



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

*Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor –
Joshua M. Sharfstein, MD, Secretary*

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Lenna Israbian-Jamgochian, Board President - LaVerne G. Naesea, Executive Director

October 29, 2013

The Honorable Joan Carter Conway, Chair
Education, Health & Environmental Affairs Committee
Miller Senate Office Building, 2 West Wing
11 Bladen Street
Annapolis, MD 21401 - 1991

The Honorable Peter A. Hammen, Chair
House Health and Government Operations Committee
240 House Office Building
Annapolis, MD 21401

Dear Chair Carter Conway and Chair Hammen:

The Maryland Board of Pharmacy (the "Board") offers the attached report mandated by HB 283 State Board of Pharmacy – Sunset Extension and Revisions, Section 4, Chapter 658, 2012 on the implementation of non-statutory recommendations contained in the October 2011 Sunset Evaluation Report. The Board was asked to respond to recommendations related to five specific program areas related to the Board's operations and programs: (1) drug therapy management program; 2) pharmacy technician registrations; 3) the Pharmacists' Education and Advocacy Council (PEAC) contract; 4) implementation of the Board's IT system; and 5) its 5- year financial outlook. The Board is pleased to report the following:

- The legislative changes made to the drug therapy management program have significantly improved the application process and no delays have been experienced. No additional changes are required for this program area.
- Implementation of the Board's new on-line renewal system has accelerated the time to complete processing of pharmacy technician renewal applications. However, processing of new pharmacy technician applications ranges from 9 to 10 days. Implementation of a new component to process new applications *on-line* will further decrease the time to process new pharmacy technician applications. The report recommends several actions during the interim to reduce the time for processing all categories of new applications.
- The relationship with PEAC has substantially improved. However, the Board would like to allow other vendors to bid on the contract in the future to determine whether PEAC (the only eligible vendor under current law) is the most cost effective and best qualified service provider. Of course the Board would continue to require a pharmacist mentoring component for those who bid on the contract.
- Implementation of the Board's new IT system has been fraught with delays, glitches, and setbacks. System upgrades and other corrections over the past two months appear to have addressed most concerns. Some important system components, including the configuration of

the inspection form, could not be implemented during Phase I of the project because the contract ended. The report recommends that several steps be taken to address systems issues and meet the Board's current and future information processing needs.

- The Board's financial health appears very good through FY 2018. A caveat to this projection relates to whether the Board will be allowed to retain the funds currently in its fund balance that exceed the targeted 25% ¹. The report describes projected expenditures based on known operational expenses. Unfortunately, the impact of newly mandated program areas (including regulating sterile compounders) that have not yet begun make it difficult for the Board to accurately predict funding requirements. Therefore, an important recommendation included in the report is to allow the Board to retain its fund balance through FY 2016 when a better projection may be made.

Preparing this report allowed the Board and staff to review operations, refine efforts to meet current objectives and plan for future activities. The process also strengthened the Board's commitment to protecting Maryland's pharmacy patients through effective and efficient operations and funding management. A total of eighteen (18) recommendations were made in the report. They were:

1. Add additional staff resources to support application processing;
2. Add an additional on-line component for initial registrations;
3. E-mail confirmation notices upon receipt of applications to reduce telephone inquiries;
4. Upgrade the Board's telephone system to effectively respond to and direct phone calls;
5. Amend HO §12-317 to allow other rehabilitation providers that do not consist of a majority of pharmacist members, to bid on future contracts and to require any selected provider program to include a pharmacist mentoring component;
6. Continue to work with the IT vendor to correct systems issues and assure completion of the new project;
7. Continue to develop work-a-round solutions for the IT database (e.g., additional personnel, manual processing, etc.) to assure quality customer service and convenience;
8. Develop plans for initiating Phase II of the new IT system to include completion of the establishment on-line renewal systems, development of on-line application for new practitioners (pharmacists and technicians) and establishments (distributors and pharmacies), and configuration of the *E-mobile* inspection component;
9. Evaluate whether a second vendor for the IT system should be recruited to perform Phase II;
10. Evaluate whether a new vendor for the IT system should be recruited to implement the compliance inspection system;
11. Evaluate whether contract deliverables have been met by the existing IT vendor and whether legal remedies should be pursued;
12. Revise the Board's business rules, workflow, and procedure manuals to enhance customer service, standardize recordkeeping, and improve overall operations;

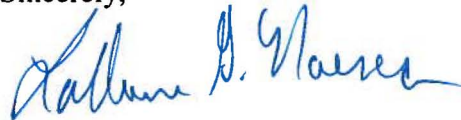
¹ Because of the several new program areas assigned to the Board since 2007, the Board has sought to maintain a 25% fund balance rather than the 20% noted by the Sunset Review analysts.

The Honorable Joan Carter Conway
The Honorable Peter A. Hammen
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13. Allow the Board to maintain its current and projected fund balance through FY 2016;
14. Approve the FY 2014 budget deficit requests and FY 2015 requested budget appropriation in order for the Board to meet existing and projected operating expenses;
15. Do not consider transferring funds from the Board's fund balance to the State General Fund until after FY 2016 ends;
16. Require the Board to report at the end of FY 2016 (October 1, 2017), whether projected expenditures and fund balances in Chart B on page 24 are accurate;
17. If the projected fund balance is greater than 10% of the Board's anticipated balance at the end of FY 2016, require the Board to reduce the fund balance by providing refunds to certain categories of licensees, reducing fees charged, and/or if required, reorganizing staff and operations; and
18. Base any future fund transfers on the effect on the Board over two years rather than one year.

Thank you for providing an opportunity for the Board to examine the five program areas related to implementation of non-statutory recommendations contained in the ten-year Sunset Review Evaluation Report. If you have any questions or concerns regarding the report content please feel free to contact me or Anna D. Jeffers, Regulations and Legislation Manager, (410) 764-4794.

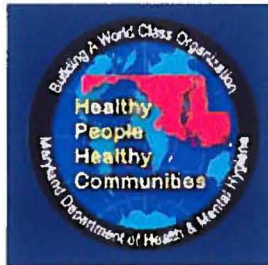
Sincerely,



LaVerne G. Naesea
Executive Director

Attachment

cc: Joshua M. Sharfstein, M.D., Secretary, Department of Health and Mental Hygiene
Marie Grant, Director, Office of Governmental Affairs, DHMH
Anna D. Jeffers, Legislative and Regulations Manager
Sarah Albert, MSAR# 9286



**MARYLAND BOARD OF PHARMACY
REPORT MANDATED BY HOUSE BILL 283
STATE BOARD OF PHARMACY – SUNSET
EXTENSION AND REVISIONS, SECTION 4,
CHAPTER 658, 2012,
TO
THE SENATE EDUCATION, HEALTH AND
ENVIRONMENTAL AFFAIRS AND HOUSE
HEALTH AND GOVERNMENT OPERATIONS
COMMITTEES

ON THE IMPLEMENTATION OF
NONSTATUTORY RECOMMENDATIONS
CONTAINED IN THE OCTOBER 2011 SUNSET
EVALUATION REPORT**

October 2013

**MARYLAND BOARD OF PHARMACY REPORT MANDATED BY
HOUSE BILL 283 STATE BOARD OF PHARMACY – SUNSET
EXTENSION AND REVISIONS, SECTION 4, CHAPTER 658, 2012,
TO
THE SENATE EDUCATION, HEALTH AND ENVIRONMENTAL
AFFAIRS AND THE HOUSE HEALTH AND GOVERNMENT
OPERATIONS COMMITTEES
ON THE IMPLEMENTATION OF NONSTATUTORY
RECOMMENDATIONS CONTAINED IN THE OCTOBER 2011 SUNSET
EVALUATION**

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Board of Pharmacy Staff

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

Executive Summary

This report responds to the General Assembly's request on the implementation of non-statutory recommendations contained in the October 2011 Sunset Evaluation Report and mandated by HB 283 State Board of Pharmacy – Sunset Extension and Revisions, Section 4, Chapter 658, 2012, required in accordance with § 2-1246 of the State Government Article. Specific information included addresses the following requested items:

(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;

The Sunset Legislation changes have significantly reduced the time that a patient must wait to be able to receive services under Drug Therapy Management (DTM) contracts. Joint approval of applications by the Board of Pharmacy and the Board of Physicians is no longer required, thus fostering improved relations between both boards. The average time for approving DTM agreements had been seven months. Now that approval by both Boards is no longer required, the participants may commence engagement in DTM agreements within 30 days of submission of their documentation. Both boards have entered into an agreement to facilitate submission of documentation to only the Board of Pharmacy and the two boards have agreed on review of basic information by the Board of Pharmacy with notification to the Board of Physicians as warranted. Since approval of the protocols and agreements are no longer required, applicants only submit required documentation. The impact from the Sunset Legislative changes has been very positive and processing applicant's agreements are now very rarely delayed.

