



Amendment #1, as modified

AMENDMENT NO. _____

Calendar No. _____

Purpose: 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—118th Cong., 1st Sess.

S. 1339

To provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. MURKOWSKI

for herself, senator Hissam, Senator Marshall

Viz:

1 At the end, add the following:

2 **SEC. 3. REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**

3 **TION STEP THERAPY PROTOCOLS.**

4 (a) **SHORT TITLE.**—This section may be cited as the
5 “Safe Step Act”.

6 (b) **REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**
7 **TION STEP THERAPY PROTOCOLS.**—The Employee Re-
8 tirement Income Security Act of 1974 is amended by in-

1 serting after section 713 of such Act (29 U.S.C. 1185b)
2 the following new section:

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

5 “(a) IN GENERAL.—In the case of a group health
6 plan or health insurance issuer offering coverage offered
7 in connection with such a plan that provides coverage of
8 a prescription drug pursuant to a medication step therapy
9 protocol, the plan or issuer shall—

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

17 “(2) where the participant or beneficiary or
18 prescriber’s request for an exception to the medica-
19 tion step therapy protocols satisfies the criteria and
20 requirements of subsection (b), cover the requested
21 drug in accordance with the terms established by the
22 health plan or coverage for patient cost-sharing
23 rates or amounts at the beginning of the plan year.

24 “(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—
25 The circumstances requiring an exception to a medication

1 step therapy protocol, pursuant to a request under sub-
2 section (a), are any of the following:

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

17 “(2) Delay of effective treatment would lead to
18 severe or irreversible consequences, or worsen dis-
19 ease progression or a comorbidity and the treatment
20 otherwise required under the protocol is reasonably
21 expected by the prescriber to be ineffective based
22 upon the documented physical or mental characteris-
23 tics of the participant or beneficiary and the known
24 characteristics of such treatment.

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

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

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

21 “(6) Other circumstances, as determined by the
22 Secretary.

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

24 “(1) IN GENERAL.—The process required by
25 subsection (a) shall—

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

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

12 “(C) provide both paper and electronic
13 means for the submission of requests for addi-
14 tional information;

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

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

23 “(I) has tried other drugs in-
24 cluded in the drug therapy class with-
25 out success; or

1 “(II) has taken the requested
2 drug for a clinically appropriate
3 amount of time to establish stability,
4 in relation to the condition being
5 treated and prescription guidelines
6 given by the prescribing physician; or

7 “(ii) other clinical information that
8 may be relevant to conducting the excep-
9 tion review;

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

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

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

23 “(2) AVAILABILITY OF PROCESS INFORMA-
24 TION.—The group health plan or health insurance
25 issuer shall make information regarding the process

1 required under subsection (a) readily available in the
2 relevant plan materials, including the summary of
3 benefits and, if available, on the website of the group
4 health plan or health insurance issuer. Such infor-
5 mation shall include—

6 “(A) the requirements for requesting an
7 exception to a medication step therapy protocol
8 pursuant to this section; and

9 “(B) any forms, supporting information,
10 and contact information, as appropriate.

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

15 “(1) Subject to paragraph (2), not later than
16 72 hours after receiving an initial exception request,
17 the plan or issuer shall respond to the participant or
18 beneficiary and, if applicable, the requesting pre-
19 scriber with either a determination of exception eligi-
20 bility or a request for additional required informa-
21 tion strictly necessary to make a determination of
22 whether the conditions specified in subsection (b)
23 are met. The plan or issuer shall respond to the par-
24 ticipant or beneficiary and, if applicable, the request-
25 ing prescriber with a determination of exception eli-

1 gibility no later than 72 hours after receipt of the
2 additional required information.

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

20 “(A) If the plan or issuer can make a de-
21 termination of exception eligibility without addi-
22 tional information, such determination shall be
23 made on an expedited basis, and no later than
24 24 hours after receipt of such request.

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

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

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

1 “(g) 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 (f), 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 “(h) REPORTING.—

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

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

23 “(i) approved;

1 “(ii) deemed approved under sub-
2 section (d)(3) due to the failure of the plan
3 or issuer to timely respond;

4 “(iii) denied and the reasons for the
5 denials;

6 “(iv) initially denied and appealed;
7 and

8 “(v) initially denied and then subse-
9 quently reversed by internal appeals or ex-
10 ternal reviews.

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

16 “(C) The number of exception requests
17 submitted by participants or beneficiaries, and
18 the number of exception requests submitted by
19 prescribers, by medical specialty.

20 “(D) The medical conditions for which
21 participants and beneficiaries were granted ex-
22 ceptions due to the likelihood that switching
23 from a prescription drug will likely cause an ad-
24 verse reaction by, or physical or mental harm

1 to, the participant or beneficiary, as described
2 in subsection (b)(3).

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

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

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

1 appeals and external reviews; and trends, if any, in
2 exception requests by medical specialty or medical
3 condition.”.

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

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

9 (d) EFFECTIVE DATE.—

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

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