

JAN 15 2025

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. The legislature finds that health insurance
2 plans are increasingly making use of step therapy protocols
3 which require patients to try one or more prescription drug
4 alternatives before insurance coverage is provided for the
5 particular prescription drug selected by the patient's health
6 care provider. Step therapy protocols can serve an important
7 role in controlling health care costs when they are based on
8 well-developed scientific standards and administered in a
9 flexible manner that considers the individual needs of patients.
10 However, requiring a patient to follow a step therapy protocol
11 may have adverse and even dangerous consequences for a patient
12 who may not realize a benefit from taking a required
13 prescription drug alternative or suffer harm if the step therapy
14 protocol requires use of a drug that is inappropriate for the
15 patient.

16 The legislature further finds that without uniform
17 statewide policies in place for step therapy protocols,



1 residents of the State may have varying access to appropriate
2 health care treatment depending on their particular insurance
3 carrier. It is imperative that step therapy protocols in the
4 State preserve health care providers' right to make treatment
5 decisions in the best interest of the patient.

6 The legislature finds that it is necessary for the
7 protection of public health and safety to require health
8 insurers to base step therapy protocols on appropriate clinical
9 practice guidelines or published peer reviewed data developed by
10 independent experts with knowledge of the condition or
11 conditions under consideration. To protect the interest of
12 patients statewide, step therapy protocols should include
13 provisions to exempt patients for whom step therapy would be
14 inappropriate and should ensure that patients have access to a
15 fair, transparent, and independent process for requesting an
16 exception to a step therapy protocol when the patients'
17 physician deems it to be appropriate.

18 Accordingly, the purpose of this Act is to require all
19 insurers in the State to adopt minimum standards for the use of
20 step therapy protocols to ensure the fair, consistent, and



1 transparent provision of prescription drugs to residents of the
2 State.

3 SECTION 2. Chapter 431, Hawaii Revised Statutes, is
4 amended by adding a new section to article 10A to be
5 appropriately designated and to read as follows:

6 "§431:10A- Step therapy protocol; requirements;
7 exceptions. (a) Clinical review criteria used to establish a
8 step therapy protocol shall be based on clinical practice
9 guidelines. Clinical practice guidelines shall:

10 (1) Recommend that the prescription drugs be taken in the
11 specific sequence required by the step therapy
12 protocol;

13 (2) Be developed and endorsed by a multidisciplinary panel
14 of experts that manages conflicts of interest among
15 the members of the writing and review groups by:

16 (A) Requiring members to disclose any potential
17 conflict of interests with entities, including
18 insurers, health plans, and pharmaceutical
19 manufacturers and recuse themselves of voting if
20 they have a conflict of interest;



- 1 (B) Using a methodologist to work with writing groups
- 2 to provide objectivity in data analysis and
- 3 ranking of evidence through the preparation of
- 4 evidence tables and facilitating consensus; and
- 5 (C) Offering opportunities for public review and
- 6 comments;
- 7 provided that in the absence of a panel, peer reviewed
- 8 publications shall suffice;
- 9 (3) Be based on high quality studies, research, and
- 10 medical practices;
- 11 (4) Be established under an explicit and transparent
- 12 process that:
- 13 (A) Minimizes biases and conflicts of interest;
- 14 (B) Explains the relationship between treatment
- 15 options and outcomes;
- 16 (C) Rates the quality of the evidence supporting
- 17 recommendations; and
- 18 (D) Considers relevant patient subgroups and
- 19 preferences;



1 (5) Be continually updated through a review of new
2 evidence, research, and newly developed treatments;
3 and

4 (6) Consider the needs of atypical patient populations and
5 diagnoses;

6 Nothing in this subsection shall be construed to require an
7 insurer, utilization review organization, or health care
8 provider to create any new entity to develop clinical review
9 criteria used for step therapy protocols.

10 (b) When coverage of a prescription drug for the treatment
11 of any medical condition is restricted for use by an insurer or
12 utilization review organization through the use of a step
13 therapy protocol, the patient and the prescribing practitioner
14 shall have access to request a step therapy exception through a
15 clear and convenient process which shall be readily accessible
16 through the insurer or utilization review organization's
17 website. An insurer or utilization review organization may use
18 its existing medical exceptions or appeal process to satisfy
19 this requirement; provided that the process complies with the
20 requirements of this section. An insurer or utilization review
21 organization shall upon written request:



1 (1) Provide all written clinical review criteria relating
2 to a particular condition or disease or a step therapy
3 exception determination;

4 (2) Display the requested clinical review criteria and
5 other clinical information on its website; and

6 (3) Distribute the requested clinical review criteria and
7 other clinical information to a health care
8 professional on the behalf of a patient.