(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;

Currently, the total number of pharmacy technician registrants is nearly 8,600. Each month the licensing staff processes approximately 250 renewals and 100 new registrations for pharmacy technicians. As a result of implementation of on-line renewal application services, the length of the renewal process for pharmacy technicians has been decreasing. The average timeframe for handling a hardcopy pharmacy technician license renewal takes about 3 business days and new pharmacy technician applications have begun to average 9 – 10 days from receipt to initial registration. The new computer system allows the licensing staff to accelerate the process. The licensing staff can now quickly review the applications and are able to complete the update within 1 business day.

To better support customer service needs for new pharmacy technician applicants and further decrease the time process for registering new applicants in Maryland, the Board recommends the following:

- 1. Add additional staff resources to support application processing;**
- 2. Add an additional on-line component for initial registrations;**

3. **Email confirmation notices upon receipt of applications to reduce telephone inquiries; and**
4. **Upgrade the Board's telephone system to effectively respond to and direct phone calls.**

(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;

The Board's contractual relationship with PEAC has improved following the several initiatives undertaken over the past two years. Although PEAC's pharmacist mentoring component has some value; it may not be the only determinant of whether the services provided are most effective in attracting, treating and reducing recidivism of impaired licensees. Some states have contracts with rehabilitation programs that are comprised of pharmacists, but not the vast majority.

The Board recommends amending HO §12-317 to allow other rehabilitation providers, that do not consist of a majority of pharmacist members, to bid on future contracts and to require that the selected provider's program include a pharmacist mentoring component.

(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

The implementation of the Board's IT system has not been without setbacks and ongoing problems. Several manual *work-a-rounds* have been put in place to address many of the reported concerns; however their implementation has not been without costs to the Board in terms of excessive use of staff time to perform manual processes, limited manpower resources that have created high volume backlogs, limited convenience to many licensees in their abilities to use the on-line features and/or submit timely renewals. Recommended next steps include the follow:

1. **Continue to work with the vendor to correct systems issues and assure completion of the new project;**
2. **Continue to develop work-a-round solutions (e.g., additional personnel, manual processing, etc.) to assure quality customer service and convenience;**
3. **Develop plans for initiating Phase II to include completion of the Establishment on-line renewal systems, development of on-line application for new practitioners (pharmacists and technicians) and establishments (distributors and pharmacies), and configuration of the *E-mobile* inspection component;**
4. **Evaluate whether a second vendor should be recruited to perform Phase II;**
5. **Evaluate whether a new vendor should be recruited to implement the compliance inspection system;**
6. **Evaluate whether contract deliverables have been met by the vendor and whether legal remedies should be pursued; and**
7. **Revise the Board's business rules, workflow, and procedure manuals to enhance customer service, standardize recordkeeping, and improve overall operations.**

(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.

The effect of the transfer of Board funds to State General Fund in FY 2010, 2011 and 2012, have minimally impacted the Board's financial health because projected revenue and expenditures for those three fiscal years did not come to fruition when expected. However, the need to fund activities projected between FY 2014 and the present still exist.

The Board has provided an analysis of its five year fiscal outlook based on many known factors. However the impact of new statutory mandates under the Board's authority cannot be determined. Given the demonstrated costs for current operations and known expenses over the next five years, as well as the unpredictability of costs for certain other programs and operations and related revenue, the Board feels that it would be reasonable to retain the fund balances as described in section 5 of this Report.

Along with the many new areas of responsibility in the past few years, Board and staff members have experienced difficulty in meeting performance standards for timely processing applications, completion of investigations and meeting other responsibilities necessary to assure patient safety and adequate customer service. To assure that Board performance standards for licensees and assuring compliance by those licensed, several recommendations are offered. They are:

- 1. Allow the Board to maintain its current and projected fund balance through FY 2016;**
- 2. Approve the FY 2014 budget deficit requests and FY 2015 requested budget appropriation in order for the Board to meet existing and projected operating expenses;**
- 3. Do not consider transferring funds from the Board's fund balance to the State General Fund until after FY 2016 ends;**
- 4. Require the Board to report at the end of FY 2016 (October 1, 2017), whether projected expenditures and fund balances in Chart B are accurate;**
- 5. If the projected fund balance is greater than 10% of the projected balance at the end of FY 2016, require the Board to take proactive steps to reduce the fund balance by providing refunds to certain categories of licensees, reducing fees charged, or if required reorganizing staff and operations; and**
- 6. Base any future fund transfers on the effect on the Board over two years rather than one year.**

Responding to the General Assembly request allowed the Board an opportunity to provide a full overview of the achievements and challenges faced in recent years. Acceptance of the report recommendations will ensure a healthy fiscal outlook, guarantee the Board's ability to streamline operations, address, meet customer/licensee demands, and meet its mandate to protect Maryland pharmacy patients. The Board thanks the Legislature for engaging with the Board of Pharmacy in extensive review of Board operations and taking steps to shore up its future.

DRUG THERAPY MANAGEMENT PROGRAM

(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.

Background:

House Bill 781 - Physicians and Pharmacists - Therapy Management Contracts, Chapter 249, passed during the 2002 legislative session to allow licensed physicians and pharmacists to enter into therapy management agreements that specified treatment protocols to be used in monitoring and providing care to patients. The agreements allow pharmacists to help manage a patient's medications in collaboration with a physician. The program was slated to terminate under House Bill 233, Chapter 650 (2008), but was ultimately made permanent under Senate Bill 165 and House Bill 600, Chapter 44 and 45 (2010). The Board of Physicians and the Board of Pharmacy jointly promulgate regulations to implement the Drug Therapy Management (DTM) program.

The original implementing regulations, COMAR 10.34.29.01 - .11, Drug Therapy Management, established a Joint Committee, consisting of representatives from the Board of Physicians and the Board of Pharmacy, to review and recommend actions by the respective Boards regarding approval of drug therapy management applications. The regulations detailed the requirements for approval of drug therapy management contracts and the overall approval process, including requiring submission of the pharmacist(s)' training credentials, the proposed DTM agreements, and related protocols for managing a patient's particular disease state.

During the preliminary Sunset Review of the Board in 2011, legislative analysts suggested that the DTM program has been underutilized for several reasons:

- 1) Statute and regulations outlining the DTM Program are lengthy and complex;
- 2) The application process is onerous and time consuming, with some agreements and protocols awaiting approval for years;
- 3) 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;
- 4) The 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; and
- 5) The requirement that physician-pharmacist agreements and individual drug protocols be approved by both boards appears inconsistent with similar agreements regulated by other health occupation boards and with the drug therapy management laws in other states.

Description of the Modifications

To increase participation and remove the onerous process required for initiating DTM agreements, HB 283, State Board of Pharmacy - Sunset Extension and Revisions, Chapter 658, 2012, removed the requirement that both Boards had to approve Drug Therapy Management Protocols and Physician-Pharmacist Agreements. Pursuant to the new statutory requirements, as amended by the Sunset Legislation, COMAR 10.34.29 Drug Therapy Management was revised and became effective April 15, 2013.

New Process for Establishing DTM Agreements

The Board of Pharmacy and the Board of Physicians entered into a memorandum of agreement so that the process for establishing DTM agreements under COMAR 10.34.29 will not be onerous. It entails the pharmacist(s) and physician that plan to engage in a DTM agreement submit required documentation only to the Board of Pharmacy. Acting as the agent for the Board of Physicians, the Board of Pharmacy confirms that the proposed physicians have active statuses and also reviews the pharmacist(s) active licensure status, training credentials, and qualifications to engage in the treatment protocols for the disease state(s) listed in the agreement. The Board of Pharmacy sends a letter to the application contact person within 30 days of receipt of the application, indicating any additional information or concerns of either Board or to advise that the DTM practice has been documented by both the Boards in accordance with COMAR 10.34.29.

Program Data:

Ten (10) physician-pharmacist agreements and protocols were approved before the revisions under the Sunset Legislation. Three new physician-pharmacist agreements and sets of protocols have been received since the Sunset Legislation passed and the regulations became effective April 15, 2013.

