Sunset Review: Evaluation of the State Board of Pharmacy

Department of Legislative Services
Office of Policy Analysis

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DEPARTMENT OF LEGISLATIVE SERVICES
OFFICE OF THE EXECUTIVE DIRECTOR
MARYLAND GENERAL ASSEMBLY

October 31, 2001

Karl S. Aro
Executive Director

The Honorable Thomas V. Mike Miller, Jr.
The Honorable Casper R. Taylor, Jr.
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 re-authorize them. This report was prepared to assist the Senate Education, Health, and Environmental Affairs and House Environmental Matters Committees, the committees designated to review the board, in making recommendations to the General Assembly. The board is scheduled to terminate on July 1, 2003.

Overall, the State Board of Pharmacy is well run. However, DLS makes a series of administrative recommendations to strengthen the operations of the board. Four statutory recommendations are also made. First, because the continued regulation of the pharmacy industry is essential to public protection, we recommend that the board's termination date be extended by ten years. Second, we recommend that the requirement to license pharmaceutical manufacturers be repealed. The federal government has strict regulatory oversight over drug manufacturers and State regulation, at this time, is not necessary. Third, we recommend the codification of the current practice of inspecting pharmacies on an annual basis. Fourth, we recommend limited discovery of self-reported medication errors to strengthen pharmacies' quality assurance programs and allow the board to track where errors occur. 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 members and staff throughout the review process. The board was provided a draft copy of the report for factual review and comment prior to its publication, and the board's written comments are included as an appendix to this report.

Sincerely,

Karl S. Aro
Executive Director

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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 on July 1, 2003. The board plays a significant role in regulating Maryland's pharmacy industry. DLS has found that the board is well run and performing its statutory requirements in a satisfactory manner. The findings and recommendations of this evaluation are summarized below.

There is a continued need for regulation by the State of the pharmacy industry.

Recommendation 1: The Board of Pharmacy should be continued, and the General Assembly should extend its termination date to July 1, 2013. In addition, uncodified language should be adopted requiring the board to report to the Senate Education, Health, and Environmental Affairs and House Environmental Matters Committees on or before October 1, 2002, on the implementation of the recommendations contained in this sunset evaluation report.

The board is currently examining whether it should develop different categories of pharmacy permits. Pharmacies may be classified by setting or specialty. Differentiating between pharmacy types would allow the board to customize regulation to suit a particular practice setting and its unique issues.

Recommendation 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 currently licenses pharmacists, pharmacies, drug distributors, and drug manufacturers. The U.S. Food and Drug Administration (FDA) extensively regulates drug manufacturers, and the board's involvement with manufacturers is negligible.

Recommendation 3: The General Assembly should repeal the requirement for State manufacturing permits.

Many areas of the country are currently experiencing a pharmacist shortage. The board is establishing a task force to examine the possibility of a shortage in Maryland.

Recommendation 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.

The Division of Drug Control (DDC) works with the board in conducting inspections of pharmacies, distributors, and manufacturers. While DDC conducts pharmacy inspections about once a year, as verified by an audit of inspection files, it does not conduct routine inspections of other permit holders. Current statute does not include any requirements for the frequency or timing of inspections.

Recommendation 5: The General Assembly should amend statute to codify the current practice of annual inspections of pharmacies.

The board relies on DDC to enforce compliance with board regulations through inspections. Regulations include basic

requirements for quality assurance systems as well as the training and supervision of unlicensed personnel. The focus of inspections is too narrow to assess compliance with these requirements.

Recommendation 6: The board and DDC should revise the inspection form and process so that inspectors assess: (1) the adequacy of quality assurance systems to ensure that all prescriptions are correct; and (2) the adequacy of training and supervision of unlicensed personnel working in pharmacies.

DDC inspection reports are on carbon-copy forms and kept in paper files. There is no database that keeps record of the frequency or outcome of inspections. If DDC or the board requires any inspection information, staff must search and compile information from the paper files. The outdated record keeping system severely limits the effectiveness of both the board and DDC.

Recommendation 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.

When investigating complaints against pharmacies or pharmacists, the board requests that an individual fill out a standardized complaint form. However, the form does not capture all the information needed for investigations. Recognizing that the problem with complaint forms could compromise the effectiveness of an investigation, the board is considering revising its complaint form.

The board currently conducts full disciplinary hearings on more serious complaints. These hearings can be quite time consuming. In recent years, several full board disciplinary hearings have required extensive time commitments from the board.

Recommendation 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 has contracted with the Pharmacists' Education and Assistance Committee (PEAC) since 1983 to provide rehabilitative services for pharmacists with substance abuse problems. In disciplinary cases where the board refers a licensee for treatment with PEAC, the company is responsible for keeping the board informed about a licensee's progress. The board may not always be receiving adequate information from PEAC in a timely manner. The board has made a first step by initiating a series of meetings with PEAC to improve reports to the board.

Recommendation 9: The board should assert its contractual authority with 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.

For the past several years, board revenues have not covered board expenditures. This shortfall approached almost $300,000 in fiscal 2001. The increase in the revenue-expense gap was driven by higher personnel expenditures. The board should shift resources to meet its workload needs; although reallocation would

not lower expenditures, it would slow growth in the budget.

Recommendation 10: The board should reallocate existing resources instead of adding positions unless there is sufficient justification for new positions.

In an effort to address a projected deficit in fiscal 2003, the board is considering raising fees in January 2003. The board must raise its fees to cover its costs and maintain a financial cushion of approximately 20 percent of the board's annual budget. The board projects the proposed fee increase would provide a surplus of $340,000 in fiscal 2003. However, the surplus fund balance would grow quickly, since the surplus in annual revenue is likely to continue. If revenue and expense trends remain relatively constant, the board's fund balance could increase to between $750,000 and $1 million within a few years. This level would far exceed the target level of 20 percent, or $250,000.

Recommendation 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 is in the process of implementing two sets of quality assurance regulations focused on addressing medication errors. The first set of quality assurance regulations requires pharmacies to implement a general quality assurance policy. However, the board needs legislative authority to shield licensees from legal discovery in an effort to make licensees self-report their medication errors. Self-reporting medication errors is crucial for the board, allowing it to analyze errors made in every part of the dispensing process and better implement regulatory solutions.

Recommendation 12: Statute should be amended to limit discovery to facilitate pharmacists in voluntarily tracking medication errors. The board should take timely action in implementing more stringent quality assurance measures to reduce medication errors. In addition, the board should continue to work closely with the Board of Nursing and BPQA in an effort to reduce medical errors in all phases of the dispensing process.

In an effort to facilitate quality health care delivery in Maryland, the board is currently examining collaborative practice agreements between prescribers and pharmacists. During the 2001 interim, the House Environmental Matters Committee formed a work group on drug therapy management and cooperative procedures comprising stakeholders, including the board and BPQA. The work group has been examining the issues of liability, privacy and confidentiality, the potential for inducement by health maintenance organizations to enter into collaborative practice agreements, and other issues. The board should continue to assess the advantages and disadvantages of using collaborative practice agreements in Maryland as well as the practical implications of regulating such agreements.

