Attachment A2

Authorizing Legislation

TITLE VII—PUBLIC HEALTH PROVISIONS: Subtitle Q of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

Subtitle Q—Creating Opportunities That Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies

SEC. 7161. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Part J of title III of the Public Health Service Act (42 U.S.C. 280b et seq.) is amended by inserting after section 392 (42 U.S.C. 280b–1) the following:

"SEC. 392A. 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 and expand any evidence-based prevention activities described in paragraph (2);
"(B) provide training and technical assistance to States, localities, and Indian tribes for purposes of carrying out such activity; and
"(C) award grants to States, localities, and Indian tribes for purposes of carrying out such activity.
"(2) EVIDENCE-BASED PREVENTION ACTIVITIES.—An evidence-based prevention activity described in this paragraph is any of the following activities:
"(A) Improving the efficiency and use of a new or currently operating prescription drug monitoring program, including by—
"(i) encouraging all authorized users (as specified by the State or other entity) to register with and use the program;
"(ii) enabling such users to access any updates to information collected by the program in as close to real-time as possible;
"(iii) improving the ease of use of such program;
"(iv) providing for a mechanism for the program to notify authorized users of any potential misuse or abuse of controlled substances and any detection of inappropriate prescribing or dispensing practices relating to such substances;
"(v) encouraging the analysis of prescription drug monitoring data for purposes of providing de-identified, aggregate reports based on such analysis to State public health agencies, State substance abuse agencies, State licensing boards, and other appropriate State agencies, as permitted under applicable Federal and State law and the policies of the prescription drug monitoring program and not containing any protected health information, to prevent inappropriate prescribing, drug diversion, or abuse and misuse of controlled substances, and to facilitate better coordination among agencies;
"(vi) enhancing interoperability between the program and any health information technology (including certified health information technology), including by integrating program data into such technology;

"(vii) updating program capabilities to respond to technological innovation for purposes of appropriately addressing the occurrence and evolution of controlled substance overdoses;

"(viii) facilitating and encouraging data exchange between the program and the prescription drug monitoring programs of other States;

"(ix) enhancing data collection and quality, including improving patient matching and proactively monitoring data quality;

"(x) providing prescriber and dispenser practice tools, including prescriber practice insight reports for practitioners to review their prescribing patterns in comparison to such patterns of other practitioners in the specialty; and

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

"(B) Promoting community or health system interventions.

"(C) Evaluating interventions to prevent controlled substance overdoses.

"(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.

"(3) ADDITIONAL GRANTS.—The Director may award grants to States, localities, and Indian Tribes—

"(A) to carry out innovative projects for grantees to rapidly respond to controlled substance misuse, abuse, and overdoses, including changes in patterns of controlled substance use; and

"(B) for any other evidence-based activity for preventing controlled substance misuse, abuse, and overdoses as the Director determines appropriate.

"(4) RESEARCH.—The Director, in coordination with the Assistant Secretary for Mental Health and Substance Use and the National Mental Health and Substance Use Policy Laboratory established under section 501A, as appropriate and applicable, may conduct studies and evaluations to address substance use disorders, including preventing substance use disorders or other related topics the Director determines appropriate.

"(b) ENHANCED CONTROLLED SUBSTANCE OVERDOSE DATA COLLECTION, ANALYSIS, AND DISSEMINATION 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 data collection activities described in paragraph (2);

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

"(C) award grants to States, localities, and Indian tribes for purposes of carrying out 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 emergency departments as a result of the abuse of alcohol or other drugs).

"(2) CONTROLLED SUBSTANCE OVERDOSE DATA COLLECTION AND ANALYSIS ACTIVITIES.—A controlled substance overdose data collection, analysis, and dissemination activity described in this paragraph is any of the following activities:

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

"(B) Enhancing the comprehensiveness of controlled substance overdose data by collecting information on such overdoses from appropriate sources such as toxicology reports, autopsy reports, death scene investigations, and emergency departments.

