

111TH CONGRESS
2D SESSION

S. 3906

To reduce preterm labor and delivery and the risk of pregnancy-related deaths and complications due to pregnancy, and to reduce infant mortality caused by prematurity.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 29, 2010

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

A BILL

To reduce preterm labor and delivery and the risk of pregnancy-related deaths and complications due to pregnancy, and to reduce infant mortality caused by prematurity.

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 “Prematurity Research
5 Expansion and Education for Mothers who deliver Infants
6 Early Act” or the “PREEMIE Act”.

7 **SEC. 2. PURPOSES.**

8 It is the purpose of this Act to—

1 (1) reduce preterm birth, its associated disabil-
2 ities, and deaths of babies born preterm;

3 (2) expand research into the causes of preterm
4 birth; and

5 (3) promote the development, availability, and
6 use of evidence-based standards of care for pregnant
7 women at risk of preterm labor or other serious
8 pregnancy-related complications and for infants born
9 preterm.

10 **SEC. 3. RESEARCH AND ACTIVITIES AT THE NATIONAL IN-**
11 **STITUTES OF HEALTH.**

12 Part B of title IV of the Public Health Service Act
13 (42 U.S.C. 284 et seq.) is amended by adding at the end
14 the following:

15 **“SEC. 409K. EXPANSION AND COORDINATION OF RESEARCH**
16 **RELATING TO PRETERM LABOR AND DELIV-**
17 **ERY AND INFANT MORTALITY.**

18 “(a) IN GENERAL.—The Secretary, acting through
19 the Director of NIH, shall expand, intensify, and coordi-
20 nate the activities of the National Institutes of Health
21 with respect to research on the causes of preterm labor
22 and delivery, tools to detect, prevent, or reduce prevalence
23 of preterm labor and delivery, and the care and treatment
24 of preterm infants. Research supported under this section
25 shall integrate clinical, public health, basic, and behavioral

1 and social science disciplines together with bioinformatics,
2 engineering, mathematical, and computer sciences to ad-
3 dress the causes of preterm labor and delivery collabo-
4 ratively.

5 “(b) CLINICAL PROGRAM.—There shall be estab-
6 lished within the National Institutes of Health a multi-
7 center clinical program (that shall be initially established
8 utilizing existing networks) designed to—

9 “(1) investigate problems in clinical obstetrics,
10 particularly those related to prevention of low birth
11 weight, prematurity, and medical problems of preg-
12 nancy;

13 “(2) improve the care and outcomes of neo-
14 nates, especially very-low-birth weight infants; and

15 “(3) enhance the understanding of DNA and
16 proteins as they relate to the underlying processes
17 that lead to preterm birth to aid in formulating
18 more effective interventions to prevent preterm
19 birth.

20 “(c) TRANS-DISCIPLINARY CENTERS FOR PRETERM
21 BIRTH RESEARCH.—

22 “(1) IN GENERAL.—The Director of NIH shall
23 award grants and contracts to public and nonprofit
24 private entities to pay all or part of the cost of plan-
25 ning, establishing, improving and providing basic op-

1 erating support for trans-disciplinary research cen-
2 ters for prematurity.

3 “(2) ELIGIBILITY.—To be eligible to receive a
4 grant or contract under paragraph (1), an entity
5 shall submit to the Director an application at such
6 time, in such manner, and containing such informa-
7 tion as the Director may require, including, if appro-
8 priate, an assurance that the entity will carry out
9 programs related to prematurity research that in-
10 clude neonatal and maternal-fetal medicine multi-
11 center research networks with a focus on clinical
12 trials.

13 “(3) FOCUS.—Activities carried out under this
14 subsection shall focus primarily on basic research
15 and progress logically over time to include the need
16 for translational, interventional, and clinical re-
17 search.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
19 is authorized to be appropriated to carry out this section,
20 such sums as may be necessary for each of fiscal years
21 2011 through 2016, of which—

22 “(1) for fiscal year 2011, such sums as may be
23 necessary shall be made available for planning
24 grants under subsection (c); and

1 “(2) for each of fiscal years 2012 through
 2 2016, such sums as may be necessary for each such
 3 fiscal year for establishing centers under such sub-
 4 section.

5 “(e) REPORT.—The Director of NIH shall include in
 6 the report under section 402A(c) information on the ac-
 7 tivities of the trans-disciplinary research centers for pre-
 8 maturity under subsection (c).”.

