### 110TH CONGRESS 1ST SESSION

# H. R. 1812

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 29, 2007

Ms. Lee (for herself, Mr. Payne, Mr. Rush, Ms. Woolsey, Mr. Cohen, Mr. Grijalva, and Mr. Jefferson) 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,

### 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 2007".
- 5 (b) 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
- its study of hormone therapy three years early be-
- cause of findings that the combination of estrogen
- and progestin increases the risk of heart disease,
- stroke, blood clots, and breast cancer, and that es-
- trogen alone increases the risk of stroke and, in
- women over 65 years of age, increases the risk of de-
- mentia.
- 17 (2) The National Institutes of Health has stat-
- ed unequivocally that while menopause is a natural

- process in women's lives, some women at midlife experience hot flashes, night sweats, vaginal dryness, sleep disturbances, and mood disturbances that disrupt quality of life. Women who have had menopause induced by surgery, chemotherapy, or radiation are more likely to experience these symptoms.
  - (3) Women deserve relief from menopause-related symptoms.
  - (4) The National Institutes of Health have stated that while estrogen and progestin have been found to be effective remedies for these symptoms, these remedies are not without risk.
  - (5) Concerned about these risks, women seek alternative types of treatments for symptoms that disrupt quality of life, such as hot flashes, night sweats, vaginal dryness, sleep disturbances, and mood disturbances.
  - (6) The National Institutes of Health have found that although there are many alternatives to synthetic hormones available, including bio-identical or "natural" hormones as well as herbal remedies and food supplements, the effectiveness and long-term safety of these products need to be rigorously 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.
	REPLACEMENT THERAPY.  (a) In General.—Section 1861(s)(2) of the Social
15	
15 16	(a) In General.—Section 1861(s)(2) of the Social
15 16 17	(a) In General.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—
15 16 17 18	<ul> <li>(a) In General.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—</li> <li>(1) by striking "and" at the end of subpara-</li> </ul>
15 16 17 18	<ul> <li>(a) In General.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—</li> <li>(1) by striking "and" at the end of subparagraph (Z);</li> </ul>
15 16 17 18 19 20	<ul> <li>(a) In General.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—</li> <li>(1) by striking "and" at the end of subparagraph (Z);</li> <li>(2) by adding "and" at the end of subparagraph.</li> </ul>
15 16 17 18 19 20 21	<ul> <li>(a) In General.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—</li> <li>(1) by striking "and" at the end of subparagraph (Z);</li> <li>(2) by adding "and" at the end of subparagraph (AA); and</li> </ul>
15 16 17 18 19 20 21	<ul> <li>(a) In General.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended— <ul> <li>(1) by striking "and" at the end of subparagraph (Z);</li> <li>(2) by adding "and" at the end of subparagraph (AA); and</li> <li>(3) by adding at the end the following new sub-</li> </ul> </li> </ul>

1	ternative therapy for hormone replacement therapy
2	for treatment of menopausal symptoms if the ther-
3	apy is recommended by a health care provider who
4	is licensed, accredited, or certified under State law,
5	if it has been proven safe and effective in peer-re-
6	viewed scientific studies, and if it is administered
7	only after the health care provider obtains the in-
8	formed consent of the patient to receive it;".
9	(b) Effective Date.—The amendments made by
10	subsection (a) shall apply to therapies furnished on or
11	after the date of the enactment of this Act.
12	SEC. 4. MEDICAID COVERAGE OF ALTERNATIVE TREAT-
13	MENTS FOR MENOPAUSAL HORMONE RE-
13 14	MENTS FOR MENOPAUSAL HORMONE RE- PLACEMENT THERAPY.
14	PLACEMENT THERAPY.
14 15	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section
14 15 16	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section  1902(a)(10) of the Social Security Act (42 U.S.C.
14 15 16 17	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section  1902(a)(10) of the Social Security Act (42 U.S.C.  1396a(a)(10)) is amended—
14 15 16 17	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section  1902(a)(10) of the Social Security Act (42 U.S.C.  1396a(a)(10)) is amended—  (1) in subparagraph (A) in the matter before
14 15 16 17 18	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended—  (1) in subparagraph (A) in the matter before clause (i), by striking "and (21)" and inserting ",
14 15 16 17 18 19 20	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended—  (1) in subparagraph (A) in the matter before clause (i), by striking "and (21)" and inserting ", (21), and (28)"; and
14 15 16 17 18 19 20 21	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended—  (1) in subparagraph (A) in the matter before clause (i), by striking "and (21)" and inserting ", (21), and (28)"; and  (2) in subparagraph (C)(iv)—
14 15 16 17 18 19 20 21	PLACEMENT THERAPY.  (a) REQUIREMENT FOR COVERAGE.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended—  (1) in subparagraph (A) in the matter before clause (i), by striking "and (21)" and inserting ", (21), and (28)"; and  (2) in subparagraph (C)(iv)—  (A) by striking "and (17)" and inserting

