

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.

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## 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

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## 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 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 (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           “(ii) an alternative therapy for hormone re-  
2           placement therapy for treatment of menopausal  
3           symptoms if the therapy is recommended by a health  
4           care provider who is licensed, accredited, or certified  
5           under State law, if it has been proven safe and effec-  
6           tive in peer-reviewed scientific studies, and if it is  
7           administered only after the health care provider ob-  
8           tains the informed consent of the patient to receive  
9           it;”.

10          (b) EFFECTIVE DATE.—The amendments made by  
11          subsection (a) shall apply to therapies furnished on or  
12          after the date of the enactment of this Act.

13          **SEC. 4. MEDICAID COVERAGE OF ALTERNATIVE TREAT-**  
14                                   **MENTS FOR MENOPAUSAL HORMONE RE-**  
15                                   **PLACEMENT THERAPY.**

16          (a) REQUIREMENT FOR COVERAGE.—Section  
17          1902(a)(10) of the Social Security Act (42 U.S.C.  
18          1396a(a)(10)) is amended—

19                   (1) in subparagraph (A) in the matter before  
20                   clause (i), by striking “and (28)” and inserting “,  
21                   (28), and (29)”; and

22                   (2) in subparagraph (C)(iv)—

23                                   (A) by striking “and (17)” and inserting  
24                                   “,(17), and (29)”; 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 Pro-  
 12 tection and Affordable Care Act (Public Law 111–  
 13 148), 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.

○