

106TH CONGRESS
1ST SESSION

H. R. 3274

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to provide protection for beneficiaries of group and individual health insurance coverage, group health plans, and Medicare+Choice plans in the use of prescription drug formularies.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 9, 1999

Mr. GUTIERREZ introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, 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 amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to provide protection for beneficiaries of group and individual health insurance coverage, group health plans, and Medicare+Choice plans in the use of prescription drug formularies.

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.**

2 This Act may be cited as the “Patients’ Formulary
3 Rights Act of 1999”.

4 **SEC. 2. PATIENT PROTECTIONS AGAINST ABUSE OF**
5 **FORMULARIES FOR PRESCRIPTION DRUGS.**

6 (a) GROUP HEALTH PLANS.—

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

11 **“SEC. 2707. STANDARDS RELATING TO USE OF**
12 **FORMULARIES AND THERAPEUTIC SUBSTI-**
13 **TUTION.**

14 “(a) REQUIREMENTS ON USE OF FORMULARIES.—

15 “(1) IN GENERAL.—A group health plan, and a
16 health insurance issuer offering group health insur-
17 ance coverage, shall not use a formulary unless the
18 plan or issuer—

19 “(A) notifies participants, beneficiaries,
20 and enrollees, prior to initial enrollment or cov-
21 erage, and makes available at any time to
22 health care professionals who prescribe pre-
23 scription drugs under the plan or coverage of
24 the information described in paragraph (2);

25 “(B) notifies participants, beneficiaries,
26 enrollees, and health care providers who pre-

1 scribe covered prescription drugs under the plan
2 or coverage on a routine and annual basis of
3 any changes in (including deletions from) the
4 formulary; and

5 “(C) in the case of a participant, bene-
6 ficiary, or enrollee who is provided coverage for
7 a prescription drug at the time the drug is re-
8 moved from the formulary, to permit the partic-
9 ipant, beneficiary, or enrollee to continue to
10 have the drug prescribed for treatment of the
11 same condition for which it was previously pre-
12 scribed.

13 “(2) INFORMATION TO BE DISCLOSED.—The in-
14 formation described in this paragraph is as follows
15 (with respect to prescription drug coverage under a
16 group health plan or health insurance coverage):

17 “(A) EXTENT OF THERAPEUTIC SUBSTI-
18 TUTION.—What constitutes the practice or
19 therapeutic substitution that may be effected
20 under the plan or coverage.

21 “(B) FORMULARY.—A complete list of all
22 the prescription drugs included in the formulary
23 and any changes in the formulary and how deci-
24 sions to include drugs in the formulary are
25 made.

1 “(C) ACCESS TO NONFORMULARY
2 DRUGS.—The fact that a patient can have a
3 prescription filled as written (rather than sub-
4 ject to therapeutic substitution) if the pre-
5 scribing health care professional uses a ‘dis-
6 pense as written’ or similar endorsement.

7 “(D) PAYMENT FOR NONFORMULARY
8 DRUGS.—Whether or not the plan or coverage
9 will cover or pay for prescription drugs not in-
10 cluded in the formulary and, if it will, the ex-
11 tent of such coverage or payment.

12 “(E) COST-SHARING.—The copayments
13 and other cost-sharing that is applicable under
14 the plan or coverage for prescription drugs in-
15 cluded on the formulary and for those not in-
16 cluded on the formulary.

17 “(F) LIMITS ON PAYMENTS.—Limitations
18 on the dollar amount the plan or coverage will
19 cover for outpatient prescription drugs, includ-
20 ing any such limits on a per year, per lifetime,
21 or per diagnosis basis.

22 “(3) FORMULARY DEFINED.—For purposes of
23 this subsection, the term ‘formulary’ includes any
24 method under which a plan or issuer limits the par-
25 ticular drugs (among those that may be legally pre-

1 scribed for treatment) for which coverage is made
2 available under the plan or health insurance cov-
3 erage offered by the issuer.

4 “(b) NOTICE OF REQUIREMENT.—A group health
5 plan under this part shall comply with the notice require-
6 ment under section 714(b) of the Employee Retirement
7 Income Security Act of 1974 with respect to the require-
8 ments of this section as if such section applied to such
9 plan.

10 “(c) FORMULARY DEFINED.—For purposes of this
11 section, the term ‘formulary’ includes any method under
12 which a plan or issuer limits the particular drugs (among
13 those that may be legally prescribed for treatment) for
14 which coverage is made available under the plan or health
15 insurance coverage offered by the issuer.”.

16 (B) Section 2723(c) of such Act (42 U.S.C.
17 300gg-23(c)) is amended by striking “section 2704”
18 and inserting “sections 2704 and 2707”.

