Sunset Review: Evaluation of the State Board of Pharmacy



Department of Legislative Services October 2011

Sunset Review: Evaluation of the State Board of Pharmacy

Department of Legislative Services
Office of Policy Analysis
Annapolis, Maryland

October 2011

Primary Staff for This Report

Jennifer Ellick

Other Staff Who Contributed to This Report

Jennifer B. Chasse
Laura McCarty
Erin K. McMullen
Nancy Scaggs

For further information concerning this document contact:

Library and Information Services
Office of Policy Analysis
Department of Legislative Services
90 State Circle
Annapolis, Maryland 21401

Baltimore Area: 410-946-5400 / Washington Area: 301-970-5400
Other Areas: 1-800-492-7122, Extension 5400
TDD: 410-946-5401 / 301-970-5401
Maryland Relay Service: 1-800-735-2258
E-mail: libr@mlis.state.md.us
Home Page: http://mlis.state.md.us

DEPARTMENT OF LEGISLATIVE SERVICES
OFFICE OF POLICY ANALYSIS
MARYLAND GENERAL ASSEMBLY

Karl S. Aro
Executive Director

Warren G. Deschenaux
Director

October 31, 2011

The Honorable Thomas V. Mike Miller, Jr.
The Honorable Michael E. Busch
Honorable Members of the General Assembly

Ladies and Gentlemen:

The Department of Legislative Services (DLS) has completed its evaluation of the State Board of Pharmacy as required by the Maryland Program Evaluation Act. This evaluation process is more commonly known as "sunset review" because the agencies subject to evaluation are usually subject to termination; typically, legislative action must be taken to reauthorize them. This report was prepared to assist the committees designated to review the board – the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee – in making their recommendations to the full General Assembly. The board is scheduled to terminate on July 1, 2013.

DLS finds that there is a continued need for regulation of the pharmacy industry and that the board generally complies with its statutory mandate. In recent years, the board has dealt admirably with significantly expanded duties associated with the regulation of an industry that continues to grow at a rapid rate. Nonetheless, the board has struggled with some issues that should be addressed, such as staff retention and the management of an influx of pharmacy technician registrations.

DLS identified specific issues that are affecting the board's licensing, registration, and compliance functions and makes a series of recommendations intended to enhance the board's efficiency and accountability to the public, including that the board expand its use of Managing for Results goals; establish a formal process for information-sharing with the Department of Health and Mental Hygiene's Division of Drug Control; seek reclassification of certain positions from the Department of Budget and Management to enhance staff retention and address concerns regarding the inspection of pharmacies; and report to specified committees of the General Assembly on the board's implementation of sanctioning guidelines and the status of the board's contractual relationship with the Pharmacists' Education and Advocacy Council.

Legislative Services Building · 90 State Circle · Annapolis, Maryland 21401-1991
410-946-5510 · FAX 410-946-5529 · TDD 410-946-5401
301-970-5510 · FAX 301-970-5529 · TDD 301-970-5401
Other areas in Maryland 1-800-492-7122

Additionally, DLS found that the Drug Therapy Management Program, which is regulated jointly by the board and the State Board of Physicians, has been underutilized due in part to an onerous administrative process. Thus, DLS recommends amending statute to remove potential barriers to participation and align the program with the policies of other Maryland health occupations boards and drug therapy management programs in other states.

In total, DLS offers 15 recommendations, including that the board's termination date be extended by 10 years to July 1, 2023. Draft legislation to implement the recommended statutory changes is included as an appendix to this report.

We would like to acknowledge the cooperation and assistance provided by the board and the Department of Health and Mental Hygiene throughout the review process. The department and the board were provided a draft copy of the report for factual review and comment prior to its publication; the board's written comments are included as an appendix to this report.

Sincerely,

Warren G. Deschenaux
Director

WGD/JBC/mlm

Contents

Executive Summary

Pursuant to the Maryland Program Evaluation Act, the Department of Legislative Services (DLS) has evaluated the State Board of Pharmacy, which is scheduled to terminate July 1, 2013. DLS finds that there is a continued need for regulation of the pharmacy industry by the State but has identified certain areas in which the board could strengthen its authority and improve its service to pharmacy professionals and the public.

Numerous statutory changes have impacted the board since it last underwent a full sunset evaluation in 2001, and DLS recognizes that the board has generally been successful in keeping pace with these changes, as well as taking proactive steps to address emerging issues in the fast-growing pharmacy industry. However, some areas in need of improvement remain. The findings and 15 recommendations of this evaluation are summarized below.

The board jointly administers the Drug Therapy Management Program with the State Board of Physicians. The program 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. DLS finds the administrative process associated with the program to be onerous and participation in the program to be low. Furthermore, DLS finds the program's joint approval process to be inconsistent with the policies of other health occupations boards and with the approval processes of drug therapy management programs in other states. DLS makes the following recommendation based on these findings:

Recommendation 1: 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.

The board faces legislative and regulatory issues of ever-increasing complexity. Many of these issues are unfamiliar to new members, yet training for such members is limited. The learning curve is particularly steep with regard to the legislative and regulatory processes. Accordingly, DLS makes the following recommendation:

Recommendation 2: The Department of Health and Mental Hygiene (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.

The board's licensing functioning expanded significantly when the board began registering pharmacy technicians in fiscal 2008. The registration process proved challenging for the board, although – as a result of administrative changes implemented by the board – the length of the registration process has been decreasing. The board's new information technology (IT) system will automate the process and should further reduce the length of the application period. DLS offers the following recommendations to further improve the board's licensing function:

Recommendation 3: The board should expand its 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.

Recommendation 4: 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).

Although the board assumed annual inspection responsibilities from DHMH's Division of Drug Control (DDC) in fiscal 2009, DDC continues to conduct some pharmacy inspections. DLS finds that DDC and the board are not duplicating each other's efforts in conducting their respective inspections, as DDC's inspections vary in purpose and scope from the board's annual inspections. However, DLS finds that communications between the two entities are generally informal and could be improved. Thus, DLS makes the following recommendation:

Recommendation 5: 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.

In addition to inspecting pharmacies, the board is charged with receiving, investigating, and responding to questions and complaints; monitoring licensees and permit holders who are under board disciplinary orders; and reporting disciplinary action to national databases. DLS finds that the majority of complaints received by the board are resolved informally. The board is currently working toward implementation of recent legislation requiring the adoption of sanctioning guidelines, which should promote uniformity in the complaint resolution process; however, the board's Task Force to Study Sanctioning Guidelines has not yet terminated, and no guidelines have yet been adopted. It is therefore likely that the board will not have had significant experience in the use of the guidelines by the December 2011 reporting date specified in statute. Accordingly, DLS recommends the following:

Recommendation 6: 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).

The board has, in recent years, had significant difficulties attracting and retaining the appropriate pharmacist staff to lead its Compliance Unit. In addition, while the board advises that the use of pharmacy technicians as inspectors is a growing trend in many states due to the limited availability of funds, DLS notes concerns as to whether pharmacy technicians can, with any level of on-the-job training, reach the level of expertise held by pharmacists and/or necessary to mastering the finer points of the inspection process. DLS therefore makes the following recommendations:

Recommendation 7: 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 position 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.

Recommendation 8: 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.

While investigating complaints, the board sometimes encounters a licensee or registrant with a substance abuse problem. The board is authorized by statute to contract with a pharmacist rehabilitation committee that evaluates and provides assistance to such individuals. However, statute requires the committee with which the board contracts to consist of a majority of pharmacists, and only one pharmacist rehabilitation committee in Maryland meets this requirement: the Pharmacists' Education and Advocacy Council (PEAC), with which the board has contracted since PEAC's establishment in 1983. In fiscal 2007, the board significantly reduced PEAC's contract due to the board's inability to receive information from PEAC in a timely manner. However, the board and PEAC have more recently taken certain steps to improve their relationship. DLS finds these changes – though recent – to be promising, and thus makes the following recommendation:

Recommendation 9: 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.

The board's assumption of several new program areas in recent years has created certain inefficiencies within the board with regard to customer service, staff training, and recordkeeping. While the board advises that it expects its new IT system to streamline board operations significantly, DLS offers the following recommendations to further improve board operations:

Recommendation 10: 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.

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

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

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

The board's fund balance consistently remains above the recommended 20% threshold for health occupations boards of its size. However, the board anticipates spending down its fund balance in the next two years due to a decline in revenues from wholesale distributor permits. In addition, while the board anticipates that current surplus funds are sufficient to meet the costs for the development and implementation of a new IT system, DLS notes some concerns about the maintenance of the system in future years. Furthermore, the Budget Reconciliation and Financing Act (BRFA) has in recent years required the board to transfer increasingly large amounts of its funds to the general fund; future fund transfers under BRFA may impact the board's ability to implement its new database and maintain an adequate fund balance. Based on these findings, DLS makes the following recommendation:

Recommendation 14: 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 BRFA 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.

The board has struggled in recent years to retain staff, which has undoubtedly affected staff morale and board operations. However, DLS notes that, overall, the board has done an excellent job of keeping up with the many recent changes to State regulation of the pharmacy industry – making prospects for improving board operations generally good. In addition, the anticipated implementation of the board's long-awaited new IT system should streamline board operations significantly. However, these and other changes recommended by DLS will take time to implement and yield results.

Recommendation 15: Legislation should be enacted to extend the termination date for the board by 10 years to July 1, 2023. Additionally, uncodified language should be adopted to require the board to report, by October 1, 2013, to specified committees on the implementation status of the nonstatutory recommendations made in this report.

Chapter 1. Introduction and Overview of the Board

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. In most cases, 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 a sunset review in 2001. Ensuing legislation (Chapter 157 of 2002) extended the board's termination date by 10 years to July 1, 2013, and required the board to report to certain committees of the General Assembly on the implementation of recommendations contained in the sunset report.

In 2010, DLS conducted a preliminary sunset evaluation to assist LPC in deciding whether to waive the board from a full evaluation in advance of the board's July 1, 2013 termination date. In its preliminary sunset evaluation, DLS determined that the board is necessary and beneficial to the protection of Maryland citizens but identified certain operational issues warranting further examination. As a result, DLS recommended that a full sunset evaluation be conducted before the board's authority is extended.

