

111TH CONGRESS
1ST SESSION

H. R. 3242

To improve the health of women through the establishment of Offices of Women's Health within the Department of Health and Human Services.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2009

Mrs. MALONEY (for herself, Mr. MURPHY of Connecticut, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To improve the health of women through the establishment of Offices of Women's Health within the Department of Health and Human Services.

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 "Women's Health Office
5 Act of 2009".

1 **SEC. 2. HEALTH AND HUMAN SERVICES OFFICE ON WOM-**
2 **EN'S HEALTH.**

3 (a) ESTABLISHMENT.—Part A of title II of the Pub-
4 lic Health Service Act (42 U.S.C. 202 et seq.) is amended
5 by adding at the end the following:

6 **“SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON**
7 **WOMEN'S HEALTH.**

8 “(a) ESTABLISHMENT OF OFFICE.—There is estab-
9 lished within the Office of the Secretary, an Office on
10 Women's Health (referred to in this section as the ‘Of-
11 fice’). The Office shall be headed by a Deputy Assistant
12 Secretary for Women's Health who may report to the Sec-
13 retary.

14 “(b) DUTIES.—The Secretary, acting through the Of-
15 fice, with respect to the health concerns of women, shall—

16 “(1) establish short-range and long-range goals
17 and objectives within the Department of Health and
18 Human Services and, as relevant and appropriate,
19 coordinate with other appropriate offices on activi-
20 ties within the Department that relate to disease
21 prevention, health promotion, service delivery, re-
22 search, and public and health care professional edu-
23 cation, for issues of particular concern to women;

24 “(2) provide expert advice and consultation to
25 the Secretary concerning scientific, legal, ethical,
26 and policy issues relating to women's health;

1 “(3) monitor the Department of Health and
2 Human Services’ offices, agencies, and regional ac-
3 tivities regarding women’s health and stimulate ac-
4 tivities and facilitate coordination of such depart-
5 mental and agency offices on women’s health;

6 “(4) establish a Department of Health and
7 Human Services Coordinating Committee on Wom-
8 en’s Health, which shall be chaired by the Deputy
9 Assistant Secretary for Women’s Health and com-
10 posed of senior level representatives from each of the
11 agencies and offices of the Department of Health
12 and Human Services;

13 “(5) establish a National Women’s Health In-
14 formation Center to—

15 “(A) facilitate the exchange of information
16 regarding matters relating to health informa-
17 tion, health promotion, preventive health serv-
18 ices, research advances, and education in the
19 appropriate use of health care;

20 “(B) facilitate access to such information;

21 “(C) assist in the analysis of issues and
22 problems relating to the matters described in
23 this paragraph; and

24 “(D) provide technical assistance with re-
25 spect to the exchange of information (including

1 facilitating the development of materials for
2 such technical assistance);

3 “(6) coordinate efforts to promote women’s
4 health programs and policies with the private sector;
5 and

6 “(7) through publications and any other means
7 appropriate, provide for the exchange of information
8 between the Office and recipients of grants, con-
9 tracts, and agreements under subsection (c), and be-
10 tween the Office and health professionals and the
11 general public.

12 “(c) GRANTS AND CONTRACTS REGARDING DU-
13 TIES.—

14 “(1) AUTHORITY.—In carrying out subsection
15 (b), the Secretary may make grants to, and enter
16 into cooperative agreements, contracts, and inter-
17 agency agreements with, public and private entities,
18 agencies, and organizations.

19 “(2) EVALUATION AND DISSEMINATION.—The
20 Secretary shall directly or through contracts with
21 public and private entities, agencies, and organiza-
22 tions, provide for evaluations of projects carried out
23 with financial assistance provided under paragraph
24 (1) and for the dissemination of information devel-
25 oped as a result of such projects.

1 “(d) REPORTS.—Not later than 1 year after the date
2 of enactment of this section, and every second year there-
3 after, the Secretary shall prepare and submit to the appro-
4 priate committees of Congress a report describing the ac-
5 tivities carried out under this section during the period
6 for which the report is being prepared.

