Department of Legislative Services

Maryland General Assembly
2014 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 1108 (Senators Conway and Dyson)
Education, Health, and Environmental Affairs Health and Government Operations

Sterile Compounding Permits - Definition of "Compounding", Study, and Recommendations

This bill specifies that the definition of "compounding" does not include mixing, reconstituting, or other similar acts routinely performed (1) by, or under the supervision of, an oncologist, rheumatologist, or hematologist who administers chemotherapy, biologic therapy, supportive care medication, rheumatology therapy, or any other treatment of cancer, a rheumatology condition, or a blood condition and (2) in accordance with directions contained in approved labeling provided by the product's manufacturer, other manufacturer directions consistent with the labeling, and other direction or guidance from the U.S. Food and Drug Administration (FDA). The bill also requires the Secretary of Health and Mental Hygiene to convene a related workgroup and submit a specified study.

The bill takes effect July 1, 2014.

Fiscal Summary

State Effect: The bill does not materially affect the finances of the State Board of Pharmacy. The Department of Health and Mental Hygiene can convene the required workgroup with existing resources.

Local Effect: None.

Small Business Effect: Meaningful for certain oncology, rheumatology, and hematology practices that are exempt from certain board requirements.

Analysis

Bill Summary: The workgroup must study appropriate national safety standards for mixing, reconstituting, and similar acts routinely performed by, or under supervision of, an oncologist, rheumatologist, or hematologist who administers specified therapies, treatments, or supportive care medication. The Secretary must submit a report by December 15, 2014, on the results of the study and the Secretary's recommendations for appropriate oversight.

Current Law: "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug only (1) as a result of a practitioner's prescription drug order or initiative based on the practitioner/patient relationship in the course of professional practice; (2) for the purpose of, or incidental to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device; or (3) in anticipation of a prescription drug based on routine, regularly observed prescribing patterns. "Sterile compounding" means compounding of biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797, must be prepared using aseptic techniques. "USP 797" means the standards set forth in the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations."

Chapter 397 of 2013 regulates facilities or practitioners that perform sterile compounding or distribute a sterile drug product into or within Maryland. Sterile compounding facilities (including a pharmacy, a health care practitioner's office, or any other setting in which sterile compounding is performed) must hold a sterile compounding permit from the board. A person that prepares and distributes sterile drug products into or within the State must hold both a manufacturer permit or other permit from the FDA and a wholesale distributor permit from the board. The board must adopt regulations requiring that each sterile compounded preparation must be dispensed or administered in accordance with a prescription from an authorized prescriber.

Background: Under the Food and Drug Administration Modernization Act of 1997, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

However, the USP Expert Committee on Sterile Compounding that developed USP 797 noted that even the mixing and reconstituting processes that are carried out per package insert directions should be subject to the requirements of USP 797 because (1) FDA-approved labeling and product package inserts rarely describe environmental quality (*e.g.*, ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration); (2) beyond-use exposure and storage dates or

times for sterile products that have either been opened or prepared for administration are not specified in all package inserts for all sterile products; and (3) when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.

USP 797 includes five microbial contamination risk levels: (1) immediate-use; (2) low-risk; (3) low-risk with 12-hour beyond-use dates; (4) medium-risk; and (5) high-risk. An immediate-use compounded sterile product (CSP) is defined as:

- being only for use in emergency situations or when preparation of the CSP under low-risk level conditions would subject the patient to additional risk due to delays in therapy;
- no storage or batch compounding;
- applying only to products that would otherwise be considered low-risk;
- an exemption from low-risk level requirements, including ISO 5 conditions, if all of the following are met:
    - simple transfer of not more than three commercially manufactured packages of sterile nonhazardous drugs or diagnostic radiopharmaceuticals;
    - compounding is a continuous process lasting less than one hour;
    - aseptic technique is utilized and CSP is under constant surveillance to minimize contamination;
    - administration begins not later than one hour after preparation begins;
    - if not administered immediately, CSP is labeled appropriately, including the exact one-hour beyond-use date and time; and
    - CSP will be discarded if administration has not begun within one hour.

The Department of Labor, Licensing, and Regulation's Maryland Occupational and Safety Health program is in the process of drafting proposed regulations on occupational exposure to hazardous drugs. The regulations will cover safe handling practices, engineering controls, medical surveillance, and personal protective equipment. The regulations are anticipated to be promulgated later this year.

In a community-based setting, chemotherapy is mixed in an office infusion center and then immediately administered either intravenously or by injection to the patient. Oncologists are required to comply with State and federal occupational safety and health requirements.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): American Society for Health-Systems Pharmacists, Department of Health and Mental Hygiene, Department of Legislative Services

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