The board has been examining the implications of requiring certain unlicensed personnel, also known as pharmacy technicians, to be certified by the national Pharmacy Technician Certification Board (PTCB) in order to perform specific tasks. Requiring certification for pharmacy technicians would increase the level of health care services provided in pharmacies; however, required certification could also deter some individuals

from seeking jobs in pharmacies, further exacerbating any current pharmacist and pharmacy staff shortage.

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

Chapter 1. Introduction

The Sunset Review Process

The Maryland Program Evaluation Act, § 8-401 *et seq.* of the State Government Article, provides a system of periodic legislative review of the regulatory, licensing, and other governmental activities of various units of State government. The Act is informally referred to as the "sunset law" and the associated review process as "sunset review" or "sunset evaluation" because governmental units subject to the Act are usually scheduled to terminate unless affirmatively re-established by the General Assembly. The goal of the sunset review process is to promote accountability in government operations.

The State Board of Pharmacy is one of 68 entities currently subject to evaluation. The board last underwent a full evaluation as part of sunset review in 1991. The Legislative Policy Committee decides whether to waive an agency from full evaluation. A preliminary evaluation of the board conducted in 2000 recommended a full evaluation to assess complaint activity, the board's financial status, and regulatory issues.

This evaluation was undertaken to provide the General Assembly with additional information in making the determination about whether to reauthorize the board and for what period of time. Recommendations for improving the operations of the board and for statutory changes are made later in this document.

Research Activities

To complete this evaluation, staff of the Department of Legislative Services (DLS) engaged in extensive research activities, including:

- reviewing State statute and regulations regarding the pharmacy profession;
- interviewing board staff, board members, and staff of the Division of Drug Control (DDC);
- attending board and committee meetings;
- reviewing board and committee meeting minutes;
- visiting the board's offices to analyze administrative processes and procedures;
- auditing inspection and complaint files;

- analyzing license, financial, complaint, and inspection data;
- interviewing trade industry representatives; and
- conducting detailed research on the pharmacy profession.

Report Organization

This chapter provides an overview of the pharmacy profession, a description of the State Board of Pharmacy, a summary of the sunset review process, and a list of the research activities undertaken to complete this evaluation. **Chapter 2** contains an analysis of the board's operations and fiscal status. **Chapter 3** presents the findings and recommendations of the Department of Legislative Services. **Appendix 1** contains a roster of the current board membership and staff. **Appendix 2** contains draft legislation to implement the statutory recommendations in this report. **Appendix 3** contains a copy of the Division of Drug Control's pharmacy inspection form. **Appendix 4** contains the board's written response to a draft of this evaluation report. Appropriate factual corrections and clarifications have been made throughout the document.

The State Board of Pharmacy

The Board of Pharmacy's mission is to protect the public's health through the licensing and regulation of the pharmacy industry. As in other areas of health care, regulating the pharmacy industry is complex because of the involvement of other State and federal entities. At the State level, the board shares regulatory responsibilities with the Division of Drug Control, which is housed under the Laboratories Administration in the Department of Health and Mental Hygiene (DHMH). Both the board and the DDC work closely with two federal agencies: the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA). The FDA sets standards to protect public health and the DEA enforces federal statutes on controlled dangerous substances.

While there is some overlap between the board and other regulatory entities, the board retains the distinction as the only agency that licenses the members of the pharmacy industry. By holding the industry to quality standards, licensing plays a critical role in ensuring public health. In fact, licensing could become even more important since changes in the industry have made the public more vulnerable. Therefore, the board's regulatory role should be continued and perhaps even strengthened to protect public health adequately.

Recommendation 1: The Board of Pharmacy should be continued, and the General Assembly should extend its termination date to July 1, 2013. In addition, uncodified language should be adopted requiring the board to report to the Senate Education, Health, and Environmental Affairs and House Environmental Matters Committees on the implementation of the recommendations contained in this sunset evaluation report.

Along with 17 other health occupations boards, the Board of Pharmacy operates under the Office of the Secretary in DHMH. Although DHMH does provide administrative and policy support, almost all day-to-day activities are managed by the board and staff. The board consists of ten professional members and two consumer members. As outlined in statute, the professional members represent different segments of the industry, including independent pharmacies, chain pharmacies, hospitals, long-term care facilities, and home care.

Board members spend a great deal of time dedicated to board issues. This dedication can sometimes be difficult to maintain because most board members also hold full-time jobs. To reduce the strain on members, it is important that all board vacancies be filled. While there are no current vacancies, the Governor's office has delayed filling some vacancies in the past.

Staff consist of a total of nine permanent positions, three contractual positions, and one temporary position. Permanent positions include an executive director, a compliance officer and an assistant, a licensing coordinator, an information systems coordinator, a database specialist, a part-time legal advisor on regulatory issues, and office support personnel. Most staff have worked for the board for an extended period of time, which is unusual for many health occupations boards. With such tenure, the staff are able to provide a high level of support to board members.

The Changing Face of the Pharmacy Industry

Since the last full sunset review in 1991, the pharmacy industry has been transformed by the emerging dominance of managed care and rapidly evolving technology. Members of the industry have had to adapt quickly to new demands to survive in the changing market. Sometimes these adaptations have improved patient care, but some changes have compromised the quality of services. The result is an industry that is more complex and difficult to regulate.

The Role of the Pharmacy Industry in the Health Care System

The practice of pharmacy has been profoundly affected by systemic changes in health care. As managed care has become more common, the pharmacy industry has been faced with more scrutiny by the insurance companies. Complying with insurance restrictions requires extensive paperwork and coordination with health care providers. This task leaves less time for direct patient care.

Managed care has also led to new practice developments in other health occupations. For example, physicians have delegated some of their traditional prescriptive authority to physician assistants and nurses. Giving other health practitioners prescriptive authority provides increased flexibility to furnish better health care for consumers; however, it also creates verification problems for pharmacists who are expected to verify each prescription. Physician assistants and nurses do not have blanket prescriptive authority and are limited to prescribing only the drugs authorized by regulation and in their delegation agreement with the supervising physician. Pharmacists are responsible for ensuring that a particular health care practitioner has prescriptive authority as well as verifying the extent of that authority to prescribe specific drugs.

As health care delivery has become more complex, the issue of medical errors has come to the forefront. Recent studies have indicated that medical errors may result in 44,000 to 98,000 deaths in U.S. hospitals annually. Deaths from errors in the prescription and administration of medications may claim as many as 7,000 lives annually, exceeding the number of deaths attributed to workplace injuries. Medically induced injuries and death not only represent a major public health problem, but also result in mounting economic costs and a loss of trust in the medical profession.

Patient confidentiality is also a primary concern in all areas of health care delivery. Maryland has taken several steps to protect patient confidentiality, particularly medical records. In addition, on August 21, 1996, then President Bill Clinton signed into law the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In part, HIPAA regulates privacy requirements for all medical records and individually identifiable health information. The privacy requirements cover all medical records, whether in written or electronic form or communicated orally. HIPAA requires administrative, physical, and technological safeguards to ensure data integrity, confidentiality, and availability. Pharmacies will be required to conform to HIPAA confidentiality requirements by February 26, 2003, including making available a complaint process for customers who believe confidentiality requirements have been breached. The U.S. Department of Health and Human Services has final authority in dispute resolution and criminal prosecution.