The Practice of Pharmacy in Maryland

Pharmacists dispense prescription drugs and advise patients, physicians, and other health care practitioners on dosage selection as well as on the potential interactions and side effects of medications. Because most medications are now produced by pharmaceutical companies in standard dosages, compounding (*i.e.*, mixing ingredients to create medications) comprises only a small part of a pharmacist's current practice. Most pharmacists work in either a community setting (such as a retail drugstore) or in a health care facility (such as a hospital).

Pharmacists are accountable for the accuracy of every prescription they fill and often rely on pharmacy technicians (to whom they may delegate prescription filling and administrative tasks, and whose work they supervise) to assist them in dispensing medications. Pharmacists also frequently oversee pharmacy students serving as interns.

The State Board of Pharmacy regulates the practice of pharmacy in Maryland. The board's mission is to protect Maryland consumers and to promote quality health care in the field 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.

Pharmacy Industry Expected to Continue to Grow Quickly

Approximately 269,900 pharmacists were employed nationwide in 2008. According to the *Occupational Handbook* published by the Bureau of Labor Statistics within the U.S. Department of Labor, the pharmacy industry is projected to grow 17% (faster than the average for all occupations) by 2018. Furthermore, employment for pharmacy technicians is anticipated to grow 31% within the same timeframe. In fact, according to the Governor's Workforce Investment Board's 2010 *Maryland's Workforce Indicators*, pharmacy technicians comprise 1 of 15 occupations projected to grow the fastest between 2008 and 2018 (with a projected 2.9% annual growth rate and 317 annual openings). The industry's rapid growth – due, in part, to an aging U.S. population and the expanding use of pharmaceutical products – is thus expected to continue in coming years.

History and Current Structure of the State Board of Pharmacy

The board was created by the General Assembly in 1902 and, along with 17 other health occupations boards, operates under the Office of the Secretary in the Department of Health and Mental Hygiene (DHMH), which provides administrative and policy support. However, almost all day-to-day activities are managed by the board and its staff, which consists of a total of 23 permanent positions, including an executive director, a compliance officer, a legislative and regulations manager, a licensing manager, several inspectors, and other support personnel.

The board comprises 12 members, 10 of whom are licensed practicing pharmacists and 2 of whom are consumers. Pharmacist members must have at least five years of professional 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 compiled by various pharmacy associations. Consumer members must 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 operates with a president, secretary, and treasurer, and it currently has no vacancies.

The full board meets on the third Wednesday of each month and accomplishes most of its work through nine committees: Disciplinary, Executive, Licensing, and Practice (all of which meet monthly); and Budget, Editorial, Legislative, Personnel, and Public Relations (all of which meet on an as needed basis). Committee composition is largely prescribed in board bylaws, with appointments made by the president. Additionally, *ad hoc* committees are formed as issues arise.

Report Objective

Rather than focusing on whether there is a continued need for State regulation of or involvement in the practice of pharmacy, this full evaluation report focuses on whether the board complies with statutory policy objectives by exploring issues raised in the 2010 preliminary evaluation and other emerging issues. Specific issues addressed in the report include:

- legislative and regulatory issues faced by the board – including drug therapy management, the administration of vaccinations by pharmacists, prescription drug monitoring and disposal programs, electronic prescribing, and dispensing by nonpharmacists – and how these issues have been addressed by the board;

- the licensing, permitting, and registration processes used by the board and how these could be improved;

- the efficiency, uniformity, and fairness of the board's processes for resolving complaints and taking disciplinary action;

- the rehabilitation services provided by the board and through the Pharmacists' Education and Advocacy Council of Maryland (PEAC) and how communication between PEAC and the board could be improved;

- the relationship and communication between the board and the Division of Drug Control (DDC) in DHMH with regard to pharmacy inspections and how this relationship could be improved;

- the accounting by the board for the cost of implementing a new database system; and

- the sufficiency of board personnel given the board's recently expanded duties and the increasingly complex licensing and regulatory issues faced by the board.

Research Activities

DLS utilized several standard research activities to complete this full evaluation of the board.

- **Literature and Document Reviews –** DLS reviewed several sources of literature on the regulation and practice of pharmacy, including but not limited to the National Conference of State Legislatures (NCSL), the Council of State Governments, and the National Association of Boards of Pharmacy for information on regulation in other states; literature from pertinent State and national professional associations, such as the Maryland Pharmacists Association and the American Pharmacists Association; the Annotated Code of Maryland; the Code of Maryland Regulations (COMAR); complaint and licensing files; board meeting minutes; and internal board documents such as administrative policies, annual reports, and financial records.

- **Structured Interviews –** Numerous structured interviews were conducted to supplement the literature and data review. All board officers, selected board members and staff, and representatives from DDC, the Maryland Pharmacists Association, the National Association of Chain Drug Stores, Epic Pharmacies, the University of Maryland School of Pharmacy, and PEAC were interviewed for this report. These interviews focused on board management and operations; staff responsibilities and workload; board resources and software; customer service; and the board's relationship with other health occupations boards, DHMH staff, and various professional associations. Responses are neither quoted in nor included as an appendix to this report but were used to identify potential issues concerning board management, operations, and statutory authority.

- **Site Visits/Observation –** DLS attended meetings of the full board, as well as committee meetings and disciplinary hearings, to gain a better understanding of the issues confronting the board and the disciplinary process. In addition, DLS observed and evaluated pharmacy inspections conducted by both the board and DDC.

- **Survey of Other State Boards of Pharmacy** – DLS conducted an online survey of other state boards of pharmacy to gather additional information on collaborative drug therapy management practices in other states.

Report Organization

This report consists of five chapters. **Chapter 1** includes a review of the organization and history of the board. **Chapter 2** explains statutory and regulatory issues facing the board, including recent legislative and regulatory changes. **Chapter 3** outlines issues related to the licensing, compliance, and inspection processes, as well as general board operations. **Chapter 4** addresses financial issues, including the board's annual budget and fund balance. **Chapter 5** summarizes and concludes the report.

Five appendices are included as supplements to the report. **Appendix 1** displays the status of the board's implementation of the recommendations made by DLS in its 2001 sunset evaluation report. Current and 2002 fee schedules for pharmacists, pharmacies, and distributors are shown in **Appendix 2**, while the pharmacy technician and drug therapy management fees are listed in **Appendix 3**. **Appendix 4** contains draft legislation to implement the statutory recommendations contained in this report. Finally, the State Board of Pharmacy reviewed a draft of this report and provided the written comments included as **Appendix 5**. Appropriate factual corrections and clarifications have been made throughout the document; therefore, references in board comments may not reflect this published version of the report.

Chapter 2. Statutory and Regulatory Issues

Numerous statutory changes (detailed in **Exhibit 2.1**) have impacted the State Board of Pharmacy since it last underwent a full sunset evaluation in 2001. New programs mandated by statute have included the approval of drug therapy management agreements, the registration of pharmacy technicians, the licensure of wholesale distributors under a more comprehensive statute, the registration of pharmacists trained to administer immunizations, and the implementation of prescription drug repository and monitoring programs. The board has adopted regulatory changes to address these and other emerging issues, including the electronic transmission of prescriptions. Overall, the board has kept pace very well with the many changes that have impacted the practice of pharmacy over the last decade, and the current board members' engagement with legislative and regulatory issues facing the board is obvious. The board's legislative committee meets frequently during the legislative session, and the board's practice committee meets monthly throughout the year to make recommendations for statutory and regulatory changes.

Pharmacy Technicians Required to Register with the Board

In its 2001 sunset evaluation report, the Department of Legislative Services (DLS) recommended that the board examine and implement a regulatory system to provide quality assurance for unlicensed pharmacy personnel. Chapter 523 of 2006 addressed this recommendation by (1) requiring pharmacy technicians to register with the board; and (2) authorizing licensed pharmacists to delegate certain pharmacy acts to pharmacy technicians under specified circumstances. Additional discussion of the board's regulation of pharmacy technicians can be found in **Chapter 3** of this report.

Regulation of Wholesale Distributors Enhanced

Although the board has regulated wholesale distributors of prescription drugs since 1987, its regulation of distributors has tightened in recent years in an effort to enhance patient safety and secure the State's prescription drug supply chain. Specifically, the Wholesale Distributor Permitting and Prescription Drug Integrity Act (Chapters 352 and 353 of 2007) imposed upon wholesale distributors additional permitting requirements, including a pedigree (or history of the distribution chain) for prescription drugs. More recently, Chapters 239 and 240 of 2010 clarified 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 the Department of Health and Mental Hygiene (DHMH). 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, and out-of-state wholesale distributors that receive a permit by reciprocity are subject to criminal history records

checks and surety bond requirements. Additional discussion of the regulation of wholesale distributors can be found in **Chapter 3** of this report.

Exhibit 2.1

Major Legislative Changes Since the 2001 Sunset Evaluation

Year	Chapter	Change
2002	157	Extends the termination date of the board by 10 years to July 1, 2013.
		Codifies the board's practice of annually inspecting pharmacies.
		Repeals the State manufacturer's permit.
		Limits discovery and admissibility of certain evidence to facilitate pharmacists in voluntarily tracking medication errors.
	249	Authorizes physicians and pharmacists to enter into voluntary drug therapy management contracts.
2003	318	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.
2004	339	Authorizes a licensed pharmacist to administer an influenza vaccination.
2006	287	Establishes the Prescription Drug Repository Program to accept donated prescription drugs to dispense to eligible individuals.
	408	Requires the board to revoke a license if a licensee is convicted of selling or delivering a drug different from that ordered.
	523	Establishes registration requirements for pharmacy technicians.
		Authorizes pharmacists to delegate certain pharmacy acts to pharmacy technicians.
2007	352/353	Expand the requirements for a wholesale distributor of prescription drugs or devices to obtain a permit from the board.
		Require prescription drugs distributed outside the "normal distribution channel" to have a pedigree that records each distribution.
		Establish a civil fine of up to $500,000 for violation of the Act.
2008	215/216	Authorize a pharmacist to dispense medication from a remote location for the benefit of a nursing home that uses a remote automated medication system.
	618/619	Authorize a pharmacist to administer a vaccination for pneumococcal pneumonia or herpes zoster to an adult with a prescription from a physician.

