II

Calendar No. 442

114TH CONGRESS
2D SESSION

S. 2256

To establish programs for health care provider training in Federal health care and medical facilities, to establish Federal co-prescribing guidelines, to establish a grant program with respect to naloxone, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 5, 2015

Mr. KAINE (for himself and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 27, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To establish programs for health care provider training in Federal health care and medical facilities, to establish Federal co-prescribing guidelines, to establish a grant program with respect to naloxone, 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 ''Co-Prescribing Saves Lives Act of 2015''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Together, the misuse of heroin and opioids account for approximately 25,000 deaths in the United States per year.

(2) Drug overdose was the leading cause of injury death in the United States in 2013, and among people 25 to 64 years old, drug overdose caused more deaths than motor vehicle fatalities in 2013.

(3) According to the Centers for Disease Control and Prevention, in the United States, fatal opioid-related drug overdose rates have more than quadrupled since 1990 and have never been higher. Each day in the United States, 46 people die from an overdose of prescription painkillers. Nearly 2,000,000 Americans aged 12 or older either abused or were dependent on opioids in 2013.

(4) Naloxone is a safe and effective antidote to all opioid-related overdoses, including heroin and fentanyl, and is a critical tool in preventing fatal opioid overdoses in both health care and at-home settings.

~~(5) The opioid overdose antidote naloxone has reversed more than 26,000 overdose cases between 1996 and 2014, according to the Centers for Disease Control and Prevention.~~

~~SEC. 3. HEALTH CARE PROVIDER TRAINING IN FEDERAL HEALTH CARE AND MEDICAL FACILITIES.~~

~~(a) GUIDELINES.—~~

~~(1) HHS GUIDELINES.—The Secretary of Health and Human Services shall establish health care provider training guidelines for all Federal health care facilities, including Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))) and facilities of the Indian Health Service, and shall provide training to all providers described in subsection (b), in accordance with subsection (c).~~

~~(2) DEPARTMENT OF VETERANS AFFAIRS GUIDELINES.—The Secretary of Veterans Affairs shall establish health care provider training guidelines for all medical facilities of the Department of Veterans Affairs, and shall provide training to all providers described in subsection (b), in accordance with subsection (c).~~

(3) DEPARTMENT OF DEFENSE GUIDELINES.—The Secretary of Defense shall establish health care provider training guidelines for all medical facilities of the Department of Defense, and shall provide training to all providers described in subsection (b), in accordance with subsection (c).

(b) AFFECTED HEALTH CARE PROVIDERS.—The guidelines developed under paragraphs (1) through (3) of subsection (a) shall ensure that training on the appropriate and effective prescribing of opioid medications is provided to all health care providers who are—

(1) Federal employees and who prescribe controlled substances as part of their official responsibilities and duties as Federal employees;

(2) contractors in a health care or medical facility of an agency described in paragraph (1), (2), or (3) of subsection (a) who—

(A) spend 50 percent or more of their clinical time under contract with the Federal Government; and

(B) prescribe controlled substances under the terms and conditions of their contract or agreement with the Federal Government; or

(3) clinical residents and other clinical trainees who spend 50 percent or more of their clinical time

practicing in health care or medical facility of an agency described in paragraph (1), (2), or (3) of subsection (a).

(c) TRAINING REQUIREMENTS.—

(1) TRAINING TOPICS.—The training developed under paragraphs (1) through (3) of subsection (a) shall address, at a minimum, best practices for appropriate and effective prescribing of pain medications, principles of pain management, the misuse potential of controlled substances, identification of potential substance use disorders and referral to further evaluation and treatment, and proper methods for disposing of controlled substances.

(2) TRAINING APPROACHES.—The training approaches developed in accordance with this section may include both traditional continuing education models and models that pair intensive coaching for the highest volume prescribers with case-based courses for other prescribers.

(3) CONSISTENCY WITH CONSENSUS GUIDELINES.—To the extent practicable, training adopted under subsection (a) shall be consistent with consensus guidelines on pain medication prescribing developed by the Centers for Disease Control and Prevention.

(4) TRAINING FREQUENCY.—Each agency described in paragraphs (1) through (3) of subsection (a) shall provide training of the health care providers in accordance with this section not later than 18 months after the date of enactment of this Act, and every 3 years thereafter.

(d) DEFINITIONS.—For purposes of this section, the term ''controlled substance'' has the meaning given such term in section 102 of the Controlled Substances Act (21 U.S.C. 802).

SEC. 4. NALOXONE CO-PRESCRIBING IN FEDERAL HEALTH CARE AND MEDICAL FACILITIES.

(a) NALOXONE CO-PRESCRIBING GUIDELINES.—Not later than 180 days after the date of enactment of this Act.

(1) The Secretary of Health and Human Services shall establish naloxone co-prescribing guidelines applicable to all Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))) and the health care facilities of the Indian Health Service.

(2) The Secretary of Defense shall establish co-prescribing guidelines applicable to all Department of Defense medical facilities.

(3) The Secretary of Veterans Affairs shall establish co-prescribing guidelines applicable to all Department of Veterans Affairs medical facilities.