9 (c) A step therapy exception shall be granted to a patient
10 whose relevant medical condition is:

11 (1) Currently stabilized by a particular prescription drug
12 prescribed by the patient's health care provider,
13 regardless of any current or prior insurance coverage,
14 and the patient's health care provider has prescribed
15 continued treatment with the same prescription drug;

16 or

17 (2) Not currently stabilized by a particular prescription
18 drug and if any prescription drug required under the
19 applicable step therapy protocol:



- 1 (A) Is contraindicated or will likely cause an
2 adverse reaction by or physical or mental harm to
3 the patient;
 - 4 (B) Is expected to be ineffective based on the known
5 clinical characteristics of the patient and the
6 known characteristics of the prescription drug;
 - 7 (C) Has been previously prescribed to the patient or
8 is in the same pharmacologic class or has the
9 same mechanism of action as another prescription
10 drug that has been prescribed to the patient and
11 was discontinued by the patient's health care
12 provider due to lack of efficacy or
13 effectiveness, diminished effect, or an adverse
14 event, regardless of any current or prior
15 insurance coverage of the prescription drug; or
 - 16 (D) Will not serve the best interest of the patient,
17 based on medical necessity.
- 18 (d) An insurer or utilization review organization shall
19 make a step therapy exception determination within seventy-two
20 hours of receipt of a request for an exception or filing of an
21 appeal; provided that if exigent circumstances exist, a



1 determination shall be made within twenty-four hours; provided
2 further that if no determination has been made within the time
3 specified, the exception shall be deemed to be granted.

4 If a request for a step therapy exception is incomplete or
5 additional clinically relevant information is required, the
6 insurer or utilization review organization shall notify the
7 prescribing practitioner within seventy-two hours of submission
8 of a request for an exception, or within twenty-four hours in
9 exigent circumstances, what additional or clinically relevant
10 information is required to approve or deny the step therapy
11 exception request or appeal pursuant to the criteria disclosed
12 in subsection (a). Once the requested information is submitted,
13 the applicable time period for an insurer or utilization review
14 organization to make a step therapy exception determination
15 shall apply.

16 Upon the grant of a step therapy exception, the insurer or
17 utilization review organization shall authorize coverage for the
18 particular prescription drug prescribed by the patient's health
19 care provider. Any adverse determination under this subsection
20 shall be subject to appeal pursuant to the insurer or
21 utilization review organization's existing appeal procedures.



1 (e) Every insurer or utilization review organization
2 subject to this section shall certify annually to the insurance
3 commissioner that the insurer or utilization review
4 organization's step therapy protocol meets the requirements of
5 this section. Any proposed change in protocol or clinical
6 review criteria shall be submitted to the insurance commissioner
7 for approval before it may be implemented by the insurer or
8 utilization review organization.

9 (f) Notwithstanding any law to the contrary, the insurance
10 division of the department of commerce and consumer affairs
11 shall adopt rules necessary for the purposes of this section.

12 (g) Each insurer or utilization review organization shall
13 annually submit a report to the insurance division of the
14 department of commerce and consumer affairs, on forms prescribed
15 by the insurance division of the department of commerce and
16 consumer affairs, that includes the following:

17 (1) The number of step therapy exception requests
18 received;

19 (2) The type of health care providers or the medical
20 specialties of the health care providers submitting
21 step therapy exception requests;



1 (3) The number of step therapy exception requests that
2 were:

3 (A) Denied, including the reasons for the denials;

4 (B) Approved;

5 (C) Initially denied and then appealed; and

6 (D) Initially denied and then subsequently reversed

7 by the internal appeals or external reviews; and

8 (4) The medical conditions under which patients were

9 granted step therapy exceptions due to the likelihood

10 that switching from the prescription drug will likely

11 cause an adverse reaction by or physical or mental

12 harm to the insured.

13 (h) This section applies to any state regulated plan or

14 health insurance coverage offered in connection with a state

15 regulated plan that provides coverage of a prescription drug

16 pursuant to a policy that meets the definition of a step therapy

17 protocol, regardless of whether the policy is described as a

18 step therapy protocol.

