PROPOSED RULE MAKING

Agency: Department of Health

Title of rule and other identifying information: (Describe Subject)
Chapter 246-339 WAC--Blood establishments. The Department of Health (department) is proposing adding a new chapter to Title 246 WAC to establish requirements and set fees related to an online public registry to ensure the transparency of blood collecting or distributing establishments pursuant to Substitute House Bill (SHB) 2580 (Chapter 47, Laws of 2016) that was codified into chapter 70.335 RCW.

Hearing location(s):
Department of Health Town Center 2 - Conference Room 158
111 Israel Road SE
Tumwater, WA 98501

Submit written comments to:
Name: Susan Walker, Lab Quality Assurance Supervisor
Address: Department of Health
20425 72nd Avenue S., Suite 310
Kent, WA 98032
e-mail: https://fortress.wa.gov/doh/policyreview
fax 253.395.6365 by (date) 04/25/2017

Assistance for persons with disabilities: Contact Susan Walker by 04/20/2017
TTY (800) 833-6388 or ( ) 711

Date: 4/25/17 Time: 2:30 p.m.

Date of intended adoption: 05/02/2017 (Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
Chapter 246-339 WAC--Blood establishments. The proposal establishes requirements for an online public registration process for blood-collecting or blood-distributing establishments that collect or distribute blood for allogeneic transfusion in Washington state, and which are licensed by the U.S. Food and Drug Administration (FDA). The purpose of the online public registry is to ensure the safety and transparency of Washington's blood supply.

Reasons supporting proposal:
The proposed rules comply with chapter 70.335 RCW that allows the department to: (1) establish a registration process for blood establishments; (2) create and maintain an online public registry of all registered blood establishments that supply blood products for transfusion in Washington state; and (3) set fees for those blood establishments applying for or renewing a registration. The public registry will allow hospitals and other institutions that use blood for transfusion in Washington to see that blood establishments are in good standing with the FDA.

Statutory authority for adoption:
RCW 43.70.040 and chapter 70.335 RCW

Is rule necessary because of a:
Federal Law? Yes No
Federal Court Decision? Yes No
State Court Decision? Yes No
If yes, CITATION:

Statute being implemented:
chapter 70.335 ROW
Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None

<table>
<thead>
<tr>
<th>Name of proponent: (person or organization)</th>
<th>Washington State Department of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of agency personnel responsible for:</td>
<td></td>
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<tr>
<td>Name</td>
<td>Office Location</td>
</tr>
<tr>
<td>Drafting ..................................</td>
<td>20425 72nd Ave S, #310, Kent, WA 98032</td>
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<td>Implementation .........................</td>
<td>20425 72nd Ave S, #310, Kent, WA 98032</td>
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<tr>
<td>Enforcement .............................</td>
<td>20425 72nd Ave S, #310, Kent, WA 98032</td>
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</tbody>
</table>

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

- [ ] Yes. Attach copy of small business economic impact statement.
  
  A copy of the statement may be obtained by contacting:
  
  Name:
  
  Address:
  
  phone
  fax
  e-mail

- [x] No. Explain why no statement was prepared.
  
  A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(c), a SBEIS is not required for proposed rules that adopt or incorporate by reference - without material change - federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

Is a cost-benefit analysis required under RCW 34.05.328?

- [ ] Yes  A preliminary cost-benefit analysis may be obtained by contacting:
  
  Name:
  
  Address:
  
  phone
  fax
  e-mail

- [x] No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(iii) exempts rules that adopt or incorporate by reference without material change federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards.
NEW SECTION

WAC 246-339-001 Purpose. The purpose of this chapter is to implement chapter 70.335 RCW by establishing an online public registry and all necessary requirements for registered blood-collecting or distributing blood establishments or organizations that supply blood products for allogeneic transfusion in Washington state. This public registry of Washington state registered blood establishments is intended to help ensure public transparency, trust, and confidence in the safety of the community blood supply.

NEW SECTION

WAC 246-339-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Allogeneic transfusion" means a blood transfusion where the donated blood comes from an individual other than the recipient.

(2) "Autologous donation" means the infusion or transfer of human blood cells back into the individual from whom the cells were recovered.

(3) "Blood establishment" means a blood-collecting or distributing blood establishment or organization that collects or distributes blood for allogeneic transfusion in Washington state. This chapter does not apply to a hospital licensed under chapter 70.41 or 71.12 RCW unless the hospital collects blood directly from donors for the purpose of allogeneic transfusions. For the purposes of this chapter, blood establishment does not include organizations that collect source plasma as defined in this section.

(4) "Change in standing" means that a blood establishment is the subject of titled letters, fines, suspensions, or revocations of its United States Food and Drug Administration (FDA) license, or judicial consent decrees.

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

(6) "Directed donation" means a donation of blood or blood products to a specific recipient who is personally known by the donor before donation.

(7) "FDA" means United States Food and Drug Administration.

(8) "Judicial consent decree" means an agreement between the FDA and a blood establishment that outlines steps that a blood establishment must take in order to return to full, independent production. The consent decree mandates that a blood establishment initiate change, and that change is usually associated with the way the blood establishment is manufacturing a product in order to bring it into compliance with the FDA's requirements.

(9) "Source plasma" means the fluid portion of human blood collected and intended as source material for further manufacturing use.
The definition excludes single donor plasma products intended for intravenous use.

(10) "Titled letter" or "warning letter" means an FDA-issued correspondence that notifies blood establishments about violations that the FDA has documented during its inspections or investigations. Typically, a warning letter notifies a responsible individual or firm that the FDA considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the act), its regulations, and other federal statutes.

