SENATE BILL REPORT
SHB 2580

As Reported by Senate Committee On:
Health Care, February 25, 2016

Title: An act relating to establishing a public registry for the transparency of blood establishments.

Brief Description: Establishing a public registry for the transparency of blood establishments.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Cody, Rodne, Robinson, Johnson and Jinkins).

Brief History: Passed House: 2/17/16, 98-0.
Committee Activity: Health Care: 2/25/16, 2/25/16 [DPA].

SENATE COMMITTEE ON HEALTH CARE

Majority Report: Do pass as amended.
Signed by Senators Becker, Chair; Dammeier, Vice Chair; Cleveland, Ranking Minority Member; Angel, Bailey, Brown, Conway, Frockt, Jayapal, Keiser, Parlette and Rivers.

Staff: Mich'l Needham (786-7442)

Background: The federal Food and Drug Administration (FDA) requires that an entity obtain a biologics license prior to introducing, or delivering for introduction, a biological product into interstate commerce. Biological products include blood and blood components intended for transfusion or for further manufacture into injectable products. An entity that holds a biologics license must comply with FDA standards, including standards for personnel, work rooms, equipment, laboratories, records maintenance, and retention of samples. For a license holder that manufactures blood and blood components, there are more specific standards that must be met that include registration with the FDA.

In addition to obtaining a biologics license from the FDA, a blood establishment must be licensed with the Department of Health (Department) as a medical test site. A medical test site includes any facility or site that analyzes materials from the human body for the purposes of health care, treatment, or screening. To become licensed, a medical test site must demonstrate the ability to comply with applicable standards related to the accuracy of testing, staffing requirements, recordkeeping, quality assurance, and quality control.

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.

Summary of Bill (Recommended Amendments): "Blood-collecting or distributing establishments" (blood establishments) are defined as organizations that collect or distribute blood for allogeneic transfusion in Washington. Hospitals are excluded from the definition unless the hospital collects blood directly from donors for transfusions.

Blood establishments may not collect or distribute blood for transfusion in Washington unless they are registered with the Department. To become registered, a blood establishment must hold a license issued by the FDA and submit an application and fee to the Department. The application must include:

- the name and contact information for the blood establishment;
- a copy of the blood establishment's FDA license, unless the applicant is a hospital that is not required to be licensed by the FDA;
- a list of the blood establishment's clients in Washington;
- any titled letters, fines, or license suspensions issued by the FDA in the two years prior to application;
- any judicial consent decrees issued in the two years prior to application; and
- other information required by the Department.

The registration must be renewed annually through the submission of updated application information. A blood establishment must notify the Department within 14 days of the termination of a blood establishment's FDA license. The Department must deny or revoke the registration of any blood establishment that ceases to be licensed by the FDA. The Department may also seek an injunction against an entity that is collecting or distributing blood without a registration.

The Department must maintain an online public registry of all registered blood establishments that supply blood for transfusion in Washington. The Department must update the registry within two weeks of receiving application-related information from a blood establishment, including any FDA or judicial action against its FDA license. The Department must notify all clients of a blood establishment within two weeks of being notified that it has had an FDA or judicial action against its FDA license or if it no longer holds an FDA license.

EFFECT OF CHANGES MADE BY HEALTH CARE COMMITTEE (Recommended Amendments): Clarifies that hospitals are excluded unless the hospital collects blood directly from donors for transfusions; clarifies that the requirements do not apply in the case of individual patient medical need, as determined by a qualified providers; modifies references to the registry to remove all clients that each establishment serves.

Appropriation: None.

Fiscal Note: Available.

Committee/Commission/Task Force Created: No.

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

Staff Summary of Public Testimony: PRO: This bill will advance the public confidence in the blood supply. The public deserves easy access to the knowledge that we meet all the FDA requirements and that a license is in good standing. The DOH registry will allow the information to be easily found and help patients, doctors, and hospitals know where the blood is coming from. The FDA site is very difficult to find information. This language has been worked with DOH, hospital association, and Bloodworks and the amendments in the striking amendment are agreed on fixes that we didn't have time to make on the House floor.

Persons Testifying: PRO: Dr. Jim AuBuchon, Lisa Thatcher, Bloodworks.

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