NOTICE

FORTHCOMING STERILE COMPOUNDING PERMITS

Beginning January 1, 2015, any sterile compounding facility that performs sterile compounding for patient-specific dispensing into, out of, or within Maryland will be required to apply for a Maryland Sterile Compounding Permit. An entity that performs compounding of sterile drug products for office use, or other distribution in Maryland, will be required to obtain a Maryland wholesale distributor's permit and a FDA registration or permit.

- To prepare for January 1, 2015, the Board has posted the Sterile Compounding Permit Application on its website for download
- Beginning January 1, 2015, the Board will accept applications for sterile compounding permits.
- **Please be advised that the Board <u>will not</u> accept any applications or fees until January 1, 2015. <u>Any applications or fees received before January 1, 2015 will be returned to the sender.</u>**
- Sterile compounding facilities with completed applications on file with the Board by **<u>February 18, 2015</u>** will not be subject to Board action for sterile compounding without a permit, until such time that the Board makes a final determination on the application.

****LINK TO APPLICATION****

Answers to Frequently Asked Questions (FAQ's) about application requirements are provided below for your convenience.

1. Are any sterile compounding facilities that perform sterile compounding for patient-specific dispensing in Maryland exempt from obtaining a sterile compounding permit?

Yes. Oncologists, hematologists, rheumatologists are exempt from the sterile compounding permit.

<u>A. Oncology, hematology, and rheumatology practices</u>

SB 1108 Sterile Compounding Permits – Definition of "Compounding" established a specific exemption from obtaining a sterile compounding permit for oncology, hematology, and rheumatology practices.

2. Will dentists be required to obtain a sterile compounding permit?

For most dental products USP 797 does not address, or apply to, those products used in activating, bonding or taking impressions during dental procedures.

USP 797 and MD sterile compounding requirements do apply to IV sedation medications and IV general anesthesia medications. If the products are compounded and used within an hour,

however; those products would fall under the “Immediate Use” exemption as defined in USP 797.

For preparation of any IV products that do not fall under the “Immediate Use” exemption, the Sterile Compounding Committee recommends that a dental practice review its sterile compounding needs in terms of volume, cost and practicality. Following are options that would comply with federal and state law, and USP 797: (1) using a compounding aseptic isolator (also known as a “glove box”), as set forth in USP 797; (2) contracting with a pharmacy to compound the product pursuant to a patient-specific prescription; or (3) contracting with an FDA-registered outsourcing facility to provide the IV products for office use inventory.

3. What requirements must be met in order to obtain a sterile compounding permit?

An application form must be completed and submitted to the Maryland Board of Pharmacy that includes the applicant’s name, address and contact information, practitioner license number, and the highest USP 797 risk level of compounding engaged in by the applicant and the required fee.

An applicant is subject to an inspection conducted by the Maryland Board of Pharmacy (Board), a designee of the Board; or the U.S. Food and Drug Administration that indicates compliance with USP 797 Standards. If an applicant is outside the State, an inspection must be obtained from a designee of the Board to demonstrate compliance with USP 797 Standards.

The application must include a statement of current compliance with USP 797 Standards. Reports and corrective actions taken or proposed in response to adverse events identified 12 months before submission of the application must also be included.

The applicant must also submit evidence that the sterile compounding facility employs at least one licensed health care practitioner who has training in compounding sterile preparations, clean room technology, laminar flow technology, quality assurance techniques, and clinical application of intravenous drug therapy; and evidence of good standing with any other State licensing entity; or licensing entity in the state in which the applicant is located.

The Board may require any other documentation to support its evaluation of the application. Please refer to COMAR 10.34.19 when the regulations become effective on January 1, 2015.

4. Can one application be used for all of an applicant’s sterile compounding facilities?

No. A separate sterile compounding permit is required for each sterile compounding facility at which sterile compounding is performed.

5. Are sterile compounding permits transferrable?

No. A sterile compounding permit is not transferable.

6. If an entity would like to compound for office use, what kind of license is required?

The entity would have to obtain a Maryland wholesale distributor permit and either register with the FDA as an Outsourcing Facility or obtain an FDA manufacturer's permit, as appropriate.

7. What will the permits cost?

E. Sterile Compounding Permit Fees.

(1) Sterile compounding permit initial fee — $700;

(2) Sterile compounding permit renewal fee — $600; and

(3) Sterile compounding reinstatement fee (payable if renewal fee is received after January 31) — $600.

F. Sterile Drug Product Waiver Fees.

(1) Sterile drug product waiver application fee — $1,750;

(2) Sterile drug product waiver application fee for an additional sterile drug product for a person with an existing sterile drug product waiver — $700; and

(3) Sterile drug product waiver amendment fee — $700.

8. How do I renew my sterile compounding permit?

See COMAR 10.34.19.17H:

(1) A sterile compounding permit expires on May 31 of the next even-numbered year after its effective date, unless the sterile compounding permit is renewed for a 2-year term as provided in this regulation.

(2) Before a sterile compounding permit expires, the sterile compounding permit may be renewed for an additional 2-year term if the applicant:

(a) Otherwise is entitled to the permit;

(b) Pays a renewal fee as set forth in COMAR 10.34.09; and

(c) Submits to the Board a renewal application on the form the Board requires.

9. How do I register as an FDA Outsourcing Facility?

Please go to this website for information:

http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm