

Preliminary Evaluation of the State Board of Pharmacy

Recommendation: Full Evaluation

The Sunset Review Process

This evaluation was undertaken under the auspices of the Maryland Program Evaluation Act (§ 8-401 *et seq.* of the State Government Article), which establishes a process better known as “sunset review” because most of the agencies subject to review are also subject to termination. Since 1978, the Department of Legislative Services (DLS) has evaluated about 70 State agencies according to a rotating statutory schedule as part of sunset review. The review process begins with a preliminary evaluation conducted on behalf of the Legislative Policy Committee (LPC). Based on the preliminary evaluation, LPC decides whether to waive an agency from further (or full) evaluation. If waived, legislation to reauthorize the agency typically is enacted. Otherwise, a full evaluation typically is undertaken the following year.

The State Board of Pharmacy last underwent a full evaluation as part of sunset review in 2001. Ensuing legislation, Chapter 157 of 2002, extended the termination date of the board by 10 years to July 1, 2013, and required the board to report to committees of the General Assembly on the implementation of recommendations contained in the sunset report.

In conducting this preliminary evaluation, DLS staff reviewed prior evaluations of the board, applicable State law and regulations, recent legislative and regulatory actions, the board’s operating budget, board meeting minutes, licensing data, complaint and disciplinary data, annual reports, and board newsletters. DLS staff conducted interviews with the executive director, board president, and board staff. DLS also examined data on national industry trends, attended two board meetings, and spoke with staff from the Division of Drug Control (DDC) at the Department of Health and Mental Hygiene (DHMH), the Maryland Pharmacists Association, the National Association of Chain Drug Stores, the Pharmacist Education and Advocacy Council, and the National Association of Boards of Pharmacy.

The board reviewed a draft of this preliminary evaluation and provided the written comments attached as **Appendix 2**. Appropriate factual corrections and clarifications have been made throughout the document; therefore, references in board comments may not reflect the final version of the report.

The Practice of Pharmacy

Pharmacists distribute prescription drugs to individuals and advise their patients, physicians, and other health care practitioners on the selection of dosages, interactions, and side effects of medications. Compounding, or mixing ingredients to form medications, remains only a small part of a pharmacist's current practice, because most medicines are produced by pharmaceutical companies in standard dosages. The majority of pharmacists work in a community setting, such as a retail drugstore, or in a health care facility such as a hospital.

Pharmacists are responsible for the accuracy of every prescription filled and often rely on pharmacy technicians to assist them in dispensing medications. Therefore, pharmacists may also delegate prescription filling and administrative tasks to pharmacy technicians and supervise their work. In addition, pharmacists also frequently oversee pharmacy students serving as interns.

Pharmacy Industry Expected to Grow Quickly

According to the U.S. Department of Labor's Bureau of Labor Statistics' *Occupational Handbook*, approximately 269,900 pharmacists were employed nationwide in 2008, and projections show that the industry will increase 17% by 2018 – faster than the average for all occupations. Additionally, employment for pharmacy technicians is anticipated to grow 31%. This growth is due, in part, to the aging of the U.S. population and expanded use of pharmaceutical products.

The State Board of Pharmacy

In Maryland, the practice of pharmacy is regulated by the State Board of Pharmacy. The board was created by the General Assembly in 1902 and is housed within DHMH. The board's mission is to protect Maryland consumers and to promote quality health care in the field of pharmacy through 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. DDC, which is housed under the Laboratories Administration at DHMH, registers manufacturers, distributors, and dispensers of controlled dangerous substances and ensures the availability of drugs for legitimate medical and scientific purposes, while working to prevent drug abuse.

The board comprises 12 members. Ten members are licensed practicing pharmacists and two are consumers. Pharmacist members must have at least five years of experience and are appointed by the Governor with the advice of the Secretary of Health and Mental Hygiene, who makes recommendations to the Governor from a list provided by various pharmacy associations. Consumer members may not have any connection with the practice of pharmacy and are appointed by the Governor with the advice of the Secretary of Health and Mental Hygiene and

the consent of the Senate. All members are appointed for staggered four-year terms and may not serve more than two consecutive terms. Generally, members continue to serve until a replacement is appointed. The board currently has no vacancies.

Statutory and Regulatory Changes Affecting the Board Since 2001

Since the last full sunset evaluation of the board in 2001, numerous statutory changes have impacted the board, as detailed in **Exhibit 1**. The board has done an excellent job at keeping pace with changes impacting the practice of pharmacy. The board's practice committee meets regularly to make recommendations for statutory and regulatory changes. In addition, the board's legislative committee meets frequently during the legislative session.

Several new programs have been mandated by statute since 2001, including the approval of drug therapy management agreements, the registration of pharmacy technicians, licensure of wholesale distributors under a more comprehensive statute, and the registration of pharmacists trained to administer immunizations. The board has also adopted regulatory changes to reflect the emergence of electronic transmission of prescriptions (e-prescribing).

Establishment of the Drug Therapy Management Program

Chapter 249 of 2002 created the Drug Therapy Management Program, which 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 therapy management contract allows a pharmacist to modify, continue, or discontinue a specified drug therapy under written, disease-state specific protocols approved by a patient's physician. The program was initially established with a termination date of May 31, 2008, which was later extended to September 30, 2010, by Chapter 650 of 2008. Ultimately, Chapters 44 and 45 of 2010 repealed the termination date, making the program permanent. Additional discussion of the Drug Therapy Management Program can be found later in this report.

Registration of Pharmacy Technicians

In the 2001 sunset evaluation report, DLS recommended that the board implement a regulatory system that provides quality assurance for unlicensed pharmacy personnel. Chapter 523 of 2006 addressed this recommendation by requiring an individual to be registered with the board prior to practicing as a pharmacy technician and performing specified delegated pharmacy acts. Additionally, Chapter 523 authorizes a licensed pharmacist to delegate pharmacy acts under specified circumstances.