Changes in the Pharmacy Profession

As the health care system evolves, the requirements of the pharmacy profession have also changed. There is a need for better trained individuals who can negotiate the complexity of the system and deliver a higher quality of health care. To meet this need, schools of pharmacy are transforming bachelor programs into a six-year track that will award a doctor of pharmacy, also known as a Pharm.D.

There are reports of a national shortage of pharmacists because growth in the profession has not kept pace with an increasing number of prescriptions. To fill in the gaps from the pharmacist shortage and to lower costs, pharmacies increasingly rely on support personnel, such as pharmacy technicians, to fill prescriptions. This shift may create greater risk to the public since support personnel do not always have adequate training. While some states have chosen to regulate support staff directly, other states, like Maryland, hold pharmacists responsible for the quality of support personnel.

Many states have enacted legislation to establish the use of collaborative practice agreements between physicians and pharmacists. These agreements permit pharmacists to increase their involvement in patient care and manage medication for certain patients, primarily for chronic illnesses like hypertension. If warranted, pharmacists may adjust a patient's prescription without a physician's order. This type of agreement increases access to care since pharmacists are more readily available than physicians. Legislation to authorize collaborative practice agreements was introduced in Maryland during the 1998 and 2001 sessions. However, concern over the appropriateness of expanding the pharmacist's role stalled the legislation, and the bills did not pass.

Changes in Technology

As in many other fields, the revolution in information technology has changed the way the pharmacy industry does business. The Internet has created opportunities to increase efficiency and improve consumers' access to care. Health care providers, pharmacies, and insurers can transmit prescription information electronically. This method can reduce paperwork and shorten the billing process, but it could also compromise patient confidentiality. Questions have arisen about the appropriate use of patient information to market medications as well as the security of data transmitted electronically. The HIPAA confidentiality standards require standardized formats for all data regarding medical records and individually identifiable health information, including insurance and payment information.

The Internet also permits ordering prescriptions online, creating new issues of prescription verification, drug integrity, and proper dispensing. While "Internet pharmacies" can improve consumer access to needed medications by offering both

convenience and in many cases lower prices, they increase the likelihood that some pharmacies may operate outside of laws or regulations.

Technological changes have also impacted how local pharmacies process prescriptions. Many pharmacies have turned to automation in an effort to increase efficiency and reduce overhead costs. Pharmacies often use interactive voice response (IVR) telephone systems that allow consumers and physicians to key in refill requests. In addition, both community and institutional pharmacies may use automated dispensing systems that can dispense bulk tablets and capsules and prepackaged medications and verify the accuracy of filled prescriptions. Some companies claim their dispensing systems can reduce medications errors; however, the new technology may also lead to different types of dispensing mistakes.

Chapter 2. Board Operations and Fiscal Status

Licensing Is the Core Function of the Board

Licensing is the core function of the board. With the authority to issue and revoke licenses, the board can enforce standards of care for the pharmacy industry. Thus, licensing allows the board to meet its statutory obligation to regulate and discipline the pharmacy industry.

There are four primary types of licenses and permits: pharmacist license, pharmacy permit, distributor permit, and manufacturer permit. The board also can issue a home hemodialysis distribution permit, although no one has applied for this permit in recent history.

Requirements for Pharmacist Licensure

To become licensed as a pharmacist, each applicant must meet the following requirements:

- have at least a bachelor's degree in pharmacy from a program accredited by the American Council on Pharmaceutical Education -- since most schools only offer a Pharm.D. program, new applicants usually exceed the licensing requirements for education;

- complete an internship; and

- pass the appropriate exams, including a knowledge-based exam developed by the National Association of Boards of Pharmacy (NABP); a federal and State law exam, also developed by NABP; a laboratory test developed by the board; and an oral English competency exam.

Under certain circumstances, the board is authorized to waive some of these requirements. If an applicant is a graduate of a foreign medical school, the board may waive the requirement that the applicant's program be accredited. Instead, the applicant must take an additional exam.

The board may also waive some requirements for an applicant who already has a pharmacist license from another state. Once the board verifies with NABP that the license is in good standing, the board requires the applicant to accomplish the following:

- provide evidence of at least 520 hours of pharmacy experience after graduating from an accredited program;

- pass an oral competency exam; and

- pass a written exam on Maryland law administered by the board. At the time of the preliminary review, the board was not in compliance with this requirement because the board merely offered a self-graded test after a seminar on Maryland law. Recognizing this problem, the board recently developed and implemented a graded exam for all reciprocity candidates.

Pharmacy Permits May Become Specialized

Pharmacies must meet the board's requirements for staffing, equipment, record-keeping, and prescription-filling procedures. The board monitors compliance with these requirements with regular inspections conducted by the Division of Drug Control (DDC). There is more discussion about the relationship between the board and DDC further in this analysis.

In addition to a permit from the board, pharmacies that handle controlled dangerous substances (CDS) must also obtain CDS permits from DDC and the U. S. Drug Enforcement Agency (DEA). DDC and DEA work in tandem to alert each other of any potential problems with CDS permit holders.

The board has held preliminary discussions on developing different categories of permits for pharmacies. Pharmacies may be classified by setting or specialty. Differentiating between types of pharmacies would allow the board to develop separate sets of regulations. Each set would be customized to suit the particular practice issues that exist in that setting or speciality. Currently, specialty pharmacies must apply for a waiver to opt out of regulations that apply to more general pharmacies.

As the board's discussions about differentiating pharmacy types continue, the board could become embroiled in concerns about reimbursement issues. Eligibility for third-party reimbursement sometimes depends on the pharmacy setting. Many individuals can only obtain insurance coverage for prescriptions in inpatient settings. Therefore, a pharmacy's revenue could be affected by how it was classified by the board. However, this kind of reimbursement issue is not central to the board's mission of public safety. Ensuring quality of care should be the board's primary consideration when considering the development of separate categories of permits.

The board expects to address the issue of pharmacy permit categories in the next two years. Other issues, such as medication errors and collaborative practice, have left the board with few resources to devote to the permit issue at this time.

Recommendation 2: The board should continue to examine the issue of establishing different types of pharmacy permits to improve the overall quality of care.

State Distributor Permits Are Required Under Federal Law

Distributors must comply with the board's regulations on storing drugs and maintaining distribution records. Permits are required for both in-state distributors and out-of-state distributors that ship to customers in Maryland. If the distributor handles controlled dangerous substances, the distributor must also obtain CDS permits from DDC and DEA.

State licensure is required by federal law for most distributors. The federal Prescription Drug Marketing Act of 1987 requires this licensure to enhance consumer protection. The board complies with federal law by setting standards for the storage and handling of drugs. These standards are codified in regulations.

Some distributors are also regulated by the U.S. Food and Drug Administration (FDA). If a distributor repackages any drugs, the FDA monitors the distributor's compliance with appropriate regulations. The FDA does not monitor distributors that ship drugs without any repackaging; they must only comply with State requirements.

State Regulation of Manufacturers Is Unnecessary

Manufacturers must meet statutory requirements to receive a permit from the board. The number of permits has doubled from 25 permits in 1992 to 52 permits in 2001. However, State statute on manufacturer's permits only establishes a broad outline of the requirements. The board has not elaborated on these requirements by issuing regulations.