"(C) Modernizing the system for coding causes of death related to controlled substance overdoses to use an electronic-based system.

"(D) Using data to help identify risk factors associated with controlled substance overdoses.

"(E) Supporting entities involved in providing information on controlled substance overdoses, such as coroners, medical examiners, and public health laboratories to improve accurate testing and standardized reporting of causes and contributing factors to controlled substances overdoses and analysis of various opioid analogues to controlled substance overdoses.

"(F) Working to enable and encourage the access, exchange, and use of information regarding controlled substance overdoses among data sources and entities.

"(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, section 399O of this Act, and section 102 of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), there is authorized to be appropriated $496,000,000 for each of fiscal years 2019 through 2023.".

(b) EDUCATION AND AWARENESS.—Section 102 of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198) is amended—

(1) by amending subsection (a) to read as follows:

"(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in coordination with the heads of other departments and agencies, shall advance education and awareness regarding the risks related to misuse and abuse of opioids, as appropriate, which may include developing or improving existing programs, conducting activities, and awarding grants that advance the education and awareness of—

"(1) the public, including patients and consumers—

"(A) generally; and

"(B) regarding such risks related to unused opioids and the dispensing options under section 309(f) of the Controlled Substances Act, as applicable; and

"(2) providers, which may include—

"(A) providing for continuing education on appropriate prescribing practices;

"(B) education related to applicable State or local prescriber limit laws, information on the use of non-addictive alternatives for pain management, and the use of overdose reversal drugs, as appropriate;

"(C) disseminating and improving the use of evidence-based opioid prescribing guidelines across relevant health care settings, as appropriate, and updating guidelines as necessary;

"(D) implementing strategies, such as best practices, to encourage and facilitate the use of prescriber guidelines, in accordance with State and local law;

"(E) disseminating information to providers about prescribing options for controlled substances, including such options under section 309(f) of the Controlled Substances Act, as applicable; and

"(F) disseminating information, as appropriate, on the National Pain Strategy developed by or in consultation with the Assistant Secretary for Health; and

"(3) other appropriate entities."; and

(2) in subsection (b)—

(A) by striking "opioid abuse" each place such term appears and inserting "opioid misuse and abuse"; and

(B) in paragraph (2), by striking "safe disposal of prescription medications and other" and inserting "non-addictive treatment options, safe disposal options for prescription medications, and other applicable".

SEC. 7162. 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, acting through the Director of the Centers for Disease Control and Prevention, in coordination with the heads of other departments and agencies as appropriate, shall support States or localities 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;

"(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 of and access to PDMPs by providers and their delegates, to the extent that State laws allow;

"(ii) in consultation with the Office of the National Coordinator for Health Information Technology, 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) in consultation with the Office of the National Coordinator for Health Information Technology, 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) LEGISLATION.—As a condition on the receipt of support under this section, the Secretary shall require a State or locality to demonstrate that it 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 or locality, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

"(1) the reporting of dispensing in the State or locality of a controlled substance to an ultimate user so the reporting 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 or locality 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;

"(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;

"(3) may conduct analyses of controlled substance program data for purposes of providing appropriate State agencies with aggregate reports based on such analyses in as close to real-time as practicable, regarding prescription patterns flagged as potentially presenting a risk of misuse, abuse, addiction, overdose, and other aggregate information, as appropriate and in compliance with applicable Federal and State laws and provided that such reports shall not include protected health information; and

"(4) may access information about prescriptions, such as claims data, to ensure that such prescribing and dispensing history is updated in as close to real-time as practicable, in compliance with applicable Federal and State laws and provided that such information shall not include protected health information.

"(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. To the extent possible, such guidelines shall be consistent with standards recognized by the Office of the National Coordinator for Health Information Technology.

"(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 this section, the Secretary shall—

"(1) complete a study that—

"(A) determines the progress of grantees 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 grantees 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 grantees 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 or locality 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 or localities in implementing technological alternatives to centralized 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 or localities 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 or locality may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.

"(2) LIMITATION.—A State or locality 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 or locality 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.".