Exhibit 1
Major Legislative Changes Since the 2001 Sunset Evaluation

<u>Year</u>	<u>Chapter</u>	<u>Change</u>
2002	157	<p>Extends the termination date of the board by 10 years to July 1, 2013.</p> <p>Codifies the board's practice of annually inspecting pharmacies.</p> <p>Repeals the State manufacturer's permit.</p> <p>Limits discovery and admissibility of certain evidence to facilitate pharmacists in voluntarily tracking medication errors.</p>
	249	<p>Authorizes physicians and pharmacists to enter into voluntary drug therapy management contracts.</p>
2003	318	<p>Requires a pharmacist or a pharmacist's designee to inform consumers of the availability of a generically equivalent drug and the approximate cost difference as compared to the brand name drug.</p>
2004	339	<p>Authorizes a licensed pharmacist to administer an influenza vaccination.</p>
2006	287	<p>Establishes the Prescription Drug Repository Program to accept donated prescription drugs to dispense to eligible individuals.</p>
	408	<p>Requires the board to revoke a license if a licensee is convicted of selling or delivering a drug different from that ordered.</p>
	523	<p>Establishes registration requirements for pharmacy technicians.</p> <p>Authorizes pharmacists to delegate certain pharmacy acts to pharmacy technicians.</p>
2007	352/353	<p>Expand the requirements for a wholesale distributor of prescription drugs or devices to obtain a permit from the board.</p> <p>Require prescription drugs distributed outside the "normal distribution channel" to have a pedigree that records each distribution.</p> <p>Establish a civil fine of up to \$500,000 for violation of the Act.</p>
2008	215/216	<p>Authorize a pharmacist to dispense medication from a remote location for the benefit of a nursing home that uses a remote automated medication system.</p>

- 618/619 Authorize a pharmacist to administer a vaccination for pneumococcal pneumonia or herpes zoster to an adult with a prescription from a physician.
- 650 Extends the termination date of the Drug Therapy Management Program from May 31, 2008, to September 30, 2010.
- 2009 45 Requires specified pharmacy permit holders to inform consumers of the process for resolving incorrectly filled prescriptions.
- 170 Allows wholesale distributors to secure a surety bond of \$50,000 if their annual net income is less than \$10 million.
- 304 Authorizes a pharmacist to administer any vaccination that the board, Board of Physicians, and Board of Nursing determines is in the best interest of the community and is administered in accordance with regulations adopted jointly by the three boards.
- 314/315 Establish standards for licensed physicians and pharmacists who wish to provide drug therapy management to patients in a group model health maintenance organization.
- 532/533 Extend the term a pharmacy permit is valid from one to two years.
- Alter requirements for the board regarding renewal notices.
- 2010 44/45 Repeal the September 30, 2010 termination date for the Drug Therapy Management Program.
- 239/240 Clarify the conditions under which the board may exempt wholesale distributors under “deemed status” from initial and routine inspection requirements.
- Authorize the Department of Health and Mental Hygiene to purchase and distribute drugs for public health purposes exempt from wholesale purchaser requirements.
- Require out-of-state wholesale distributors to be accredited by a board-approved wholesale distributor accreditation organization if they do not qualify for reciprocity in the State.

Source: Laws of Maryland

Enhanced Regulation of Wholesale Distributors

A wholesale distributor is a person that is engaged in the wholesale distribution of prescription drugs or prescription devices. There are 13 different categories of wholesale distributors including manufacturers, warehouse, and some retail pharmacies. While the board

has regulated wholesale distributors since 1987, the regulation of distributors in Maryland has become more stringent in recent years to enhance patient safety and secure the State's prescription medicine supply chain.

The Wholesale Distributor Permitting and Prescription Drug Integrity Act (Chapters 352 and 353 of 2007) imposes additional permitting requirements for wholesale prescription drug distributors. Among other requirements, Chapters 352 and 353 require a pedigree, or history of the distribution chain, for prescription drugs. Chapters 239 and 240 of 2010 clarify the conditions under which the board may exempt wholesale distributors under "deemed status" from initial and routine inspection requirements and exempt purchases and distributions made for public health purposes by DHMH. Under Chapters 239 and 240, wholesale distributors in states that do not qualify for a permit by reciprocity must be accredited by an organization approved by the board in order to seek a permit in Maryland. Out-of-state wholesale distributors that receive a permit by reciprocity are subject to criminal history records checks and surety bond requirements.

Administration of Vaccinations by Licensed Pharmacists

Pharmacists have become more involved in patient care through several key pieces of legislation – Chapter 339 of 2004, Chapters 618 and 619 of 2008, and Chapter 304 of 2009 – that permit licensed pharmacists to administer specific vaccinations. Pharmacists who meet specified training requirements may now administer any vaccination that has been determined by the Board of Pharmacy, with the agreement of the Board of Physicians and the Board of Nursing, to be in the best health interests of the community. Currently, pharmacists may administer influenza, pneumococcal pneumonia, or herpes zoster vaccinations. As of June 2010, 970 pharmacists were certified to administer vaccinations.

Electronic Prescriptions Alter Pharmacy Practice; May Require Additional Statutory Changes in Maryland for Utilization

Recently, the emergence of e-prescribing, the electronic generation and transmission of a prescription between a prescriber and a pharmacy, has altered the practice of pharmacy nationally. By eliminating illegible handwritten prescriptions, e-prescribing has the potential to reduce medication errors and prevent injuries. According to the Institute of Medicine, such medication errors annually cost the health care system \$77 billion and cause approximately 7,000 deaths. Although e-prescribing has the ability to enhance the practice of pharmacy, as of 2007, fewer than 20% of health care providers were using e-prescribing. In comparison, 95% of retail chain pharmacies, such as Rite Aid and CVS, can accept e-prescriptions.

As of June 2010, the federal Drug Enforcement Administration permits e-prescribing of controlled dangerous substances. However, the American Pharmacists Association advises that reprogramming e-prescribing systems may take up to 18 months. Therefore, pharmacists may not see their first e-prescription for controlled dangerous substances for some time.

E-prescribing is regulated under the Code of Maryland Regulations (COMAR). The board revised its regulations (COMAR 10.34.20) to reflect verification of electronic prescriptions through an electronic intermediary certified by the Maryland Health Care Commission, and to permit e-prescribing of controlled dangerous substances in accordance with applicable State and federal statutes and regulations. However, according to the U.S. Department of Health and Human Services, all states, including Maryland have laws and/or regulations that may impede e-prescribing of controlled dangerous substances.

More specifically, the Health-General Article indicates that prescriptions for controlled dangerous substances must be oral or written. If the prescription is written, it must be on a separate prescription form. In addition, the Criminal Law Article requires a manually signed written prescription for a Schedule II controlled dangerous substance unless the controlled dangerous substance is dispensed directly to the ultimate user by an authorized prescriber who is not a pharmacist. Additionally, the prescription must be dispensed in accordance with regulations, and reduced to writing and kept on file with a pharmacist. Substances listed on Schedules III through V may be written, faxed, or oral, provided that any oral prescription is reduced to writing by the pharmacist. The board advises that, because DDC issues permits for controlled dangerous substances, DDC is likely to be the entity that intakes review of and proposes updates to statutes impacting authorized prescribers.

Board Has Implemented Most Recommendations from 2001 Sunset Review

In addition to the statutory changes impacting the board and the practice of pharmacy, the board has also implemented a significant number of the recommendations made by DLS in its 2001 sunset evaluation report. **Appendix 1** describes the status of the board's implementation of recommendations made in the 2001 sunset report including board actions related to the registration of pharmacy technicians and the inspection of pharmacies.

