

SENATE BILL REPORT

SSB 6558

As Amended by House, March 4, 2016

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: 2/02/16, 2/04/16 [DPS].

Passed Senate: 2/12/16, 49-0.

Passed House: 3/04/16, 97-0.

SENATE COMMITTEE ON HEALTH CARE

Majority Report: That Substitute Senate Bill No. 6558 be substituted therefor, and the substitute bill do pass.

Signed by Senators Becker, Chair; Dammeier, Vice Chair; Cleveland, Ranking Minority Member; Angel, Bailey, Baumgartner, Brown, Conway, Frockt, Jayapal, Keiser, Parlette and Rivers.

Staff: Mich'l Needham (786-7442)

Background: The 2015 Legislature passed ESSB 5460 which allowed hospitals to transfer medications to their clinics, and allowed the hospital license to include any individual practitioner's office or multipractitioner clinic owned and operated by a hospital to be identified by the hospital on the hospital pharmacy license application or renewal. The 2015 legislation was intended to streamline the regulatory process and to avoid individually licensing all hospital owned clinics and practices as pharmacies. The Washington State Pharmacy Quality Assurance Commission (PQAC) regulates the practice of pharmacy and the distribution, manufacturing, and delivery of pharmaceuticals. PQAC has held stakeholder conversations about the bill but has not initiated formal rule making to

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implement the new provisions. Stakeholder conversations have identified some areas that may need further clarification.

Summary of Substitute Bill: A hospital that elects to include one or more offices or clinics under its pharmacy license no longer must maintain the office or clinic through at least one pharmacy inspection or 24 months. The definition of the hospital that excludes clinics, or physician's offices where patients are not regularly kept for 24-hours, does not limit the ability of the hospital to include individual practitioner's offices or clinics owned and operated by a hospital on the pharmacy application or renewal. A hospital that elects to include one or more offices or clinics must describe the type of services relevant to the practice of pharmacy provided at each location, as requested by the Commission. Any updates required for the application forms to accomplish the licensure option must be made no later than 90 days after the effective date of this section.

The law must be interpreted 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. PQAC 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 services provided at each location.

If PQAC determines that rules are necessary for the immediate implementation of the inspection standards, it must adopt emergency rules not later than 90 days after the effective date of this section. DOH must ensure that the emergency rules remain in effect while the permanent rules are developed with no interruption in the licensure option.

Appropriation: None.

Fiscal Note: Available.

Committee/Commission/Task Force Created: Yes.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Original Bill: PRO: This is a good bill it is just unfortunate it is necessary because PQAC didn't respond to last year's bill. The 2015 bill extended the pharmacy license to affiliated clinics but it has been eight months since the law passed and PQAC has not started formal activity or released interim guidance. This bill is necessary to allow hospitals to use a systems approach and to keep any facilities from being closed because they may not have the appropriate license. We are working with the department on some revisions and clarifications. Inpatient hospital care is only a small part of total patient care. We have outpatient centers, infusion centers, and clinics and it is important to standardize the care with a systems approach that keeps all the facilities together. It is important to have clear guidelines that are tied to the level of services provided at each clinic. We do not want to be forced to get separate licenses that do not support the systems approach to care. The department is working with stakeholders on amendments.

OTHER: There is a problem with the Office of Inspections and the lack of communication between the commission and the inspectors. We have been working with the department and

commission to improve communication to clarify who will be the rule-making authority and who will provide clear interpretations for inspectors in a timely manner.

Persons Testifying on Original Bill: PRO: Senator Parlette, prime sponsor; Ian Corbridge, WA St. Hospital Association; Vikki Noyes, Confluence Health; Glenn Adams, Confluence Health; Timothy Farrell, HSQA Department of Health.

OTHER: Jeff Rochon, WA St. Pharmacy Association.

Persons Signed In To Testify But Not Testifying on Original Bill: No one.

House Amendment(s):

- Provides that the language of the bill does not 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.
- Changes provisions describing the use of the expedited rule-making process to the emergency rule-making process.