

111TH CONGRESS
1ST SESSION

H. R. 584

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 15, 2009

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 Labor, 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 2009”.

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 alternative treatments for menopausal hormone replacement therapy.
- Sec. 4. Medicaid coverage of alternative treatments for menopausal hormone replacement 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 system.

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 (DD);

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

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

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

1 (B) by striking “through (24)” and insert-
2 ing “through (28)”.

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 (27)

8 (2) by redesignating paragraph (28) as para-
9 graph (29); and

10 (3) by inserting after paragraph (27) the fol-
11 lowing new paragraph:

12 “(28) 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) GROUP HEALTH PLANS.—

8 (1) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—

10 (A) IN GENERAL.—Subpart 2 of part A of
11 title XXVII of the Public Health Service Act is
12 amended by adding at the end the following
13 new section:

14 **“SEC. 2708. 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 health insurance coverage, provides benefits for outpatient prescription drugs, the plan or coverage may not exclude or restrict benefits for hormone replacement therapy for
20 treatment of menopausal symptoms.
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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 health insurance coverage, provides bene-
5 fits for hormone replacement therapy for treatment
6 of menopausal symptoms, the plan or coverage may
7 not exclude or restrict benefits for an alternative
8 therapy for hormone replacement therapy for treat-
9 ment 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
20 714(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.”.

23 (B) CONFORMING AMENDMENT.—Section
24 2723(c) of such Act (42 U.S.C. 300gg–23(c)) is

1 amended by striking “section 2704” and insert-
2 ing “sections 2704 and 2708”.

3 (2) ERISA AMENDMENTS.—

4 (A) IN GENERAL.—Subpart B of part 7 of
5 subtitle B of title I of the Employee Retirement
6 Income Security Act of 1974 is amended by
7 adding at the end the following new section:

8 **“SEC. 715. STANDARD RELATING TO COVERAGE OF MENO-**
9 **PAUSAL HORMONE REPLACEMENT THERAPY**
10 **AND ALTERNATIVE TREATMENTS FOR MENO-**
11 **PAUSAL HORMONE REPLACEMENT THERAPY.**

12 **“(a) REQUIREMENTS.—**

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

20 **“(2) ALTERNATIVE TREATMENTS FOR MENO-**
21 **PAUSAL HORMONE REPLACEMENT THERAPY.—**If a
22 group health plan, or a health insurance issuer offer-
23 ing group health insurance coverage, provides bene-
24 fits for hormone replacement therapy for treatment
25 of menopausal symptoms, the plan or coverage may

1 not exclude or restrict benefits for an alternative
2 therapy for hormone replacement therapy for treat-
3 ment of menopausal symptoms if—

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

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

9 “(C) it is administered only after the
10 health care provider obtains the informed con-
11 sent of the patient to receive it.

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

22 (B) CONFORMING AMENDMENTS.—

23 (i) Section 731(c) of such Act (29 U.S.C.
24 1191(c)) is amended by striking “section 711”
25 and inserting “sections 711 and 715”.

1 (ii) Section 732(a) of such Act (29 U.S.C.
 2 1191a(a)) is amended by striking “section 711”
 3 and inserting “sections 711 and 715”.

4 (iii) The table of contents in section 1 of
 5 such Act is amended by inserting after the item
 6 relating to section 714 the following new item:

“Sec. 715. Standard relating to coverage of menopausal hormone replacement
 therapy and alternative treatments for menopausal hormone re-
 placement therapy.”.

7 (3) INTERNAL REVENUE CODE AMEND-
 8 MENTS.—

9 (A) IN GENERAL.—Subchapter B of chap-
 10 ter 100 of the Internal Revenue Code of 1986
 11 is amended by adding at the end the following:

12 **“SEC. 9813. STANDARD RELATING TO COVERAGE OF MENO-**
 13 **PAUSAL HORMONE REPLACEMENT THERAPY**
 14 **AND ALTERNATIVE TREATMENTS FOR MENO-**
 15 **PAUSAL HORMONE REPLACEMENT THERAPY.**

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

21 “(b) ALTERNATIVE TREATMENTS FOR MENOPAUSAL
 22 HORMONE REPLACEMENT THERAPY.—If a group health
 23 plan provides benefits for hormone replacement therapy
 24 for treatment of menopausal symptoms, the plan may not

1 exclude or restrict benefits for an alternative therapy for
2 hormone replacement therapy for treatment of meno-
3 pausal symptoms if—

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

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

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

12 (A) CONFORMING AMENDMENTS.—

13 (i) Section 4980D(d)(1) of such Code
14 is amended by striking “section 9811” and
15 inserting “sections 9811 and 9813”.