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

1 **“SEC. 714. STANDARDS RELATING TO USE OF**
2 **FORMULARIES AND THERAPEUTIC SUBSTI-**
3 **TUTION.**

4 “(a) REQUIREMENTS ON USE OF FORMULARIES.—

5 “(1) IN GENERAL.—A group health plan, and a
6 health insurance issuer offering group health insur-
7 ance coverage, shall not use a formulary unless the
8 plan or issuer—

9 “(A) notifies participants, beneficiaries,
10 and enrollees, prior to initial enrollment or cov-
11 erage, and makes available at any time to
12 health care professionals who prescribe pre-
13 scription drugs under the plan or coverage of
14 the information described in paragraph (2);

15 “(B) notifies participants, beneficiaries,
16 enrollees, and health care providers who pre-
17 scribe covered prescription drugs under the plan
18 or coverage on a routine and annual basis of
19 any changes in (including deletions from) the
20 formulary; and

21 “(C) in the case of a participant, bene-
22 ficiary, or enrollee who is provided coverage for
23 a prescription drug at the time the drug is re-
24 moved from the formulary, to permit the partic-
25 ipant, beneficiary, or enrollee to continue to
26 have the drug prescribed for treatment of the

1 same condition for which it was previously pre-
2 scribed.

3 “(2) INFORMATION.—The information de-
4 scribed in this paragraph is as follows (with respect
5 to prescription drug coverage under a group health
6 plan or health insurance coverage):

7 “(A) EXTENT OF THERAPEUTIC SUBSTI-
8 TUTION.—What constitutes the practice or
9 therapeutic substitution that may be effected
10 under the plan or coverage.

11 “(B) FORMULARY.—A complete list of all
12 the prescription drugs included in the formulary
13 and any changes in the formulary and how deci-
14 sions to include drugs in the formulary are
15 made.

16 “(C) ACCESS TO NONFORMULARY
17 DRUGS.—The fact that a patient can have a
18 prescription filled as written (rather than sub-
19 ject to therapeutic substitution) if the pre-
20 scribing health care professional uses a ‘dis-
21 pense as written’ or similar endorsement.

22 “(D) PAYMENT FOR NONFORMULARY
23 DRUGS.—Whether or not the plan or coverage
24 will cover or pay for prescription drugs not in-

1 cluded in the formulary and, if it will, the ex-
2 tent of such coverage or payment.

3 “(E) COST-SHARING.—The copayments
4 and other cost-sharing that is applicable under
5 the plan or coverage for prescription drugs in-
6 cluded on the formulary and for those not in-
7 cluded on the formulary.

8 “(F) LIMITS ON PAYMENTS.—Limitations
9 on the dollar amount the plan or coverage will
10 cover for outpatient prescription drugs, includ-
11 ing such any such limits on a per year, per life-
12 time, or per diagnosis basis.

13 “(b) NOTICE UNDER GROUP HEALTH PLAN.—The
14 imposition of the requirement of this section shall be treat-
15 ed as a material modification in the terms of the plan de-
16 scribed in section 102(a)(1), for purposes of assuring no-
17 tice of such requirements under the plan; except that the
18 summary description required to be provided under the
19 last sentence of section 104(b)(1) with respect to such
20 modification shall be provided by not later than 60 days
21 after the first day of the first plan year in which such
22 requirement apply.

23 “(c) FORMULARY DEFINED.—For purposes of this
24 section, the term ‘formulary’ includes any method under
25 which a plan or issuer limits the particular drugs (among

1 those that may be legally prescribed for treatment) for
 2 which coverage is made available under the plan or health
 3 insurance coverage offered by the issuer.”.

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

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

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

“Sec. 714. Standards relating to use of formularies and therapeutic substitution.”.

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

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

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

“Sec. 9813. Standards relating to use of formularies and therapeutic substitution.”; and

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

1 **“SEC. 9813. STANDARDS RELATING TO USE OF**
2 **FORMULARIES AND THERAPEUTIC SUBSTI-**
3 **TUTION.**

4 “(a) REQUIREMENTS ON USE OF FORMULARIES.—

5 “(1) IN GENERAL.—A group health plan shall
6 not use a formulary unless the plan or issuer—

7 “(A) notifies participants and beneficiaries,
8 prior to initial enrollment or coverage, and
9 makes available at any time to health care pro-
10 fessionals who prescribe prescription drugs
11 under the plan of the information described in
12 paragraph (2);

13 “(B) notifies participants, beneficiaries,
14 and health care providers who prescribe covered
15 prescription drugs under the plan on a routine
16 and annual basis of any changes in (including
17 deletions from) the formulary; and

18 “(C) in the case of a participant or bene-
19 ficiary who is provided coverage for a prescrip-
20 tion drug at the time the drug is removed from
21 the formulary, to permit the participant or ben-
22 eficiary to continue to have the drug prescribed
23 for treatment of the same condition for which
24 it was previously prescribed.

25 “(2) INFORMATION.—The information de-
26 scribed in this paragraph is as follows (with respect

1 to prescription drug coverage under a group health
2 plan):

3 “(A) EXTENT OF THERAPEUTIC SUBSTI-
4 TUTION.—What constitutes the practice or
5 therapeutic substitution that may be effected
6 under the plan.

