II

112TH CONGRESS
1ST SESSION

S. 507

To provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

IN THE SENATE OF THE UNITED STATES

MARCH 8, 2011

Mr. ROCKEFELLER 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 provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

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 ''Prescription Drug Abuse Prevention and Treatment Act of 2011''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Nonmedical use of prescription pain relievers is a matter of increasing public health concern. According to the Substance Abuse and Mental

Health Services Administration, the proportion of all substance abuse treatment admissions aged 12 or older that reported any pain reliever abuse increased more than 400 percent between 1998 and 2008, from 2.2 to 9.8 percent.

(2) In 2008, among the population of the United States aged 12 or older, nonmedical use of prescription pain relievers was the second most prevalent type of illicit drug use, after marijuana use.

(3) When used properly under medical supervision, prescription opiates enable individuals with chronic pain to lead productive lives. However, when taken without a physician's oversight and direction, opiates can cause serious adverse health effects, resulting in dependence, abuse, and death.

(4) As with any controlled substance, there is a risk of abuse of methadone and other opiates.

(5) Methadone is an extensively tested, federally approved, and widely accepted method of treating addiction to prescription pain relievers or opiates.

(6) For more than 30 years, this synthetic prescription drug has been used for pain management and treatment for addiction to heroin, morphine, and other opioid drugs.

(7) The efficacy and lower cost of methadone has resulted in its being prescribed for pain management.

(8) Prescriptions for methadone have increased by nearly 700 percent from 1998 through 2006.

(9) According to the Centers for Disease Control and Prevention, the number of poisoning deaths involving methadone increased nearly 7-fold from almost 790 in 1999 to almost 5,420 in 2006, which is the most rapid increase among opioid analgesics and other narcotics involved in poisoning deaths.

(10) The age-specific rates of methadone death are higher for persons age 35 to 44 and 45 to 54 than for other age groups. However, the rate of methadone deaths in younger individuals (age 15 to 24) increased 11-fold from 1999 through 2005.

(11) Deaths from methadone and other opiates may actually be underreported. There is no comprehensive database of drug-related deaths in the United States.

(12) The lack of standardized reporting by Medical Examiners precludes a uniform definition of ''cause of death'' on death certificates.

(13) The Controlled Substances Act (21 U.S.C. 801 et seq.) requires that every person who dis-

penses or who proposes to dispense controlled narcotics, including methadone, whether for pain management or opioid treatment obtain a registration from Drug Enforcement Administration. Unfortunately there is no requirement as a condition of receiving the registration that these practitioners receive any education on the use of these controlled narcotics, including methadone.

(14) Current Federal oversight of methadone and other opioids is inadequate to address the growing number of opioid-related overdoses and deaths.

(15) Federal legislation is needed to avert opioid abuse, misuse, and death, without reducing patient access to needed care.

SEC. 3. CONSUMER EDUCATION CAMPAIGN.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

"SEC. 506C. CONSUMER EDUCATION CAMPAIGN.

''(a) IN GENERAL.—The Administrator shall award grants to States and nonprofit entities for the purpose of conducting culturally sensitive consumer education about opioid abuse, including methadone abuse. Such education shall include information on the dangers of opioid abuse, how to prevent opioid abuse including through safe dis-

posal of prescription medications and other safety precautions, and detection of early warning signs of addiction.

''(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a State or nonprofit entity; and

''(2) submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

''(c) PRIORITY.—In awarding grants under this section, the Administrator shall give priority to applicants that are States or communities with a high incidence of abuse of methadone and other opioids, and opioid-related deaths.

''(d) EVALUATIONS.—The Administrator shall develop a process to evaluate the effectiveness of activities carried out by grantees under this section at reducing abuse of methadone and other opioids.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2012 through 2016.''.

SEC. 4. PRACTITIONER EDUCATION.

(a) EDUCATION REQUIREMENTS.—

(1) REGISTRATION CONSIDERATION.—Section 303(f) of the Controlled Substances Act (21 U.S.C.

823(f)) is amended by inserting after paragraph (5) the following:

''(6) The applicant's compliance with the training requirements described in subsection (g)(3) during any previous period in which the applicant has been subject to such training requirements.''.

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

''(3)(A) To be registered to prescribe or otherwise dispense methadone or other opioids, a practitioner described in paragraph (1) shall comply with the 16-hour training requirement of subparagraph (B) at least once during each 3-year period.