9 **SEC. 4. RESEARCH AND ACTIVITIES AT THE CENTERS FOR**
 10 **DISEASE CONTROL AND PREVENTION.**

11 (a) EPIDEMIOLOGICAL STUDIES.—Section 3 of the
 12 Prematurity Research Expansion and Education for
 13 Mothers who deliver Infants Early Act (42 U.S.C. 247b–
 14 4f) is amended by striking subsection (b) and inserting
 15 the following:

16 “(b) STUDIES AND ACTIVITIES ON THE RELATION-
 17 SHIP BETWEEN PREMATUREITY AND BIRTH DEFECTS.—

18 “(1) IN GENERAL.—The Secretary of Health
 19 and Human Services, acting through the Director of
 20 the Centers for Disease Control and Prevention,
 21 shall, subject to the availability of appropriations—

22 “(A) conduct ongoing epidemiological stud-
 23 ies on the clinical, biological, social, environ-
 24 mental, genetic and behavioral factors relating
 25 to prematurity;

1 “(B) conduct activities to improve national
2 data to facilitate tracking the burden of
3 preterm birth;

4 “(C) develop, implement, and evaluate
5 novel methods for prevention to better under-
6 stand the growing problem of late preterm
7 birth;

8 “(D) conduct etiologic and epidemiologic
9 studies of preterm birth;

10 “(E) expand research on obesity, racial,
11 and ethnic disparities as they relate to preterm
12 birth; and

13 “(F) conduct ongoing epidemiological stud-
14 ies on the effectiveness of community based
15 interventions.

16 “(2) REPORT.—Not later than 2 years after the
17 date of enactment of this Act, and every 2 years
18 thereafter, the Secretary of Health and Human
19 Services, acting through the Director of the Centers
20 for Disease Control and Prevention, shall submit to
21 the appropriate committees of Congress reports con-
22 cerning the progress and any results of studies con-
23 ducted under paragraph (1).”.

24 (b) REAUTHORIZATION.—Section 3(e) of the Pre-
25 maturity Research Expansion and Education for Mothers

1 who deliver Infants Early Act (42 U.S.C. 247b–4f(e)) is
 2 amended by striking “\$5,000,000” and all that follows
 3 through “2011” and inserting the following: “such sums
 4 as may be necessary for each of fiscal years 2012 through
 5 2016”.

6 **SEC. 5. RESEARCH AND ACTIVITIES AT THE HEALTH RE-**
 7 **SOURCES AND SERVICES ADMINISTRATION.**

8 (a) **TELEMEDICINE DEMONSTRATION PROJECT ON**
 9 **HIGH RISK PREGNANCIES.**—Section 330I of the Public
 10 Health Service Act (42 U.S.C. 254c–14) is amended—

11 (1) by redesignating subsections (q) through (s)
 12 as subsections (r) through (t), respectively;

13 (2) by inserting after subsection (p), the fol-
 14 lowing:

15 “(q) **TELEMEDICINE DEMONSTRATION PROJECT ON**
 16 **HIGH RISK PREGNANCIES.**—

17 “(1) **IN GENERAL.**—The Director shall award
 18 grants under this section to eligible entities to estab-
 19 lish demonstration projects for—

20 “(A) the provision of preconception,
 21 antepartum, intrapartum, and obstetric services
 22 to high risk women of child bearing age re-
 23 motely by Ob/Gyn’s, nurse practitioners, cer-
 24 tified nurse-midwives, certified midwives, or

1 other health care providers using telehealth;
 2 and

3 “(B) for the conduct of educational activi-
 4 ties regarding risk factors for preterm birth.

5 “(2) ELIGIBILITY.—To be eligible to receive a
 6 grant under paragraph (1), an entity shall submit
 7 an application to the Director at such time, in such
 8 manner, and containing such information as the Di-
 9 rector may require.”; and

10 (3) in subsection (t) (as so redesignated)—

11 (A) in paragraph (1), by striking “and” at
 12 the end;

13 (B) in paragraph (2), by striking the pe-
 14 riod and inserting “; and”; and

15 (C) by adding at the end the following:

16 “(3) for grants under subsection (q), such sums
 17 as may be necessary for each of fiscal years 2011
 18 through 2015.”.

