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115TH CONGRESS
2D SESSION

H. R. 5865

To establish programs related to prevention of prescription opioid misuse, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 17, 2018

Mr. CARTWRIGHT introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Ways and Means, and Education and the Workforce, 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 establish programs related to prevention of prescription opioid misuse, 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 ''Addiction Prevention and Responsible Opioid Practices Act''.

SEC. 2. FEDERAL LICENSURE OF PHARMACEUTICAL REPRESENTATIVES WHO PROMOTE CERTAIN OPIOIDS.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 569D. FEDERAL LICENSURE OF PHARMACEUTICAL REPRESENTATIVES WHO PROMOTE CERTAIN OPIOIDS.

''(a) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall establish a licensure program for pharmaceutical representatives described in subsection (b).

''(b) LICENSURE PROGRAM.—

''(1) REQUIREMENT.—Beginning on January 1, 2020, no individual described in paragraph (2) may engage in the marketing or promoting of opioid drugs unless such individual is licensed under this section.

''(2) INDIVIDUALS REQUIRED TO OBTAIN LICENSURE.—An individual required to obtain a license under this section is any individual who, on behalf of a drug manufacturer, engaged, on more than 15 days in a calendar year, in the marketing or promotion to health care professionals, including educational or sales communications, meetings or

paid events, and the provision of goods, gifts, and samples, of any opioid drug (other than methadone) that is listed in schedule II of section 202(c) of the Controlled Substances Act.

''(3) LICENSURE PERIOD.—Each license issued under this section shall be valid for 3 years, and may be renewed for additional 3-year periods.

''(c) REQUIREMENTS.—An individual required to obtain a license under this section shall—

''(1) submit to the Secretary, at such time and in such manner as the Secretary may require—

''(A) such information as the Secretary may require; and

''(B) a registration fee in the amount of $3,000;

''(2) certify that such individual has completed training on ethics, pharmaceutical marketing regulations, the 'CDC Guidelines for Prescribing Opioids for Chronic Pain', published by the Centers for Disease Control and Prevention in 2016 (or any successor document) or the 'FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics', and applicable Federal laws pertaining to drug marketing, labeling, and clinical trials, as the Secretary may require;

''(3) certify that such individual will not engage in any illegal, fraudulent, misleading, or other deceptive marketing of schedule II opioid drugs; and

''(4) file with the Secretary annual reports disclosing the names of providers visited and any drug samples or gifts such individual gives any such provider.

''(d) MANUFACTURER REPORTING REQUIREMENTS.—The manufacturer who employs or contracts with any individual required to obtain a license under this section shall include in reports required under section 1128G of the Social Security Act the name of each such licensed individual that provides payments or other transfers of value required to be reported under such section 1128G that relates to an opioid drug that is listed in schedule II of the Controlled Substances Act.''.

SEC. 3. WITHDRAWAL OF APPROVAL OF CERTAIN OPIOIDS.

(a) IN GENERAL.—Notwithstanding any other provision of law, any ultra-high-dose opioid shall be considered a drug that presents an imminent hazard to the public health within the meaning of section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and the Secretary of Health and Human Services shall suspend the approval of such drug, in accordance with such section 505(e).

(b) DEFINITION.—In this section, the term ''ultra-high-dose opioid'' means an opioid drug for which the daily dosage provided for in the approved label exceeds the morphine milligram equivalents per day outlined in the report entitled ''CDC Guidelines for Prescribing Opioids for Chronic Pain'', published by the Centers for Disease Control and Prevention in 2016 (or any successor document).

SEC. 4. EXPANDING AVAILABILITY OF INFORMATION IN THE ARCOS DATABASE.

Section 307(d) of the Controlled Substances Act (21 U.S.C. 827(d)) is amended by adding at the end the following:

''(3) The Attorney General shall make available to the medical licensing board and board of pharmacy for each State the information in the Automation of Reports and Consolidated Orders System, or any subsequent automated system developed by the Attorney General to monitor the sale, delivery, and disposal of controlled substances within such State.''.

