

HOUSE BILL REPORT

SSB 6558

As Reported by House Committee On: Health Care & Wellness

Title: An act relating to allowing a hospital pharmacy license to include individual practitioner offices and multipractitioner clinics owned and operated by a hospital and ensuring such offices and clinics are inspected according to the level of service provided.

Brief Description: Allowing a hospital pharmacy license to include individual practitioner offices and multipractitioner clinics owned and operated by a hospital and ensuring such offices and clinics are inspected according to the level of service provided.

Sponsors: Senate Committee on Health Care (originally sponsored by Senators Parlette and Cleveland).

Brief History:

Committee Activity:

Health Care & Wellness: 2/19/16, 2/26/16 [DPA].

Brief Summary of Substitute Bill (As Amended by Committee)

- Clarifies provisions regarding allowing hospital pharmacy licenses to include individual practitioner offices and multipractitioner clinics owned, operated, or under common control with a hospital.
- Requires interpretation of the provisions regulating the practice of pharmacy to be in a manner that supports regulatory, inspection, and investigation standards that are reasonable and appropriate based on the level of risk and the type of services provided in a pharmacy.
- Provides timelines in which the Pharmacy Quality Assurance Commission must adopt rules regarding pharmacy inspection standards and updates to application or renewal forms for hospital pharmacy licenses.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass as amended. Signed by 14 members: Representatives Cody, Chair; Riccelli, Vice Chair; Schmick, Ranking Minority Member; Harris, Assistant Ranking

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Minority Member; Caldier, Clibborn, DeBolt, Jinkins, Johnson, Moeller, Robinson, Short, Tharinger and Van De Wege.

Staff: Ariele Landstrom (786-7190).

Background:

Pharmacy Licensing.

The Pharmacy Quality Assurance Commission (Commission) regulates the practice of pharmacy, and the distribution, manufacturing, and delivery of pharmaceuticals within and into the state. The Commission issues licenses, registrations, and certifications to qualified persons and entities and responds to complaints or reports of unprofessional conduct.

The owner of each pharmacy must: (1) file with the Department of Health (DOH) a declaration of ownership and location; and (2) pay an original license fee and an annual renewal fee for a license of location, which entitles the owner to operate the pharmacy at the specified location. The pharmacy owner must immediately notify the DOH of any change of location or ownership.

Pharmacies are subject to periodic inspections by the Commission to determine compliance with laws regulating the practice of pharmacy, including requirements regarding licenses, patient health and safety, professional responsibilities, and facilities.

Legislation enacted in 2015 allows a licensed hospital applying for a pharmacy license of location to include any individual practitioner's office or multipractitioner clinic owned and operated by a hospital and identified by the hospital on the pharmacy application or renewal. A hospital that includes one or more offices or clinics on its pharmacy application must maintain the office or clinic under its pharmacy license through at least one pharmacy inspection or 24 months.

Summary of Amended Bill:

Intent.

The Legislature intends to clarify its directive in the legislation enacted in 2015 to require the Pharmacy Quality Assurance Commission (Commission) to allow hospital pharmacy licenses to include individual practitioner offices and multipractitioner clinics owned, operated, or under common control with a hospital and that the offices and clinics must be regulated, inspected, and investigated according to the level of service provided. The Legislature intends to specify a timeline for implementation for such a system.

Pharmacy Licensing.

The owner of a pharmacy applying for a license of location must file with the Commission, instead of the DOH, a declaration of ownership and location.

The definition of "hospital" to exclude "clinics, or physician's offices where patients are not regularly kept as bed patients for 24 hours or more" does not limit the ability of a hospital to

include individual practitioner's offices or multipractitioner clinics owned, operated, or under common control with a hospital on the pharmacy application or renewal.

A hospital that elects to include one or more offices or clinics on its pharmacy application no longer must maintain the office or clinic under its pharmacy license through at least one pharmacy inspection or 24 months.

In addition to an individual practitioner's office or multipractitioner clinic owned or operated by a hospital, an office or clinic under common control with a hospital may also be included in the hospital's pharmacy license of location. A hospital that elects to include one or more offices or clinics on its pharmacy application must describe the type of services relevant to the practice of pharmacy provided at each office or clinic as requested by the Commission.