- 1 (b) Description of Covered Therapies.—Sec-
- 2 tion 1905(a) of such Act (42 U.S.C. 1396d(a)) is amend-
- 3 ed—
- 4 (1) by striking "and" at the end of paragraph
- 5 (27);
- 6 (2) by redesignating paragraph (28) as para-
- 7 graph (29); and
- 8 (3) by inserting after paragraph (27) the fol-
- 9 lowing new paragraph:
- 10 "(28) an alternative therapy for hormone re-
- 11 placement therapy for treatment of menopausal
- symptoms if the therapy is recommended by a health
- care provider who is licensed, accredited, or certified
- under State law, if it has been proven safe and effec-
- tive in peer-reviewed scientific studies, and if it is
- administered only after the health care provider ob-
- tains the informed consent of the patient to receive
- 18 it; and".
- 19 (c) Effective Date.—The amendments made by
- 20 this section apply to therapies furnished on or after the
- 21 date of the enactment of this Act, without regard to
- 22 whether or not final regulations to carry out such amend-
- 23 ments have been promulgated by such date.

1	SEC. 5. COVERAGE OF MENOPAUSAL HORMONE REPLACE-
2	MENT THERAPY AND ALTERNATIVE TREAT-
3	MENTS FOR MENOPAUSAL HORMONE RE-
4	PLACEMENT THERAPY UNDER GROUP
5	HEALTH PLANS AND INDIVIDUAL HEALTH IN-
6	SURANCE COVERAGE.
7	(a) Group Health Plans.—
8	(1) Public Health Service act amend-
9	MENTS.—
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. 2707. STANDARD RELATING TO COVERAGE OF MENO-
15	PAUSAL HORMONE REPLACEMENT THERAPY
16	AND ALTERNATIVE TREATMENTS FOR MENO-
17	PAUSAL HORMONE REPLACEMENT THERAPY.
18	"(a) Requirements.—
19	"(1) Menopausal Hormone Replacement
20	THERAPY.—If a group health plan, or a health in-
21	surance issuer offering group health insurance cov-
22	erage, provides benefits for outpatient prescription
23	drugs, the plan or coverage may not exclude or re-
24	strict benefits for hormone replacement therapy for
25	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.—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 2707".
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. 714. 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 714".