Most permit holders also must obtain CDS permits from DDC and DEA because they handle controlled dangerous substances. In addition, manufacturers are heavily regulated by the FDA to ensure production quality. They must comply with an extensive set of guidelines that cover every aspect of the production process. To ensure that manufacturers are compliant, the FDA conducts an initial inspection when a plant opens, regular inspections about every two years, and an inspection when there is a problem.

manufacturers are compliant, the FDA conducts an initial inspection when a plant opens, regular inspections about every two years, and an inspection when there is a problem.

In contrast to the FDA's extensive regulatory program, the board's involvement with manufacturers is minimal. The board issues permits to manufacturers after the DDC has made an initial inspection. This inspection is mostly limited to determining if the manufacturing plant is clean and organized. The division and the board do not have the expertise to conduct a more in-depth review of production processes. Unless the board receives a complaint, the board does not initiate any subsequent inspections. Complaints about manufacturers are virtually nonexistent. Even if the board were to receive a complaint, the board might not have the ability to take action because State requirements are vague.

The board could strengthen its enforcement of existing statute by implementing extensive regulations and enhancing inspection efforts. To make these actions meaningful, the board and DDC would need to develop expertise in manufacturing processes. However, the FDA already devotes a tremendous amount of time, expertise, and resources to regulating manufacturers. It is unlikely that the board could contribute anything that is not already provided by the federal government. Therefore, the requirement for a State permit only adds an extraneous and unnecessary layer of regulation.

Although the number of manufacturers has increased, there is still no need for the extra layer of regulation. The number of permits still remains quite small and can be adequately monitored by federal regulators. Repealing the requirement for the State permit would have virtually no impact on the regulatory environment. It would also have almost no impact on the board, since the board dedicates limited resources to manufacturers. The only real change would be a decrease of about $15,000 in revenue from the permits, which the board could absorb.

Recommendation 3: The General Assembly should repeal the requirement for State manufacturing permits.

Board Is Efficient in Processing Licenses

All applications for licenses or permits are reviewed and approved by board members on the Licensing Committee. With the exception of reciprocity candidates, the committee makes the final decision about an application. Only applications for reciprocity are reviewed by the full board. The board and staff have a well-organized system to review all initial and renewal applications.

Processing initial applications is more time consuming because board staff must make sure all requirements are met. If the application is for a pharmacy, distributor, or manufacturer permit, the board requests that DDC inspect the location to ensure compliance with regulations and statute.

Processing renewal applications is less intensive since the board already scrutinized the licensees when they first submitted applications. Pharmacists must renew their licenses every two years, whereas pharmacies, distributors, and manufacturers must renew annually. The renewal process for pharmacists is the most time consuming because pharmacists must demonstrate that they have met the continuing education requirements of 30 credits in the two-year licensing period by listing their coursework. Staff conducts audits of about 10 percent of the applications to ensure that pharmacists have accurately reported their continuing education credits.

The renewal process may soon be improved by the use of electronic applications. The board plans to accept renewal application over the Internet sometime in fiscal 2002. Initial licensure and permit applications will still be processed on paper because of the need for original signatures.

The board has been aggressive in using the Internet to streamline other licensing-related functions. Staff has tracked the type of licensing questions received by phone, letter, or e-mail. If there is a frequently asked question, staff posts the information on the board's web page. This strategy has reduced the time that staff spends answering questions. Putting licensure verification information on the web page has also reduced staff time related to responding to verification questions.

Market Demands Drive Increase in Licensing

Over the past four years, there has been significant growth in all sectors of the pharmacy industry, as shown in **Exhibit 2.1**. In response to an increasing demand for prescriptions, the number of pharmacists and pharmacies has grown quickly at a respective rate of 20 percent and 16 percent. Growth has been even more dramatic in the manufacturing and distributing sectors with four-year increases of 73 percent and 108 percent. According to the board, the reasons behind this growth are diverse. Some growth is likely the result of more biotechnology research and related drug development. Some also might be related to the board's increased aggressiveness in licensing out-of-state distributors.

Exhibit 2.1
Four-Year Growth in Licenses and Permits Held
FY 1998 - 2001

	1998	1999	2000	2001	4-Year Growth
Pharmacists	5,591	6,319	6,654	6,736	20%
Pharmacies	1,135	1,198	1,282	1,318	16%
Distributors	314	384	450	542	73%
Manufacturers	25	37	44	52	108%
Total	9,063	9,937	10,430	10,649	17%

Note: Fiscal 1998 to 2001 figures are actual.

Source: Board of Pharmacy

Board Investigates the Possible Pharmacist Shortage

Even though Exhibit 2.1 demonstrates growth of a number of pharmacists, anecdotal evidence suggests that there is a shortage of pharmacists in Maryland. This concern has been echoed on the national level by the U.S. Department of Health and Human Services (HHS). In a recent report titled *The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists*, HHS outlined the evidence of a national pharmacist shortage. There are not enough pharmacists to meet market demands. The growth in the number of prescriptions has outpaced growth in the pharmacy profession. The result may be a lower quality of care because pharmacists have less time to ensure that prescriptions are filled correctly and that the consumer understands how to take medications.

To examine the possibility of a shortage in Maryland, the board is establishing a task force. With representatives from the board, the industry, and academia, the task force will develop potential solutions to the problem. Before the task force takes this step, it should first assess the extent of the pharmacist shortage in Maryland, as research has focused on the national level.

Recommendation 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.

The Board Depends on the Division of Drug Control for Inspections

The Division of Drug Control has many roles within the Department of Health and Mental Hygiene (DHMH). Working with the Board of Pharmacy is one of its major responsibilities. However, DDC also interacts with other health occupations boards because of its responsibility to issue controlled dangerous substance permits. The permits are issued to health care facilities, physicians, dentists, and podiatrists.

The Board of Pharmacy is dependent on information provided by the Division of Drug Control in making licensing decisions about pharmacies, distributors, and manufacturers. Such vital information comes from DDC's initial and follow-up inspections of any permit holder. DDC is authorized to conduct these inspections under the Health Occupations Article, which gives the Secretary of DHMH discretion in delegating this responsibility.

DDC conducts initial inspections soon after an applicant requests a permit. To ensure continuing compliance with standards, DDC conducts follow-up inspections at pharmacies about once a year. This fact was verified by DLS through an audit of pharmacy inspection files. DDC does not conduct routine follow-up inspections of distributors or manufacturers.

Statute does not mandate routine inspections of any permit holders. Since DDC is already conducting annual inspections of pharmacies, there should be no additional cost to continue this practice; consequently, statute should be amended to require annual inspections of pharmacies. While it is inconsistent that DDC does not conduct routine inspections of any permit holders other than pharmacies, there is no strong evidence that other permit holders require routine inspections by the State, particularly since the DEA conducts periodic inspections of distributors and manufacturers.

Recommendation 5: The General Assembly should amend statute to codify the current practice of annual inspections of pharmacies.

Regulations Related to Pharmacy Inspections Are Vague

Inspections are the main tool to enforce compliance with regulations for pharmacies, distributors, and manufacturers. DDC inspectors use a checklist, developed in conjunction with the board, to evaluate all permit holders. However, this checklist

does not fully reflect the board's quality assurance mission. As shown in **Appendix 3**, the focus of the checklist is narrow, with an emphasis on requirements such as refrigerator temperature and the accuracy of posted pharmacy hours.

