

CERTIFICATION OF ENROLLMENT

SUBSTITUTE HOUSE BILL 2580

Chapter 47, Laws of 2016

64th Legislature
2016 Regular Session

BLOOD ESTABLISHMENTS--REGISTRATION

EFFECTIVE DATE: 6/9/2016

Passed by the House March 7, 2016
Yeas 96 Nays 0

FRANK CHOPP

Speaker of the House of Representatives

Passed by the Senate March 2, 2016
Yeas 47 Nays 0

BRAD OWEN

President of the Senate

Approved March 29, 2016 3:51 PM

JAY INSLEE

Governor of the State of Washington

CERTIFICATE

I, Barbara Baker, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SUBSTITUTE HOUSE BILL 2580** as passed by House of Representatives and the Senate on the dates hereon set forth.

BARBARA BAKER

Chief Clerk

FILED

March 30, 2016

**Secretary of State
State of Washington**

SUBSTITUTE HOUSE BILL 2580

AS AMENDED BY THE SENATE

Passed Legislature - 2016 Regular Session

State of Washington 64th Legislature 2016 Regular Session

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

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) "Blood-collecting or distributing establishment" or
5 "establishment" means any organization that collects or distributes
6 blood for allogeneic transfusion in Washington. This chapter does not
7 apply to a hospital licensed under chapter 70.41 or 71.12 RCW unless
8 the hospital collects blood directly from donors for the purpose of
9 allogeneic transfusions. For the purposes of this chapter, "blood-
10 collecting or distributing establishment" or "establishment" does not
11 include organizations that collect source plasma for the production
12 of plasma derivatives by fractionation.

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

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

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

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

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

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

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

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

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

35 (ii) Judicial consent decrees; and

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

37 (3) The department shall register a blood-collecting or
38 distributing establishment if it holds a license issued by the United
39 States food and drug administration, or if the applicant is a

1 hospital that meets the criteria in section 2(1) of this act, and
2 submits an application and fees as required by this section.

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

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

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

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

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

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

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

36 (3) The department shall notify all of a blood-collecting or
37 distributing establishment's Washington clients within fourteen days
38 of receiving notice under section 3 of this act that the
39 establishment has experienced a change in standing in its United

1 States food and drug administration license or no longer holds a
2 license issued by the United States food and drug administration.

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

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

Passed by the House March 7, 2016.

Passed by the Senate March 2, 2016.

Approved by the Governor March 29, 2016.

Filed in Office of Secretary of State March 30, 2016.

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