19 (b) PUBLIC AND HEALTH CARE PROVIDER EDU-
 20 CATION.—Section 399Q of the Public Health Service Act
 21 (42 U.S.C. 280g–5) is amended—

22 (1) in subsection (b), by striking subparagraphs
 23 (A) through (F) and inserting the following:

24 “(A) the core risk factors for preterm
 25 labor;

1 “(B) medically indicated deliveries before
2 39 weeks;

3 “(C) outcomes for infants born before 39
4 weeks;

5 “(D) risk factors for preterm delivery;

6 “(E) the importance of preconception- and
7 prenatal care;

8 “(F) smoking cessation and weight mainte-
9 nance;

10 “(G) treatments and outcomes for babies
11 born premature;

12 “(H) the informational needs of families
13 during the stay of an infant in a neonatal in-
14 tensive care unit;

15 “(I) preventable birth injuries;

16 “(J) oral health; and

17 “(K) the use of progesterone;” and

18 (2) in subsection (c), by striking “\$5,000,000”
19 and all that follows through “2011” and insert the
20 following: “such sums as may be necessary for each
21 of fiscal years 2011 through 2016”.

22 **SEC. 6. OTHER ACTIVITIES.**

23 (a) NATIONAL EDUCATIONAL CAMPAIGN.—

24 (1) ESTABLISHMENT.—The Secretary of Health
25 and Human Services, (referred to in this section as

1 the “Secretary”) acting through the Surgeon Gen-
2 eral and in consultation with Director of the Na-
3 tional Institute on Child Health and Human Devel-
4 opment, shall establish and implement a national
5 science-based consumer education campaign on the
6 prevention of preterm birth.

7 (2) TARGETING.—The campaign established
8 under paragraph (1) shall target women of child-
9 bearing age, high risk populations, ethnic and mi-
10 nority groups, and individuals with a low socio-
11 economic status.

12 (3) CONTRACTS.—The Secretary shall imple-
13 ment the campaign under paragraph (1) through the
14 awarding of competitive contracts to entities submit-
15 ting applications to the Secretary (at such time and
16 in such form and manner as the Secretary may re-
17 quire), and may include the use of television, radio,
18 the Internet, and other commercial marketing
19 venues.

20 (b) ADVISORY COMMITTEE ON INFANT MOR-
21 TALITY.—

22 (1) STRATEGIC PLAN.—The Advisory Com-
23 mittee on Infant Mortality of the Department of
24 Health and Human Services shall annually develop
25 and annually update and submit to the Secretary a

1 strategic plan for the conduct of preterm birth re-
2 lated research.

3 (2) ANNUAL REPORT.—Not later than January
4 1, 2011, and each January 1 thereafter, the Advi-
5 sory Committee on Infant Mortality shall submit to
6 the Secretary, and make available to the general
7 public, a report concerning the activities of the Advi-
8 sory Committee related to infant mortality, pre-
9 maturity, and low birthweight.

10 (3) MEMBERSHIP.—The Secretary shall ensure
11 that the membership of the Advisory Committee on
12 Infant Mortality includes the following:

13 (A) Representatives provided for in the
14 original charter of the Advisory Committee.

15 (B) A representative of the National Cen-
16 ter for Health Statistics.

17 (c) PILOT PROGRAMS.—

18 (1) IN GENERAL.—The Secretary, acting
19 through the Administration of the Agency for
20 Healthcare Research and Quality, the Director of
21 the Centers for Disease Control and Prevention, the
22 Administrator of the Health Resources and Services
23 Administration, the Director of the Centers for
24 Medicare & Medicaid Services, the Assistant Sec-
25 retary for Planning and Evaluation of the Depart-

1 ment of Health and Human Services, and the heads
 2 of other appropriate agencies, shall conduct and re-
 3 port on research studies and demonstration projects
 4 that test maternity care models that are designed to
 5 reduce the rate of preterm birth.

6 (2) GRANTS.—The Secretary may carry out
 7 this subsection through the awarding of grants to el-
 8 igible entities.

9 (3) ELIGIBILITY.—To be eligible to receive a
 10 grant under this section an entity shall—

11 (A) be—

12 (i) a hospital or hospital systems that
 13 utilizes evidence-based best practices; or

14 (ii) a prematurity prevention network
 15 or other types of collaborative; and

16 (B) submit to the Secretary an application
 17 at such time, in such manner, and containing
 18 such information as the Secretary may require.

19 (4) TARGETING.—In awarding grants under
 20 this subsection, the Secretary shall target those
 21 areas with a demonstrated persistent high rate of
 22 preterm birth.

23 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
 24 authorized to be appropriated to carry out this section,

- 1 such sums as may be necessary for each of fiscal years
- 2 2011 through 2016.