7 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
8 purpose of carrying out this section, there are authorized
9 to be appropriated such sums as may be necessary for
10 each of the fiscal years 2010 through 2014.

11 “(f) LIMITATION ON TERMINATION OF OFFICE.—
12 Notwithstanding any other provision of law, the Office es-
13 tablished under this section may not be terminated, reor-
14 ganized, or have any of its powers or duties transferred
15 unless such termination, reorganization, or transfer is ap-
16 proved through the adoption of a joint resolution of ap-
17 proval.”.

18 (b) TRANSFER OF FUNCTIONS.—There are trans-
19 ferred to the Office on Women’s Health (established under
20 section 229 of the Public Health Service Act, as added
21 by this section), all functions exercised by the Office on
22 Women’s Health of the Public Health Service prior to the
23 date of enactment of this section, including all personnel
24 and compensation authority, all delegation and assign-
25 ment authority, and all remaining appropriations. All or-

1 ders, determinations, rules, regulations, permits, agree-
2 ments, grants, contracts, certificates, licenses, registra-
3 tions, privileges, and other administrative actions that—

4 (1) have been issued, made, granted, or allowed
5 to become effective by the President, any Federal
6 agency or official thereof, or by a court of competent
7 jurisdiction, in the performance of functions trans-
8 ferred under this subsection; and

9 (2) are in effect at the time this section takes
10 effect, or were final before the date of enactment of
11 this section and are to become effective on or after
12 such date;

13 shall continue in effect according to their terms until
14 modified, terminated, superseded, set aside, or revoked in
15 accordance with law by the President, the Secretary, or
16 other authorized official, a court of competent jurisdiction,
17 or by operation of law.

18 **SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVEN-**
19 **TION OFFICE OF WOMEN'S HEALTH.**

20 Part A of title III of the Public Health Service Act
21 (42 U.S.C. 241 et seq.) is amended by adding at the end
22 the following:

1 **“SEC. 310A. CENTERS FOR DISEASE CONTROL AND PREVEN-**
2 **TION OFFICE OF WOMEN’S HEALTH.**

3 “(a) **ESTABLISHMENT.**—There is established within
4 the Office of the Director of the Centers for Disease Con-
5 trol and Prevention, an office to be known as the Office
6 of Women’s Health (referred to in this section as the ‘Of-
7 fice’). The Office shall be headed by a director who shall
8 be appointed by the Director of such Centers.

9 “(b) **PURPOSE.**—The Director of the Office shall—

10 “(1) report to the Director of the Centers for
11 Disease Control and Prevention on the current level
12 of the Centers’ activity regarding women’s health
13 conditions across, where appropriate, age, biological,
14 and sociocultural contexts, in all aspects of the Cen-
15 ters’ work, including prevention programs, public
16 and professional education, services, and treatment;

17 “(2) establish short-range and long-range goals
18 and objectives within the Centers for women’s health
19 and, as relevant and appropriate, coordinate with
20 other appropriate offices on activities within the
21 Centers that relate to prevention, research, edu-
22 cation and training, service delivery, and policy de-
23 velopment, for issues of particular concern to
24 women;

25 “(3) identify projects in women’s health that
26 should be conducted or supported by the Centers;

1 “(4) consult with health professionals, non-
2 governmental organizations, consumer organizations,
3 women’s health professionals, and other individuals
4 and groups, as appropriate, on the policy of the Cen-
5 ters with regard to women; and

6 “(5) serve as a member of the Department of
7 Health and Human Services Coordinating Com-
8 mittee on Women’s Health (established under sec-
9 tion 229(b)(4)).

10 “(c) COORDINATING COMMITTEE.—

11 “(1) ESTABLISHMENT.—In carrying out sub-
12 section (b), the Director of the Office shall establish
13 a committee to be known as the Coordinating Com-
14 mittee on Women’s Health (referred to in this sub-
15 section as the ‘Coordinating Committee’).

16 “(2) COMPOSITION.—The Coordinating Com-
17 mittee shall be composed of the directors of the na-
18 tional centers and other appropriate officials of the
19 Centers for Disease Control and Prevention.

