Department of Legislative Services

Maryland General Assembly
2012 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 274 (Chair, Education, Health, and Environmental Affairs Committee)

Education, Health, and Environmental Affairs Health and Government Operations

State Board of Pharmacy - Sunset Extension and Revisions

This bill extends the termination date of the State Board of Pharmacy by 10 years to July 1, 2023, and requires an evaluation of the board by July 1, 2022. The bill removes the requirement that the State Board of Pharmacy and the State Board of Physicians jointly approve physician-pharmacist agreements and protocols used under the Drug Therapy Management Program and, instead, requires physicians and pharmacists who enter into such agreements to submit a copy of the agreement and any subsequent modifications to their respective licensing board.

The bill takes effect July 1, 2012.

Fiscal Summary

State Effect: Special fund revenues and expenditures for the State Board of Pharmacy are maintained beyond FY 2013. The FY 2013 budget includes $2.8 million for board operations. Special fund revenues for the board and the State Board of Physicians decrease by a minimal amount beginning in FY 2013 from a reduction in the amount of fees currently charged for the Drug Therapy Management Program. The bill's reporting requirements can be handled with existing budgeted resources.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: The bill authorizes the board to assess a fee, as established in regulation, for approval of a pharmacist to enter into a physician-pharmacist agreement under the Drug Therapy Management Program. The bill alters the dates on which pharmacy permits and wholesale distributor permits expire from December 31 to May 31. The board must extend the renewal of permits expiring December 31, 2012, and December 31, 2013, to accommodate the revised permit renewal date of May 31. The bill also includes two uncodified reporting requirements.

Current Law/Background:

The State Board of Pharmacy

The 12-member State Board of Pharmacy regulates the practice of pharmacy by licensing pharmacists, registering pharmacy technicians, issuing permits to pharmacies and wholesale distributors, setting pharmacy practice standards, developing and enforcing regulations and legislation, resolving complaints, and educating the public. More than 19,000 licenses, registrations, and permits issued by the board were held by pharmacists, pharmacy technicians, pharmacies, and wholesale distributors in fiscal 2011.

Drug Therapy Management Program

The board jointly administers the Drug Therapy Management Program with the State Board of Physicians. Established by Chapter 249 of 2002, the program authorizes a physician and a pharmacist to enter into a therapy management contract that specifies treatment protocols that may be used to provide care to a patient. A pharmacist may order laboratory tests and other patient care measures related to monitoring or improving the outcomes of drug or device therapy based on disease-specific, mutually agreed-upon protocols.

Before collaborating on drug therapy management, a pharmacist and a physician must apply to the board for a physician-pharmacist agreement and approval of each individual protocol to be used. Each pharmacist must be approved by the board to participate in a therapy management contract. To qualify, a pharmacist must have a doctoral degree or equivalent training, may not have any public final disciplinary orders within the previous five years, and must meet significant relevant advanced training and experience requirements as set in regulation. Applicants pay a $250 application fee, which includes review and disposition of the physician-pharmacist agreement and one protocol. Additional protocols require a fee of $50. Agreements can be renewed every two years for a fee of $200.

Once a pharmacist is approved by the board, all application materials and protocols are sent to the joint committee, which consists of two members of the board and two members of the State Board of Physicians. The joint committee reviews and makes recommendations regarding the final approval of the agreement and protocol(s) to the board and the State Board of Physicians. Both boards must approve the physician-pharmacist agreement.

As of October 2011, there were only nine physician-pharmacist agreements. In the 2011 sunset evaluation of the board (discussed in more detail below), the Department of Legislative Services (DLS) identified several potential reasons why participation in the program is low. First, statute and regulations outlining the program are lengthy and complex. Second, the application process is onerous and time consuming. Third, the pharmacy and physician boards disagree on the program's legislative intent, as well as the scope of the program and the types of diseases that should be treated under it, which leads to disagreements on and significant delays in the approval process. Furthermore, there is concern that the State Board of Physicians denies protocols that are authorized under statute, which both hinders collaborative practice and further prolongs the approval process by requiring repeated resubmissions and revisions.

DLS found that nationally only 8 of the 45 states that authorize drug therapy management require agreements (or protocols) to be approved. Arizona, Nevada, Montana, and Washington require the agreements to be approved by the board of pharmacy only. West Virginia and Louisiana require approval by both the pharmacy and physician boards. In Wyoming, while both boards jointly review applications and protocols, approval is conducted by the pharmacy board only. New Hampshire requires approval of protocols by the board of pharmacy only. In addition to these states, Virginia requires approval of protocols that are "outside the standard of care"; however, in practice no such protocols have ever been submitted for approval. The remaining states generally allow qualified pharmacists and physicians to enter into drug therapy management contracts and establish drug therapy management protocols that follow established statutory and regulatory guidelines without any board approval or notice.

