

**Calendar No. 442**114<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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.

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**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]

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**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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Co-Prescribing Saves  
3 Lives Act of 2015”.

4 **SEC. 2. FINDINGS.**

5 Congress finds as follows:

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

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

13 (3) According to the Centers for Disease Con-  
14 trol and Prevention, in the United States, fatal  
15 opioid-related drug overdose rates have more than  
16 quadrupled since 1990 and have never been higher.  
17 Each day in the United States, 46 people die from  
18 an overdose of prescription painkillers. Nearly  
19 2,000,000 Americans aged 12 or older either abused  
20 or were dependent on opioids in 2013.

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

1           (5) The opioid overdose antidote naloxone has  
2 reversed more than 26,000 overdose cases between  
3 1996 and 2014, according to the Centers for Dis-  
4 ease Control and Prevention.

5 **SEC. 3. HEALTH CARE PROVIDER TRAINING IN FEDERAL**  
6 **HEALTH CARE AND MEDICAL FACILITIES.**

7 (a) **GUIDELINES.—**

8           (1) **HHS GUIDELINES.—**The Secretary of  
9 Health and Human Services shall establish health  
10 care provider training guidelines for all Federal  
11 health care facilities, including Federally qualified  
12 health centers (as defined in paragraph (4) of sec-  
13 tion 1861(aa) of the Social Security Act (42 U.S.C.  
14 1395x(aa))) and facilities of the Indian Health Serv-  
15 ice, and shall provide training to all providers de-  
16 scribed in subsection (b), in accordance with sub-  
17 section (c).

18           (2) **DEPARTMENT OF VETERANS AFFAIRS**  
19 **GUIDELINES.—**The Secretary of Veterans Affairs  
20 shall establish health care provider training guide-  
21 lines for all medical facilities of the Department of  
22 Veterans Affairs, and shall provide training to all  
23 providers described in subsection (b), in accordance  
24 with subsection (c).

1           ~~(3) DEPARTMENT OF DEFENSE GUIDELINES.—~~

2           The Secretary of Defense shall establish health care  
3           provider training guidelines for all medical facilities  
4           of the Department of Defense, and shall provide  
5           training to all providers described in subsection (b),  
6           in accordance with subsection (c).

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

12           ~~(1) Federal employees and who prescribe con-~~  
13          trolled substances as part of their official respon-  
14          sibilities and duties as Federal employees;

15           ~~(2) contractors in a health care or medical facil-~~  
16          ity of an agency described in paragraph (1), (2), or  
17          ~~(3) of subsection (a) who—~~

18           ~~(A) spend 50 percent or more of their clin-~~  
19          ical time under contract with the Federal Gov-  
20          ernment; and

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

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

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

4 (c) TRAINING REQUIREMENTS.—

5 (1) TRAINING TOPICS.—The training developed  
6 under paragraphs (1) through (3) of subsection (a)  
7 shall address, at a minimum, best practices for ap-  
8 propriate and effective prescribing of pain medica-  
9 tions, principles of pain management, the misuse po-  
10 tential of controlled substances, identification of po-  
11 tential substance use disorders and referral to fur-  
12 ther evaluation and treatment, and proper methods  
13 for disposing of controlled substances.

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

20 (3) CONSISTENCY WITH CONSENSUS GUIDE-  
21 LINES.—To the extent practicable, training adopted  
22 under subsection (a) shall be consistent with con-  
23 sensus guidelines on pain medication prescribing de-  
24 veloped by the Centers for Disease Control and Pre-  
25 vention.

1           (4) TRAINING FREQUENCY.—Each agency de-  
2           scribed in paragraphs (1) through (3) of subsection  
3           (a) shall provide training of the health care pro-  
4           viders in accordance with this section not later than  
5           18 months after the date of enactment of this Act,  
6           and every 3 years thereafter.

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

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

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

16               (1) The Secretary of Health and Human Serv-  
17               ices shall establish naloxone co-prescribing guidelines  
18               applicable to all Federally qualified health centers  
19               (as defined in paragraph (4) of section 1861(aa) of  
20               the Social Security Act (42 U.S.C. 1395x(aa))) and  
21               the health care facilities of the Indian Health Serv-  
22               ice.

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

1           (3) The Secretary of Veterans Affairs shall es-  
2           tablish co-prescribing guidelines applicable to all De-  
3           partment of Veterans Affairs medical facilities.

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

8           (c) DEFINITIONS.—In this section:

9           (1) CO-PRESCRIBING.—The term “co-pre-  
10          scribing” means, with respect to an opioid overdose  
11          reversal drug, the practice of prescribing such drug  
12          in conjunction with an opioid prescription for pa-  
13          tients at an elevated risk of overdose, or in conjunc-  
14          tion with an opioid agonist approved under section  
15          505 of the Federal Food, Drug, and Cosmetic Act  
16          (21 U.S.C. 355) for the treatment of opioid use dis-  
17          orders, or in other circumstances in which a provider  
18          identifies a patient at an elevated risk for an inten-  
19          tional or unintentional drug overdose from heroin or  
20          prescription opioid therapies.