20 “(3) CHAIRPERSON.—The Director of the Of-
21 fice shall serve as the Chairperson of the Coordi-
22 nating Committee.

23 “(4) DUTIES.—With respect to women’s health,
24 the Coordinating Committee shall assist the Director
25 of the Office in—

1 “(A) identifying the need for programs and
2 activities that focus on women’s health;

3 “(B) identifying needs regarding the co-
4 ordination of activities, including intramural
5 and extramural multidisciplinary activities; and

6 “(C) making recommendations to the Di-
7 rector of the Centers for Disease Control and
8 Prevention concerning findings made under
9 subparagraphs (A) and (B).

10 “(d) REPORTS.—Not later than 1 year after the date
11 of enactment of this section, and every second year there-
12 after, the Director of the Office shall prepare and submit
13 to the appropriate committees of Congress a report de-
14 scribing the activities carried out under this section during
15 the period for which the report is being prepared.

16 “(e) DEFINITION.—As used in this section, the term
17 ‘women’s health conditions’, with respect to women of all
18 age, ethnic, and racial groups, means diseases, disorders,
19 and conditions—

20 “(1) unique to, significantly more serious for,
21 or significantly more prevalent in women; and

22 “(2) for which the factors of medical risk or
23 type of medical intervention are different for women,
24 or for which there is reasonable evidence that indi-

1 cates that such factors or types may be different for
2 women.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated such sums as may be necessary for
6 each of the fiscal years 2010 through 2014.

7 “(g) LIMITATION ON TERMINATION OF OFFICE.—
8 Notwithstanding any other provision of law, the Office es-
9 tablished under this section may not be terminated, reor-
10 ganized, or have any of its powers or duties transferred
11 unless such termination, reorganization, or transfer is ap-
12 proved through the adoption of a joint resolution of ap-
13 proval.”.

14 **SEC. 4. OFFICE OF WOMEN’S HEALTH RESEARCH.**

15 Section 486(a) of the Public Health Service Act (42
16 U.S.C. 287d(a)) is amended by inserting “and who shall
17 report directly to the Director” before the period at the
18 end thereof.

19 **SEC. 5. SUBSTANCE ABUSE AND MENTAL HEALTH SERV-**
20 **ICES ADMINISTRATION.**

21 Section 501(f) of the Public Health Service Act (42
22 U.S.C. 290aa(f)) is amended—

23 (1) in paragraph (1), by inserting “who shall
24 report directly to the Administrator” before the pe-
25 riod;

1 (2) by redesignating paragraph (4) as para-
2 graph (5); and

3 (3) by inserting after paragraph (3), the fol-
4 lowing:

5 “(4) OFFICE.—Nothing in this subsection shall
6 be construed to preclude the Secretary from estab-
7 lishing within the Substance Abuse and Mental
8 Health Administration an Office of Women’s
9 Health.”.

10 **SEC. 6. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
11 **ITY ACTIVITIES REGARDING WOMEN’S**
12 **HEALTH.**

13 Part D of title IX of the Public Health Service Act
14 (42 U.S.C. 299c et seq.) is amended—

15 (1) by redesignating sections 937 and 938 as
16 sections 938 and 939, respectively;

17 (2) by inserting after section 936 the following:

18 **“SEC. 937. ACTIVITIES REGARDING WOMEN’S HEALTH.**

19 “(a) ESTABLISHMENT.—There is established within
20 the Office of the Director, an Office of Women’s Health
21 and Gender-Based Research (referred to in this section
22 as the ‘Office’). The Office shall be headed by a director
23 who shall be appointed by the Director of Healthcare and
24 Research Quality.

