114TH CONGRESS
1ST SESSION

S. 636

To reduce prescription drug misuse and abuse.

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2015

Mr. UDALL introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To reduce prescription drug misuse and abuse.

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 ''Increasing the Safety of Prescription Drug Use Act of 2015''.

TITLE I—HHS PROGRAMS

SEC. 101. AMENDMENT TO PURPOSE.

Paragraph (1) of section 2 of the National All Schedules Prescription Electronic Reporting Act of 2005 (Public Law 109–60) is amended to read as follows:

''(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that—

''(A) health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

''(B) appropriate law enforcement, regulatory, and State professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and prescribing and dispensing practices of errant prescribers or pharmacists; and''.

SEC. 102. PRESCRIPTION DRUG MONITORING PROGRAM.

(a) CONTROLLED SUBSTANCE MONITORING PROGRAM.—Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A), by striking ''or'';

(B) in subparagraph (B), by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(C) to maintain and operate an existing State-controlled substance monitoring program.'';

(2) by amending subsection (b) to read as follows:

''(b) MINIMUM REQUIREMENTS.—The Secretary shall maintain and, as appropriate, supplement or revise (after publishing proposed additions and revisions in the Federal Register and receiving public comments thereon) minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).'';

(3) in subsection (c)—

(A) in paragraph (1)(B)—

(i) in the matter preceding clause (i), by striking ''(a)(1)(B)'' and inserting ''(a)(1)(B) or (a)(1)(C)'';

(ii) in clause (i), by striking ''program to be improved'' and inserting ''program to be improved or maintained'';

(iii) by redesignating clauses (iii) and (iv) as clauses (iv) and (v), respectively;

(iv) by inserting after clause (ii), the following:

''(iii) a plan to apply the latest advances in health information technology in order to incorporate prescription drug monitoring program data directly into the workflow of prescribers and dispensers to ensure timely access to patients' controlled prescription drug history;'';

(v) in clause (iv) (as so redesignated), by inserting before the semicolon the following: ''and at least one health information technology system such as electronic health records, health information exchanges, and e-prescribing systems''; and

(vi) in clause (v) (as so redesignated), by striking ''public health'' and inserting ''public health or public safety'';

(B) in paragraph (3)—

(i) by striking ''If a State that submits'' and inserting the following:

''(A) IN GENERAL.—If a State that submits'';

(ii) by inserting before the period at the end ''and include timelines for full implementation of such interoperability. The State shall also describe the manner in

which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for the implementation of such interoperability''; and

(iii) by adding at the end the following:

''(B) MONITORING OF EFFORTS.—The Secretary shall monitor State efforts to achieve interoperability, as described in subparagraph (A).'';

(C) in paragraph (5)—

(i) by striking ''implement or improve'' and inserting ''establish, improve, or maintain''; and

(ii) by adding at the end the following: ''The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).'';

(4) in subsection (d)—

(A) in the matter preceding paragraph (1)—

(i) by striking ''In implementing or improving'' and all that follows through ''(a)(1)(B)'' and inserting ''In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)''; and

(ii) by striking ''public health'' and inserting ''public health or public safety''; and

(B) by adding at the end the following:

''(5) The State shall report on interoperability with the controlled substance monitoring program of Federal agencies, where appropriate, 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, real-time or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.'';

(5) in subsection (e), by adding at the end the following:

''(5) The State shall—

''(A) ensure that the database—

''(i) is interoperable with the controlled substance monitoring program of other States and other Federal agencies and across appropriate State agencies, including health agencies, as determined by the Secretary;

''(ii) is interoperable with electronic health records and e-prescribing, where appropriate; and

''(iii) provides automatic, real-time or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient;

''(B) require practitioners to use State database information to help determine whether to prescribe or renew a prescription for a controlled substance; and

''(C) require dispensers, or their designees, where permitted, to enter data required by the Secretary, including the name of the patient,

the date, and prescription dose, into the database for a controlled substance.