SEC. 5. CONTINUING MEDICAL EDUCATION AND PRESCRIPTION DRUG MONITORING PROGRAM REGISTRATION FOR PRESCRIBERS.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(k)(1) The Attorney General shall not register, or renew the registration of, a practitioner under subsection (f) who is licensed under State law to prescribe controlled substances in schedule II, III, or IV, unless the practitioner submits to the Attorney General, for each such registration or renewal request, a written certification that—

''(A)(i) the practitioner has, during the 1-year period preceding the registration or renewal request, completed a training program described in paragraph (2); or

''(ii) the practitioner, during the applicable registration period, will not prescribe such controlled substances in amounts in excess of a 72-hour supply (for which no refill is available); and

''(B) the practitioner has registered with the prescription drug monitoring program of the State in which the practitioner practices, if the State has such program.

''(2) A training program described in this paragraph is a training program that—

''(A) follows the best practices for pain management, as described in the 'Guideline for Prescribing Opioids for Chronic Pain' as published by the Centers for Disease Control and Prevention in 2016, or any successor thereto, or the 'FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics' as published by the Food and Drug Administration in 2017, or any successor thereto;

''(B) includes information on—

''(i) recommending non-opioid and non-pharmacological therapy;

''(ii) establishing treatment goals and evaluating patient risks;

''(iii) prescribing the lowest dose and fewest number of pills considered effective;

''(iv) addictive and overdose risks of opioids;

''(v) diagnosing and managing substance use disorders, including linking patients to evidence-based treatment;

''(vi) identifying narcotics-seeking behaviors; and

''(vii) using prescription drug monitoring programs; and

''(C) is approved by the Secretary of Health and Human Services.''.

SEC. 6. REPORT ON PRESCRIBER EDUCATION COURSES FOR MEDICAL AND DENTAL STUDENTS.

Each school of medicine, school of osteopathic medicine, and school of dentistry participating in a program under title IV of the Higher Education Act of 1965 (20 U.S.C. 1070a et seq.), as a condition for such participation, shall submit an annual report to the Secretary of Education and the Secretary of Health and Human Services on any prescriber education courses focused specifically on pain management and responsible opioid prescribing practices that such school requires students to take, and whether such courses are consistent with the most recently published version of the ''Guideline for Prescribing Opioids for Chronic Pain'' of the Centers for Disease Control and Prevention or the ''FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics'', as published by the Food and Drug Administration in 2017. The Secretary of Education and the Secretary of Health and Human Services shall compile the reports submitted by such schools and submit an annual summary of such reports to Congress.

SEC. 7. REQUIREMENTS UNDER PRESCRIPTION DRUG MONITORING PROGRAMS.

(a) IN GENERAL.—Beginning 1 year after the date of enactment of this Act, each State that receives funding under any of the programs described in subsection (c) shall—

(1) require practitioners, or their designees, in the State to consult the database of the prescription drug monitoring program before writing prescriptions for controlled substances (as such term is defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) in schedule II, III, or IV under section 202 of such Act (21 U.S.C. 812);

(2) require dispensers of controlled substances in schedule II, III, or IV, or their designees, to input data into the database of the prescription drug monitoring program within 24 hours of filling a qualifying prescription, as required by the Attorney General and the Secretary of Health and Human Services, including patient identifier information, the national drug code of the dispensed drug, date of dispensing the drug, quantity and dosage of the drug dispensed, form of payment, Drug Enforcement Administration registration number of the practitioner, Drug Enforcement Administration registration number of the dispenser;

(3) allow practitioners and dispensers to designate other appropriate individuals to act as agents of such practitioners and dispensers for purposes of obtaining and inputing data from the database for purposes of complying with paragraphs (1) and (2), as applicable;

(4) provide informational materials for practitioners and dispensers to identify and refer patients with possible substance use disorders to professional treatment specialists;

(5) establish formal data sharing agreements to foster electronic connectivity with the prescription drug monitoring programs of each State (if such State has such a program) with which the State shares a border, to facilitate the exchange of information through an established technology architecture that ensures common data standards, privacy protection, and secure and streamlined information sharing;

