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

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



1 residents' access to appropriate treatment may be dependent upon
2 their insurance carrier instead of on their medical provider.
3 It is imperative that step therapy protocols in the State
4 preserve health care providers' right to make treatment decisions
5 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 review 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 must include
13 provisions to exempt patients for whom step therapy would be
14 inappropriate to ensure that patients have access to a fair,
15 transparent, and independent process for requesting an exemption
16 to a step therapy protocol when the patients' physician deems it
17 to be appropriate.

18 The purpose of this Act is to require all insurers in the
19 State to adopt minimum standards including clinical review
20 criteria and procedural transparency to preserve the health and
21 safety of Hawaii's residents.



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

4 "§431:10A- Step therapy protocol; exceptions. (a)
5 Clinical review criteria used to establish a step therapy
6 protocol shall:

7 (1) Be based on clinical practice guidelines that
8 recommend that the prescription drugs shall be taken
9 in the specific sequence required by the step therapy
10 protocol; and

11 (A) Were developed and endorsed by a
12 multidisciplinary panel of experts that manages
13 conflicts of interest among the members of the
14 writing and review groups by:

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



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- 1 (ii) Using a methodologist to work with writing
2 groups to provide objectivity in data
3 analysis and ranking of evidence through
4 preparing evidence tables and facilitating
5 consensus; and
- 6 (iii) Offering opportunities for public review and
7 comments;
- 8 (B) Are based on high quality studies, research, and
9 medical practices that employ explicit and
10 transparent processes to:
- 11 (i) Minimize biases and conflicts of interest;
12 (ii) Explain the relationship between treatment
13 options and outcomes;
- 14 (iii) Rate the quality of the evidence supporting
15 recommendations; and
- 16 (iv) Consider relevant patient subgroups and
17 preferences;
- 18 (4) Be continually updated through a review of new
19 evidence, research, and newly developed treatments;
20 and



1 (5) Take into account the needs of atypical patient
2 populations and diagnoses.

3 No insurer, utilization review organization, or health care
4 provider shall be required to create any new entity to develop
5 clinical review criteria used for step therapy protocols. In
6 the absence of the capacity to meet any requirement of this
7 subsection, peer reviewed publications may be relied upon.

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

19 (c) A step therapy exception shall be granted if,
20 regardless of any current or prior insurance coverage, the
21 patient's relevant medical condition is currently stabilized by



1 a particular prescription drug prescribed by the patient's
2 health care provider and the patient's health care provider has
3 prescribed continued treatment with the same prescription drug.

4 A step therapy exception shall be granted to a patient whose
5 relevant medical condition is not currently stabilized by a
6 particular prescription drug if any prescription drug required
7 under the applicable step therapy protocol:

8 (1) Is contraindicated or will likely cause an adverse
9 reaction by or physical or mental harm to the patient;

10 (2) Is expected to be ineffective based on the known
11 clinical characteristics of the patient and the known
12 characteristics of the prescription drug;

13 (3) Has been previously prescribed to the patient or is in
14 the same pharmacologic class or has the same mechanism
15 of action as another prescription drug that has been
16 prescribed to the patient and was discontinued by the
17 patient's health care provider due to lack of efficacy
18 or effectiveness, diminished effect, or an adverse
19 event, regardless of any current or prior insurance
20 coverage of the prescription drug; or



1 (4) Will not serve the best interest of the patient, based
2 on medical necessity.

3 (d) An insurer or utilization review organization shall
4 make a step therapy exception determination within seventy-two
5 hours of receipt of a request for determination or filing of an
6 appeal or within twenty-four hours if exigent circumstances
7 exist. If no determination has been made within the time
8 specified, the exception shall be deemed to be granted.

9 Upon the grant of a step therapy exception, the insurer or
10 utilization review organization shall authorize coverage for the
11 particular prescription drug prescribed by the patient's health
12 care provider. Any adverse determination under this subsection
13 shall be subject to appeal pursuant to the insurer or
14 utilization review organization's existing appeal procedures.

15 (e) Every insurer or utilization review organization
16 subject to this section shall certify annually to the insurance
17 commissioner that the insurer or utilization review
18 organization's step therapy protocol meets the requirements of
19 this section. Any proposed change in protocol or clinical
20 review criteria shall be submitted to the insurance commissioner



1 for approval before it may be implemented by the insurer or
2 organization.

3 (f) Nothing in this section shall be interpreted to
4 prevent:

5 (1) An insurer or utilization review organization from
6 requiring a patient to try an AB-rated generic
7 equivalent drug prior to providing coverage for a
8 name-brand prescription drug; or

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

12 (g) As used in this section, unless the context indicates
13 otherwise:

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

18 "Clinical practice guidelines" means a systematically
19 developed statement to assist decisionmaking by health care
20 providers and patients about appropriate health care for
21 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 "Step therapy protocol" means a protocol or program that
7 requires the use of specified prescription drugs in a specific
8 sequence as a condition of coverage under a pharmacy or medical
9 benefit plan.

10 "Step therapy exception determination" means a
11 determination as to whether a step therapy protocol should apply
12 in a particular situation or be overridden in favor of immediate
13 coverage of a health care provider's selected prescription drug
14 based on a review of the patient's or prescriber's request for
15 an override, along with supporting rationale and documentation.

16 "Utilization review organization" means an entity that
17 conducts utilization reviews, other than an insurer that
18 performs utilization reviews for its own policies."