Board Maintains Licensing Function in a Growing Industry

The board's primary function is to issue and renew licenses, registrations, and permits for pharmacists, pharmacy technicians, pharmacies, and wholesale distributors. Licenses, registrations, and permits are renewed on a biennial basis. Since fiscal 2008, the total number of licensees/registrants/permit holders has increased significantly due to the registration of pharmacy technicians beginning in fiscal 2008.

As shown in **Exhibit 2**, in fiscal 2010, 18,288 licenses, registrations, and permits were held by pharmacists, pharmacy technicians, pharmacies, and wholesale distributors. This represents an 80% increase since fiscal 2006. The vast majority of this growth resulted from the registration of pharmacy technicians, which began in fiscal 2008. The number of pharmacists has also increased by 800 (10%) since fiscal 2006.

Exhibit 2
Licenses, Registrations, and Permits Held
Fiscal 2006-2011

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>Projected FY 2011¹</u>
Pharmacist	7,812	7,901	8,112	8,393	8,612	8,320
Pharmacy Technician	-	-	1,183	6,162	7,118	12,000
Pharmacy	1,556	1,589	1,602	1,613	1,683	1,633
Wholesale Distributor	788	839	904	797	872	832
Total	10,156	10,329	11,801	16,965	18,288	22,785

¹ The projected number of registered pharmacy technicians in fiscal 2011 is based on the number of technicians still in training and anticipated to register. The projected number of wholesale distributor permits in fiscal 2011 assumes some distributors may not renew due to new National Association of Boards of Pharmacy accreditation requirements.

Note: The board did not begin registering pharmacy technicians until fiscal 2008.

Source: State Board of Pharmacy

Licensure of Pharmacists

To become a licensed pharmacist, an applicant must be a graduate of a school or college of pharmacy that is approved by the board or accredited by the American Council on Pharmaceutical Education. Currently, schools only offer a Doctor of Pharmacy (Pharm.D.) degree, replacing the Bachelor of Pharmacy degree, which is no longer awarded. Prior to licensure, pharmacists must pass the North American Pharmacist Licensure Examination (NAPLEX), the Multistate Pharmacy Jurisprudence Examination, and an oral competency exam. In addition, an applicant for licensure must complete 1,000 hours of a school-supervised professional experience program conducted by a school of pharmacy accredited by the American Council of Pharmaceutical Education, or 1,560 hours of full-time training under the direct supervision of a licensed pharmacist. As a condition of license renewal, pharmacists must also complete 30 hours of continuing education credits that are approved by the board; however, pharmacists renewing for the first time are not required to complete continuing education credits.

The board issues new and renewal pharmacy applications in a timely manner, with the majority of applications processed in two to three days; however, if there are concerns regarding an applicant's qualifications, or an application is incomplete when received by the board, the licensing process can take six to eight weeks.

Registration of Pharmacy Technicians

Chapter 523 of 2006 established registration requirements for pharmacy technicians that mandate that technicians work under the direct supervision of a pharmacist. In addition, pharmacy technicians must submit to criminal history records checks and complete a board-approved training program prior to registering with the board. Pharmacy technicians are also required to complete 20 hours of approved continuing pharmaceutical education as a condition of registration renewal; however, for the first renewal period the board only requires 10 hours of continuing education. While registration of pharmacy technicians has allowed the board to have control over previously unregulated pharmacy personnel, the registration process has proved to be challenging and laborious for the board.

The board planned to begin registering pharmacy technicians in fiscal 2008; however, implementing the registration program was a slow process as the board had only approved three technician training programs by the end of fiscal 2008. Subsequently, many applicants had to wait until 2009 to apply for registration. Originally, it took six to eight months to approve an application. In part, this delay was due to a high volume of applicants (approximately 100 per week). Furthermore, the criminal history records checks required of applicants created additional delays since results for pharmacy technicians and wholesale distributors are transmitted to the board in identical formats, making it difficult for board staff to quickly determine whether the records were affiliated with a wholesale distributor or pharmacy technician application. This confusion also created delays in issuing wholesale distributor permits. The board advises that it currently takes approximately 8 to 10 weeks to process completed pharmacy technician applications.

While the board has effectively reduced the amount of time it takes to issue a pharmacy technician registration, the registration process remains challenging due to the volume of incomplete applications. The board estimates that approximately 33% of applications are incomplete upon receipt. The board recently instituted a new policy of returning an incomplete application to the applicant with a cover letter indicating the steps the applicant must take to complete an application. Applicants must then resubmit their complete application within one year of the initial application date to avoid paying an additional application fee. **The pharmacy technician registration process should be evaluated to further reduce the lengthy application period.**

Pharmacy Permits

A pharmacy is an establishment where prescription or nonprescription drugs or devices are compounded, dispensed, or distributed. A pharmacy permit is required of an individual in order to establish or operate a pharmacy in the State. To apply for a pharmacy permit, the owner of the pharmacy establishment must submit an application to the board, and all applicants located in Maryland must arrange for an opening inspection of the pharmacy premises. During the inspection, a pharmacy must meet the board's requirements for staffing, equipment,

recordkeeping, and prescription dispensing procedures to qualify for a pharmacy permit. Once a pharmacy has obtained a permit, the board monitors compliance with these requirements during annual inspections. In addition to a permit from the board, pharmacies that dispense controlled dangerous substances must register with DDC and adhere to additional inspections performed by DDC.

A pharmacy located out of state that ships, mails, or delivers drugs or devices to Maryland residents must file for a nonresident pharmacy permit. In addition to submitting an application to the board, a nonresident pharmacy must submit a copy of the most recent inspection report conducted by the state's regulatory or licensing agency in which the pharmacy is located.

In the 2001 sunset evaluation report, DLS recommended that the board examine the issue of establishing different types of pharmacy permits to improve the overall quality of care. While the board has not established different pharmacy permits, the board has revised its regulations for waiver of full service requirements for recognized pharmaceutical specialties, sterile pharmaceutical compounding, and prescription drug repository programs. In addition, the board advises that it is in the process of promulgating revisions to regulations for inpatient institutional pharmacies, pharmaceutical services to patients in comprehensive care facilities, and home infusion pharmacies. Furthermore, regulations for nuclear pharmacies and non-sterile pharmaceutical compounding are expected to be developed in the future. The board has also created new inspection forms for conducting hospital, sterile compounding, and long-term care pharmacy inspections.

Wholesale Distributor Permits

A wholesale distributor permit is issued by the board to distribute prescription drugs or prescription devices into, out of, or within the State. As a part of the application process, a representative from the applicant's place of business and the representative's immediate supervisor must submit fingerprints so the board can complete a criminal history records check of the applicant. Within 30 days after the board receives a completed application, including the results of all required criminal history records checks, the board must notify the applicant of the board's acceptance or rejection of the application.

