

**RCW 70.335.030 Registration required—Applications for registration—Criteria—Suspension—Expiration—Fees.** (1) A blood-collecting or distributing establishment may not collect or distribute blood for transfusion in Washington, unless it is registered by the department.

(2) A blood-collecting or distributing establishment shall submit an application for registration to the department on a form prescribed by the department. The application must, at a minimum, contain the following information:

(a) The name, address, and telephone number of the blood-collecting or distributing establishment;

(b) A copy of the establishment's United States food and drug administration license, unless the applicant is a hospital that meets the criteria in RCW 70.335.020(1);

(c) A list of the establishment's clients in Washington;

(d) Any of the following issued upon, or active against, the establishment in the two years prior to the application:

(i) Titled letters, fines, or license suspensions or revocations issued by the United States food and drug administration; or

(ii) Judicial consent decrees; and

(e) Any other information required by the department.

(3) The department shall register a blood-collecting or distributing establishment if it holds a license issued by the United States food and drug administration, or if the applicant is a hospital that meets the criteria in RCW 70.335.020(1), and submits an application and fees as required by this section.

(4) The department shall deny or revoke the registration of an establishment upon a determination that it no longer holds a license issued by the United States food and drug administration.

(5) The department shall issue a summary suspension of the registration if the blood-collecting or distributing establishment no longer holds a license issued by the United States food and drug administration. The summary suspension remains in effect until proceedings under RCW 43.70.115 have been completed by the department. The issue in the proceedings is limited to whether the blood-collecting or distributing establishment is qualified to hold a registration under this section.

(6) A registration expires annually on the date specified on the registration. The department shall establish the administrative procedures and requirements for registration renewals, including a requirement that the establishment update the information provided under subsection (2) of this section both annually and within fourteen days of a change in standing of the establishment's United States food and drug administration license.

(7) An establishment applying for or renewing a registration under this section shall pay a fee in an amount set by the department in rule. In no case may the fee exceed the amount necessary to defray the costs of administering this chapter.

(8) This section does not apply in the case of individual patient medical need, as determined by a qualified provider. [2016 c 47 s 3.]