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



1 "§432:1- Step therapy protocol; exceptions. (a)

2 Clinical review criteria used to establish a step therapy
3 protocol shall:

4 (1) Be based on clinical practice guidelines that
5 recommend that the prescription drugs shall be taken
6 in the specific sequence required by the step therapy
7 protocol; and

8 (A) Were developed and endorsed by a
9 multidisciplinary panel of experts that manages
10 conflicts of interest among the members of the
11 writing and review groups by:

12 (i) Requiring members to disclose any potential
13 conflict of interests with entities,
14 including insurers, health plans, and
15 pharmaceutical manufacturers and recuse
16 themselves of voting if they have a conflict
17 of interest;

18 (ii) Using a methodologist to work with writing
19 groups to provide objectivity in data
20 analysis and ranking of evidence through



- 1 preparing evidence tables and facilitating
2 consensus; and
3 (iii) Offering opportunities for public review and
4 comments;
5 (B) Are based on high quality studies, research, and
6 medical practices that employ explicit and
7 transparent processes to:
8 (i) Minimize biases and conflicts of interest;
9 (ii) Explain the relationship between treatment
10 options and outcomes;
11 (iii) Rate the quality of the evidence supporting
12 recommendations; and
13 (iv) Consider relevant patient subgroups and
14 preferences;
15 (4) Be continually updated through a review of new
16 evidence, research, and newly developed treatments;
17 and
18 (5) Take into account the needs of atypical patient
19 populations and diagnoses.
20 No mutual benefit society, utilization review organization,
21 or health care provider shall be required to create any new



1 entity to develop clinical review criteria used for step therapy
2 protocols. In the absence of the capacity to meet any
3 requirement of this subsection, peer reviewed publications may
4 be relied upon.

5 (b) When coverage of a prescription drug for the treatment
6 of any medical condition is restricted for use by a mutual
7 benefit society or utilization review organization through the
8 use of a step therapy protocol, the patient and the prescribing
9 practitioner shall have access to a clear, readily accessible,
10 and convenient process to request a step therapy exception
11 determination, which shall be publicly available through the
12 mutual benefit society or utilization review organization's
13 website. An mutual benefit society or utilization review
14 organization may use its existing medical exceptions or appeal
15 process to satisfy this requirement; provided that the process
16 complies with the requirements of this section.

17 (c) A step therapy exception shall be granted if,
18 regardless of any current or prior insurance coverage, the
19 patient's relevant medical condition is currently stabilized by
20 a particular prescription drug prescribed by the patient's
21 health care provider and the patient's health care provider has



1 prescribed continued treatment with the same prescription drug.

2 A step therapy exception shall be granted to a patient whose
3 relevant medical condition is not currently stabilized by a
4 particular prescription drug if any prescription drug required
5 under the applicable step therapy protocol:

6 (1) Is contraindicated or will likely cause an adverse
7 reaction by or physical or mental harm to the patient;

8 (2) Is expected to be ineffective based on the known
9 clinical characteristics of the patient and the known
10 characteristics of the prescription drug;

11 (3) Has been previously prescribed to the patient or is in
12 the same pharmacologic class or has the same mechanism
13 of action as another prescription drug that has been
14 prescribed to the patient and was discontinued by the
15 patient's health care provider due to lack of efficacy
16 or effectiveness, diminished effect, or an adverse
17 event, regardless of any current or prior insurance
18 coverage of the prescription drug; or

19 (4) Will not serve the best interest of the patient, based
20 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
4 determination or filing of an appeal or within twenty-four hours
5 if exigent circumstances exist. If no determination has been
6 made within the time specified, the exception shall be deemed to
7 be granted.

8 Upon the grant of a step therapy exception, the mutual
9 benefit society or utilization review organization shall
10 authorize coverage for the particular prescription drug
11 prescribed by the patient's health care provider. Any adverse
12 determination under this subsection shall be subject to appeal
13 pursuant to the mutual benefit society or utilization review
14 organization's existing appeal procedures.

15 (e) Every mutual benefit society or utilization review
16 organization subject to this section shall certify annually to
17 the insurance commissioner that the mutual benefit society or
18 utilization review organization's step therapy protocol meets
19 the requirements of this section. Any proposed change in
20 protocol or clinical review criteria shall be submitted to the
21 insurance commissioner for approval before it may be implemented



1 by the mutual benefit society or utilization review
2 organization.

3 (f) Nothing in this section shall be interpreted to
4 prevent:

5 (1) A mutual benefit society or utilization review
6 organization from requiring a patient to try an AB-
7 rated generic equivalent drug prior to providing
8 coverage for a name-brand prescription drug; or

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

12 (g) As used in this section, unless the context indicates
13 otherwise:

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

18 "Clinical practice guidelines" means a systematically
19 developed statement to assist decision making by health care
20 providers and patients about appropriate health care for
21 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 a mutual benefit society or utilization
4 review organization to determine the medical necessity and
5 appropriateness of health care services.

6 "Step therapy protocol" means a protocol or program that
7 requires the use of specific prescription drugs in a specific
8 sequence as a condition of coverage under a pharmacy or medical
9 benefit plan.

10 "Step therapy exception determination" means a
11 determination as to whether a step therapy protocol should apply
12 in a particular situation or be overridden in favor of immediate
13 coverage of a health care provider's selected prescription drug
14 based on a review of the patient's or prescriber's request for
15 an exception and supporting rationale and documentation.

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

20 SECTION 4. Section 432D:23, Hawaii Revised Statutes, is
21 amended to read as follows:



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Report Title:

Health Insurance; Prescription Drugs; Step Therapy Protocol

Description:

Establishes requirements for step therapy protocols to ensure patient access to the particular prescription drugs prescribed by health care providers. Establishes insurance coverage requirements and standards for appeal of coverage determinations.

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