Impact of Changes:

The Sunset Legislation changes have significantly reduced the time that patients must wait to be able to receive services under DTM contracts. Joint approval of applications by the two Boards is no longer required, thus fostering improved relations between the Board of Pharmacy and Board of Physicians. The average time for approving DTM agreements had been seven months. Now that approval by both Boards is no longer required, the participants may commence engagement in DTM agreements within 30 days of submission of their documents. Since approval of the protocols and agreements are no longer required, applicants only submit required documentation. See the website link following for information. The application packet can be accessed from either Board's website at: <http://dhmh.maryland.gov/pharmacy/SitePages/pharmacist.aspx>

Legislative History:

- 2002 - House Bill 781 - Physicians and Pharmacists - Therapy Management Contracts, allows a licensed physician and a licensed pharmacist to enter into time-limited agreements to treat specific disease-states using approved protocols.
- HB 781 specified that the Board of Physicians and the Board of Pharmacy jointly promulgate regulations to implement the legislation within 6 months of October 1, 2002.
- 2003 - Due to unanticipated delays related to limited available staff resources during the 2003 legislative session, the regulations, COMAR 10.34.29.01 - .11, Drug Therapy Management, did not become effective until December 11, 2003.
- 2005 - Following a series of initial meetings between representatives on the Joint Committee, program review procedures were implemented and acceptance of applications began in January 2005.

- 2006 - The first application was approved in February 2006 and the University of Maryland School of Pharmacy was contracted to conduct the evaluation study beginning in April 2006.
- On October 1, 2006 the Board of Physicians and the Board of Pharmacy prepared a Drug Therapy Management Report to the General Assembly on the effect of the Act and their recommendations for legislative or regulatory action.
- 2007 - Based on the request from the University of Maryland, and the fact that the program was delayed two years and eight months before it was fully implemented, the Board of Pharmacy recommended and requested that legislation be introduced in the 2007 Legislative Session to extend the ending date of the Drug Therapy Management program from May 31, 2008 to October 1, 2010. The Board determined that it would be timelier to wait until the 2008 session to introduce legislation to extend the sunset date.
- 2008 - House Bill 233 - Physicians and Pharmacists - Therapy Management Contracts - Extension of Law, taking effect on June 1, 2008 and extending the Drug Therapy Management Program until September 30, 2010.
- 2010 - House Bill 600 – Health Occupations – Therapy Management Contracts – Repeal of Sunset, repealed the termination of the provisions of law relating to licensed physician–pharmacist agreements and physician–pharmacist therapy management contracts. Drug Therapy Management became a permanent program of the Board.
- 2012 - HB 283, State Board of Pharmacy - Sunset Extension and Revisions, passed removing “approval” by both Boards of Drug Therapy Management Protocols and Physician-Pharmacist Agreements.
- 2013 - Pursuant to the new statutory requirements, as amended by the Sunset Legislation, COMAR 10.34.29 Drug Therapy Management was revised and became effective April 15, 2013.

PHARMACY TECHNICIAN REGISTRATION PROCESS

(2) The Board's progress in further reduction of 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.

Background:

Registration for pharmacy technicians was established in FY 2007, which allowed the Board to better monitor previously unregulated pharmacy support personnel. Operationally, the changes resulted in a lengthy and labor-intensive applications review process that required up to six weeks for staff to register the hundreds of new pharmacist technicians. Many of the applications were not complete and were held on "open" status which added inefficiencies to the process. Despite notifying applicants of the need for additional information, they would call Board staff to inquire about the status of their submissions. In response, the Board introduced a policy of returning incomplete applications to applicants with a summary of what was missing. They were advised that they could reapply without paying an additional fee if done within a year of the original fee paid. This administrative change helped to decrease the length of the registration procedure, but not significantly.

The total number of new and renewal applications received at the Board had grown from an average of 7000 annually before the addition of pharmacy technicians and other categories (non-resident pharmacists, distributors, vaccines, repositories, etc.) to approximately 15,000. Except for pharmacists and pharmacy on-line renewals, the other categories of applicants were required to submit paper applications that staff reviewed and manually entered into several different ACCESS databases. This process was time-consuming and required significant staff resources.

Pharmacists and pharmacy technicians remain the largest categories. On average, the Board received 750 renewals and 500 new applications of all types monthly. This statistic did not include applications received during the distributor and pharmacy renewal periods. In order to further improve the licensing process, the Board began to implement a new information technology system (MIS) system to automate the registration process for pharmacy technicians and all other categories of licensees. The new system expanded on features in the old ACCESS database system to improve the workflow. Comprised of four components: EGov, Verifications, Mylicense Office (also known as MLO) and E-mobile, it was designed to allow pharmacists, technicians, pharmacies and distributors to renew on-line and submit payments in addition to other uses.

Overall, the implementation of this new system has helped expedite processing of renewals for pharmacy technicians, created a more efficient working environment, and improved communications between units. The on-line renewal feature for pharmacy technicians has helped reduce the amount of paperwork received and processed by Licensing Unit staff. Also, the establishment of a Verification page on the Board's website provided a platform for applicants and their employers to check registrants' application statuses on-line. This function helped reduce the volume of phone calls for status checking and allowed licensing staff to concentrate on other tasks without interruption. Another essential piece of the new system was that it enabled cross-viewing of registrants' records among different units. Data entry staff in the Licensing, Fiscal and Compliance Units were permitted to update, track and view all activities and

information about licensees so that there is better communication and reduces time lapses and processing of applications.

Outcomes:

After the implementation of the new system in October 2012, the staff experienced problems with the functionality of several of its features. This significantly impacted the normal processing and printing of licenses. Board staff was required to manually review and process licenses, and issue letters to all applicants to verify they were eligible to practice while they awaited their physical registration documents. Also, although the new system allowed Licensing Unit staff to be cross-trained on data entry for any application type, it created an extra data entry step by Board staff responsible for processing the Board’s mail. Initial progress in further reducing the length of the pharmacy technician registration process was slow. (See IT section of this report on page 16.) Since the system’s implementation it has taken no longer than three days to process applications for renewing pharmacy technicians. System glitches related to on-line payments are still being addressed. In a few cases, the upfront processing by the staff that process the mail has delayed the time it takes licensing staff to issue renewal registrations, but the average processing time has remained close to three days since November 2012.

In order for Licensing Unit staff to view and process a new pharmacy technician registrant’s application however, front desk personnel is now required to create an initial profile by entering applicants’ demographic information and payment information. It has taken up to several business days following receipt of a new pharmacy technician registrant’s application for the profile to be entered before it is forwarded for further processing by licensing staff. With minimum staff support at the front end, this additional workload tremendously backs up the process and prolongs the length of processing a new pharmacy technician registrant’s application at the Board.

The chart below reflects the average numbers of days per month that it has taken since the system was implemented, to process new pharmacy technician registrants applications, from the date the applications were received to the date the registrations were issued.

Processing time for New Pharmacy Technician Registrants’ Applications from Receipt at the Board until Issuance of a Registration

Month	Average Number of Days *
October 2012	46
November 2012	50
December 2012	55
January 2013	47
February 2013	42
March 2013	43
April 2013	28
May 2013	34
June 2013	33
July 2013	22
August 2013	9

Chart Explanation

The time to process on-line renewals has not been reported in this chart since the range has been from one to three days since November 2012. Also, since some new registrants' applications are immediately returned if they are incomplete or a response to a request for more information is slow, they have also not been included in the count. Some applications needed review by Board committees and then were forwarded to the full Board for a vote, which may have skewed the numbers of days per month slightly higher.

In November and December 2012, Board staff was able to print the registrations. However, staff was forced to do double work by inputting all applications in the system and issuing a license to applicants that had been manually processed the previous month. The last two months in 2012 also had numerous State holidays when the Board offices were closed. The backlog of mail, because of additional processing activities and holiday closings, caused staff to work overtime to ensure continuous processing of the backlog registrations.

Between January and March 2013, the Board had begun to "catch-up" from the holiday rush and worked diligently to process most new applications within four weeks. However, beginning in April through to June, two major events occurred: the number of new pharmacist applications received at the Board grew significantly due to three new Maryland pharmacy schools first graduations; and the distributor renewal period began March through May 31, 2013. As a consequence of system glitches, staff was required to manually process most of the applications for the distributors.

