

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1410

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

MARCH 17, 2005

Ms. LEE (for herself, Mr. PAYNE, and Mr. OWENS) 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, 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”.

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) 50 million women in the United States suf-  
10 fer from symptoms or conditions related to meno-  
11 pause, including osteoporosis, hot flashes, heart dis-  
12 ease, and depression.

13 (2) The Women’s Health Initiative terminated  
14 its study on the synthetic version of hormone re-  
15 placement therapy (HRT) three years early due to  
16 findings that the combination of estrogen and pro-  
17 gesterin increases the risk of heart disease, stroke,  
18 blood clots, and breast cancer.

1           (3) Only 35 percent of women in the United  
2 States who are undergoing menopause take pre-  
3 scribed synthetic HRT for treatment of menopausal  
4 symptoms.

5           (4) Natural estrogen and progestin, which may  
6 not be available by prescription, could be useful in  
7 treating menopause symptoms and related condi-  
8 tions.

9           (5) 33 percent of women in the United States  
10 who are undergoing menopause routinely use alter-  
11 native treatments for menopausal symptoms, such as  
12 Soy, Black Cohosh, Chasteberry, Pro-Gest, Hops,  
13 Red Clover, Dong Quai, Evening Primose Oil, Vita-  
14 min E, Flax Seed Oil, Ginseng, and natural DHEA.

15           (6) Women deserve relief from ailments relating  
16 to menopause.

17           (7) Government insurance programs such as  
18 medicare, medicaid, the Federal Employees Health  
19 Benefits Program (FEHBP), and the Department  
20 of Veterans' Affairs do not cover non-prescription al-  
21 ternative HRT treatments.

22           (8) Most private insurance does not cover non-  
23 prescription alternative HRT treatments.

1 **SEC. 3. MEDICARE COVERAGE OF MENOPAUSAL HORMONE**  
2 **REPLACEMENT THERAPY AND ALTERNATIVE**  
3 **TREATMENTS FOR MENOPAUSAL HORMONE**  
4 **REPLACEMENT THERAPY.**

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

7 (1) by striking “and” at the end of subpara-  
8 graph (Y);

9 (2) by adding “and” at the end of subpara-  
10 graph (Z); and

11 (3) by adding at the end the following new sub-  
12 paragraph:

13 “(AA)(i) hormone replacement therapy for  
14 treatment of menopausal symptoms and (ii) an al-  
15 ternative therapy for hormone replacement therapy  
16 for treatment of menopausal symptoms if the ther-  
17 apy is recommended by a health care provider who  
18 is licensed, accredited, or certified under State law,  
19 if it has been proven safe and effective in peer-re-  
20 viewed scientific studies, and if it is administered  
21 only after the health care provider obtains the in-  
22 formed consent of the patient to receive it;”.

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

1 **SEC. 4. MEDICAID COVERAGE OF ALTERNATIVE TREAT-**  
2 **MENTS FOR MENOPAUSAL HORMONE RE-**  
3 **PLACEMENT THERAPY.**

4 (a) **REQUIREMENT FOR COVERAGE.**—Section  
5 1902(a)(10) of the Social Security Act (42 U.S.C.  
6 1396a(a)(10)) is amended—

7 (1) in subparagraph (A) in the matter before  
8 clause (i), by striking “and (21)” and inserting “,  
9 (21), and (27)”;

10 (2) in subparagraph (C)(iv)—

11 (A) by striking “and (17)” and inserting  
12 “, (17), and (27)”;

13 (B) by striking “through (24)” and insert-  
14 ing “through (28)”.

15 (b) **DESCRIPTION OF COVERED THERAPIES.**—Sec-  
16 tion 1905(a) of such Act (42 U.S.C. 1396d(a)) is amend-  
17 ed—

18 (1) by redesignating paragraph (28) as para-  
19 graph (29); and

20 (2) by inserting after paragraph (27) the fol-  
21 lowing new paragraph:

22 “(28) an alternative therapy for hormone re-  
23 placement therapy for treatment of menopausal  
24 symptoms if the therapy is recommended by a health  
25 care provider who is licensed, accredited, or certified  
26 under State law, if it has been proven safe and effec-

1       tive in peer-reviewed scientific studies, and if it is  
 2       administered only after the health care provider ob-  
 3       tains the informed consent of the patient to receive  
 4       it; and”.

