

112TH CONGRESS
1ST SESSION

H. R. 383

To provide for coverage of hormone replacement therapy for treatment of menopausal symptoms, and for coverage of an alternative therapy for hormone replacement therapy for such symptoms, under the Medicare and Medicaid Programs, group health plans and individual health insurance coverage, and other Federal health insurance programs.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 20, 2011

Ms. LEE of California introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and the Workforce, Oversight and Government Reform, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide for coverage of hormone replacement therapy for treatment of menopausal symptoms, and for coverage of an alternative therapy for hormone replacement therapy for such symptoms, under the Medicare and Medicaid Programs, group health plans and individual health insurance coverage, and other Federal health insurance programs.

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; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
 3 “Menopausal Hormone Replacement Therapies and Alter-
 4 native Treatments and Fairness Act of 2011”.

5 (b) **TABLE OF CONTENTS.**—The table of contents of
 6 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Medicare coverage of menopausal hormone replacement therapy and al-
 ternative treatments for menopausal hormone replacement
 therapy.

Sec. 4. Medicaid coverage of alternative treatments for menopausal hormone re-
 placement therapy.

Sec. 5. Coverage of menopausal hormone replacement therapy and alternative
 treatments for menopausal hormone replacement therapy under
 group health plans and individual health insurance coverage.

Sec. 6. Coverage of menopausal hormone replacement therapy and alternative
 treatments for menopausal hormone replacement therapy under
 FEHBP.

Sec. 7. Coverage of alternative treatments for menopausal hormone replacement
 therapy under Department of Veterans Affairs health care sys-
 tem.

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

9 (1) The Women’s Health Initiative terminated
 10 its study of hormone therapy three years early be-
 11 cause of findings that the combination of estrogen
 12 and progestin increases the risk of heart disease,
 13 stroke, blood clots, and breast cancer, and that es-
 14 trogen alone increases the risk of stroke and, in
 15 women over 65 years of age, increases the risk of de-
 16 mentia.

17 (2) The National Institutes of Health has stat-
 18 ed unequivocally that while menopause is a natural

1 process in women's lives, some women at midlife ex-
2 perience hot flashes, night sweats, vaginal dryness,
3 sleep disturbances, and mood disturbances that dis-
4 rupt quality of life. Women who have had meno-
5 pause induced by surgery, chemotherapy, or radi-
6 ation are more likely to experience these symptoms.

7 (3) Women deserve relief from menopause-re-
8 lated symptoms.

9 (4) The National Institutes of Health have stat-
10 ed that while estrogen and progestin have been
11 found to be effective remedies for these symptoms,
12 these remedies are not without risk.

13 (5) Concerned about these risks, women seek
14 alternative types of treatments for symptoms that
15 disrupt quality of life, such as hot flashes, night
16 sweats, vaginal dryness, sleep disturbances, and
17 mood disturbances.

18 (6) The National Institutes of Health have
19 found that although there are many alternatives to
20 synthetic hormones available, including bio-identical
21 or "natural" hormones as well as herbal remedies
22 and food supplements, the effectiveness and long-
23 term safety of these products need to be rigorously
24 studied in diverse populations.

1 (7) Government insurance programs, such as
2 Medicare, Medicaid, the Federal Employees Health
3 Benefits Program (FEHBP), and the Department
4 of Veterans Affairs, do not cover non-prescription al-
5 ternative treatments for menopause-related symp-
6 toms because of a lack of demonstrated safety and
7 efficacy of these products.

8 (8) Most private health insurance coverage does
9 not cover non-prescription alternative treatments for
10 menopause-related symptoms because of a lack of
11 demonstrated safety and efficacy of these products.

12 **SEC. 3. MEDICARE COVERAGE OF MENOPAUSAL HORMONE**
13 **REPLACEMENT THERAPY AND ALTERNATIVE**
14 **TREATMENTS FOR MENOPAUSAL HORMONE**
15 **REPLACEMENT THERAPY.**

16 (a) IN GENERAL.—Section 1861(s)(2) of the Social
17 Security Act (42 U.S.C. 1395x(s)(2)) is amended—

18 (1) by striking “and” at the end of subpara-
19 graph (EE);

20 (2) by adding “and” at the end of subpara-
21 graph (FF); and

22 (3) by adding at the end the following new sub-
23 paragraph:

24 “(GG)(i) hormone replacement therapy for
25 treatment of menopausal symptoms; and

1 (B) by striking “through (24)” and insert-
2 ing “through (29)”.

