

# Chapter 246-339 WAC

## BLOOD ESTABLISHMENTS

### WAC

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**WAC 246-339-001 Purpose.** The purpose of this chapter is to implement chapter 70.335 RCW by establishing an online public registry and all necessary requirements for registered blood-collecting or distributing blood establishments or organizations that supply blood products for allogeneic transfusion in Washington state. This public registry of Washington state registered blood establishments is intended to help ensure public transparency, trust, and confidence in the safety of the community blood supply.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-001, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-010 Definitions.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Allogeneic transfusion" means a blood transfusion where the donated blood comes from an individual other than the recipient.

(2) "Autologous donation" means the infusion or transfer of human blood cells back into the individual from whom the cells were recovered.

(3) "Blood establishment" means a blood-collecting or distributing blood establishment or organization that collects or distributes blood for allogeneic transfusion in Washington state. This chapter does not apply to a hospital licensed under chapter 70.41 or 71.12 RCW unless the hospital collects blood directly from donors for the purpose of allogeneic transfusions. For the purposes of this chapter, blood establishment does not include organizations that collect source plasma as defined in this section.

(4) "Change in standing" means that a blood establishment is the subject of titled letters, fines, suspensions, or revocations of its United States Food and Drug Administration (FDA) license, or judicial consent decrees.

(5) "Department" means the Washington state department of health.

(6) "Directed donation" means a donation of blood or blood products to a specific recipient who is personally known by the donor before donation.

(7) "FDA" means United States Food and Drug Administration.

(8) "Judicial consent decree" means an agreement between the FDA and a blood establishment that outlines steps that a blood establishment must take in order to return

to full, independent production. The consent decree mandates that a blood establishment initiate change, and that change is usually associated with the way the blood establishment is manufacturing a product in order to bring it into compliance with the FDA's requirements.

(9) "Source plasma" means the fluid portion of human blood collected and intended as source material for further manufacturing use. The definition excludes single donor plasma products intended for intravenous use.

(10) "Titled letter" or "warning letter" means an FDA-issued correspondence that notifies blood establishments about violations that the FDA has documented during its inspections or investigations. Typically, a warning letter notifies a responsible individual or firm that the FDA considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the act), its regulations, and other federal statutes.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-010, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-020 Registration of a blood establishment.** Starting July 1, 2017, any blood establishment collecting or distributing blood for the purpose of allogeneic transfusion in Washington state must be registered with the department in accordance with chapter 70.335 RCW. To be eligible for registration with the department, the blood establishment must hold a current FDA blood establishment license, and must provide to the department proof of the blood establishment's current FDA licensure at the time of initial registration or renewal registration unless the applicant is a hospital that meets the criteria in RCW 70.335.020(1). Applicants for initial registration and renewal registration with the department must follow the procedures established under this chapter.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-020, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-025 Exemptions for blood establishment registration.** A blood establishment is exempt from the requirements of this chapter if it meets one or more of the following:

(1) Hospitals licensed under chapter 70.41 or 71.12 RCW unless the hospital collects blood directly from donors for the purpose of allogeneic transfusions.

(2) Organizations that collect source plasma for the production of plasma derivatives by fractionation.

(3) Cases of individual patient medical need, as determined by a qualified health care provider, such as:

(a) An autologous or directed donation as defined in WAC 246-339-010; and

(b) An out-of-state blood establishment that supplies blood products for allogeneic transfusion based upon a request from a Washington state registered blood establish-

ment in order to meet individual patient need, as determined by a qualified health care provider.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 18-22-073, § 246-339-025, filed 11/1/18, effective 12/2/18; WSR 17-14-026, § 246-339-025, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-030 Initial application for blood establishment registration.** Initial application procedure. To register with the department a blood establishment must:

(1) Submit a completed application on forms provided by the department that are signed by the owner or authorized representative that includes all of the following:

(a) The name, current and valid email address, mailing address, and telephone number of the blood establishment.

(b) Proof of the blood establishment's current FDA licensure unless the applicant is a hospital that meets the criteria in RCW 70.335.020(1).

