**HB 181**

# Department of Legislative Services

Maryland General Assembly
2015 Session

## FISCAL AND POLICY NOTE

House Bill 181 (Delegate Hill, *et al.*)
Health and Government Operations Education, Health, and Environmental Affairs

**State Board of Pharmacy - Sterile Compounding - Compliance by Nonresident Pharmacies and Repeal of Permit Requirement**

This emergency bill repeals (1) the requirement that sterile compounding facilities hold a sterile compounding permit from the State Board of Pharmacy; (2) the requirement that a person that prepares and distributes sterile drug products into or within the State hold both a manufacturer's permit or other permit from the U.S. Food and Drug Administration (FDA) and a wholesale distributor's permit from the board; and (3) the board's authority to issue a waiver of these requirements. Instead, the bill requires nonresident pharmacies that dispense "compounded sterile preparations" to Maryland patients to (1) comply with USP 797 (as defined in the bill) 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.

## Fiscal Summary

**State Effect:** Special fund expenditures for the State Board of Pharmacy increase by $73,600 in FY 2016 to monitor nonresident pharmacy compliance with USP 797. The Governor's proposed FY 2016 budget includes $54,584 for one grade 16 position for this purpose. Revenues are not affected.

| (in dollars) | FY 2016 | FY 2017 | FY 2018 | FY 2019 | FY 2020 |
|---|---|---|---|---|---|
| Revenues | $0 | $0 | $0 | $0 | $0 |
| SF Expenditure | 73,600 | 70,900 | 74,200 | 77,700 | 81,200 |
| Net Effect | ($73,600) | ($70,900) | ($74,200) | ($77,700) | ($81,200) |

*Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect*

**Local Effect:** None.

**Small Business Effect:** Potential meaningful. Physician practices that engage in sterile compounding are no longer required to obtain a permit from the board or operate under sterile compounding requirements.

## Analysis

**Bill Summary:** "Compounded sterile preparations" means biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797, must be compounded using aseptic techniques. "USP 797" means the standards set forth in the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding - Sterile Preparations."

The bill specifies that a wholesale distributor applicant or permit holder that prepares sterile drug products must demonstrate compliance with applicable good manufacturing practice standards (rather than with such standards *or* USP 797) at the time of application and on renewal. The bill also repeals the criminal penalties and civil fines for operating a sterile compounding facility without a permit.

**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 board. A person that prepares and distributes sterile drug products into or within the State must hold both a manufacturer's permit or other permit from FDA and a wholesale distributor's permit from the board. A wholesale distributor applicant or permit holder that prepares sterile drug products must submit to the board an inspection report conducted by FDA or a board designee at the time of application and renewal that demonstrates compliance with applicable federal good manufacturing standards *or* USP 797. The board may issue a waiver to a sterile compounding facility or a person that prepares and distributes a sterile drug product into or within Maryland under limited circumstances.

Subject to hearing provisions, the board may deny a sterile compounding permit to any applicant, reprimand a permit holder, place a permit holder on probation, or suspend or revoke a permit. Instead of or in addition to such disciplinary action, the board may impose a fine of up to $10,000, payable to the State Board of Pharmacy Fund. A person who operates a sterile compounding facility without a permit is guilty of a misdemeanor and subject to a fine of up to $1,000 and/or imprisonment for up to one year. The board may also issue a civil fine of up to $50,000, payable to the State Board of Pharmacy Fund.

The board is required to adopt regulations that require compliance with USP 797 and, among other things, establish requirements for reporting of adverse events and evidence of environmental contamination.

Subsequent to passage of Chapter 397, the federal Drug Quality and Security Act (DQSA) was enacted in November 2013. DQSA provides oversight of (1) sterile drug products produced in bulk quantities and (2) sterile compounding performed by health care practitioners for identified individual patients. Traditional compounding pharmacies remain under the oversight of state boards of pharmacies.

**Background:** The board published notice of final action regarding regulations implementing Chapter 397 in June 2014, with an effective date of January 1, 2015. The Maryland State Medical Society (MedChi) raised concerns regarding the applicability of sterile compounding permit requirements to physician office practices. In November 2014, the board voted to postpone the effective date of the regulations to July 1, 2015, and announced that it would not accept applications for sterile compounding permits or waivers or enforce permit requirements until July 1, barring any legislative changes.

Following meetings between the Department of Health and Mental Hygiene, the board, the State Board of Physicians, and MedChi, and in light of passage of the federal DQSA, the department announced willingness to repeal Chapter 397, while retaining some elements of the law. Specifically, the board sought to retain authority to require (1) inspections of nonresident pharmacies that perform compounding and (2) reporting of adverse events.

This bill repeals Chapter 397 and requires nonresident pharmacies to provide inspection reports to the board demonstrating compliance with Chapter 397. The bill does not address adverse reporting (the bill repeals the requirement that the board adopt regulations for reporting of adverse events and evidence of environmental contamination). However, the board indicates that this requirement will be promulgated through regulations.

**State Fiscal Effect:** The fiscal and policy note for Chapter 397 of 2013 estimated that board special fund expenditures would increase by $363,300 in fiscal 2014 to issue sterile compounding permits. Special fund revenues were anticipated to increase by $210,000 in fiscal 2014 from sterile compounding permit fees and by an additional unknown amount from the issuance of additional wholesale distributor permits and the imposition of civil fines for operating a sterile compounding facility without a permit. A potential minimal increase in general fund revenues and expenditures was also anticipated due to the bill's criminal penalty provisions. As Chapter 397 was never fully implemented, these revenues and expenditures were never realized.

Thus, this analysis assumes nonimplementation as the baseline. Under this emergency bill, special fund expenditures for the State Board of Pharmacy increase by $73,577 in fiscal 2016, which assumes expenditures are incurred beginning July 1, 2015. This estimate reflects the cost of hiring one grade 19 laboratory scientist surveyor to review inspection reports (and ultimately reporting of adverse events at nonresident pharmacies). It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

| | |
|---|---|
| Position | 1 |
| Salary and Fringe Benefits | $68,707 |
| One-time Start-up Costs | 4,285 |
| Ongoing Operating Expenses | 585 |
| **Total FY 2016 State Expenditures** | **$73,577** |

The Governor's proposed fiscal 2016 budget includes $54,584 to fund such a position. Future year expenditures reflect annual increases and employee turnover as well as annual increases in ongoing operating expenses.

The board advises that states are currently *voluntarily* sharing USP 797 compliance reports and that Maryland receives approximately 8 to 10 inspection reports on nonresident pharmacies each month. It does not currently have the expertise to review these reports. There are 626 nonresident pharmacies holding a pharmacy permit from the State Board of Pharmacy; however, it is unknown how many perform sterile compounding and will be *required* to submit reports to the board.

## Additional Information

**Prior Introductions:** None.

**Cross File:** SB 69 (Senator Conway) - Education, Health, and Environmental Affairs.

**Information Source(s):** Department of Health and Mental Hygiene, Department of Legislative Services

**Fiscal Note History:** First Reader - February 10, 2015
md/ljm

Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510