3 (b) DESCRIPTION OF COVERED THERAPIES.—Sec-
4 tion 1905(a) of such Act (42 U.S.C. 1396d(a)) is amend-
5 ed—

6 (1) by striking “and” at the end of paragraph
7 (28);

8 (2) by redesignating paragraph (29) as para-
9 graph (30); and

10 (3) by inserting after paragraph (28) the fol-
11 lowing new paragraph:

12 “(29) an alternative therapy for hormone re-
13 placement therapy for treatment of menopausal
14 symptoms if the therapy is recommended by a health
15 care provider who is licensed, accredited, or certified
16 under State law, if it has been proven safe and effec-
17 tive in peer-reviewed scientific studies, and if it is
18 administered only after the health care provider ob-
19 tains the informed consent of the patient to receive
20 it; and”.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section apply to therapies furnished on or after the
23 date of the enactment of this Act, without regard to
24 whether or not final regulations to carry out such amend-
25 ments have been promulgated by such date.

1 **SEC. 5. COVERAGE OF MENOPAUSAL HORMONE REPLACEMENT THERAPY AND ALTERNATIVE TREATMENTS FOR MENOPAUSAL HORMONE REPLACEMENT THERAPY UNDER GROUP HEALTH PLANS AND INDIVIDUAL HEALTH INSURANCE COVERAGE.**

7 (a) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—

8 (1) IN GENERAL.—Title XXVII of the Public
9 Health Service Act is amended by inserting after
10 section 2728 of such Act (42 U.S.C. 300gg–28), as
11 redesignated by section 1001(2) of the Patient Protection and Affordable Care Act (Public Law 111–
12 148), the following new section:

14 **“SEC. 2729. STANDARD RELATING TO COVERAGE OF MENOPAUSAL HORMONE REPLACEMENT THERAPY AND ALTERNATIVE TREATMENTS FOR MENOPAUSAL HORMONE REPLACEMENT THERAPY.**

18 **“(a) REQUIREMENTS.—**

19 **“(1) MENOPAUSAL HORMONE REPLACEMENT THERAPY.—**If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides benefits for outpatient prescription drugs, the plan or coverage may not exclude or restrict benefits for hormone replacement therapy for treatment of menopausal symptoms.

1 “(2) ALTERNATIVE TREATMENTS FOR MENO-
2 PAUSAL HORMONE REPLACEMENT THERAPY.—If a
3 group health plan, or a health insurance issuer offer-
4 ing group or individual health insurance coverage,
5 provides benefits for hormone replacement therapy
6 for treatment of menopausal symptoms, the plan or
7 coverage may not exclude or restrict benefits for an
8 alternative therapy for hormone replacement therapy
9 for treatment of menopausal symptoms if—

10 “(A) the therapy is recommended by a
11 health care provider who is licensed, accredited,
12 or certified under State law;

13 “(B) it has been proven safe and effective
14 in peer-reviewed scientific studies; and

15 “(C) it is administered only after the
16 health care provider obtains the informed con-
17 sent of the patient to receive it.

18 “(b) NOTICE.—A group health plan under this part
19 shall comply with the notice requirement under section
20 716(b) of the Employee Retirement Income Security Act
21 of 1974 with respect to the requirements of this section
22 as if such section applied to such plan. A health insurance
23 issuer under this part shall comply with the notice require-
24 ment under such section with respect to the requirements

1 of this section as if such section applied to such issuer
2 and such issuer were a group health plan.

3 “(c) EFFECTIVE DATE.—Notwithstanding any other
4 provision of law, this section shall apply with respect to
5 plan years beginning on or after the date of the enactment
6 of the Menopausal Hormone Replacement Therapies and
7 Alternative Treatments and Fairness Act of 2011 and
8 with respect to health insurance coverage issued on or
9 after such date.”.

10 (2) CONFORMING AMENDMENT.—Section
11 2724(c) of such Act (42 U.S.C. 300gg–23(c)), as re-
12 designated by sections 1001(4) and 1563(c)(14)(B)
13 of the Patient Protection and Affordable Care Act
14 (Public Law 111–148) is amended by striking “sec-
15 tion 2704” and inserting “sections 2704 and 2729”.