In addition to a criminal history records check and payment of application fees, to obtain a permit a wholesale distributor must obtain a surety bond 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) payable to the board. If the applicant's annual gross receipts for the previous tax year are less than \$10 million, the surety bond amount is reduced to \$50,000. The purpose of the surety bond is to secure payment of any fines or penalties imposed by the board and any fees and costs incurred by the State relating to the permit.

When the board first began receiving surety bonds with wholesale distributor applications, board staff was unaware that surety bonds had to be payable to the board. Recently, it has come to the board's attention that some surety bonds that the board currently has

on file are not payable to the board. This could make it difficult for the board to recoup fines if a wholesale distributor violates State law. The board's staff attorney has since advised board staff that a surety bond must be payable to the board before a wholesale distributor application can be processed. Furthermore, if board staff is unsure about a bond's authenticity, staff is instructed to contact the board's staff attorney to review the bond. **The wholesale distributor permit process could be improved. More specifically, further investigation is needed to determine if procedures are in place to ensure that surety bonds issued during the fiscal 2011 renewal period are made payable to the board.**

Drug Therapy Management Program

In addition to issuing licenses, registrations, and permits, the board oversees the Drug Therapy Management Program through participation in a joint committee with the Board of Physicians. Drug therapy management contracts allow pharmacists to help manage a patient's medications in collaboration with a physician. Pharmacists may order laboratory tests and other patient care measures related to monitoring or improving the outcomes of drug or device therapy. This eliminates the need for patients to schedule a doctor's appointment solely for medication management.

Chapter 249 of 2002 required DHMH to assess outcomes achieved by drug therapy management contracts. Therefore, the department contracted with the University of Maryland from 2007 to 2009 to evaluate the program. During the evaluation process, the University of Maryland found that applying for a physician-pharmacist agreement is typically a six-month process and involves a great deal of paperwork and strict oversight by both boards. Therefore, some physicians and pharmacists have not wanted to expend the time and expertise to prepare protocols and application materials because therapy management agreements were originally scheduled to terminate in fiscal 2010. According to the board, there are currently six physician-pharmacist agreements. Four agreements are specific to metabolic syndrome and two are specific to antithrombosis (management of patients on anticoagulants or blood thinners). As noted in the University of Maryland's evaluation, the program affected 195 patients as of December 2009. A more recent estimate is not available as the board only tracks the number of approved physician-pharmacist agreements.

Now that the program has been made permanent, the board theorizes that more physicians and pharmacists will submit applications for therapy management agreements; however, further investigation is needed to determine if the laborious application process is the only factor deterring practitioners from applying for physician-pharmacist agreements. Options for reducing the lengthy application time for the drug therapy management program should be explored.

Prescription Drug Repository Program

The board also oversees the Prescription Drug Repository Program. This program accepts donated prescription drugs at drop-off sites designated by the board for the purpose of dispensing the drugs to eligible individuals. The program only accepts and dispenses drugs in their original unopened, sealed, and tamper-evident unit dose packaging, and with an expiration date at least 90 days from the date the drug is donated. Any person, including an individual, drug manufacturer, or health care facility may donate prescription drugs. As of June 2010, the board had approved 12 prescription drug repository drop-off sites.

Board Complaint Resolution Process

The board is charged with receiving, investigating, and responding to questions and complaints; monitoring licenses and permit holders who are under board disciplinary orders; and reporting disciplinary action to national databases. The board's Compliance Unit receives complaints from a variety of sources. An individual may obtain a complaint form from the board's website and complaints may be filed by fax, phone, mail, in person, or via email. All information related to the complaint is compiled and presented to the board's disciplinary committee for review and action. The disciplinary committee then makes recommendations regarding board actions to the full board. In some instances, a complaint is outside the board's jurisdiction, in which case, the complaint is referred to the appropriate authority. The board has improved its complaint tracking system through participation in State Stat.

On average, the board receives approximately 125 complaints per year, most of which are related to dispensing errors or customer service. As shown in **Exhibit 3**, the number of complaints submitted to the board has increased in recent years. In part, this reflects the expansion of the board's jurisdiction to include pharmacy technicians and more stringent regulation of wholesale distributors; however, it remains unclear as to why the board is taking more informal actions.

Complaints received by the board increased to 129 in fiscal 2007 due to 17 nonjurisdictional complaints that were ultimately referred to other agencies. Without these complaints, the board would have processed only 112 complaints that year. Complaints peaked at 155 in fiscal 2009. According to the board, this increase included 9 new complaints about pharmacy technicians (who became registered for the first time the prior year) and 16 complaints about wholesale distributors (for which more stringent regulations were implemented the prior year). Without these complaints the board would have processed only 130 complains. DLS notes that during fiscal 2008 and 2009, an estimated 90% of complaints were resolved by the board within 90 days. The board aims to resolve 100% of complaints in 90 days by fiscal 2011.

Exhibit 3
Resolution of Complaints Received
Fiscal 2006-2010

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
New Complaints Processed	96	129	115	155	129
Complaints Resolved					
<i>Formal Charges</i>	16	12	19	18	30
<i>Informal Action</i>	43	38	96	112	82
New Complaints Carried Over to the Next Fiscal Year*	14	-	3	-	17

*Data was unavailable for fiscal 2007 and 2009; therefore, the number of complaints carried over to the next fiscal year is unknown.

Note: Complaints Resolved includes only those complaints on which the board took action and may include actions taken on complaints opened in prior years. Complaints Resolved and New Complaints Carried Over do not sum to the number of New Complaints Processed as some complaints are closed without action or referred to other entities and, as noted, Complaints Resolved may include action taken on complaints from prior years.

Source: State Board of Pharmacy, Department of Legislative Services

Complaints Are Largely Addressed Informally

Since fiscal 2006, the board has addressed approximately 15% of the total number of complaints processed with formal actions. Examples of formal actions include placing a licensee, registrant, or permit holder on probation or suspending or revoking a license, registration, or permit. Formal actions can also include fines determined by statute.