1 “(b) PURPOSE.—The official designated under sub-
2 section (a) shall—

3 “(1) report to the Director on the current
4 Agency level of activity regarding women’s health,
5 across, where appropriate, age, biological, and
6 sociocultural contexts, in all aspects of Agency work,
7 including the development of evidence reports and
8 clinical practice protocols and the conduct of re-
9 search into patient outcomes, delivery of health care
10 services, quality of care, and access to health care;

11 “(2) establish short-range and long-range goals
12 and objectives within the Agency for research impor-
13 tant to women’s health and, as relevant and appro-
14 priate, coordinate with other appropriate offices on
15 activities within the Agency that relate to health
16 services and medical effectiveness research, for
17 issues of particular concern to women;

18 “(3) identify projects in women’s health that
19 should be conducted or supported by the Agency;

20 “(4) consult with health professionals, non-
21 governmental organizations, consumer organizations,
22 women’s health professionals, and other individuals
23 and groups, as appropriate, on Agency policy with
24 regard to women; and

1 “(5) serve as a member of the Department of
2 Health and Human Services Coordinating Com-
3 mittee on Women’s Health (established under sec-
4 tion 229(b)(4)).

5 “(c) COORDINATING COMMITTEE.—

6 “(1) ESTABLISHMENT.—In carrying out sub-
7 section (b), the official designated under subsection
8 (a) shall establish a committee to be known as the
9 Coordinating Committee on Women’s Health (re-
10 ferred to in this subsection as the ‘Coordinating
11 Committee’).

12 “(2) COMPOSITION.—The Coordinating Com-
13 mittee shall be composed of the official designated
14 under subsection (a) and the directors of the centers
15 and offices of the Agency.

16 “(3) CHAIRPERSON.—The official designated
17 under subsection (a) shall serve as the Chairperson
18 of the Coordinating Committee.

19 “(4) DUTIES.—With respect to research on
20 women’s health, the Coordinating Committee shall
21 assist the official designated under subsection (a)
22 in—

23 “(A) identifying the need for such re-
24 search, and making an estimate each fiscal year

1 of the funds needed to adequately support the
2 research;

3 “(B) identifying needs regarding the co-
4 ordination of research activities, including in-
5 tramural and extramural multidisciplinary ac-
6 tivities; and

7 “(C) making recommendations to the Di-
8 rector of the Agency concerning findings made
9 under subparagraphs (A) and (B).

10 “(d) REPORTS.—Not later than 1 year after the date
11 of enactment of this section, and every second year there-
12 after, the official designated under subsection (a) shall
13 prepare and submit to the appropriate committees of Con-
14 gress a report describing the activities carried out under
15 this section during the period for which the report is being
16 prepared.

17 “(e) LIMITATION ON TERMINATION OF OFFICE.—
18 Notwithstanding any other provision of law, the Office es-
19 tablished under this section may not be terminated, reor-
20 ganized, or have any of its powers or duties transferred
21 unless such termination, reorganization, or transfer is ap-
22 proved through the adoption of a joint resolution of ap-
23 proval.”; and

24 (3) by adding at the end of section 938 (as re-
25 designated by paragraph (1)) the following:

1 “(f) WOMEN’S HEALTH.—For the purpose of car-
 2 rying out section 937 regarding women’s health, there are
 3 authorized to be appropriated such sums as may be nec-
 4 essary for each of the fiscal years 2010 through 2014.”.

5 **SEC. 7. HEALTH RESOURCES AND SERVICES ADMINISTRA-**
 6 **TION OFFICE OF WOMEN’S HEALTH.**

7 Title VII of the Social Security Act (42 U.S.C. 901
 8 et seq.) is amended by adding at the end the following:

9 **“SEC. 713. OFFICE OF WOMEN’S HEALTH.**

10 “(a) ESTABLISHMENT.—The Secretary shall estab-
 11 lish within the Office of the Administrator of the Health
 12 Resources and Services Administration, an office to be
 13 known as the Office of Women’s Health. The Office shall
 14 be headed by a director who shall be appointed by the Ad-
 15 ministrator.