16 (3) APPLICATION RULE.—For purposes of ap-
17 plying section 2729 of the Public Health Service
18 Act, as inserted by paragraph (1), to individual
19 health insurance coverage before 2014, the provi-
20 sions of such section shall be treated as also in-
21 cluded under part B of title XXVII of the Public
22 Health Service Act.

23 (b) ERISA AMENDMENTS.—

24 (1) IN GENERAL.—Subpart B of part 7 of sub-
25 title B of title I of the Employee Retirement Income

1 Security Act of 1974 is amended by adding at the
2 end the following new section:

3 **“SEC. 716. STANDARD RELATING TO COVERAGE OF MENO-**
4 **PAUSAL HORMONE REPLACEMENT THERAPY**
5 **AND ALTERNATIVE TREATMENTS FOR MENO-**
6 **PAUSAL HORMONE REPLACEMENT THERAPY.**

7 “(a) REQUIREMENTS.—

8 “(1) MENOPAUSAL HORMONE REPLACEMENT
9 THERAPY.—If a group health plan, or a health in-
10 surance issuer offering group health insurance cov-
11 erage, provides benefits for outpatient prescription
12 drugs, the plan or coverage may not exclude or re-
13 strict benefits for hormone replacement therapy for
14 treatment of menopausal symptoms.

15 “(2) ALTERNATIVE TREATMENTS FOR MENO-
16 PAUSAL HORMONE REPLACEMENT THERAPY.—If a
17 group health plan, or a health insurance issuer offer-
18 ing group health insurance coverage, provides bene-
19 fits for hormone replacement therapy for treatment
20 of menopausal symptoms, the plan or coverage may
21 not exclude or restrict benefits for an alternative
22 therapy for hormone replacement therapy for treat-
23 ment of menopausal symptoms if—

1 “(A) the therapy is recommended by a
2 health care provider who is licensed, accredited,
3 or certified under State law;

4 “(B) it has been proven safe and effective
5 in peer-reviewed scientific studies; and

6 “(C) it is administered only after the
7 health care provider obtains the informed con-
8 sent of the patient to receive it.

9 “(b) NOTICE UNDER GROUP HEALTH PLAN.—The
10 imposition of the requirement of this section shall be treat-
11 ed as a material modification in the terms of the plan de-
12 scribed in the last sentence of section 102(a), for purposes
13 of assuring notice of such requirements under the plan;
14 except that the summary description required to be pro-
15 vided under the fourth sentence of section 104(b)(1) with
16 respect to such modification shall be provided by not later
17 than 60 days after the first day of the first plan year in
18 which such requirement applies.”.

19 (2) CONFORMING AMENDMENTS.—

20 (A) Section 731(c) of such Act (29 U.S.C.
21 1191(c)) is amended by striking “section 711”
22 and inserting “sections 711 and 716”.

23 (B) Section 732(a) of such Act (29 U.S.C.
24 1191a(a)) is amended by striking “section 711”
25 and inserting “sections 711 and 716”.

1 (C) The table of contents in section 1 of
 2 such Act is amended by inserting after the item
 3 relating to section 714 the following new item:

“Sec. 716. Standard relating to coverage of menopausal hormone replacement therapy and alternative treatments for menopausal hormone replacement therapy.”.

4 (c) INTERNAL REVENUE CODE AMENDMENTS.—

5 (1) IN GENERAL.—Subchapter B of chapter
 6 100 of the Internal Revenue Code of 1986 is amend-
 7 ed by adding at the end the following:

8 **“SEC. 9816. STANDARD RELATING TO COVERAGE OF MENO-**
 9 **PAUSAL HORMONE REPLACEMENT THERAPY**
 10 **AND ALTERNATIVE TREATMENTS FOR MENO-**
 11 **PAUSAL HORMONE REPLACEMENT THERAPY.**

12 “(a) MENOPAUSAL HORMONE REPLACEMENT THER-
 13 APY.—If a group health plan provides benefits for out-
 14 patient prescription drugs, the plan may not exclude or
 15 restrict benefits for hormone replacement therapy for
 16 treatment of menopausal symptoms.