19 (i) Nothing in this section shall be construed to prevent:

20 (1) An insurer or utilization review organization from

21 requiring a patient to try an AB-rated generic



1 equivalent drug or interchangeable biological product
2 before providing coverage for a name-brand
3 prescription drug, unless the requirement meets the
4 qualifications for a step therapy exception pursuant
5 to subsection (c);

6 (2) An insurer or utilization review organization from
7 requiring a pharmacist to effect substitutions of
8 prescription drugs pursuant to section 328-92; or

9 (3) A health care provider from prescribing any
10 prescription drug that the provider finds to be
11 medically appropriate for the patient.

12 (j) For the purposes of this section:

13 "AB-rated generic equivalent drug" means a prescription
14 drug product that is considered by the federal Food and Drug
15 Administration to be therapeutically equivalent to a particular
16 name brand prescription drug.

17 "Clinical practice guidelines" means a systematically
18 developed statement to assist decision-making by health care
19 providers and patients about appropriate health care for
20 specific clinical circumstances and conditions.



1 "Clinical review criteria" means the written screening
2 procedures, decision abstracts, clinical protocols, and practice
3 guidelines used by an insurer or utilization review organization
4 to determine the medical necessity and appropriateness of health
5 care services.

6 "Interchangeable biological product" has the same meaning
7 as defined in section 328-91.

8 "Medically appropriate" means health services and supplies
9 that under the applicable standard of care are appropriate:

10 (1) To improve or preserve health, life, or function;

11 (2) To slow the deterioration of health, life, or
12 function; or

13 (3) For the early screening, prevention, evaluation,
14 diagnosis, or treatment of a disease, condition,
15 illness, or injury.

16 "Step therapy exception determination" means a
17 determination as to whether a step therapy protocol should apply
18 in a particular situation or be overridden in favor of immediate
19 coverage of a health care provider's selected prescription drug
20 based on a review of the patient's or prescriber's request for
21 an exception and supporting rationale and documentation.



1 "Step therapy protocol" means a protocol or program that
2 requires the use of specific prescription drugs in a specific
3 sequence as a condition of coverage under a policy.

4 "Utilization review organization" means an entity that
5 conducts utilization reviews, other than an insurer that
6 performs utilization reviews for its own policies."

7 SECTION 3. Chapter 432, Hawaii Revised Statutes, is
8 amended by adding a new section to article 1 to be appropriately
9 designated and to read as follows:

10 "§432:1- Step therapy protocol; requirements;
11 exceptions. (a) Clinical review criteria used to establish a
12 step therapy protocol shall be based on clinical practice
13 guidelines. Clinical practice guidelines shall:

14 (1) Recommend that the prescription drugs be taken in the
15 specific sequence required by the step therapy
16 protocol;

17 (2) Be developed and endorsed by a multidisciplinary panel
18 of experts that manages conflicts of interest among
19 the members of the writing and review groups by:

20 (A) Requiring members to disclose any potential
21 conflict of interests with entities, including



- 1 insurers, health plans, and pharmaceutical
- 2 manufacturers and recuse themselves of voting if
- 3 they have a conflict of interest;
- 4 (B) Using a methodologist to work with writing groups
- 5 to provide objectivity in data analysis and
- 6 ranking of evidence through the preparation of
- 7 evidence tables and facilitating consensus; and
- 8 (C) Offering opportunities for public review and
- 9 comments;
- 10 provided that in the absence of a panel, peer reviewed
- 11 publications shall suffice;
- 12 (3) Be based on high quality studies, research, and
- 13 medical practices;
- 14 (4) Be established under an explicit and transparent
- 15 process that:
- 16 (A) Minimizes biases and conflicts of interest;
- 17 (B) Explains the relationship between treatment
- 18 options and outcomes;
- 19 (C) Rates the quality of the evidence supporting
- 20 recommendations; and



1 (D) Considers relevant patient subgroups and
2 preferences;

3 (5) Be continually updated through a review of new
4 evidence, research, and newly developed treatments;
5 and

6 (6) Consider the needs of atypical patient populations and
7 diagnoses;

8 Nothing in this subsection shall be construed to require a
9 mutual benefit society, utilization review organization, or
10 health care provider to create any new entity to develop
11 clinical review criteria used for step therapy protocols.

