114TH CONGRESS
2D SESSION

S. 3075

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

IN THE SENATE OF THE UNITED STATES

JUNE 16, 2016

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Finance

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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. OPIOID ACTION PLAN.

(a) ADVISORY COMMITTEE.—

(1) NEW DRUG APPLICATION.—Except as provided in paragraph (4), prior to the approval of a new drug that is an opioid under section 505 of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), the Commissioner of Food and Drugs shall refer such drug to an advisory committee of the Food and Drug Administration to seek recommendations from such Committee.

(2) PEDIATRIC OPIOID LABELING.—The Commissioner of Food and Drugs shall convene the Pediatric Advisory Committee of the Food and Drug Administration to seek recommendations from such Committee regarding a framework for the inclusion of information in the labeling of drugs that are opioids relating to the use of such drugs in pediatric populations before such Commissioner approves any labeling changes for drugs that are opioids intended for use in pediatric populations.

(3) PUBLIC HEALTH EXEMPTION.—If the Commissioner of Food and Drugs finds that referring a new opioid drug or drugs to an advisory committee of the Food and Drug Administration as required under paragraph (1) is not in the interest of protecting and promoting public health, and has submitted a notice containing the rationale for such a finding to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of

Representatives, or if the matter that would be considered by such advisory committee with respect to any such drug or drugs concerns bioequivalence, sameness of active ingredient, or other criteria applicable to applications submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), the Commissioner shall not be required to refer such drug or drugs to an advisory committee as required under paragraph (1).

(4) SUNSET.—Unless Congress reauthorizes paragraphs (1) and (2), the requirements of such paragraphs shall cease to be effective on October 1, 2022.

(b) EDUCATION FOR PRESCRIBERS OF OPIOIDS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, as part of the Food and Drug Administration's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, and in consultation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Agency for Healthcare Research and Quality, the Administrator of the Drug Enforcement Administration, and relevant stakeholders, shall

develop recommendations regarding education programs for prescribers of opioids required to be disseminated under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), including recommendations for which prescribers should participate in such programs and how often participation in such programs is necessary.

(c) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall issue guidance on if and how the approved labeling of a drug that is an opioid and is the subject of an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) may include statements that such drug deters abuse.

SEC. 3. OPIOID INFORMATIONAL DOCUMENTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505–1 the following:

"SEC. 505–2. OPIOID INFORMATIONAL DOCUMENTS.

"(a) DEVELOPMENT OF MATERIALS.—The Commissioner shall develop informational documents describing to consumers of opioid drugs the risk factors for opioid-related harm, and shall submit such documents to the Director of the Centers for Disease Control and Prevention for approval.

''(b) LABELING REQUIREMENT.—The manufacturer of any opioid drug approved under section 505 shall ensure that the appropriate informational documents developed under subsection (a), and approved by the Director of the Centers for Disease Control and Prevention, are included in the labeling of such drug.''.

(b) ENFORCEMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(dd) If it is an opioid drug and the labeling does not include the informational documents required under section 505–2.''.

SEC. 4. STRENGTHENING CONSIDERATIONS FOR DEA NARCOTIC QUOTAS.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

''(i)(1) In fixing manufacturing quotas under this section the Attorney General shall take into consideration the impact of the manufacturing quotas on diversion and efforts to reduce the costs, injuries, and deaths associated with the abuse of prescription opioids and heroin in the United States.

''(2)(A) Not later than 1 year after the date of enactment of this subsection and every year thereafter, the At-

torney General shall publish the approved manufacturing quota for each manufacturer of fentanyl, oxycodone, hyrdocodone, oxymorphone, and hyrdomorphone for that year.

''(B) For any year in which the approved manufacturing quota for a manufacturer for any substance described in subparagraph (A) is higher than the approved manufacturing quota for a manufacturer for the substance in the previous year, the Attorney General shall publish a report explaining why the public health benefits of increasing such quota outweigh the consequences of having an increased volume of such substance available for sale, and potential diversion, in the United States.

