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# **Sunset Review: Evaluation of the State Board of Pharmacy**

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**Presentation to the  
House Health and Government Operations Committee  
*Delegate Peter A. Hammen, Chairman***

**Health Facilities and Occupations Subcommittee  
*Delegate Eric M. Bromwell, Chairman***

**Department of Legislative Services  
Office of Policy Analysis  
Annapolis, Maryland**

**December 6, 2011**

# Presentation Overview

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- History, purpose, and composition of board
- Growth in pharmacy industry
- Expansion of board's duties
- Focus of 2011 sunset evaluation
- Findings and recommendations relating to statutory changes; licensing, registration, and compliance processes; administrative issues; fund balance; and extension of board's termination date
- Conclusion

# State Board of Pharmacy

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- Established in 1902 to protect public health through licensing and regulation of pharmacy industry
- Currently regulates pharmacies, pharmacists, pharmacy technicians, and wholesale drug distributors
- Functions primarily to license, register, and issue permits to pharmacy professionals; inspect pharmacies; and receive and investigate complaints from the public
- Composed of 12 members: 10 licensed practicing pharmacists and 2 consumers
- Meets on third Wednesday of each month and accomplishes most work through nine committees

# Growth in the Pharmacy Industry

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## Licenses, Registrations, and Permits Held Fiscal 2007-2011

	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
Pharmacist	7,901	8,112	8,393	8,612	8,708
Pharmacy Technician	-	1,183	6,162	7,118	8,052
Pharmacy	1,589	1,602	1,613	1,683	1,761
Wholesale Distributor	839	904	797	872	759
<b>Total</b>	<b>10,329</b>	<b>11,801</b>	<b>16,965</b>	<b>18,285</b>	<b>19,280</b>

Notes: The board did not begin registering pharmacy technicians until fiscal 2008. The board began issuing permits biennially rather than annually to wholesale distributors in fiscal 2008 and to pharmacies in fiscal 2010.

Source: State Board of Pharmacy

# Legislative Changes and Expansion of the Board's Duties

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- Drug Therapy Management Program
- Registration of pharmacy technicians
- Licensure of wholesale distributors under more comprehensive statute
- Assumption of annual pharmacy inspections
- Registration of pharmacists trained to administer immunizations
- Implementation of Prescription Drug Repository and Monitoring programs

# Focus of the 2011 Sunset Evaluation

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- Sunset evaluation explored issues including:
  - legislative and statutory issues faced by board
  - how board's licensing, registration, inspection, and complaint resolution processes could be improved
  - board's accounting for cost of implementing new information technology (IT) system
  - sufficiency of board personnel
- The Department of Legislative Services (DLS) recognizes positive changes board has implemented thus far; however, some areas in need of improvement still exist
- Based on these findings, DLS makes a total of 15 recommendations

# Drug Therapy Management Program

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- Jointly administered by board and State Board of Physicians
- Authorizes a physician and a pharmacist to enter into a therapy management contract specifying treatment protocols that may be used to provide care to a patient
- Administrative process is onerous and participation is low
- Program's joint approval process is inconsistent with the policies of other health occupations boards and with similar programs in other states

# **Drug Therapy Management Program (Cont.)**

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**Recommendation 1 (pg. 14): Statute should be amended to remove 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. Furthermore, the board, in collaboration with the State Board of Physicians, should submit a follow-up report to specified committees by October 1, 2013, on the impact of these modifications to the program, including the number of physician-pharmacist agreements and drug therapy management protocols on file with the boards**

# Dispensing by Nonpharmacist Practitioners

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- Board has no authority to inspect/regulate dispensing practitioners who are not pharmacists
- 1,265 dispensing permits are held by nonpharmacist practitioners (most of whom are physicians) in Maryland
- All relevant health occupations boards, along with the Department of Health and Mental Hygiene (DHMH), should work to ensure that all dispensing providers are complying with the same rules and standards
- Given its expertise, board could take the lead in coordinating with other boards to develop practical training guidelines for dispensing practitioners