Year	Chapter	Change
	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, State Board of Physicians, and State 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 DHMH 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.
	533/534	Set standardized guidelines for all health occupations boards regarding disciplinary processes, board membership, and other administrative matters. Require boards to adopt sanctioning guidelines. Require boards to collect racial and ethnic information about applicants.
2011	166	Establishes the Prescription Drug Monitoring Program to monitor the prescribing and dispending of all Schedule II through V controlled dangerous substances.
	546/547	Expand the Prescription Drug Repository Program to include the acceptance by a pharmacy of prescription drugs and medical supplies turned in to the pharmacy for proper disposal in accordance with program policies.

Year	Chapter	Change
	559/560	Authorize a pharmacist to administer an influenza vaccine to any individual age nine or older in accordance with regulations adopted by the board in consultation with DHMH.

Source: Laws of Maryland

Pharmacists Authorized to Administer Vaccinations

Pharmacists have become more involved in patient care through several pieces of legislation (Chapter 339 of 2004, Chapters 618 and 619 of 2008, Chapter 304 of 2009, and Chapters 559 and 560 of 2011), which allow licensed pharmacists to administer certain vaccinations. Pharmacists who meet specified training requirements may administer any vaccination that has been determined by the State Board of Pharmacy – with agreement from the State Board of Physicians and the State Board of Nursing – to be in the best health interests of the community. Currently, vaccinations that may be administered by pharmacists are subject to certain minimum patient age requirements and limited to influenza, pneumococcal pneumonia, and herpes zoster vaccinations. As of September 2011, 2,550 pharmacists were certified to administer vaccinations.

Prescription Drug Repository Program Expanded to Include Acceptance of Drugs for Disposal

The board oversees the Prescription Drug Repository Program, which authorizes the acceptance of donated prescription drugs at board-designated drop-off sites for the purpose of dispensing the drugs to eligible individuals. The program accepts for donation only drugs that are in their original unopened, sealed, and tamper-evident unit-dose packaging, and that have an expiration date of at least 90 days from the donation date. Any individual, drug manufacturer, or health care facility may donate prescription drugs through the program. As of September 2011, the board had approved 10 prescription drug repository drop-off sites, with 4 additional applications pending board approval.

In addition, recent legislation (Chapters 546 and 547 of 2011) expands the scope of the program to allow the acceptance of prescription drugs and medical supplies returned to a pharmacy for proper disposal (rather than donation). Each pharmacy for which a pharmacy permit has been issued must dispose of returned prescription drugs or medical supplies in accordance with program policies.

Prescription Drug Monitoring Program Established

Prescription drug abuse is a growing problem in the United States and has been attributed, in part, to the increased availability of prescription drugs. State prescription drug monitoring programs address this issue by requiring pharmacies to log each prescription they fill. Chapter 166 of 2011 establishes the Prescription Drug Monitoring Program (PDMP) within DHMH to monitor the prescribing and dispensing of all Schedule II through V controlled dangerous substances (CDS). For each monitored prescription drug dispensed, a dispenser must electronically submit data to PDMP in accordance with regulations adopted by the Secretary of Health and Mental Hygiene. Under certain circumstances, a dispenser may submit data by other means. In addition, an Advisory Board on Prescription Drug Monitoring must make recommendations to the Secretary of Health and Mental Hygiene relating to the design and implementation of the program, including regulations, legislation, and sources of funding.

Statutory Changes May Be Required for Utilization of Electronic Prescriptions (e-prescribing)

The emergence of e-prescribing (*i.e.*, 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 an estimated 7,000 deaths. The vast majority of retail chain pharmacies (such as Rite Aid and CVS) as well as many other health care providers are equipped to accept e-prescriptions.

E-prescribing is regulated under the Code of Maryland Regulations (COMAR). The board recently 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 CDS in accordance with applicable State and federal statutes and regulations. As of September 2011, the federal Drug Enforcement Administration permits e-prescribing of CDS.

However, e-prescribing is an emerging practice that continues to evolve, and – according to the U.S. Department of Health and Human Services – all states (including Maryland) have laws and/or regulations that could impede e-prescribing of CDS. Specifically, Maryland's Health-General Article indicates that prescriptions for CDS must be either oral or written and that written prescriptions must be made on a separate prescription form. In addition, the Criminal Law Article requires a manually signed written prescription for Schedule II CDS unless dispensed directly to the ultimate user by an authorized provider who is not a pharmacist. The prescription must also be dispensed in accordance with regulations, reduced to writing, and kept on file with a pharmacist. CDS listed on Schedules III through V may be written, faxed, or oral, provided that any oral prescriptions are reduced to writing by the pharmacist.

The board advises that, because the Division of Drug Control (DDC) issues permits for CDS, DDC is likely the most appropriate entity to review and propose updates to statutes impacting authorized prescribers of CDS. **Thus, if Maryland desires to modify State law to facilitate e-prescribing, DDC should take the lead in reviewing current statute and determining what changes should be made.**

Drug Therapy Management Program Has Been Underutilized

According to the American Pharmacists Association, as of 2008, 45 states had authorized collaborative drug therapy management between a pharmacist and a physician. Generally, authority to practice drug therapy management is incorporated in state pharmacy practice acts within the definition of a pharmacist's scope of practice.

In Maryland, 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. Therapy management contracts allow pharmacists to help manage a patient's medications in collaboration with a physician. 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. The program was initially set to terminate on May 31, 2008; however, Chapter 650 of 2008 extended the termination date to September 30, 2010, and Chapters 44 and 45 of 2010 ultimately repealed the termination date, making the program permanent.

Administrative Process Is Onerous

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. An applicant pays a $250 application fee, which includes review and disposition of the physician-pharmacist agreement and one protocol. Additional protocols require a fee of $50.

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. Agreements are valid for two years and may be renewed for a fee of $200.

Chapter 249 of 2002 required DHMH to assess outcomes achieved by drug therapy management contracts. The department contracted with the University of Maryland to evaluate the program from 2007 to 2009. The University of Maryland found that applying for a physician-pharmacist agreement typically took six months and involved significant paperwork and strict oversight by both boards. The evaluation noted that physicians and pharmacists had been reluctant to expend the time and expertise necessary to prepare protocols and application materials because they were onerous (and, at the time, the program was scheduled to terminate).

Participation in Drug Therapy Management Is Low

According to the boards, there are currently only nine physician-pharmacist agreements in Maryland: three are specific to metabolic syndrome; three to antithrombosis (management of patients on anticoagulants or blood thinners); two to tobacco use and dependence; and one to anxiety. DLS identified several potential reasons why participation in the drug therapy management program continues to be low. First, statute and regulations outlining the Drug Therapy Management Program are lengthy and complex. Second, as reflected in the University of Maryland evaluation of the program, the application process is onerous and time consuming, with some agreements and protocols awaiting approval for *years*. Third, based on DLS observations of Joint Committee proceedings, 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. This 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 the drug therapy management statute, which both hinders collaborative practice and further prolongs the approval process by requiring repeated resubmissions and revisions.

Joint Approval Inconsistent with Other Boards and Other States

In addition to identifying obstacles to participation, DLS also notes that the requirement that physician-pharmacist agreements and individual drug protocols be approved by both boards appears inconsistent with similar agreements regulated by other health occupations boards and with the drug therapy management laws in other states.

Boards of Nursing and Physicians No Longer Approve Nurse Practitioner Agreements. A similar joint committee structure was historically used by the State Board of Nursing and the State Board of Physicians to govern agreements between nurse practitioners and physicians. However, Chapters 77 and 78 of 2010 eliminated joint board approval of such agreements. Instead, nurse practitioners may practice independently if they have an approved attestation that they have a collaboration agreement in place with a licensed physician and will refer to and consult with physicians as needed. Neither board approves such attestations, but the State Board of Nursing must maintain approved attestations and make them available to the State Board of Physicians upon request.

Only Eight Other States Require Approval of Drug Therapy Agreements. To obtain additional information about drug therapy management in other states, DLS contacted the National Association of Boards of Pharmacy and conducted an informal survey of other state boards of pharmacy. DLS found that 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, while 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.

Requirement for Joint Approval of Agreements and Protocols Should Be Repealed. Based on DLS observations and findings, if the General Assembly wishes to foster collaborative drug therapy management between pharmacists and physicians (as can be inferred from the removal of the termination date on the program in 2010), the program could benefit from revision. Simplification of the governing statute and regulations and removal of current barriers to participation may be first steps. In particular, Maryland law should be amended to repeal the dual board approval requirement as well as the boards' authority to charge fees for the program.

Recommendation 1: Statute should be amended to remove the requirement that physician-pharmacist agreements and drug therapy management protocols be approved by the State Board of Pharmacy 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 the Senate Education, Health, and Environmental Affairs and the House Health and Government Operations committees by October 1, 2013, on the impact of these modifications to the drug therapy management program, including the number of physician-pharmacist agreements and drug therapy management protocols on file with the boards.

Emerging Regulatory Issues Include Dispensing by Nonpharmacist Practitioners

One issue that the board is currently confronting is the regulation of dispensing practitioners other than pharmacists. The board has no authority to inspect (and thus keeps no

records with regard to) such practitioners. Rather, under current law, a licensed dentist, physician, or podiatrist may personally prepare and dispense his or her own prescriptions if the practitioner (1) holds a written dispensing permit from his or her respective licensing board; (2) meets certain specified criteria; and (3) does not have a substantial financial interest in a pharmacy, direct patients to a single pharmacist or pharmacy, or receive remuneration for referring patients to a pharmacist or pharmacy. According to the respective boards, a total of 1,265 dispensing permits are held by nonpharmacist practitioners in Maryland, including approximately 1,170 physicians (State Board of Physicians), 55 dentists (State Board of Dental Examiners), and 40 podiatrists (State Board of Examiners of Podiatrists).

