

BIRTH DEFECTS PREVENTION, RISK REDUCTION, AND
AWARENESS ACT OF 2010

SEPTEMBER 28, 2010.—Committed to the Committee of the Whole House on the
State of the Union and ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 5462]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5462) to authorize the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to establish and implement a birth defects prevention, risk reduction, and public awareness program, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendments are as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Birth Defects Prevention, Risk Reduction, and Awareness Act of 2010”.

SEC. 2. BIRTH DEFECTS PREVENTION, RISK REDUCTION, AND AWARENESS.

(a) PROGRAM.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by inserting after section 317T (42 U.S.C. 247b-22) the following new section:

“SEC. 317U. BIRTH DEFECTS PREVENTION, RISK REDUCTION, AND AWARENESS.

“(a) GRANT PROGRAM.—The Secretary shall establish and implement a birth defects prevention and public awareness program to award grants to States or organizations for the provision of pregnancy and breastfeeding information services.

“(b) PREFERENCE.—In the case of States or organizations that are otherwise equally qualified, the Secretary, in awarding a grant under this section, shall give preference to—

“(1) States that made pregnancy and breastfeeding information services available on January 1, 2006; and

“(2) organizations that will provide pregnancy and breastfeeding information services in such States.

“(c) MATCHING FUNDS.—The Secretary may only award a grant under this section to a State or organization that agrees, with respect to the costs to be incurred in carrying out the grant activities, to make available (directly or through donations from public or private entities) non-Federal funds toward such costs in an amount equal to not less than 25 percent of the amount of the grant.

“(d) COORDINATION.—The Secretary shall ensure that activities carried out using a grant under this section are coordinated, to the maximum extent practicable, with other birth defects prevention and environmental health activities of the Federal Government, including activities carried out by the Health Resources and Services Administration and the Centers for Disease Control and Prevention with respect to pediatric environmental health specialty units and children’s environmental health centers.

“(e) EVALUATION.—In furtherance of the program established under subsection (a), the Secretary shall provide for an evaluation of pregnancy and breastfeeding information services to identify efficient and effective models of—

“(1) providing information;

“(2) raising awareness and increasing knowledge about birth defects prevention measures;

“(3) modifying risk behaviors; or

“(4) other outcome measures as determined appropriate by the Secretary.

“(f) PREGNANCY AND BREASTFEEDING INFORMATION SERVICES DEFINED.—For purposes of this section, the term ‘pregnancy and breastfeeding information services’ includes only—

“(1) information services to provide accurate, evidence-based, clinical information regarding maternal exposures during pregnancy or breastfeeding that may be associated with birth defects or other health risks to an infant that is breastfed, such as exposures to medications, chemicals, infections, foodborne pathogens, illnesses, nutrition, or lifestyle factors;

“(2) the provision of accurate, evidence-based information weighing risks of exposures during breastfeeding against the benefits of breastfeeding; and

“(3) the provision of information described in paragraph (1) or (2) through counselors, Web sites, fact sheets, telephonic or electronic communication, community outreach efforts, or other appropriate means.

“(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$4,500,000 for fiscal year 2012, \$5,500,000 for fiscal year 2013, \$6,500,000 for fiscal year 2014, \$7,500,000 for fiscal year 2015, and \$8,500,000 for fiscal year 2016.”.

Amend the title so as to read:

A bill to amend title III of the Public Health Service Act to authorize the Secretary of Health and Human Services to establish and implement a birth defects prevention, risk reduction, and public awareness program.

PURPOSE AND SUMMARY

H.R. 5462, the “Birth Defects Prevention, Risk Reduction, and Awareness Act of 2010”, was introduced by Rep. Rosa L. DeLauro (D-CT) on May 28, 2010, and referred to the Committee on Energy and Commerce.

The goal of H.R. 5462 is to authorize funding for the establishment and implementation of a birth defects prevention and public awareness program. The bill amends the Public Health Service Act to establish a program to award grants to states or organizations for the provision of pregnancy and breastfeeding information services.

BACKGROUND AND NEED FOR LEGISLATION

Pregnancy risk information services provide clinical information and consultation to pregnant women and their healthcare providers regarding exposures to medications, chemicals, illicit drugs, alcohol, infections, and illnesses that may pose a risk of birth defects, a risk to the pregnancy, or a risk to the mother while pregnant. These services also provide information on exposures during breastfeeding.

