

**Calendar No. 246**114<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION**S. 799**

To combat the rise of prenatal opioid abuse and neonatal abstinence syndrome.

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**IN THE SENATE OF THE UNITED STATES**

MARCH 19, 2015

Mr. McCONNELL (for himself and Mr. CASEY, Ms. AYOTTE, Mr. PORTMAN, Mr. ISAKSON, Ms. BALDWIN, Mr. WHITEHOUSE, Mr. CORKER, Mr. BROWN, Mr. COONS, Mrs. GILLIBRAND, Mrs. CAPITO, Mrs. FISCHER, Mr. VITTER, Mr. BOOZMAN, Mr. COTTON, Mr. DONNELLY, Mr. KING, Mr. CARPER, Ms. COLLINS, Mrs. MURRAY, and Mr. TOOMEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

OCTOBER 1, 2015

Reported by Mr. ALEXANDER, with an amendment and an amendment to the title

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

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**A BILL**

To combat the rise of prenatal opioid abuse and neonatal abstinence syndrome.

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 “Protecting Our Infants  
3 Act of 2015”.

4 **SEC. 2. FINDINGS.**

5 Congress finds as follows:

6 (1) Opioid prescription rates have risen dra-  
7 matically over the past several years. According to  
8 the Centers for Disease Control and Prevention, in  
9 some States, there are as many as 96 to 143 pre-  
10 scriptions for opioids per 100 adults per year.

11 (2) In recent years, there has been a steady rise  
12 in the number of overdose deaths involving heroin.  
13 According to the Centers for Disease Control and  
14 Prevention, the death rate for heroin overdose dou-  
15 bled from 2010 to 2012.

16 (3) At the same time, there has been an in-  
17 crease in cases of neonatal abstinence syndrome (re-  
18 ferred to in this section as “NAS”). In the United  
19 States, the incidence of NAS has risen from 1.20  
20 per 1,000 hospital births in 2000 to 3.39 per 1,000  
21 hospital births in 2009.

22 (4) NAS refers to medical issues associated  
23 with drug withdrawal in newborns due to exposure  
24 to opioids or other drugs in utero.

25 (5) The average cost of treatment in a hospital  
26 for NAS increased from \$39,400 in 2000 to \$53,400

1 in 2009. Most of these costs are born by the Med-  
2 icaid program.

3 (6) Preventing opioid abuse among pregnant  
4 women and women of childbearing age is crucial.

5 (7) Medically-appropriate opioid use in preg-  
6 nancy is not uncommon, and opioids are often the  
7 safest and most appropriate treatment for moderate  
8 to severe pain for pregnant women.

9 (8) Addressing NAS effectively requires a focus  
10 on women of childbearing age, pregnant women, and  
11 infants from preconception through early childhood.

12 (9) NAS can result from the use of prescription  
13 drugs as prescribed for medical reasons, from the  
14 abuse of prescription drugs, or from the use of ille-  
15 gal opioids like heroin.

16 (10) For pregnant women who are abusing  
17 opioids, it is most appropriate to treat and manage  
18 maternal substance use in a non-punitive manner.

19 (11) According to a report of the Government  
20 Accountability Office (referred to in this section as  
21 the “GAO report”), more research is needed to opti-  
22 mize the identification and treatment of babies with  
23 NAS and to better understand long-term impacts on  
24 children.

1           (12) According to the GAO report, the Depart-  
 2           ment of Health and Human Services does not have  
 3           a focal point to lead planning and coordinating ef-  
 4           forts to address prenatal opioid use and NAS across  
 5           the department.

6           (13) According to the GAO report, “given the  
 7           increasing use of heroin and abuse of opioids pre-  
 8           scribed for pain management, as well as the in-  
 9           creased rate of NAS in the United States, it is im-  
 10          portant to improve the efficiency and effectiveness of  
 11          planning and coordination of Federal efforts on pre-  
 12          natal opioid use and NAS”.

