THE SENATE
THIRTY-THIRD LEGISLATURE, 2025
STATE OF HAWAII

S.B. NO. 226

JAN 15 2025

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

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

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

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

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

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

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

transparent provision of prescription drugs to residents of the State.

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

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

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

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

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

(B) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

(C) Offering opportunities for public review and comments;

provided that in the absence of a panel, peer reviewed publications shall suffice;

(3) Be based on high quality studies, research, and medical practices;

(4) Be established under an explicit and transparent process that:

(A) Minimizes biases and conflicts of interest;

(B) Explains the relationship between treatment options and outcomes;

(C) Rates the quality of the evidence supporting recommendations; and

(D) Considers relevant patient subgroups and preferences;

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

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

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

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

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

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

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

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

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

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

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

(B) Is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug;

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

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

(d) An insurer or utilization review organization shall make a step therapy exception determination within seventy-two hours of receipt of a request for an exception or filing of an appeal; provided that if exigent circumstances exist, a

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

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

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

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

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

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

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

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

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

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

(B) Approved;

(C) Initially denied and then appealed; and

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

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

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

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

(1) An insurer or utilization review organization from requiring a patient to try an AB-rated generic

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

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

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

(j) For the purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

insurers, health plans, and pharmaceutical manufacturers and recuse themselves of voting if they have a conflict of interest;

(B) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

(C) Offering opportunities for public review and comments;

provided that in the absence of a panel, peer reviewed publications shall suffice;

(3) Be based on high quality studies, research, and medical practices;

(4) Be established under an explicit and transparent process that:

(A) Minimizes biases and conflicts of interest;

(B) Explains the relationship between treatment options and outcomes;

(C) Rates the quality of the evidence supporting recommendations; and

(D) Considers relevant patient subgroups and preferences;

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

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

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

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

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

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

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

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

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

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

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

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

(B) Is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug;

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Approved;

(C) Initially denied and then appealed; and

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

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

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

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

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

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

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

(j) For the purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

"§432D-23 Required provisions and benefits. Notwithstanding any provision of law to the contrary, each policy, contract, plan, or agreement issued in the State after

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

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

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

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

INTRODUCED BY: _____

S.B. NO. 226

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.