

SHB 2580 - S COMM AMD
By Committee on Health Care

ADOPTED 03/02/2016

1 Strike everything after the enacting clause and insert the
2 following:

3 NEW SECTION. **Sec. 1.** The legislature finds that maintaining
4 public trust and confidence in the safety of the community blood
5 supply is important to the health care system. Patients in Washington
6 needing lifesaving transfusions rightly expect safe blood and blood
7 donors in Washington rightly expect their contributions will be
8 managed with diligent care and compliance with all regulatory
9 standards and expectations so their donation will benefit patients in
10 need. The United States food and drug administration establishes
11 regulations, good manufacturing practices, and guidance that defines
12 the minimum standards for blood establishments and, in cases of
13 repeated violations and noncompliance by licensed blood
14 establishments, may impose measures that include fines, judicial
15 consent decrees, and suspension or revocation of licensure. It is
16 therefore the intent of the legislature that blood-collecting or
17 distributing establishments be registered with the department of
18 health to help ensure public transparency.

19 NEW SECTION. **Sec. 2.** The definitions in this section apply
20 throughout this chapter unless the context clearly requires
21 otherwise.

22 (1) "Blood-collecting or distributing establishment" or
23 "establishment" means any organization that collects or distributes
24 blood for allogeneic transfusion in Washington. This chapter does not
25 apply to a hospital licensed under chapter 70.41 or 71.12 RCW unless
26 the hospital collects blood directly from donors for the purpose of
27 allogeneic transfusions. For the purposes of this chapter, "blood-
28 collecting or distributing establishment" or "establishment" does not
29 include organizations that collect source plasma for the production
30 of plasma derivatives by fractionation.

1 (2) "Change in standing" means that a blood-collecting or
2 distributing establishment is the subject of titled letters, fines,
3 suspensions, or revocations of its United States food and drug
4 administration license, or judicial consent decrees.

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

6 NEW SECTION. **Sec. 3.** (1) A blood-collecting or distributing
7 establishment may not collect or distribute blood for transfusion in
8 Washington, unless it is registered by the department.

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

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

15 (b) A copy of the establishment's United States food and drug
16 administration license, unless the applicant is a hospital that meets
17 the criteria in section 2(1) of this act;

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

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

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

23 (ii) Judicial consent decrees; and

24 (e) Any other information required by the department.

25 (3) The department shall register a blood-collecting or
26 distributing establishment if it holds a license issued by the United
27 States food and drug administration, or if the applicant is a
28 hospital that meets the criteria in section 2(1) of this act, and
29 submits an application and fees as required by this section.

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

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

1 blood-collecting or distributing establishment is qualified to hold a
2 registration under this section.

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

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

14 (8) This section does not apply in the case of individual patient
15 medical need, as determined by a qualified provider.

16 NEW SECTION. **Sec. 4.** (1) The department shall create and
17 maintain an online public registry of all registered blood-collecting
18 or distributing establishments that supply blood products for
19 transfusion in Washington.

20 (2) The department shall, within fourteen days of receipt,
21 publish in the public registry the information received from each
22 registered blood-collecting or distributing establishment under
23 section 3 of this act, including changes in the standing of the
24 establishment's United States food and drug administration license.

25 (3) The department shall notify all of a blood-collecting or
26 distributing establishment's Washington clients within fourteen days
27 of receiving notice under section 3 of this act that the
28 establishment has experienced a change in standing in its United
29 States food and drug administration license or no longer holds a
30 license issued by the United States food and drug administration.

31 NEW SECTION. **Sec. 5.** The department may, in the manner provided
32 by law and upon the advice of the attorney general, who shall
33 represent the department in the proceedings, maintain an action in
34 the name of the state for an injunction or other process against any
35 blood-collecting or distributing establishment to restrain or prevent
36 the operation of the establishment without a registration issued
37 under this chapter.

1 NEW SECTION. **Sec. 6.** Sections 1 through 5 of this act
2 constitute a new chapter in Title 70 RCW."

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3 On page 1, line 2 of the title, after "establishments;" strike
4 the remainder of the title and insert "and adding a new chapter to
5 Title 70 RCW."

EFFECT: (1) Clarifies that hospitals are excluded unless the hospital collects blood directly from donors for transfusions.

(2) Clarifies that the requirements do not apply in the case of individual patient medical need, as determined by a qualified provider.

(3) Modifies references to the registry to remove all clients that each establishment serves.

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