Manually processing the distributor renewal applications was given priority over the processing of pharmacy technician applications. The volume of graduate and distributor applications slowed in early July. This, along with the continuous work by the Board's MIS Unit to address system issues, enabled Board staff to begin again processing a new pharmacy technician registrant's application from three days to four weeks from date of receipt. During the month of August the time to process new registrant pharmacy technician applications dropped to an average of 9 days from receipt at the Board to issuance.

Conclusion and Recommendations:

Currently, the total number of pharmacy technician registrants is approximately 8,600. On average, 350 pharmacy technician renewals and 100 new registrant applications are received monthly. The new registrant volume is high because many individuals are still meeting qualifications to fill vacancies previously allowed to be met by unlicensed or registered personnel at pharmacies. Despite the length of time required to process a new pharmacy technician registrant's application, a promising result of the on-line system has been a reduction in time to process renewal applications (now ranging from 1 to 3 business days). In fact, Board staff can quickly process a significant number of renewal applications and update them often in 1 business day.

The Board feels it can continue the average of 9 days to process new technician applications, except during the heaviest renewal periods, (graduation periods, pharmacy and distributor renewal periods and holidays), when it may again increase to more than 30 days to process. Any further decrease in processing time for new pharmacy technician applications would be contingent upon acquiring additional processing staff and implementing a component in the new MIS system for applicants to submit new applications on-line.

To better meet customer service needs for new pharmacy technician applicants and further decrease the time required to process registering new applicants in Maryland, the Board recommends the following:

1. Add additional application processing staff resources to support application processing;
2. Add an additional on-line component for initial technician applicants to register (as well as all new categories of applicants);
3. Email confirmation notices upon receipt of applications to reduce telephone inquiries;
and
4. Upgrade the Board's telephone system to effectively respond to and direct phone calls.

PHARMACIST'S EDUCATION AND ADVOCACY COUNCIL (PEAC)

(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.

Background:

The Board of pharmacy is authorized under HO §12-317 to contract with a pharmacist rehabilitation committee to evaluate and provide assistance to any pharmacist or registered technician seeking assistance for alcoholism, drug abuse, chemical dependency or other physical, emotional or mental condition. If the Board elects to contract with a pharmacist rehabilitation committee, the statute requires that it consist of a majority of pharmacists. Presently only one entity in Maryland is eligible and contracted to meet this requirement; the Pharmacist Education and Advocacy Council (PEAC). PEAC is an education, referral and monitoring contractor comprised of an Executive Director, Program Coordinator, Treasurer, Counselor, Webmaster and volunteer pharmacist monitors.

History of Relationship between Board and PEAC

PEAC has been a sole source contractor with the Board for more than 15 years. Initial contracts with the provider included a link with the University of Maryland School of Pharmacy. However, ties between the school and PEAC were severed more than 12 years ago, and PEAC became an independent contractor. The program was subsequently moved from the pharmacy school grounds and administered from the Executive Director and Program Coordinator's home (these two staff are married). The move raised some concern by Board members regarding confidentiality and client access issues.

Up until FY 2007, the Board had contracted PEAC to monitor pharmacists under public Board orders and those who anonymously and voluntarily enrolled in the program through the use of volunteer pharmacist mentors. The program did not have professional mental health providers on staff and therefore provided treatment referrals. PEAC had also not been satisfactorily fulfilling all the conditions of their contract. Of greatest concern was the fact that PEAC had failed to report some clients under Board orders to the Board when the terms of their orders were violated. Other concerns were that some clients, if deemed financially able, were asked to pay out of pocket for PEAC services -- despite funding under the Board contract; limited documentation was submitted to demonstrate how contract funds were used; and PEAC had a very low rate of client enrollment, having never exceeded serving 15 clients -- including those mandated under public orders.

Along with the above Board concerns, other vendors who offered to provide direct client treatment, in addition to monitoring and mentoring services, had expressed interest in competing for the contract (including at the time, Sheppard Pratt and Spring Grove outpatient programs). Thus, during the 2007 legislative session, the Board proposed amending HO §12-317 (see HB 144) to allow providers who were not comprised of a majority of pharmacists, to bid on the contract. The amendment was eventually withdrawn following strong opposition from pharmacist stakeholders. Subsequently, the Board reduced PEAC's contract and began directly monitoring licensees under public Board orders. PEAC continued to serve volunteer anonymous

clients, although services did not significantly improve until after 2011 when the Board assigned two of its members as liaisons with PEAC. The assignment goal was to improve services, accountability, communications and the Board's overall relationship with PEAC.

Outcome of Board Actions:

PEAC now adheres to stringent fiscal and statistical reporting schedules, and requires all clients to sign contracts that require certain employment, drug screening, counseling and therapy requirements to be met. Additionally its pharmacist mentors visit licensees' employment sites (if they work) and monitor their substance abuse activities through receipt of routine drug screening (urine and saliva) reports from various labs. PEAC also reports to the Board when a client violates conditions set forth in their clients' contracts. Two clients were referred in 2012 and one in 2011, indicating compliance with this provision of the Board contract. PEAC also provides timely information for inclusion in the Board's annual report. Board liaisons working with PEAC have noted that there is also a need to review the continuity of monitoring and support to impaired licensees who were anonymously under contract with PEAC and following receipt of a Board public disciplinary order, switched to monitoring by the Board. The liaisons have suggested that the Board should evaluate whether all impaired licensees, volunteer and those under Board orders, should be served by the contracted rehabilitation committee.

Nonetheless, even after the Board began regulating pharmacy technicians and covering them under the PEAC contract, the highest number of clients ever served by PEAC in one month has been 26, with a current range in the number of clients of 16 – 20 per month. A study by McAuliffe, et. al. reported that 46 percent of pharmacists had used prescription drugs without a prescription. Sixty-two percent of pharmacy students surveyed had used a prescription drug with no prescription. Also, 20 percent of pharmacists reported they had used a prescription drug without a prescription at least five times or more in their lives.

It is fairly safe to assume that at least 10% of the more than 6000 pharmacists living in Maryland are, or have been confronted with alcohol or drug dependency. The Board would hope to reach through the contract more than .05% (30+) of the pharmacist population as well as a similar percentage (equivalent to 45) of the over 9000 pharmacy technicians in the State. PEAC attributes the low number of clients served to the fact that many of the practitioners' employers refer impaired practitioners to their internal employee assistance programs (EAP) or will terminate employees rather than risking patient harm or inventory loss.

Conclusion and Recommendations:

PEAC's pharmacist mentoring component has some value, however it may not be the only determinant of whether the services provided are most effective in attracting, treating and reducing recidivism of impaired licensees. Some states have contracts with rehabilitation programs that are comprised of pharmacists, but not the vast majority. Those programs do not consist of a majority of pharmacists. Programs do not consist of a majority of pharmacists have expressed an interest in bidding on the Board's rehabilitation contract. These programs are well established, have licensed medical and mental health workers on staff, and have attracted much higher numbers of impaired professionals seeking treatment.

The Board's contractual relationship with PEAC has improved following the several initiatives undertaken over the past two years. Unfortunately, the Board must reserve commenting on the effectiveness of the program, because it has not had an ability to compare PEAC's performance with other providers. Also, there has been little feedback from the clients PEAC served, and PEAC's ability to attract and serve a greater percentage of impaired pharmacists and pharmacy technicians is quite dismal.

Based on these finding the following recommendation is offered:

1. Amend HO §12-317 to allow other rehabilitation providers, that do not consist of a majority of pharmacist members, to bid on future contracts and to require that the selected provider's program include a pharmacist mentoring component.

IMPLEMENTATION OF IT SYSTEM

(4) The implementation of Board's IT system, including positive and negative outcomes, and the effect, of the IT system on the Board's staffing need.

Background:

The Sunset evaluation identified customer service lapses at the Board. The report indicated a need for the Board to improve public access and customer service, recommending that the board update its website regularly; cross-train staff on use of the board's new IT system; and standardizing its recordkeeping to reduce staff turnover (which had been impacting the Board's ability to maintain consistent and accurate data).

The Board anticipated an opportunity to address/respond to recommendations after its new IT system was implemented. The contract for the system entails installing four (4) components in a SQL database system:

Mylicense (aka MLO) – The back end component that would allow data entry staff (licensing, fiscal and compliance) to be cross-trained on entering, tracking and viewing all information about licensees;

Egov – A website application that would allow licensees to renew licenses, submit payments and change certain demographic information on-line;

Verifications – A website application that would allow any customer in the public to verify the status of licensees (e.g., active, suspended), certain demographic information, and the expiration of licenses or permits; and

E-mobile – An application that would allow field inspectors to enter inspection data and access the MyLicense data base to confirm licensee and permit holder statuses.

