HOUSE BILL REPORT
HB 1813

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to freedom of pharmacy choice.

Brief Description: Concerning freedom of pharmacy choice.

Sponsors: Representatives Schmick, Macri, Graham and Chambers.

Brief History:
Committee Activity:
Health Care & Wellness: 1/24/22, 2/2/22 [DPS].

Brief Summary of Substitute Bill

- Imposes requirements on pharmacy benefit managers.
- Defines critical access pharmacy.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 13 members: Representatives Cody, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Bronoske, Davis, Macri, Maycumber, Riccelli, Rude, Simmons, Stonier, Tharinger and Ybarra.

Minority Report: Without recommendation. Signed by 2 members: Representatives Caldier, Assistant Ranking Minority Member; Harris.

Staff: Kim Weidenaar

Background:

Benefit Manager Registration.

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

All health care benefit managers (HCBMs), including pharmacy benefit managers (PBMs), must be registered by the Insurance Commissioner (Commissioner). Applications for registration must include the identity of the HCBM and the individuals and entities with a controlling interest in the HCBM, and whether the HCBM does business as a PBM or a different type of benefit manager, in addition to other required information. Registered HCBMs must pay licensing and renewal fees. The fees must be set at an amount that ensures the registration, renewal, and oversight activities of the Commissioner are self-supporting.

Prior to approving an application, the Commissioner must find that the HCBM has not committed any act that resulted in the denial, suspension, or revocation of a registration, has the capacity to comply with state and federal laws, and has designated a person responsible for such compliance.

An HCBM may not provide services to a health carrier or an employee benefits program without a written agreement describing the rights and responsibilities of the parties. The HCBM must file with the Commissioner every benefit management contract and contract amendment between the HCBM and a provider, pharmacy, pharmacy services administration organization, or other HCBM. Enrollees in health plans issued on or after January 1, 2022, must be notified in writing of each HCBM contracted within the carrier to provide any benefit management services in the administration of the plan.

Pharmacy Benefit Manager Regulation.
A PBM is a person that contracts with pharmacies on behalf of an insurer, third party payer, or the prescription drug purchasing consortium to:

- process claims;
- provide retail network management;
- pay pharmacies or pharmacists;
- negotiate rebates;
- manage pharmacy networks; or
- make credentialing determinations.

A PBM may not:

- cause or knowingly permit to be used any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;
- charge a pharmacist or pharmacy a fee related to the adjudication of a claim, credentialing, participation, certification, accreditation, or enrollment in a network, including a fee for the receipt and processing of a pharmacy claim, for the development or management of claims processing services in a PBM network, or for participating in a PBM network;
- require accreditation standards inconsistent with or more stringent than accreditation standards established by a national accreditation organization;
- reimburse a pharmacy or pharmacist an amount less than the amount the PBM reimburses an affiliate for providing the same services; or

- retroactively deny or reduce a claim or aggregate of claims after the claim or aggregate of claims has been adjudicated, unless the original claim was submitted fraudulently or the denial or reduction is the result of a pharmacy audit.

Enforcement.
The Commissioner must provide notice of an inquiry or complaint against an HCBM concurrently to the HCBM and any carrier to which the inquiry or complaint pertains. The Commissioner may take any of the following actions based on an adverse finding against an HCBM:

- place on probation, suspend, revoke, or refuse to issue or renew the HCBM's registration;
- issue a cease and desist order against the HCBM and contracting carrier;
- fine the HCBM or the contracting carrier up to $5,000 per violation—the contracting carrier is only liable for actions conducted under the contract;
- issue an order requiring corrective action against the HCBM or the contracting carrier; or
- temporarily suspend, based on a finding that the public safety or welfare requires and emergency action, the HCBM's registration.

A carrier or program contracting with an HCBM is responsible for the HCBM's violations, including the failure to produce records requested or required by the Commissioner. No carrier or program may offer as a defense that the violation arose from the act or omission of an HCBM or other person acting on behalf or at the direction of the carrier, rather than from the direct act or omission of the carrier or program.

Critical Access Pharmacy.
The Health Care Authority is authorized to define "critical access pharmacy" in rule for purposes related to the state's Prescription Drug Purchasing Consortium. As of January 2022, "critical access pharmacy" is not defined in rule.

United States Food and Drug Administration Risk Evaluation and Mitigation Strategies.
The United States Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the FDA can apply to certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. An REMS may require participants to conduct activities that support the safe use of the medication, such as requiring that pharmacists become certified in the REMS and agree to carry out a set of activities designed to mitigate the risk of the drug. These types of requirements or activities are also referred to as "elements to assure safe use."

Summary of Substitute Bill:

A pharmacy benefit manager (PBM) that administers a prescription drug benefit may not:

- require a covered person to use a mail order pharmacy;

- impose different days allowance to fill for using one participating pharmacy over another;
- require a covered person to obtain prescriptions from a mail order pharmacy unless the prescription drug is a specialty or limited distribution prescription drug;
- reimburse a covered person's chosen participating pharmacy an amount less than the amount the PBM reimburses participating affiliated pharmacies; or
- reimburse a nonparticipating pharmacy more than a participating pharmacy.

