H-0746.1

HOUSE BILL 1879

State of Washington 66th Legislature 2019 Regular Session

By Representatives Jinkins, Cody, Harris, Macri, and DeBolt

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 abstracts, clinical protocols, and practice guidelines used by a health carrier, health plan, or utilization review organization to determine the medical necessity and appropriateness of health care services.

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

(4) "Medically necessary" 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 delegate of the health carrier, such as a pharmacy benefit manager or third-party administrator, 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" means that a 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.

(9) "Utilization review organization" means an entity that conducts utilization review, other than a health carrier or health plan performing utilization review for its own health benefit plans.

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

(1) Clinical review criteria used to establish a prescription drug utilization management protocol must be based on clinical practice guidelines that:

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

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

(ii) 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

(iii) Offering opportunities for public review and comments;

(b) Are based on high quality studies, research, and medical practice;

(c) Are created by an explicit and transparent process that:

(i) Minimizes biases and conflicts of interest;

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

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

(iv) Considers relevant patient subgroups and preferences; and

(d) Are continually updated through a review of new evidence, research, and newly developed treatments.

(2) In the absence of clinical guidelines that meet the requirements in subsection (1)(a) of this section, peer-reviewed publications may be substituted.

(3) When establishing a prescription drug utilization management protocol, a utilization review organization shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(4) This section does not require health carriers, health plans, or the state to set up a new entity to develop clinical review criteria used for prescription drug utilization management.

(5) This section applies only to health insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2021.

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

(1) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health plan, or utilization 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, health plan, or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process must be easily accessible on the health carrier, health plan, or utilization review organization's web site. Approval criteria must be clearly posted on its 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, related information and documentation that must be submitted in order to be considered a completed request.

(3) An exception must be expeditiously granted if:

(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 necessity; and

(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, health plan, or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

(5) The health carrier, health plan, or utilization review organization shall respond to an exception request or an appeal within seventy-two hours of receipt. In cases where exigent circumstances exist, a health carrier, health plan, or utilization

review organization shall respond within twenty-four hours of receipt. If a response by a health carrier, health plan, or utilization review organization is not received within the time allotted, the exception or appeal is deemed granted.

(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 request, a health carrier, health plan, or utilization 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 policy language and an external appeals process. If the request from the participating provider or facility is denied for administrative reasons, or for not including all the necessary information, the health carrier, health plan, or utilization review organization must inform the provider or facility what additional information is needed and the deadline for its submission.

(8) The health carrier, health plan, or utilization 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) Any exception as defined in section 1 of this act is eligible for appeal by an insured.

(11) This section does not prevent:

(a) A health carrier, health plan, or utilization review organization from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug; and

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

(12) This section applies only to health insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2021.

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

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