The new system was scheduled to be implemented in November 2011. It was expected to improve customer service and access, automated updates, standardize recordkeeping and enhance the Board's overall operations. As a result of several setbacks related to staff turnover and vendor delays, the new system was not implemented until October 2012. The contract with the vendor expired before configuration of certain components was completed. They included: E-Mobile and the pharmacy and distributor renewal applications in *MLO*. The vendor was not paid for these components.

Several system glitches in the components that were installed and configured continue to be addressed. Substantial backlogs in processing and entering application data forced the Board to seek temporary clerical staff to support manual processing¹. The Board's IT staff (MIS) has

¹ While the Licensing staff is no longer required to enter demographic data for initial applicants, the Board's mail clerk has a higher volume of data entry as a consequence of having to enter all new applicant demographics into the single system. This workload increase should subside once the Board implements on-line access for new applicants (Phase II).

focused most attention on correcting glitches in the activated Egov (on-line renewal system for pharmacists and technicians) and the Verification software.

Effect of Implementation of the New System on the Board's Staffing Need:

The MIS system is an off the shelf (COTS) application that required customization to reflect the Board's business rules, workflow and legal requirements.

Positive Outcomes:

The new system has several positive features that have enhanced Board operations. Specifically:

1. All Board units are able to review and share data in the integrated program/system. They are no longer dependent on synchronization of multiple, and separate, databases used in the previous Microsoft Access-based system.
2. The Board has greater system security and audit capabilities to determine which user performs an activity related to licensee files. It can now also authorize specific personnel to perform specific tasks;
3. Board Units now have the ability to flag licensees in order to alert all staff of issues related to actions (fines, bounced checks, delinquent taxes, etc.) and whether they have been addressed or are still pending;
4. Staff users are able to view flags (or "Hold/Alerts") for licensees and permit holders and know to check with Managers for clearance before continuing to process related documents;
5. The Board's new payment processor provides more detailed information about payments received and allows renewing licensees to submit payments on-line;
6. The system is capable of allowing custom reports to be accessed by Boards staff;
7. The new system provides users an ability to upload scanned documents and photographs into the system and link them to a specific licensee or permit holder; and
8. The public verification site, accessed through DHMH's SharePoint web portal is positively integrated with BOP's licensing database.

Negative Outcomes:

Since the pharmacist and technician on-line renewal systems (*Egov*) went "live", technical issues created more burden to the Board's MIS staff. The vendor has worked daily with the MIS staff to repair configuration tools, and transfer the necessary technical knowledge to MIS staff.² Problems experienced by Board staff and the license clients are also affected by these concerns.

Glitches in the MLO application caused licensees' responses to renewal application questions to be only partially visible to licensing staff, difficulty in viewing and confirming on-line payments, and similar problems. MIS staff were required to perform manual searches in the back-end of the data base system to retrieve information, export it and convert information to a viewable report formats before licensing staff could complete processing of some applications. At times receipts for on-line payments had to be manually retrieved and emailed to licensees.

² Once the repairs are addressed and technical knowledge transferred, MIS staff will be able to independently repair and customize system components.

Between April and May 2013, the Board manually entered and processed over 300 mailed-in distributor renewal applications, while still receiving training on the use of the new MIS to process on-line renewals through the system.³ Additionally, Unit staff members responded to over 100 phone calls and emails from distributor applicants daily.

Unrelated to the on-line renewal system, licensing staff was required to wait up to eight weeks for the receipt of federal criminal background results for non-resident distributor personnel⁴. To improve customer service, the Board voted to allow applicants that submitted otherwise complete applications to continue working under their expired permits until the Board received and completed review of the background reports. This action however also caused more strain on staff resources.

Use of the E-Mobile component during inspections took up to four hours because so many manual tasks were required. Most inspections had taken less than two hours to complete when using the access system. Ultimately, the inspectors resumed use of that and had to manually upload inspection reports into the new system. The *E-mobile* component must be configured to provide the functionality required for field inspections. This is an integral part of the Board's compliance enforcement. The Board is considering the purchase of software enhancements from a different vendor to correct this problem.

The vendor was contracted to deliver a completely functioning, SQL-based system that would successfully allow BOP to process on-line renewals. As noted, several manual *work-a-rounds* have been put in place to address many of the reported concerns; however their implementation has not been without costs to the Board in terms of excessive use of staff time to perform manual processes, limited manpower resources that led to high volume backlogs, inconveniences to some renewing licensees in accessing the on-line system or some of its features.

The MIS unit has been perpetually occupied with concerns related to the new system. In addition to providing daily user support as discussed previously, they have experienced continued frustrating issues which are summarized on the below grid:

Component	MyLicense Office (MLO)	
Date opened	Short Description of Issue	STATUS/ Date Expected resolution
2/6/2013	Facility renewals not setup in production.	Resolved: Sept. 2013
2/21/2013	Unable to custom-generate control numbers on printed licenses sequentially.	Resolved: Sept. 2013
3/15/2013	Often receive an error message when printing licenses in MLO	Resolved: Oct. 2013

³ This processing backlog was further compounded by a significant influx of new pharmacist applications mailed to the Board as a result graduating pharmacists from two new Maryland pharmacy schools (in addition to the usual number of pharmacist graduates. Also, non-resident pharmacists serving Maryland patients were required to be licensed by the Board October 1, 2012.

⁴ The Board began requiring distributor personnel to acquire criminal background checks in the state where their company is located rather than from Maryland. This resulted in their also having to also secure federal background checks through their home state agencies.

5/5/2013	FEIN in MLO doesn't match with actual Distributor FEIN	Resolved 5/13/13
5/7/2013	MLO: Removal of distributor renewals did not remove renewal fee from records	Resolved 5/23/13
5/16/2013	Not able to enter answers when doing paper renewals for facilities.	Resolved: Sept. 2013
7/23/2013	The on-line renewal question/answers were doubled on MLO.	Ongoing/Development:
7/31/2013	SQL errors accessing CHECKLIST TEMPLATES in MLO Setup Utility.	Resolved 8/6/13
8/6/2013	printing in TEST MLO is unavailable	Resolved 8/22/13
Component	eGov on-line application	
Date opened	Short Description of Issue	Date/Expected resolution
Oct 2012 & 1/22/2013	Renewal Questions not showing full answer text from eGov	Resolved: Sept. 2013
2/6/2013	Facility renewals not setup in PRODUCTION or TEST environment.	Resolved: Oct. 2013
11/8/2012 & 3/7/2013	Some on-line renewals get stuck in eGov and are not processed.	Pending close:monitoring
4/26/2013	Payment Processor in Test eGov not Working	Resolved 8/27/13
5/6/2013	FEIN in MLO doesn't match with actual Distributor FEIN	Resolved 5/13/13
5/16/2013	404 web page errors before and after making a payment on-line for some Distributors.	Resolved: Sept. 2013
Component	On-line Verification component	
Date opened	Short Description of Issue	Date/Expected resolution
2/15/2013	Unable to make changes in Verification application.	Resolved: Sept. 2013
Component	Mobile Inspection application	
Date opened	Short Description of Issue	Date/Expected resolution
Fall 2012	Problems with the sort order for our "Community Pharmacy" template for inspections.	Unresolved
Fall 2012	Mobile site is not configured in PRODUCTION	Unresolved
6/14/2013	Need technical support/admin documentation for Winmobile application	Unresolved

Conclusion and Recommendations:

The Board had expected the new MIS system to be completed in October 2012. It was only partially completed as a consequence of Board and vendor issues. The Board had anticipated services to customers to have improved. Most customers have expressed satisfaction with the ability to renew on line. However, some individuals and all establishments are not able to renew on line which has created quite an inconvenience. The Board expected more standardized recordkeeping and it has been standardized greatly for individual pharmacists and pharmacy technicians, though again, information collected from establishments by both the Licensing and Compliance Inspection Units, requires much work and has not seen any improvements.

Finally the Board anticipated its overall operations to improve as a result of the MIS implementation project. On many levels, operations have greatly improved. Many of the issues were resolved immediately prior to submission of this report. The remaining issues contribute to delays in processing a few on-line renewal applications, limit licensees' access to the *EGov* and *Verification* systems on the Board's website, and continue to interfere with the Board's ability to meet staffing and customer service goals.