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

10 **SEC. 5. COVERAGE OF MENOPAUSAL HORMONE REPLACE-**  
 11 **MENT THERAPY AND ALTERNATIVE TREAT-**  
 12 **MENTS FOR MENOPAUSAL HORMONE RE-**  
 13 **PLACEMENT THERAPY UNDER GROUP**  
 14 **HEALTH PLANS AND INDIVIDUAL HEALTH IN-**  
 15 **SURANCE COVERAGE.**

16       (a) GROUP HEALTH PLANS.—

17       (1) PUBLIC HEALTH SERVICE ACT AMEND-  
 18       MENTS.—(A) Subpart 2 of part A of title XXVII of  
 19       the Public Health Service Act is amended by adding  
 20       at the end the following new section:

21 **“SEC. 2707. STANDARD RELATING TO COVERAGE OF MENO-**  
 22 **PAUSAL HORMONE REPLACEMENT THERAPY**  
 23 **AND ALTERNATIVE TREATMENTS FOR MENO-**  
 24 **PAUSAL HORMONE REPLACEMENT THERAPY.**

25       “(a) REQUIREMENTS.—

1           “(1) MENOPAUSAL HORMONE REPLACEMENT  
2           THERAPY.—If a group health plan, or a health in-  
3           surance issuer offering group health insurance cov-  
4           erage, provides benefits for outpatient prescription  
5           drugs, the plan or coverage may not exclude or re-  
6           strict benefits for hormone replacement therapy for  
7           treatment of menopausal symptoms.

8           “(2) ALTERNATIVE TREATMENTS FOR MENO-  
9           PAUSAL HORMONE REPLACEMENT THERAPY.—If a  
10          group health plan, or a health insurance issuer offer-  
11          ing group health insurance coverage, provides bene-  
12          fits for hormone replacement therapy for treatment  
13          of menopausal symptoms, the plan or coverage may  
14          not exclude or restrict benefits for an alternative  
15          therapy for hormone replacement therapy for treat-  
16          ment of menopausal symptoms if—

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

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

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

1 “(b) NOTICE.—A group health plan under this part  
2 shall comply with the notice requirement under section  
3 714(b) of the Employee Retirement Income Security Act  
4 of 1974 with respect to the requirements of this section  
5 as if such section applied to such plan.”.

6 (B) Section 2723(c) of such Act (42 U.S.C.  
7 300gg-23(c)) is amended by striking “section 2704”  
8 and inserting “sections 2704 and 2707”.

9 (2) ERISA AMENDMENTS.—(A) Subpart B of  
10 part 7 of subtitle B of title I of the Employee Re-  
11 tirement Income Security Act of 1974 is amended by  
12 adding at the end the following new section:

13 **“SEC. 714. STANDARD RELATING TO COVERAGE OF MENO-**  
14 **PAUSAL HORMONE REPLACEMENT THERAPY**  
15 **AND ALTERNATIVE TREATMENTS FOR MENO-**  
16 **PAUSAL HORMONE REPLACEMENT THERAPY.**

17 “(a) REQUIREMENTS.—

18 “(1) MENOPAUSAL HORMONE REPLACEMENT  
19 THERAPY.—If a group health plan, or a health in-  
20 surance issuer offering group health insurance cov-  
21 erage, provides benefits for outpatient prescription  
22 drugs, the plan or coverage may not exclude or re-  
23 strict benefits for hormone replacement therapy for  
24 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 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 UNDER GROUP HEALTH PLAN.—The  
19           imposition of the requirement of this section shall be treat-  
20           ed as a material modification in the terms of the plan de-  
21           scribed in section 102(a)(1), for purposes of assuring no-  
22           tice of such requirements under the plan; except that the  
23           summary description required to be provided under the  
24           last sentence of section 104(b)(1) with respect to such  
25           modification shall be provided by not later than 60 days

1 after the first day of the first plan year in which such  
2 requirement apply.”.

