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HOUSE BILL 2580

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State of Washington

64th Legislature

2016 Regular Session

By Representatives Cody, Rodne, Robinson, Johnson, and Jinkins

Read first time 01/15/16. Referred to Committee on Health Care & Wellness.

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 in Washington be registered with the  
20 department of 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. "Blood-collecting or  
7 distributing establishment" or "establishment" does not include  
8 organizations that collect source plasma for the production of plasma  
9 derivatives by fractionation.

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

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

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

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

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

24       (b)    A copy of the establishment's United States food and drug  
25 administration license;

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

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

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

31       (ii)    Judicial consent decrees; and

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

33       (3)    The department shall register a blood-collecting or  
34 distributing establishment if it holds a license issued by the United  
35 States food and drug administration and submits an application and  
36 fees as required by this section.

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

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

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

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

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

25 (2) The department shall, within fourteen days of receipt,  
26 publish in the public registry the information received from each  
27 registered blood-collecting or distributing establishment under  
28 section 3 of this act, including changes in the standing of the  
29 establishment's United States food and drug administration license  
30 and changes in the establishment's client list.

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

37 NEW SECTION. **Sec. 5.** The department may, in the manner provided  
38 by law and upon the advice of the attorney general, who shall

1 represent the department in the proceedings, maintain an action in  
2 the name of the state for an injunction or other process against any  
3 blood-collecting or distributing establishment to restrain or prevent  
4 the operation of the establishment without a registration issued  
5 under this chapter.

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

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