



(Original Signature of Member)

119TH 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. ALLEN introduced the following bill; which was referred to the Committee  
on \_\_\_\_\_

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**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) REQUIRED EXCEPTIONS PROCESS FOR MEDICA-  
4 TION STEP THERAPY PROTOCOLS.—The Employee Re-  
5 tirement Income Security Act of 1974 is amended by in-  
6 serting after section 713 of such Act (29 U.S.C. 1185b)  
7 the following new section:

8 **“SEC. 713A. REQUIRED EXCEPTIONS PROCESS FOR MEDI-**  
9 **CATION STEP THERAPY PROTOCOLS.**

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

15 “(1) implement a clear, prompt, and trans-  
16 parent process for a participant or beneficiary (or  
17 the prescribing health care provider (referred to in  
18 this section as the ‘prescriber’) on behalf of the par-  
19 ticipant or beneficiary) to request an exception to  
20 such medication step therapy protocol, pursuant to  
21 subsection (b); and

22 “(2) where the participant or beneficiary or  
23 prescriber’s request for an exception to the medica-  
24 tion step therapy protocols satisfies the criteria and  
25 requirements of subsection (b), cover the requested  
26 drug in accordance with the terms established by the

1 plan or coverage for patient cost-sharing rates or  
2 amounts at the beginning of the plan year.

3 “(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—

4 The circumstances requiring an exception to a medication  
5 step therapy protocol, pursuant to a request under sub-  
6 section (a), are any of the following:

7 “(1) Any treatments otherwise required under  
8 the protocol, or treatments in the same pharma-  
9 cological class or having the same mechanism of ac-  
10 tion, including treatments provided prior to the ef-  
11 fective date of the participant’s or beneficiary’s cov-  
12 erage under the plan or coverage, have been ineffec-  
13 tive in the treatment of the disease or condition of  
14 the participant or beneficiary, when prescribed con-  
15 sistent with clinical indications, clinical guidelines, or  
16 other peer-reviewed evidence, based on the pre-  
17 scribing health care professional’s judgement or rel-  
18 evant information provided by the participant or  
19 beneficiary (including the medical records of the par-  
20 ticipant or beneficiary).

21 “(2) Delay of effective treatment would lead to  
22 severe or irreversible consequences, or worsen dis-  
23 ease progression or a comorbidity and the treatment  
24 otherwise required under the protocol is reasonably  
25 expected by the prescriber to be ineffective based

1       upon the documented physical or mental characteris-  
2       tics of the participant or beneficiary and the known  
3       characteristics of such treatment.

4       “(3) Any treatments otherwise required under  
5       the protocol are contraindicated for the participant  
6       or beneficiary or have caused, or are likely to cause,  
7       based on clinical, peer-reviewed evidence, an adverse  
8       reaction or other physical or mental harm to the  
9       participant or beneficiary.

10       “(4) Any treatment otherwise required under  
11       the protocol has prevented, will prevent, or is likely  
12       to prevent a participant or beneficiary from achiev-  
13       ing or maintaining reasonable and safe functional  
14       ability in performing occupational responsibilities or  
15       activities of daily living (as defined in section  
16       441.505 of title 42, Code of Federal Regulations (or  
17       successor regulations)).

18       “(5) The participant or beneficiary is stable for  
19       his or her disease or condition on the prescription  
20       drug or drugs selected by the prescriber and has  
21       previously received approval for coverage of the rel-  
22       evant drug or drugs for the disease or condition by  
23       any public or private health plan.

24       “(6) Other circumstances, as determined by the  
25       Secretary.

1 “(c) REQUIREMENT OF A CLEAR PROCESS.—

2 “(1) IN GENERAL.—The process required by  
3 subsection (a) shall—

4 “(A) provide the prescriber or participant  
5 or beneficiary an opportunity to present such  
6 prescriber’s clinical rationale and relevant med-  
7 ical information for the group health plan or  
8 health insurance issuer to evaluate such request  
9 for exception;

10 “(B) develop and use a standard form and  
11 instructions for the request of an exception  
12 under subsection (b), available in paper and  
13 electronic forms, and allow for submission of  
14 such form by paper and electronic means;

15 “(C) provide both paper and electronic  
16 means for the submission of requests for addi-  
17 tional information;

