H-1946.1

SUBSTITUTE HOUSE BILL 1879

State of Washington 66th Legislature 2019 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Jinkins, Cody, Harris, Macri, DeBolt, Pollet, Robinson, Tharinger, and Doglio)

READ FIRST TIME 02/22/19.

AN ACT Relating to regulating and reporting of utilization management in prescription drug benefits; adding new sections to chapter 48.43 RCW; and creating a new section.

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

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 admissions, procedures, and services under the auspices of the applicable plan.

(3) "Emergency fill" means a limited dispensed amount of medication that allows time for the processing of a step therapy or prior authorization request.

(4) "Medically appropriate" means health services and supplies 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. Prior authorization occurs before the service is delivered.

(7) "Step therapy exception" or "exception" means an exception to the step therapy protocol granted in cases where the circumstances demonstrate that the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(8) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are covered by a health carrier or health plan.

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:

(1) Clinical review criteria used to establish a prescription drug utilization management protocol must be evidence-based clinical review criteria. 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, objective and relevant clinical information about the enrollee's condition, specific medical necessity criteria, patient safety, or other criteria that meet an accepted, medically applicable standard of care.

(2) The requirements of RCW 48.43.016 (3) and (4) and 48.43.520(1) apply to health carriers and review organizations that utilize prescription drug utilization management protocols.

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 restricted for use by a health carrier or review organization through the use of a prescription drug utilization management protocol, the patient and prescribing practitioner must have access to a clear, readily accessible, and convenient process to request an exception. 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 request.

(3) An exception 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 an 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 required prescription drug is not in the best interest of the patient, based on medical appropriateness; or

(e) The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan.

(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) The health carrier or review organization shall approve or deny an exception request or an appeal within seventy-two hours of receipt of all documentation required by the health carrier or review organization as disclosed under subsection (2) of this section. In cases where exigent circumstances exist, a health carrier or review organization shall approve or deny a request within twenty-four hours of receipt of all documentation required by the health carrier or review organization as disclosed under subsection (2) of this section. If a response by a health carrier or review organization is not received within the time allotted, the exception or appeal is deemed granted.

(b) For purposes of this subsection, "exigent circumstances" exist 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 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 service was approved or denied. The health carrier must provide a specific reason for the denial and use evidence-based peer reviewed literature for the basis of the denial. If the denial is based on specific payer policy,

clinical criteria, or peer-reviewed literature, the denial must include specific language relied on for the denial and information about an external appeals process. 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 while the prescription drug utilization management is addressed, including the appeals process.

(9) A health carrier must provide ninety 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; or

(b) 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.

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