

Department of Legislative Services
Maryland General Assembly
2014 Session

FISCAL AND POLICY NOTE
Revised

House Bill 1088

(Delegate Morhaim, *et al.*)

Health and Government Operations

Education, Health, and Environmental Affairs

Health Occupations - Compound Drugs - Provision to Ophthalmologists for Office
Use

This bill authorizes a pharmacy, subject to the requirement to obtain a sterile compounding permit, to provide to an ophthalmologist for office use, without a patient-specific prescription, certain compound drugs for emergency treatment. The bill also authorizes a sterile compounding facility to provide these compound drugs for emergency treatment to an ophthalmologist, for office use, without a patient-specific prescription. A pharmacy must require the ophthalmologist to inform the pharmacy, while a sterile compounding facility must require the ophthalmologist to inform the sterile compounding facility, as to the identity of any patient to whom the drugs are administered.

The bill takes effect July 1, 2014.

Fiscal Summary

State Effect: The bill's reporting requirement can be handled by the State Board of Pharmacy using existing budgeted resources. Revenues are not affected.

Local Effect: None.

Small Business Effect: Minimal. Small business ophthalmology practices could regain access to certain sterile compounded medications as specified under the bill.

Analysis

Bill Summary: A pharmacy and a sterile compounding facility may provide compound antibiotics for the emergency treatment of bacterial endophthalmitis or viral retinitis and compound antivasular endothelial growth factor agents for the emergency treatment of neovascular glaucoma, wet macular degeneration, or macular edema.

The board must monitor any changes to the federal Drug Quality and Security Act (DQSA) and related federal regulations and guidelines as those changes relate to the authority of a sterile compounding facility to provide prescription drugs to ophthalmologists for office use as authorized under the bill and report to the Governor and the General Assembly by January 1, 2015.

Current Law: 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 State Board of Pharmacy. 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 U.S. Food and Drug Administration (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. The board may issue a waiver, to a sterile compounding facility or a person that prepares and distributes sterile drug products into or within the State, of any requirements relating to sterile compounding permits, only (1) for specified sterile compounded preparations or sterile drug products for which there is a clinical need; (2) in exigent circumstances that otherwise prevent health care providers from obtaining, in the size and strength needed, the specified sterile compounded preparations or sterile drug products; and (3) if the sterile compounding facility or other person meets requirements established by the board.

DQSA, enacted on November 27, 2013, authorized an entity that compounds sterile drugs to register with FDA as an outsourcing facility. An outsourcing facility qualifies for exemptions from certain FDA requirements. Outsourcing facilities must (1) comply with current good manufacturing practices; (2) be inspected by FDA according to a risk-based schedule; and (3) meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound. As of April 18, 2014, 38 entities had registered with FDA as outsourcing facilities. According to the board, a federal outsourcing facility registration authorizes entities to compound sterile drugs and ship them to Maryland (including for office use) *without a patient-specific prescription* as long as the outsourcing facility also obtains a Maryland wholesale distributor permit.

Although DQSA does not discuss office stock compounding (creation of standardized drug products to be kept as stock in a physician's office), it does allow anticipatory compounding (compounding prior to receipt of a prescription) in "limited quantities." However, this term is not defined; thus, it is unclear what amount of anticipatory compounding is permissible under federal law.

Wholesale distributors – which may include manufacturers, warehouses, and some retail pharmacies – must be issued a permit by the board before engaging in the wholesale distribution of prescription drugs or devices into, out of, or within the State. As a part of the initial application process, both a representative from the applicant's place of business and the representative's immediate supervisor must submit fingerprints for the purposes of a criminal history records check (CHRC). Within 30 days after the board receives a completed application, including the results of all required CHRCs, the board must notify the applicant of the board's acceptance or rejection of the application. To obtain a permit, a wholesale distributor must also obtain either a surety bond (made payable to the board) of \$100,000 or other equivalent means of security acceptable to the State (*e.g.*, an irrevocable letter of credit or a deposit in a trust account or financial institution). If the applicant's annual gross receipts for the previous tax year total less than \$10 million, the requisite surety bond amount is reduced to \$50,000. The purpose of the surety bond is to secure the payment of any fines or penalties imposed by the board and any fees and costs incurred by the State relating to the permit.

Background: Compounding can serve an important public health need if a patient cannot be treated with an FDA-approved medication. However, compounded drugs are not FDA-approved, and poor compounding practices can result in contamination or medications that do not contain the strength, quality, or purity required. In recent years, compounding came under scrutiny by FDA because of the emergence of firms with pharmacy licenses making and distributing drugs outside the bounds of traditional pharmacy compounding that operate more like drug manufacturers than pharmacies. Some of the adverse event reports received by FDA associated with compounded medications have had devastating repercussions. Thus, both federal and State regulation of sterile compounding expanded significantly in 2013.

The American Academy of Ophthalmology (AAO) and other national ophthalmology organizations have expressed concerns that recent actions to enforce patient-specific prescription requirements for sterile compounded drugs may preclude access to essential drugs necessary for the treatment of patients with vision-threatening conditions, particularly in emergency situations. According to AAO, ophthalmologists frequently need to have certain medications on hand to treat situations on an urgent or emergent basis, including treatment of endophthalmitis (a serious infection of the eye), neovascular glaucoma, and macular degeneration. In many cases, delayed treatment of these conditions can result in permanent loss of vision or even loss of the eye itself.

Additional Comments: According to the board, both State and federal law prohibit a Maryland pharmacy from dispensing a sterile compounded product to an ophthalmologist without a patient-specific prescription. Therefore, in order to obtain sterile compounded drugs for administration in the office, an ophthalmologist must use an outsourcing facility registered with FDA that has also obtained a Maryland wholesale distributor permit. However, federal law appears to permit some anticipatory compounding under limited circumstances.

According to the Maryland Society of Eye Physicians and Surgeons, ophthalmologists have sought to obtain compounded drugs through the waiver process established in Chapter 397 of 2013, but they have been denied by the board. The board advises ophthalmologists to obtain needed compounded drugs from an outsourcing facility; however, few such facilities have received FDA approval, and according to the society, none provides the compounded drugs for emergency treatment that ophthalmologists need.

In March 2014, the Office of the Attorney General advised that the bill is *not* preempted by federal law; however, unless and until federal law is changed, ophthalmologists will only be able to obtain compounded drugs from a permissible facility under federal law, even under the bill.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): U.S. Food and Drug Administration, American Academy of Ophthalmology, Maryland Society of Eye Physicians and Surgeons, Department of Health and Mental Hygiene, Department of Legislative Services

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