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115TH CONGRESS
2D SESSION

H. R. 5812

To amend the Public Health Service Act to authorize the Director of the Centers for Disease Control and Prevention to carry out certain activities to prevent controlled substances overdoses, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2018

Mr. GRIFFITH (for himself, Mr. PALLONE, and Mr. FITZPATRICK) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to authorize the Director of the Centers for Disease Control and Prevention to carry out certain activities to prevent controlled substances overdoses, 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 ''Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act of 2018'' or the ''CONNECTIONS Act''.

SEC. 2. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

"SEC. 399V–7. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.

''(a) EVIDENCE-BASED PREVENTION GRANTS.—

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—

''(A) to the extent practicable, carry out any evidence-based prevention activity described in paragraph (2);

''(B) provide training and technical assistance to States, localities, and Indian tribes for purposes of carrying out any such activity; and

''(C) award grants to States, localities, and Indian tribes for purposes of carrying out any such activity.

''(2) EVIDENCE-BASED PREVENTION ACTIVITIES.—An evidence-based prevention activity described in this paragraph is any of the following activities:

''(A) With respect to a State, improving the efficiency and use of the State prescription drug monitoring program by—

"(i) encouraging all authorized users (as specified by the State) to register with and use the program and making the program easier to use;

"(ii) enabling such users to access any updates to information collected by the program in as close to real-time as possible;

"(iii) providing for a mechanism for the program to automatically flag any potential misuse or abuse of controlled substances and any detection of inappropriate prescribing practices relating to such substances;

"(iv) enhancing interoperability between the program and any electronic health records system, including by integrating the use of electronic health records into the program for purposes of improving clinical decisionmaking;

"(v) continually updating program capabilities to respond to technological innovation for purposes of appropriately addressing a controlled substance overdose

epidemic as such epidemic may occur and evolve;

''(vi) facilitating data sharing between the program and the prescription drug monitoring programs of neighboring States; and

''(vii) meeting the purpose of the program established under section 399O, as described in section 399O(a).

''(B) Achieving community or health system interventions through activities such as—

''(i) establishing or improving controlled substances prescribing interventions for insurers and health systems;

''(ii) enhancing the use of evidence-based controlled substances prescribing guidelines across sectors and health care settings; and

''(iii) implementing strategies to align the prescription of controlled substances with the guidelines described in clause (ii).

''(C) Evaluating interventions to better understand what works to prevent overdoses, including those involving prescription and illicit controlled substances.

"(D) Implementing projects to advance an innovative prevention approach with respect to new and emerging public health crises and opportunities to address such crises, such as enhancing public education and awareness on the risks associated with opioids.

"(b) ENHANCED SURVEILLANCE OF CONTROLLED SUBSTANCE OVERDOSE GRANTS.—

"(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—

"(A) to the extent practicable, carry out any controlled substance overdose surveillance activity described in paragraph (2);

"(B) provide training and technical assistance to States for purposes of carrying out any such activity;

"(C) award grants to States for purposes of carrying out any such activity; and

"(D) coordinate with the Assistant Secretary for Mental Health and Substance Use to collect data pursuant to section 505(d)(1)(A) (relating to the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs).

''(2) CONTROLLED SUBSTANCE OVERDOSE SURVEILLANCE ACTIVITIES.—A controlled substance overdose surveillance activity described in this paragraph is any of the following activities:

''(A) Enhancing the timeliness of reporting data to the public, including data on fatal and nonfatal overdoses of controlled substances.

''(B) Enhancing comprehensiveness of data on controlled substances overdoses by collecting information on such overdoses from appropriate sources such as toxicology reports, autopsy reports, death scene investigations, and other risk factors.

''(C) Using data to help identify risk factors associated with controlled substances overdoses.

''(D) With respect to a State, supporting entities involved in providing information to inform efforts within the State, such as by coroners and medical examiners, to improve accurate testing and reporting of causes and contributing factors to controlled substances overdoses.

''(E) Working to enable information sharing regarding controlled substances overdoses among data sources.

''(c) DEFINITIONS.—In this section:

''(1) CONTROLLED SUBSTANCE.—The term 'controlled substance' has the meaning given that term in section 102 of the Controlled Substances Act.

''(2) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section and section 399O, there is authorized to be appropriated $486,000,000 for each of fiscal years 2019 through 2023.''.

SEC. 3. PRESCRIPTION DRUG MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended to read as follows:

''SEC. 399O. PRESCRIPTION DRUG MONITORING PROGRAM.