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

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

5           (B) may include patients on a first course  
 6           opioid treatment, patients using extended-re-  
 7           lease and long-acting opioid analgesic, and pa-  
 8           tients with a respiratory disease or other co-  
 9           morbidity.

10 **SEC. 5. GRANT PROGRAM TO STATE DEPARTMENTS OF**  
 11           **HEALTH TO EXPAND NALOXONE CO-PRE-**  
 12           **SCRIBING.**

13           (a) **ESTABLISHMENT.**—Not later than 180 days after  
 14 the date of the enactment of this Act, the Secretary of  
 15 Health and Human Services (referred to in this section  
 16 as the “Secretary”) shall establish a competitive 4-year  
 17 co-prescribing opioid overdose reversal drugs grant pro-  
 18 gram to provide State departments of health with re-  
 19 sources to develop and apply co-prescribing guidelines, and  
 20 to provide for increased access to naloxone.

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



1           (1) identifies community partners for a co-pre-  
2           scribing program;

3           (2) identifies which providers will be trained in  
4           such program and the criteria that will be used to  
5           identify eligible patients to participate in such pro-  
6           gram; and

7           (3) describes how the program will seek to iden-  
8           tify State, local, or private funding to continue the  
9           program after expiration of the grant.

10          (c) **PRIORITIZATION.**—In awarding grants under this  
11          section, the Secretary shall give priority to eligible State  
12          departments of health that propose to base State guide-  
13          lines on guidelines on co-prescribing already in existence  
14          at the time of application, such as guidelines of the De-  
15          partment of Veterans Affairs or national medical societies,  
16          such as the American Society of Addiction Medicine or  
17          American Medical Association.

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

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

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

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

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

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

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

19          (7) To conduct community outreach, in con-  
20          junction with community-based organizations, de-  
21          signed to raise awareness of co-prescribing practices,  
22          and the availability of opioid overdose reversal  
23          drugs.

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

1        appropriate treatment, including medication assisted  
 2        treatment and appropriate counseling and behavioral  
 3        therapies. Such protocols shall be consistent with na-  
 4        tionally recognized patient placement criteria, such  
 5        as the criteria of the American Society of Addiction  
 6        Medicine.

7        (e) **EVALUATIONS BY RECIPIENTS.**—As a condition  
 8        of receipt of a grant under this section, a State depart-  
 9        ment of health shall, for each year for which grant funds  
 10       are received, submit to the Secretary information on ap-  
 11       propriate outcome measures specified by the Secretary to  
 12       assess the outcomes of the program funded by the grant.

13       (f) **DEFINITION.**—In this section, the term “co-pre-  
 14       scribing” has the meaning given such term in section 4.

15       **SEC. 6. AUTHORIZATION OF APPROPRIATIONS.**

16       There is authorized to be appropriated to carry out  
 17       this Act \$2,500,000 for each of fiscal years 2016 through  
 18       2020.

19       **SECTION 1. SHORT TITLE.**

20       *This Act may be cited as the “Co-Prescribing Saves*  
 21       *Lives Act of 2016”.*

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

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

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

10           (2) *The Secretary of Defense shall, as appro-*  
11 *priate, provide information to prescribers within De-*  
12 *partment of Defense medical facilities on best prac-*  
13 *tices for co-prescribing naloxone for patients receiving*  
14 *chronic opioid therapy and patients being treated for*  
15 *opioid use disorders.*

16           (3) *The Secretary of Veterans Affairs shall, as*  
17 *appropriate, provide information to prescribers with-*  
18 *in Department of Veterans Affairs medical facilities*  
19 *on best practices for co-prescribing naloxone for pa-*  
20 *tients receiving chronic opioid therapy and patients*  
21 *being treated for opioid use disorders.*

22           (b) *DEFINITIONS.—In this section:*

23           (1) *CO-PRESCRIBING.—The term “co-pre-*  
24 *scribing” means, with respect to an opioid overdose*  
25 *reversal drug, the practice of prescribing such drug in*

1       *conjunction with an opioid prescription for patients*  
2       *at an elevated risk of overdose, or in conjunction with*  
3       *an opioid agonist approved under section 505 of the*  
4       *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
5       *355) for the treatment of opioid use disorders, or in*  
6       *other circumstances in which a provider identifies a*  
7       *patient at an elevated risk for an intentional or unin-*  
8       *tentional drug overdose from heroin or prescription*  
9       *opioid therapies.*

10           (2) *ELEVATED RISK OF OVERDOSE.—The term*  
11       *“elevated risk of overdose” has the meaning given*  
12       *such term by the Secretary of Health and Human*  
13       *Services, which—*

14                   (A) *may be based on the criteria provided*  
15                   *in the Opioid Overdose Toolkit published by the*  
16                   *Substance Abuse and Mental Health Services Ad-*  
17                   *ministration; and*

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

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