ESHB 1879 - S COMM AMD
By Committee on Health & Long Term Care

ADOPTED 04/12/2019

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 clinical practice guidelines used by a health carrier or prescription drug utilization management entity as an element in the evaluation of medical necessity and appropriateness of requested prescription drugs under a 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 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 prescription drug utilization management entity, 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 protocols.

(6) "Prescription drug utilization management entity" means an entity affiliated with, under contract with, or acting on behalf of a health carrier to perform prescription drug utilization management.

(7) "Prior authorization" means a mandatory process that a carrier or prescription drug utilization management entity 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.

(8) "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 updated on a regular basis 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 through which the prescription drug utilization management can be overridden in favor of coverage of a prescription drug prescribed by a treating health care provider. A health carrier or prescription drug utilization management entity may use its existing medical exceptions process to satisfy this requirement. The process must be easily accessible on the health carrier and prescription drug utilization management entity's web site. Approval criteria must be clearly posted on the health carrier and prescription drug utilization management entity's web site. This information must be in plain language and understandable to providers and patients.

(2) Health carriers must disclose all rules and criteria related to the prescription drug utilization management process to all participating providers, including the specific information and documentation that must be submitted by a health care provider or patient to be considered a complete exception request.

(3) An exception request must be granted if the health carrier or prescription drug utilization management entity determines that the evidence submitted by the provider or patient is sufficient to establish that:

(a) The required prescription drug is contraindicated or will likely cause a clinically predictable adverse reaction by 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 or another prescription drug in the same pharmacologic class or a drug with the same mechanism of action while under his or her current or a previous health plan, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(d) The patient is currently experiencing a positive therapeutic outcome on a prescription drug recommended by the patient's provider for the medical condition under consideration while on his or her current or immediately preceding health plan, and changing to the required prescription drug may cause clinically predictable adverse reactions, or physical or mental harm to, the patient; 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 prescription drug utilization management entity 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 prescription drug utilization management entity must:

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

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

(b) For urgent exception requests, the health carrier or prescription drug utilization management entity must:

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

(ii) Within one business day of receipt of sufficient information from the treating health care provider as disclosed under subsection (2) of this section, approve a request if the information provided meets at least one of the conditions referenced in subsection (3) of this section or if deemed medically appropriate, or deny a request if the requested service does not meet at least one of the conditions referenced in subsection (3) of this section.

(c) If a response by a health carrier or prescription drug utilization management entity is not received within the time frames established under this section, the exception request is deemed granted.

(d) For purposes of this subsection, exception 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 a treating health care provider determines an emergency fill is necessary to keep the patient stable while the exception request is being processed. This exception shall not be used to solely justify any further exemption.

(7) When responding to a prescription drug utilization management exception request, a health carrier or prescription drug utilization management entity shall clearly state in their response if the exception request was approved or denied. The health carrier must use clinical review criteria as referenced in section 2 of this act for the basis of any denial. Any denial must be based upon and include the specific clinical review criteria relied upon for the denial and include information regarding how to appeal denial of the exception request. If the exception request from a treating health care provider is denied for administrative reasons, or for not including all the necessary information, the health carrier or prescription drug utilization management entity must inform the provider what additional information is needed and the deadline for its submission.

(8) The health carrier or prescription drug utilization management entity must permit a stabilized patient to remain on a drug during an exception request process.

(9) A health carrier must provide sixty days' notice to providers and patients for any new policies or procedures applicable to prescription drug utilization management protocols. New health carrier policies or procedures may not be applied retroactively.

(10) This section does not prevent:

(a) A health carrier or prescription drug utilization management entity 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 prescription drug utilization management entity 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 insurance commissioner shall adopt rules necessary for the implementation of this act."

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On page 1, line 2 of the title, after "benefits;" strike the remainder of the title and insert "adding new sections to chapter 48.43 RCW; and creating a new section."

EFFECT: (1) Adds a definition for "prescription drug utilization management entity" and replaces references to "review organization."
(2) Makes technical changes to clarify language.

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