While some formal actions are taken, DLS found that the majority of complaints are subject to informal actions. Informal actions represent 73% to 86% of all board action. Most informal actions taken by the board relate to dispensing errors. The board advises that it handles these complaints in a uniform manner and that informal actions, such as letters of education or board-sanctioned continuing education requirements, educate the pharmacist with the goal of preventing future dispensing errors. However, some board members indicate that the outcome of a dispensing error should be taken into account when disciplining licensees. Specifically, dispensing errors that lead to more serious outcomes could be addressed with formal disciplinary actions. **While the board is efficient in processing complaints, further study of whether the outcome of a dispensing error should be taken into account when determining appropriate disciplinary sanctions for licensees could be beneficial. This includes assuring complaints are handled in a uniform manner.**

Rehabilitation Services Provided by the Pharmacists Education and Advocacy Council

When investigating complaints, the board sometimes encounters a licensee or registrant with a substance abuse problem. Since treatment of substance abuse is outside of the board's expertise, statute permits the board to fund a pharmacist rehabilitation committee that evaluates and provides assistance to any pharmacist or registered pharmacy technician in need of treatment and rehabilitation for alcoholism; drug abuse; chemical dependency; or other physical, emotional, or mental condition. Statute requires that the committee consist of a majority of pharmacists. However, the board advises that, under current law, the only group the board can recognize as a pharmacist rehabilitation committee is the Pharmacists Education and Advocacy Council (PEAC). The board has used the services of PEAC since its establishment in 1983.

During the 2007 legislative session, the board sought to amend statute to require the committee to consist of one pharmacist (instead of a majority of pharmacists) to allow other vendors to compete with PEAC for the board's rehabilitation services, as the board had difficulty obtaining information from PEAC in a timely manner. Furthermore, PEAC did not have licensed mental health providers on staff when legislation was introduced, and the board wanted to allow vendors with greater mental health expertise to compete for its services. Ultimately, the bill was withdrawn. In fiscal 2007, the board significantly reduced PEAC's contract, and the organization began providing services only to licensees who entered rehabilitation treatment voluntarily. In prior years, PEAC provided services to impaired practitioners who were under board disciplinary orders and practitioners who voluntarily and anonymously entered into treatment. By reducing PEAC's contract, a portion of the funds PEAC used to receive from the board is now used to monitor licensees and registrants in house who are under board orders that mandate rehabilitation services.

The reduction in PEAC's contract resulted from the board's inability to receive information from PEAC in a timely manner; however, DLS notes it is unclear as to whether the current contractual agreement between PEAC and the board is optimal. More recently, the board and PEAC have taken steps to improve their relationship by appointing two board members to serve as PEAC liaisons to handle administrative problems as they arise. Furthermore, PEAC has altered its reporting process to provide greater clarity to the board in regards to how many licensees and registrants the organization monitors in a given year. **While these recent changes are promising, further investigation is needed to assess the relationship between PEAC and the board.**

Board Assumed Annual Pharmacy Inspections from Division of Drug Control

In addition to its other duties, the board is responsible for inspecting pharmacies. The 2001 sunset evaluation recommended that the board codify its practice of annually inspecting pharmacies. At the time, the Secretary of Health and Mental Hygiene had delegated DDC to act as the board's agent in performing all initial and follow-up inspections of pharmacies,

distributors, and wholesalers. In 2002, the board acted upon DLS’ recommendation and codified the annual inspection of pharmacies; however, inspection duties remained with DDC, which at the time, inspected pharmacies biennially. DDC indicated that, when annual inspections were mandated by statute, it was not given the resources, such as additional inspectors, to comply with the new statutory requirements.

The board and DDC began meeting in January 2007 to develop plans to transition annual pharmacy inspection responsibilities from DDC to the board, and in the beginning of fiscal 2009, the board assumed annual inspection responsibilities. The board employs a pharmacist inspector to provide day-to-day supervision of pharmacy technicians who serve as the board’s inspectors. A pharmacist compliance officer supervises the inspector and the entire compliance unit, which performs all inspections. The board advises that the use of technicians is a growing trend in many states due to the limited availability of funds. Since assuming inspection responsibilities, the board has updated community and hospital pharmacy inspection forms and developed new inspection forms for long-term care and sterile compounding pharmacies.

As shown in **Exhibit 4**, the number of pharmacy inspections has nearly tripled from 425 in fiscal 2006 to almost 1,200 in fiscal 2010. The board advises the drop in annual pharmacy inspections in fiscal 2009 was a result of the newly established wholesale distributor inspection requirements mandated by Chapters 352 and 353 of 2007, which required the board to inspect wholesale distributor facilities. This made it difficult for the board to maintain the annual pharmacy inspections. The board advises the 632 pharmacy inspections it completed in fiscal 2009 do not reflect the 158 wholesale distributors inspected by the board that year. Therefore, total inspections for fiscal 2009 were 794.

Exhibit 4
Pharmacy Inspections
Fiscal 2006-2010

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Total Pharmacy Inspections	425	739	1,100	636	1,198
Conducted by the Board	0	0	0	632	1,173
Conducted by DDC	425	739	1,100	4	25

Note: The total number of inspections includes annual, opening, and closing inspections. Beginning in fiscal 2009, the board assumed the annual pharmacy inspection responsibility from DDC. The board also conducts opening inspections, while DDC currently performs closing inspections.

Source: State Board of Pharmacy, Division of Drug Control

In the 2001 sunset evaluation report, DLS recommended that DHMH commit to the development of a pharmacy inspection database to be used jointly by DDC and the board. While

the board created a database and an online inspection form, a shared database with DDC was not created. The board advises that the transfer of inspection responsibilities from DDC to the board eliminated the need for a shared database. However, DLS notes that DDC still performs closing inspections and, if the closing and opening inspections occur at the same location, DDC performs both inspections. Furthermore, DDC performs controlled dangerous substance inspections, and the board has recently begun to document a pharmacy's controlled dangerous substance inventory and forward the results to DDC during the board's annual inspections. DLS advises it is unclear if board inspectors have the appropriate training to collect information on a pharmacy's controlled dangerous substance inventory and if checking the controlled dangerous substance inventory during annual inspections is duplicating DDC's controlled dangerous substance inspections. **Since a database has never been shared between DDC and the board, further investigation is needed to determine if communication between the two entities has improved since the 2001 sunset evaluation.**

Wholesale Distributor Inspections Took Significant Resources; Inspections No Longer Required for Most Distributors

Although the board has been able to dramatically increase the number of pharmacy inspections it performs, the board encountered difficulties performing inspections in fiscal 2009 due to the newly established wholesale distributor inspection requirements mandated by Chapters 352 and 353 of 2007. Under these Acts, the board was required to adopt regulations requiring routine inspections of wholesale distributor facilities, including those that operate out of state. However, the board was authorized to grant "deemed status" to wholesale distributors accredited by an accreditation organization whose standards were equal to or more stringent than State requirements. Wholesale distributors granted "deemed status" were exempted from the inspection requirement. The board was also authorized to issue a permit by reciprocity to a wholesale distributor that held a license or permit issued by another state if the board determined that the requirements of the other state were substantially equivalent to Maryland's requirements. Distributors with reciprocal permits were also exempted from the inspection requirement. Despite these exemptions, many out-of-state wholesale distributors did not meet the standards needed to obtain a permit of reciprocity or "deemed status" and subsequently had to be inspected by the board. Therefore, board inspectors had to travel out of state or the board had to subcontract with a vendor in order to inspect all wholesale distributors in states that did not satisfy reciprocity standards.