State funding for pregnancy risk information services has declined dramatically in recent years. According to the Organization of Teratology Specialists, in 1995 there were more than 30 pregnancy risk information services across the country. Today there are fewer than 15 and those that remain have sustained budget cuts forcing reductions in staffing, counseling availability, satellite locations, and outreach to both the medical community and the public.

In addition, there are currently no federal programs that provide the grant support proposed in the bill for these counseling services. Various efforts based at the Department of Health and Human Services (HHS) provide research and information services with respect to birth defects and their causes. One of these efforts is the National Center for Birth Defects and Developmental Disabilities administered through the Centers for Disease Control and Prevention (CDC). None is designed, however, to provide the counseling and clinical information services authorized in H.R. 5462.

COMMITTEE CONSIDERATION

H.R. 5462, the “Birth Defects Prevention, Risk Reduction, and Awareness Act of 2010”, was introduced by Ms. DeLauro of Connecticut on May 28, 2010, and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on June 8, 2010. On September 15, 2010, the Subcommittee held a legislative hearing on the bill. The Subcommittee met in open markup session to consider H.R. 5462 on September 16, 2010. An amendment in the nature of a substitute (manager’s amendment) offered by Mr. Pallone of New Jersey was adopted by a voice vote. Subsequently, H.R. 5462 was favorably forwarded to the full Committee, amended, by a voice vote.

On September 23, 2010, the Committee on Energy and Commerce met in open markup session and considered H.R. 5462 as approved by the Subcommittee. There were no amendments offered in full Committee and subsequently the Committee ordered H.R. 5462

favorably reported to the House, as amended by the Subcommittee on Health, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. A motion by Mr. Waxman ordering H.R. 5462 reported to the House, as amended, was approved by a voice vote. There were no record votes taken during consideration of this bill.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause (2)(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations are reflected in the descriptive portions of this report, including the finding that state funding for pregnancy risk information services has declined dramatically in recent years.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 5462 would result in no new budget authority, entitlement authority, or tax expenditures or revenues.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal of providing for a grant program regarding the provision of pregnancy and breastfeeding information services.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional authority for H.R. 5462 is provided under article I, section 8, clauses 3 and 18 of the Constitution of the United States.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 5462 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

FEDERAL ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation does not establish or authorize the establishment of an advisory committee within the definition of 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch where the bill relates to terms and conditions of employment or access to public services and accommodations. H.R. 5462 contains no such provisions.

FEDERAL MANDATES STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act of 1974 (as amended by section 101(a)(2) of the Unfunded Mandates Reform Act, Public Law 104–4) requires a statement on whether the provisions of the report include unfunded mandates. In compliance with this requirement the Committee adopts as its own the analysis of federal mandates prepared by the Director of the Congressional Budget Office regarding H.R. 5462.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate of H.R. 5462 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 5462 from the Director of Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 27, 2010.

Hon. HENRY A. WAXMAN,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 5462, the Birth Defects Prevention, Risk Reduction, and Awareness Act of 2010.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lara Robillard, who can be reached at 226–9010.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 5462—Birth Defects Prevention, Risk Reduction, and Awareness Act of 2010

Summary: H.R. 5462 would amend the Public Health Service Act to establish a program to award grants to states and other organizations for the provision of pregnancy and breastfeeding information services. CBO estimates that implementing H.R. 5462 would cost \$18 million over the 2011–2015 period, assuming appropria-

tion of the authorized amounts. Enacting H.R. 5462 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 5462 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 5462 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2011	2012	2013	2014	2015	2011– 2015
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Authorization Level	0	5	6	7	8	24
Estimated Outlays	0	2	4	5	7	18

Note: Components may not sum to totals because of rounding.

Basis of estimate: H.R. 5462 would direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention (CDC), to establish a program to promote public awareness for prevention of birth defects. To implement the program, the Secretary would award grants to states or organizations for the provision of information about pregnancy and breastfeeding. Pregnancy and breastfeeding information is defined as clinical information regarding maternal exposure during pregnancy or breastfeeding that may be associated with birth defects or other infant health risks.

In making grant decisions, the Secretary would give preference to states that have previously made available pregnancy and breastfeeding information and to organizations that will make such information available. The Secretary could only award grants to states and organizations that make available nonfederal matching funds equal to at least 25 percent of the amount of the grant.

