Maryland General Assembly
Department of Legislative Services

Proposed Regulations
Department of Health and Mental Hygiene

(DLS Control No. 15-264)

Overview and Legal and Fiscal Impact

The regulations alter requirements for sterile pharmaceutical compounding and add new requirements for inspections, reporting, and distribution of sterile compounded medications for office use.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies beyond that already estimated in the fiscal and policy note for Chapter 5 of 2015.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:
Board of Pharmacy: Sterile Pharmaceutical Compounding:
COMAR 10.34.19.03, .05-.07, .09, and .17-.19

Legal Analysis

Background

Current State Board of Pharmacy regulations govern licensed pharmacies in Maryland engaging in compounding or mixing sterile prescription solutions or suspensions to be administered parenterally or by irrigation, inhalation, or intraocular routes and compounding of radiopharmaceuticals, except in specified circumstances. These regulations do not apply to nonresident pharmacies or other facilities (such as a health care practitioner's office). The compounding, preparation, and dispensing of compounded sterile preparations must be accomplished in a pharmacy environment subject to State and federal laws, regulations, and standards. The current regulations specify special handling, packaging, labeling, and beyond-use dating; recordkeeping; batch preparation; minimum requirements for facilities, equipment, supplies, policies and procedures, and attire; training of staff, patients, and caregivers; and quality assurance. USP 797 requirements are incorporated by reference. "USP 797" means the standards set forth in the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations."

Chapter 5 of 2015 required nonresident pharmacies that dispense compounded sterile preparations to Maryland patients to (1) comply with USP 797 and board regulations governing

the compounding of sterile preparations and (2) submit an inspection report that demonstrates such compliance as a condition of obtaining a pharmacy permit from the board. Chapter 5 also specifies that a wholesale distributor applicant or permit holder that prepares sterile drug products must demonstrate compliance with applicable good manufacturing practice standards at the time of application and on renewal.

Summary of Regulations

The regulations alter requirements for sterile pharmaceutical compounding and add new requirements for inspections, reporting, and distribution of sterile compounded medications for office use. The regulations require pharmacies that engage in sterile compounding to have a controlled environment that meets USP 797 Standards.

The regulations require the board to inspect pharmacies located in Maryland at least annually and specify the testing, documentation, and other information that must be provided as part of the inspection process. The board or its designee must inspect nonresident pharmacies upon initial application and upon renewal. Within 90 days before the date of application, inspections of nonresident pharmacies may be conducted by a designee of the board, the U.S. Food and Drug Administration, or another appropriate state entity which indicates compliance with USP 797 Standards. The board may inspect a pharmacy at any time to verify compliance with permit requirements or investigate a complaint.

A pharmacy must document and perform routine testing as required by USP 797 Standards for the appropriate risk levels of sterile compounded preparations. A pharmacy must report to the board within 5 calendar days specified adverse events, deficiencies, disciplinary actions, and changes in accreditation status.

Unless otherwise authorized, a person that prepares and distributes sterile compounded medications for office use into, out of, or within the State must hold a manufacturer's permit or other permit designated by the U.S. Food and Drug Administration to ensure the safety of sterile compounded medications for office use and, if applicable, a wholesale distributor's permit issued by the board.

The regulations make other minor changes and define terms.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites §§ 12-205, 12-503, and 12-505 of the Health Occupations Article as statutory authority for the regulations. Section 12-205 authorizes the board to adopt rules and regulations to carry out the provisions of law for which the board is responsible; that are necessary to protect the public health, safety, and welfare; and that establish standards for practicing pharmacy and operating pharmacies. Section 12-503

establishes requirements for the date of issuance and the dispensing of a prescription. Section 12-505 establishes requirements for labeling of a prescription. Sections 12-503 and 12-505 relate to provisions of the current regulations that are unchanged in the regulations.

Although not cited by the department, §§ 12-403 and 12-6C-03 of the Health Occupations Article provide statutory authority for the regulations. Section 12-403(f) and (g) establish requirements for nonresident pharmacies to obtain a pharmacy permit from the board. As described above under *Background*, Chapter 5 of 2015 required a nonresident pharmacy that will dispense compounded sterile preparations to patients in the State to obtain and submit to the board a report of an inspection that (1) demonstrates compliance with USP 797; and (2) within 90 days before the date of application, is conducted by a board designee or other entity approved by the board. Chapter 5 also required a nonresident pharmacy that is dispensing compounded sterile preparations to patients in the State to comply with USP 797 and regulations adopted by the board governing the compounding of sterile preparations. Section 12-6C-03 requires a wholesale distributor to obtain a permit from the board before engaging in wholesale distribution in the State.

With the addition of §§ 12-403 and 12-6C-03 of the Health Occupations Article, the relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies beyond that already estimated in the fiscal and policy note for Chapter 5 of 2015.

Agency Estimate of Projected Fiscal Impact

The regulations implement Chapter 5 of 2015 (Senate Bill 69), which, in addition to repealing certain requirements relating to sterile compounding, requires nonresident pharmacies that dispense compounded sterile preparations to Maryland patients to (1) comply with USP 797 standards and board regulations governing the compounding of sterile preparations and (2) submit an inspection report that demonstrates such compliance as a condition of obtaining a pharmacy permit from the board. The regulations also make additional clarifying and conforming changes. The board advises that the regulations have no impact on State or local governments as the requirements can be addressed with current staffing. The Department of Legislative Services concurs and notes that any fiscal impact was already reflected in the fiscal and policy note for Senate Bill 69 of 2015, which projected an increase of $73,577 in special fund expenditures for the board beginning in fiscal 2016 for one position to monitor nonresident pharmacy compliance with USP 797.

Impact on Budget

There is no impact on the State operating or capital budget beyond that already assumed in the fiscal and policy note for Senate Bill 69 of 2015. One grade 16 position ($54,584) is included in the fiscal 2016 budget to monitor nonresident pharmacy compliance with USP 797.

Agency Estimate of Projected Small Business Impact

The board advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

Contact Information

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