13 **SEC. 3. DEVELOPING RECOMMENDATIONS FOR PRE-**  
 14 **VENTING AND TREATING PRENATAL OPIOID**  
 15 **ABUSE AND NEONATAL ABSTINENCE SYN-**  
 16 **DROME.**

17          (a) IN GENERAL.—The Secretary of Health and  
 18          Human Services (referred to in this Act as the “Sec-  
 19          retary”), acting through the Director of the Agency for  
 20          Healthcare Research and Quality (referred to in this sec-  
 21          tion as the “Director”), shall conduct a study and develop  
 22          recommendations for preventing and treating prenatal  
 23          opioid abuse and neonatal abstinence syndrome, soliciting  
 24          input from nongovernmental entities, including organiza-  
 25          tions representing patients, health care providers, hos-

1 pitals, other treatment facilities, and other entities, as ap-  
2 propriate.

3 (b) REPORT.—Not later than 1 year after the date  
4 of enactment of this Act, the Director shall publish on the  
5 Internet Web site of the Agency for Healthcare Research  
6 and Quality a report on the study and recommendations  
7 under subsection (a). Such report shall address each of  
8 the issues described in paragraphs (1) through (3) of sub-  
9 section (c).

10 (c) CONTENTS.—The study described in subsection  
11 (a) and the report under subsection (b) shall include—

12 (1) a comprehensive assessment of existing re-  
13 search with respect to the prevention, identification,  
14 treatment, and long-term outcomes of neonatal ab-  
15 stinence syndrome, including the identification and  
16 treatment of pregnant women or women who may  
17 become pregnant who use opioids or other drugs;

18 (2) an evaluation of—

19 (A) the causes of and risk factors for  
20 opioid use disorders among women of reproduc-  
21 tive age, including pregnant women;

22 (B) the barriers to identifying and treating  
23 opioid use disorders among women of reproduc-  
24 tive age, including pregnant and postpartum  
25 women and women with young children;

1           (C) current practices in the health care  
2 system to respond to and treat pregnant women  
3 with opioid use disorders and infants born with  
4 neonatal abstinence syndrome;

5           (D) medically indicated use of opioids dur-  
6 ing pregnancy;

7           (E) access to treatment for opioid use dis-  
8 orders in pregnant and postpartum women; and

9           (F) access to treatment for infants with  
10 neonatal abstinence syndrome; and

11       (3) recommendations on—

12           (A) preventing, identifying, and treating  
13 neonatal abstinence syndrome in infants;

14           (B) treating pregnant women who are de-  
15 pendent on opioids; and

16           (C) preventing opioid dependence among  
17 women of reproductive age, including pregnant  
18 women, who may be at risk of developing opioid  
19 dependence.

20 **SEC. 4. IMPROVING PREVENTION AND TREATMENT FOR**  
21 **PRENATAL OPIOID ABUSE AND NEONATAL**  
22 **ABSTINENCE SYNDROME.**

23       (a) **REVIEW OF PROGRAMS.**—The Secretary shall  
24 lead a review of planning and coordination within the De-

1 partment of Health and Human Services related to pre-  
2 natal opioid use and neonatal abstinence syndrome.

3 (b) STRATEGY TO CLOSE GAPS IN RESEARCH AND  
4 PROGRAMMING.—In carrying out subsection (a), the Sec-  
5 retary shall develop a strategy to address research and  
6 program gaps, including such gaps identified in findings  
7 made by reports of the Government Accountability Office.  
8 Such strategy shall address—

9 (1) gaps in research, including with respect  
10 to—

11 (A) the most appropriate treatment of  
12 pregnant women with opioid use disorders;

13 (B) the most appropriate treatment and  
14 management of infants with neonatal absti-  
15 nence syndrome; and

16 (C) the long-term effects of prenatal opioid  
17 exposure on children; and

18 (2) gaps in programs, including—

19 (A) the availability of treatment programs  
20 for pregnant and postpartum women and for  
21 newborns with neonatal abstinence syndrome;  
22 and

23 (B) guidance and coordination in Federal  
24 efforts to address prenatal opioid use or neo-  
25 natal abstinence syndrome.

1 (e) REPORT.—Not later than 1 year after the date  
 2 of enactment of this Act, the Secretary shall submit to  
 3 the Committee on Health, Education, Labor, and Pen-  
 4 sions of the Senate and the Committee on Energy and  
 5 Commerce of the House of Representatives a report on  
 6 the findings of the review described in subsection (a) and  
 7 the strategy developed under subsection (b).