18 “(D) clearly set forth all required informa-  
19 tion and the specific criteria that will be used  
20 to determine whether an exception is warranted,  
21 which may require disclosure of—

22 “(i) the medical history or other  
23 health records of the participant or bene-  
24 ficiary demonstrating that the participant  
25 or beneficiary seeking an exception—

1                   “(I) has tried other drugs in-  
2                   cluded in the drug therapy class with-  
3                   out success; or

4                   “(II) has taken the requested  
5                   drug for a clinically appropriate  
6                   amount of time to establish stability,  
7                   in relation to the condition being  
8                   treated and prescription guidelines  
9                   given by the prescribing physician; or  
10                  “(ii) other clinical information that  
11                  may be relevant to conducting the excep-  
12                  tion review;

13                  “(E) not require the submission of any in-  
14                  formation or supporting documentation beyond  
15                  what is strictly necessary (as determined by the  
16                  Secretary) to determine whether a circumstance  
17                  listed in subsection (b) exists;

18                  “(F) clearly outline conditions under which  
19                  an exception request warrants expedited resolu-  
20                  tion from the group health plan or health insur-  
21                  ance issuer, pursuant to subsection (d)(2); and

22                  “(G) allow a representative of a participant  
23                  or beneficiary, which may include a designated  
24                  third-party advocate, to act on behalf of the  
25                  participant or beneficiary.

1           “(2) AVAILABILITY OF PROCESS INFORMA-  
2           TION.—The group health plan or health insurance  
3           issuer shall make information regarding the process  
4           required under subsection (a) readily available in the  
5           relevant plan materials, including the summary of  
6           benefits and, if available, on the website of the group  
7           health plan or health insurance issuer. Such infor-  
8           mation shall include—

9                   “(A) the requirements for requesting an  
10           exception to a medication step therapy protocol  
11           pursuant to this section; and

12                   “(B) any forms, supporting information,  
13           and contact information, as appropriate.

14           “(d) TIMING FOR DETERMINATION OF EXCEP-  
15           TION.—The process required under subsection (a)(1) shall  
16           provide for the disposition of requests received under such  
17           paragraph in accordance with the following:

18                   “(1) Subject to paragraph (2), not later than  
19           72 hours after receiving an initial exception request,  
20           the plan or issuer shall respond to the participant or  
21           beneficiary and, if applicable, the requesting pre-  
22           scriber with either a determination of exception eligi-  
23           bility or a request for additional required informa-  
24           tion strictly necessary to make a determination of  
25           whether the conditions specified in subsection (b)

1 are met. The plan or issuer shall respond to the par-  
2 ticipant or beneficiary and, if applicable, the request-  
3 ing prescriber, with a determination of exception eli-  
4 gibility no later than 72 hours after receipt of the  
5 additional required information.

6 “(2) In the case of a request under cir-  
7 cumstances in which the applicable medication step  
8 therapy protocol may seriously jeopardize the life or  
9 health of the participant or beneficiary, may jeop-  
10 ardize the ability of the participant or beneficiary to  
11 regain maximum function, or may subject the partic-  
12 ipant or beneficiary to severe pain that cannot be  
13 adequately managed without the treatment that is  
14 the subject of the request, the plan or issuer shall  
15 conduct a review of the request and respond to the  
16 participant or beneficiary and, if applicable, the re-  
17 questing prescriber, with either a determination of  
18 exception eligibility or a request for additional re-  
19 quired information strictly necessary to make a de-  
20 termination of whether the conditions specified in  
21 subsection (b) are met, in accordance with the fol-  
22 lowing:

23 “(A) If the plan or issuer can make a de-  
24 termination of exception eligibility without addi-  
25 tional information, such determination shall be



1           made on an expedited basis, and no later than  
2           24 hours after receipt of such request.

3           “(B) If the plan or issuer requires addi-  
4           tional information before making a determina-  
5           tion of exception eligibility, the plan or issuer  
6           shall respond to the participant or beneficiary  
7           and, if applicable, the requesting prescriber,  
8           with a request for such information within 24  
9           hours of the request for a determination, and  
10          shall respond with a determination of exception  
11          eligibility as quickly as the condition or disease  
12          requires, and no later than 24 hours after re-  
13          ceipt of the additional required information.

14          “(e) DURATION OF A GRANT.—If an exception to a  
15          medication step therapy protocol is granted under this sec-  
16          tion to a participant or beneficiary, coverage for the re-  
17          quested drug shall remain in effect with respect to such  
18          participant or beneficiary for not less than one year.