12 (b) When coverage of a prescription drug for the treatment
13 of any medical condition is restricted for use by a mutual
14 benefit society or utilization review organization through the
15 use of a step therapy protocol, the patient and the prescribing
16 practitioner shall have access to request a step therapy
17 exception through a clear and convenient process which shall be
18 readily accessible through the mutual benefit society or
19 utilization review organization's website. A mutual benefit
20 society or utilization review organization may use its existing
21 medical exceptions or appeal process to satisfy this



1 requirement; provided that the process complies with the
2 requirements of this section. A mutual benefit society or
3 utilization review organization shall upon written request:

4 (1) Provide all written clinical review criteria relating
5 to a particular condition or disease or a step therapy
6 exception determination;

7 (2) Display the requested clinical review criteria and
8 other clinical information on its website; and

9 (3) Distribute the requested clinical review criteria and
10 other clinical information to a health care
11 professional on the behalf of a patient.

12 (c) A step therapy exception shall be granted to a patient
13 whose relevant medical condition is:

14 (1) Currently stabilized by a particular prescription drug
15 prescribed by the patient's health care provider,
16 regardless of any current or prior insurance coverage,
17 and the patient's health care provider has prescribed
18 continued treatment with the same prescription drug;

19 or



- 1 (2) Not currently stabilized by a particular prescription
2 drug and if any prescription drug required under the
3 applicable step therapy protocol:
- 4 (A) Is contraindicated or will likely cause an
5 adverse reaction by or physical or mental harm to
6 the patient;
- 7 (B) Is expected to be ineffective based on the known
8 clinical characteristics of the patient and the
9 known characteristics of the prescription drug;
- 10 (C) Has been previously prescribed to the patient or
11 is in the same pharmacologic class or has the
12 same mechanism of action as another prescription
13 drug that has been prescribed to the patient and
14 was discontinued by the patient's health care
15 provider due to lack of efficacy or
16 effectiveness, diminished effect, or an adverse
17 event, regardless of any current or prior
18 insurance coverage of the prescription drug; or
- 19 (D) Will not serve the best interest of the patient,
20 based on medical necessity.



1 (d) A mutual benefit society or utilization review
2 organization shall make a step therapy exception determination
3 within seventy-two hours of receipt of a request for an
4 exception or filing of an appeal; provided that if exigent
5 circumstances exist, a determination shall be made within
6 twenty-four hours; provided further that if no determination has
7 been made within the time specified, the exception shall be
8 deemed to be granted.

9 If a request for a step therapy exception is incomplete or
10 additional clinically relevant information is required, the
11 mutual benefit society or utilization review organization shall
12 notify the prescribing practitioner within seventy-two hours of
13 submission of a request for an exception, or within twenty-four
14 hours in exigent circumstances, what additional or clinically
15 relevant information is required to approve or deny the step
16 therapy exception request or appeal pursuant to the criteria
17 disclosed in subsection (a). Once the requested information is
18 submitted, the applicable time period for a mutual benefit
19 society or utilization review organization to make a step
20 therapy exception determination shall apply.



1 Upon the grant of a step therapy exception, the mutual
2 benefit society or utilization review organization shall
3 authorize coverage for the particular prescription drug
4 prescribed by the patient's health care provider. Any adverse
5 determination under this subsection shall be subject to appeal
6 pursuant to the mutual benefit society or utilization review
7 organization's existing appeal procedures.

8 (e) Every mutual benefit society or utilization review
9 organization subject to this section shall certify annually to
10 the insurance commissioner that the mutual benefit society or
11 utilization review organization's step therapy protocol meets
12 the requirements of this section. Any proposed change in
13 protocol or clinical review criteria shall be submitted to the
14 insurance commissioner for approval before it may be implemented
15 by the mutual benefit society or utilization review
16 organization.

17 (f) Notwithstanding any law to the contrary, the insurance
18 division of the department of commerce and consumer affairs
19 shall adopt rules necessary for the purposes of this section.

20 (g) Each mutual benefit society or utilization review
21 organization shall annually submit a report to the insurance



1 division of the department of commerce and consumer affairs, on
2 forms prescribed by the insurance division of the department of
3 commerce and consumer affairs, that includes the following:

4 (1) The number of step therapy exception requests
5 received;

6 (2) The type of health care providers or the medical
7 specialties of the health care providers submitting
8 step therapy exception requests;

9 (3) The number of step therapy exception requests that
10 were:

11 (A) Denied, including the reasons for the denials;

12 (B) Approved;

13 (C) Initially denied and then appealed; and

14 (D) Initially denied and then subsequently reversed
15 by the internal appeals or external reviews; and

16 (4) The medical conditions under which patients were
17 granted step therapy exceptions due to the likelihood
18 that switching from the prescription drug will likely
19 cause an adverse reaction by or physical or mental
20 harm to the insured.