8 **SEC. 5. IMPROVING DATA ON AND PUBLIC HEALTH RE-**  
 9 **SPONSE TO NEONATAL ABSTINENCE SYN-**  
 10 **DROME.**

11 (a) DATA AND SURVEILLANCE.—The Director of the  
 12 Centers for Disease Control and Prevention shall, as ap-  
 13 propriate—

14 (1) provide technical assistance to States to im-  
 15 prove the availability and quality of data collection  
 16 and surveillance activities regarding neonatal absti-  
 17 nence syndrome, including—

18 (A) the incidence and prevalence of neo-  
 19 natal abstinence syndrome;

20 (B) the identification of causes for neo-  
 21 natal abstinence syndrome, including new and  
 22 emerging trends; and

23 (C) the demographics and other relevant  
 24 information associated with neonatal abstinence  
 25 syndrome;

1           (2) collect available surveillance data described  
2           in paragraph (1) from States, as applicable; and

3           (3) make surveillance data collected pursuant to  
4           paragraph (2) publically available on an appropriate  
5           Internet Web site.

6           (b) PUBLIC HEALTH RESPONSE.—The Director of  
7           the Centers for Disease Control and Prevention shall en-  
8           courage increased utilization of effective public health  
9           measures to reduce neonatal abstinence syndrome.

10   **SECTION 1. SHORT TITLE.**

11           *This Act may be cited as the “Protecting Our Infants*  
12           *Act of 2015”.*

13   **SEC. 2. ADDRESSING PROBLEMS RELATED TO PRENATAL**  
14           **OPIOID USE.**

15           (a) REVIEW OF PROGRAMS.—*The Secretary of Health*  
16           *and Human Services (referred to in this Act as the “Sec-*  
17           *retary”)* shall conduct a review of planning and coordina-  
18           *tion related to prenatal opioid use, including neonatal ab-*  
19           *stinence syndrome, within the agencies of the Department*  
20           *of Health and Human Services.*

21           (b) STRATEGY.—*In carrying out subsection (a), the*  
22           *Secretary shall develop a strategy to address gaps in re-*  
23           *search and gaps, overlap, and duplication among Federal*  
24           *programs, including those identified in findings made by*

1 *reports of the Government Accountability Office. Such strat-*  
2 *egy shall address—*

3 *(1) gaps in research, including with respect to—*

4 *(A) the most appropriate treatment of preg-*  
5 *nant women with opioid use disorders;*

6 *(B) the most appropriate treatment and*  
7 *management of infants with neonatal abstinence*  
8 *syndrome; and*

9 *(C) the long-term effects of prenatal opioid*  
10 *exposure on children;*

11 *(2) gaps, overlap, or duplication in—*

12 *(A) substance use disorder treatment pro-*  
13 *grams for pregnant and postpartum women; and*

14 *(B) treatment program options for*  
15 *newborns with neonatal abstinence syndrome;*

16 *(3) gaps, overlap, or duplication in Federal ef-*  
17 *forts related to education about, and prevention of,*  
18 *neonatal abstinence syndrome; and*

19 *(4) coordination of Federal efforts to address*  
20 *neonatal abstinence syndrome.*

21 *(c) REPORT.—Not later than 1 year after the date of*  
22 *enactment of this Act, the Secretary shall submit to the*  
23 *Committee on Health, Education, Labor, and Pensions of*  
24 *the Senate and the Committee on Energy and Commerce*  
25 *of the House of Representatives a report concerning the*

1 *findings of the review conducted under subsection (a) and*  
2 *the strategy developed under subsection (b).*

3 **SEC. 3. DEVELOPING RECOMMENDATIONS FOR PRE-**  
4 **VENTING AND TREATING PRENATAL OPIOID**  
5 **USE DISORDERS.**

6 (a) *IN GENERAL.*—*The Secretary shall conduct a*  
7 *study and develop recommendations for preventing and*  
8 *treating prenatal opioid use disorders, including the effects*  
9 *of such disorders on infants. In carrying out this subsection*  
10 *the Secretary shall—*