''(6) Notwithstanding section 543 and any other provision of law, the data required to be entered under paragraph (5)(C) shall include information with respect to methadone that is dispensed to a patient, if applicable.

''(7) The State shall ensure that—

''(A) any person who receives patient information through the database may disclose and use such information only to carry out the official duties of that person with regard to the patient; and

''(B) notwithstanding subsection (f)(1)(B), no information kept in accordance with a database established, improved, or maintained through a grant under this section may be used to conduct a criminal investigation or substantiate any criminal charges against a patient or to conduct any investigation of a patient relating to methadone use of the patient.'';

(6) in subsections (e), (f)(1), and (g), by striking ''implementing or improving'' each place it appears and inserting ''establishing, improving, or maintaining'';

(7) in subsection (f)—

(A) in paragraph (1)(B) by striking ''misuse of a schedule II, III, or IV substance'' and inserting ''misuse of a controlled substance included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act''; and

(B) by adding at the end the following:

''(3) EVALUATION AND REPORTING.—Subject to subsection (g), a State receiving a grant under subsection (a) shall provide the Secretary with aggregate data and other information determined by the Secretary to be necessary to enable the Secretary—

''(A) to evaluate the success of the State's program in achieving its purposes; or

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

''(4) RESEARCH BY OTHER ENTITIES.—A department, program, or administration receiving nonidentifiable information under paragraph (1)(D) may make such information available to other entities for research purposes.'';

(8) by striking subsection (k);

(9) by redesignating subsections (h) through (j) as subsections (i) through (k), respectively;

(10) in subsections (c)(1)(A)(iv) and (d)(4), by striking ''subsection (h)'' each place it appears and inserting ''subsection (i)'';

(11) by inserting after subsection (g) the following:

''(h) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving a grant under subsection (a) shall take steps to—

''(1) facilitate prescriber and dispenser use of the State's controlled substance monitoring system; and

''(2) educate prescribers and dispenser on the benefits of the system both to them and society.'';

(12) in subsection (k)(2)(A), as redesignated—

(A) in clause (ii), by striking ''or affected'' and inserting '', established or strengthened initiatives to ensure linkages to substance use disorder services, or affected''; and

(B) in clause (iii), by striking ''including an assessment'' and inserting ''between controlled substance monitoring programs and health information technology systems, and including an assessment'';

(13) in subsection (l)(1), by striking ''establishment, implementation, or improvement'' and inserting ''establishment, improvement, or maintenance'';

(14) in subsection (m)(8), by striking ''and the District of Columbia'' and inserting '', the District of Columbia, and any commonwealth or territory of the United States''; and

(15) by amending subsection (n), to read as follows:

''(o) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $7,000,000 for each of fiscal years 2016 through 2020.''.

(b) CONFIDENTIALITY OF RECORDS.—Section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)) is amended by inserting ''or, with respect to methadone, as required under section 399O(e)(6)'' before the period at the end.

(c) REQUIREMENTS FOR FEDERAL HEALTH CARE PROGRAMS.—Health care practitioners (as defined in paragraph (7) of section 399O(m) of the Public Health Service Act (42 U.S.C. 280g–3(m))) and dispensers (as defined in paragraph (4) of such section) who participate in or are employed by a Federal health care program or federally funded health care program, including the Indian

Health Service, the Department of Veterans Affairs, the Department of Defense, the Federal Bureau of Prisons, the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), a State Medicaid plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), the Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.), and Federally qualified health centers, shall use the databases of the controlled substance monitoring programs under section 399O of the Public Health Service Act (42 U.S.C. 280g–3), if such databases are available to the practitioner or dispenser.

SEC. 103. PILOT PROJECT.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall award grants to one or more States to carry out a 1-year pilot project to develop a standardized peer review process and methodology to review and evaluate prescribing and pharmacy dispensing patterns, through a review of prescription drug monitoring programs (referred to in this section as ''PDMP'') in the States receiving such grants.

