

Suspend the Rules and Pass the Bill, HR. 3680, with an Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

114TH CONGRESS
2^D SESSION

H. R. 3680

To provide for the Secretary of Health and Human Services to carry out a grant program for co-prescribing opioid overdose reversal drugs.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 1, 2015

Mr. SARBANES introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for the Secretary of Health and Human Services to carry out a grant program for co-prescribing opioid overdose reversal drugs.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Co-Prescribing to Re-
5 duce Overdoses Act of 2016”.

1 **SEC. 2. OPIOID OVERDOSE REVERSAL DRUGS PRE-**
2 **SCRIBING GRANT PROGRAM.**

3 (a) ESTABLISHMENT.—

4 (1) IN GENERAL.—Not later than six months
5 after the date of the enactment of this Act, the Sec-
6 retary of Health and Human Services may establish,
7 in accordance with this section, a five-year opioid
8 overdose reversal drugs prescribing grant program
9 (in this Act referred to as the “grant program”).

10 (2) MAXIMUM GRANT AMOUNT.—A grant made
11 under this section may not be for more than
12 \$200,000 per grant year.

13 (3) ELIGIBLE ENTITY.—For purposes of this
14 section, the term “eligible entity” means a federally
15 qualified health center (as defined in section
16 1861(aa) of the Social Security Act (42 U.S.C.
17 1395x(aa)), an opioid treatment program under part
18 8 of title 42, Code of Federal Regulations, any prac-
19 titioner dispensing narcotic drugs pursuant to sec-
20 tion 303(g) of the Controlled Substances Act (21
21 U.S.C. 823(g)), or any other entity that the Sec-
22 retary deems appropriate.

23 (4) PRESCRIBING.—For purposes of this section
24 and section 3, the term “prescribing” means, with
25 respect to an opioid overdose reversal drug, such as
26 naloxone, the practice of prescribing such drug—

1 (A) in conjunction with an opioid prescrip-
2 tion for patients at an elevated risk of overdose;

3 (B) in conjunction with an opioid agonist
4 approved under section 505 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 355)
6 for the treatment of opioid abuse disorder;

7 (C) to the caregiver or a close relative of
8 patients at an elevated risk of overdose from
9 opioids; or

10 (D) in other circumstances, as identified
11 by the Secretary, in which a provider identifies
12 a patient is at an elevated risk for an inten-
13 tional or unintentional drug overdose from her-
14 oin or prescription opioid therapies.

15 (b) APPLICATION.—To be eligible to receive a grant
16 under this section, an eligible entity shall submit to the
17 Secretary of Health and Human Services, in such form
18 and manner as specified by the Secretary, an application
19 that describes—

20 (1) the extent to which the area to which the
21 entity will furnish services through use of the grant
22 is experiencing significant morbidity and mortality
23 caused by opioid abuse;

24 (2) the criteria that will be used to identify eli-
25 gible patients to participate in such program; and

1 (3) how such program will work to try to iden-
2 tify State, local, or private funding to continue the
3 program after expiration of the grant.

4 (c) USE OF FUNDS.—An eligible entity receiving a
5 grant under this section may use the grant for any of the
6 following activities, but may use not more than 20 percent
7 of the grant funds for activities described in paragraphs
8 (4) and (5):

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

11 (2) To train and provide resources for health
12 care providers and pharmacists on the prescribing of
13 opioid overdose reversal drugs, such as naloxone.

14 (3) To establish mechanisms and processes for
15 tracking patients participating in the program de-
16 scribed in paragraph (1) and the health outcomes of
17 such patients.

18 (4) To purchase opioid overdose reversal drugs,
19 such as naloxone, for distribution under the program
20 described in paragraph (1).

21 (5) To offset the co-pays and other cost sharing
22 associated with opioid overdose reversal drugs, such
23 as naloxone, to ensure that cost is not a limiting fac-
24 tor for eligible patients.

1 (6) To conduct community outreach, in con-
2 junction with community-based organizations, de-
3 signed to raise awareness of prescribing practices,
4 and the availability of opioid overdose reversal
5 drugs, such as naloxone.

