SHB 1879 - H AMD **221**
By Representative Jinkins

ADOPTED 03/08/2019

Strike everything after the enacting clause and insert the following:

"NEW SECTION. **Sec. 1.** A new section is added to chapter 48.43 RCW to read as follows:

The definitions in this section apply throughout this section and sections 2 and 3 of this act unless the context clearly requires otherwise.

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

(2) "Clinical review criteria" means the written screening procedures, decision rules, medical protocols, and practice guidelines used by a health carrier or review organization as an element in the evaluation of medical necessity and appropriateness of requested prescription drugs under the health plan.

(3) "Emergency fill" means a limited dispensed amount of medication that allows time for the processing of prescription drug utilization management.

(4) "Medically appropriate" means health services, supplies, and prescription drugs that under the applicable standard of care are appropriate: (a) To improve or preserve health, life, or function; (b) to slow the deterioration of health, life, or function; or (c) for the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

(5) "Prescription drug utilization management" means a set of formal techniques used by a health carrier or review organization, that are designed to monitor the use of or evaluate the medical necessity, appropriateness, efficacy, or efficiency of prescription drugs including, but not limited to, prior authorization and step therapy protocol.

(6) "Prior authorization" means a mandatory process that a carrier or its designated or contracted representative requires a provider or facility to follow to determine if a service is a benefit and meets the requirements for medical necessity, clinical appropriateness, level of care, or effectiveness in relation to the applicable plan.

(7) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition will be covered by a health carrier.

NEW SECTION. **Sec. 2.** A new section is added to chapter 48.43 RCW to read as follows:

For health plans delivered, issued for delivery, or renewed on or after January 1, 2021, clinical review criteria used to establish a prescription drug utilization management protocol must be evidence-based and continually updated through review of new evidence, research, and newly developed treatments.

NEW SECTION. **Sec. 3.** A new section is added to chapter 48.43 RCW to read as follows:

For health plans delivered, issued for delivery, or renewed on or after January 1, 2021:

(1) When coverage of a prescription drug for the treatment of any medical condition is subject to prescription drug utilization management, the patient and prescribing practitioner must have access to a clear, readily accessible, and convenient process to request an exception where the prescription drug utilization management is overridden in favor of coverage of the selected prescription drug of the prescribing health care provider. A health carrier or review organization may use its existing medical exceptions process to satisfy this requirement. The process must be easily accessible on the health carrier or review organization's web site. Approval criteria must be clearly posted on the health carrier or review organization's web site, providing specific information on documentation and other criteria. This information must be in plain language and understandable to providers and patients.

(2) Health carriers must disclose all rules related to the prescription drug utilization management process to all participating providers, including the specific information and documentation that

must be submitted in order to be considered a completed exception request.

(3) An exception request must be granted if sufficient evidence is submitted by the provider and patient to establish that:

(a) The required prescription drug is contraindicated or will likely cause a clinically predictable adverse reaction by, or physical or mental harm to, the patient;

(b) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

(c) The patient has tried the required prescription drug while under his or her current or a previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(d) The patient is currently receiving a positive therapeutic outcome on a prescription drug recommended by the patient's provider for the medical condition under consideration while on a current or the immediately preceding health benefit plan; or

(e) The required prescription drug is not in the best interest of the patient, based on documentation of medical appropriateness, because the patient's use of the prescription drug is expected to:

(i) Create a barrier to the patient's adherence to or compliance with the patient's plan of care;

(ii) Negatively impact a comorbid condition of the patient;

(iii) Cause a clinically predictable negative drug interaction; or

(iv) Decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities.

(4) Upon the granting of an exception, the health carrier or review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

(5)(a) For nonurgent exception requests, the health carrier or review organization must:

(i) Within three business days notify the provider that additional information, as disclosed under subsection (2) of this section, is required in order to approve or deny the exception, if the information provided is not sufficient to approve or deny the request; and

(ii) Within three business days of receipt of sufficient information as disclosed under subsection (2) of this section, approve a request if the information provided meets at least one of the conditions outlined in subsection (3) of this section, or deny a request if the requested service does not meet at least one of the conditions outlined in subsection (3) of this section.

