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(Original Signature of Member)

115TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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.

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IN THE HOUSE OF REPRESENTATIVES

Mr. WENSTRUP introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

\_\_\_\_\_  
**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 “Restoring the Patient’s  
5       Voice Act of 2017”.

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 that any of the cir-  
20 cumstances listed in subsection (b) exists, authorize  
21 coverage for the prescription drug without regard to  
22 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, are contraindicated or have been  
4           ineffective in the treatment of the disease or condi-  
5           tion of the participant or beneficiary.

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

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

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

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

18           “(4) The treatment otherwise required under  
19           the protocol is not in the best interest of the partici-  
20           pant or beneficiary, based on medical necessity, be-  
21           cause the participant or beneficiary’s use of such  
22           treatment is expected to decrease the participant or  
23           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           drugs selected by the prescribing health care pro-  
9           vider.

10          “(c) CLEAR PROCESS.—The process required by sub-  
11          section (a)(1) shall make information regarding such proc-  
12          ess readily available on the website of the group health  
13          plan, including—

14                 “(1) the requirements for requesting an excep-  
15                 tion to a medication step therapy protocol pursuant  
16                 to this section; and

17                 “(2) any necessary forms and contact informa-  
18                 tion.

19          “(d) TIMING FOR GRANTING EXCEPTION.—The proc-  
20          ess required by subsection (a)(1) shall provide for the dis-  
21          position of requests received under such paragraph in ac-  
22          cordance with the following:

23                 “(1) Such a request shall be granted as quickly  
24                 as the disease or condition of the participant or ben-

1        efficiary requires, but no later than 3 days after the  
2        day of receipt of the request.

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

8                       “(A) on an expedited basis; and

9                       “(B) no later than 24 hours after receipt  
10       of such request.

11       “(e) MEDICATION STEP THERAPY PROTOCOL.—In  
12       this section, the term ‘step therapy protocol’ means a pro-  
13       tocol or program that establishes a specific sequence in  
14       which prescription drugs that—

15               “(1) are for a specified disease or condition,  
16       and

17               “(2) are medically necessary for a particular  
18       patient,

19       are covered under a pharmacy or medical benefit by a  
20       group health plan or a health insurance issuer offering  
21       group or individual health insurance coverage.”.

22       (b) TECHNICAL CORRECTION; CLERICAL CHANGE.—  
23       The table of contents in section 1 of the Employee Retire-  
24       ment Income Security Act of 1974 (29 U.S.C. 1001 et

1 seq.) is amended by inserting after the item relating to  
2 section 714 the following new items:

Sec. 715. Additional market reforms.

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

3 (c) **EFFECTIVE DATE.**—The amendment made by  
4 subsection (a) applies to plan years beginning no sooner  
5 than 6 months after the date of enactment of this Act.