Under COMAR 10.13.01, a dispensing permit is valid for five years and subject to a fee of $50, payable to the respective board. A licensed dentist, physician, or podiatrist must dispense prescription drugs to a patient only when a pharmacy is not conveniently available to the patient. (Determination of "conveniently available" must be made by the patient based upon factors to be determined solely at the discretion of the patient.) The practitioner must maintain a single form in the chart of each patient to whom prescription drugs are dispensed; such a form must, at a minimum, indicate that a pharmacy is not conveniently available to the patient, state that the determination that a pharmacy is not conveniently available was made solely by the patient, and be signed and dated by the patient before any prescription drugs are dispensed to the patient. Any dentist, physician, or podiatrist who violates these provisions may be subject to discipline by his or her respective licensing board.

DDC, rather than the board, currently inspects dispensing permit holders. According to the board, DDC inspections have identified a failure on the part of some dispensing permit holders to abide by dispensing laws and regulations. Specifically, not all permit holders were found to be personally preparing or dispensing medications or following proper recordkeeping, storage, or labeling requirements. The board – noting that the exception in current law that authorizes certain practitioners to dispense to patients for whom a pharmacy is not "conveniently available" was initially intended only to provide patient access to prescription drugs in rural areas – has advised that regulatory and/or legislative changes are needed to (1) centralize the issuance of dispensing permits with the board (which holds expertise in the practice of pharmacy); and (2) authorize the board to enforce, with regard to other licensed health care providers that dispense prescription drugs, the same standards of practice that are expected of pharmacists. In addition, DLS notes that, although 1,265 dispensing permits were held by practitioners in fiscal 2011, DDC conducted only 301 inspections of dispensing practitioners in that fiscal year.

However, recent regulatory and statutory efforts in this area have stalled or failed. In fiscal 2009, the board submitted proposed regulations (COMAR 10.13.01.02-.04) that would have limited dispensing by a dentist, physician, or podiatrist, but these regulations have not been published for final adoption. Furthermore, recently proposed legislation (Senate Bill 884 of 2011) that would have required dispensing practitioners to hold a dispensing permit from the board did not pass. That legislation also would have (1) authorized a permit holder to dispense prescription drugs to a patient only when a pharmacy is not "conveniently available" (*i.e.*, within

a 10-mile radius of the patient's home); and (2) established disciplinary provisions for permit holders and requirements for the initial issuance, renewal, and reinstatement of dispensing permits.

Three states – Massachusetts, Montana, and Utah – prohibit physician dispensing of prescription drugs, but most states authorize the practice with specific restrictions. (Although some of these states regulate veterinarians as dispensing practitioners, DLS notes that veterinarians in Maryland are not regulated under the Health Occupations Article. DLS further notes that, although DDC is authorized to inspect the offices of CDS permit-holding veterinarians, it does not currently do so.) Some examples of how other states regulate practitioner dispensing are as follows:

- *Virginia* issues two types of licenses to physicians: one type that authorizes a physician to practice pharmacy when good cause is shown that pharmacy services are not readily available (in general, when there is not a pharmacy within at least 15 to 20 miles); and a second, more common, type that allows a physician to dispense to the physician's own patients, so long as the physician complies with specified regulations and does not delegate the dispensing.

- *New Jersey* limits the quantity of drugs dispensed to a seven-day supply, limits the fee that may be charged for a drug, and requires disclosure to the patient of the availability of the drug from sources outside the practitioner's office. These requirements do not apply if the dispensing office is located 10 or more miles from the nearest pharmacy.

- *Pennsylvania* allows a practitioner (physician, dentist, veterinarian, or other prescriber) to dispense drugs to the practitioner's own patients after diagnosis or treatment, so long as the actual practitioner does not delegate the dispensing.

- *Florida* allows a practitioner who is authorized to prescribe drugs to dispense drugs to the practitioner's own patients in the regular course of practice. The practitioner must comply with all state pharmacy laws and is subject to state inspection for compliance.

- *Georgia* allows a practitioner (physician, dentist, podiatrist, or veterinarian) to dispense to the practitioner's own patients. The practitioner must adhere to the same standards, recordkeeping requirements, and other requirements for the dispensing of drugs applicable to pharmacists.

Prescribing by nonpharmacists is one of several issues in which the board's authority unavoidably overlaps with that of other health occupations boards, and any legislative or regulatory changes in this area must balance not only each board's respective authority, but also patient access and patient safety. **At a minimum, however, all of the relevant health occupations boards (along with DHMH) should work to ensure that all dispensing providers are complying with the same rules and safety standards. One method for**

improving compliance would be for the board to coordinate with the other relevant boards to develop practical training guidelines for dispensing practitioners.

New Board Members Should Receive Additional Training on Legislative and Regulatory Issues

The board faces legislative and regulatory issues of ever increasing complexity. Many of the issues faced by the board are unfamiliar to new members; yet training for new members is limited to two brief training sessions (one of which is a general training session conducted by DHMH for new members from all health occupations boards). With regard to the legislative and regulatory processes, the learning curve for most new members is particularly steep. DLS recognizes that some aspects of new board member training require time and are necessarily completed "on the job." However, new board members would benefit from more opportunities for formal training.

Recommendation 2: 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.

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.

Chapter 3. Licensing, Inspections, Compliance, and Board Operations

Board Generally Effective in Handling Core Functions and Operations

Central to the State Board of Pharmacy's operations are its licensing and compliance functions, and the board has done an admirable job of maintaining these functions given the significant expansion of the board's duties in recent years. While board operations are generally good, the Department of Legislative Services (DLS) makes a number of recommendations in this chapter to improve board operations as well as better position the board to deal with ongoing and future changes as the pharmacy industry continues to evolve.

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 all now renewed on a biennial basis. As shown in **Exhibit 3.1**, more than 19,000 licenses, registrations, and permits were held by pharmacists, pharmacy technicians, pharmacies, and wholesale distributors in fiscal 2011. Although most of this growth resulted from the registration of pharmacy technicians, the number of pharmacists has also increased by 10% (807) since fiscal 2007. In fact, projections for fiscal 2012 show that the total number of licensees, registrants, and permit holders will have doubled since fiscal 2007.

The board advises that its fiscal 2012 projections for licensed pharmacists and permit-holding pharmacies are based on the averages from preceding fiscal years, and they do not account for any projected growth or attrition. Thus, given that both of these categories have steadily grown since fiscal 2007, actual numbers for these categories in fiscal 2012 are likely to be higher than what is projected by the board. The number of pharmacy technicians projected by the board for fiscal 2012 does, however, factor in projected growth, and is based upon the number of technicians still in training and anticipated to register.

The board further advises that, while the numbers of most licensees, registrants, and permit holders have steadily increased in recent years, the number of wholesale distributors (most of which are out of state) has fluctuated somewhat due to a variety of factors, including ongoing changes in National Association of Boards of Pharmacy accreditation requirements.

Exhibit 3.1
Licenses, Registrations, and Permits Held
Fiscal 2007-2012

	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	Projected FY 2012
Pharmacist	7,901	8,112	8,393	8,612	8,708	8,589
Pharmacy Technician	-	1,183	6,162	7,118	8,052	9,758
Pharmacy	1,589	1,602	1,613	1,683	1,761	1,690
Wholesale Distributor	839	904	797	872	759	795
Total	**10,329**	**11,801**	**16,965**	**18,285**	**19,280**	**20,832**

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 pharmacies in fiscal 2010.

Source: State Board of Pharmacy

Licensure of Pharmacists

To become a licensed pharmacist, an applicant must graduate from a school or college of pharmacy that is approved by the board or accredited by the American Council on Pharmaceutical Education. Pharmacy schools have replaced the Bachelor of Pharmacy degree, which is no longer awarded, with the Doctor of Pharmacy (Pharm.D.) degree. 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 either 1,000 hours of a school-supervised professional experience program conducted by an accredited school of pharmacy, or 1,560 hours of full-time training under the direct supervision of a licensed pharmacist. As a condition of license renewal, pharmacists other than those renewing for the first time must also complete 30 hours of board-approved continuing education credits.

The board issues both initial and renewal pharmacist applications (available online) in a timely manner, with the vast majority of applications processed in two to three days (although if an application is incomplete or raises concerns regarding an applicant's qualifications, the licensing process could take as long as six to eight weeks). The board consistently meets its Managing for Results (MFR) goals for pharmacist licensure, but DLS notes that the board uses MFR goals with regard to pharmacist licensure only – and not with regard to the registration of pharmacy technicians or the permitting of pharmacies or wholesale distributors.

Recommendation 3: 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.

Registration of Pharmacy Technicians

Chapter 523 of 2006 requires pharmacy technicians to work under the direct supervision of a pharmacist and establishes registration requirements for technicians. Specifically, pharmacy technicians must submit to a criminal history records check 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, although for the first renewal period the board requires only 10 hours of continuing education. The registration of pharmacy technicians has given the board regulatory control over previously unregulated pharmacy personnel, but the registration process has proved, in its first years of implementation, to be challenging and labor-intensive for the board.

Initially, the board had planned to begin registering pharmacy technicians in fiscal 2008; however, implementing the registration program was a slow process, and the board had only managed to approve three technician training programs by the end of fiscal 2008. Subsequently, many applicants were forced to wait until fiscal 2009 to apply for registration – a process that originally took six to eight months to complete. In part, the length of the application process was due to a high volume of applicants (approximately 100 per week). Furthermore, the criminal history records checks required of applicants created additional delays because results for pharmacy technicians and wholesale distributors were initially 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, now resolved, also created some delays in issuing wholesale distributor permits.) The board advises that it currently takes approximately two to six weeks to process most completed initial pharmacy technician registration applications.

The registration process for pharmacy technicians remains challenging due to the volume of incomplete applications received by the board, which 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 his or her application; the applicant must then resubmit a complete application within one year of the initial application date to avoid paying an additional application fee.