These inspections created additional costs for the board, which were not offset by permit fees. Additionally, wholesale distributor inspections diverted resources from the board's newly acquired annual inspection responsibilities. Chapters 239 and 240 of 2010 eliminated the need for the board to perform most out-of-state wholesale distributor inspections, and now the board has been able to focus on performing annual inspections of pharmacies. DLS notes the board (or an entity acting on the board's behalf) is still responsible for inspecting all in-state wholesale distributors and out-of-state wholesale distributors that are virtual manufacturers or distributors of prescription gases, since there are no existing accreditation organizations for these entities.

Board Revenues and Expenditures Have Rapidly Increased

Over the past five years, board revenues, expenditures, and staff resources have rapidly increased. As shown in **Exhibit 5**, between fiscal 2006 and 2011, revenues have increased by 66% but expenditures have increased by 89%.

Since fiscal 2006, board revenues have averaged about \$1.91 million annually. The rapid increase in annual revenues largely reflects the registration of pharmacy technicians and the issuance of wholesale distributor permits. Expenditures for the past five years have averaged approximately \$1.88 million, ranging from approximately \$1.3 million in fiscal 2006 to \$2.4 million in fiscal 2010. This can largely be attributed to the 10 new positions created since fiscal 2006 to support new program areas such as the registration of pharmacy technicians, the issuance of wholesale distributor permits, and the inspection of pharmacies. Despite increased costs, board revenues have consistently been sufficient to cover expenses.

One reason for increased board expenditures in recent years is the delayed implementation of the board's in-house, integrated database system. The board had 27 separate databases to handle its Fiscal, Licensure, and Compliance Unit's needs. In 2006, the board contracted with Towson University's Regional Economic Studies Institute (RESI) to combine most of the 27 databases into 1 comprehensive database. Initially, the database was scheduled to be completed by fiscal 2008; however, contractor delays interfered with the completion of the system. Therefore, a new agreement was reached that required RESI to complete the database by fiscal 2009. The board advises that, as of February 2009, the database was only 80% complete; therefore, the board decided to end its contract with RESI as the institute required further funding to complete the project. The board began to consider other options to create a comprehensive database including hiring a contractor to complete the work that RESI began. In June 2010, the board voted to contract with Systems Automation to develop a new database. Overall, implementing a database has been an extremely costly venture for the board.

In recent years, some health occupations boards have been required to transfer funds to the general fund through the Budget Reconciliation and Financing Act (BRFA). In fiscal 2010, BRFA required the board to transfer \$98,544 to the general fund, and in fiscal 2011 the board is required to transfer \$200,000.

While the board anticipates that current surplus funds are sufficient to meet the costs for the development and implementation of a new database system, the board has expressed some concerns about maintaining the database in future years. First, the board is concerned whether remaining surplus funds will be sufficient to support maintenance and system upgrades. Second, any future fund transfers under BRFA may impact the board's ability to implement and maintain the new database system. **Since the board anticipates spending down its fund balance, it remains uncertain as to how it will account for future costs associated with development of a new database.**

Exhibit 5
Fiscal History of the State Board of Pharmacy
Fiscal 2006-2011

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>Projected FY 2011</u>
Authorized Positions	13	16	17	23	23	23
Beginning Fund Balance	\$877,449	\$1,090,227	\$985,688	\$962,722	\$926,214	\$997,462
Revenues Collected	1,559,918	1,612,082	1,752,509	2,241,441	2,366,726	2,592,035
Total Funds Available	2,437,367	2,702,309	2,738,197	3,204,164	3,292,941	3,589,497
Total Expenditures	\$1,347,140	\$1,716,620	\$1,775,475	\$2,277,950	\$2,196,935	\$2,539,794
Direct Costs	1,153,697	1,491,994	1,515,460	2,126,328	1,910,397	2,208,558
Indirect Costs	193,443	224,626	260,015	151,622	286,538	331,236
Ending Fund Balance	\$1,090,227	\$985,688	\$962,722	\$926,214	\$1,096,006	\$1,049,703
Transfer to General Fund					\$98,544	\$200,000
Balance as % of Expenditures	81%	58%	54%	41%	43%	41%
Target Fund Balance	\$269,428	\$343,324	\$355,095	\$455,590	\$459,096	\$507,959

Note: Numbers may not sum to total due to rounding.

Source: State Board of Pharmacy

Board Maintains Adequate Fund Balance but Anticipates Spend Down

While the board's fund balance consistently remains above the recommended 20% threshold for health occupations boards of its size, DLS notes the board's ending fund balance has gradually become a smaller percentage of the board's expenditures, decreasing from 81% in fiscal 2006 to 43% in fiscal 2010. Additionally, the board has projected that its fund balance will continue to decline, representing 17% of the board's expenditures by fiscal 2013. The board anticipates spending down its fund balance in the next two years due to a decline in revenues from wholesale distributor permits. The board estimates that the number of wholesale distributor renewal permits will fall to approximately 700 during fiscal 2011, and the number of new permits issued by the board will also decrease as a result of the new accreditation requirement for distributors who do not qualify for a permit by reciprocity.

Board Is Special Funded by Fee Revenues

All but one of the health occupations boards are entirely special funded by the fees collected for licensing, certification, registration, and other board services. In the case of the board, all fees are deposited into the State Board of Pharmacy Fund.

Beginning February 1, 2010, new fees and certain increases to existing fees became effective. The board was approved to raise fees in order to address the expansion of board responsibilities. Other new and existing fees were approved to limit the amount of the fee increases paid by each licensed group and to discourage delinquent submissions, respectively. Additional fees were also established for the registration, renewal, and reinstatement of pharmacy technicians in 2008 and have not been adjusted since. Both current and 2002 fee schedules for pharmacists, pharmacies, and distributors are shown in **Exhibit 6**.

While the majority of fees issued by the board increased in February 2010, drug therapy management and the recently established pharmacy technician fees remained unchanged, with the exception of the newly created pharmacy technician training approval program fee. The pharmacy technician and drug therapy management fees are listed in **Exhibit 7**.

Exhibit 6
Comparison of Board Fees: Pharmacists, Pharmacies, and Distributors
2002 Fees vs. Current Fees

	Fees Effective <u>in 2002</u>	Fees Effective <u>in 2010</u>
Pharmacist Fees		
Examination fee	\$100	\$150
Reciprocity fee	120	300
Renewal fee	150	225
Reinstatement fee (up to two years)*	65	300
Reinstatement fee (more than two years)*	80	300
Pharmacy Fees		
Initial fee	300	700
Renewal fee	250	600
Late fee	150	200
Reinstatement fee*	150	550
Wholesale Distributor Fees		
Initial fee	500	1,750
Renewal fee	500	1,750
Reinstatement fee*	-	1,500

* This fee is payable *in addition* to the renewal fee.