(6) notwithstanding section 399O(f)(1)(B) of the Public Health Service Act (42 U.S.C. 280g–3(f)(1)(B)), authorize direct access to the State's database of the prescription drug monitoring program to all State law enforcement agencies, State boards responsible for the licensure, regulation, or

discipline of practitioners, pharmacists, or other persons authorized to prescribe, administer, or dispense controlled substances; and

(7) in order to enhance accountability in prescribing and dispensing patterns, not fewer than 4 times per year, proactively provide informational reports on aggregate trends and individual outliers, based on information available through the State prescription drug monitoring program to—

(A) the State entities and persons described in paragraph (6); and

(B) the Medicaid agency and the department of public health of the State.

(b) TRANSPARENCY IN PRESCRIBING PRACTICES AND INTERVENTION FOR HIGH PRESCRIBERS.—

(1) STATE REPORTING REQUIREMENT.—Each State that receives funding under any of the programs described in subsection (c) shall, twice per year, submit to the Secretary of Health and Human Services and the Administrator of the Drug Enforcement Administration—

(A) a list of all practitioners and dispensers who, in the applicable reporting period, have prescribed or dispensed schedule II, III, or IV opioids in the State;

(B) the amount of schedule II, III, or IV opioids that were prescribed and dispensed by each individual practitioner and dispenser described in subparagraph (A); and

(C) any additional information that the Secretary and Administrator may require to support surveillance and evaluation of trends in prescribing or dispensing of schedule II, III, or IV opioids, or to identify possible non-medical use and diversion of such substances.

(2) ANNUAL REPORT.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services, in consultation with the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of Veterans Affairs, and the Director of the Indian Health Service, shall submit to Congress, and make public, a report identifying outliers among the medical specialties and geographic areas with the highest rates of opioid prescribing in the Nation, by ZIP code.

(3) DEVELOPMENT OF ACTION PLAN.—

(A) INITIAL PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in con-

sultation with the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of Veterans Affairs, and the Director of the Indian Health Service, shall submit to Congress a plan of action, including warning letters and enforcement mechanisms, for addressing outliers in opioid prescribing practices and ensuring an adequate Federal response to protect the public health.

(B) UPDATED PLAN.—The Secretary of Health and Human Services shall submit to Congress updates to the plan of action described in subparagraph (A), as such Secretary, in consultation with the heads of agencies described in such subparagraph, determines appropriate.

(c) PROGRAMS DESCRIBED.—The programs described in this subsection are—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748);

(2) the controlled substance monitoring program under section 399O of the Public Health Service Act (42 U.S.C. 280g–3);

(3) the Prescription Drug Overdose: Prevention for States program of the Centers for Disease Control and Prevention;

(4) the Prescription Drug Overdose: Data-Driven Prevention Initiative of Centers for Disease Control and Prevention;

(5) the Enhanced State Opioid Overdose Surveillance program of the Centers for Disease Control and Prevention;

(6) the opioid grant program under section 1003 of the 21st Century Cures Act (Public Law 114–255); and

(7) the State Opioid Response Grant program described under the heading ''SUBSTANCE ABUSE TREATMENT'' under the heading ''SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION'' of title II of division H of the Consolidated Appropriations Act, 2018 (Public Law 115–141).

(d) DEFINITIONS.—In this section, the terms ''dispenser'' and ''practitioner'' have the meanings given such

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

SEC. 8. INTEROPERABILITY OF CERTIFIED HEALTH INFORMATION TECHNOLOGY.

Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)) is amended by adding at the end the following:

''(F) INTEROPERABILITY.—Beginning on January 1, 2021, the National Coordinator shall not certify electronic health records as health information technology that is in compliance with applicable certification criteria under this paragraph unless such technology is interoperable with the prescription drug monitoring programs of each State that, at the time of the request for such certification, has such a program.''.

SEC. 9. STUDIES RELATED TO OVERDOSE DISCHARGE AND FOLLOW-UP POLICIES.