As a result of administrative changes such as this, the length of the registration process for pharmacy technicians (still a developing program that has only just completed its first full renewal period) has been steadily decreasing. The board advises that implementation of a new information technology (IT) system (discussed in detail in **Chapter 4** of this report) – which is anticipated to occur in November 2011 and which will automate the registration process for

pharmacy technicians and streamline the licensing process generally – should further reduce the length of the application period.

Recommendation 4: The board should report to the Senate Education, Health, and Environmental Affairs and House Health and Government Operations 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).

Pharmacy Permits

A pharmacy is an establishment where prescription or nonprescription drugs or devices are compounded, dispensed, or distributed. A pharmacy permit is required to establish or operate a pharmacy in the State. To qualify for a pharmacy permit, resident pharmacies (that is, pharmacies located within Maryland) must arrange for an opening inspection, during which the pharmacy must meet the board's requirements for staffing, equipment, recordkeeping, and prescription dispensing procedures. Once a pharmacy has obtained a permit, the board monitors compliance with these requirements during routine annual inspections. Pharmacies that dispense controlled dangerous substances (CDS) must also register with the Division of Drug Control (DDC) in the Department of Health and Mental Hygiene (DHMH) and comply with 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. Along with its application to the board, a nonresident pharmacy must submit a copy of the most recent inspection report conducted by the regulatory or licensing agency of the state in which the pharmacy is located. (If no such report is provided, the board must conduct its own inspection.)

In its 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. Although the board did not establish 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 has recently promulgated revisions to regulations for inpatient institutional pharmacies and advises that it has almost finished promulgating revisions to regulations for pharmaceutical services to patients in comprehensive care facilities and home infusion pharmacies. In addition, the board has created new inspection forms for conducting hospital, sterile compounding, and long-term care pharmacy inspections, and expects to develop future regulations for nuclear pharmacies and nonsterile pharmaceutical compounding.

Wholesale Distributor Permits

Wholesale distributors – which may include manufacturers, warehouses, and some retail pharmacies – must be issued a permit by the board before engaging in the wholesale distribution of prescription drugs or prescription devices into, out of, or within the State. As a part of the initial application process, both a representative from the applicant's place of business and the representative's immediate supervisor must submit fingerprints for the purposes of a criminal history records check. 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.

To obtain a permit, a wholesale distributor must also obtain either a surety bond (made payable to the board) 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). If the applicant's annual gross receipts for the previous tax year total less than $10 million, the requisite surety bond amount is reduced to $50,000. The purpose of the surety bond is to secure the payment of any fines or penalties imposed by the board and any fees and costs incurred by the State relating to the permit. (To date, the board has not exercised its authority to use a surety bond to recoup fines incurred.)

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. Subsequently, it came to the board's attention that some surety bonds that the board had on file were not made payable to the board, which could make it difficult for the board to recoup fines in the event that a wholesale distributor violated State law. However, procedures are now in place to ensure that surety bonds issued in the wholesale distributor permitting process are made payable to the board. Specifically, the board's staff attorney has advised board staff that a surety bond must be made payable to the board before a wholesale distributor application can be processed. Furthermore, in the event that board staff is unsure about a bond's authenticity, staff is instructed to contact the board's staff attorney to review the bond. Finally, the board's website prominently features a sample surety bond, and the board advises (and DLS confirms) that the receipt of insufficient surety bonds has ceased to be an issue for the board. However, board staff is still instructed to inspect each surety bond received and immediately contact the applicant in the event that the applicant's surety bond is insufficient.

Strong Inspection and Complaint Resolution Processes Could Be Further Improved with Stable Leadership

Central to the board's compliance function are its inspection and complaint resolution processes. Staff in the board's Compliance Unit conducts routine inspections of pharmacies, investigates cases arising from pharmacy inspections or complaints received by the board, and assists the board in resolving such cases. Although the board has suffered from high employee

turnover in its Compliance Unit (as discussed later in this chapter), DLS was impressed with the quality of the unit's current leadership. Accordingly, DLS makes a number of recommendations in this chapter to improve not only the board's compliance function generally, but also the board's ability to retain quality staff within the function.

Annual Pharmacy Inspections Assumed from Division of Drug Control

In its 2001 sunset evaluation, DLS recommended that the board's goal of annually inspecting pharmacies be codified, and the General Assembly acted upon this in the 2002 session. 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. DDC, which is housed under the Laboratories Administration at DHMH, registers manufacturers, distributors, and dispensers of CDS and ensures the availability of drugs for legitimate medical and scientific purposes, while working to prevent drug abuse. However, DDC was not given sufficient resources to comply with the annual inspection mandate and continued to inspect pharmacies on a biennial basis.

The board and DDC began meeting in January 2007 to develop plans to transition annual pharmacy inspection responsibilities from DDC to the board; in the beginning of fiscal 2009, the board assumed annual inspection responsibilities. Currently, 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 lead inspector as well as the entire Compliance Unit. 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 3.2**, the number of pharmacy inspections has more than tripled from 425 in fiscal 2006 to 1,359 in fiscal 2011. From fiscal 2006 to 2008, during which time DDC was still conducting routine pharmacy inspections on behalf of the board, the number of pharmacy inspections increased steadily due (according to DDC) to the division's increased ability to hire and retain inspector staff. The number of pharmacy inspections continued to increase after the board assumed annual inspection duties in fiscal 2009. Although the number of inspections conducted by the board decreased slightly in fiscal 2011 (due in large part, according to the board, to an inspector position that was vacant for much of that year), the board now succeeds in inspecting pharmacies on a nearly annual basis. DLS notes that the board has kept up with its annual inspections at an admirable pace, given significant turnover at key positions in its Compliance Unit (as discussed later in this chapter). With more stable leadership in the Compliance Unit, DLS anticipates that the board would be able to inspect every permit-holding pharmacy on an annual basis.

Exhibit 3.2
Pharmacy Inspections
Fiscal 2006-2011

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Total Pharmacy Inspections	425	739	1,100	1,164	1,551	1,359
Conducted by the Board	0	0	0	669	1,136	992
Conducted by DDC	425	739	1,100	495	415	367

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 and a small number of opening inspections.

Source: State Board of Pharmacy; Department of Health and Mental Hygiene, Division of Drug Control

In its 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. However, while the board created a database and an online inspection form, it did not create a shared database with DDC. 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 (including 67 in fiscal 2011) and, if the closing and opening inspections occur at the same location (as was the case 28 times in fiscal 2011), DDC performs both inspections. Furthermore, DDC performs CDS inspections of pharmacies – although DLS notes that these have been decreasing steadily since fiscal 2009, as DDC's focus has shifted to the inspection of dispensing practitioners, as mentioned in **Chapter 2** of this report. (Pharmacy inspections now comprise a minority of the inspections conducted by DDC, which in fiscal 2011 conducted 301 inspections of dispensing practitioners, 109 inspections of methadone programs, and 117 special investigations.)

DLS advises that DDC and the board are not duplicating each other's efforts in conducting their respective inspections, as DDC's inspections vary greatly from the board's annual inspections. Board inspections address CDS only in that they include an audit of a pharmacy's Schedule II CDS inventory. Board inspectors are not assigned to audit a pharmacy's inventory of Schedule III through V CDS. The board advises that it would alert DDC to any problems uncovered by its CDS audits, but that there have been no such discoveries since the board's new compliance officer began employment with the board in January 2011.

DLS was impressed with the professionalism and willingness to cooperate between the inspection units of both DDC and the board. In general, however, communications between the two entities are informal and could be improved.

Recommendation 5: The board, in conjunction with the Division of Drug Control in DHMH, 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.

Inspections No Longer Required for Most Wholesale 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. In fact, from fiscal 2009 to 2010, the board was able to nearly double the amount of pharmacy inspections it conducted. DLS notes the board (or an entity acting on the board's behalf) is still responsible for inspecting all in-state wholesale distributors (which comprise fewer than one-fourth of all permit-holding 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.

Complaint Resolution Process Generally Timely

In addition to inspecting pharmacies, the board is charged with receiving, investigating, and responding to questions and complaints; monitoring licensees 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 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 StateStat. Specifically, the board began tracking not only newly reported complaints but also pending complaints carried over from previous years.

In fiscal 2011, the board received nearly 300 complaints, most of which were related to dispensing errors or customer service. As shown in **Exhibit 3.3**, the number of complaints submitted to the board has more than doubled 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.

DLS notes that, in fiscal 2011, an estimated 90% of complaints were resolved by the board within 90 days, exceeding the board's target of 85%.

Exhibit 3.3
Resolution of Complaints Received
Fiscal 2007-2011

	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
New Complaints Received	129	115	166	203	298
Complaints Resolved*					
Formal Charges**	12	19	35	35	45
Informal Action	38	96	112	82	113
No Action or Referred Elsewhere	-	-	-	90	103
Pending Complaints Carried Over to the Next Fiscal Year	-	3	19	15	52

Note: Dashes (-) indicate that data were unavailable.

*Complaints Resolved and New Complaints Carried Over do not sum to the number of New Complaints Processed, as Complaints Resolved may include action taken on complaints from prior years and some data were unavailable.

**Formal Charges does not, prior to fiscal 2009, necessarily include complaints that were resolved in case resolution conferences as this data were unavailable and the board was therefore unable to confirm how staff previously accounted for such cases. The board's recordkeeping practices are discussed generally later in this chapter.

Source: State Board of Pharmacy; Department of Legislative Services

Complaints Largely Addressed Informally

Since fiscal 2007, the board has addressed approximately 16% 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 may also include fines as determined by statute.

While some formal actions are taken, DLS found that the majority of complaints are subject to informal actions. Since fiscal 2007, informal actions (most of which have related to dispensing errors) have accounted for nearly half of all board actions. 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 pharmacists, 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 and that dispensing errors that lead to more serious outcomes should be addressed with formal disciplinary actions.

Currently, the board is working toward implementation of Chapters 533 and 534 of 2010 (requiring the adoption of sanctioning guidelines), which should promote uniformity in the complaint resolution process. However, the board's Task Force to Study Sanctioning Guidelines has not yet terminated, and no guidelines have yet been adopted. It is therefore likely that the board will not have had significant experience in the use of the guidelines by the December 2011 reporting date (as specified by Chapters 533 and 534 of 2010).