(b) METHODOLOGY.—The recipients of a grant under this section shall develop a systematic, standardized methodology to identify and investigate questionable or inap-

propriate prescribing and dispensing patterns of substances on schedule II or III under section 202 of the Controlled Substances Act (21 U.S.C. 812). Such peer review methodology and prescribing and dispensing patterns shall be shared with the appropriate State health profession board.

(c) REQUIREMENTS.—A State receiving a grant under this section—

(1) with respect to controlled substances for which a prescriber is required to have a license issued by the Drug Enforcement Administration in order to prescribe such controlled substances, shall make the information with respect to such controlled substances from the PDMP available to State regulation and licensing boards; and

(2) with respect to any other controlled substances, may make the information with respect to such controlled substances from the PDMP available to State regulation and licensing boards.

(d) SUBGRANTEES.—A quality improvement organization with which the Secretary has entered into a contract under part B of title XI of the Social Security Act (42 U.S.C. 1320c et seq.) may serve as the subgrantee under this subsection to develop peer review processes as described in subsection (a).

SEC. 104. PRESCRIPTION DRUG AND OTHER CONTROLLED SUBSTANCE ABUSE PREVENTION.

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:

"SEC. 399V–6. PRESCRIPTION DRUG AND OTHER CONTROLLED SUBSTANCE ABUSE PREVENTION.

''(a) TRAINING GRANTS.—

''(1) IN GENERAL.—The Secretary shall award 5-year grants to eligible entities to facilitate training in order to increase the capacity of health care providers to conduct patient screening and brief interventions, such as in health care settings, to prevent the abuse of prescription drugs and other controlled substances. The grant program under this section may be coordinated with the Screening Brief Intervention and Referral to Treatment grant program of the Substance Abuse and Mental Health Services Administration, or other appropriate program.

''(2) ELIGIBLE ENTITIES.—In this subsection, the term 'eligible entity' includes—

''(A) States;

''(B) continuing education entities, such as health profession boards or health accrediting bodies; and

"(C) other appropriate health or professional education organizations or institutions.

"(b) FEDERAL HEALTH CARE WORKERS.—Health care providers who participate in or are employed by a Federal health care program, including the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, the Federal Bureau of Prisons, the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), a State Medicaid plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.), and Federally qualified health centers, shall screen patients for abuse of prescription drugs or other controlled substances, conduct brief interventions, and provide referrals for known or suspected abuse of prescription drugs or other controlled substances, as appropriate.

"(c) EXPANSION OF PRESCRIBING AUTHORITY.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall award grants to States for the purpose of evaluating the prospect of the health professions board of such States reviewing and expanding prescribing authorities of providers, such as advance practice nurses and physician as-

sistants, in order to control the abuse of prescription drugs or other controlled substances with respect to specific drugs and other controlled substances, as appropriate.''.

SEC. 105. PRESCRIPTION DRUG ABUSE TRAINING AND SCREENING PROGRAMS.

(a) CONTINUING EDUCATION GRANTS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall award grants to States to develop continuing education criteria and review processes that allow State health profession boards or State agencies to certify appropriate education and training for informed and safe prescribing of opioids and other drugs on schedule II and III under section 202 of the Controlled Substances Act (21 U.S.C. 812).

(b) REGISTRATION WITH DEA.—A practitioner who registers or renews a registration under section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) shall, at the time of registering, certify to the Attorney General that such practitioner has completed continuing medical education or nursing continuing education, as applicable—

(1) in the case of a practitioner registering for the first time, with respect to prescription drug abuse; and

(2) in the case of a practitioner renewing a registration, with respect to medical understanding of the proper use of all drugs listed in the schedules under section 202 of the Controlled Substances Act (21 U.S.C. 812).

(c) SCREENING PROGRAM.—The Attorney General shall require that a practitioner registered under section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) conduct patient screening for potential drug misuse or abuse before prescribing a drug listed on schedule II or III under section 202 of the Controlled Substances Act (21 U.S.C. 812), according to standards established by the applicable State licensing body.