While inspectors should ensure that pharmacies are compliant with these types of requirements, inspectors should also assess the overall quality of care; moreover, given the level of concern about medication errors, the inspections should also focus on quality assurance. In 10.34.21.03 of the Code of Maryland Regulations (COMAR), the responsibilities for pharmacies related to quality assurance are outlined as follows:

- **Quality Assurance:** Establish written polices and procedures to ensure the safety and accuracy of the prescription process.

- **Unlicensed Personnel:** Pharmacies must ensure that unlicensed personnel receive appropriate training and maintain levels of competency.

Yet inspectors do not routinely evaluate the adequacy of quality assurance systems and the quality of unlicensed personnel -- the very issues most vital to protecting public health.

The board and DDC may assert that it is difficult to evaluate quality assurance systems and unlicensed personnel because the regulations are too vague. However, it is important for the board and DDC to begin to incorporate these requirements into the inspection process. The board may soon develop more specific regulations as part of efforts to address medication error and unlicensed personnel issues. When developing these regulations, the board should be mindful of how DDC could assess compliance with the regulations during inspections.

Recommendation 6: The board and DDC should revise the inspection form and process so that inspectors assess: (1) the adequacy of quality assurance systems to ensure that all prescriptions are correct; and (2) the adequacy of training and supervision of unlicensed personnel working in pharmacies.

Outdated Record Keeping for Inspections Limits Effectiveness

DDC operates almost entirely on paper. Inspection reports are on carbon-copy forms and kept in paper files. There is no database that keeps record of the frequency or outcome of inspections. If DDC or the board requires any inspection information, staff must search and compile information from the paper files.

The outdated record-keeping system severely limits the effectiveness of both the board and DDC. For example:

- Board staff do not have time to review the inspection reports that the division forwards each month. Therefore, it is likely that some violations fall through the cracks. These are probably not the most major violations because DDC does phone board staff when inspectors identify significant problems in the field. Nevertheless, minor violations may still require board attention. If inspection reports were placed on a database, the board could develop a system to track both major and minor violations.

- Inspectors in the field do not have access to historical inspection files. If an inspector identifies a problem, the inspector cannot easily determine if this problem has occurred before. It is important to understand the pattern of problems to assess the seriousness of a violation.

- The board and DDC do not have the ability to monitor and analyze trends in inspections. This information would be helpful in understanding how to improve regulation of the industry.

Developing a database to track pharmacy inspections would require significant resources. While the board could potentially contribute technical assistance and training, it is likely that general fund support would also be needed from DHMH.

Recommendation 7: DHMH should commit to the development of a pharmacy inspection database to be used jointly by DDC and the board.

The Critical Role of Disciplinary Authority in Protecting Public Health

The board uses its disciplinary authority to enforce regulations and statutes to protect the public's health. As with other health occupations boards, the board relies primarily on complaints from consumers to identify problems with licensees. The Division of Drug Control is another important source of information, as inspectors sometimes find problems while on routine inspections.

Complaints Increasing, Primarily Due to Customer Service Issues

Between fiscal 1996 and 2001, the number of complaints increased by 72 percent, as shown in **Exhibit 2.2**. It is not clear if this substantial increase is the result of more problems in the pharmacy industry or simply greater public awareness of the board's complaint process.

Exhibit 2.2
Trends in Complaints for the Board of Pharmacy
FY 1996 - 2001

Fiscal Year	Errors	Patient Confidentiality	Unprofessionalism	Other	Total
1996	31	1	15	29	76
1997	41	0	11	22	74
1998	36	4	16	71	127
1999	44	1	17	67	129
2000	51	4	16	45	116
2001	87	5	10	29	131

Note: Other includes controlled dangerous substance and continuing education violations.

Source: State Board of Pharmacy, DLS Preliminary Sunset Evaluation of the Board of Pharmacy

The board is very concerned about the growth in complaints related to dispensing errors, which have increased by 181 percent over the last six years. As discussed later in this analysis, the board is attempting to take a proactive approach by developing proposals for regulatory and statutory changes on medication error reporting.

It is difficult to identify all the causes of the increase in complaints because the board only tracks broad categories of complaints. However, the board staff and a Department of Legislative Services (DLS) review of complaint records suggest that much of the growth in complaints is driven by customer service issues. Consumers are more frequently complaining about wait times and insurance issues.

The board is in the process of refining the complaint tracking system by adding more complaint categories. The board expects to complete this process in fiscal 2002. The expanded number of categories will make it easier to analyze complaint trends. If resources permit, the board plans to place prior-year data in the new categories. This would allow the board to develop a better sense of complaint trends.

Complaint Form Needs to Be Revised

The complaint process begins when the board receives a complaint from the public or DDC. Members of the public who have complaints must file their complaints in writing by completing a standard form. This form requests basic information on the

complaint, but it may fail to solicit the more precise information needed for an investigation.

The problems with the complaint form may be most apparent with complaints about dispensing errors. On the complaint form, consumers are asked to tell the board about their problem with incorrectly dispensed medication. However, they are not asked to describe the drug that they were prescribed or the drug that was actually dispensed. If consumers have not kept the incorrectly dispensed drug, the board may have difficulty identifying which drug was dispensed because consumers do not always keep the incorrect medication. Recognizing that the problem with complaint forms might compromise the effectiveness of an investigation, the board is considering revising its complaint form. The board should revise the form; a better complaint form will improve the quality and efficiency of investigations.

Disciplinary Committee Reviews Complaints

Once the initial investigation is complete, board staff presents findings to the Disciplinary Committee. If the committee wants to proceed in investigating the complaint, members will often ask staff to gather more information. Occasionally the committee dismisses a complaint because it does not fall under the board's jurisdiction.

When gathering further evidence for the committee, staff conducts thorough investigations. After the evidence is presented, the committee discusses whether the complaint should be forwarded to the full board. Sometimes the committee decides to handle less serious complaints itself. The committee may only take informal actions such as sending letters of education or admonishment.

At the time of the preliminary evaluation, there was a concern about the consistency of the disciplinary process. There was no guarantee that similar cases would be reviewed by the same set of board members because the membership of the Disciplinary Committee changed constantly. However, the committee now has a stable set of members. Thus, the committee is able to be conscientious about precedents when making a decision about a case and disciplinary actions can be consistently applied.

Full Board Also Reviews Serious Complaints

When more serious complaints are sent to the full board, the board reviews the evidence and hears the concerns of the Disciplinary Committee. If the board finds that a complaint is valid, it may take either informal or formal action. For formal actions, the board refers the case to the Office of the Attorney General.

For the majority of cases referred to the attorney general, the licensee requests that the case be settled before the disciplinary hearing. The attorney general, the board, and the licensee must agree to the terms of any settlement agreement. These agreements require the licensee to meet certain conditions to retain or reinstate a license. These conditions usually require the board to monitor the licensee for some period of time.

If the involved parties do not enter into a settlement agreement, the full board must conduct a disciplinary hearing. These hearings can be quite time consuming if both the attorney general and the licensee have extensive evidence to present. Lengthy hearings impose a heavy burden on board members, as most must take time off from full-time jobs to attend. In recent years, several full board disciplinary hearings each year have required extensive time commitments from the board.

Recommendation 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.