The bill would authorize the appropriation of specific amounts each year for fiscal year 2012 through 2016. Based on historical patterns of spending for grant programs administered by CDC and assuming appropriation of the authorized amounts, CBO estimates that implementing the bill would cost \$18 million over the 2012–2015 period and an additional \$14 million after 2015.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 5462 contains no intergovernmental or private-sector mandates as defined in UMRA. Grant funds authorized in the bill would benefit states that provide information services regarding pregnancy and breastfeeding. Any costs to states, including matching funds, would be incurred voluntarily as a condition of federal assistance.

Estimate prepared by: Federal costs: Lara Robillard; Impact on state, local, and tribal governments: Lisa Ramirez-Branum; Impact on the private sector: Sarah Axteen.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the Act may be cited as the “Birth Defects Prevention, Risk Reduction, and Awareness Act of 2010”.

Section 2. Birth defects prevention, risk reduction, and awareness

Section 2 requires the Secretary of Health and Human Services to establish and implement a birth defects prevention and public awareness program about pregnancy and breastfeeding information services. It also requires the Secretary to award grants to states and organizations for the provision of pregnancy and breastfeeding information services. In awarding such grants, preference is to be given to states or organizations providing pregnancy and breastfeeding services on January 1, 2006.

The section authorizes \$4.5 million for FY2012; \$5.5 million for FY2013; \$6.5 million for FY2014; \$7.5 million for FY2015; and \$8.5 million for FY2016 to carry out the activities under this section.

EXPLANATION OF AMENDMENT

During the Subcommittee on Health markup of H.R. 5462, Mr. Pallone of New Jersey offered an amendment in the nature of a substitute (manager’s amendment), which was adopted by a voice vote. The substance of this substitute amendment is reflected in the section-by-section analysis contained in this report.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * *

SEC. 317U. BIRTH DEFECTS PREVENTION, RISK REDUCTION, AND AWARENESS.

(a) *GRANT PROGRAM.*—The Secretary shall establish and implement a birth defects prevention and public awareness program to award grants to States or organizations for the provision of pregnancy and breastfeeding information services.

(b) *PREFERENCE.*—In the case of States or organizations that are otherwise equally qualified, the Secretary, in awarding a grant under this section, shall give preference to—

(1) *States that made pregnancy and breastfeeding information services available on January 1, 2006; and*

(2) organizations that will provide pregnancy and breastfeeding information services in such States.

(c) *MATCHING FUNDS.*—The Secretary may only award a grant under this section to a State or organization that agrees, with respect to the costs to be incurred in carrying out the grant activities, to make available (directly or through donations from public or private entities) non-Federal funds toward such costs in an amount equal to not less than 25 percent of the amount of the grant.

(d) *COORDINATION.*—The Secretary shall ensure that activities carried out using a grant under this section are coordinated, to the maximum extent practicable, with other birth defects prevention and environmental health activities of the Federal Government, including activities carried out by the Health Resources and Services Administration and the Centers for Disease Control and Prevention with respect to pediatric environmental health specialty units and children's environmental health centers.

(e) *EVALUATION.*—In furtherance of the program established under subsection (a), the Secretary shall provide for an evaluation of pregnancy and breastfeeding information services to identify efficient and effective models of—

- (1) providing information;
- (2) raising awareness and increasing knowledge about birth defects prevention measures;
- (3) modifying risk behaviors; or
- (4) other outcome measures as determined appropriate by the Secretary.

(f) *PREGNANCY AND BREASTFEEDING INFORMATION SERVICES DEFINED.*—For purposes of this section, the term “pregnancy and breastfeeding information services” includes only—

- (1) information services to provide accurate, evidence-based, clinical information regarding maternal exposures during pregnancy or breastfeeding that may be associated with birth defects or other health risks to an infant that is breastfed, such as exposures to medications, chemicals, infections, foodborne pathogens, illnesses, nutrition, or lifestyle factors;
- (2) the provision of accurate, evidence-based information weighing risks of exposures during breastfeeding against the benefits of breastfeeding; and
- (3) the provision of information described in paragraph (1) or (2) through counselors, Web sites, fact sheets, telephonic or electronic communication, community outreach efforts, or other appropriate means.

(g) *AUTHORIZATION OF APPROPRIATIONS.*—To carry out this section, there are authorized to be appropriated \$4,500,000 for fiscal year 2012, \$5,500,000 for fiscal year 2013, \$6,500,000 for fiscal year 2014, \$7,500,000 for fiscal year 2015, and \$8,500,000 for fiscal year 2016.

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