(b) For urgent exception requests, the health carrier or review organization must:

(i) Within one business day notify the provider that additional information, as disclosed under subsection (2) of this section, is required in order to approve or deny the exception, if the information provided is not sufficient to approve or deny the request; and

(ii) Within one business day of receipt of sufficient information as disclosed under subsection (2) of this section, approve a request if the information provided meets at least one of the conditions outlined in subsection (3) of this section, or deny a request if the requested service does not meet at least one of the conditions outlined in subsection (3) of this section.

(c) If a response by a health carrier or review organization is not received within the time allotted, the exception or appeal is deemed granted.

(d) For purposes of this subsection, requests are considered urgent when an enrollee is experiencing a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.

(6) Health carriers must cover an emergency supply fill if the health care provider determines an emergency fill is necessary to keep the patient stable while the exception request is being processed.

(7) When responding to a prescription drug utilization management exception request, a health carrier or review organization shall clearly state in their response if the exception request was approved or denied. The health carrier must use clinical review criteria as outlined in section 2 of this act for the basis of any denial. The denial must include the specific clinical review criteria relied on for the denial and information about any internal and external appeals process for the denial of the prescription drug utilization management exception request. If the exception request from the

provider or facility is denied for administrative reasons, or for not including all the necessary information, the health carrier or review organization must inform the provider or facility what additional information is needed and the deadline for its submission.

(8) The health carrier or review organization must permit a stabilized patient to remain on a drug during an exception or appeals process.

(9) A health carrier must provide sixty days' notice for any new rules that apply to prescription drug utilization management protocols. New health carrier rules or policies may not be applied retroactively.

(10) This section does not prevent:

(a) A health carrier or review organization from requiring a patient to try an AB-rated generic equivalent or a biological product that is an interchangeable biological product prior to providing coverage for the equivalent branded prescription drug;

(b) A health carrier or review organization from denying an exception for a drug that has been removed from the market due to safety concerns from the federal food and drug administration; or

(c) A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

NEW SECTION. **Sec. 4.** The commissioner shall adopt rules necessary for the implementation of this act."

Correct the title.

EFFECT: (1) Requires an exception to be granted if sufficient evidence is submitted to establish:

(a) The patient is currently receiving a positive therapeutic outcome on a prescription drug recommended by their provider for the medical condition under consideration while on a current or the immediately preceding health benefit plan; or

(b) The required prescription drug is not in the best interest of the patient, based on documentation of medical appropriateness, because the patient's use of the prescription drug is expected to: Create a barrier to the patient's adherence to or compliance with the patient's plan of care; negatively impact a comorbid condition of the patient; cause a clinically predictable negative drug interaction; or decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities.

(2) Modifies the time periods in which a health carrier or review organization must respond to and accept or deny an exception request.

(3) States that a health carrier or review organization is not prevented from denying an exception for a drug that has been removed

from the market due to safety concerns from the federal Food and Drug Administration.

(4) Removes the requirement that health carriers and review organizations that utilize prescription drug utilization management protocols allow only health care providers that hold a license, certificate, or registration, in good standing and in the same or related field as the health care provider being reviewed, to consult and make decisions to deny, limit, or terminate a person's coverage.

(5) Modifies definitions and terms.

(6) Modifies the requirement that health carriers or review organizations provide notice for any new rules, from 90 days' to 60 days' notice.

(7) Requires health carriers and review organizations to include the specific clinical review criteria relied on for a denial of an exception request as well as information about any internal appeals process in addition to any external appeals process.

(8) Removes language stating that a health carrier may include a prior authorization requirement for its prescription drug benefit and its exception process that is based on accepted peer reviewed clinical studies, federal food and drug administration black box warnings, whether the drug is available over-the-counter, the enrollee's condition, medical necessity criteria, and patient safety.

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