Recommendation 6: The board should report again to the Senate Education, Health, and Environmental Affairs and House Health and Government Operations 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).

Board Struggles to Retain Quality Leadership in Compliance Unit

Although DLS was impressed with the work ethic and professionalism of the current leadership of the board's Compliance Unit, the board has in recent years had significant difficulties attracting and retaining the appropriate pharmacist staff to lead the unit; in fact, over the past six years, the board has hired five different pharmacists to fill that role. Although not required by statute to do so, the board has consistently employed a pharmacist to lead the unit due to the technical expertise needed to investigate complaints. (DLS notes that other health occupations boards such as the State Board of Physicians and the State Board of Dental Examiners use licensed staff to fill similar positions.) The board attributes the unit's high turnover rate to the noncompetitive salary that the board offers its pharmacist personnel and advises that without higher salaries for pharmacists the board will continue to have difficulty recruiting and retaining qualified pharmacist staff. The board had previously sought to resolve

this issue by amending statute through Senate Bill 1013 and House Bill 736 of 2007 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. The position classification for the leader of the Compliance Unit is not appropriate and has resulted in a high turnover rate for pharmacist staff.

Recommendation 7: 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 position from the Department of Budget and Management to ensure that the Compliance Unit has more stable leadership and is led by an experienced pharmacist.

The board advises that the use of pharmacy technicians in the inspection function is a growing trend in many states due to the limited availability of funds. DLS found the board's Compliance Unit in general to be highly professional and notes that the board's inspectors have done an admirable job of improving the rate of routine pharmacy inspections. However, an overwhelming preference for inspectors who are trained pharmacists was reported to DLS. (DDC inspectors are all trained pharmacists.) It was reported that many pharmacists resent being inspected by pharmacy technicians. In addition, concerns were raised as to whether pharmacy technicians can, with any level of on-the-job training, reach the level of expertise held by pharmacists and/or necessary to mastering the finer points of the inspection process.

Recommendation 8: 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 the Department of Budget and Management.

Rehabilitation Services Provided by the Pharmacists' Education and Advocacy Council Limited in Recent Years

While investigating complaints, the board sometimes encounters a licensee or registrant with a substance abuse problem. Because the treatment of substance abuse is beyond the scope of the board's expertise, the board is authorized by statute to contract with 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, and only one pharmacist rehabilitation

committee in Maryland meets this requirement: the Pharmacists' Education and Advocacy Council (PEAC). The board has used the services of PEAC since its establishment in 1983.

Stakeholders and current board members generally expressed to DLS satisfaction with current statute, as well as a shared belief that pharmacists should play a major role in rehabilitating other pharmacists. The board had previously sought, however, to amend statute through House Bill 144 of 2007 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 board generally monitors 10 to 12 such licensees and registrants at a time and advises that one staff member is assigned to dedicate 25% of the staff member's time to monitoring participants of the in-house program.

The reduction in PEAC's contract resulted from the board's inability to receive information from PEAC in a timely manner. 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 regard to how many licensees and registrants the organization monitors in a given year. PEAC is now scheduled to report to the board on the fourth day of each month. These changes are promising, but recent – and the board advises that PEAC's reports to the board are sometimes a few days late. Thus, the board should allow more time for these changes to take hold before reassessing its contractual relationship with PEAC.

Recommendation 9: The board should report to the Senate Education, Health, and Environmental Affairs and House Health and Government Operations 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.

Board Could Benefit from Administrative Changes to General Operations

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.

The board has a total of 23 authorized full-time staff but is currently trying to fill 2.5 vacancies, including 2 office secretaries and 1 (part-time, 50%) pharmacist inspector. Although the board has been able to acquire an additional seven regular positions since fiscal 2007, the board appears to lack the ability to retain an appropriate number of personnel to meet its needs. 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. Although the board resolves complaints in a timely manner and has improved the timeliness of its registration and permitting processes, stakeholders reported lapses in the board's customer service and response time and board staff described an unwieldy volume of daily inquiries.

DLS notes that the board, which has struggled for years to update its information technology (IT) system (as discussed in **Chapter 4**), expects to implement a new system in November 2011. The board advises that the new system will streamline board operations significantly. Thus, the board's staffing needs may be expected to change in the near future.

Recommendation 10: The board should report to the Senate Education, Health, and Environmental Affairs and House Health and Government Operations 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.

One of the customer service lapses that DLS identified concerned the board's website, which lacks or incorrectly states critical information (including contact information for staff), and is not updated regularly. For example, monthly board meeting minutes have not been posted to the website since March 2011. Contact information listed on the website for certain programs leads callers to staff members who do not work on those programs. DLS notes that the board recently lost a staff member who contributed significantly to the board's web content but further notes the importance of providing accurate and up-to-date information to the public through the board's website.

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

As alluded to above, employee turnover and temporary absences can result in major setbacks to board operations, particularly with regard to the processing of applications within the board's licensing function. Board members and staff reported a lack of staff training and, in particular, cross-training. Staff members lack knowledge of board functions beyond their own

roles. Cross-training of staff is necessary to ensure that inevitable vacancies and absences do not unduly impede the board's regular operations. DLS notes that all staff will need to be trained to use the board's new IT system (expected to be implemented in November 2011), which presents an opportunity for cross-training.

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

Finally, in preparing this report, DLS encountered several instances in which data provided by the board were inconsistent with data provided during DLS' preliminary sunset evaluation of the board, conducted last year. In a number of cases, discrepancies were attributed to staff turnover. However, it is imperative that the board maintain consistent recordkeeping regardless of changes in personnel.

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

Chapter 4. Financial Issues

Board Is Special Funded by Fee Revenues

All but two of the health occupations boards are entirely special funded by the fees collected for licensing, certification, registration, and other board services. With respect to the State Board of Pharmacy, 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 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 fiscal 2008 and have not been adjusted to date. Initial and renewal pharmacy permit fees more than doubled to account for the change from annual to biennial permit renewal in fiscal 2010, while wholesale distributor fees also more than doubled to account for a change from annual to biennial permit renewal beginning in fiscal 2008. Current and 2002 fee schedules for pharmacists, pharmacies, and distributors are shown in **Appendix 2**.

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 **Appendix 3**.

Board Revenues and Expenditures Have Rapidly Increased

In recent years, board revenues, expenditures, and staff resources have rapidly increased. As shown in **Exhibit 4.1**, between fiscal 2007 and 2011, revenues increased by 85% while expenditures increased by 47% – although revenues began exceeding expenditures only in fiscal 2010 and 2011. The Department of Legislative Services (DLS) notes that, although expenditures were held artificially low during much of this period due to State cost-containment measures, the board's expenditures during this period also reflect multiple, significant one-time expenses associated with the development of a new database (discussed below). The board projects its expenditures to exceed revenues by approximately 11% in fiscal 2012, due in part to additional one-time expenses associated with the new database as well as an anticipated decline in the number of wholesale distributor permits (discussed in more detail below), pharmacy permits, and pharmacist licenses. However, as DLS noted in **Chapter 3**, the board's projections for pharmacy permits and pharmacist licenses are likely inaccurate, and in fact growth can be expected to occur in both of these categories. Thus, the board's revenues for fiscal 2012 will likely be higher than what is projected by the board and may in fact continue to exceed expenditures.

Exhibit 4.1

Fiscal History of the State Board of Pharmacy

Fiscal 2007-2012

	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	Projected FY 2012
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
Total Funds Available	**$2,702,309**	**$2,738,197**	**$3,204,164**	**$3,292,941**	**$3,972,842**	**$3,609,500**
Total Expenditures	**$1,716,620**	**$1,775,475**	**$2,277,950**	**$2,196,935**	**$2,522,902**	**$2,613,502**
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
Ending Fund Balance	**$985,688**	**$962,722**	**$926,214**	**$1,096,006**	**$1,449,940**	**$995,998**
Transfer to General Fund				**$98,544**	**$200,000**	**$237,888**
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

*Prior to any transfers to the general fund.

Note: Numbers may not sum to total due to rounding. In addition, some of the numbers provided by the board were slightly inconsistent with numbers provided during the board's preliminary evaluation and/or failed to sum to the total in a way that is not attributable to rounding and for which no satisfactory explanation was given. Thus, the numbers shown here represent DLS's interpretation of the available data. The board's recordkeeping practices are discussed in Chapter 3.

Source: State Board of Pharmacy; Department of Health and Mental Hygiene

Since fiscal 2007, board revenues have averaged approximately $2.19 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 $2.10 million, ranging from $1.72 million in fiscal 2007 to $2.52 million in fiscal 2011. This is largely attributable to the seven new positions created since fiscal 2007 to support new program areas such as the registration of pharmacy technicians, issuance of wholesale distributor permits, and inspection of pharmacies. However, despite the combination of increased costs and increasingly substantial transfers to the general fund, the board has consistently been able to cover its expenses due to its sizable fund balance.

Recent Increase in Expenditures Partly Attributable to Cost of New Database System

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, licensing, and compliance needs. Near the beginning of fiscal 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. Subsequently, 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 had paid RESI about $300,000 for its services.) The board then 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. (The board estimates the total cost of its contract with Systems Automation to be $366,500.) The board advises that it now expects to implement its new database system in November 2011. Overall, however, implementing a database has been an extremely costly venture for the board.

Transfers to the General Fund Supportable Due to Sufficient Revenue Stream in Recent Years

In each of the last three fiscal years, the Budget Reconciliation and Financing Act (BRFA) has required the board to transfer some of its funds to the general fund. Specifically, the board was required by BRFA to transfer to the general fund $98,544 in fiscal 2010, $200,000 in fiscal 2011, and $237,888 in fiscal 2012. As noted, the board has been able to cover its expenses due to its large fund balance. However, future fund transfers under BRFA may impact the board's ability to implement the new database system and maintain an adequate fund balance.