''(B) The training requirement of this subparagraph is that the practitioner has completed not less than 16 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) with respect to—

''(i) the treatment and management of opioid-dependent patients;

''(ii) pain management treatment guidelines; and

''(iii) early detection of opioid addiction, including through such methods as Screening, Brief Intervention, and Referral to Treatment (SBIRT),

that is 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, the American Academy of Pain Management, the American Pain Society, the American Academy of Pain Medicine, the American Board of Pain Medicine, the American Society of Interventional Pain Physicians, or any other organization that the Secretary determines is appropriate for purposes of this subparagraph.''.

(b) REQUIREMENTS FOR PARTICIPATION IN OPIOID TREATMENT PROGRAMS.—Effective July 1, 2012, a physician practicing in an opioid treatment program shall comply with the requirements of section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) with respect to required minimum training at least once during each 3-year period.

(c) DEFINITION.—In this section, the term ''opioid treatment program'' has the meaning given such term in section 8.2 of title 42, Code of Federal Regulations (or any successor regulation).

(d) FUNDING.—The Drug Enforcement Administration shall fund the enforcement of the requirements specified in section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) through the use of a portion of the licensing fees paid by controlled substance prescribers under the Controlled Substances Act (21 U.S.C. 801 et seq.).

SEC. 5. MORATORIUM ON METHADONE HYDROCHLORIDE TABLETS.

(a) IN GENERAL.—Notwithstanding any other provision of law, during the period beginning on the date of enactment of this Act and ending on the date described in subsection (b), no individual or entity may prescribe or otherwise dispense a 40-mg diskette of methadone unless such prescription or dispensation is consistent with the methadone 40-mg diskette policy of the Drug Enforcement Administration as in effect on the date of enactment of this Act, except that such prohibition shall extend to hospitals unless such hospitals provide for direct patient supervision with respect to such methadone.

(b) ENDING DATE OF MORATORIUM.—The moratorium under subsection (a) shall cease to have force and effect—

(1) on the date that the Controlled Substances Clinical Standards Commission publishes in the Fed-

eral Register dosing guidelines for all forms of methadone, in accordance with section 506D(b)(1)(A) of the Public Health Service Act (as added by section 7); and

(2) if, as part of such dosing guidelines, such Commission finds that 40-mg diskettes of methadone are safe and clinically appropriate.

SEC. 6. OPERATION OF OPIOID TREATMENT PROGRAMS.

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

''(i)(1) An opioid treatment program that is registered under this section, and that closes for business on any weekday or weekend day, including a Federal or State holiday, shall comply with the requirements of this subsection.

''(2) The program shall make acceptable arrangements for each patient who is restricted, by Federal regulation or guideline or by the determination of the program medical director, from having a take home dose of a controlled substance related to the treatment involved, to receive a dose of that substance under appropriate supervision during the closure.

''(3) The Administrator of the Substance Abuse and Mental Health Services Administration shall issue a notice

that references regulations on acceptable arrangements under this subsection, or shall promulgate regulations on such acceptable arrangements.''.

SEC. 7. ESTABLISHMENT OF THE CONTROLLED SUBSTANCES CLINICAL STANDARDS COMMISSION.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by section 3, is further amended by adding at the end the following:

''SEC. 506D. ESTABLISHMENT OF THE CONTROLLED SUBSTANCES CLINICAL STANDARDS COMMISSION.

''(a) IN GENERAL.—The Secretary shall establish a Controlled Substances Clinical Standards Commission (referred to in this section as the 'Commission'), to be composed of representatives from the Administration, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Pain Management Consortia of the National Institutes of Health, and other agencies that the Secretary may deem necessary, to develop—

''(1) appropriate and safe dosing guidelines for all forms of methadone, including recommendations for maximum daily doses of all forms as provided for in subsection (b)(1);

''(2) benchmark guidelines for the reduction of methadone abuse, as provided for in subsection (b)(2);

''(3) appropriate conversion factors for use by health care providers in transitioning patients from one opioid to another;

''(4) specific guidelines for initiating pain management with methadone that prescribing practitioners shall comply with in order to meet certification requirements set forth in part C of the Controlled Substances Act (21 U.S.C. 821 et seq.); and

''(5) patient and practitioner education guidelines for both methadone maintenance therapy and pain management that apply to safe and effective use and include detoxification.