16 “(b) PURPOSE.—The Director of the Office shall—

17 “(1) report to the Administrator on the current
 18 Administration level of activity regarding women’s
 19 health across, where appropriate, age, biological, and
 20 sociocultural contexts;

21 “(2) establish short-range and long-range goals
 22 and objectives within the Health Resources and
 23 Services Administration for women’s health and, as
 24 relevant and appropriate, coordinate with other ap-
 25 propriate offices on activities within the Administra-

1 tion that relate to health care provider training,
2 health service delivery, research, and demonstration
3 projects, for issues of particular concern to women;

4 “(3) identify projects in women’s health that
5 should be conducted or supported by the bureaus of
6 the Administration;

7 “(4) consult with health professionals, non-
8 governmental organizations, consumer organizations,
9 women’s health professionals, and other individuals
10 and groups, as appropriate, on Administration policy
11 with regard to women; and

12 “(5) serve as a member of the Department of
13 Health and Human Services Coordinating Com-
14 mittee on Women’s Health (established under sec-
15 tion 229(b)(4) of the Public Health Service Act).

16 “(c) COORDINATING COMMITTEE.—

17 “(1) ESTABLISHMENT.—In carrying out sub-
18 section (b), the Director of the Office shall establish
19 a committee to be known as the Coordinating Com-
20 mittee on Women’s Health (referred to in this sub-
21 section as the ‘Coordinating Committee’).

22 “(2) COMPOSITION.—The Coordinating Com-
23 mittee shall be composed of the directors of the bu-
24 reaus of the Administration.

1 “(3) CHAIRPERSON.—The Director of the Of-
2 fice shall serve as the Chairperson of the Coordi-
3 nating Committee.

4 “(4) DUTIES.—With respect to women’s health,
5 the Coordinating Committee shall assist the Director
6 of the Office in—

7 “(A) identifying the need for programs and
8 activities that focus on women’s health;

9 “(B) identifying needs regarding the co-
10 ordination of activities, including intramural
11 and extramural multidisciplinary activities; and

12 “(C) making recommendations to the Ad-
13 ministrators concerning findings made under
14 subparagraphs (A) and (B).

15 “(d) REPORTS.—Not later than 1 year after the date
16 of enactment of this section, and every second year there-
17 after, the Director of the Office shall prepare and submit
18 to the appropriate committees of Congress a report de-
19 scribing the activities carried out under this section during
20 the period for which the report is being prepared.

21 “(e) DEFINITIONS.—For purposes of this section:

22 “(1) ADMINISTRATION.—The term ‘Administra-
23 tion’ means the Health Resources and Services Ad-
24 ministration.

1 “(2) ADMINISTRATOR.—The term ‘Adminis-
2 trator’ means the Administrator of the Health Re-
3 sources and Services Administration.

4 “(3) OFFICE.—The term ‘Office’ means the Of-
5 fice of Women’s Health established under this sec-
6 tion in the Administration.

7 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
8 purpose of carrying out this section, there are authorized
9 to be appropriated such sums as may be necessary for
10 each of the fiscal years 2010 through 2014.

11 “(g) LIMITATION ON TERMINATION OF OFFICE.—
12 Notwithstanding any other provision of law, the Office es-
13 tablished under this section may not be terminated, reor-
14 ganized, or have any of its powers or duties transferred
15 unless such termination, reorganization, or transfer is ap-
16 proved through the adoption of a joint resolution of ap-
17 proval.”.

18 **SEC. 8. FOOD AND DRUG ADMINISTRATION OFFICE OF**
19 **WOMEN’S HEALTH.**

20 Chapter IX of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 391 et seq.) is amended by adding at the
22 end the following:

23 **“SEC. 911. OFFICE OF WOMEN’S HEALTH.**

24 “(a) ESTABLISHMENT.—There is established within
25 the Office of the Commissioner, an office to be known as

1 the Office of Women’s Health (referred to in this section
2 as the ‘Office’). The Office shall be headed by a director
3 who shall be appointed by the Commissioner of Food and
4 Drugs.