Fund Balance Adequate but Spend Down Anticipated

The board's fund balance consistently remains above the recommended 20% threshold for health occupations boards of its size. However, 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 anticipates that the number of initial and renewal permits for wholesale distributors will decrease due to new accreditation requirements for distributors who do not qualify for a permit by reciprocity.) Furthermore, 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 (including support maintenance and system upgrades) in future years. The remaining balance on the board's contract for its new database is $145,700. In addition, the board anticipates the ongoing cost of maintenance associated with the new database to total approximately $50,000 annually beginning in fiscal 2012.

Recommendation 14: Before modifying its fees, the board should prepare a five-year financial outlook and report to the Senate Education, Health, and Environmental Affairs and House Health and Government Operations committees by October 1, 2013, on its ability to maintain a healthy fiscal outlook. The board's report should discuss the effects of BRFA 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.

Chapter 5. Conclusion

In recent years, the staff of the State Board of Pharmacy has dealt admirably with significantly expanded duties associated with the regulation of an industry that continues to grow at a rapid rate. At the same time, board members have continuously demonstrated their engagement with and careful consideration of the complex and ever-increasing issues facing the board.

The board has struggled in recent years to retain staff, which has undoubtedly affected staff morale and board operations. However, the Department of Legislative Services (DLS) notes that, overall, the board has done an excellent job of keeping up with the many recent changes to State regulation of the pharmacy industry – making prospects for improving board operations generally good. In addition, the anticipated implementation of the board's long-awaited new IT system should streamline board operations significantly. However, these and other changes recommended by DLS will take time to implement and yield results.

Recommendation 15: Legislation should be enacted to extend the termination date for the board by 10 years to July 1, 2023. Additionally, uncodified language should be adopted to require the board to report, by October 1, 2013, to the Senate Education, Health, and Environmental Affairs and House Health and Government Operations committees on the implementation status of the nonstatutory recommendations made in this report.

DLS has recommended a number of changes to the operations of the board. While the recommendations will not completely resolve all operational problems, collectively they can significantly improve board operations. However the board, like any other organization, must tackle new challenges as they arise. If it fails to do so, new problems will certainly emerge and undermine any progress made by these or any other recommended improvements. Nevertheless, for the time being, these changes should help the board provide better services to both its licensees and the consumers of pharmacy services in Maryland.

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

	Recommendation	Status of Implementation
1.	The State Board of Pharmacy should be continued, and the General Assembly should extend its termination date to July 1, 2013. 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.	Implemented by Chapter 157 of 2002. 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.	Implemented by Chapter 157 of 2002.
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
5. The General Assembly should amend statute to codify annual inspections of pharmacies.	Chapter 157 of 2002 codified annual inspection of 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 the Division of Drug Control (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. 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.
10. The board should reallocate existing resources instead of adding positions unless there is sufficient justification for new positions.	With the assumption of several new program areas, the board has been required to increase staff as needed; however, the board has struggled somewhat with certain required tasks, including the timely processing of applications within the board's licensing function.
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.	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.
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 State Board of Nursing and Board of Physicians Quality Assurance (now the State Board of Physicians) in an effort to reduce medical errors in all phases of the dispensing process.	Chapter 157 of 2002 limited discovery of certain evidence to facilitate voluntary tracking of medication errors by pharmacists. The board promulgated Patient Safety Improvement regulations (COMAR 10.34.26.01) that became effective October 27, 2003.

Recommendation	Status of Implementation
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.	Chapter 523 of 2006 established registration requirements for pharmacy technicians beginning in fiscal 2007. The new regulatory system proved to be a significant undertaking, and the board did not actually begin registering pharmacy technicians until fiscal 2008.

Appendix 2. Comparison of Board Fees: Pharmacists, Pharmacies, and Distributors 2002 Fees vs. Current Fees

	Fees Effective in 2002	Fees Effective in 2011
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

Appendix 3. 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

Appendix 4. Draft Legislation

J2 2lr0568

Bill No.: _____

Requested: _____

Committee: _____

By: **Leave Blank**

Drafted by: Goodman
Typed by: Carol
Stored – 10/28/11
Proofread by _____
Checked by _____

A BILL ENTITLED

AN ACT concerning

State Board of Pharmacy – Sunset Extension and Revisions

FOR the purpose of continuing the State Board of Pharmacy in accordance with the provisions of the Maryland Program Evaluation Act (sunset law) by extending to a certain date the termination provisions relating to the statutory and regulatory authority of the Board; repealing certain provisions requiring certain physician–pharmacist agreements to be approved by the State Board of Physicians and the State Board of Pharmacy; repealing certain provisions that prohibit the State Board of Physicians and the State Board of Pharmacy from approving certain physician–pharmacist agreements under certain circumstances; repealing certain provisions relating to the time period during which a physician–pharmacist agreement is valid; requiring a certain physician and a certain pharmacist to submit a copy of a certain agreement to a certain board; requiring a therapy management contract to apply only to conditions for which protocols have been agreed to by certain parties; repealing a certain provision requiring the establishment of certain fees in regulations; repealing a requirement that certain regulations include provisions that establish a certain procedure; prohibiting certain regulations from requiring certain boards to approve certain physician–pharmacist agreements or the protocols specified in the agreements; requiring that an evaluation of the State Board of Pharmacy and the statutes and regulations that relate to the Board be performed on or before a certain date; requiring the State Board of Pharmacy to submit certain

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets] indicate matter deleted from existing law.

reports to certain committees of the General Assembly on or before certain dates; altering a certain definition; making a conforming change; and generally relating to the State Board of Pharmacy.

BY repealing and reenacting, without amendments,
Article – Health Occupations
Section 12–6A–01(a)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–6A–01(f), 12–6A–03, 12–6A–07, 12–6A–10, and 12–802
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, without amendments,
Article – State Government
Section 8–403(a)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, with amendments,
Article – State Government
Section 8–403(b)(45)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health Occupations

12–6A–01.

(a) In this subtitle the following words have the meanings indicated.

(f) "Physician–pharmacist agreement" means an **[**approved**]** agreement between a licensed physician and a licensed pharmacist that is disease–state specific and specifies the protocols that may be used.

12–6A–03.

(a) A licensed physician and a licensed pharmacist who wish to enter into therapy management contracts shall have a physician–pharmacist agreement **[**that is approved by the Board of Pharmacy and the Board of Physicians**]**.

[(b) The Board of Physicians and the Board of Pharmacy may not approve a physician–pharmacist agreement if the Boards find there is:

(1) Inadequate training, experience, or education of the physicians or pharmacists to implement the protocol or protocols specified in the agreement; or

(2) A failure to satisfy requirements of:

(i) This title or Title 14 of this article; or

(ii) Regulations established by the Board of Physicians and the Board of Pharmacy adopted under this subtitle.

(c) A physician–pharmacist agreement shall be valid for 2 years from the date of its final approval by the Board of Physicians and the Board of Pharmacy unless renewed in accordance with established regulations adopted under this subtitle.**]**

(B) (1) A LICENSED PHYSICIAN WHO HAS ENTERED INTO A PHYSICIAN–PHARMACIST AGREEMENT SHALL SUBMIT TO THE BOARD OF PHYSICIANS A COPY OF THE PHYSICIAN–PHARMACIST AGREEMENT AND ANY SUBSEQUENT MODIFICATIONS MADE TO THE PHYSICIAN–PHARMACIST AGREEMENT OR THE PROTOCOLS SPECIFIED IN THE PHYSICIAN–PHARMACIST AGREEMENT.

(2) A LICENSED PHARMACIST WHO HAS ENTERED INTO A PHYSICIAN–PHARMACIST AGREEMENT SHALL SUBMIT TO THE BOARD OF PHARMACY A COPY OF THE PHYSICIAN–PHARMACIST AGREEMENT AND ANY SUBSEQUENT MODIFICATIONS MADE TO THE PHYSICIAN–PHARMACIST

AGREEMENT OR THE PROTOCOLS SPECIFIED IN THE PHYSICIAN–PHARMACIST AGREEMENT.

12–6A–07.

(a) A therapy management contract shall apply only to conditions for which protocols have been **[**approved by the Board of Physicians and the Board of Pharmacy under**]** **AGREED TO BY A LICENSED PHYSICIAN AND A LICENSED PHARMACIST IN ACCORDANCE WITH** the regulations adopted under this subtitle.

(b) A therapy management contract shall terminate 1 year from the date of its signing, unless renewed by the licensed physician, licensed pharmacist, and patient.

(c) A therapy management contract shall include:

(1) A statement that none of the parties involved in the therapy management contract have been coerced, given economic incentives, excluding normal reimbursement for services rendered, or involuntarily required to participate;

(2) Notice to the patient indicating how the patient may terminate the therapy management contract;

(3) A procedure for periodic review by the physician, of the drugs modified pursuant to the agreement or changed with the consent of the physician; and

(4) Reference to **[**an approved**]** **A** protocol, which will be provided to the patient upon request.

(d) Any party to the therapy management contract may terminate the contract at any time.

[(e) Fees paid to the Board of Physicians and Board of Pharmacy related to therapy management shall be established in regulations.**]**

12–6A–10.

(a) Subject to subsection (b) of this section, the Board of Pharmacy, together with the Board of Physicians, shall jointly develop and adopt regulations to implement the provisions of this subtitle.

(b) The regulations adopted under subsection (a) of this section**:**

(1) **[**shall**]** **SHALL** include provisions that:

[(1)**]** **(I)** Define the criteria for physician–pharmacist agreements; **AND**

[(2)**]** **(II)** Establish guidelines concerning the use of protocols, including communication, documentation, and other relevant factors; and

[(3) Establish a procedure to allow for the approval, modification, continuation, or disapproval of specific protocols by the Board of Physicians and the Board of Pharmacy.**]**

(2) MAY NOT REQUIRE THE BOARD OF PHYSICIANS OR THE BOARD OF PHARMACY TO APPROVE A PHYSICIAN–PHARMACIST AGREEMENT OR THE PROTOCOLS SPECIFIED IN A PHYSICIAN–PHARMACIST AGREEMENT.