16 (ii) The table of sections for sub-
17 chapter B of chapter 100 of such Code is
18 amended by adding at the end the fol-
19 lowing new item:

“Sec. 9813. Standard relating to coverage of menopausal hormone replacement
therapy and alternative treatments for menopausal hormone re-
placement therapy.”

20 (4) EFFECTIVE DATE.—The amendments made
21 by this subsection shall apply with respect to group
22 health plans for plan years beginning on or after the
23 date of the enactment of this Act.

24 (b) INDIVIDUAL HEALTH INSURANCE.—

1 (1) IN GENERAL.—Part B of title XXVII of the
2 Public Health Service Act is amended by inserting
3 after section 2753 the following new section:

4 **“SEC. 2754. STANDARD RELATING TO COVERAGE OF MENO-**
5 **PAUSAL HORMONE REPLACEMENT THERAPY**
6 **AND ALTERNATIVE TREATMENTS FOR MENO-**
7 **PAUSAL HORMONE REPLACEMENT THERAPY.**

8 “(a) IN GENERAL.—The provisions of section
9 2708(a) shall apply to health insurance coverage offered
10 by a health insurance issuer in the individual market in
11 the same manner as they apply to health insurance cov-
12 erage offered by a health insurance issuer in connection
13 with a group health plan in the small or large group mar-
14 ket.

15 “(b) NOTICE.—A health insurance issuer under this
16 part shall comply with the notice requirement under sec-
17 tion 715(b) of the Employee Retirement Income Security
18 Act of 1974 with respect to the requirements referred to
19 in subsection (a) as if such section applied to such issuer
20 and such issuer were a group health plan.”.

21 (2) CONFORMING AMENDMENT.—Section
22 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2))
23 is amended by striking “section 2751” and inserting
24 “sections 2751 and 2754”.

1 (3) EFFECTIVE DATE.—The amendments made
2 by this subsection shall apply with respect to thera-
3 pies furnished on or after the date of the enactment
4 of this Act.

5 (c) COORDINATION OF ADMINISTRATION.—The Sec-
6 retary of Labor, the Secretary of the Treasury, and the
7 Secretary of Health and Human Services shall ensure,
8 through the execution of an interagency memorandum of
9 understanding among such Secretaries, that—

10 (1) regulations, rulings, and interpretations
11 issued by such Secretaries relating to the same mat-
12 ter over which two or more such Secretaries have re-
13 sponsibility under the provisions of this section (and
14 the amendments made thereby) are administered so
15 as to have the same effect at all times; and

16 (2) coordination of policies relating to enforcing
17 the same requirements through such Secretaries in
18 order to have a coordinated enforcement strategy
19 that avoids duplication of enforcement efforts and
20 assigns priorities in enforcement.

1 **SEC. 6. COVERAGE OF MENOPAUSAL HORMONE REPLACEMENT THERAPY AND ALTERNATIVE TREATMENTS FOR MENOPAUSAL HORMONE REPLACEMENT THERAPY UNDER FEHBP.**

5 (a) IN GENERAL.—Section 8902 of title 5, United
6 States Code, is amended by adding at the end the following new subsection:

8 “(p)(1) If a contract or plan provides benefits for out-patient prescription drugs, the contract or plan may not
9 exclude or restrict benefits for hormone replacement therapy for treatment of menopausal symptoms.

12 “(2) If a contract or plan provides benefits for hormone replacement therapy for treatment of menopausal
13 symptoms, the contract or plan may not exclude or restrict
14 benefits for an alternative therapy for hormone replacement therapy for treatment of menopausal symptoms if—

17 “(A) the therapy is recommended by a health
18 care provider who is licensed, accredited, or certified
19 under State law;

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

22 “(C) it is administered only after the health
23 care provider obtains the informed consent of the
24 patient to receive it.”.

25 (b) EFFECTIVE DATE.—The amendment made by
26 this section shall apply with respect to contracts made and

1 plans approved on or after the date of the enactment of
2 this Act.

3 **SEC. 7. COVERAGE OF ALTERNATIVE TREATMENTS FOR**
4 **MENOPAUSAL HORMONE REPLACEMENT**
5 **THERAPY UNDER DEPARTMENT OF VET-**
6 **ERANS AFFAIRS HEALTH CARE SYSTEM.**

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

10 “(H) An alternative therapy for hormone re-
11 placement therapy for treatment of menopausal
12 symptoms if the therapy is recommended by a health
13 care provider who is licensed, accredited, or certified
14 under State law, if the therapy has been proven safe
15 and effective in peer-reviewed scientific studies, and
16 if it is administered only after the health care pro-
17 vider obtains the informed consent of the patient to
18 receive it.”.

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

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