The Board's business rules and workflow are in transition and have not been completely revised. There is much more work to be completed before the new system will enhance operations, improve customer service and stabilize staffing issues. A major cause for the many problems

experienced in implementing the system was the limited technical support available from the vendor immediately after the new system went into production. The vendor invested substantial staff resources to resolve the many issues discussed in this report beginning in February 2013. They attributed most problems with the *MLO* and *Verification* components to the need for systems upgrades that were developed after the Board's system went "live." However, the on-line renewal system for pharmacies and wholesale distributors, as well as, the E-mobile system component are of continued concern.

In July 2013, the vendor proposed a four-phased effort to update the new system and transfer technical and program user knowledge to Board staff. They are now working with Board users and MIS personnel on a project to: 1) document the Board's business rules and test the system functions; 2) install the upgrades to the *MLO* & *Egov* systems; 3) provide user training; and 4) transfer system knowledge to MIS staff so they are able to customize and configure system components, as needed.

The Board has also appointed a steering committee in August 2013 to monitor the progress of this critical project. The committee provides staff guidance and recommends actions. In addition, the Executive Director has been in continuous communications with the vendor's client services representative, while the MIS Manager has worked directly with the vendor's helpdesk technicians. The vendor has also been advised that the outcome of the Boards' project may impact their ability to contract for Phase II of the Board's project or secure future State contracts. The Board is also evaluating administrative or legal options it may take if the results of recent initiatives and the overall project outcomes are not positive.

Recommended next steps include the follow:

- 1. Continue to work with the vendor to correct systems issues and assure completion of the new project;**
- 2. Continue to develop work-a-round solutions (e.g., additional personnel, manual processing, etc.) to assure quality customer service and convenience;**
- 3. Develop plans for initiating Phase II to include completion of the configuration of the Establishment on-line renewal systems, development of on-line application for new practitioners (pharmacists and technicians) and establishments (distributors and pharmacies);**
- 4. Evaluate whether a second vendor should be recruited to perform Phase II;**
- 5. Evaluate whether a new vendor should be recruited to implement the *E-mobile* compliance inspection system;**
- 6. Evaluate whether contract deliverables have been met by the vendor and whether legal remedies should be pursued; and**
- 7. Revise the Board's business rules, workflow, and procedure manuals to enhance customer service, standardize recordkeeping, and improve overall operations.**

FIVE YEAR FINANCIAL OUTLOOK

(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 (BRFA) of 2009, 2010, 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.

A. Background

The Board was required, through the Budget Reconciliation and Financing Act (BRFA), to transfer to the general fund, \$98,544 in fiscal 2010, \$267,687 in fiscal 2011, and \$237,888 in fiscal 2012. The 2011 Sunset Review reported that despite the transfers, the Board's fund balance consistently remained above the recommended threshold for health occupation boards of its size. Because of the several new program areas assigned to the Board since 2007, the Board has sought to maintain a 25% fund balance rather than the 20% noted by the Sunset Review analysts.

The Board anticipated spending down the fund balance in FY 2012 and FY 2013 because it expected the amount of fees collected from wholesale distributors to decrease, implementation and maintenance costs for its new database system, and personnel costs required to meet the Board's expanded oversight authority. The Sunset Report noted that many of the Board's previous expenditures were one-time only. It also noted a steady growth in the number of licensee categories and predicted collected fees would affect the Board's ability to spend down to the recommended threshold.

The Board's current fund balance has remained above the targeted 25% threshold for several reasons that include:

- Changes in statutory requirements for wholesale distributors and other practitioner categories for which fees were collected that contributed to an overall increase in the number of licensees;
- Delays in fully completing the contracted scope of work for Phase I of the new database system, and in initiating Phase II and on-going maintenance contracts;
- Delays in the Board's physical move of offices from the first to the fifth floor that setback timing in contract negotiations for new building telephone and AV systems;
- Slow initiation of contract for initiating a major scanning project; and
- Delays in approval of personnel vacancies and recruitment of new personnel positions to support expanded Board operations.

This report presents the Board's projected 5 year financial outlook, as well as an assessment of its ability to maintain an adequate fund balance.

Statutory Changes:

HB 334/SB 132 - Jurisdiction Over Nonresident Pharmacies, Chapters 183 and 182 - HB 334/SB 132 passed during the 2012 legislative session required non-resident pharmacies to employ

at least one Maryland licensed pharmacist to dispense medications to Maryland patients in accordance with State laws. From January 2012 through the end of FY 2013, 548 non-resident pharmacist were issued Maryland licenses resulting in additional non-projected revenue.

SB 133/HB 316 –State Board of Pharmacy - Wholesale Distributor Permits - Permit and Application Requirements, Chapters 462 and 463, 2012 - Wholesale Distributor legislation changed the biennial renewal dates for wholesale distributors (WSD) and pharmacies from the end of December to the end of May. This report presents the Board’s projected 5 year financial outlook, as well as an assessment of its ability to maintain an adequate fund balance.

The change was made to assure timely processing of applications and to better accommodate permit holders who had previously been required to renew during the holiday season. The WSD’s first renewal period under the statutory change ended in May 2013 and the first renewal period for pharmacies will end May 2014. The fees collected for WSDs will be used during FY 2014 and 2015 to support personnel, vehicles and other resources necessary for on-site inspections of in-state WSDs, and to contract with a vendor to inspect out-of-state WSD permit applicants.

SB133/HB 316 also began allowing manufacturers that distribute their own FDA-approved prescription devices to meet the same requirements as manufacturers that distribute their own prescription drugs. This allowance made it significantly less difficult for prescription device manufacturers to meet requirements in order to acquire Maryland WSD permits and unanticipated revenue received from over 200 new device manufacturers between FY 2012 and 2013.

HB 868 - Health Occupations - State Board of Pharmacy - Waivers - Pharmacies That Only Dispense Devices, Chapter 393, 2013 - Following a change in federal law, many dispensers of prescription devices/DME became aware that they needed a Maryland pharmacy permit in order to dispense in Maryland. The Board was contacted by these entities to apply for a permit and also to request support for legislation that would waive the pharmacist requirement so that they could operate with existing personnel. The Board supported the request and following enactment, approximately 100 new prescription device/DME pharmacies applied for and were issued pharmacy permits. The increase resulted in unanticipated revenue in FY 2013.

Delays in Implementing Project Contracts:

Scanning Project

The Board will be relocating its offices from the first to the fifth floor in the next 3-6 months. The move was initially planned to take place at the end of FY 2013. The Board has a significant accumulation of files from over sixty years that may now be scanned into the new MIS system. To avoid the burden of moving files to the new location where there is not sufficient space for storage, the Board has initiated a scanning project that entails two phases. Five temporary employees were approved by the Department of Budget and Management to perform data entry, sorting, filing, and packing boxes for transport to State Archives between September 2013 and March 2014. The employees will cost an additional \$64,000. Part two of the plan entails contracting a scanning vendor to scan and catalog the documents into the MIS system. The Board received a price quote of \$288,094 from Maryland Works to scan over one million documents. (An additional 12,000 will be requested to address any related incidentals.) The project is underway, and 5 temporary employees have been recruited. The scanning contract is planned to begin no later than December 2013 (FY

14). The costs for this project, including other moving expenses were not included in the Board's 2014 appropriation.

MIS Project

The Board experienced significant delays that prevented the completion of Phase I implementation of its new SQL-based MIS system and a delay in initiating Phase II and entering into annual maintenance contracts. (See Section 4 of this Report.) The delays resulted in unspent contract funds that had been appropriated and delays in software purchases and other equipment. Funds will be required between FY 2014 and FY 2015 to complete the project and annual maintenance and upgrade contracts will need to be developed for subsequent years. If funds are not available when required, a budget deficit request will be made to transfer funds from the fund balance.

Other Contracts

In preparation for the office move to the fifth floor, the Board anticipated requiring funds to install new upgrades to the building's telephone and AV systems before the end of FY 2013. A firm estimate of cost for these projects cannot be provided because they will be shared among other Boards that will benefit from the upgrades. However, the Board expects that its share of the costs will exceed \$50,000, which was not included in the FY 2014 budget. If funds are not available when this amount is required, a budget deficit request will be made for a transfer from the fund balance.

Personnel Vacancies and Recruitment of New Personnel:

At the end of FY 2011, the Board experienced several high level position vacancies resulting in a surplus in this budgeted category. The vacancies were not filled until the second and third quarters of FY 2012 and one new position was approved late in FY 2012, resulting in increases to the fund balance. A few other periods of vacancies during FY 2013 added to the fund balance.