# Board Member Training

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- Board faces legislative and regulatory issues of ever-increasing complexity
- Many of these issues are unfamiliar to new members, yet training is limited
- Learning curve is particularly steep with regard to legislative and regulatory processes

**Recommendation 2 (pg. 17): DHMH should expand the general training it currently offers to new members of all health occupations boards to include additional training on the legislative and regulatory processes**

# Licensing, Permitting, and Registration Processes

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- Board generally effective in handling core functions and operations
- Board maintains licensing function in growing industry
- Board meets its Managing for Results (MFR) goals for pharmacist licensure, but it uses MFR goals with regard to pharmacist licensure only

**Recommendation 3 (pg. 21): The board should expand use of Managing for Results goals to track not only the board's regulation of pharmacists, but also regulation of pharmacy technicians, pharmacies, and wholesale distributors**

# Licensing, Permitting, and Registration Processes (Cont.)

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- Chapter 523 of 2006 establishes registration requirements for pharmacy technicians
- Board began registering some pharmacy technicians in fiscal 2008, but most had to wait until fiscal 2009
- Registration process challenging due to volume of applications (incomplete applications in particular), but length of registration period has been decreasing
- Board has implemented administrative changes
- Board's new IT system will automate and streamline process

**Recommendation 4 (pg. 22): The board should report to specified committees by October 1, 2013, on the board's progress in further reducing the length of the pharmacy technician registration process following the implementation of the new IT system. In addition, the board should report, for each full month following the system's implementation, the average wait time from the date of application to the date of registration (or rejection)**

# Inspection and Complaint Resolution Processes

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- Board assumed annual inspection responsibilities from DHMH's Division of Drug Control (DDC) in fiscal 2009
- DDC continues to conduct some pharmacy inspections, which vary in purpose and scope from board's annual inspections
- Communications between board and DDC are generally informal

**Recommendation 5 (pg. 26):** The board, in conjunction with DDC, should establish a formal process for information sharing between the two entities. Such a process might include the creation or use of a shared database (which was a recommendation in the 2001 sunset evaluation report) or include regular reports and/or meetings between the two entities. In particular, each entity should share information regarding dates of inspections and any violations found

# Inspection and Complaint Resolution Processes (Cont.)

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- Most complaints received by board are resolved informally
- Board is currently working toward implementation of Chapters 533 and 534 of 2010 (requiring adoption of sanctioning guidelines), which should promote uniformity
- Board will likely not have had significant experience in use of guidelines by reporting date specified in statute

**Recommendation 6 (pg. 28): The board should report again to specified committees on its implementation and use of sanctioning guidelines by December 1, 2012 (by which time the board is expected to have been using the guidelines for about one year)**

# Inspection and Complaint Resolution Processes (Cont.)

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- Board has had significant difficulties attracting and retaining appropriate pharmacist staff to lead Compliance Unit
- Over past six years, board has hired five different pharmacists to fill role

**Recommendation 7 (pg. 29): Because of the technical expertise required to properly investigate complaints – and given high turnover in recent years – the board should seek reclassification of the compliance manager from the Department of Budget and Management (DBM) to ensure that the Compliance Unit has more stable leadership and is led by an experienced pharmacist**

# Inspection and Complaint Resolution Processes (Cont.)

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- Use of pharmacy technicians as inspectors is a growing trend in many states due to limited availability of funds
- Concerns have been raised as to whether pharmacy technicians can reach the level of expertise held by pharmacists and/or necessary to mastering finer points of inspection process

**Recommendation 8 (pg. 29):** The board should review the possibility of replacing at least some of its nonpharmacist inspectors with pharmacist inspectors (who could be used to conduct the board's most challenging inspections) as attrition occurs or, in the alternative, requiring its inspectors to have a bachelor's degree and investigative experience, which would align the board's requirements with those of other comparable health occupations boards. Depending on the board's determinations, the board should seek reclassification of its inspector positions from DBM

# Inspection and Complaint Resolution Processes (Cont.)

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- Board contracts with Pharmacists' Education and Advocacy Council (PEAC) to provide assistance to licensees and registrants who have substance abuse problems
- In fiscal 2007, board significantly reduced PEAC's contract due to board's inability to receive information from PEAC in a timely manner
- Board and PEAC have recently taken steps to improve relationship

