HOUSE BILL REPORT
ESHB 1879

As Amended by the Senate

Title: An act relating to regulating and reporting of utilization management in prescription drug benefits.

Brief Description: Regulating and reporting of utilization management in prescription drug benefits.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Jinkins, Cody, Harris, Macri, DeBolt, Pollet, Robinson, Tharinger and Doglio).

Brief History:
Committee Activity:
Health Care & Wellness: 2/12/19, 2/22/19 [DPS].
Floor Activity:
Passed House: 3/8/19, 95-0.
Senate Amended.
Passed Senate: 4/12/19, 46-0.

Brief Summary of Engrossed Substitute Bill

- Requires clinical review criteria used to establish a prescription drug utilization management protocol be evidence-based.
- Requires a health carrier or review organization that restricts coverage of a prescription drug through a prescription drug utilization management protocol to provide the patient and the prescribing practitioner with access to a clear, readily accessible, and convenient process to request an exception.
- Establishes requirements and timelines for step therapy exception requests.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 10 members: Representatives Cody, Chair; Macri, Vice Chair; Caldier, Assistant Ranking Minority Member; Davis, Harris, Jinkins, Riccelli, Robinson, Stonier and Tharinger.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Minority Report: Do not pass. Signed by 4 members: Representatives Schmick, Ranking Minority Member; Chambers, Maycumber and Thai.

Minority Report: Without recommendation. Signed by 1 member: Representative DeBolt.

Staff: Kim Weidenaar (786-7120).

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 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 Engrossed Substitute Bill:

For health plans issued 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 continually updated through review of new evidence, research, and newly developed treatments.

When coverage of a prescription drug for the treatment of any medical condition is subject to prescription drug utilization management, the patient and the prescribing practitioner must have access to a clear, readily accessible, and convenient process to request an exception. A carrier or review organization may use its existing medical exceptions process to satisfy this requirement. The process and approval criteria must be easily accessible on the entity's website, in plain language, and understandable to providers and patients.

Carriers must disclose all rules related to the prescription drug utilization management process to all participating providers, including the information and documentation that must be completed in order for a request to be complete.

A step therapy exception must be granted if sufficient evidence is submitted by the provider and patient to establish that:

- the required prescription drug is:
    - contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient;
    - expected to be ineffective based on known clinical characteristics of the patient and prescription drug regimen; and
    - not in the best interest of the patient based on medical appropriateness because the patient's use of the prescription drug is expected to:
        - create a barrier to the patient's adherence to or compliance with the patient's plan of care;
        - negatively impact a comorbid condition of the patient;
        - cause a clinically predictable negative drug interaction; or
        - decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities;
- the patient has tried the required prescription drug while under the current or a previous health insurance, 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; or
- the patient is currently receiving a positive therapeutic outcome on a prescription drug recommended by their health care provider for the medical condition under consideration while on a current or the immediately preceding health benefit plan.

Upon granting an exception, the carrier or review organization must authorize coverage for the prescription drug prescribed by the patient's treating health care provider. For non-urgent exception requests, carriers or review organizations must notify a provider within one business day if additional information is required to approve or deny the request. Once all required information is received, a health carrier or review organization must, within three business days, approve a request if the information provided meets the exception criteria or deny the request.

For urgent exception requests, carriers or review organizations must notify a provider within one business day if additional information is required to approve or deny the request. Once all required information is received, a carrier or review organization must within three business days approve a request if the information provided meets the exception criteria or deny the request. 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.

If a response by a carrier or review organization is not received within the time allotted, the exception or appeal is deemed granted.

Carriers must cover an emergency supply fill if a health care provider determines an emergency fill is necessary to keep the patient stable while the exception is being processed. Emergency fill means a limited dispensed amount of medication that allows time for the processing of a step-therapy or prior authorization request.

When responding to a prescription drug utilization management exception request, a carrier or review organization must clearly state in the response if the service was approved or denied. The carrier must use clinical review criteria as a basis for any denial. The denial must include the specific clinical review criteria relied on for the denial and information about any internal and external appeals process for the denial of a prescription drug utilization management exception request.

If it is denied for administrative reasons, or for not including all of the necessary information, the carrier or review organization must inform the provider or facility what additional information is needed and the deadline for its submission.

The carrier or review organization must allow a stabilized patient to remain on a drug while the prescription drug utilization management is addressed, including the appeals process. Carriers must provide 60 days notice for any new rules that apply to prescription drug utilization management protocols. New rules or policies may not be applied retroactively.

A carrier or review organization may require 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 drug.

The insurance commissioner may adopt rules necessary to implement this act.

EFFECT OF SENATE AMENDMENT(S):

The Senate amendment:

- modifies definitions;
- makes technical changes to clarify language;
- replaces the use of "review organization" with "prescription drug utilization management entity" and defines "prescription drug utilization management entity;"
- removes the provision requiring an exception request to be granted if the required prescription drug would likely cause physical or mental harm to the patient;
- modifies the provision requiring an exception request to be granted if a patient is currently experiencing a positive therapeutic outcome on a prescription drug recommended by the patient's provider while on the current or immediately preceding health plan, so that it must be granted only if changing to the required prescription drug may cause clinically predictable adverse reactions, or physical or mental harm to, the patient; and
- states that an emergency fill exception may not be used to solely justify any further exemption.

Appropriation: None.

Fiscal Note: Preliminary fiscal note available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) This bill is supported by 23 patient groups. Patients deserve an understanding about how the step therapy protocol process works, and there needs to be a process for people who have unique conditions and need access to the appropriate drug. When treatment is delayed it can further an individual's disease state or have adverse effects.

Many individuals have co-existing conditions, where certain drugs could be contraindicated for people with different conditions. Typically a patient is put on the right drug for them in the end, but it is often a long and difficult process.

These groups are not asking for the removal of processes that limit access to certain prescriptions; these are tools that are used to control health care costs. However, there are scenarios where the drug being prescribed is the one that needs to be used. Accordingly, there must be a transparent exception process, which includes coverage for emergency fills and are based on good scientific studies.

(Opposed) None.

(Other) This bill started from a better place than similar bills in previous years. However, there are concerns about section 2 regarding the therapeutics committees, which are the committees that choose the formularies. Section 2 has a number of requirements related to conflicts of interest, which are not needed and unnecessary.

There is confusion about why an exception request must be responded to within 72 hours if the patient is allowed to be on the drug already. Additionally the public employees and school employee plans should be included.

There is support for a different approach that was based on an amendment from last year. That approach would require a health carrier to notify enrollees of the exception process and requires coverage of the drug during the process. It also requires notification if a drug is removed from the formulary among other things.

Persons Testifying: (In support) Representative Jinkins, prime sponsor; Erin Dziedzic, National Psoriasis Foundation; and Katie Kolan, Washington State Medical Association.

(Other) Carrie Tellefson, Pharmaceutical Care Management Association; Meg Jones, Association of Washington Health Care Plans; Zach Snyder, Regence Blue Shield; and Len Sorrin, Premera Blue Cross.

Persons Signed In To Testify But Not Testifying: None.