''(b) GUIDELINES.—

''(1) PUBLICATION OF DOSING GUIDELINES.—

''(A) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Commission established under subsection (a) shall publish in the Federal Register—

''(i) safe and clinically appropriate dosing guidelines for all forms of methadone used for both pain management and opioid treatment programs, including rec-

ommendations for maximum daily doses of all forms, including recommendations for the induction process for patients who are newly prescribed methadone;

''(ii) requirements for individual patient care plans, including initial and follow-up patient physical examination guidelines, and recommendations for screening patients for chronic or acute medical conditions that may cause an immediate and adverse reaction to methadone;

''(iii) appropriate conversion factors for use by health care providers in transitioning patients from one opioid to another;

''(iv) specific guidelines for initiating pain management with methadone, that prescribing physicians or other clinicians shall comply with in order to meet Drug Enforcement Administration certification and re-certification requirements; and

''(v) consensus guidelines for pain management with prescription opioid drugs.

"(B) UPDATING OF GUIDELINES.—Not later than 3 years after the publication of guidelines under subparagraph (A), and at least every 3 years thereafter, the Commission shall update such guidelines.

"(2) PUBLICATION OF BENCHMARK GUIDELINES.—

"(A) IN GENERAL.—Not later than 3 years after the date of enactment of this section, the Commission established under subsection (a) shall publish in the Federal Register—

"(i) the initial benchmark guidelines for the reduction of methadone abuse to be used—

"(I) by opioid treatment programs in providing methadone therapy; and

"(II) by entities in the initial accreditation or certification, and the re-accreditation and re-certification, of such opioid treatment programs;

"(ii) a model policy for dispensing methadone to be used by pharmacists that dispense methadone, which should include

education and training guidelines for such pharmacists;

''(iii) the continuing education guidelines that all prescribers shall comply with in order to meet Drug Enforcement Administration certification and re-certification requirements, as set forth in section 303(g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(3)), which should include a minimum of 16 training hours at least every 3 years that include the integration of both addiction and pain management curricula; and

''(iv) patient education guidelines for both opioid treatment programs and pain management, including recommendations for patient counseling prior to and during opioid addiction treatment or treatment for pain.

''(B) UPDATING OF GUIDELINES.—Not later than 1 year after the publication of guidelines under subparagraph (A), and at least annually thereafter, the Commission shall update the guidelines published under clauses (iii) and (iv) of such subparagraph.

"(3) CONSULTATION.—In developing and publishing the guidelines under this section, the Commission shall consult with relevant professional organizations with expertise in the area of addiction, relevant professional organizations with expertise in the area of pain management, physician groups, pharmacy groups (including the National Association of Boards of Pharmacy), patient representatives, and any other organization that the Secretary determines is appropriate for purposes of this section.

"(c) WEBSITE.—Not later than 180 days after the date of enactment of this section, the Commission shall establish and operate a Commission website.

"(d) METHADONE TOOLKIT.—Not later than 1 year after the date of enactment of this section, the Commission shall establish, and distribute to practitioners that are registered to prescribe or otherwise dispense methadone, a methadone toolkit. The Commission shall make the components of the toolkit that are available in electronic form available on the Commission website.

"(e) PRACTITIONER EDUCATION PROGRAM.—The Commission shall develop a practitioner education program that shall be used for the practitioner education described in section 303(g)(3) of the Controlled Substances

Act, and shall make such program available to providers of such practitioner education.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2012 through 2016.''.

SEC. 8. PRESCRIPTION MONITORING PROGRAM.

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

(1) in subsection (d)(1), by inserting ''(including prescribers of methadone)'' after ''dispensers'';

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

''(5) Subject to the requirements of section 543, the State shall, at the request of a Federal, State, or local officer whose duties include enforcing laws relating to drugs, provide to such officer information from the database relating to an individual who is the subject of an active drug-related investigation conducted by the officer's employing government entity.''; and

(3) by striking subsection (n) and inserting the following:

''(n) APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $25,000,000 for each of fiscal years 2012 through 2016.''.

SEC. 9. MORTALITY REPORTING.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by section 7, is further amended by adding at the end the following:

''SEC. 506E. MORTALITY REPORTING.