CHART A		Fund Balances with Approved Budget Allocation								
	<u>1</u> <u>FY</u>	<u>2</u> <u>Prior Balance</u> <u>(Carryover)</u>	<u>3</u> <u>Revenue</u>	<u>4</u> <u>Expenditures</u>	<u>5</u> <u>Fund Balance</u>	<u>6</u> <u>BRFA</u>	<u>7</u> <u>Fund</u> <u>Balance</u> <u>after BRFA</u>	<u>8</u> <u>%</u> <u>With</u> <u>Prior</u> <u>Bal.</u>	<u>9</u> <u>Fund</u> <u>Balance</u> <u>without Prior</u> <u>Balance</u> <u>(Carryover)</u>	<u>10</u> <u>Targeted</u> <u>25% without</u> <u>Prior</u> <u>Balance</u>
Actual	'07	\$1,090,227	\$1,612,082	\$1,716,620	\$985,688		\$985,688	57%	-\$104,539	-6%
Actual	'08	\$985,688	\$1,752,509	\$1,775,475	\$962,723		\$962,723	54%	-\$22,965	-1%
Actual	'09	\$962,723	\$2,241,441	\$2,277,950	\$926,215		\$926,215	41%	-\$36,509	-2%
Actual	'10	\$926,215	\$2,376,799	\$2,133,036	\$1,169,977	\$98,544	\$1,071,433	55%	\$243,763	11%
Actual	'11	\$1,071,433	\$3,210,246	\$2,522,902	\$1,758,777	\$267,687	\$1,491,090	70%	\$687,344	27%
Actual	'12	\$1,491,090	\$2,985,916	\$2,418,330	\$2,058,676	\$237,888	\$1,820,788	85%	\$567,586	23%
Actual	'13	\$1,820,788	\$3,713,014	\$2,700,653	\$2,833,149		\$2,833,149	105%	\$1,012,361	37%
Est.	'14	\$2,833,149	\$2,827,116	\$2,907,703	\$2,752,562		\$2,752,562	95%	-\$80,587	-3%
Est.	'15	\$2,752,562	\$3,750,025	\$2,907,703	\$3,594,884		\$3,594,884	124%	\$842,322	29%
Est.	'16	\$3,594,884	\$2,827,116	\$2,907,703	\$3,514,297		\$3,514,297	121%	-\$80,587	-3%
Est.	'17	\$3,514,297	\$3,700,025	\$2,907,703	\$4,306,619		\$4,306,619	148%	\$792,322	27%

B. Five Year Fiscal Outlook Based on Current Approved Budget (FY 2014 – FY 2018)

The Board’s annual fund balance increased as a result of circumstances described above. Chart A illustrates however that without the carryover balance the Board is operating well within the targeted fund balance – and well below the target balance in some years (see columns 9 and 10). Columns 2 and 3 also show that Board expenditures exceed projected revenues in fiscal years 2014, 2016, and 2018 – the years when distributors do not renew. Wholesale distributors are the largest category of licensees from which revenue is generated. This group renews in odd years (2013, 2015, and 2017). Chart A clearly **illustrates that any** consideration of transferring funds from the Board’s fund balance should be based on the effect over two years rather than one as has been done in the past. Chart A does not, however; include recently approved expenditures that are above the 2014 appropriation; nor does it include other expenditures requested to cover other projected operation activities needed in FY 2014 and subsequent fiscal years.

C. Five Year Outlook Based on Previously Unknown Fiscal Needs (FY 2014 – FY 2018)

Chart B reflects a more realistic picture of the Board’s five year outlook. The Board received approval after its FY 2014 appropriation for recruitment of 5 temporary employees to support the scanning project prior to relocation to new space (see Background section of this report). The scanning vendor contract, though not yet approved, also was not included the Board’s FY 2014 appropriation. The five-year revenue stream and expenditures projected in Chart B are based on the addition of recently mandated responsibilities, including regulating non-resident pharmacists, virtual manufactures, device distributors, sterile compounding facilities, and sterile drug product manufacturers. The mandate to regulate all sterile compounding facilities and sterile drug product manufacturers will become a reality, effective April 1, 2014. This new program area requires four new permanent staff to license, inspect, analyze adverse reports, and perform other functions compliance (investigate complaints, coordinate hearings, etc.).

CHART B Board of Pharmacy 5 Year Projected Financial Needs					
	FY 14	FY 15	FY 16	FY 17	FY 18
Fund Balance	2833149	2100323	2275465	1527698	17028404
Projected Revenue	2827116	3750025	2827116	3750025	2827116
Projected Expenditures	-3560208	-3574883	-3574883	-3574883	-3574883
Fund Balance	2100323	2275465	1527698	1702840	955073
% of Total Budget	59.00%	65.65%	42.73%	47.63%	26.72%

Perpetual backlogs in license processing, as well as significant increases in the number of open investigations related to consumer complaints, pharmacy and wholesale distributor inspections and technician and distributor criminal background reports, led to the Board's request for additional staff in its FY 2015 Budget submission. Additional staff requested includes a deputy director, administrative specialist, 2 licensing specialists, 2 compliance investigators, and an additional MIS specialist. These positions are needed to support supervision and oversight of a greatly expanded set of personnel; perform increase data entry since the implementation of the new MIS system (See Sections 2 and 4 of this report); and meet operational requirements related to expanded responsibilities. None of the aforementioned positions were included with projected expenditures in Chart A. Chart B reflects the projected costs for all permanent staff required between FY 2014 and FY 2018.

Other one-time and short-term expenses required for staff training, physically moving to the new location and implementing new telephone and other AV systems, to better serve customers and protect Maryland patients are reflected in Chart B. It is important to note that if all projected expenditures are made the Board's fund balance will be 26.72% in FY 2018. The fund balances projected in previous years, though greater than the recommended threshold, will prevent the need for the Board to increase fees for any license categories.

The final Chart C in this section provides details about the figures presented in Chart B for anticipated expenditures between FY 2014 and 2018. Requests for certain position upgrades, although not reflected in Chart B and C may also be made over the next five years. Those requests will be based on assessments of expanded technical skills, expertise and tasks required of certain personnel to perform more difficult and complicated activities related to the Board's expanded areas of responsibilities.

CHART C DESCRIPTION OF FIVE YEAR PROJECTED EXPENDITURES					
	FY 14 Approved Budget Allocation	FY 15 Budget Allocations Requested	FY 16 Projected Budget Allocation	FY 17 Projected Budget Allocation	FY 18 Projected Budget Allocation
FY 14 Approved Budget Allocation	2,907,703	2,907,703	2,907,703	2,907,703	2,907,703
5 Approved Temps (Scanning Pro.) See Note 1	64,360	0	0	0	0
Scanning Project See Note 2	288,094	0	0	0	0
Incidentals for Scanning Project See Note 2a	12,000	0	0	0	0
Requested New PINs (FY 2014) See Note 3	287,785	287,785	287,785	287,785	287,785
FY 2015 Requested PINs See Note 4		331,900	331,900	331,900	331,900
Additional PIN Request (FY 2015) See Note 5		47,495	47,495	47,495	47,495

Subtotal for Additional Staff/Projects	652,239	667,180	667,180	667,180	667,180
Total Projected Financial Need Note 6	3,559,942	3,574,883	3,574,883	3,574,883	3,574,883

FY 14 Current Allocation \$2,907,703 (Approved Appropriation)

Note 1: 5 Office Service Clerk temps Grade 8/Base @\$25,744/each - This expenditure is approved. Assuming that cost will be absorbed in the current budget allocation.

Note 2: The Scanning Project was not included in FY 14 budget and is currently not yet approved. A budget deficit for FY 14 includes this project.

Note 2a: Provides for any unexpected incidentals or cost overruns related to the scanning project.

Note 3: 2 Pharmacist III; 1 Lab Scientist Surveyor II; and 1 Office Service Clerk (Sterile Compounding) was not included in FY 14 budget however. A budget deficit for FY 14 to include these positions has been submitted for approval. The Board has also requested that these positions are added in proposed budgets in subsequent years

Note 4: New Positions for FY 15 - 1 APS specialist, 2 compliance investigators, 2 licensing specialists, and 1 deputy (pharmacist)

Note 5: Web Master Contractor (Grade 18/1) \$47,495 is not included in FY 15 budget request; will be added to FY 15 and subsequent years

Note 6: FY 16, 17 and 18 Projections based on FY 15 Budget Allocation Request

Conclusion and Recommendations:

The effect of the transfer of Board funds to State General Fund in FY 2010, 2011 and 2012, have minimally impacted the Board’s financial health because projected revenue and expenditures for those three fiscal years did not come to fruition when expected. In fact as discussed above, changes in statutory laws, the establishment fee collection periods, as well as contract delays and personnel vacancies actually added to the Board’s current fund balance. However, the need to fund activities projected between FY 2010 and the present still exist.