1 (h) This section applies to any state regulated plan or
2 health insurance coverage offered in connection with a state
3 regulated plan that provides coverage of a prescription drug
4 pursuant to a policy that meets the definition of a step therapy
5 protocol, regardless of whether the policy is described as a
6 step therapy protocol.

7 (i) Nothing in this section shall be construed to prevent:

8 (1) A mutual benefit society or utilization review
9 organization from requiring a patient to try an AB-
10 rated generic equivalent drug or interchangeable
11 biological product before providing coverage for a
12 name-brand prescription drug, unless the requirement
13 meets the qualifications for a step therapy exception
14 pursuant to subsection (c);

15 (2) A mutual benefit society or utilization review
16 organization from requiring a pharmacist to effect
17 substitutions of prescription drugs pursuant to
18 section 328-92; or

19 (3) A health care provider from prescribing any
20 prescription drug that the provider finds to be
21 medically appropriate for the patient.



1 (j) For the purposes of this section:

2 "AB-rated generic equivalent drug" means a prescription
3 drug product that is considered by the federal Food and Drug
4 Administration to be therapeutically equivalent to a particular
5 name brand prescription drug.

6 "Clinical practice guidelines" means a systematically
7 developed statement to assist decision-making by health care
8 providers and patients about appropriate health care for
9 specific clinical circumstances and conditions.

10 "Clinical review criteria" means the written screening
11 procedures, decision abstracts, clinical protocols, and practice
12 guidelines used by a mutual benefit society or utilization
13 review organization to determine the medical necessity and
14 appropriateness of health care services.

15 "Interchangeable biological product" has the same meaning
16 as defined in section 328-91.

17 "Medically appropriate" means health services and supplies
18 that under the applicable standard of care are appropriate:

19 (1) To improve or preserve health, life, or function;

20 (2) To slow the deterioration of health, life, or

21 function; or



1 (3) For the early screening, prevention, evaluation,
2 diagnosis, or treatment of a disease, condition,
3 illness, or injury.

4 "Step therapy exception determination" means a
5 determination as to whether a step therapy protocol should apply
6 in a particular situation or be overridden in favor of immediate
7 coverage of a health care provider's selected prescription drug
8 based on a review of the patient's or prescriber's request for
9 an exception and supporting rationale and documentation.

10 "Step therapy protocol" means a protocol or program that
11 requires the use of specific prescription drugs in a specific
12 sequence as a condition of coverage under a policy.

13 "Utilization review organization" means an entity that
14 conducts utilization reviews, other than a mutual benefit
15 society that performs utilization reviews for its own health
16 benefit plans."

17 SECTION 4. Section 432D-23, Hawaii Revised Statutes, is
18 amended to read as follows:

19 "**§432D-23 Required provisions and benefits.**

20 Notwithstanding any provision of law to the contrary, each
21 policy, contract, plan, or agreement issued in the State after



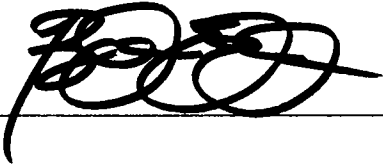
1 January 1, 1995, by health maintenance organizations pursuant to
 2 this chapter, shall include benefits provided in sections
 3 431:10-212, 431:10A-115, 431:10A-115.5, 431:10A-116, 431:10A-
 4 116.2, 431:10A-116.5, 431:10A-116.6, 431:10A-119, 431:10A-120,
 5 431:10A-121, 431:10A-122, 431:10A-125, 431:10A-126, 431:10A-132,
 6 431:10A-133, 431:10A-134, 431:10A-140, [~~and 431:10A-134,~~] and
 7 431:10A- and chapter 431M."

8 SECTION 5. This Act does not affect rights and duties that
 9 matured, penalties that were incurred, and proceedings that were
 10 begun before its effective date.

11 SECTION 6. Statutory material to be repealed is bracketed
 12 and stricken. New statutory material is underscored.

13 SECTION 7. This Act shall take effect upon its approval,
 14 and shall apply to all health insurance and health benefit
 15 plans, contracts, and agreements issued or renewed in this State
 16 after December 31, 2025.

17

INTRODUCED BY: 

Report Title:

Health Insurance; Prescription Drugs; Step Therapy Protocol;
Clinical Review Criteria; Clinical Practice Guidelines;
Exceptions

Description:

Establishes requirements for the clinical review criteria and clinical practical guidelines used to establish step therapy protocols. Provides a process for a patient to request an exception to using step therapy protocols. Establishes insurance coverage requirements relating to the use of step therapy protocols and standards to appeal an adverse step therapy exception determination.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