Maryland Program Evaluation Act

The State Board of Pharmacy is 1 of approximately 70 regulatory entities and activities currently subject to periodic evaluation under the Maryland Program Evaluation Act. The Act establishes a process better known as "sunset review" as most entities evaluated are also subject to termination, including the board, which is scheduled to terminate July 1, 2013. The sunset review process begins with a preliminary evaluation conducted by DLS on behalf of the Legislative Policy Committee (LPC). LPC decides whether to waive an entity from further (or full) evaluation. If waived, legislation to reauthorize the entity typically is enacted. Otherwise, a full evaluation usually is

undertaken the following year. A copy of the DLS sunset report on the board can be found at http://dls.state.md.us/Content.aspx?page=104.

DLS conducted a full sunset evaluation of the board in 2011. DLS found that board staff has dealt admirably with significantly expanded duties associated with the regulation of an industry that continues to grow at a rapid rate, and board members have demonstrated their engagement with and careful consideration of the complex and ever-increasing issues facing the board.

DLS found the administrative process associated with the Drug Therapy Management Program to be onerous and the joint approval process inconsistent with the policies of other health occupations boards and with the approval processes of drug therapy management programs in other states. Thus, DLS recommended repeal of the requirement that physician-pharmacist agreements and drug therapy management protocols be approved by both the board and the State Board of Physicians. Instead, participating pharmacists and physicians should be required to submit copies of all agreements and protocols to their respective board and to promptly submit any modifications.

DLS recommended that legislation be enacted to extend the termination date of the board by 10 years to July 1, 2023, and that the board report to specified legislative committees on the implementation of the nonstatutory recommendation made in its report by October 1, 2013. Additional recommendations contained in the report include that the board should:

- prepare a five-year financial outlook and report on its ability to maintain a healthy fiscal outlook;
- expand use of Managing for Results goals to track regulation of pharmacy technicians, pharmacies, and wholesale distributors;
- in conjunction with the Division of Drug Control, establish a formal process for information sharing between the two entities;
- seek reclassification of the compliance manager position;
- review the possibility of replacing at least some of its nonpharmacist inspectors with pharmacist inspectors or requiring inspectors to have a bachelor's degree and investigative experience;
- make administrative changes such as updating its website regularly, providing relevant staff with cross training, and standardizing recordkeeping; and
- submit reports on implementation of its new information technology system, progress in reducing the length of the pharmacy technician registration process, implementation and use of sanctioning guidelines, and the status of the board's contractual relationship with the Pharmacists' Education and Advocacy Council.

The bill generally implements the recommendations in the DLS sunset evaluation.

State Revenues: Special fund revenues for the State Board of Pharmacy decline by a minimum amount beginning in fiscal 2013 due to a reduction in fees associated with the Drug Therapy Management Program. Currently, applicants pay a $250 application fee for review and approval of a physician-pharmacist agreement and one protocol. According to the State Board of Pharmacy, this fee includes $50 for a research and evaluation component; $100 for the State Board of Pharmacy to approve pharmacists for participation, review and approve physician-pharmacist agreements, and review and approve protocols; and $100 that is forwarded to the State Board of Physicians to cover administrative expenses associated with the review and approval of physician-pharmacist agreements and protocols. Legislative Services notes that the only fee that will continue under the bill is the fee paid to the State Board of Pharmacy to continue to cover the cost of approving pharmacists for participation in drug therapy management.

Special fund revenues for the State Board of Physicians also decline by a minimal amount beginning in fiscal 2013 due to the anticipated elimination of the $100 fee currently payable to the board for review and approval of physician-pharmacist agreements and protocols.

In the case of both boards, any reduction in fee revenues is anticipated to be minimal given the low participation rate in this program to date. The State Board of Pharmacy indicates that a total of only 16 drug therapy management applications have been submitted since the program's inception to date.

Additional Information

Prior Introductions: None.

Cross File: HB 283 (Chair, Health and Government Operations Committee) - Health and Government Operations.

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

Fiscal Note History: First Reader - February 6, 2012
ncs/ljm Revised - Senate Third Reader - March 30, 2012
Revised - Updated Budget Information - May 21, 2012

Analysis by: Jennifer B. Chasse

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