HB 462

Department of Legislative Services

Maryland General Assembly
2002 Session

FISCAL NOTE

House Bill 462 (Chairman, Environmental Matters Committee)
Environmental Matters Education, Health, and Environmental Affairs

Health Occupations - State Board of Pharmacy - Sunset Extension

This bill extends the sunset date for the State Board of Pharmacy (SBP) from July 1, 2003 to July 1, 2013 and requires another sunset evaluation on or before July 1, 2012. The bill eliminates the requirement for a State pharmaceutical manufacturing permit and establishes that any pharmacy with a State permit must be inspected annually. It also limits discovery and admissibility of evidence by including a committee or individual designated by a pharmacy permit holder to evaluate and improve health care, evaluate its performance, and act on disciplinary matters in the definition of a medical review committee.

The board is required to report to the Senate Education, Health, and Environmental Affairs and the House Environmental Matters committees on or before October 1, 2002 on implementation of recommendations from the Department of Legislative Services (DLS) in the sunset evaluation of October 2001. The bill is effective July 1, 2002.

Fiscal Summary

State Effect: Special fund revenues and expenditures for this board would be maintained beyond FY 2003. The proposed FY 2003 budget assumes $1.5 million in revenues for SBP and includes special fund expenditures of $1.1 million. Out-year revenues and expenditures are expected to remain relatively constant except for revenue fluctuations due to biennial license renewal schedules.

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law: SBP is to terminate operations as of July 1, 2003.

The board is subject to the Maryland Program Evaluation Act, also known as the "Sunset Law," which provides a system of periodic legislative review of the regulatory, licensing, and other activities of various units of State government. "Sunset review" determines the need for certain programs, services, and other governmental functions and is intended to make governmental activities responsive to the public interest.

The law specifies that the definitions of "distribute" and "practice pharmacy" do not include the operations of a person who holds a manufacturing permit. A person must hold a manufacturing permit issued by the board before the person may manufacture or package drugs, medicines, devices, cosmetics, dentifrices, or toilet articles in the State. The SBP is authorized to deny a permit to an applicant for a manufacturing or distribution permit, reprimand or place a permit holder on probation, or suspend or revoke a permit. A manufacturing or distribution permit holder who violates any of the relevant provisions of the pharmacy title is guilty of a misdemeanor and subject to a maximum fine of $1,000, imprisonment for up to one year, or both.

The Secretary of Health and Mental Hygiene, SBP, or their agents have the authority to enter any place where drugs are manufactured, packaged, stocked, or offered for sale. They also have the authority to inspect the drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, and toilet articles there.

A medical review committee, which has authority to evaluate the qualifications, performance, and competence of a health care provider, among other things, does not include an individual or committee designated by a pharmacy permit holder.

Background: The members of the pharmacy industry are regulated by the 12-member SBP, which was created to protect public health through licensing and regulation. Regulation of the pharmacy industry is complex due to the involvement of other State and federal entities. At the State level, the board shares regulatory responsibilities with the Division of Drug Control (DDC), which is part of the Laboratories Administration in the Department of Health and Mental Hygiene (DHMH). Both the SBP and DDC work closely with two federal agencies: the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). The FDA sets standards to protect public health, and the DEA enforces federal laws on controlled dangerous substances.

This bill arises out of the sunset evaluation of SBP performed by DLS during 2001. In its report, DLS recommended that SBP be continued and its termination date extended to

July 1, 2013. In addition, pursuant to DLS recommendations, this bill requires SBP to report to the Senate Education, Health, and Environmental Affairs and House Environmental Matters committees on the recommendations in the report on or before October 1, 2002. Other DLS recommendations include:

- SBP should continue to examine the issue of establishing different types of pharmacy permits to improve the overall quality of care.

- Legislation should be enacted to repeal the requirement for State manufacturing permits, as that segment of the industry is already extensively regulated by federal agencies.

- The SBP task force should report to the General Assembly on its assessment of a possible pharmacist shortage in Maryland and potential solutions.

- Legislation should be enacted to codify the current practice of annual pharmacy inspections.

- SBP and DDC should revise the inspection form and process to improve evaluation of quality assurance systems and the adequacy of training and supervision of unlicensed personnel working in pharmacies.

- DHMH should develop a pharmacy inspection database to be used jointly by SBP and DDC.

- SBP should monitor its time commitment for full board disciplinary hearings and possibly consider using the services of the Office of Administrative Hearings. The board should also consider proposing legislation to authorize SBP disciplinary hearings with a subset of board members.

- SBP should ensure that it is receiving adequate information from the Pharmacists' Education and Assistance Committee to monitor pharmacists referred to the committee. SBP should evaluate the contract to improve service or consider seeking other vendors.

- SBP should reallocate existing resources instead of adding positions to address workload.

- SBP should develop a new proposal to raise fees so that a sufficient financial cushion is produced but not an excessive fund balance.
- To facilitate voluntary tracking of medication errors by pharmacists, legislation is needed to limit discovery. SBP should take action to implement more stringent quality assurance measures and work more closely with the State Board of Nursing and the Board of Physician Quality Assurance to reduce medical errors in the dispensing process.

- SBP should continue to examine the various issues associated with requiring certification of unlicensed personnel. SBP should also implement a regulatory system to ensure unlicensed personnel meet minimum standards as determined by SBP.

State Fiscal Effect: Special fund revenues and expenditures for SBP will be maintained beyond fiscal 2003, because the bill proposes to continue SBP. In fiscal 2002, projected special fund revenues are $779,834. For fiscal 2003, the beginning fund balance is projected to be $317,841 and the projected revenue is $1,527,310, with the fluctuation due to the effect of biennial licensing. The fiscal 2003 budget allowance is $1,120,689.

The board advises that the bill's elimination of the manufacturing permit requirement (and consequently, manufacturing permit fees) will result in a decrease in board revenues of $16,825 annually. This amount represents approximately 1% of fiscal 2003 projected revenues.

Additional Information

Prior Introductions: None.

Cross File: SB 418 (Senator Hollinger) (Chairman, Health Subcommittee) – Education, Health, and Environmental Affairs.

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

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