Note: The board advises that initial and renewal pharmacy permit fees more than doubled to account for the change from annual to biennial permit renewal beginning in fiscal 2010. Wholesale distributor fees also more than doubled to account for the change from annual to biennial permit renewal beginning in fiscal 2008.

Source: State Board of Pharmacy; Code of Maryland Regulations 10.34.09.02

Exhibit 7
Schedule of Fees: Pharmacy Technicians and
Drug Therapy Management Contracts

Pharmacy Technician Fees

Registration fee	\$45
Renewal fee	45
Reinstatement fee*	45
Pharmacy student administration fee for exemption	45
Training approval program **	200

Therapy Management Contract Fees

Physician-pharmacist agreement application fee (includes the review of the agreement and one protocol)	250
Student application fee	50
Protocol review fee	50
Physician-pharmacist agreement renewal fee	200
Physician-pharmacist amendment fee	25
Protocol amendment fee	25

*This fee is payable *in addition* to the renewal fee.

**The training approval program fee became effective in February 2010.

Source: State Board of Pharmacy; Code of Maryland Regulations 10.34.09 and 10.34.29.11

Unclear Whether Board Has Sufficient Personnel Resources

In addition to a full-time executive director, the board has a total of 22 full-time staff to handle the licensing function, secretarial/reception duties, and pharmacy investigations. The board also has one contractual help desk employee and one temporary staff member assisting the Licensing Unit. Although the board has been able to acquire an additional 10 regular positions since fiscal 2006, the board appears to lack an appropriate number of personnel to meet its current needs. Additionally, the board is currently trying to fill four vacancies. DLS notes that the board faces more complex licensing and regulatory issues than many comparably sized boards, making it more difficult to meet the board's staffing needs.

In addition to operating with less than a full staff, the board has had difficulties attracting and retaining the appropriate pharmacist staff to lead the Compliance Unit. While not required by statute, the board has consistently employed a pharmacist to lead the Compliance Unit due to the technical expertise needed to investigate complaints. DLS notes that other health occupations boards use licensed staff to fill similar positions. Over the past five years, the board

has hired four different pharmacists to staff the unit. The board attributes this high turnover rate to the uncompetitive salary that the board offers its pharmacist personnel. Without higher salaries for pharmacists, the board advises it will continue to have difficulty recruiting and retaining qualified staff. During the 2007 legislative session, the board sought to resolve this issue by amending statute to allow the board, in consultation with the Secretary of Health and Mental Hygiene, to determine the appropriate job classification and salary grades for all board employees. Ultimately, the legislation failed and the board has been unable to resolve this issue. **Further investigation is needed to determine if the number of board personnel should be expanded and assess the appropriateness of position classifications and their impact on the board's high turnover rate for pharmacist staff.**

Recommendations

The board has aggressively kept pace with the many changes in the pharmacy industry and is dedicated to protecting Maryland consumers and promoting quality care in the pharmacy field. Throughout the evaluation process, the board and its staff were cooperative, professional, and responsive. However, the assumption of new program areas such as the registration of pharmacy technicians, issuing permits to wholesale distributors, and annually inspecting pharmacies has created numerous inefficiencies within the board. Board members and staff identified many of the issues associated with these new program areas throughout the preliminary evaluation process. **Therefore, the Department of Legislative Services recommends a full evaluation of the State Board of Pharmacy to address the following issues:**

- **Pharmacy Technicians:** Due to the lengthy application time and the various processing issues the board has encountered with issuing pharmacy technician registrations, a full evaluation should review the registration process and provide recommendations on how to improve and reduce the current application period.
- **Wholesale Distributors:** A full evaluation should review the wholesale distributor permitting process and provide recommendations for improvement. Such an evaluation should determine if procedures are in place to ensure that surety bonds issued during the fiscal 2011 renewal period are made payable to the board. This includes reviewing the surety bonds the board has on file to confirm bonds are made payable to the board and not a different entity. This will ensure the board's ability to recoup fines levied on wholesale distributors in violation of State law and regulations.
- **Personnel:** Due to the multiple new programs the board has undertaken, it should be determined if the board needs additional staff to meet administrative needs. Additionally, options for reducing the high turnover rate for the pharmacist position at the board should be assessed, including the possibility of reclassifying the position.

- **In-house Database:** A full evaluation should determine how the board is accounting for the unanticipated cost of implementing the new database system using Systems Automation.
- **Rehabilitation Services:** The board currently monitors licensees and registrants in house who are under board orders that mandate rehabilitation services; however, PEAC receives board funding to provide similar services to licensees and registrants who enter rehabilitation treatment voluntarily. DLS advises that it is unclear whether this duplication of efforts is optimal. Therefore, a full evaluation is needed to assess the relationship between PEAC and the board.
- **Protocols for Disciplinary Action:** Although the board is diligent in reviewing complaints, most complaints are resolved informally. A full evaluation should determine if informal disciplinary sanctions have been effective at addressing dispensing errors and if the outcome of a dispensing error needs to be taken into consideration when determining appropriate disciplinary actions.
- **Pharmacy Inspections:** Since a database has never been shared between DDC and the board, further investigation is needed to determine if communication between the two entities has improved since the 2001 sunset evaluation. A full evaluation should determine if board inspectors have the appropriate training to collect information on the controlled dangerous substance inventory and if checking for controlled dangerous substances during annual inspections is duplicating DDC's inspections. Therefore, a full evaluation must compare inspection practices of DDC and the board.
- **Drug Therapy Management:** The board, in conjunction with the State Board of Physicians, has approved few drug therapy management agreements due to the low volume of applicants. Since the program has been made permanent, the board theorizes that more physicians and pharmacists will submit applications for therapy management agreements; however, a full evaluation could determine if the laborious application process is the only factor deterring practitioners from applying for physician-pharmacist agreements. Options for reducing the lengthy application time for the drug therapy management program could be assessed.