The prohibition on not requiring a covered person to use a mail order pharmacy does not apply to a health maintenance organization (HMO) that is an integrated delivery system in which covered persons primarily use pharmacies owned and operated by the HMO.

A PBM must:
- provide fair and reasonable reimbursement to the covered person's participating pharmacy of choice;
- include a provision in contracts with participating pharmacies and pharmacy services administrative organizations (PSAOs) that authorizes the pharmacy to decline to fill a prescription if the PBM refuses to reimburse the pharmacy at a rate that is at least equal to the pharmacy's acquisition cost of the drug;
- maintain an adequate and accessible pharmacy network that must provide for convenient access for covered persons to pharmacies and critical access pharmacies; and
- permit the covered person to receive delivery or mail order through any participating pharmacy.

A PSAO must include the same provision as PBMs in contracts with participating pharmacies that authorizes the pharmacy to decline to fill a prescription if the PSAO refuses to reimburse the pharmacy at a rate that is at least equal to the pharmacy's acquisition cost of the drug.

If a covered person is using a mail order pharmacy, the PBM must:
- allow for dispensing at local participating pharmacies under the following circumstances to ensure patient access to prescription drugs:
    - if there are delays in mail order;
    - if the prescription drug arrives in an unusable condition; or
    - if the prescription drug does not arrive; and
- ensure patients have easy and timely access to prescription counseling by a pharmacist.

The above requirements apply to health benefit plans issued or renewed on or after January 1, 2023.

For purposes of these requirements, an "affiliated pharmacy" is a pharmacy that directly or indirectly through one or more intermediaries is owned by, controlled by, or is under

common ownership or control of a PBM, or where the PBM has financial interest in the pharmacy. A "specialty or limited distribution prescription drug" is a drug that's distribution is limited by a federal food and drug administration's element to assure safe use.

The Health Care Authority's (HCA) authorization to define a critical access pharmacy is removed and a "critical access pharmacy" is defined as a pharmacy in Washington that is further than a 15-mile radius from any other pharmacy, is the only pharmacy on an island, or provides critical services to vulnerable populations. If one critical access pharmacy's 15-mile radius intersects with that of another critical access pharmacy, both must be considered a critical access pharmacy if either critical access pharmacy's closure could result in impaired access for rural areas or for vulnerable populations. The HCA's Chief Pharmacy Officer may also identify pharmacies as critical access based on their unique ability to care for a population.

If a PBM offers a distinct reimbursement to rural pharmacies, it must provide a similar reimbursement to critical access pharmacies if the critical access pharmacy agrees to the terms and conditions set for affiliated pharmacies and the network as established by the health plan.

Substitute Bill Compared to Original Bill:

The substitute bill:

- removes the provisions prohibiting a pharmacy benefit manager (PBM) from:
    - requiring a covered person to contact the PBM or mail order pharmacy in order to fill the prescription drug at a pharmacy of the person's choice;
    - prohibiting or limiting a covered person from selecting a participating pharmacy of the person's choice;
    - imposing different cost sharing, monetary advantages, or penalties for using one participating pharmacy over another;
    - limiting a covered person's access to prescription drugs at a participating pharmacy of the person's choice by adding prescription drugs to a specialty or limited distribution tier; and
    - coercing a covered person to use a mail order pharmacy;
- prohibits a PBM from reimbursing a nonparticipating pharmacy more than a participating pharmacy;
- removes the requirement that a PBM must:
    - provide reimbursement to participating pharmacies that is not less than a pharmacy's cost; and
    - apply the same cost-sharing, fees, and other conditions upon enrollees regardless of where the covered person obtains the prescription drug;
- modifies the definition of "critical access pharmacy" by changing the radius from 10 miles to 15 miles;
- requires PBMs that offer distinct reimbursement to rural pharmacies, to provide similar reimbursement to critical access pharmacies, if the pharmacy agrees to the

terms and conditions set for affiliated pharmacies and the network as established by the plan;
- makes a technical correction specifying that the provisions regulating PBMs apply to health benefit plans issued or renewed on or after January 1, 2023; and
- defines "covered person" and corrects any references from "enrollees" to "covered persons."

Appropriation: None.

Fiscal Note: Available. New fiscal note requested on February 2, 2022.

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

Staff Summary of Public Testimony:

(In support) The patient or consumer should have a choice of pharmacy. For some patients it might be an hour to the nearest pharmacy so they may want to choose a mail order pharmacy. However, for those that want to fill their prescription at a local pharmacy, they should be able to do so. Many people who use insulin must go through mail order pharmacies, and if their insulin is delayed, they cannot get their insulin at the local pharmacy or they must pay out-of-pocket. Consumers need choice.

