Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1813

Brief Description: Concerning freedom of pharmacy choice.

Sponsors: Representatives Schmick, Macri, Graham and Chambers.

Brief Summary of Bill

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

Hearing Date: 1/24/22

Staff: Kim Weidenaar

Background:

Benefit Manager Registration.
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. 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.

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.

A 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 a 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 a 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 a 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 a 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.

U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategies.
The U.S. 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. A 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 Bill:

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

- require or coerce a covered person to use a mail order pharmacy;
- require a covered person to contact the PBM or mail order pharmacy in order to fill the prescription drug at a pharmacy of the covered person's choice;
- impose different cost-sharing, different days allowance to fill, monetary advantages, or penalties for using one participating pharmacy over another;
- prohibit or limit a covered person from selecting a participating pharmacy of the covered person's choice;
- 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 pharmacy benefit manager reimburses participating affiliated pharmacies; or
- limit a covered person's access to prescription drugs at the participating pharmacy of their choice by adding a prescription drug to a specialty tier or limited distribution tier formulary unless the drug is a specialty or limited distribution prescription drug.

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 that is not less than a pharmacy's cost;
- 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;
- regardless of the participating pharmacy, including mail order pharmacies, where the covered person obtains the prescription drug, apply the same cost-sharing, fees, and other conditions upon the covered person; 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 PSOA 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 pharmacy benefit manager 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 on or renewed 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 pharmacy benefit manager, or where the pharmacy benefit manager 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 10-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 10-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.

Appropriation: None.

Fiscal Note: Requested on January 18, 2022.

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