7 “(B) FORMULARY.—A complete list of all
8 the prescription drugs included in the formulary
9 and any changes in the formulary and how deci-
10 sions to include drugs in the formulary are
11 made.

12 “(C) ACCESS TO NONFORMULARY
13 DRUGS.—The fact that a patient can have a
14 prescription filled as written (rather than sub-
15 ject to therapeutic substitution) if the pre-
16 scribing health care professional uses a ‘dis-
17 pense as written’ or similar endorsement.

18 “(D) PAYMENT FOR NONFORMULARY
19 DRUGS.—Whether or not the plan will cover or
20 pay for prescription drugs not included in the
21 formulary and, if it will, the extent of such cov-
22 erage or payment.

23 “(E) COST-SHARING.—The copayments
24 and other cost-sharing that is applicable under
25 the plan for prescription drugs included on the

3 “(F) LIMITS ON PAYMENTS.—Limitations
4 on the dollar amount the plan will cover for
5 outpatient prescription drugs, including such
6 any such limits on a per year, per lifetime, or
7 per diagnosis basis.

8 “(b) FORMULARY DEFINED.—For purposes of this
9 section, the term ‘formulary’ includes any method under
10 which a plan or issuer limits the particular drugs (among
11 those that may be legally prescribed for treatment) for
12 which coverage is made available under the plan.”

(B) CONFORMING AMENDMENT.—Section 4980D(d)(1) of such Code is amended by striking “section 9811” and inserting “sections 9811 and 9813”.

(b) INDIVIDUAL HEALTH INSURANCE.—(1) Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

21 “SEC. 2753. STANDARD RELATING PATIENT FREEDOM OF
22 CHOICE.

23 “(a) IN GENERAL.—The provisions of section
24 2707(a) shall apply to health insurance coverage offered
25 by a health insurance issuer in the individual market in

1 the same manner as they apply to health insurance cov-
 2 erage offered by a health insurance issuer in connection
 3 with a group health plan in the small or large group mar-
 4 ket.

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

11 (2) Section 2762(b)(2) of such Act (42 U.S.C.
 12 300gg–62(b)(2)) is amended by striking “section 2751”
 13 and inserting “sections 2751 and 2753”.

14 (c) MEDICARE+CHOICE PLANS.—Section 1852 of
 15 the Social Security Act (42 U.S.C. 1395w–22) is amended
 16 by adding at the end the following new subsection:

17 “(1) FORMULARY REQUIREMENTS.—

18 “(1) IN GENERAL.—A Medicare+Choice orga-
 19 nization shall comply with the requirements of sec-
 20 tion 2707 of the Public Health Service Act with re-
 21 spect to a Medicare+Choice plan it offers in the
 22 same manner as such requirements apply to health
 23 insurance coverage offered in connection with a
 24 group health plan.

1 “(2) CONSTRUCTION.—Nothing in paragraph
2 (1) shall be construed as superseding other require-
3 ments of this part, except to the extent the Sec-
4 retary specifically finds that such other requirements
5 are less stringent, and do not duplicate, the require-
6 ments referred to in such paragraph.”.

7 (d) EFFECTIVE DATES.—

8 (1) GROUP HEALTH PLANS AND GROUP
9 HEALTH INSURANCE COVERAGE.—Subject to para-
10 graph (4), the amendments made by subsection (a)
11 apply with respect to group health plans for plan
12 years beginning on or after January 1, 2001.

13 (2) INDIVIDUAL HEALTH INSURANCE COV-
14 ERAGE.—The amendments made by subsection (b)
15 apply with respect to health insurance coverage of-
16 fered, sold, issued, renewed, in effect, or operated in
17 the individual market on or after such date.

18 (3) MEDICARE+CHOICE PLANS.—The amend-
19 ments made by subsection (b) apply with respect to
20 Medicare+Choice plans offered on or after such
21 date.

22 (4) COLLECTIVE BARGAINING EXCEPTION.—In
23 the case of a group health plan maintained pursuant
24 to 1 or more collective bargaining agreements be-
25 tween employee representatives and 1 or more em-

1 ployers ratified before the date of enactment of this
2 Act, the amendments made subsection (a) shall not
3 apply to plan years beginning before the later of—

4 (A) the date on which the last collective
5 bargaining agreements relating to the plan ter-
6 minates (determined without regard to any ex-
7 tension thereof agreed to after the date of en-
8 actment of this Act), or

9 (B) January 1, 2001.

10 For purposes of subparagraph (A), any plan amend-
11 ment made pursuant to a collective bargaining
12 agreement relating to the plan which amends the
13 plan solely to conform to any requirement added by
14 subsection (a) shall not be treated as a termination
15 of such collective bargaining agreement.

16 (e) 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 Act (and the

1 amendments made thereby) are administered so as
2 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.

○