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 714".
4	(iii) The table of contents in section 1 of
5	such Act is amended by inserting after the item
6	relating to section 713 the following new item:
	"Sec. 714. Standard relating to coverage of menopausal hormone replacement therapy and alternative treatments for menopausal hormone replacement 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-
12 13	"SEC. 9813. STANDARD RELATING TO COVERAGE OF MENO- PAUSAL HORMONE REPLACEMENT THERAPY
13	PAUSAL HORMONE REPLACEMENT THERAPY
13 14	PAUSAL HORMONE REPLACEMENT THERAPY AND ALTERNATIVE TREATMENTS FOR MENO-
13 14 15 16	PAUSAL HORMONE REPLACEMENT THERAPY AND ALTERNATIVE TREATMENTS FOR MENO- PAUSAL HORMONE REPLACEMENT THERAPY.
13 14 15 16	PAUSAL HORMONE REPLACEMENT THERAPY  AND ALTERNATIVE TREATMENTS FOR MENO- PAUSAL HORMONE REPLACEMENT THERAPY.  "(a) MENOPAUSAL HORMONE REPLACEMENT THER-
13 14 15 16	PAUSAL HORMONE REPLACEMENT THERAPY  AND ALTERNATIVE TREATMENTS FOR MENO- PAUSAL HORMONE REPLACEMENT THERAPY.  "(a) MENOPAUSAL HORMONE REPLACEMENT THERAPY.  APY.—If a group health plan provides benefits for out-
113 114 115 116 117	PAUSAL HORMONE REPLACEMENT THERAPY  AND ALTERNATIVE TREATMENTS FOR MENO- PAUSAL HORMONE REPLACEMENT THERAPY.  "(a) MENOPAUSAL HORMONE REPLACEMENT THERAPY.  APY.—If a group health plan provides benefits for outpatient prescription drugs, the plan may not exclude or
113 114 115 116 117 118 119	PAUSAL HORMONE REPLACEMENT THERAPY  AND ALTERNATIVE TREATMENTS FOR MENO- PAUSAL HORMONE REPLACEMENT THERAPY.  "(a) MENOPAUSAL HORMONE REPLACEMENT THERAPY.—If a group health plan provides benefits for outpatient prescription drugs, the plan may not exclude or restrict benefits for hormone replacement therapy for
13 14 15 16 17 18 19 20	PAUSAL HORMONE REPLACEMENT THERAPY  AND ALTERNATIVE TREATMENTS FOR MENO- PAUSAL HORMONE REPLACEMENT THERAPY.  "(a) MENOPAUSAL HORMONE REPLACEMENT THERAPY.—If a group health plan provides benefits for outpatient prescription drugs, the plan may not exclude or restrict benefits for hormone replacement therapy for treatment of menopausal symptoms.
13 14 15 16 17 18 19 20 21	PAUSAL HORMONE REPLACEMENT THERAPY AND ALTERNATIVE TREATMENTS FOR MENO- PAUSAL HORMONE REPLACEMENT THERAPY.  "(a) MENOPAUSAL HORMONE REPLACEMENT THERAPY.—If a group health plan provides benefits for outpatient prescription drugs, the plan may not exclude or restrict benefits for hormone replacement therapy for treatment of menopausal symptoms.  "(b) ALTERNATIVE TREATMENTS FOR MENOPAUSAL

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	(B) 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 replacement 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 2752 the following new section:
4	"SEC. 2753. 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	2707(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 714(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 2753".

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

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

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1	SEC. 6. COVERAGE OF MENOPAUSAL HORMONE REPLACE-
2	MENT THERAPY AND ALTERNATIVE TREAT-
3	MENTS FOR MENOPAUSAL HORMONE RE-
4	PLACEMENT THERAPY UNDER FEHBP.
5	(a) In General.—Section 8902 of title 5, United
6	States Code, is amended by adding at the end the fol-
7	lowing new subsection:
8	"(p)(1) If a contract or plan provides benefits for out-
9	patient prescription drugs, the contract or plan may not
10	exclude or restrict benefits for hormone replacement ther-
11	apy for treatment of menopausal symptoms.
12	"(2) If a contract or plan provides benefits for hor-
13	mone replacement therapy for treatment of menopausal
14	symptoms, the contract or plan may not exclude or restrict
15	benefits for an alternative therapy for hormone replace-
16	ment 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
- symptoms if the therapy is recommended by a health
- care provider who is licensed, accredited, or certified
- under State law, if the therapy has been proven safe
- and effective in peer-reviewed scientific studies, and
- if it is administered only after the health care pro-
- 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.