

116TH CONGRESS
1ST SESSION

H. R. 2279

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide an exceptions process for any medication step therapy protocol, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2019

Mr. RUIZ (for himself and Mr. WENSTRUP) introduced the following bill;
which was referred to the Committee on Education and Labor

A BILL

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide an exceptions process for any medication step therapy protocol, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe Step Act”.

1 **SEC. 2. REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**
2 **TION STEP THERAPY PROTOCOLS.**

3 (a) IN GENERAL.—The Employee Retirement Income
4 Security Act of 1974 is amended by inserting after section
5 715 of such Act (29 U.S.C. 1185d) the following new sec-
6 tion:

7 **“SEC. 716. REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**
8 **TION STEP THERAPY PROTOCOLS.**

9 “(a) IN GENERAL.—In the case of a group health
10 plan (or health insurance coverage offered in connection
11 with such a plan) that provides coverage of a prescription
12 drug pursuant to a medication step therapy protocol, the
13 plan or coverage shall—

14 “(1) implement a clear process for a participant
15 or beneficiary (or the prescribing health care pro-
16 vider) to request an exception to such medication
17 step therapy protocol; and

18 “(2) if such a request demonstrates (through
19 supporting documentation, if necessary) that any of
20 the circumstances listed in subsection (b) exists, au-
21 thorize coverage for the prescription drug without
22 regard to such medication step therapy protocol.

23 “(b) EXPEDITED APPROVAL.—The circumstances
24 warranting an exception to a medication step therapy pro-
25 tocol, pursuant to a request under subsection (a), are any
26 of the following:

1 “(1) The treatment otherwise required under
2 the protocol, or a drug or drugs in the same phar-
3 macological class or having the same mechanism of
4 action, are contraindicated or have been ineffective
5 in the treatment of the disease or condition of the
6 participant or beneficiary.

7 “(2) The treatment otherwise required under
8 the protocol is reasonably expected to be ineffective
9 based upon—

10 “(A) the known physical or mental charac-
11 teristics of the participant or beneficiary, in-
12 cluding medical history; and

13 “(B) the known characteristics of such
14 treatment.

15 “(3) The treatment otherwise required under
16 the protocol will cause or is likely to cause an ad-
17 verse reaction or other physical harm to the partici-
18 pant or beneficiary.

19 “(4) The treatment otherwise required under
20 the protocol is not in the best interest of the partici-
21 pant or beneficiary, based on medical necessity, be-
22 cause the participant or beneficiary’s use of such
23 treatment is expected to decrease the participant or
24 beneficiary’s ability—

1 “(A) to achieve or maintain reasonable and
2 safe functional ability in performing daily ac-
3 tivities or occupational responsibilities; or

4 “(B) to adhere to the treatment plan as
5 defined by the prescribing health care provider.

6 “(5) The participant or beneficiary is stable for
7 his or her disease or condition on the prescription
8 drug or drugs selected by the prescribing health care
9 provider.

10 “(c) CLEAR PROCESS.—The process required by sub-
11 section (a)(1)—

12 “(1) shall make information regarding such
13 process readily available on the website of the group
14 health plan, including—

15 “(A) the requirements for requesting an
16 exception to a medication step therapy protocol
17 pursuant to this section; and

18 “(B) any necessary forms, supporting in-
19 formation, and contact information; and

20 “(2) may not require the submission of any in-
21 formation or supporting documentation beyond what
22 is strictly necessary to determine whether any of the
23 circumstances listed in subsection (b) exists.

24 “(d) TIMING FOR GRANTING EXCEPTION.—The proc-
25 ess required by subsection (a)(1) shall provide for the dis-

1 position of requests received under such paragraph in ac-
2 cordance with the following:

3 “(1) Such a request shall be granted as quickly
4 as the disease or condition of the participant or ben-
5 eficiary requires, but no later than 3 days after the
6 day of receipt of the request.

7 “(2) For circumstances in which the applicable
8 medication step therapy protocol may seriously jeop-
9 ardize the life, health, or ability to regain maximum
10 function of the participant or beneficiary, such a re-
11 quest shall be granted—

12 “(A) on an expedited basis; and

13 “(B) no later than 24 hours after receipt
14 of such request.

15 “(e) MEDICATION STEP THERAPY PROTOCOL.—In
16 this section, the term ‘medication step therapy protocol’
17 means a protocol or program that establishes a specific
18 sequence in which prescription drugs that—

19 “(1) are for a specified disease or condition;
20 and

21 “(2) are medically necessary for a particular
22 patient,

23 are covered under a pharmacy or medical benefit by a
24 group health plan or a health insurance issuer offering
25 group or individual health insurance coverage.

1 “(f) CLARIFICATION.—This section shall apply with
2 respect to any group health plan (or health insurance cov-
3 erage offered in connection with such a plan) that provides
4 coverage of a prescription drug pursuant to a policy that
5 meets the definition of the term ‘medication step therapy
6 protocol’ in subsection (e), regardless of whether such pol-
7 icy is described by such group health plan (or health insur-
8 ance coverage) as a step therapy protocol.”.

9 (b) TECHNICAL CORRECTION; CLERICAL CHANGE.—
10 The table of contents in section 1 of the Employee Retire-
11 ment Income Security Act of 1974 (29 U.S.C. 1001 et
12 seq.) is amended by inserting after the item relating to
13 section 714 the following new items:

“Sec. 715. Additional market reforms.

“Sec. 716. Required exceptions process for medication step therapy protocols.”.

14 (c) EFFECTIVE DATE.—

15 (1) IN GENERAL.—The amendment made by
16 subsection (a) applies to plan years beginning no
17 sooner than 6 months after the date of the enact-
18 ment of this Act.

19 (2) REGULATIONS.—Not later than the date
20 that is 9 months after the date of the enactment of
21 this Act, the Secretary of Labor shall issue final reg-
22 ulations, through notice and comment rulemaking,
23 to implement the provisions of section 716 of the

- 1 Employee Retirement Income Security Act of 1974,
- 2 as added by subsection (a).