5 “(b) PURPOSE.—The Director of the Office shall—

6 “(1) report to the Commissioner of Food and
7 Drugs on current Food and Drug Administration
8 (referred to in this section as the ‘Administration’)
9 levels of activity regarding women’s participation in
10 clinical trials and the analysis of data by sex in the
11 testing of drugs, medical devices, and biological
12 products across, where appropriate, age, biological,
13 and sociocultural contexts;

14 “(2) establish short-range and long-range goals
15 and objectives within the Administration for issues
16 of particular concern to women’s health within the
17 jurisdiction of the Administration, including, where
18 relevant and appropriate, adequate inclusion of
19 women and analysis of data by sex in Administration
20 protocols and policies;

21 “(3) provide information to women and health
22 care providers on those areas in which differences
23 between men and women exist;

24 “(4) consult with pharmaceutical, biologics, and
25 device manufacturers, health professionals with ex-

1 pertise in women’s issues, consumer organizations,
2 and women’s health professionals on Administration
3 policy with regard to women;

4 “(5) make annual estimates of funds needed to
5 monitor clinical trials and analysis of data by sex in
6 accordance with needs that are identified; and

7 “(6) serve as a member of the Department of
8 Health and Human Services Coordinating Com-
9 mittee on Women’s Health (established under sec-
10 tion 229(b)(4) of the Public Health Service Act).

11 “(c) COORDINATING COMMITTEE.—

12 “(1) ESTABLISHMENT.—In carrying out sub-
13 section (b), the Director of the Office shall establish
14 a committee to be known as the Coordinating Com-
15 mittee on Women’s Health (referred to in this sub-
16 section as the ‘Coordinating Committee’).

17 “(2) COMPOSITION.—The Coordinating Com-
18 mittee shall be composed of the directors of the cen-
19 ters of the Administration.

20 “(3) CHAIRPERSON.—The Director of the Of-
21 fice shall serve as the Chairperson of the Coordi-
22 nating Committee.

23 “(4) DUTIES.—With respect to women’s health,
24 the Coordinating Committee shall assist the Director
25 of the Office in—

1 “(A) identifying whether there is a need
2 for further studies and, if so, developing strate-
3 gies to foster such studies;

4 “(B) identifying issues in specific areas of
5 women’s health that fall within the mission of
6 the Administration;

7 “(C) identifying whether any need exists
8 for the coordination of Administration activi-
9 ties, including internal and external activities;

10 “(D) maintaining the Administration’s
11 focus in areas of importance to women;

12 “(E) supporting the development of meth-
13 odologies to determine how to obtain data spe-
14 cific to women (including data relating to the
15 age of women and the membership of women in
16 ethnic or racial groups); and

17 “(F) supporting the development and ex-
18 pansion of clinical trials of treatments and
19 therapies for which obtaining such data has
20 been determined to be an appropriate function.

21 “(d) REPORTS.—Not later than 1 year after the date
22 of enactment of this section, and every second year there-
23 after, the Director of the Office shall prepare and submit
24 to the appropriate committees of Congress a report de-

1 scribing the activities carried out under this section during
2 the period for which the report is being prepared.

3 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated such sums as may be necessary for
6 each of the fiscal years 2010 through 2014.

7 “(f) LIMITATION ON TERMINATION OF OFFICE.—
8 Notwithstanding any other provision of law, the Office es-
9 tablished under this section may not be terminated, reor-
10 ganized, or have any of its powers or duties transferred
11 unless such termination, reorganization, or transfer is ap-
12 proved through the adoption of a joint resolution of ap-
13 proval.”.

14 **SEC. 9. NO NEW REGULATORY AUTHORITY.**

15 Nothing in this Act and the amendments made by
16 this Act may be construed as establishing regulatory au-
17 thority or modifying any existing regulatory authority.

18 **SEC. 10. LIMITATION ON TERMINATION.**

19 Notwithstanding any other provision of law, a Fed-
20 eral office of women’s health (including the Office of Re-
21 search on Women’s Health of the National Institutes of
22 Health) or Federal appointive position with primary re-
23 sponsibility over women’s health issues (including the As-
24 sociate Administrator for Women’s Services under the
25 Substance Abuse and Mental Health Services Administra-

1 tion) that is in existence on the date of enactment of this
2 Act shall not be terminated, reorganized, or have any of
3 its powers or duties transferred unless such termination,
4 reorganization, or transfer is approved through the adop-
5 tion of a joint resolution of approval.

○