Any updates to the application, renewal, or related forms that are necessary for a hospital to include one or more offices or clinics on its pharmacy application or renewal must be made no later than 90 days after the bill's effective date. Nothing in the provisions that allow a hospital to include an individual practitioner's office or multipractitioner clinic on its pharmacy license limit the ability of a hospital to transfer drugs to another location consistent with federal laws regardless of whether or not an election has been made with respect to adding the receiving location to the hospital's pharmacy license.

Interpretation and Rule-making.

Interpretation of the provisions regulating the practice of pharmacy must be in a manner that supports regulatory, inspection, and investigation standards that are reasonable and appropriate based on the level of risk and the type of services provided in a pharmacy, including pharmacy services provided in a hospital and pharmacy services provided in an individual practitioner's office or multipractitioner clinic owned, operated, or under common control with a hospital regardless of the office or clinic's physical address.

The Commission must provide clear and specific information regarding the standards to which particular pharmacy services will be held, as appropriate, based on the type of pharmacy service provided at a particular location.

If the Commission determines that rules are necessary for the immediate implementation of the provisions regarding inspection standards, it must adopt emergency rules no later than 90 days after the effective date of the bill. The Commission must then begin the process to adopt any necessary permanent rules and ensure the emergency rules remain in effect until the permanent rules are adopted. The Commission must also ensure that during the transition to permanent rules there is no interruption to the required updates to forms that are necessary for a hospital to include one or more offices or clinics on its pharmacy application or renewal.

Amended Bill Compared to Substitute Bill:

The amended bill provides that the provisions that allow a hospital to include an individual practitioner's office or multipractitioner clinic on its pharmacy license do not limit the hospital's ability to transfer drugs to another location, but the transfer must be consistent with

federal laws. The amended bill also changes provisions that require the use of an expedited rule-making process to an emergency rule-making process.

Appropriation: None.

Fiscal Note: Available.

Effective Date of Amended 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) In 2015 the Legislature passed a bill to transfer medications from a hospital to its own clinics. It has been nine months since that bill was passed and the Pharmacy Quality Assurance Commission (Commission) has not adopted rules or provided interim guidance to hospitals. Hospitals are still unable to access the licensing structure that was intended by the 2015 bill. There are barriers to support implementation. This bill addresses these barriers and provides clarification and guidance to the Commission in implementing the law. This bill affirms that a clinic can indeed be under a hospital's pharmacy license, provides clarity on how a hospital would include its clinics on its pharmacy license, and ensure that inspections and oversight are risk based and tied to the level of services that is being provided by the clinics. The law will be able to be fully implemented going forward. The Commission seems to need direction to do their work. The bill tries to clarify components that the Department of Health and the Commission felt were needed for them to implement the law.

Rural hospitals have tight budgets. There is a need to efficiently and effectively provide medications to patients in an in-patient and out-patient clinic setting. Hospitals have been able to provide essential medications to clinics with no problems. This practice enhances medication management across the system and helps control costs. Orders for medications for a hospital pharmacy or a clinic can be done cost-effectively through the same channels. Some hospitals have clinics attached to the hospital. Licensing these clinics separately is burdensome and inefficient. There is a concern about what standards clinics will be held to for inspections.

This bill provides additional clarity for implementation. A technical change is needed regarding the emergency rule-making procedure.

Work has been done to modernize the law, recognizing that the system has changed a lot since the structure was set in place where a hospital was intended to provide acute care; non-hospital clinics provided non-acute care; and pharmacies provided drugs to the latter. There were technical concerns about the 2015 law involving federal law, particularly with respect to 340B drug pricing. There were misunderstandings about what the difference is between a hospital pharmacy license and a regular pharmacy license. The 2015 law extended pharmacy licenses to the clinics that the hospitals own. Different standards apply to hospital

pharmacies because they provide different kinds of drugs for different kinds of care. There is currently not a more appropriate standard for the hospital-owned clinics.

(Opposed) None.

Persons Testifying: Ian Colbridge and Lisa Thatcher, Washington State Hospital Association; Cheryl Pell; and Drew Bouton, Department of Health.

Persons Signed In To Testify But Not Testifying: None.