SEC. 106. FDA REVIEW OF NALOXONE.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall conduct a review of naloxone to consider whether naloxone should cease to be subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) and be available as a behind-the-counter drug, in order to increase access of such drug to community-based organizations and street outreach organizations.

SEC. 107. PRESCRIPTION DRUG DISPOSAL.

The Secretary of Health and Human Services shall convene or coordinate with an existing entity an inter-

agency working group to encourage States and local governments to increase opportunities for disposal of opiates, such as frequent ''take-back programs'' and fixed medicine disposal sites at law enforcement public buildings, and to reduce opportunities for abuse of opiates, such as establishing opioid dispensing limits at hospital emergency departments.

SEC. 108. GAO REPORT.

The Comptroller General of the United States shall review prescription drug abuse programs and policies in Federal agencies and best practices with respect to prescription drug abuse programs of the States and, not later than 18 months after the date of enactment of this Act, shall issue a report to Congress on its findings and recommendations on ways to reduce prescription drug abuse.

TITLE II—TREAT ACT

SEC. 201. SHORT TITLE.

This title may be cited as the ''Recovery Enhancement for Addiction Treatment Act'' or the ''TREAT Act''.

SEC. 202. EXPANSION OF PATIENT LIMITS UNDER WAIVER.

Section 303(g)(2)(B) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(B)) is amended—

(1) in clause (i), by striking ''physician'' and inserting ''practitioner'';

(2) in clause (iii)—

(A) by striking ''30'' and inserting ''100''; and

(B) by striking '', unless, not sooner'' and all that follows through the end and inserting a period; and

(3) by inserting at the end the following new clause:

''(iv) Not earlier than 1 year after the date on which a qualifying practitioner obtained an initial waiver pursuant to clause (iii), the qualifying practitioner may submit a second notification to the Secretary of the need and intent of the qualifying practitioner to treat an unlimited number of patients, if the qualifying practitioner—

''(I)(aa) satisfies the requirements of item (aa), (bb), (cc), or (dd) of subparagraph (G)(ii)(I); and

''(bb) agrees to fully participate in the Prescription Drug Monitoring Program of the State in which the qualifying practitioner is licensed, pursuant to applicable State guidelines; or

''(II)(aa) satisfies the requirements of item (ee), (ff), or (gg) of subparagraph (G)(ii)(I);

''(bb) agrees to fully participate in the Prescription Drug Monitoring Program of the State in which the qualifying practitioner is licensed, pursuant to applicable State guidelines;

''(cc) practices in a qualified practice setting; and

''(dd) has completed not less than 24 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) with respect to the treatment and management of opiate-dependent patients for substance use disorders provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.''.

SEC. 203. DEFINITIONS.

Section 303(g)(2)(G) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)) is amended—

(1) by striking clause (ii) and inserting the following:

"(ii) The term 'qualifying practitioner' means the following:

"(I) A physician who is licensed under State law and who meets 1 or more of the following conditions:

"(aa) The physician holds a board certification in addiction psychiatry from the American Board of Medical Specialties.

"(bb) The physician holds an addiction certification from the American Society of Addiction Medicine.

"(cc) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

"(dd) The physician holds a board certification from the American Board of Addiction Medicine.

"(ee) The physician has completed not less than 8 hours of train-

ing (through classroom situations, seminar at professional society meetings, electronic communications, or otherwise) with respect to the treatment and management of opiate-dependent patients for substance use disorders provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

''(ff) The physician has participated as an investigator in 1 or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by this sponsor of such approved drug.

''(gg) The physician has such other training or experience as the Secretary determines will demonstrate the ability of the physician to treat and manage opiate-dependent patients.

''(II) A nurse practitioner or physician assistant who is licensed under State law and meets all of the following conditions:

''(aa) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for pain.