17 “(b) ALTERNATIVE TREATMENTS FOR MENOPAUSAL
 18 HORMONE REPLACEMENT THERAPY.—If a group health
 19 plan provides benefits for hormone replacement therapy
 20 for treatment of menopausal symptoms, the plan may not
 21 exclude or restrict benefits for an alternative therapy for
 22 hormone replacement therapy for treatment of meno-
 23 pausal symptoms if—

1 “(1) the therapy is recommended by a health
2 care provider who is licensed, accredited, or certified
3 under State law;

4 “(2) it has been proven safe and effective in
5 peer-reviewed scientific studies; and

6 “(3) it is administered only after the health
7 care provider obtains the informed consent of the
8 patient to receive it.”

9 (2) CONFORMING AMENDMENTS.—

10 (A) Section 4980D(d)(1) of such Code is
11 amended by striking “section 9811” and insert-
12 ing “sections 9811 and 9816”.

13 (B) The table of sections for subchapter B
14 of chapter 100 of such Code is amended by
15 adding at the end the following new item:

 “Sec. 9816. Standard relating to coverage of menopausal hormone replacement
 therapy and alternative treatments for menopausal hormone re-
 placement therapy.”

16 (d) COORDINATION OF ADMINISTRATION.—The Sec-
17 retary of Labor, the Secretary of the Treasury, and the
18 Secretary of Health and Human Services shall ensure,
19 through the execution of an interagency memorandum of
20 understanding among such Secretaries, that—

21 (1) regulations, rulings, and interpretations
22 issued by such Secretaries relating to the same mat-
23 ter over which two or more such Secretaries have re-
24 sponsibility under the provisions of this section (and

1 the amendments made thereby) are administered so
2 as to have the same effect at all times; and

3 (2) coordination of policies relating to enforcing
4 the same requirements through such Secretaries in
5 order to have a coordinated enforcement strategy
6 that avoids duplication of enforcement efforts and
7 assigns priorities in enforcement.

8 (e) EFFECTIVE DATE.—The amendments made by
9 subsections (b) and (c) shall apply with respect to group
10 health plans for plan years beginning on or after the date
11 of the enactment of this Act.

12 **SEC. 6. COVERAGE OF MENOPAUSAL HORMONE REPLACE-**
13 **MENT THERAPY AND ALTERNATIVE TREAT-**
14 **MENTS FOR MENOPAUSAL HORMONE RE-**
15 **PLACEMENT THERAPY UNDER FEHBP.**

16 (a) IN GENERAL.—Section 8902 of title 5, United
17 States Code, is amended by adding at the end the fol-
18 lowing new subsection:

19 “(p)(1) If a contract or plan provides benefits for out-
20 patient prescription drugs, the contract or plan may not
21 exclude or restrict benefits for hormone replacement ther-
22 apy for treatment of menopausal symptoms.

23 “(2) If a contract or plan provides benefits for hor-
24 mone replacement therapy for treatment of menopausal
25 symptoms, the contract or plan may not exclude or restrict

1 benefits for an alternative therapy for hormone replace-
2 ment therapy for treatment of menopausal symptoms if—

3 “(A) the therapy is recommended by a health
4 care provider who is licensed, accredited, or certified
5 under State law;

6 “(B) it has been proven safe and effective in
7 peer-reviewed scientific studies; and

8 “(C) it is administered only after the health
9 care provider obtains the informed consent of the
10 patient to receive it.”.

11 (b) EFFECTIVE DATE.—The amendment made by
12 this section shall apply with respect to contracts made and
13 plans approved on or after the date of the enactment of
14 this Act.

15 **SEC. 7. COVERAGE OF ALTERNATIVE TREATMENTS FOR**
16 **MENOPAUSAL HORMONE REPLACEMENT**
17 **THERAPY UNDER DEPARTMENT OF VET-**
18 **ERANS AFFAIRS HEALTH CARE SYSTEM.**

19 (a) IN GENERAL.—Section 1701(6) of title 38,
20 United States Code, is amended by adding at the end the
21 following new subparagraph:

22 “(H) An alternative therapy for hormone
23 replacement therapy for treatment of meno-
24 pausal symptoms if the therapy is recommended
25 by a health care provider who is licensed, ac-

1 credited, or certified under State law, if the
2 therapy has been proven safe and effective in
3 peer-reviewed scientific studies, and if it is ad-
4 ministered only after the health care provider
5 obtains the informed consent of the patient to
6 receive it.”.

7 (b) EFFECTIVE DATE.—The amendment made by
8 subsection (a) shall apply to therapies furnished on or
9 after the date of the enactment of this Act.

○