''(C) For any substance described in subparagraph (A) that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act after the date of enactment of this subsection, the Attorney General shall publish a report explaining what factors were taken into consideration in setting the manufacturing quota for the substance.

''(3) Not later than 90 days after the date of enactment of this subsection, the Attorney General shall submit to Congress a report on—

''(A) how the Attorney General will ensure that the process of fixing manufacturing quotas under

this section takes into consideration efforts to reduce the costs, injuries, and deaths associated with the abuse of prescription opioids and heroin;

''(B) formal steps that will be taken to improve data collection from approved drug collection receptacles, mail-back programs, and take-back events on the volume and class of controlled substances that are collected; and

''(C) how the information described in subparagraphs (A) and (B) will influence the quota-setting process of the Attorney General in the following year.''.

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;

''(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 Congress 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.

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 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), the controlled substance monitoring program under section 399O of the Public Health Service Act (42 U.S.C. 280g–3), or the Prescription Drug Overdose: Prevention for States program of the Centers for Disease Control and Prevention 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 mon-

itoring 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 infor-

mation 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, workers compensation programs, 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 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), the controlled substance monitoring program under section 399O of the Public Health Service Act (42 U.S.C. 280g–3), or the Prescription Drug Overdose: Prevention for States program of the Centers for Disease Control and Prevention 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 the 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 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 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) 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).

(d) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other amounts appropriated to carry out the Prescription Drug Overdose: Prevention for States program of the Centers for Disease Control and Prevention, for purposes of enhancing the utilization, interoperability, and integration of State prescription drug monitoring programs, there are authorized to be appropriated $70,000,000 for each of fiscal years 2017 through 2021.

SEC. 8. DEVELOPMENT OF NEW PAIN-RELATED MEASURES UNDER THE MEDICARE HOSPITAL VALUE-BASED PURCHASING PROGRAM TO ELIMINATE FINANCIAL INCENTIVES TO OVER-PRESCRIBE OPIOIDS.

Section 1886(o)(2)(B) of the Social Security Act (42 U.S.C. 1395ww(o)(2)(B)) is amended—

(1) in clause (i)(II), by inserting ", subject to clause (iii)," after "shall"; and

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

"(iii) DEVELOPMENT OF NEW PAIN-RELATED MEASURES.—

"(I) MORATORIUM UNTIL NEW MEASURES APPLICABLE.—For value-based incentive payments made with respect to discharges occurring during fiscal year 2018 and each subsequent fiscal year (before the first fiscal year in which new measures are applicable under subclause (II)(cc)), the Secretary shall ensure that measures selected under subparagraph (A) (such as measures related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey) do not

include measures based on any assessments by patients, with respect to hospital stays of such patients, of—

"(aa) the need of such patients, during such stay, for medicine for pain;

"(bb) how often, during such stay, the pain of such patients was well controlled; or

"(cc) how often, during such stay, the staff of the hospital in which such stay occurred did everything they could to help the patient with the pain experienced by the patient.

"(II) DEVELOPMENT OF NEW MEASURES.—

"(aa) DEVELOPMENT.—Not later than 3 years after the date of enactment of this clause, the Secretary shall develop measures of patient experience of care with respect to pain management that balance the breadth of effective pain management tools with

awareness for the role of over-prescribing (including, if appropriate, opioid-seeking behaviors) in the prescription opioid epidemic.

''(bb) CONSULTATION.—The Secretary shall consult with relevant stakeholders in developing measures under item (aa).

''(cc) APPLICATION FOR VALUE-BASED INCENTIVE PAYMENTS.—For value-based incentive payments made with respect to discharges occurring during a fiscal year beginning on or after the date on which the Secretary develops new measures under item (aa), the Secretary shall ensure that measures selected under subparagraph (A) (such as measures related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey) include such new measures.''.

SEC. 9. 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. 10. 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. 11. 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. 12. 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) limiting first-time opioid prescriptions to a patient for acute pain to a 72-hour supply;

(2) allowing patients or practitioners to request that a prescription for a schedule II opioid be partially filled by a pharmacist; 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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