Title: An act relating to authorizing state purchased health care programs to maximize appropriate prescription drug use in a cost-effective manner.

Brief Description: Concerning prescription drug use in state purchased health care programs.

Sponsors: Senate Committee on Ways & Means (originally sponsored by Senators Keiser and Shin; by request of Governor Gregoire).

Brief History:

Committee Activity:


Brief Summary of Engrossed Substitute Bill
(As Amended by House)

- Imposes a restriction on dispense as written authority when there is evidence the prescriber's frequency of using dispense as written varies significantly from other prescribers, for a patient's first course of treatment if there is a less expensive and equally effective therapeutic alternative generic drug available, and for off-label use of drugs when there are less expensive and equally effective drugs available to treat the same conditions.
- Provides exceptions to the restrictions on dispense as written authority when the prescribed drugs are medically necessary.
- Allows the state to designate less expensive and equally effective generic drugs as preferred drugs without review by the Pharmacy and Therapeutics Committee.
- Allows the state to designate equally effective over-the-counter drugs as preferred drugs.
- Requires pharmacies to dispense prescribed nonpreferred drugs for refills of antipsychotic, antidepressant, chemotherapy, antiretroviral, immunosuppressive, and antiepileptic drugs, or for a specific treatment of Hepatitis C.

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.
Majority Report: Do pass as amended. Signed by 14 members: Representatives Linville, Chair; Ericks, Vice Chair; Cody, Conway, Darneille, Haigh, Hunt, Hunter, Kagi, Kenney, Kessler, Pettigrew, Seaquist and Sullivan.

Minority Report: Do not pass. Signed by 8 members: Representatives Alexander, Ranking Minority Member; Bailey, Assistant Ranking Minority Member; Dammeier, Assistant Ranking Minority Member; Chandler, Hinkle, Priest, Ross and Schmick.

Staff: Erik Cornellier (786-7116) and Dave Knutson (786-7146)

Background:

The 2003 Legislature created an evidence-based prescription drug program for state agencies that purchase prescription drugs directly or through reimbursement to pharmacies. Currently, the Department of Social and Health Services medical assistance program, the Health Care Authority's self-insured program, and the Department of Labor and Industries participate in the program's preferred drug list (PDL). The PDL is a list of prescription drug classes that have gone through an evidence-based review process to determine the safety, efficacy, and effectiveness of drug classes. The state contracts with the Center for Evidence-Based Policy, Oregon Health and Science University, to independently review the prescription drug classes, and their recommendations are reviewed by the Washington State Pharmacy and Therapeutics (P&T) Committee, an independent group of pharmacy doctors and medical doctors, which then makes recommendations regarding the preferred drugs on the PDL.

The evidence-based prescription program includes provisions that allow the substitution of a preferred drug for a nonpreferred drug in a given therapeutic class, except where a practitioner has indicated the prescription for the nonpreferred drug must be dispensed as written, or if the prescription is for a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug, or for the refill of an immunodulator/antiviral treatment for Hepatitis C. When a substitution is made, the pharmacist must notify the prescriber of the specific drug and dose dispensed.

The PDL process currently requires that new generic drugs await an updated P&T Committee review of the drug classes before being designated as preferred drugs. Additionally there are some drug classes where both brand-name and generic drugs are included as preferred. Although federal law precludes drug manufacturers from marketing drugs for non-Food and Drug Administration (FDA) approved use, prescribers are allowed to prescribe drugs for non-FDA approved use, or off-label use, at their discretion.

Summary of Amended Bill:

The state purchasing program may impose restrictions on an endorsing practitioner’s authority to require that a prescription be dispensed as written in cases where there is
evidence the prescriber’s frequency of using this authority varies significantly from other prescribers.

The state purchasing program may impose restrictions on an endorsing practitioner’s authority to require that a prescription be dispensed as written for off-label use of a product when there is a less expensive and equally effective FDA approved product to treat the condition and the Drug Use Review Board has reviewed the appropriateness of the limitation. The endorsing practitioner may request the off-label drug through the prior authorization process when it is medically necessary.

When a less expensive and equally effective generic product in a drug class previously reviewed by the P&T Committee becomes available, the state program may immediately designate the generic drug as a preferred drug. If an equally effective over-the-counter drug becomes available within a therapeutic class, the program may designate the over-the-counter drug as a preferred drug.

Pharmacies must dispense prescribed nonpreferred drugs for refills of antipsychotic, antidepressant, chemotherapy, antiretroviral, immunosuppressive, and antiepileptic drugs, or for a specific treatment of Hepatitis C.

The bill has an emergency clause and takes effect immediately.