''(a) PROGRAM.—

''(1) IN GENERAL.—Each fiscal year, the Secretary, in consultation with the Director of National Drug Control Policy, acting through the Director of the Centers for Disease Control and Prevention, the

Assistant Secretary for Mental Health and Substance Use, and the National Coordinator for Health Information Technology, shall support States for the purpose of improving the efficiency and use of PDMPs, including—

"(A) establishment and implementation of a PDMP;

"(B) maintenance of a PDMP;

"(C) improvements to a PDMP by—

"(i) enhancing functional components to work toward—

"(I) universal use of PDMPs among providers and their delegates, to the extent that State laws allow, within a State;

"(II) more timely inclusion of data within a PDMP;

"(III) active management of the PDMP, in part by sending proactive or unsolicited reports to providers to inform prescribing; and

"(IV) ensuring the highest level of ease in use and access of PDMPs by providers and their delegates, to the extent that State laws allow;

"(ii) improving the intrastate interoperability of PDMPs by—

"(I) making PDMPs more actionable by integrating PDMPs within electronic health records and health information technology infrastructure; and

"(II) linking PDMP data to other data systems within the State, including—

"(aa) the data of pharmacy benefit managers, medical examiners and coroners, and the State's Medicaid program;

"(bb) worker's compensation data; and

"(cc) prescribing data of providers of the Department of Veterans Affairs and the Indian Health Service within the State;

"(iii) improving the interstate interoperability of PDMPs through—

"(I) sharing of dispensing data in near-real time across State lines; and

"(II) integration of automated queries for multistate PDMP data and analytics into clinical workflow to improve the use of such data and analytics by practitioners and dispensers; or

"(iv) improving the ability to include treatment availability resources and referral capabilities within the PDMP.

"(2) STATE LEGISLATION.—As a condition on the receipt of support under this section, the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations—

"(A) to provide for the implementation of the PDMP; and

"(B) to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.

"(b) PDMP STRATEGIES.—The Secretary shall encourage a State, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

"(1) the reporting of dispensing in the State of a controlled substance to an ultimate user so the re-

porting occurs not later than 24 hours after the dispensing event;

''(2) the consultation of the PDMP by each prescribing practitioner, or their designee, in the State before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event;

''(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;

''(4) the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected;

''(5) the availability of data in the PDMP to other States, as allowable under State law; and

''(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.

''(c) DRUG MISUSE AND ABUSE.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving support under this section—

''(1) shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances; and

''(2) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the PDMP maintained by the State indicates an unlawful diversion or abuse of a controlled substance.

''(d) EVALUATION AND REPORTING.—As a condition on receipt of support under this section, the State shall report on interoperability with PDMPs of other States and Federal agencies, where appropriate, intrastate interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.

''(e) EVALUATION AND REPORTING.—A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—

''(1) to evaluate the success of the State's program in achieving the purpose described in subsection (a); or

''(2) to prepare and submit to the Congress the report required by subsection (i)(2).

''(f) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving support under this section shall take steps to—

''(1) facilitate prescribers and dispensers, and their delegates, as permitted by State law, to use the PDMP, to the extent practicable; and

''(2) educate prescribers and dispensers, and their delegates on the benefits of the use of PDMPs.

''(g) ELECTRONIC FORMAT.—The Secretary may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs.

''(h) RULES OF CONSTRUCTION.—

''(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

''(2) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

''(3) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of this Act.

''(4) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

''(i) PROGRESS REPORT.—Not later than 3 years after the date of enactment of the CONNECTIONS Act, the Secretary shall—

''(1) complete a study that—

''(A) determines the progress of States in establishing and implementing PDMPs consistent with this section;

''(B) provides an analysis of the extent to which the operation of PDMPs has—

"(i) reduced inappropriate use, abuse, diversion of, and overdose with, controlled substances;

"(ii) established or strengthened initiatives to ensure linkages to substance use disorder treatment services; or

"(iii) affected patient access to appropriate care in States operating PDMPs;

"(C) determine the progress of States in achieving interstate interoperability and intrastate interoperability of PDMPs, including an assessment of technical, legal, and financial barriers to such progress and recommendations for addressing these barriers;

"(D) determines the progress of States in implementing near real-time electronic PDMPs;

"(E) provides an analysis of the privacy protections in place for the information reported to the PDMP in each State receiving support under this section and any recommendations of the Secretary for additional Federal or State requirements for protection of this information;

"(F) determines the progress of States in implementing technological alternatives to cen-

tralized data storage, such as peer-to-peer file sharing or data pointer systems, in PDMPs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

''(G) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in PDMPs, and the criteria used by the Secretary to determine whether such penalties qualify as appropriate for purposes of subsection (a)(2); and

''(2) submit a report to the Congress on the results of the study.

''(j) ADVISORY COUNCIL.—

''(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.

''(2) LIMITATION.—A State may not use Federal funds for the operations of an advisory council to assist in the establishment, improvement, or maintenance of a PDMP.

''(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council to assist in the establishment, improvement, or

maintenance of a PDMP, a State should consult with appropriate professional boards and other interested parties.

''(k) DEFINITIONS.—For purposes of this section:

''(1) The term 'controlled substance' means a controlled substance (as defined in section 102 of the Controlled Substances Act) in schedule II, III, or IV of section 202 of such Act.

''(2) The term 'dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the internet or other means to effect such delivery.

''(3) The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

''(4) The term 'interstate interoperability' with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

''(5) The term 'intrastate interoperability' with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.

''(6) The term 'nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

''(7) The term 'PDMP' means a prescription drug monitoring program that is State-controlled.

''(8) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

''(9) The term 'State' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

''(10) The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned by the person or by a member of the person's household.

''(11) The term 'clinical workflow' means the integration of automated queries for prescription drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.''.

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