NEW SECTION

WAC 246-339-020 Registration of a blood establishment. Starting July 1, 2017, any blood establishment collecting or distributing blood for the purpose of allogeneic transfusion in Washington state must be registered with the department in accordance with chapter 70.335 RCW. To be eligible for registration with the department, the blood establishment must hold a current FDA blood establishment license, and must provide to the department proof of the blood establishment's current FDA licensure at the time of initial registration or renewal registration. Applicants for initial registration and renewal registration with the department must follow the procedures established under this chapter.

NEW SECTION

WAC 246-339-025 Exemptions for blood establishment registration. A blood establishment is exempt from the requirements of this chapter if it meets one or more of the following:

(1) Hospitals licensed under chapter 70.41 or 71.12 RCW unless the hospital collects and distributes blood directly from donors for the purpose of allogeneic transfusions.

(2) Organizations that collect source plasma for the production of plasma derivatives by fractionation.

(3) Cases of individual patient medical need, as determined by a qualified health care provider, such as:
   (a) An autologous or directed donation as defined in WAC 246-339-010; and
   (b) An out-of-state blood establishment that supplies blood products for allogeneic transfusion based upon a request from a Washington state registered blood establishment in order to meet individual patient need, as determined by a qualified health care provider.

NEW SECTION

WAC 246-339-030 Initial application for blood establishment registration. Initial application procedure. To register with the department a blood establishment must:
(1) Submit a completed application on forms provided by the department that are signed by the owner or authorized representative that includes all of the following:
   (a) The name, current and valid email address, mailing address, and telephone number of the blood establishment.
   (b) Proof of the blood establishment's current FDA licensure.
   (c) A list of all of the blood establishment's clients in Washington state as required by chapter 70.335 RCW, including current and valid email addresses for all clients of a blood establishment.
   (d) A copy of any of the following disciplinary actions issued upon, or active against, the blood establishment's FDA license in the two years prior to submission of the initial application to the department:
      (i) Titled letters, fines, license suspensions, or revocations issued by the FDA.
      (ii) Judicial consent decrees.
      (e) Any other information required by the department.
   (2) Submit the designated fee(s) with the application as required by WAC 246-339-990.

NEW SECTION

WAC 246-339-035 Renewal registration process. (1) The department will issue a renewal registration for a Washington state registered blood establishment when the owner or authorized representative of the blood establishment:
   (a) Submits a completed application provided by the department at least five working days prior to the expiration of the current registration, which is signed by the owner or authorized representative that includes the following:
      (i) The name, current and valid email address, mailing address, and telephone number of the blood establishment.
      (ii) Proof of the blood establishment's current FDA licensure.
      (iii) A list of all of the blood establishment's clients in Washington state as required by chapter 70.335 RCW, including current and valid email addresses for all clients of a blood establishment.
      (iv) A copy of any of the following disciplinary actions issued upon, or active against, the blood establishment's FDA license in the two years prior to the submission of a renewal application to the department:
         (A) Titled letters, fines, or license suspensions or revocations issued by the FDA.
         (B) Judicial consent decrees.
         (v) Any other information as required by the department.
   (b) Submits the designated fee(s) with the application for renewal registration pursuant to WAC 246-339-990.
   (c) Meets all of the requirements set forth under chapter 70.335 RCW and this chapter.
   (2) The renewal registration will expire one year from the date of issuance.
NEW SECTION
WAC 246-339-040  Change of ownership requirements. (1) If there is a change in ownership of a Washington state registered blood establishment, the new owner must submit to the department within five working days of the change in ownership:
   (a) New blood establishment application packet per WAC 246-339-030; and
   (b) Any applicable fees as required in WAC 246-339-990.
(2) The registration will expire one year from the date of issuance as provided in WAC 246-339-035.
(3) The Washington state blood establishment registration is not transferable.

NEW SECTION
WAC 246-339-045  Blood establishment notification requirements. A Washington state registered blood establishment will notify the department within fourteen days of a change in standing of its FDA license. The notification will include:
   (1) The name, email address, mailing address, and telephone number of the blood establishment.
   (2) A list of all of the blood establishment's clients in Washington including their current and valid email addresses.
   (3) Copies of any of the following disciplinary actions issued upon, or active against, the blood establishment's FDA license:
      (a) Titled letters, fines, or license suspensions or revocations issued by the FDA.
      (b) Judicial consent decrees.

NEW SECTION
WAC 246-339-050  Grounds for action against blood establishments. (1) The department will deny an initial or renewal application for registration if the applicant or Washington state registered blood establishment no longer holds a license issued by the FDA.
(2) The department may suspend or revoke a registration of a Washington state registered blood establishment if the blood establishment no longer holds a license issued by the FDA.
(3) In accordance with chapter 70.335 RCW, the department will issue a summary suspension of the registration if a Washington state registered blood establishment no longer holds a license issued by the FDA. The summary suspension will remain in effect until proceedings are completed under RCW 43.70.115 and will be limited to the issue of whether the blood establishment is qualified to hold a registration under this chapter or chapter 70.335 RCW.
(4) The department may investigate and maintain an action under RCW 70.335.050 if a blood establishment has operated without having a valid registration under this chapter.
NEW SECTION

WAC 246-339-990  Fees.  (1) Registrations must be renewed every year from the date of issuance.
   (2) The following nonrefundable fees will be charged for registration:

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<th>Fee Type</th>
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<td>Annual renewal fee</td>
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<tr>
<td>Late renewal fee</td>
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<td>Application fee - Change of ownership</td>
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