12–802.

Subject to the evaluation and reestablishment provisions of the Program Evaluation Act, this title and all rules and regulations adopted under this title shall terminate and be of no effect after July 1, **[**2013**]** **2023**.

Article – State Government

8–403.

(a) On or before December 15 of the 2nd year before the evaluation date of a governmental activity or unit, the Legislative Policy Committee, based on a preliminary evaluation, may waive as unnecessary the evaluation required under this section.

(b) Except as otherwise provided in subsection (a) of this section, on or before the evaluation date for the following governmental activities or units, an evaluation shall be made of the following governmental activities or units and the statutes and regulations that relate to the governmental activities or units:

(45) Pharmacy, State Board of (§ 12–201 of the Health Occupations Article: July 1, **[**2012**]** **2022**);

SECTION 2. AND BE IT FURTHER ENACTED, That, on or before December 1, 2012, the State Board of Pharmacy shall submit a report to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee, in accordance with § 2–1246 of the State Government Article, on the implementation and use of the sanctioning guidelines required by Chapters 533 and 534 of the Acts of the General Assembly of 2010.

SECTION 3. AND BE IT FURTHER ENACTED, That, on or before October 1, 2013, the State Board of Pharmacy (Board) shall submit a report to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee, in accordance with § 2–1246 of the State Government Article, on the implementation of nonstatutory recommendations contained in the October 2011 sunset evaluation report on the Board, published by the Department of Legislative Services, including:

(1) the impact of modifications made to the drug therapy management program, including the number of physician–pharmacist agreements and the number of drug therapy management protocols on file with the Board and the State Board of Physicians;

(2) the Board's progress in further reducing the length of the pharmacy technician registration process following implementation of the Board's new Information Technology (IT) system, including information, for each full month following implementation of the IT system, on the average wait time from the date of application to the date of an applicant's registration or rejection;

(3) the status of the Board's contractual relationship with the Pharmacists Education and Advocacy Council (PEAC) and whether any statutory changes are necessary to allow other vendors to compete with PEAC;

(4) the implementation of the Board's IT system, including both positive and negative outcomes, and the effect, if any, of the IT system on the Board's staffing needs; and

(5) the Board's 5–year financial outlook and an analysis of the Board's ability to maintain a healthy fiscal outlook, including the effect of transfers from the Board's fund balance under the Budget Reconciliation and Financing Acts of 2009, 2010, and 2011, costs associated with the Board's new database, and any additional personnel costs resulting from the recommendations of the Department of Legislative Services contained in the sunset evaluation report on the Board dated October 2011, on the Board's ability to maintain an adequate fund balance.

SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2012.

Appendix 5. Written Comments of the State Board of Pharmacy

STATE OF MARYLAND
DHMH
Department of Health and Mental Hygiene
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor
Joshua M. Sharfstein, M.D., Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue ● Baltimore, Maryland 21215-2299
Michael Souranis, Board President - LaVerne G. Naesea, Executive Director

October 31, 2011

Mr. Warren G. Deschenaux, Director
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 Sunset Review Evaluation

Dear Mr. Deschenaux:

Thank you for the opportunity to comment on the exposure draft Sunset Review: Evaluation of the State Board of Pharmacy. The Board has identified in the attached, a few statements and/or factual errors that could lead the legislature to misinterpret Board responsibilities and activities.

Nonetheless, the Board is impressed by Ms. Jennifer Ellick's and her colleagues' abilities to review and comprehend its complicated pharmacy issues, as well as its operational concerns in a relatively short period. Please relay the Board's compliments and appreciation to all staff members, whose reviews reflected a generally thorough depiction of the Board and its activities.

Again, thank you for allowing the Board of Pharmacy to comment on the draft review. The Board looks forward to discussing the 15 recommendations when they are presented to the legislature during the upcoming session. If there are questions regarding the Board comments, please feel free to contact me at (410) 764-4794.

Respectfully,

LaVerne G. Naesea
Executive Director

CC: Michael Souranis, President, Maryland Board of Pharmacy
Joshua Sharfstein
Marie Grant
Mindy McConville
Patrick Dooley
Jennifer Ellick

Written Comments of the
Maryland Board of Pharmacy

Italicized language represents quotes from the report.

- In general the Board of Pharmacy supports all of the recommendations provided. Page 1, 4th paragraph – *Pharmacists dispense prescription drugs and advise patients, physicians and other health care practitioners on dosage selection as well as on potential interactions and side effects of medications.*

The Board notes that a distinction should be made between the pharmacists' role as consultants and advisors to health care practitioners and their health care practitioner roles of dispensing to patients and counseling them about medications, potential side effects and interactions between prescribed drugs.

- **Page 14, Recommendation 1** – ***Statute should be amended to remove the requirement that physician-pharmacist agreements and protocols be approved by the Board of Pharmacy and the Board of Physicians……***

The Board strongly supports this recommendation.

- **Page 15, 2nd & 3rd paragraphs** -***2nd …The practitioner must maintain a single form in the chart of each patient to whom prescription drugs are dispensed, such a form must at a minimum, indicate that a pharmacy is not conveniently available to the patient…and be signed and dated by the patient before any prescription drugs are dispensed to the patient…3rd…The Board --noting that the exception in current law…was initially intended only to provide patient access to prescription drugs in rural areas – has advised that regulatory and/or legislative changes are needed to (1) centralize the issuance of dispensing permits with the board …. and (2) authorize the board [of pharmacy] to enforce, with regard to other licensed health care providers that dispense….***

Since this requirement in paragraph 2 has not been generally followed, and therefore, 'conveniently located' has been defined for their patients by most dispensing practitioners instead; the Board of Pharmacy feels strongly that 'conveniently located' should be defined in standardized terms (e.g., mileage or patient accessibility to pharmacy services) in order to support the original intent of the law. Additionally, to ensure that all dispensing boards meet the same safety rules and standards, the Board of Pharmacy urges annual inspection monitoring of all authorized dispensers be required and enforced. (Currently only pharmacies are required to be inspected annually)

- **Page 16, last paragraph - …At a minimum, however, all of the relevant health occupations boards(along with DHMH) should work to ensure that all dispensing providers are complying with the same rules and safety standards….**

The Board strongly supports this recommendation.

- Page 22, Recommendation 4 - *…the board should report, for each full month following the [IT] system's implementation, the average wait time from the date of application to the date of registration (or rejection), as well as the effect (if any) of the system on the board's staffing needs.*

This recommendation may need to be amended to acknowledge the lag times related to the Board's receipt and review of criminal background reports that are of concern to the Board. The processing time will be significantly different for those applicants that have "clean" reports, because it will take a minimum of six weeks for the Licensing Committee review and make recommendation to be voted upon at the full Board meetings if a report is not "clean"."

- Page 23, 3rd paragraph – *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. Subsequently, it came to the board's attention that some surety bonds …were not made payable to the board, which could make it difficult for the board to recoup fines….*

Though this statement is partially correct, most staff were aware of the requirement for making the bonds payable to the Board. However, the majority of initial problem related to staff reviews of surety bonds related to the fact that staff did not recognize when some distributors who owned more than one distributor permit had attached copies of the same surety bond on multiple applications for different locations. The site names were the same, but the addresses were different, therefore requiring separate bonding. This also would have made it difficult for the board to have recouped fines, if required. This problem was corrected immediately upon discovery and has not been a processing concern subsequently.

- Page 29, Recommendation 7 – …the *board should seek reclassification of the compliance manager position from the Department of Budget and Management [DBM] to ensure that the compliance unit has more stable leadership and is led by a pharmacist.*

Recognizing the severe impact that the low starting salary (mid- $60,000), had on the retention of compliance officers at the Board, the Board was successful in 2010 in receiving approval from DBM to significantly raise the compliance officer's starting salary. Nonetheless, the Board supports this recommendation because the current starting salary for the compliance manager is still only equivalent to that of a new pharmacist graduate *with no experience* ($80,000 - $95,000), even though the Board position requires a pharmacist who has several years experience in administration, supervision and technical practice.

- Page 29, 1st full paragraph – *…an overwhelming preference for inspectors who are trained pharmacists was reported to DLS….concerns were raised as to whether pharmacy technicians can, with any level of on-the-job training, reach the level of expertise held by pharmacists and /or necessary to master the finer points of the inspection process.*

The Board requests clarification of whose "overwhelming preference" it was for inspectors to be pharmacists. The Board notes that a high majority of its customer satisfaction surveys, completed by pharmacists whose sites were inspected by pharmacy technician inspectors, rated the technician inspectors' performance as high. The survey did not suggest that there was dissatisfaction with the performance of pharmacy technician inspectors. Further, more problems have been identified and a greater number of formal disciplinary actions have been taken since the board's pharmacy technician inspectors assumed annual pharmacy inspections from DDC pharmacist inspectors. The board suggests that this may be a reason that some prefer pharmacists to perform inspections.

- Page 29, Recommendation 8 – *The Board should review the possibility of replacing at least some of its non-pharmacist inspectors with pharmacist inspectors (who could be used to conduct the board's most challenging inspections)…*

The Board notes that currently, the higher level and challenging inspections are performed by board pharmacists and that its pharmacy technician inspectors are trained by those same pharmacists. Also currently, the pharmacist inspectors and the full-time pharmacist compliance manager are assigned to review the reports and performance of all pharmacy technician inspectors.

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

The Board acknowledges the need for updating its web site regularly, but has not had the resources to do so. Contrary to the inference in the report that the board's recently staff member loss impacted updates to the Board web content, the board contends that it recognized and had unsuccessfully requested budget approval for a permanent web master/helpdesk position for three years prior to the loss of the referenced employee.

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

The Board notes that the technician and wholesale distributor databases were not designed or formatted in the same manner as the pharmacy and pharmacist databases when the two new programs began. Except for criminal background reviews and certain data entry aspects for pharmacy technician registrations and permitting wholesale distributors, board staff have been cross trained. Since, as noted in the report, the board will be moving to a new IT system in 2012, all licensing staff will be cross trained when the new system is implemented.