''(bb) The nurse practitioner or physician assistant satisfies 1 or more of the following:

''(AA) Has completed not fewer than 24 hours of training (through classroom situations, seminar at professional society meetings, electronic communications, or otherwise) with respect to the treatment and management of opiate-dependent pa-

tients for substance use disorders provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

''(BB) Has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.

''(cc) The nurse practitioner or physician assistant practices under the supervision of a licensed physician who holds an active waiver to prescribe schedule III, IV, or V narcotic medications for opioid addiction therapy, and—

"(AA) the supervising physician satisfies the conditions of item (aa), (bb), (cc), or (dd) of subclause (I); or

"(BB) both the supervising physician and the nurse practitioner or physician assistant practice in a qualified practice setting.

"(III) A nurse practitioner who is licensed under State law and meets all of the following conditions:

"(aa) The nurse practitioner is licensed under State law to prescribe schedule III, IV, or V medications for pain.

"(bb) The nurse practitioner has training or experience that the Secretary determines demonstrates specialization in the ability to treat opiate-dependent patients, such as a certification in addiction specialty accredited by the American Board of Nursing Specialties or the National Commission for Certifying Agencies, or a

certification in addiction nursing as a Certified Addiction Registered Nurse—Advanced Practice.

''(cc) In accordance with State law, the nurse practitioner prescribes opioid addiction therapy in collaboration with a physician who holds an active waiver to prescribe schedule III, IV, or V narcotic medications for opioid addiction therapy.

''(dd) The nurse practitioner practices in a qualified practice setting.''; and

(2) by adding at the end the following:

''(iii) The term 'qualified practice setting' means 1 or more of the following treatment settings:

''(I) A National Committee for Quality Assurance-recognized Patient-Centered Medical Home or Patient-Centered Specialty Practice.

''(II) A Centers for Medicaid & Medicare Services-recognized Accountable Care Organization.

"(III) A clinical facility administered by the Department of Veterans Affairs, Department of Defense, or Indian Health Service.

"(IV) A Behavioral Health Home accredited by the Joint Commission.

"(V) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act (42 U.S.C. 1396d(l)(2)(B))) or a Federally-qualified health center look-alike.

"(VI) A Substance Abuse and Mental Health Services-certified Opioid Treatment Program.

"(VII) A clinical program of a State or Federal jail, prison, or other facility where individuals are incarcerated.

"(VIII) A clinic that demonstrates compliance with the Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office issued by the Federation of State Medical Boards.

"(IX) A treatment setting that is part of an Accreditation Council for Graduate Medical Education, American Association

of Colleges of Osteopathic Medicine, or American Osteopathic Association-accredited residency or fellowship training program.

''(X) Any other practice setting approved by a State regulatory board or State Medicaid Plan to provide addiction treatment services.

''(XI) Any other practice setting approved by the Secretary.''.

SEC. 204. GAO EVALUATION.

Two years after the date on which the first notification under clause (iv) of section 303(g)(2)(B) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(B)), as added by this title, is received by the Secretary of Health and Human Services, the Comptroller General of the United States shall initiate an evaluation of the effectiveness of the amendments made by this title, which shall include an evaluation of—

(1) any changes in the availability and use of medication-assisted treatment for opioid addiction;

(2) the quality of medication-assisted treatment programs;

(3) the integration of medication-assisted treatment with routine healthcare services;

(4) diversion of opioid addiction treatment medication;

(5) changes in State or local policies and legislation relating to opioid addiction treatment;

(6) the use of nurse practitioners and physician assistants who prescribe opioid addiction medication;

(7) the use of Prescription Drug Monitoring Programs by waived practitioners to maximize safety of patient care and prevent diversion of opioid addiction medication;

(8) the findings of Drug Enforcement Agency inspections of waived practitioners, including the frequency with which the Drug Enforcement Agency finds no documentation of access to behavioral health services; and

(9) the effectiveness of cross-agency collaboration between Department of Health and Human Services and the Drug Enforcement Agency for expanding effective opioid addiction treatment.

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