In this section the Board has provided an analysis of its five year fiscal outlook based on many known factors. However, it cannot precisely predict the five year fiscal outlook and future fund balances because the timing of fee collections and implementation of new Board mandates make it difficult to project current and future resource needs to support operations. For example, although fees proposed for sterile compounding facilities and sterile drug product manufacturers are hoped to meet all related expenses, they may be too high or too low. The Board based revenue projections on the issuance of 200 – 250 permits. If the number is greater, the Board may be required to purchase additional vehicles for inspections and investigations, or acquire other resources. Conversely, there may be a significantly lower number of applicants and less monitoring required than projected, eliminating the need for additional resources. Only after the compounding statute becomes effective, will the Board or State be able to adequately plan for the number of sterile compounding permit applications that will require processing, permits that will be issued, nor the number of investigations opened, and/or facilities that will require inspections and other monitoring.

Given the demonstrated costs for current operations and known expenses over the next five years (presented in Charts B and C), as well as the unpredictability of costs for certain other programs and operations and related revenue, the Board does not feel that it would be unreasonable to retain the fund balances reflected in Chart B.

Along with the many new areas of responsibility in the past few years, Board and staff members have experienced difficulty in meeting performance standards for timely processing applications, completion of investigations and meeting other responsibilities necessary to assure patient safety and adequate customer service. To assure that these goals may continue to be met over the next five years, several recommendations are offered. They are:

1. Allow the Board to maintain its current and projected fund balance through FY 2016;
2. Approve the FY 2014 budget deficit requests and FY 2015 requested budget appropriation in order for the Board to meet existing and projected operating expenses;
3. Require the Board to report at the end of FY 2016 (October 1, 2017), whether projected expenditures and fund balances in Chart B are accurate;
4. If the projected fund balance is greater than 10% of the projected balance at the end of FY 2016, require the Board to take proactive steps to reduce the fund balance by providing refunds to certain categories of licensees, reducing fees charged, or if required reorganizing staff and operations;
5. Do not consider transferring funds from the Board's fund balance to the State General Fund until after FY 2016 ends; and
6. Base any future fund transfers on the effect on the Board over two years rather than one year.

Acceptance of the Board's recommendations will assure a healthy fiscal outlook, guarantee the Board's ability to streamline operations, address, meet customer/licensee demands, and meet its mandate to protect Maryland pharmacy patients.

REPORT CONCLUSION

The Board has worked diligently to implement recommendations from the October 2011 Sunset Evaluation Report. This report addresses five areas set forth in HB 283 State Board of Pharmacy – Sunset Extension and Revisions, Section 4, Chapter 658, 2012, which required the Board to report on the implementation of nonstatutory recommendations contained in the October 2011 Sunset Evaluation Report on the Board. This report includes detailed explanations of the nonstatutory recommendations and detailed explanations of how the Board has addressed those nonstatutory recommendations. The five areas are summarized below.

Drug therapy management had been greatly simplified by the Sunset Legislation and the application time has been reduced significantly. No more lengthy, difficult to schedule, Joint Committee Meetings or frustrated applicants waiting up to 8 months or more to begin a drug therapy management program. Upon agreement between the Board of Physicians and the Board of Pharmacy, applicants submit their applications, protocols, agreements, and contracts to the Board of Pharmacy. Board of Pharmacy staff and a designated Board of Pharmacy member review pharmacist qualifications set forth in regulations, verify licensure of all participants, and notify the contact person within 30 days to begin the drug therapy management of patients.

The pharmacy technician registration process has been greatly reduced over the past few years. The Board has utilized a new computer system which has accelerated the process so that renewals now take about three days and new applications take about nine days. The process could be better and shorter if the Board is able to hire additional staff resources to support application processing. An on-line component for initial registration and an email confirmation notice are recommended to further expedite this process. Finally, an upgrade to the Board's telephone system to effectively respond to and direct phone calls which would benefit the licensing unit, as well as the other units of the Board.

The Pharmacists' Education and Advocacy Council (PEAC) has shown improvement over the past two years as the Board has assigned two of its members as liaisons with PEAC. The Board's concern is that other vendors may be more appropriate due to the availability of mental health and addiction counselors. PEAC consists only of pharmacists. Additionally, the statistics show that many more pharmacists or pharmacy technicians may need the addiction services of PEAC, but are not participating. The Board recommends amending Health Occupations Article, §12-317 to allow other rehabilitation providers, that do not consist of a majority of pharmacist members, to bid on future contracts and to require that the selected provider's program include a pharmacist mentoring component.

The Board's IT system is a necessary part of "doing business" as a licensing Board, but the current system has been fraught with setbacks and ongoing problems. These problems have resulted in high volume backlogs and limited convenience to licensees and Board staff. The IT unit has worked tirelessly to work around many of the system failures. The Board recommends continuing to work with the existing vendor to correct systems issues and assure completion of the project. This will result in the IT unit continuing to develop work-a-round solutions (e.g., additional personnel, manual processing, etc.) to assure quality customer service and convenience while developing plans for initiating Phase II to include completion of the Establishment on-line renewal systems, development of on-line application for new practitioners

(pharmacists and technicians) and establishments (distributors and pharmacies), and configuration of the *E-mobile* inspection component. The Board will be considering if it should evaluate whether a second vendor should be recruited to perform Phase II, or whether a new vendor should be recruited to implement the compliance inspection system. Unfortunately, the Board will also be considering whether contract deliverables have been met by the existing vendor and whether legal remedies should be pursued.

The Board has provided an analysis of its five year fiscal outlook based on many known factors. However the impact of new statutory mandates under the Board's authority cannot be determined. Given the demonstrated costs for current operations and known expenses over the next five years, as well as the unpredictability of costs for certain other programs and operations and related revenue, the Board feels that it would be reasonable to retain the fund balances as the need to fund activities projected between FY 2014 and the present still exist.

Along with the many new areas of responsibility in the past few years, Board and staff members have experienced difficulty in meeting performance standards for timely processing applications, completion of investigations and meeting other responsibilities necessary to assure patient safety and adequate customer service. To assure that Board performance standards for licensees and assuring compliance by those licensed, the Board recommends allowing it to maintain its current and projected fund balance through FY 2016. The Board recommends approving the FY 2014 budget deficit requests and FY 2015 requested budget appropriation in order for the Board to meet existing and projected operating expenses. To better evaluate whether projected expenditures and fund balances are accurate as set forth in Chart B, require the Board to report at the end of FY 2016 (October 1, 2017) when many of the new initiatives are in place. If the projected fund balance is greater than 10% of the projected balance at the end of FY 2016, require the Board to take proactive steps to reduce the fund balance by providing refunds to certain categories of licensees, reducing fees charged, or if required reorganizing staff and operations. The Board suggests not transferring funds from the Board's fund balance to the State General Fund until after FY 2016 ends. Finally, the Board recommends that in the future, fund balance transfers should be based on the effect on the Board over a two year period, rather than one year.

The Board would like to thank again the Department of Legislative Services for the thorough job evaluating the Board's purpose, processes, and effectiveness. The Maryland Board of Pharmacy, over the past 10 years has been at the forefront nationally on patient safety issues. The Board has passed comprehensive patient safety regulations; established drug therapy management for coordinated patient care; established administration of vaccines by pharmacists to provide greater accessibility for patients; implemented a prescription drug repository (take back) program; initiated pharmacy technician registration; revamped its wholesale distributor law as one of the most protective in the country; revised its sterile compounding regulations and inspection forms to incorporate USP 797 standards; required out of state pharmacies dispensing into Maryland to comply with Maryland law and have a Maryland licensed pharmacist on staff; worked to pass legislation that would apply the same dispensing requirements on all persons that dispense to Maryland patients; and in early 2014 will begin issuing sterile compounding permits which will again require staff to implement a new licensing category.

The Board has worked tirelessly, often on weekends, to implement the many new programs. This report shows, in detail, the work and dedication of the Board and its staff to protect the citizens of Maryland and the need to provide greater resources to continue those efforts.