

118TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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 SENATE OF THE UNITED STATES

Ms. MURKOWSKI (for herself, Ms. HASSAN, Mr. MARSHALL, Ms. ROSEN, Mr. TILLIS, Mr. MERKLEY, Mrs. CAPITO, Ms. CORTEZ MASTO, Mrs. HYDE-SMITH, Mr. BLUMENTHAL, Ms. LUMMIS, Ms. SMITH, Mr. CRAMER, Ms. SINEMA, Ms. COLLINS, Mr. CASEY, Mr. KAINE, Mr. WICKER, and Mrs. GILLIBRAND) introduced the following bill; which was read twice and 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) IN GENERAL.—The Employee Retirement Income  
4 Security Act of 1974 is amended by inserting after section  
5 713 of such Act (29 U.S.C. 1185b) the following new sec-  
6 tion:

7 **“SEC. 713A. REQUIRED EXCEPTIONS PROCESS FOR MEDI-**  
8 **CATION 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 and transparent process  
15 for a participant or beneficiary (or the prescribing  
16 health care provider on behalf of the participant or  
17 beneficiary) to request an exception to such medica-  
18 tion step therapy protocol, pursuant to subsection  
19 (b); and

20 “(2) where the participant or beneficiary or  
21 prescribing health care provider’s request for an ex-  
22 ception to the medication step therapy protocols sat-  
23 isfies the criteria and requirements of subsection (b),  
24 cover the requested drug in accordance with the  
25 terms established by the health plan or coverage for  
26 patient cost-sharing rates or amounts at the time of

1 the participant's or beneficiary's enrollment in the  
2 health plan or health insurance coverage.

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, have been ineffective in the treatment of the  
11 disease or condition of the participant or beneficiary,  
12 when prescribed consistent with clinical indications,  
13 clinical guidelines, or other peer-reviewed evidence.

14 “(2) Delay of effective treatment would lead to  
15 severe or irreversible consequences, and the treat-  
16 ment otherwise required under the protocol is rea-  
17 sonably expected to be ineffective based upon the  
18 documented physical or mental characteristics of the  
19 participant or beneficiary and the known character-  
20 istics of such treatment.

21 “(3) Any treatments otherwise required under  
22 the protocol are contraindicated for the participant  
23 or beneficiary or have caused, or are likely to cause,  
24 based on clinical, peer-reviewed evidence, an adverse

1 reaction or other physical harm to the participant or  
2 beneficiary.

3 “(4) Any treatment otherwise required under  
4 the protocol has prevented, will prevent, or is likely  
5 to prevent a participant or beneficiary from achiev-  
6 ing or maintaining reasonable and safe functional  
7 ability in performing occupational responsibilities or  
8 activities of daily living (as defined in section  
9 441.505 of title 42, Code of Federal Regulations (or  
10 successor regulations)).

11 “(5) The participant or beneficiary is stable for  
12 his or her disease or condition on the prescription  
13 drug or drugs selected by the prescribing health care  
14 provider and has previously received approval for  
15 coverage of the relevant drug or drugs for the dis-  
16 ease or condition by any group health plan or health  
17 insurance issuer.

18 “(6) Other circumstances, as determined by the  
19 Secretary.

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

21 “(1) IN GENERAL.—The process required by  
22 subsection (a)—

23 “(A) shall provide the prescribing health  
24 care provider or beneficiary or designated third-  
25 party advocate an opportunity to present such

1 provider's clinical rationale and relevant med-  
2 ical information for the group health plan or  
3 health insurance issuer to evaluate such request  
4 for exception;

5 “(B) shall clearly set forth all required in-  
6 formation and the specific criteria that will be  
7 used to determine whether an exception is war-  
8 ranted, which may require disclosure of—

9 “(i) the medical history or other  
10 health records of the participant or bene-  
11 ficiary demonstrating that the participant  
12 or beneficiary seeking an exception—

13 “(I) has tried other drugs in-  
14 cluded in the drug therapy class with-  
15 out success; or

16 “(II) has taken the requested  
17 drug for a clinically appropriate  
18 amount of time to establish stability,  
19 in relation to the condition being  
20 treated and prescription guidelines  
21 given by the prescribing physician; or

22 “(ii) other clinical information that  
23 may be relevant to conducting the excep-  
24 tion review;

1           “(C) may not require the submission of  
2           any information or supporting documentation  
3           beyond what is strictly necessary to determine  
4           whether any of the circumstances listed in sub-  
5           section (b) exists; and

6           “(D) shall clearly outline conditions under  
7           which an exception request warrants expedited  
8           resolution from the group health plan or health  
9           insurance issuer, pursuant to subsection (d)(2).

10          “(2) AVAILABILITY OF PROCESS INFORMA-  
11          TION.—The group health plan or health insurance  
12          issuer shall make information regarding the process  
13          required under subsection (a) readily available on  
14          the internet website of the group health plan or  
15          health insurance issuer. Such information shall in-  
16          clude—

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

20                 “(B) any forms, supporting information,  
21                 and contact information, as appropriate.

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

1           “(1) Subject to paragraph (2), not later than  
2           72 hours after receiving an initial exception request,  
3           the plan or issuer shall respond to the requesting  
4           prescriber with either a determination of exception  
5           eligibility or a request for additional required infor-  
6           mation strictly necessary to make a determination of  
7           whether the conditions specified in subsection (b)  
8           are met. The plan or issuer shall respond to the re-  
9           questing provider with a determination of exception  
10          eligibility no later than 72 hours after receipt of the  
11          additional required information.

12          “(2) In the case of a request under cir-  
13          cumstances in which the applicable medication step  
14          therapy protocol may seriously jeopardize the life or  
15          health of the participant or beneficiary, the plan or  
16          issuer shall conduct a review of the request and re-  
17          spond to the requesting prescriber with either a de-  
18          termination of exception eligibility or a request for  
19          additional required information strictly necessary to  
20          make a determination of whether the conditions  
21          specified in subsection (b) are met, in accordance  
22          with the following:

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 requesting provider with a  
7           request for such information within 24 hours of  
8           the request for a determination, and shall re-  
9           spond with a determination of exception eligi-  
10          bility as quickly as the condition or disease re-  
11          quires, and no later than 24 hours after receipt  
12          of the additional required information.

13          “(e) MEDICATION STEP THERAPY PROTOCOL.—In  
14          this section, the term ‘medication step therapy protocol’  
15          means a drug therapy utilization management protocol or  
16          program under which a group health plan or health insur-  
17          ance issuer offering group health insurance coverage of  
18          prescription drugs requires a participant or beneficiary to  
19          try an alternative preferred, prescription drug or drugs be-  
20          fore the plan or health insurance issuer approves coverage  
21          for the non-preferred drug therapy prescribed.

22          “(f) CLARIFICATION.—This section shall apply with  
23          respect to any group health plan or health insurance cov-  
24          erage offered in connection with such a plan that provides  
25          coverage of a prescription drug pursuant to a policy that



1 meets the definition of the term ‘medication step therapy  
2 protocol’ in subsection (e), regardless of whether such pol-  
3 icy is described by such group health plan or health insur-  
4 ance coverage as a step therapy protocol.”.

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

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

10 (c) EFFECTIVE DATE.—

11 (1) IN GENERAL.—The amendment made by  
12 subsection (a) applies with respect to plan years be-  
13 ginning with the first plan year that begins at least  
14 6 months after the date of the enactment of this  
15 Act.

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