**Amended Bill Compared to Original Bill:**

Generic drugs in a previously reviewed drug class must be equally effective for a state purchased health care program to designate them as preferred drugs without review by the P&T Committee. The same standard applies to designating therapeutic alternative over-the-counter drugs as preferred drugs and for imposing limitations on a prescriber’s ability to write dispense as written for initial prescriptions or for off-label uses of drugs.

Pharmacies must dispense prescribed nonpreferred drugs for refills of antipsychotic, antidepressant, chemotherapy, antiretroviral, immunosuppressive, and antiepileptic drugs, or for a specific treatment of Hepatitis C.

**Appropriation:** None.

**Fiscal Note:** Available.

**Effective Date of Amended Bill:** The bill contains an emergency clause and takes effect immediately.

**Staff Summary of Public Testimony:**

(In support) The Governor’s budget and the House and Senate budgets include savings related to prescription drug purchasing. Medicaid spends about $411 million on drugs, and about 80 percent is spent on brand-name drugs. Washington spends more on brand-name
drugs in Medicaid than the entire cost of the Basic Health Plan. It would be appropriate to increase the generic utilization rate to a level that is comparable with the private sector. The patient comes first, and this bill does not interrupt therapy. The DSHS is trying to make sure that patients receive the most effective and cost-efficient drugs.

There are a handful of endorsers that are writing dispense as written for every prescription. The DSHS will try to educate those doctors first and give them a chance to explain or change their behavior before the DSHS restricts their dispense as written authority. When the DSHS imposes restrictions, it will remove them when doctors correct their prescribing behavior.

This bill also recognizes safety concerns with off-label uses of drugs. For example, doctors are inappropriately prescribing antipsychotics as sleeping aids and for children under five.

This bill strikes the appropriate balance between competing priorities because the DSHS can provide prior authorization to override the substitution provisions in cases of medical necessity. Prior authorization takes 24 to 48 hours, and temporary emergency fills are available if patients in crisis need to start on drugs right away.

Protections under current law are not eliminated in this bill. The Oregon Health and Science University and the P&T Committee identifies therapeutic alternatives based on scientific evidence. The Drug Use Review Board, which is made up of outside physicians, also serves as a watchdog for determining what is appropriate for patients.

Mental health drugs comprise approximately 40 percent of the drugs prescribed in Medicaid, and the state could not realize the same savings without including them. If a drug is on the Preferred Drug List, the state has already addressed the issue of the psychotropic appropriateness based on best available evidence.

DSHS will work to implement the bill in a way that will protect the state from liability.

(With concerns) The need for cost savings is understandable, but people with certain conditions should have continued access to brand-name drugs that are working for them. The refill provisions are unclear, and the bill should be amended to make them clearer.

(Opposed) Washington's system for caring for the mentally ill is working. Washington has a healthier population because people have access to the drugs they need. It is not surprising that costs are increasing because the population is growing. The proponents are not suggesting that this bill will increase recovery outcomes, only that it will decrease costs.

A new individual has between 20 to 25 percent chance by random selection of being helped by the first course of treatment. According to a study in New Jersey, the prescribing doctor with an intimate relationship with the patient has a far better chance of choosing the right drug the first time. Requiring generic drugs for the first course of treatment would disrupt this doctor-patient relationship.

Substituting therapeutic alternatives that are not based on the same active ingredients is not good medicine. Rather than saving money, using this process would increase costs from hospitalization.
Ineffective prescriptions could expose the state to litigation. There is nothing in this fiscal note about liability. It would only take one bad outcome to eliminate $4 to $5 million of savings. The savings in the fiscal note also do not account for increased jail costs and decomposition.

There is a letter from 16 state attorneys general to the federal government questioning similar policies. Their concern was that states should not be able to force people to use drugs for purposes that are not approved by the Food and Drug Administration. The Legislature should consider carving out antidepressants from the restrictions on dispense as written.

Identical generic agents cannot be guaranteed for biological drugs.

**Persons Testifying:** (In support) Christina Hulet, Office of the Governor; Tim Layton, Washington State Medical Association; Duane Thurman, Health Care Authority; and Mary Anne Lindeblad, Department of Social and Health Services.

(With concerns) Alia Griffins, Washington Federation of State Employees.

(Opposed) Cliff Webster, Pharmaceutical Research and Manufacturers; Jeff Gombosky, Amgen; Peter Lukevich, Partners in Crisis; Jim Adams, National Alliance on Mental Illness; Scott Weaver, Arthritis Foundation; and Brian Wiele, Epilepsy Foundation.

**Persons Signed In To Testify But Not Testifying:** None.