19          “(f) MEDICATION STEP THERAPY PROTOCOL.—In  
20          this section, the term ‘medication step therapy protocol’  
21          means a drug therapy utilization management protocol or  
22          program under which a group health plan or health insur-  
23          ance issuer offering group health insurance coverage of  
24          prescription drugs requires a participant or beneficiary to  
25          try an alternative preferred prescription drug or drugs be-

1 fore the plan or health insurance issuer approves coverage  
2 for the non-preferred drug therapy prescribed.

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

11 “(h) REPORTING.—

12 “(1) REPORTING TO THE SECRETARY.—Not  
13 later than 3 years after the date of enactment of the  
14 Safe Step Act and not later than October 1 of each  
15 year thereafter, each group health plan and health  
16 insurance issuer offering group health insurance cov-  
17 erage shall report to the Secretary, in such manner  
18 as the Secretary shall require, the following:

19 “(A) The number of step therapy exception  
20 requests received for each exception cir-  
21 cumstance described in paragraphs (1) through  
22 (6) of subsection (b), and the numbers of such  
23 requests for each such circumstance that  
24 were—

25 “(i) approved;

1 “(ii) denied, and the reasons for the  
2 denials;

3 “(iii) initially denied and appealed;  
4 and

5 “(iv) initially denied and then subse-  
6 quently reversed by internal appeals or ex-  
7 ternal reviews.

8 “(B) The number of times a plan or issuer  
9 requested additional information in response to  
10 a step therapy exception request, by exception  
11 circumstance described in paragraphs (1)  
12 through (6) of subsection (b).

13 “(C) The number of exception requests  
14 submitted by participants or beneficiaries, and  
15 the number of exception requests submitted by  
16 prescribers, by medical specialty.

17 “(D) The medical conditions for which  
18 participants and beneficiaries were granted ex-  
19 ceptions due to the likelihood that switching  
20 from a prescription drug will likely cause an ad-  
21 verse reaction by, or physical or mental harm  
22 to, the participant or beneficiary, as described  
23 in subsection (b)(3).

1           “(E) The entities responsible for providing  
2           pharmacy benefit management services for the  
3           group health plan or health insurance coverage.

4           “(2) INFORMATION.—A group health plan or  
5           health insurance issuer offering group health insur-  
6           ance coverage shall not enter into a contract with a  
7           third-party administrator or an entity providing  
8           pharmacy benefit management services on behalf of  
9           the plan or coverage that prevents the plan or issuer  
10          from obtaining from the third-party administrator or  
11          the entity providing pharmacy benefit management  
12          services any information needed for the plan or  
13          issuer to comply with the reporting requirements  
14          under paragraph (1).

15          “(3) REPORTS TO CONGRESS.—Not later than  
16          3 years after the date of enactment of the Safe Step  
17          Act, and not later than October 1 of each year  
18          thereafter, the Secretary shall submit to Congress,  
19          and make publicly available, a report that contains  
20          a summary and analysis of the information reported  
21          under paragraph (1), including an analysis of, with  
22          respect to requests for exceptions under this section,  
23          approvals, and denials, including the reasons for de-  
24          nials; appeals and external reviews; and trends, if

1       any, in exception requests by medical specialty or  
2       medical condition.”.

3       (b) CLERICAL AMENDMENT.—The table of contents  
4       in section 1 of the Employee Retirement Income Security  
5       Act of 1974 (29 U.S.C. 1001 et seq.) is amended by in-  
6       serting after the item relating to section 713 the following  
7       new item:

      “Sec. 713A. Required exceptions process for medication step therapy proto-  
          cols.”.

8       (c) EFFECTIVE DATE.—

9           (1) IN GENERAL.—The amendment made by  
10       subsection (a) applies with respect to plan years be-  
11       ginning with the first plan year that begins at least  
12       6 months after the date of the enactment of this  
13       Act.

14          (2) REGULATIONS.—Not later than 6 months  
15       after the date of the enactment of this Act, the Sec-  
16       retary of Labor shall issue final regulations, through  
17       notice and comment rulemaking, to implement the  
18       provisions of section 713A of the Employee Retire-  
19       ment Income Security Act of 1974, as added by sub-  
20       section (a).