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**SENATE BILL 6233**

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**State of Washington 65th Legislature 2018 Regular Session**

**By** Senators Cleveland, Rivers, Kuderer, Fain, and Conway

AN ACT Relating to regulating the use of step therapy protocols by providing a simple and expeditious process for exceptions to the protocols that the health care provider deems not in the best interests of the patient; 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) The legislature finds the following:

(a) Health insurance plans are increasingly making use of step therapy protocols under which patients are required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider;

(b) Such step therapy protocols, where they are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling health care costs;

(c) In some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug;

(d) Without uniform policies in the state for step therapy protocols, all patients may not receive the equivalent or most appropriate treatment; and

(e) It is imperative that step therapy protocols in the state preserve the health care provider's right to make treatment decisions in the best interest of the patient.

(2) Therefore, the legislature declares it a matter of public interest that it 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; that patients be exempt from step therapy protocols when those protocols are inappropriate or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent, and independent process for requesting an exception to a step therapy protocol when the patient's physician deems appropriate.

NEW SECTION. **Sec.**  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 3 and 4 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 patient decisions 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 an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of health care services.

(3) "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.

(4) "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.

(5) "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 an insurer or health plan.

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

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

(1) Clinical review criteria used to establish a step therapy protocol shall be based on clinical practice guidelines that:

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

(b) 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 conflict of interest with entities, including insurers, health plans, and pharmaceutical manufacturers and 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;

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

(d) 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;

(e) 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)(b) of this section, peer-reviewed publications may be substituted.

(3) When establishing a step therapy 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 insurers, health plans, or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

NEW SECTION. **Sec.**  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 an insurer, health plan, or utilization review organization through the use of a step therapy protocol, the patient and prescribing practitioner must have access to a clear, readily accessible, and convenient process to request a step therapy exception. An insurer, 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 insurer's, health plan's, or utilization review organization's web site.

(2) A step therapy 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 their 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.

(3) Upon the granting of a step therapy exception, the insurer, health plan, or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

(4) The insurer, health plan, or utilization review organization shall respond to a step therapy exception request or an appeal within seventy-two hours of receipt. In cases where exigent circumstances exist, an insurer, health plan, or utilization review organization shall respond within twenty-four hours of receipt. Should a response by an insurer, health plan, or utilization review organization not be received within the time allotted, the exception or appeal is deemed granted.

(5) Any step therapy exception as defined in section 2 of this act is eligible for appeal by an insured.

(6) This section does not prevent:

(a) An insurer, 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.

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

The commissioner shall adopt rules necessary for the implementation of sections 2 through 4 and 6 of this act.

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

Sections 2 through 5 of this act apply only to health insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2019.

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