3 (B) Section 731(e) of such Act (29 U.S.C.  
4 1191(e)) is amended by striking “section 711” and  
5 inserting “sections 711 and 714”.

6 (C) Section 732(a) of such Act (29 U.S.C.  
7 1191a(a)) is amended by striking “section 711” and  
8 inserting “sections 711 and 714”.

9 (D) The table of contents in section 1 of such  
10 Act is amended by inserting after the item relating  
11 to section 713 the following new item:

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

12 (3) INTERNAL REVENUE CODE AMEND-  
13 MENTS.—

14 (A) IN GENERAL.—Subchapter B of chap-  
15 ter 100 of the Internal Revenue Code of 1986  
16 is amended—

17 (i) in the table of sections, by insert-  
18 ing after the item relating to section 9812  
19 the following new item:

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

20 ; and

21 (ii) by inserting after section 9812 the  
22 following:

1 **“SEC. 9813. STANDARD RELATING TO COVERAGE OF MENO-**  
2 **PAUSAL HORMONE REPLACEMENT THERAPY**  
3 **AND ALTERNATIVE TREATMENTS FOR MENO-**  
4 **PAUSAL HORMONE REPLACEMENT THERAPY.**

5 “(a) MENOPAUSAL HORMONE REPLACEMENT THER-  
6 APY.—If a group health plan provides benefits for out-  
7 patient prescription drugs, the plan may not exclude or  
8 restrict benefits for hormone replacement therapy for  
9 treatment of menopausal symptoms.

10 “(b) ALTERNATIVE TREATMENTS FOR MENOPAUSAL  
11 HORMONE REPLACEMENT THERAPY.—If a group health  
12 plan provides benefits for hormone replacement therapy  
13 for treatment of menopausal symptoms, the plan may not  
14 exclude or restrict benefits for an alternative therapy for  
15 hormone replacement therapy for treatment of meno-  
16 pausal symptoms if—

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

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

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

25 (B) CONFORMING AMENDMENT.—Section  
26 4980D(d)(1) of such Code is amended by strik-

1           ing “section 9811” and inserting “sections  
2           9811 and 9813”.

3           (b) INDIVIDUAL HEALTH INSURANCE.—(1) Part B  
4 of title XXVII of the Public Health Service Act is amend-  
5 ed by inserting after section 2752 the following new sec-  
6 tion:

7           **“SEC. 2753. STANDARD RELATING TO COVERAGE OF MENO-  
8                           PAUSAL HORMONE REPLACEMENT THERAPY  
9                           AND ALTERNATIVE TREATMENTS FOR MENO-  
10                          PAUSAL HORMONE REPLACEMENT THERAPY.**

11           “(a) IN GENERAL.—The provisions of section  
12 2707(a) shall apply to health insurance coverage offered  
13 by a health insurance issuer in the individual market in  
14 the same manner as they apply to health insurance cov-  
15 erage offered by a health insurance issuer in connection  
16 with a group health plan in the small or large group mar-  
17 ket.

18           “(b) NOTICE.—A health insurance issuer under this  
19 part shall comply with the notice requirement under sec-  
20 tion 714(b) of the Employee Retirement Income Security  
21 Act of 1974 with respect to the requirements referred to  
22 in subsection (a) as if such section applied to such issuer  
23 and such issuer were a group health plan.”.

1       (2) Section 2762(b)(2) of such Act (42 U.S.C.  
2 300gg-62(b)(2)) is amended by striking “section 2751”  
3 and inserting “sections 2751 and 2753”.

4       (c) EFFECTIVE DATE.—The amendments made by  
5 this section shall apply with respect to therapies furnished  
6 on or after the date of the enactment of this Act.

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

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

18           (2) coordination of policies relating to enforcing  
19 the same requirements through such Secretaries in  
20 order to have a coordinated enforcement strategy  
21 that avoids duplication of enforcement efforts and  
22 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 “(G) 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.

○