6 (7) To establish protocols to connect patients
7 who have experienced a drug overdose with appro-
8 priate treatment, including medication assisted
9 treatment and appropriate counseling and behavioral
10 therapies.

11 (d) EVALUATIONS BY RECIPIENTS.—As a condition
12 of receipt of a grant under this section, an eligible entity
13 shall, for each year for which the grant is received, submit
14 to the Secretary of Health and Human Services informa-
15 tion on appropriate outcome measures specified by the
16 Secretary to assess the outcomes of the program funded
17 by the grant, including—

18 (1) the number of prescribers trained;

19 (2) the number of prescribers who have co-pre-
20 scribed an opioid overdose reversal drug, such as
21 naloxone, to at least one patient;

22 (3) the total number of prescriptions written for
23 opioid overdose reversal drugs, such as naloxone;

1 (4) the percentage of patients at elevated risk
2 who received a prescription for an opioid overdose
3 reversal drug, such as naloxone;

4 (5) the number of patients reporting use of an
5 opioid overdose reversal drug, such as naloxone; and

6 (6) any other outcome measures that the Sec-
7 retary deems appropriate.

8 (e) REPORTS BY SECRETARY.—For each year of the
9 grant program under this section, the Secretary of Health
10 and Human Services shall submit to the appropriate com-
11 mittees of the House of Representatives and of the Senate
12 a report aggregating the information received from the
13 grant recipients for such year under subsection (d) and
14 evaluating the outcomes achieved by the programs funded
15 by grants made under this section.

16 **SEC. 3. PROVIDING INFORMATION TO PRESCRIBERS IN**
17 **CERTAIN FEDERAL HEALTH CARE AND MED-**
18 **ICAL FACILITIES ON BEST PRACTICES FOR**
19 **PRESCRIBING OPIOID OVERDOSE REVERSAL**
20 **DRUGS.**

21 (a) IN GENERAL.—Not later than 180 days after the
22 date of enactment of this Act, the Secretary of Health and
23 Human Services (in this section referred to as the “Sec-
24 retary”) may, as appropriate, provide information to pre-
25 scribers within Federally qualified health centers (as de-

1 fined in paragraph (4) of section 1861(aa) of the Social
2 Security Act (42 U.S.C. 1395x(aa))), and the health care
3 facilities of the Indian Health Service, on best practices
4 for prescribing opioid overdose reversal drugs, such as
5 naloxone, for patients receiving chronic opioid therapy, pa-
6 tients being treated for opioid use disorders, and other pa-
7 tients that a provider identifies as having an elevated risk
8 of overdose from heroin or prescription opioid therapies.

9 (b) NOT ESTABLISHING A MEDICAL STANDARD OF
10 CARE.—The information on best practices provided under
11 this section shall not be construed as constituting or estab-
12 lishing a medical standard of care for prescribing opioid
13 overdose reversal drugs, such as naloxone, for patients de-
14 scribed in subsection (a).

15 (c) ELEVATED RISK OF OVERDOSE DEFINED.—In
16 this section, the term “elevated risk of overdose” has the
17 meaning given such term by the Secretary, which—

18 (1) may be based on the criteria provided in the
19 Opioid Overdose Toolkit published by the Substance
20 Abuse and Mental Health Services Administration
21 (SAMHSA); and

22 (2) may include patients on a first course opioid
23 treatment, patients using extended-release and long-
24 acting opioid analgesics, and patients with a res-
25 piratory disease or other co-morbidities.

1 **SEC. 4. AUTHORIZATION OF APPROPRIATIONS.**

2 There is authorized to be appropriated to carry out
3 this Act \$5,000,000 for the period of fiscal years 2017
4 through 2021.

5 **SEC. 5. CUT-GO COMPLIANCE.**

6 Subsection (f) of section 319D of the Public Health
7 Service Act (42 U.S.C. 247d–4) is amended by inserting
8 before the period at the end the following: “(except such
9 dollar amount shall be reduced by \$5,000,000 for fiscal
10 year 2018)”.