Board Needs More Timely Information on Pharmacists Who Are Being Monitored for Substance Abuse Problems

When investigating complaints against pharmacists, the board sometimes encounters a licensee with a substance abuse problem. Since treatment of substance abuse is outside of the board's scope of expertise, statute allows the board to refer the individual to a Rehabilitation Committee. The board has used the services of the Pharmacists' Education and Assistance Committee (PEAC) since its establishment in 1983. PEAC is an independent organization, sponsored by the Maryland Pharmacists Association, the Maryland Society of Health Systems Pharmacists, and the University of Maryland School of Pharmacy.

In most disciplinary cases that involve substance abuse, the board suspends or puts the licensed pharmacist on probation. As part of the consent agreement between the licensee and the board, the licensee must comply with the treatment plan developed by PEAC. PEAC is responsible for keeping the board informed about the individual's progress. If the individual is successful in treatment, the board may consider reinstating the licensee or removing the individual from probation. If treatment is not successful, the board may consider appropriate actions, such as further restricting a pharmacist's practice or permanently revoking a license.

The terms of the relationship between the board and PEAC are outlined in a one-year renewable contract. For about $25,000 a year, PEAC has agreed to provide case

management services to pharmacists under consent agreements with the board. PEAC must report to the board in a timely manner when these individuals are non-compliant with treatment. However, most treatment documentation remains confidential.

Anecdotal evidence suggests that the board does not always receive adequate information from PEAC in a timely manner. This problem makes it difficult for the board to make decisions about modifying consent agreements. While it is difficult to document the extent of this problem, it appears as though it has been ongoing.

The problems between the board and PEAC are likely the result of differing perspectives on the role of PEAC. The board needs PEAC's assistance in protecting the public from impaired pharmacists, but PEAC may place more emphasis on helping the individual pharmacist. These differences need to be reconciled if there is to be a successful working relationship between the two organizations.

The board has made a first step in improving the working relationship by meeting with PEAC. The impact of meeting will be limited if the board is not willing to exercise its contractual authority. The contract outlines the board's requirements of PEAC. If the board needs to change or elaborate on those requirements, then the board is responsible for initiating a modification to the contract. If PEAC consistently does not meet the requirements of the contract, the board needs to consider issuing a request for proposals to other vendors. The board is in the second renewable period of the contract, running from April 2001 to March 2002, and may renew for up to one more period.

It is critical that the board receive adequate information from PEAC or any alternative vendor. The board cannot make decisions about disciplinary cases without knowing if the offending pharmacists are complying with treatment.

Recommendation 9: The board should assert its contractual authority with 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.

Expenditure Growth Has Outpaced Revenues

Board Should Consider Reallocation of Resources

The Board of Pharmacy became self-supporting in 1992 when the General Assembly established special funds for most of the health occupations boards. The board's special fund is supported entirely by fees collected from licensees. As shown in **Exhibit 2.3**, the revenue from fees has been less than expenses for a number of years. The board has been able to sustain these higher expenditures by drawing down from the board's fund balance. The fund balance consists of surplus revenues from prior years.

Exhibit 2.3
Fiscal History of the State Board of Pharmacy
FY 1998 - 2003

	1998	1999	2000	2001	2002	2003
Revenues	$683,153	$647,684	$742,681	$683,828	$779,834	$1,517,310
Total Expenditures	717,678	674,178	810,132	977,771	1,041,022	1,179,531
Direct Costs	590,895	553,278	688,890	821,955	921,004	988,550
Indirect Costs	126,783	120,900	121,242	155,816	120,018	190,981
Surplus/(Deficit)	($34,525)	($26,494)	($67,451)	($293,943)	($261,188)	$337,779

Notes: FY 1998 - 2001 figures are actual. FY 2002 figures are budgeted. FY 2003 figures are projected. FY 2003 figures only include an increase in the pharmacist renewal fee from $95 to $150.
Source: State Board of Pharmacy

The annual shortfall of revenue has become greater each year. Between fiscal 1998 and 2000, the shortfall was less than $100,000 each year. However, the shortfall jumped to almost $300,000 in fiscal 2001. The increase in the revenue-expense gap was driven by higher personnel expenditures. There was considerable growth in the budget because of new positions, cost-of-living adjustments, and the introduction of the new State salary plan. This growth trend has continued through the present fiscal year.

The board may be able to curb growth in expenditures and should focus on personnel expenses, since costs for permanent and contractual positions comprise more than 50 percent of the budget. With an increasing level of automation, the board may have less of a need for clerical support. As appropriate, the board could shift clerical resources to other board functions. It is likely that the board will need more support for regulatory and disciplinary activities in the near future.

While shifting resources would not actually lower expenditures, it would slow growth in the budget. The board has indicated that it will not ask for new positions in the fiscal 2003 budget cycle. However, the budget request will likely include additional funding for indirect costs, because of an increased reliance on the Office of the Attorney General.

Recommendation 10: The board should reallocate existing resources instead of adding positions unless there is sufficient justification for new positions.

Fee Increase Necessary but Not at Level Proposed by Board

Even if the board takes cost containment measures, annual expenditures will continue to exceed annual revenue. Until now, the board has been able to close the gap with monies from its fund balance. However, the fund balance will drop to $154,000 by the end of fiscal 2002, as demonstrated in **Exhibit 2.4**. This amount will not be enough to cover the fiscal 2003 shortfall in revenue, which will have reached an annual average of about $300,000 by that point. To address this upcoming deficit, the board has voted to raise fees in January 2003.

The board must raise its fees to cover its costs and maintain a financial cushion. This financial cushion should be about 20 percent of the annual budget. The board needs such a fund balance to cover unexpected litigation expenses, the cost of implementing legislative mandates, and inflationary increases in expenses. This target level was set by DHMH in a 1999 report to the chairmen of the budget committees.

Exhibit 2.4
State Board of Pharmacy: Financial Status

Fiscal 2002 Projected Fund Balance	
Balance Carried Forward from Fiscal 2001	$415,228
Revenue in Fiscal 2002	779,834
Total Available Revenue	1,195,062
Expenditures	1,041,022
Fund Balance at End of Fiscal 2002	$154,040
Fiscal 2003 Projected Fund Balance	
Anticipated Revenue	$1,517,310
Expenditures	1,179,531
Anticipated Fund Balance	$491,819

Note: Fiscal 2003 figures only include an increase in the pharmacist renewal fee from $95 to $150.

Source: State Board of Pharmacy

In its initial proposal, the board projected that the proposed fee increase would provide a surplus of almost $340,000 in fiscal 2003. This surplus would drive the fund

balance to almost $500,000. This fund balance would grow quickly, since the surplus in annual revenue is likely to continue. If revenue and expense trends remain relatively constant, it is not unreasonable to project a fund balance in the range of $750,000 to $1 million within a few years. This level would far exceed the target level of 20 percent, which is about $250,000.

The annual surplus and fund balance could have been higher than current projections because the board was planning to raise the pharmacist renewal fee by an additional $50, which would have taken the fee to $200. However, the board reversed its decision at its October meeting and now plans to increase the fee to $150 as originally proposed. A fee level of $150 was used in setting the board's budget.

With a large fund balance, the board would not be compliant with statute. The Pharmacy Act mandates that fees be related to the expenses of the board. If the board implements the proposed fee increase, annual revenues would surpass the board's funding needs.

