechanism to ensure that the program required to be designed under subparagraph (A) is updated based on

feedback from industry members and other relevant entities.

(3) IMPLEMENTATION.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall—

(A) implement the program designed under paragraph (1) to collect and share in real time data for registrants to evaluate the orders of controlled substances from distributors to manufacturers and from pharmacies to distributors; or

(B) otherwise implement a program to collect and share in real time data for drug manufacturers and distributors, by providing access to anonymized information to help drug manufacturers and distributors identify, report, and stop suspicious orders of controlled substances and reduce diversion rates.

(4) RECOMMENDED STATUTORY AND REGULATORY CHANGES.—In designing the program required under paragraph (1), the Task Force—

(A) shall submit to the Attorney General any recommendations for necessary amendments to regulations of the Department of Justice relating to the requirements for ordering

schedule II controlled substances, so as to allow uniform electronic ordering of controlled substances in schedules II, III, IV, and V electronically through the program; and

(B) may submit to Congress any recommendations for necessary legislative changes so that a real-time data analytics solution can be used across the United States.

(5) RESPONSIBILITY OF REGISTRANTS.—All registered drug manufacturers and distributors shall be responsible for reviewing any information made available by the Attorney General and complying with any regulations regarding the program designed under paragraph (1) and implemented under paragraph (3).

(f) FUNDING.—

(1) IN GENERAL.—The Attorney General, acting through the Administrator, shall use amounts collected as fees for distributors and registrants under section 303 of the Controlled Substances Act (21 U.S.C. 823) and section 1007 of the Controlled Substances Import and Export Act (21 U.S.C. 957) to carry out this section.

(2) OFFSET.—

(A) IN GENERAL.—The Administrator may, on an equal basis and in accordance with subparagraph (B), increase the fees described in paragraph (1) for distributors and registrants to the extent necessary to defray the costs of this section.

(B) TIERED FEE.—The Administrator shall establish a tiered user fee for distributors and registrants in proportion to the volume of sales and purchases.

(g) APPLICABILITY OF FACA.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Task Force.

(2) TERMINATION.—The Task Force shall terminate on the date on which the program is fully implemented under subsection (e)(3).

(h) RULES OF CONSTRUCTION.—Nothing in this Act shall be construed as relieving any manufacturer, distributor, or other registrant from the responsibilities of the manufacturer, distributor, or other registrant, as the case may be, to—

(1) identify, stop, and report suspicious orders;

(2) maintain effective controls against diversion in accordance with section 303 of the Controlled Substances Act (21 U.S.C. 823); and

(3) comply with the requirements established in section 1301.74(b) of title 21, Code of Federal Regulations, or any successor regulation thereto, with respect to suspicious orders.

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