(b) REQUIREMENT.—The guidelines established under subsection (a) shall address naloxone co-prescribing for both pain patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(c) DEFINITIONS.—In this section:

(1) CO-PRESCRIBING.—The term ''co-prescribing'' means, with respect to an opioid overdose reversal drug, the practice of prescribing such drug in conjunction with an opioid prescription for patients at an elevated risk of overdose, or in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the treatment of opioid use disorders, or in other circumstances in which a provider identifies a patient at an elevated risk for an intentional or unintentional drug overdose from heroin or prescription opioid therapies.

(2) ELEVATED RISK OF OVERDOSE.—The term ''elevated risk of overdose'' has the meaning given such term by the Secretary of Health and Human Services, which—

(A) may be based on the criteria provided in the Opioid Overdose Toolkit published by the Substance Abuse and Mental Health Services Administration; and

(B) may include patients on a first course opioid treatment, patients using extended-release and long-acting opioid analgesic, and patients with a respiratory disease or other comorbidities.

SEC. 5. GRANT PROGRAM TO STATE DEPARTMENTS OF HEALTH TO EXPAND NALOXONE CO-PRESCRIBING.

(a) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a competitive 4-year co-prescribing opioid overdose reversal drugs grant program to provide State departments of health with resources to develop and apply co-prescribing guidelines, and to provide for increased access to naloxone.

(b) APPLICATION.—To be eligible to receive a grant under this section, a State shall submit to the Secretary, in such form and manner as the Secretary may require, an application that—

(1) identifies community partners for a co-prescribing program;

(2) identifies which providers will be trained in such program and the criteria that will be used to identify eligible patients to participate in such program; and

(3) describes how the program will seek to identify State, local, or private funding to continue the program after expiration of the grant.

(c) PRIORITIZATION.—In awarding grants under this section, the Secretary shall give priority to eligible State departments of health that propose to base State guidelines on guidelines on co-prescribing already in existence at the time of application, such as guidelines of the Department of Veterans Affairs or national medical societies, such as the American Society of Addiction Medicine or American Medical Association.

(d) USE OF FUNDS.—A State department of health receiving a grant under this section may use the grant for any of the following activities:

(1) To establish a program for co-prescribing opioid overdose reversal drugs, such as naloxone.

(2) To expand innovative models of naloxone distribution, as defined by the Secretary.

(3) To train and provide resources for health care providers and pharmacists on the co-prescribing of opioid overdose reversal drugs.

(4) To establish mechanisms and processes for tracking patients participating in the program described in paragraph (1) and the health outcomes of such patients, and ensuring that health information is de-identified so as to protect patient privacy.

(5) To purchase opioid overdose reversal drugs for distribution under the program described in paragraph (1).

(6) To offset the copayments and other cost-sharing associated with opioid overdose reversal drugs to ensure that cost is not a limiting factor for eligible individuals, as determined by the Secretary and the applicable State department of health, giving priority to individuals not otherwise insured for such services.

(7) To conduct community outreach, in conjunction with community-based organizations, designed to raise awareness of co-prescribing practices, and the availability of opioid overdose reversal drugs.

(8) To establish protocols to connect patients who have experienced a drug overdose with appro-

priate treatment, including medication assisted treatment and appropriate counseling and behavioral therapies. Such protocols shall be consistent with nationally recognized patient placement criteria, such as the criteria of the American Society of Addiction Medicine.

(c) EVALUATIONS BY RECIPIENTS.—As a condition of receipt of a grant under this section, a State department of health shall, for each year for which grant funds are received, submit to the Secretary information on appropriate outcome measures specified by the Secretary to assess the outcomes of the program funded by the grant.

(f) DEFINITION.—In this section, the term ''co-prescribing'' has the meaning given such term in section 4.

SEC. 6. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act $2,500,000 for each of fiscal years 2016 through 2020.

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Co-Prescribing Saves Lives Act of 2016''.

SEC. 2. NALOXONE CO-PRESCRIBING IN FEDERAL HEALTH CARE AND MEDICAL FACILITIES.

(a) NALOXONE CO-PRESCRIBING GUIDELINES.—Not later than 180 days after the date of enactment of this Act:

(1) The Secretary of Health and Human Services shall, as appropriate, provide information to prescribers within Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and the health care facilities of the Indian Health Service, on best practices for co-prescribing naloxone for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(2) The Secretary of Defense shall, as appropriate, provide information to prescribers within Department of Defense medical facilities on best practices for co-prescribing naloxone for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(3) The Secretary of Veterans Affairs shall, as appropriate, provide information to prescribers within Department of Veterans Affairs medical facilities on best practices for co-prescribing naloxone for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(b) DEFINITIONS.—In this section:

(1) CO-PRESCRIBING.—The term ''co-prescribing'' means, with respect to an opioid overdose reversal drug, the practice of prescribing such drug in

conjunction with an opioid prescription for patients at an elevated risk of overdose, or in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the treatment of opioid use disorders, or in other circumstances in which a provider identifies a patient at an elevated risk for an intentional or unintentional drug overdose from heroin or prescription opioid therapies.

(2) ELEVATED RISK OF OVERDOSE.—The term "elevated risk of overdose" has the meaning given such term by the Secretary of Health and Human Services, which—

(A) may be based on the criteria provided in the Opioid Overdose Toolkit published by the Substance Abuse and Mental Health Services Administration; and

(B) may include patients on a first course opioid treatment, patients using extended-release and long-acting opioid analgesic, and patients with a respiratory disease or other co-morbidities.

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