(a) STUDY.—Not later than January 1, 2021, the Secretary of Health and Human Services shall—

(1) conduct a study on the scope and circumstances of non-fatal opioid overdoses, the policies and procedures that States, health care systems, and first responders have implemented; and

(2) in partnership with stakeholder organizations with subject matter expertise, establish guidelines for hospital procedures following non-fatal opioid overdose and the administration of overdose reversal medication.

(b) STUDY AND DEVELOPMENT OF QUALITY MEASURES UNDER MEDICARE RELATED TO OPIOID ABUSE AND SUBSTANCE USE DISORDER.—Section 1890A(e) of the Social Security Act (42 U.S.C. 1395aaa–1(e)) is amended—

(1) by striking ''MEASURES.—The Administrator'' and inserting ''MEASURES.—

''(1) IN GENERAL.—The Administrator''; and

(2) by adding at the end the following new paragraph:

''(2) STUDY AND DEVELOPMENT OF QUALITY MEASURES RELATED TO OPIOID ABUSE AND SUBSTANCE USE DISORDER.—Beginning not later than 1 year after the date of enactment of this paragraph, the Administrator of the Center for Medicare and Medicaid Services shall study and through contracts develop, in coordination with appropriate subject matter organizations (such as the entity with a contract under section 1890), for use under this Act, quality measures related to standards of care for

treating individuals with non-fatal opioid overdose, discharge procedures, and linkages to appropriate substance use disorder treatment and community support services.''.

SEC. 10. MEDICAID OPIOID DRUG MAPPING TOOL.

(a) IN GENERAL.—The Secretary of Health and Human Services shall create an interactive opioid drug mapping tool, which shall be made publicly available on the internet website of the Centers for Medicare & Medicaid Services, showing prescribing practices of providers that participate in State Medicaid programs and geographic comparisons, at the State, county, and ZIP code levels, of de-identified opioid prescription claims made under State Medicaid programs under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(b) COLLECTION OF DATA FROM STATES.—The Secretary of Health and Human Services may request from States such data as the Secretary determines necessary to create the opioid mapping tool described in subsection (a).

SEC. 11. NATIONAL ACADEMY OF MEDICINE STUDY.

(a) STUDY.—The Secretary of Health and Human Services shall enter into a contract with the National Academy of Medicine to carry out a study on the addition of coverage under the Medicare program under title XVIII

of the Social Security Act of alternative treatment modalities (such as integrative medicine, including acupuncture and exercise therapy, neural stimulation, biofeedback, radiofrequency ablation, and trigger point injections) furnished to Medicare beneficiaries who suffer from acute or chronic lower back pain. Such study shall, pursuant to the contract under this paragraph, include an analysis of—

(1) scientific research on the short-term and long-term impact of the addition of such coverage on clinical efficacy for pain management of such beneficiaries;

(2) whether the lack of Medicare coverage for alternative treatment modalities impacts the volume of opioids prescribed for beneficiaries; and

(3) the cost to the Medicare program of the addition of such coverage to treat pain and mitigate the progression of chronic pain, as weighed against the cost of opioid use disorder, overdose, readmission, subsequent surgeries, and utilization and expenditures under parts B and D of such title.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, pursuant to the contract under subsection (a), the National Academy of Medicine shall submit to Congress a report on the study under subsection (a).

(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 12. EXCISE TAX ON OPIOID PAIN RELIEVERS.

(a) IN GENERAL.—Subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 4192. OPIOID PAIN RELIEVERS.

''(a) IN GENERAL.—There is hereby imposed on the manufacturer or producer of any taxable active opioid a tax equal to the amount determined under subsection (b).

''(b) AMOUNT DETERMINED.—The amount determined under this subsection with respect to a manufacturer or producer for a calendar year is 1 cent per milligram of taxable active opioid in the production or manufacturing quota determined for such manufacturer or producer for the calendar year under section 306 of the Controlled Substances Act (21 U.S.C. 826).

''(c) TAXABLE ACTIVE OPIOID.—For purposes of this section—

''(1) IN GENERAL.—The term 'taxable active opioid' means any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802), as in effect on the date of the enactment of this section) manufactured in the United

States which is opium, an opiate, or any derivative thereof.

