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 HOUSE OF REPRESENTATIVES

MARCH 23, 2021

Mr. Ruiz (for himself, Mr. Wenstrup, Mrs. McBath, and Mrs. Miller-Meeks) introduced the following bill; which was referred to the Committee on Education and Labor

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Safe Step Act”.
SEC. 2. REQUIRED EXCEPTIONS PROCESS FOR MEDICATION STEP THERAPY PROTOCOLS.

(a) IN GENERAL.—The Employee Retirement Income Security Act of 1974 is amended by inserting after section 725 of such Act (29 U.S.C. 1185d) the following new section:

“SEC. 726. REQUIRED EXCEPTIONS PROCESS FOR MEDICATION STEP THERAPY PROTOCOLS.

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

“(1) implement a clear and transparent process for a participant or beneficiary (or the prescribing health care provider on behalf of the participant or beneficiary) to request an exception to such medication step therapy protocol, pursuant to subsection (b); and

“(2) where the participant or beneficiary or prescribing health care provider’s request for an exception to the medication step therapy protocols satisfies the criteria and requirements of subsection (b), cover the requested drug in accordance with the terms established by the health plan or coverage for patient cost-sharing rates or amounts at the time of
the participant’s or beneficiary’s enrollment in the
health plan or health insurance coverage.

“(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—
The circumstances requiring an exception to a medication
step therapy protocol, pursuant to a request under sub-
section (a), are any of the following:

“(1) Any treatments otherwise required under
the protocol, or treatments in the same pharma-
cological class or having the same mechanism of ac-
tion, have been ineffective in the treatment of the
disease or condition of the participant or beneficiary,
when prescribed consistent with clinical indications,
clinical guidelines, or other peer-reviewed evidence.

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

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

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

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

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

“(c) REQUIREMENT OF A CLEAR PROCESS.—

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

“(A) shall provide the prescribing health care provider or beneficiary or designated third-party advocate an opportunity to present such
provider’s clinical rationale and relevant medical information for the group health plan or health insurance issuer to evaluate such request for exception;

“(B) shall clearly set forth all required information and the specific criteria that will be used to determine whether an exception is warranted, which may require disclosure of—

“(i) the medical history or other health records of the participant or beneficiary demonstrating that the participant or beneficiary seeking an exception—

“(I) has tried other drugs included in the drug therapy class without success; or

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

“(ii) other clinical information that may be relevant to conducting the exception review;
“(C) may not require the submission of any information or supporting documentation beyond what is strictly necessary to determine whether any of the circumstances listed in subsection (b) exists; and

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

“(2) AvAILABILITY OF PROCESS INFORMATION.—The group health plan or health insurance issuer shall make information regarding the process required under subsection (a) readily available on the internet website of the group health plan or health insurance issuer. Such information shall include—

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

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

“(d) TIMING FOR DETERMINATION OF EXCEPTION.—The process required under subsection (a)(1) shall provide for the disposition of requests received under such paragraph in accordance with the following:
“(1) Subject to paragraph (2), not later than 72 hours after receiving an initial exception request, the plan or issuer shall respond to the requesting prescriber with either a determination of exception eligibility or a request for additional required information strictly necessary to make a determination of whether the conditions specified in subsection (b) are met. The plan or issuer shall respond to the requesting provider with a determination of exception eligibility no later than 72 hours after receipt of the additional required information.

“(2) In the case of a request under circumstances in which the applicable medication step therapy protocol may seriously jeopardize the life or health of the participant or beneficiary, the plan or issuer shall conduct a review of the request and respond to the requesting prescriber with either a determination of exception eligibility or a request for additional required information strictly necessary to make a determination of whether the conditions specified in subsection (b) are met, in accordance with the following:

“(A) If the plan or issuer can make a determination of exception eligibility without additional information, such determination shall be
made on an expedited basis, and no later than
24 hours after receipt of such request.

“(B) If the plan or issuer requires addi-
tional information before making a determina-
tion of exception eligibility, the plan or issuer
shall respond to the requesting provider with a
request for such information within 24 hours of
the request for a determination, and shall re-
spond with a determination of exception eligi-
bility as quickly as the condition or disease re-
quires, and no later than 24 hours after receipt
of the additional required information.

“(e) Medication Step Therapy Protocol.—In
this section, the term ‘medication step therapy protocol’
means a drug therapy utilization management protocol or
program under which a group health plan or health insur-
ance issuer offering group health insurance coverage of
prescription drugs requires a participant or beneficiary to
try an alternative preferred, prescription drug or drugs be-
fore the plan or health insurance issuer approves coverage
for the non-preferred drug therapy prescribed.

“(f) Clarification.—This section shall apply with
respect to any group health plan or health insurance cov-
erage offered in connection with such a plan that provides
coverage of a prescription drug pursuant to a policy that
meets the definition of the term ‘medication step therapy protocol’ in subsection (e), regardless of whether such policy is described by such group health plan or health insurance coverage as a step therapy protocol.”.

(b) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following new items:

“Sec. 726. Required exceptions process for medication step therapy protocols.”.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (a) applies with respect to plan years beginning with the first plan year that begins at least 6 months after the date of the enactment of this Act.

(2) REGULATIONS.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Labor shall issue final regulations, through notice and comment rulemaking, to implement the provisions of section 726 of the Employee Retirement Income Security Act of 1974, as added by subsection (a).