''(a) MODEL OPIOID TREATMENT PROGRAM MORTALITY REPORT.—

''(1) IN GENERAL.—Not later than July 1, 2012, the Secretary, acting through the Administrator, shall require that a Model Opioid Treatment Program Mortality Report be completed and submitted to the Administrator for each individual who dies while receiving treatment in an opioid treatment program.

''(2) REQUIREMENT OF STATES THAT RECEIVE FUNDING FOR THE CONTROLLED SUBSTANCE MONITORING PROGRAM.—As a condition for receiving funds under section 399O, each State shall require that any individual who signs a death certificate where an opioid drug is detected in the body of the deceased, or where such drug is otherwise associated with the death, report such death to the Adminis-

trator by submitting a Model Opioid Treatment Program Mortality Report described in paragraph (3). Such report shall be submitted to the Administrator on or before the later of—

''(A) 90 days after the date of signing the death certificate; or

''(B) as soon as practicable after the date on which the necessary postmortem and toxicology reports become available to such individual, as required by the Secretary.

''(3) DEVELOPMENT.—The Administrator, in consultation with State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Administrator determines appropriate, shall develop a Model Opioid Treatment Program Mortality Report to be used under paragraphs (1) and (2).

''(b) NATIONAL OPIOID DEATH REGISTRY.—

''(1) IN GENERAL.—Not later than July 1, 2012, the Administrator shall establish and implement, through the National Center for Health Statistics, a National Opioid Death Registry (referred to in this subsection as the 'Registry') to track opioid-related deaths and information related to such deaths.

''(2) CONSULTATION.—In establishing the uniform reporting criteria for the Registry, the Director of the Centers for Disease Control and Prevention shall consult with the Administrator, State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Director determines is appropriate for purposes of this subsection.

''(3) REQUIREMENTS.—The registry shall be designed as a uniform reporting system for opioid-related deaths and shall require the reporting of information with respect to such deaths, including—

''(A) the particular drug formulation used at the time of death;

''(B) the dosage level;

''(C) a description of the circumstances surrounding the death in relation to the recommended dosage involved;

''(D) a disclosure of whether the medication involved can be traced back to a physician's prescription;

''(E) a disclosure of whether the individual was in an opioid treatment program at the time of death;

''(F) the age and sex of the individual; and

''(G) other non-personal information such as that included in filed National Association of Medical Examiners Pediatric Toxicology Registry case reports as required under the privacy standard for the de-identification of health information pursuant to the regulations contained in part 164 of title 45, Code of Federal Regulations.

''(4) AUTHORIZATION.—There is authorized to be appropriated $5,000,000 for each of fiscal years 2012 through 2016 to carry out this subsection.

''(c) REPORT ON REGISTRY INFORMATION.—Not later than the January 1 of the first fiscal year beginning 2 years after the date of enactment of this section, and each January 1 thereafter, the Director of the Centers for Disease Control and Prevention shall submit to the Secretary a report, based on information contained in the Registry described in subsection (b), concerning the number of methadone-related deaths in the United States for the year for which the report is submitted.''.

SEC. 10. ADDITIONAL REPORTING.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by section 9, is further amended by adding at the end the following:

"SEC. 506F. ADDITIONAL REPORTING.

"(a) REPORT ON METHADONE USAGE.—

"(1) IN GENERAL.—Not later than January 1 of the first fiscal year beginning 2 years after the date of enactment of this section, and each January 1 thereafter, the Administrator and the Commissioner of Food and Drugs shall submit to the Secretary a report containing detailed statistics on methadone usage for opioid treatment and pain management. Such statistics shall include—

"(A) information on the distribution of prescribed doses of methadone at federally qualified health centers, opioid treatment clinics, other health-related clinics, physician offices, pharmacies, and hospitals; and

"(B) information relating to adverse health events resulting from such methadone usage.

"(2) AVAILABILITY OF INFORMATION.—The Secretary shall make the reports submitted under paragraph (1) available to the general public, including through the use of the Internet website of the Department of Health and Human Services.

"(b) ANNUAL REPORT ON EFFECTIVENESS.—Not later than September 30, 2012, and annually thereafter until September 30, 2016, the Secretary shall submit to the appropriate committees of Congress, a report con-

cerning the effectiveness of the methadone maintenance therapy program. Such report shall evaluate the success of efforts to reduce opioid addiction and methadone-related deaths, including the impact of health care provider and patient education.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2012 through 2016.''.

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