**Recommendation 9 (pg. 30): The board should report to specified committees by October 1, 2013, on the status of the board's contractual relationship with PEAC and whether any statutory changes are necessary to allow other vendors to compete with PEAC**

# Administrative Issues

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- Board's assumption of new program areas created some inefficiencies within board
- New IT system expected to streamline board operations significantly

**Recommendation 10 (pg. 31):** The board should report to specified committees by October 1, 2013, on the implementation of the new IT system, including both positive and negative outcomes and the effect of the new system, if any, on staffing needs

- Board's website lacks or incorrectly states some information (including contact information for staff) and is not updated regularly

**Recommendation 11 (pg. 31):** In order to improve public access and customer service, the board should update its website regularly, with particular attention to correcting outdated information

# Administrative Issues (Cont.)

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- Employee turnover and temporary absences result in setbacks to board operations
- Staff members lack knowledge of board functions beyond own roles

**Recommendation 12 (pg. 32):** The board should provide relevant staff with cross-training in other functions, particularly with regard to the licensing function and the processing of applications

- Recordkeeping is inconsistent

**Recommendation 13 (pg. 32):** The board should standardize its recordkeeping so that staff turnover does not impact its ability to maintain consistent and accurate data

# Fund Balance

## Fiscal History of the State Board of Pharmacy Fiscal 2007-2011

	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>Projected FY 2012</u>
Authorized Positions	16	17	23	23	23	23
Beginning Fund Balance	\$1,090,227	\$985,688	\$962,722	\$926,214	\$997,462	\$1,249,940
Revenues Collected	1,612,082	1,752,509	2,241,441	2,366,726	2,975,380	2,359,560
<b>Total Funds Available</b>	<b>\$2,702,309</b>	<b>\$2,738,197</b>	<b>\$3,204,164</b>	<b>\$3,292,941</b>	<b>\$3,972,842</b>	<b>\$3,609,500</b>
<b>Total Expenditures</b>	<b>\$1,716,620</b>	<b>\$1,775,475</b>	<b>\$2,277,950</b>	<b>\$2,196,935</b>	<b>\$2,522,902</b>	<b>\$2,613,502</b>
Direct Costs	1,491,994	1,515,460	2,126,328	1,910,397	2,190,550	2,321,854
Indirect Costs	224,626	260,015	151,622	286,538	332,352	291,648
<b>Ending Fund Balance</b>	<b>\$985,688</b>	<b>\$962,722</b>	<b>\$926,214</b>	<b>\$1,096,006</b>	<b>\$1,449,940</b>	<b>\$995,998</b>
<b>Transfer to General Fund</b>				<b>\$98,544</b>	<b>\$200,000</b>	<b>\$237,888</b>
Balance as % of Expenditures	57%	54%	41%	50%	57%	38%
Target Fund Balance	\$343,324	\$355,095	\$455,590	\$459,096	\$504,580	\$522,700

# Fund Balance (Cont.)

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- Board's fund balance consistently remains above recommended threshold
- However, board anticipates decline in revenues from wholesale distributor permits and increase in expenditures associated with new database

**Recommendation 14 (pg. 36): Before modifying its fees, the board should prepare a five-year financial outlook and report to specified committees by October 1, 2013, on its ability to maintain a healthy fiscal outlook. The board's report should discuss the effects of Budget Reconciliation and Financing Act transfers, costs associated with the board's new database, and any additional personnel costs resulting from the recommendations made in this report on the board's ability to maintain an adequate fund balance**

# Conclusion

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- Board has dealt admirably with expanded duties associated with regulating a growing industry
- Prospects for improving board operations are generally good
- Board's new IT system should streamline board operations significantly, but this, along with changes recommended by DLS, will take time to implement and yield results

**Recommendation 15 (pg. 37): Extend the termination date for the board by 10 years to July 1, 2023, and require the board to report to specified committees by October 1, 2013, on the implementation status of nonstatutory recommendations made in this report**