FINAL BILL REPORT
SHB 2580

C 47 L 16
Synopsis as Enacted

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).

House Committee on Health Care & Wellness
Senate Committee on Health Care

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 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.

Summary:

Blood-collecting or distributing establishments (blood establishments) may not collect or distribute blood for transfusion in Washington unless they are registered with the Department of Health (Department). To become registered, a blood establishment must hold a license issued by the federal Food and Drug Administration (FDA) and submit an application and fee to the Department. The application must include:

- the name and contact information for the blood establishment;

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- 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.

Blood establishments are defined as organizations that collect or distribute blood for allogeneic transfusion in Washington. Hospitals are excluded from the definition except for hospitals that collect blood directly from donors for allogeneic transfusions.

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 registration requirement does not apply in cases in which a qualified provider determines that there is an individual patient medical need.

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 the blood establishment has had an FDA or judicial action against its FDA license or if it no longer holds an FDA license.

Votes on Final Passage:

House	98	0	
Senate	47	0	(Senate amended)
House	96	0	(House concurred)

Effective: June 9, 2016