(c) A list of all of the blood establishment's clients in Washington state as required by chapter 70.335 RCW, including current and valid email addresses for all clients of a blood establishment.

(d) A copy of any of the following disciplinary actions issued upon, or active against, the blood establishment's FDA license in the two years prior to submission of the initial application to the department:

(i) Titled letters, fines, license suspensions, or revocations issued by the FDA.

(ii) Judicial consent decrees.

(e) Any other information required by the department.

(2) Submit the designated fee(s) with the application as required by WAC 246-339-990.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-030, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-035 Renewal registration process.** (1) The department will issue a renewal registration for a Washington state registered blood establishment when the owner or authorized representative of the blood establishment:

(a) Submits a completed application provided by the department at least five working days prior to the expiration of the current registration, which is signed by the owner or authorized representative that includes the following:

(i) The name, current and valid email address, mailing address, and telephone number of the blood establishment.

(ii) Proof of the blood establishment's current FDA licensure unless the applicant is a hospital that meets the criteria in RCW 70.335.020(1).

(iii) A list of all of the blood establishment's clients in Washington state as required by chapter 70.335 RCW, including current and valid email addresses for all clients of a blood establishment.

(iv) A copy of any of the following disciplinary actions issued upon, or active against, the blood establishment's FDA license in the two years prior to the submission of a renewal application to the department:

(A) Titled letters, fines, or license suspensions or revocations issued by the FDA.

(B) Judicial consent decrees.

(v) Any other information as required by the department.

(b) Submits the designated fee(s) with the application for renewal registration pursuant to WAC 246-339-990.

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(c) Meets all of the requirements set forth under chapter 70.335 RCW and this chapter.

(2) The renewal registration will expire one year from the date of issuance.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-035, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-040 Change of ownership requirements.** (1) If there is a change in ownership of a Washington state registered blood establishment, the new owner must submit to the department within five working days of the change in ownership:

(a) New blood establishment application packet per WAC 246-339-030; and

(b) Any applicable fees as required in WAC 246-339-990.

(2) The registration will expire one year from the date of issuance as provided in WAC 246-339-035.

(3) The Washington state blood establishment registration is not transferable.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-040, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-045 Blood establishment notification requirements.** A Washington state registered blood establishment will notify the department within fourteen days of a change in standing of its FDA license. The notification will include:

(1) The name, email address, mailing address, and telephone number of the blood establishment.

(2) A list of all of the blood establishment's clients in Washington including their current and valid email addresses.

(3) Copies of any of the following disciplinary actions issued upon, or active against, the blood establishment's FDA license:

(a) Titled letters, fines, or license suspensions or revocations issued by the FDA.

(b) Judicial consent decrees.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-045, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-050 Grounds for action against blood establishments.** (1) The department will deny an initial or renewal application for registration if the applicant or Washington state registered blood establishment no longer holds a license issued by the FDA.

(2) The department may suspend or revoke a registration of a Washington state registered blood establishment if the blood establishment no longer holds a license issued by the FDA.

(3) In accordance with chapter 70.335 RCW, the department will issue a summary suspension of the registration if a Washington state registered blood establishment no longer holds a license issued by the FDA. The summary suspension will remain in effect until proceedings are completed under RCW 43.70.115 and will be limited to the issue of whether the blood establishment is qualified to hold a registration under this chapter or chapter 70.335 RCW.

(11/1/18)

(4) The department may investigate and maintain an action under RCW 70.335.050 if a blood establishment has operated without having a valid registration under this chapter.

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-050, filed 6/23/17, effective 7/24/17.]

**WAC 246-339-990 Fees.** (1) Registrations must be renewed every year from the date of issuance.

(2) The following nonrefundable fees will be charged for registration:

<b>Fee Type</b>	<b>Amount</b>
Initial application fee	\$13,000.00
Annual renewal fee	13,000.00
Late renewal fee	300.00
Application fee - Change of ownership	13,000.00

[Statutory Authority: RCW 43.70.040 and chapter 70.335 RCW. WSR 17-14-026, § 246-339-990, filed 6/23/17, effective 7/24/17.]