
SUBSTITUTE HOUSE BILL 2580

State of Washington 64th Legislature 2016 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Cody, Rodne, Robinson, Johnson, and Jenkins)

READ FIRST TIME 02/05/16.

1 AN ACT Relating to establishing a public registry for the
2 transparency of blood establishments; and adding a new chapter to
3 Title 70 RCW.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

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

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

4 (1)(a) "Blood-collecting or distributing establishment" or
5 "establishment" means any organization that collects or distributes
6 blood for allogeneic transfusion in Washington.

7 (b) "Blood-collecting or distributing establishment" or
8 "establishment" does not include:

9 (i) Organizations that collect source plasma for the production
10 of plasma derivatives by fractionation; or

11 (ii) Hospitals licensed under chapter 70.41 or 71.12 RCW, unless:

12 (A) The hospital is required to be licensed with the United
13 States food and drug administration as a blood establishment; or

14 (B) The hospital conducts activities solely within Washington
15 that would, if conducted in multiple states, require the hospital to
16 be licensed with the United States food and drug administration as a
17 blood establishment.

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

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

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

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

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

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

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

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

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

1 (ii) Judicial consent decrees; and

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

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

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

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

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

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

30 NEW SECTION. **Sec. 4.** (1) The department shall create and
31 maintain an online public registry of all registered blood-collecting
32 or distributing establishments that supply blood products for
33 transfusion in Washington, including all clients that each
34 establishment serves.

35 (2) The department shall, within fourteen days of receipt,
36 publish in the public registry the information received from each
37 registered blood-collecting or distributing establishment under
38 section 3 of this act, including changes in the standing of the

1 establishment's United States food and drug administration license
2 and changes in the establishment's client list.

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

9 NEW SECTION. **Sec. 5.** The department may, in the manner provided
10 by law and upon the advice of the attorney general, who shall
11 represent the department in the proceedings, maintain an action in
12 the name of the state for an injunction or other process against any
13 blood-collecting or distributing establishment to restrain or prevent
14 the operation of the establishment without a registration issued
15 under this chapter.

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

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