

119TH CONGRESS
1ST SESSION

S. 2903

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 SENATE OF THE UNITED STATES

SEPTEMBER 18 (legislative day, SEPTEMBER 16), 2025

Ms. MURKOWSKI (for herself, Ms. HASSAN, Mr. MARSHALL, Ms. ROSEN, Mr. PADILLA, Mr. HICKENLOOPER, Mr. MERKLEY, Mr. SULLIVAN, Mr. WARNOCK, Mrs. HYDE-SMITH, Ms. CORTEZ MASTO, Mr. MORAN, Mr. CRAMER, Mr. KAINE, Mr. BUDD, Mrs. SHAHEEN, Mr. BOOKER, Mr. WYDEN, and Mr. COONS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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).

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