Statute also mandates that fees be reasonable. **Exhibit 2.5** demonstrates that the board's proposed plan raises most fees between 50 percent and 100 percent. Some increase is reasonable, given that there has been considerable inflation since the board last raised fees in 1992. In fact, the board actually lowered the pharmacist fee in 1996. However, the large increases in the board's proposal could only be justified by a serious revenue shortfall. Since the financial projections demonstrate a significant revenue surplus, the increase in fees should be lowered.

Exhibit 2.5
Proposed Fee Schedule of the Board

	Current Fee	Proposed Fee
Pharmacist New	$50	$100
Pharmacist Renewal	$95	$150
Pharmacy New	$150	$300
Pharmacy Renewal	$150	$250
Distributor New/Renewal	$250	$500
Manufacturer New/Renewal	$250	$500

Source: State Board of Pharmacy

Recommendation 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.

Chapter 3. Impact of Recent Legislation and Regulatory Changes on the Board and the Pharmacy Industry

Legislation Has Addressed Changes in Industry

Keeping the statutes current is a difficult task, given the pace at which the pharmacy industry is changing. Since the last sunset review in 1991, the General Assembly has passed several significant pieces of legislation to assist in bringing the board up-to-date, as shown in **Exhibit 3.1**. Many bills have focused on reforming the board's structure so that it would be better able to meet regulatory challenges. In 1992, the General Assembly authorized a special fund be established so that the board could use licensing fees to support its operations. This fund gives the board considerable flexibility in managing its resources. In recognition of the changing workload of the board, the board was expanded from 8 to 12 members in 1997. Under the new structure, professional members must represent designated segments of the industry.

With a changing pharmacist workforce, the General Assembly has updated the licensing categories over several legislative sessions. In 1996, the legislature passed bills that outlined the circumstances under which reciprocity could be granted for pharmacists with out-of-state licenses as well as licensure requirements for foreign graduates. In 1997, the legislature approved a bill that updated much of the statute that authorizes the Board of Pharmacy. These updates include revising the definition of the practice of pharmacy, expanding the requirements for pharmacies, and establishing a permit for non-resident pharmacies.

To reflect the changing professional environment, several pieces of legislation have focused on specific regulatory issues as well as refining the board's disciplinary role. In 1997, the General Assembly passed a bill that specified when a pharmacist can refuse to fill a prescription as well as when pharmacists can refill a prescription without prior authorization from the prescribing provider. To help maintain the professionalism of pharmacists, the legislature authorized the board to develop a code of conduct for the industry and revised disciplinary proceedings. During the 2001 session, the legislature allowed the Department of Health and Mental Hygiene (DHMH) to impound and dispose of drugs or prescription records if they were abandoned or left unsecured by a pharmacy, manufacturer, distributor, or prescriber. In addition, DHMH may now impound drugs or prescription records if a permit holder or prescriber had unlawfully dispensed, distributed, manufactured, or administered controlled dangerous substances.

Exhibit 3.1
Impact of Recent Legislation on the Role of the Board of Pharmacy

Year	Chapter	Change
Structure of the Board		
1992	37	Established a special fund to support all board activities with licensing fees.
1992	433	Mandated that the Governor fill vacancies on the board within 60 days.
1992	434	Limited board members to serving two consecutive terms.
1995	380	Authorized special funds be used to support the Pharmacist Rehabilitation Committee.
1997	530	Expanded the board from 8 to 12 members, including ten professional and two consumer members; specified which segments of the industry the ten professional members should represent; and outlined the nomination and appointment process.
Licensing		
1992	37	Expanded requirements for distribution permit.
1996	390	Established circumstances under which the board may waive the requirements of the pharmacist license for individuals who are licensed in another state.
1996	511	Mandated that foreign graduates be given an exam in lieu of a degree from an accredited U.S. schools; required all graduates to take an oral competency exam.
1997	614	Updated the definition of the practice of pharmacy; expanded requirements for pharmacies, including having appropriate record keeping and technical equipment; and established non-resident pharmacy permit.
Regulatory/Disciplinary		
1992	311	Specified procedures which DHMH must use to determine when a generic drug may be substituted for a brand name.
1997	614	Specified when a pharmacist can refuse to fill a prescription; modified the circumstances under which pharmacists can refill a prescription without a written order.
1997	15	Authorized the board to adopt and enforce a code of conduct; revised disciplinary hearing and appeal procedures.
1998	125	Mandated written notice in medication shipments about what shipping circumstances would damage the drugs.
2000	169	Protected patient confidentiality by prohibiting certain types of information from being included on a prescription log.
2001	476	Authorized DHMH to issue an order of impoundment and immediately impound prescription or nonprescription drugs or prescription records.

Source: Laws of Maryland

Board Addresses Quality Control with New Regulations

The board has been aggressive in revising and issuing regulations to improve the quality and efficiency of health care delivery. Regulations since the last sunset review have addressed issues such as automated dispensing machines, labeling of prescriptions, and record keeping. As outlined in **Exhibit 3.2**, the board has been particularly active in the past year. New regulations address recent changes in pharmacy practice, such as the increasing occurrence of pharmacies transferring prescriptions to other pharmacies, and the increased use of unlicensed personnel in community pharmacies. In addition, the regulations strengthen the board's oversight by requiring pharmacies that are closing to promptly report to the Division of Drug Control (DDC) and dispose of drugs in a specified manner.

Exhibit 3.2

Recent Regulatory Actions by the Board of Pharmacy

Year	Section	Change
2001	10.34.04	Outsourcing. Establishes the minimum procedures and requirements necessary that a pharmacist or pharmacy permit holder must follow when transferring or outsourcing a prescription or prescription order to a secondary pharmacy.
2001	10.34.14	Closing of Pharmacy. Outlines the procedure that must be followed when a pharmacy closes and delineates the responsibilities of the permit holder when closing a pharmacy.
2001	10.34.16	Portable Drug Kits. Establishes the requirements that must be met when portable drug kits are distributed in home health agencies, hospices, and residential services agencies.
2001	10.34.21	Standards of Practice for Unlicensed Personnel. Establishes minimum requirements that must be met by pharmacists and pharmacy permit holders when using unlicensed personnel in the prescription area.

Source: Code of Maryland Regulations, Board of Pharmacy

Board Is Proactive in Addressing Emerging Regulatory Issues

Quality Assurance and Medication Errors

As physicians increasingly rely on drug therapies to treat patients as a means to avert surgical treatments, concern about medication errors has increased dramatically. With more and more sophisticated and powerful drugs entering the market, medication errors can have severe, sometimes fatal, consequences. In 2000, the board created an internal task force to examine methods of reducing medication errors. The board focused on a systems approach to analyze the problem. This approach focuses on identifying any underlying system flaws in the dispensing process rather than targeting the individuals involved in making errors.

Medication errors occur at all phases of the dispensing process, from a physician's prescribing the wrong medication, to a pharmacist's dispensing the wrong medication or dosage, to a consumer's misunderstanding the instructions on the prescription label. As such, the reduction of medication errors requires a multi-disciplinary approach. The board has worked with the Board of Nursing and the Board of Physician Quality Assurance (BPQA) to identify flaws in the prescription process in an effort to reduce overall errors. The board determined that the most effective way to reduce medication errors is to educate pharmacists and consumers in methods that reduce mistakes and to implement a self-reporting system for pharmacists. Pharmacists would be required to track all medication errors so the board could identify systemic problems and implement regulatory oversight as needed.

