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## 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;



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- 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 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 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



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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."

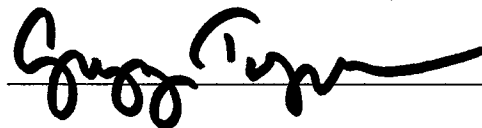
8 SECTION 5. This Act does not affect rights and duties that  
9 matured, penalties that were incurred, and proceedings that were  
10 begun before its effective date.

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:



JAN 15 2025





# H.B. NO. 216

**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.*

