

SENATE BILL REPORT

SB 6233

As of January 19, 2018

Title: 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.

Brief Description: Addressing step therapy protocols for prescription drugs.

Sponsors: Senators Cleveland, Rivers, Kuderer, Fain and Conway.

Brief History:

Committee Activity: Health & Long Term Care: 1/18/18.

Brief Summary of Bill

- Creates requirements for the clinical review criteria used by health carriers to establish step therapy protocols.
- Requires an accessible process for patients and providers to request an exception from step therapy.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Greg Attanasio (786-7410)

Background: Step therapy is a form of prior authorization whereby health carriers approve a prescription drug or class of drugs for a medical condition based on cost effectiveness and treatment best practices. Step therapy requires the patient to begin treatment with the approved drug. If the patient fails to respond to the drug or experiences an adverse effect, then coverage is allowed for another drug prescribed by the patient's health care provider.

In Washington, health carriers may design their prescription drug benefit plans to include cost control measures, including requiring preferred drug substitution in a given therapeutic class if the restriction is for a less expensive, equally therapeutic alternative product available to treat the condition. Carriers must also establish a process that a provider and an enrollee may use to request substitution for a prescribed therapy, drug, or medication that is not on the formulary. This process may not unreasonably restrict an enrollee's access to non-formulary or alternative medicines for conditions that are not responsive to treatment. Carriers must

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also have a process for an enrollee to request an expedited review based on exigent circumstances such as experiencing a health condition that may jeopardize the enrollee's life or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

Summary of Bill: Clinical Practice Guidelines. A health carrier's or utilization review organization's clinical review criteria for a step therapy protocol must be based on clinical practice guidelines that:

- are developed and endorsed by a multidisciplinary panel of experts;
- recommend the prescription drugs be taken in the specific sequence required by the step therapy protocol;
- are based on high quality studies, research, and medical practice;
- are continually updated through a review of new evidence and treatments; and
- are created by a transparent process that: (1) minimizes bias, (2) explains the relationship between the treatment options and outcomes, (3) rates the quality of the evidence supporting recommendations, and (4) considers relevant patient subgroups and preferences.

Multidisciplinary Panel. The multidisciplinary panel must require members to disclose any conflicts of interest with health care entities, insurers, health plans, and pharmaceutical manufacturers and recuse themselves when necessary. It must also use a methodologist to provide objectivity in the data analysis and provide an opportunity for public review and comments.

Alternative Process. In the absence of clinical practice guidelines, carriers may use peer-reviewed publications to establish clinical review criteria.

Exception to Step Therapy. When a prescription drug is restricted through the use of a step therapy protocol, the patient and prescribing practitioner must have clear and convenient access on the health carrier's or utilization review organization's website to request an exception. The health carrier or utilization organization must respond to the request or an appeal within 72 hours, or within 24 hours when exigent circumstances exist. If they do not respond within that time, the exception is deemed granted. An exception must be granted if:

- the required step therapy prescription drug will likely cause physical or mental harm to the patient;
- the drug is expected to be ineffective based known clinical characteristics of the patient and the drug;
- the patient tried the drug, or a substantially similar drug, under their current or previous health insurance and it was ineffective or caused an adverse event;
- the drug is not in the best interest of the patient; and
- or the patient is stable on a drug selected by their health care provider.

When an exception is granted, the insurer must authorize coverage for the drug, or generic equivalent, prescribed by the patient's provider.

Appropriation: None.

Fiscal Note: Not requested.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: The bill will ensure stability for patients who rely on a certain course of treatment. The consequences of step therapy can be severe for a number of medical conditions. Epilepsy patients who do not respond to a drug on step therapy can suffer severe injuries that result in emergency room visits, hospitalization, and additional medical bills. Patients with Crohn's disease can suffer severe side effects when taking an ineffective drug. Psoriasis patients who take ineffective drugs can develop psoriatic arthritis. Patients should have access to the appropriate drugs they need before they develop more significant medical problems.

CON: Carriers understand that step therapy is not appropriate for every patient, but exemptions to step therapy are already available.

Persons Testifying: PRO: Senator Annette Cleveland, Prime Sponsor; Kimberly Patton, citizen; Andrew Buckels, citizen; Gordon MacDonald, Crohn's and Colitis volunteer; Lisa Bayautet, citizen; Roman Daniels-Brown, Washington State Medical Association; Joan Miller, Washington Council for Behavioral Health.

CON: Kristine Brewer, Association of Washington Healthcare Plans.

Persons Signed In To Testify But Not Testifying: No one.