11 (1) *take into consideration—*

12 (A) *the review and strategy conducted and*  
13 *developed under section 2; and*

14 (B) *the lessons learned from previous opioid*  
15 *epidemics; and*

16 (2) *solicit input from States, localities, and Fed-*  
17 *erally recognized Indian tribes or tribal organizations*  
18 *(as defined in the Indian Self-Determination and*  
19 *Education Assistance Act (25 U.S.C. 450b)), and*  
20 *nongovernmental entities, including organizations*  
21 *representing patients, health care providers, hospitals,*  
22 *other treatment facilities, and other entities, as ap-*  
23 *propriate.*

24 (b) *REPORT.*—*Not later than 18 months after the date*  
25 *of enactment of this Act, the Secretary shall make available*

1 *on the appropriate Internet Website of the Department of*  
2 *Health and Human Services a report on the recommenda-*  
3 *tions under subsection (a). Such report shall address each*  
4 *of the issues described in subsection (c).*

5 *(c) CONTENTS.—The recommendations described in*  
6 *subsection (a) and the report under subsection (b) shall in-*  
7 *clude—*

8 *(1) a comprehensive assessment of existing re-*  
9 *search with respect to the prevention, identification,*  
10 *treatment, and long-term outcomes of neonatal absti-*  
11 *nence syndrome, including the identification and*  
12 *treatment of pregnant women or women who may be-*  
13 *come pregnant who use opioids or have opioid use*  
14 *disorders;*

15 *(2) an evaluation of—*

16 *(A) the causes of, and risk factors for,*  
17 *opioid use disorders among women of reproduc-*  
18 *tive age, including pregnant women;*

19 *(B) the barriers to identifying and treating*  
20 *opioid use disorders among women of reproduc-*  
21 *tive age, including pregnant and postpartum*  
22 *women and women with young children;*

23 *(C) current practices in the health care sys-*  
24 *tem to respond to, and treat, pregnant women*

1           *with opioid use disorders and infants affected by*  
2           *such disorders;*

3                   *(D) medically indicated uses of opioids dur-*  
4           *ing pregnancy;*

5                   *(E) access to treatment for opioid use dis-*  
6           *orders in pregnant and postpartum women; and*

7                   *(F) access to treatment for infants with neo-*  
8           *natal abstinence syndrome; and*

9                   *(G) differences in prenatal opioid use and*  
10          *use disorders in pregnant women between demo-*  
11          *graphic groups; and*

12          *(3) recommendations on—*

13                   *(A) preventing, identifying, and treating*  
14          *the effects of prenatal opioid use on infants;*

15                   *(B) treating pregnant women who have*  
16          *opioid use disorders;*

17                   *(C) preventing opioid use disorders among*  
18          *women of reproductive age, including pregnant*  
19          *women, who may be at risk of developing opioid*  
20          *use disorders; and*

21                   *(D) reducing disparities in opioid use dis-*  
22          *orders among pregnant women.*

1 **SEC. 4. IMPROVING DATA AND THE PUBLIC HEALTH RE-**  
2 **SPONSE.**

3 *The Secretary may continue activities, as appropriate,*  
4 *related to—*

5 *(1) providing technical assistance to support*  
6 *States and Federally recognized Indian Tribes in col-*  
7 *lecting information on neonatal abstinence syndrome*  
8 *through the utilization of existing surveillance sys-*  
9 *tems and collaborating with States and Federally rec-*  
10 *ognized Indian Tribes to improve the quality, consist-*  
11 *ency, and collection of such data; and*

12 *(2) providing technical assistance to support*  
13 *States in implementing effective public health meas-*  
14 *ures, such as disseminating information to educate*  
15 *the public, health care providers, and other stake-*  
16 *holders on prenatal opioid use and neonatal absti-*  
17 *nence syndrome.*

Amend the title so as to read: “To address problems related to prenatal opioid use.”.



**Calendar No. 246**

114<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 799**

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**A BILL**

To combat the rise of prenatal opioid abuse and  
neonatal abstinence syndrome.

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OCTOBER 1, 2015

Reported with an amendment and an amendment to the  
title