Appendix 1. Status of the Implementation of 2001 Sunset Evaluation Recommendations

<u>Recommendation</u>	<u>Status of Implementation</u>
1. The Board of Pharmacy should be continued, and the General Assembly should extend its termination date to July 1, 2013. In addition, uncodified language should be adopted requiring the board to report to the Senate Education, Health, and Environmental Affairs and House Environmental Matters Committees on or before October 1, 2002, on the implementation of the recommendations contained in this sunset evaluation report.	Chapter 157 of 2002 extended the sunset date. Follow-up report submitted.
2. The board should continue to examine the issue of establishing different types of pharmacy permits to improve the overall quality of care.	The board has revised its regulations for waiver of full service requirements for recognized pharmaceutical specialties, sterile pharmaceutical compounding, and prescription drug repository programs and is promulgating regulations for inpatient institutional pharmacies, pharmaceutical services to patients in comprehensive care facilities, and home infusion pharmacies. Regulations for nuclear pharmacies and nonsterile pharmaceutical compounding are expected to be developed in the future.
3. The General Assembly should repeal the requirement for State manufacturing permits.	Chapter 157 of 2002 repealed the State manufacturer's permit.
4. The board's task force should report to the General Assembly on its progress in assessing the extent of any pharmacist shortage in Maryland and its progress in developing potential solutions.	An interim report was submitted by the Shortage of Pharmacists Task Force; however, a final report was never submitted because appointed members of the task force could not come to a consensus regarding recommendations.

Recommendation

Status of Implementation

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| 5. The General Assembly should amend statute to codify the current practice of annual inspections of pharmacies. | Chapter 157 of 2002 codified the board's practice of annually inspecting pharmacies.

In fiscal 2009, the board assumed the pharmacy inspection function and employed one pharmacist inspector and four pharmacy technician inspectors for that purpose. |
| 6. The board and DDC should revise the inspection form and process so that inspectors assess: (1) the adequacy of quality assurance systems to ensure that all prescriptions are correct; and (2) the adequacy of training and supervision of unlicensed personnel working in pharmacies. | In October 2003, the board promulgated Patient Safety Improvement regulations (COMAR 10.34.26.01) requiring pharmacies to provide certain patient and staff education, as well as establish ongoing quality assurance programs. |
| 7. The Department of Health and Mental Hygiene should commit to the development of a pharmacy inspection database to be used jointly by DDC and the board. | The board created a database and an online inspection form, but the database is not used jointly by DDC and the board. |
| 8. The board should monitor its time commitment for full board disciplinary hearings. If full board disciplinary hearings become more frequent, the board should consider using the services of the Office of Administrative Hearings (OAH). Because OAH charges could be considerable, the board should also consider seeking the statutory changes needed to conduct disciplinary hearings with a subset of board members. | The board revised its scheduling of hearings so that board members' time commitments are not excessive.

The board continues to conduct its own hearings as referrals to OAH are cost prohibitive.

Senate Bill 300/House Bill 1321 of 2004 (failed) would have allowed a panel of three or more board members to hear disciplinary cases. |

Recommendation

Status of Implementation

- | | |
|--|--|
| 9. The board should assert its contractual authority with the Pharmacists Education and Advocacy Council (PEAC) to ensure that it receives adequate information to monitor pharmacists referred to PEAC. The board should evaluate whether changes are needed in the contract with PEAC or whether the board should seek other vendors. | House Bill 144 of 2007 (failed) would have changed the composition of the rehabilitation committee to consist of one pharmacist (instead of a majority of pharmacists) to allow other vendors to compete with PEAC. |
| 10. The board should reallocate existing resources instead of adding positions unless there is sufficient justification for new positions. | In fiscal 2007, the board reduced PEAC's contract and the organization began providing services only to licensees who entered rehabilitation treatment voluntarily. A portion of the funds PEAC used to receive is now used to monitor licensees and registrants in house who are under board orders that mandate rehabilitation services. |
| 11. The board needs to develop a new proposal to raise fees. This proposal should raise fees enough to create a sufficient financial cushion, but it should not produce an excessive fund balance. The proposal should examine the five-year impact of the fee increase on the fund balance. | With the assumption of several new program areas, the board has been required to increase staff as needed; however, this has not been conducive to effectively performing required tasks including staff processing and staffing committee-related reviews. |
| 12. Statute should be amended to limit discovery to facilitate pharmacists in voluntarily tracking medication errors. The board should take timely action in implementing more stringent quality assurance measures to reduce medication errors. In addition, the board should continue to work closely with the Board of Nursing and Board of Physicians Quality Assurance (now the Board of Physicians) in an effort to reduce medical errors in all phases of the dispensing process. | The board raised fees in fiscal 2002 and created new fees for pharmacy technicians in fiscal 2008. The board also raised numerous fees effective February 1, 2010.

Chapter 157 of 2002 limited discovery of certain evidence to facilitate voluntary tracking medication errors by pharmacists.

The board promulgated Patient Safety Improvement regulations (COMAR 10.34.26.01) that became effective October 27, 2003. |

Recommendation

13. The board should continue to examine the various issues associated with requiring certification for unlicensed personnel. Due to the increasing complexity of the pharmacy industry, increased sales volume of prescription drugs, the current pharmacist shortage, and the need to reduce medication errors in the industry, the board should implement a regulatory system that provides quality assurance for unlicensed personnel. The regulatory system should ensure that pharmacy technicians meet minimum levels of knowledge in pharmacy security, practice, and quality control, as determined by the board.

Status of Implementation

Chapter 523 of 2006 established registration requirements for pharmacy technicians. The board began registering pharmacy technicians in fiscal 2008.

Appendix 2. Written Comments of the State Board of Pharmacy



STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue -- Baltimore, Maryland 21215

Michael N. Souranis, Board President -- LaVerne G. Naesea, Executive Director

December 6, 2010

Ms. Jennifer Chase, Senior Policy Analyst
Department of Legislative Services
Office of Policy Analysis
MD General Assembly, Legislative Svcs. Bldg.
90 State Circle
Annapolis, MD 21401-1991

Re: Board of Pharmacy Written Comments to Draft Sunset Review Evaluation

Dear Ms. Chase:

Thank you for the opportunity to comment on the draft Sunset Review preliminary evaluation report. The Board has read the review and attached comments herewith. The following comments are offered to clarify information contained in the report related to Board responsibilities and activities over the past ten years. The Board was impressed with Ms. Erin McMullen's ability to review and understand its processes in a very short period of time. I would appreciate your conveying the Board's compliments and appreciation to Ms. McMullen, whose review reflects quite a comprehensive and generally accurate depiction of the Board and its activities.

I would like to thank you for the extension of the Board response period from December 3, 2010 to December 6, 2010. In addition to the recent holiday, mandated pay reduction day and on-going (very time consuming) wholesale distributor renewal period, the Board has been engaged in preparing for the upcoming legislative session. Without the granted extension, it would have been difficult to respond appropriately to the very comprehensive draft report. Thank you for your understanding!

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Ms. Jennifer B. Chase
December 6, 2010
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Again, thank you for allowing the Board of Pharmacy to comment on the draft review. If there are questions regarding the Board comments, please feel free to contact me at (410) 764-4794.

Respectfully,

LaVerne G. Naesea
Executive Director

LGN

cc: Secretary John M. Colmers
Wendy Kronmiller
Mr. Karl S. Aro
President Michael N. Souranis