

## Union Calendar No. 429

114<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4586

[Report No. 114–555]

To amend the Public Health Service Act to authorize grants to States for developing standing orders and educating health care professionals regarding the dispensing of opioid overdose reversal medication without person-specific prescriptions, and for other purposes.

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### IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 23, 2016

Mr. DOLD (for himself and Ms. CLARK of Massachusetts) introduced the following bill; which was referred to the Committee on Energy and Commerce

MAY 10, 2016

Additional sponsors: Mrs. COMSTOCK, Mr. MCGOVERN, Mr. ROKITA, Mr. PAULSEN, Mr. TURNER, and Ms. MCSALLY

MAY 10, 2016

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on February 23, 2016]

# **A BILL**

To amend the Public Health Service Act to authorize grants to States for developing standing orders and educating health care professionals regarding the dispensing of opioid overdose reversal medication without person-specific prescriptions, 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,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as “Lali’s Law”.*

5 **SEC. 2. OPIOID OVERDOSE REVERSAL MEDICATION ACCESS**  
 6 **AND EDUCATION GRANT PROGRAMS.**

7 *(a) TECHNICAL CLARIFICATION.—Effective as if in-*  
 8 *cluded in the enactment of the Children’s Health Act of*  
 9 *2000 (Public Law 106–310), section 3405(a) of such Act*  
 10 *(114 Stat. 1221) is amended by striking “Part E of title*  
 11 *III” and inserting “Part E of title III of the Public Health*  
 12 *Service Act”.*

13 *(b) AMENDMENT.—Title III of the Public Health Serv-*  
 14 *ice Act is amended by inserting after part D of such title*  
 15 *(42 U.S.C. 254b et seq.) the following new part E:*

16 **“PART E—OPIOID USE DISORDER**

17 **“SEC. 341. OPIOID OVERDOSE REVERSAL MEDICATION AC-**  
 18 **CESS AND EDUCATION GRANT PROGRAMS.**

19 *“(a) GRANTS TO STATES.—The Secretary may make*  
 20 *grants to States for—*

21 *“(1) developing standing orders for pharmacies*  
 22 *regarding opioid overdose reversal medication;*

23 *“(2) encouraging pharmacies to dispense opioid*  
 24 *overdose reversal medication pursuant to a standing*  
 25 *order;*

1           “(3) implementing best practices for persons au-  
2           thorized to prescribe medication regarding—

3                   “(A) prescribing opioids for the treatment of  
4           chronic pain;

5                   “(B) co-prescribing opioid overdose reversal  
6           medication with opioids; and

7                   “(C) discussing the purpose and adminis-  
8           tration of opioid overdose reversal medication  
9           with patients;

10           “(4) developing or adapting training materials  
11           and methods for persons authorized to prescribe or  
12           dispense medication to use in educating the public re-  
13           garding—

14                   “(A) when and how to administer opioid  
15           overdose reversal medication; and

16                   “(B) steps to be taken after administering  
17           opioid overdose reversal medication; and

18           “(5) educating the public regarding—

19                   “(A) the public health benefits of opioid  
20           overdose reversal medication; and

21                   “(B) the availability of opioid overdose re-  
22           versal medication without a person-specific pre-  
23           scription.

24           “(b) CERTAIN REQUIREMENT.—A grant may be made  
25           under this section only if the State involved has authorized

1 *standing orders regarding opioid overdose reversal medica-*  
2 *tion.*

3 “(c) *PREFERENCE IN MAKING GRANTS.*—*In making*  
4 *grants under this section, the Secretary shall give preference*  
5 *to States that—*

6 “(1) *have not issued standing orders regarding*  
7 *opioid overdose reversal medication;*

8 “(2) *authorize standing orders that permit com-*  
9 *munity-based organizations, substance abuse pro-*  
10 *grams, or other nonprofit entities to acquire, dispense,*  
11 *or administer opioid overdose reversal medication;*

12 “(3) *authorize standing orders that permit po-*  
13 *lice, fire, or emergency medical services agencies to*  
14 *acquire and administer opioid overdose reversal medi-*  
15 *cation;*

16 “(4) *have a higher per capita rate of opioid*  
17 *overdoses than other applicant States; or*

18 “(5) *meet any other criteria deemed appropriate*  
19 *by the Secretary.*

20 “(d) *GRANT TERMS.*—

21 “(1) *NUMBER.*—*A State may not receive more*  
22 *than 1 grant under this section.*

23 “(2) *PERIOD.*—*A grant under this section shall*  
24 *be for a period of 3 years.*

1           “(3) *AMOUNT.*—A grant under this section may  
2           not exceed \$500,000.

3           “(4) *LIMITATION.*—A State may use not more  
4           than 20 percent of a grant under this section for edu-  
5           cating the public pursuant to subsection (a)(5).

6           “(e) *APPLICATIONS.*—To be eligible to receive a grant  
7           under this section, a State shall submit an application to  
8           the Secretary in such form and manner and containing  
9           such information as the Secretary may require, including  
10          detailed proposed expenditures of grant funds.

11          “(f) *REPORTING.*—Not later than 3 months after the  
12          Secretary disburses the first grant payment to any State  
13          under this section and every 6 months thereafter for 3 years,  
14          such State shall submit a report to the Secretary that in-  
15          cludes the following:

16               “(1) *The name and ZIP Code of each pharmacy*  
17               *in the State that dispenses opioid overdose reversal*  
18               *medication under a standing order.*

19               “(2) *The total number of opioid overdose reversal*  
20               *medication doses dispensed by each such pharmacy,*  
21               *specifying how many were dispensed with or without*  
22               *a person-specific prescription.*

23               “(3) *The number of pharmacists in the State*  
24               *who have participated in training pursuant to sub-*  
25               *section (a)(4).*

1 “(g) *DEFINITIONS.—In this section:*

2 “(1) *OPIOID OVERDOSE REVERSAL MEDICA-*  
 3 *TION.—The term ‘opioid overdose reversal medication’*  
 4 *means any drug, including naloxone, that—*

5 “(A) *blocks opioids from attaching to, but*  
 6 *does not itself activate, opioid receptors; or*

7 “(B) *inhibits the effects of opioids on opioid*  
 8 *receptors.*

9 “(2) *STANDING ORDER.—The term ‘standing*  
 10 *order’ means a document prepared by a person au-*  
 11 *thorized to prescribe medication that permits another*  
 12 *person to acquire, dispense, or administer medication*  
 13 *without a person-specific prescription.*

14 “(h) *AUTHORIZATION OF APPROPRIATIONS.—*

15 “(1) *IN GENERAL.—To carry out this section,*  
 16 *there is authorized to be appropriated \$5,000,000 for*  
 17 *the period of fiscal years 2017 through 2019.*

18 “(2) *ADMINISTRATIVE COSTS.—Not more than 3*  
 19 *percent of the amounts made available to carry out*  
 20 *this section may be used by the Secretary for admin-*  
 21 *istrative expenses of carrying out this section.”.*

22 **SEC. 3. CUT-GO COMPLIANCE.**

23 *Subsection (f) of section 319D of the Public Health*  
 24 *Service Act (42 U.S.C. 247d–4) is amended by inserting*  
 25 *before the period at the end the following: “(except such dol-*

1 *lar amount shall be reduced by \$5,000,000 for fiscal year*  
2 *2017)*”.



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