''(2) EXCLUSIONS.—

''(A) OTHER INGREDIENTS.—In the case of a product that includes a taxable active opioid and another ingredient, subsection (a) shall apply only to the portion of such product that is a taxable active opioid.

''(B) DRUGS USED IN ADDICTION TREATMENT.—The term 'taxable active opioid' shall not include any controlled substance (as so defined) which is used exclusively for the treatment of opioid addiction as part of a medication-assisted treatment.''.

(b) CLERICAL AMENDMENTS.—

(1) The heading of subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by striking ''**Medical Devices**'' and inserting ''**Other Medical Products**''.

(2) The table of subchapters for chapter 32 of such Code is amended by striking the item relating to subchapter E and inserting the following new item:

''SUBCHAPTER E. OTHER MEDICAL PRODUCTS''.

(3) The table of sections for subchapter E of chapter 32 of such Code is amended by adding at the end the following new item:

''Sec. 4192. Opioid pain relievers.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to calendar years beginning after the date of the enactment of this Act.

SEC. 13. OPIOID CONSUMER ABUSE REDUCTION PROGRAM.

(a) OPIOID TAKE-BACK PROGRAM.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

''(h)(1) The Attorney General shall establish a national take-back program for the safe and environmentally responsible disposal of controlled substances.

''(2) In establishing the take-back program required under paragraph (1), the Attorney General—

''(A) shall consult with the Secretary and the Administrator of the Environmental Protection Agency; and

''(B) may coordinate with States, law enforcement agencies, water resource management agencies, manufacturers, practitioners, pharmacists, public health entities, transportation and incineration service contractors, and other entities and individuals, as appropriate.

''(3) The take-back program established under paragraph (1)—

''(A) shall—

''(i) ensure appropriate geographic distribution so as to provide—

''(I) reasonably convenient and equitable access to permanent take-back locations, including not less than 1 disposal site for every 25,000 residents and not less than 1 physical disposal site per town, city, county, or other unit of local government, where possible; and

''(II) periodic collection events and mail-back programs, including public notice of such events and programs, as a supplement to the permanent take-back locations described in subclause (I), particularly in areas in which the provision of access to such locations at the level described in that subclause is not possible;

''(ii) establish a process for the accurate cataloguing and reporting of the quantities of controlled substances collected; and

''(iii) include a public awareness campaign and education of practitioners and pharmacists; and

''(B) may work in coordination with State and locally implemented public and private take-back programs.

''(4) From time to time, beginning in the second calendar year that begins after the date of enactment of this subsection, the Secretary of the Treasury shall transfer from the general fund of the Treasury an amount equal to one-half of the total amount of taxes collected under section 4192 of the Internal Revenue Code of 1986 to the Attorney General to carry out this subsection. Amounts transferred under this subparagraph shall remain available until expended.''.

(b) FUNDING OF SUBSTANCE ABUSE PROGRAMS.—From time to time, beginning in the second calendar year that begins after the date of enactment of this Act, the Secretary of the Treasury shall transfer from the general fund of the Treasury an amount equal to one-half of the total amount of taxes collected under section 4192 of the Internal Revenue Code of 1986, as added by this Act, to the Director of the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration for programs of the Center, including the

Block Grants for Prevention and Treatment of Substance Abuse program under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.) and Programs of Regional and National Significance. Amounts transferred under this subsection shall remain available until expended.

SEC. 14. GAO STUDY.

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study evaluating the various State laws, commercial insurance methods, and existing research on requirements that place limitations on opioid prescribing practices and provide analysis on best practices to address over-prescribing of opioids, while ensuring that individuals who need such opioids can access them safely. Such study shall provide recommendations, including with respect to—

(1) requiring non-opioid pain treatments to be front line therapies;

(2) limiting first-time opioid prescriptions to a patient for acute pain to a 72-hour supply; and

(3) pain management treatment contracts between practitioners and patients that establish informed consent regarding the expectations, risks, long-term effects, and benefits of the course of

opioid treatment, treatment goals, the potential for opioid misuse, abuse, or diversion, and requirements and responsibilities of patients, such as submitting to a urine drug screening.

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