Community pharmacies administered 44 percent of COVID-19 vaccines, provided testing and monoclonal antibodies, and are trusted providers that consumers turned to during the pandemic. During this time, pharmacy benefit managers (PBMs) have been requiring and manipulating patients to use mail order pharmacies instead of community pharmacies. Patients should get to choose whether to get their prescription mailed or to have access at a community pharmacy. Mail order pharmacies owned by PBMs fractionalize care and increase costs. This bill is critical to give community pharmacies a chance.

This is the best piece of legislation. Independent pharmacies do yeoman's work. In certain areas, community pharmacies are the most consistent health care provider and are the first line of defense. These pharmacies are not asking for special treatment; the pharmacies just do not want an uphill battle.

Access to medications allows patients to have long, productive lives. Some medications must be obtained through special mail order, which fractures care. Pharmacy benefit managers claim that mail order reduces costs and provide specialty drugs for less, but in reality community pharmacies often provide drugs for less. Forced mail order breaks up the care team and is driving community pharmacies out of business. Mail order is not safe for some drugs that need to be kept at a certain temperature and there is also the possibility of the drugs being lost or stolen. If drugs arrive late, you cannot get reimbursed if the

prescription is filled locally.

Patients with complex, chronic conditions should be able to choose where they get their medications. When patients take their medications correctly, they do better. Individuals cannot afford to not take their medication if it is lost, delayed, stolen, or damaged.

Pharmacy benefit manager business practices harm patients. These organizations categorize drugs as specialty drugs so that patients cannot get the medications from community pharmacy and are often steered towards PBM-affiliated mail order pharmacies. Pharmacies are told that in order to sell specialty drugs, the pharmacy must become accredited, pay fees, and leave their pharmacy services administrative organization and once the pharmacy has done all of that, the PBM reimburses them below cost. There is a massive conflict of interest and advantage for PBMs to define drugs as specialty.

A half-million adults in Washington live in pharmacy deserts, which have a direct impact on Washingtonians' health and wellbeing by negatively impacting adherence to medication and exacerbating health disparities. One way to prevent pharmacy deserts is to prevent pharmacy closures. While mail order pharmacies can fill some of the gaps in pharmacy deserts, individuals in pharmacy deserts still lack access to many services provided by community pharmacies. The BIPOC communities have inherent access to care issues and often live in underserved areas. This bill increases choices for patients including those who are underserved and lack access to care.

This bill does not raise costs, but instead would lower the amount of money PBMs make on the backs of local pharmacies. The contracts with PBMs are nonnegotiable.

This bill is pro-employer, pro-patient, and pro-pharmacy. Arkansas has been fighting for this fairness for years and similar requirements for PBMs were upheld by the United States Supreme Court. This bill helps stop the unethical self-dealing by PBMs.

(Opposed) Requiring PBMs to reimburse at cost will only encourage spending. It also does not account for situations in which a pharmacy commits fraud and does not allow for the use of quality measures. While this bill should be opposed, some do have an interest in working with the committee to focus on rural pharmacies and what may be done to help those pharmacies.

This bill has the potential to increase drug costs. This bill removes incentive to purchase the lowest cost generic drug that is available and undermines preferred pharmacy networks. If a member goes to a preferred pharmacy, the PBM shares the savings with the member. This bill says that PBMs cannot pass on those savings.

If this bill allows a pharmacy to refuse to fill a prescription if the reimbursement isn't high enough, this may create an access issue. This bill also includes a lot of provisions regarding specialty pharmacies and there are concerns that these provisions will drive up cost. It also

includes a concept of critical access pharmacies, but it is unclear what problem this is trying to solve.

Prescription drug costs are the largest and fastest growing portion of the premium dollar. This growth is why health plans work with PBMs to come up with the best ways to provide the best prices possible. It is odd that many of the payment provisions in this bill move away from value-based purchasing. The bill also focuses heavily on mail order pharmacies, but 90 percent of claims are still filled at community pharmacies. Very few health plans have a requirement that enrollees must use mail order, and if the plan requires mail order, it is because the sponsoring employer has requested reduced costs. Health plans value rural pharmacies and cannot have adequate networks without them.

Persons Testifying: (In support) Representative Joe Schmick, prime sponsor; Jenny Arnold, Washington State Pharmacy Association; Rick Hughes, Ray's Pharmacy; Julie Akers; Ryan Oftebro, Kelley-Ross Pharmacy; Jennifer Bacci; Seth Greiner, National Multiple Sclerosis Society; Katie Kolan, AIDS Healthcare Foundation; Richard McCoy; John Vinson, Arkansas Pharmacists Association; Albert Sardinas, Washington Build-Back Black Alliance; and George Bartell.

(Opposed) William Head, Pharmaceutical Care Management Association; LuGina Mendez-Harper, Prime Therapeutics; and Chris Bandoli, Association of Washington Healthcare Plans.

Persons Signed In To Testify But Not Testifying: None.