Pharmacists are highly unlikely to track or report medication errors if reporting their mistakes subjects them to potential liability and malpractice claims. In an effort to encourage pharmacists to voluntarily report their medication errors to the board, the board is seeking statutory authority to shield self-reported medication errors from legal discovery. The board will not require pharmacists to self-report medication errors until the board has obtained statutory authority to limit discovery.

In an interim effort to reduce medication errors, the board has drafted proposed regulations that would require all pharmacies to implement a quality assurance program. The proposed regulations establish minimal requirements that a pharmacy permit holder must follow in order to reduce the potential for medication errors, including educating patients and pharmacy staff. However, the board needs statutory authority to limit discovery before it can effectively implement self-reporting.

In addition to focusing on self-reporting errors and increasing education efforts of pharmacy staff and consumers, the board has already addressed issues concerning the regulation and quality assurance of automated dispensing systems and is considering

requiring certification of unlicensed personnel. These measures will help address two of the areas where medication errors frequently occur.

Recommendation 12: Statute should be amended to limit discovery to facilitate pharmacists in voluntarily tracking medication errors. The board should take timely action in implementing more stringent quality assurance measures to reduce medication errors. In addition, the board should continue to work closely with the Board of Nursing and BPQA in an effort to reduce medical errors in all phases of the dispensing process.

Collaborative Practice Agreements

In an effort to facilitate quality health care delivery in Maryland, the board is currently examining collaborative practice agreements between prescribers and pharmacists. Collaborative practice agreements currently are permitted in approximately 30 states. In Maryland, similar arrangements already occur in closed health system settings such as hospitals, and recent legislation has sought to extend these types of agreements into community pharmacies. Other states impose various restrictions on collaborative practice agreements, including: (1) limiting pharmacists to increasing the number of refills only; (2) limiting agreements to hospital settings only; (3) permitting only "pharmacist clinicians" to enter into agreements; and (4) limiting pharmacists to either modifying or discontinuing existing prescriptions only.

Legislation to authorize collaborative practice agreements was first introduced in Maryland during the 1998 session. House Bill 1187 would have authorized a licensed pharmacist to enter into a collaborative practice agreement, approved by the board, with a licensed physician, licensed dentist, or licensed podiatrist to engage in drug therapy management. The bill specified the requirements necessary for approval and renewal of the collaborative practice agreement by the board and the conditions under which a pharmacist could provide drug therapy management. The bill, after amendments, failed the House's floor vote. In the 2001 session, Senate Bill 772 was introduced, with similar provisions to the 1998 bill. Aware of concerns about adequate record keeping, communication between prescriber and pharmacist, and obtaining informed consent from the consumer, the bill also contained a September 30, 2005, sunset date and required the board to report to the Governor and the General Assembly regarding the effect of the legislation, including recommendations for further legislative or regulatory action. The bill passed the Senate but was referred for interim study by the House Environmental Matters Committee.

During the 2001 interim, the Environmental Matters Committee formed a Work Group on Drug Therapy Management and Cooperative Procedures comprising stakeholders, including the board and BPQA, to work out concerns and prepare draft

legislation for the 2002 session. The work group has met four times and is currently looking at the issues of liability, privacy and confidentiality concerns, the potential for inducement by health maintenance organizations (HMOs) to enter into collaborative practice agreements, therapeutic substitution concerns, and the determination of appropriate disease states that would benefit from collaborative practice agreements.

These agreements offer obvious advantages in efficiently delivering health care to consumers. Particularly in chronic diseases, such as diabetes and high blood pressure, it is often the pharmacist who is first aware that an adjustment in drug therapy would be appropriate. In that instance, depending on the parameters for assessment and treatment changes established by the treating physician, dentist, or podiatrist, the pharmacist could adjust the dosage. However, certain practical aspects of implementing the agreements must be considered, including the extent to which a pharmacist can modify a physician's prescription, the board's ability to regulate adequate reporting and communication between physician and pharmacist, and the ability to obtain informed consent from a patient. In addition, the board must consider other issues raised by the agreements. For example, permitting a pharmacist to write or modify a prescription for a customer could pose a conflict of interest if the pharmacist stands to benefit financially from the prescription modification.

There is also the potential for HMOs and other managed care entities to abuse the use of collaborative practice agreements. HMOs may benefit greatly by implementing these agreements between their physicians and pharmacists and help deliver health care more efficiently to more patients. However, managed care settings may also inappropriately impose collaborative practice agreements on health care practitioners in an effort to reduce costs.

The board should continue to look at the advantages and disadvantages of using collaborative practice agreements in Maryland as well as the practical implications of regulating such agreements.

Pharmacy Technicians and Unlicensed Personnel -- Certification

As the number of prescriptions continues to increase dramatically, pharmacies are relying more on unlicensed personnel, also called pharmacy technicians. While some states have chosen to regulate support staff directly, other states, like Maryland, hold pharmacists responsible for the quality of support personnel. The board promulgated regulations last year that hold pharmacists and pharmacy permit holders liable for the acts of unlicensed personnel.

Approximately 25 states require specific educational or training standards for pharmacy technicians. The board is exploring the issue of certifying pharmacy

technicians in an effort to increase health care quality. At present, unlicensed personnel have very limited authority to complete many of the tasks necessary to fill a prescription. An unlicensed person cannot, for example, compound a prescription; receive oral orders for new prescriptions, refills for prescriptions containing controlled dangerous substances, or prescription transfers between pharmacies; or provide information to the public or a health care professional concerning prescription or non-prescription drugs or devices. In addition, an unlicensed person cannot be responsible for the pharmacy area in a store, requiring a pharmacist to be present at all times and to appropriately secure the pharmacy area when leaving.

The board is examining the implications of requiring certain unlicensed personnel to be certified by the national Pharmacy Technician Certification Board (PTCB) in order to perform specific tasks. Established in 1995 through the efforts of four pharmacy organizations -- the American Pharmaceutical Association, American Society of Health-System Pharmacists, Illinois Council of Health-System Pharmacists, and Michigan Pharmacists Association -- the PTCB has certified almost 100,000 pharmacy technicians in the past six years.

The PTCB certification examination applies to all practice settings, including retail and institutional. The certification exam tests an applicant's knowledge in three areas: (1) assisting the pharmacist in processing prescriptions and customer service; (2) maintaining medication and inventory control systems; and (3) administration and management of pharmacy practice. Once a pharmacy technician has passed the exam, he or she may use the designation of CPhT. To continue to hold certification, a CPhT is required to obtain 20 hours of continuing education for recertification every two years.

The board may require an individual to obtain PTCB certification in order to function as a pharmacy technician in Maryland. Unlicensed personnel who do not obtain certification may continue to assist the pharmacist with nontechnical duties, such as handling sales transactions.

Requiring certification for pharmacy technicians would increase the level of health care services provided in pharmacies; however, required certification could also deter some individuals from seeking jobs in pharmacies, further exacerbating the current pharmacist and pharmacy staff shortage.

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

Appendix 1. Board Membership and Staff

Board Members

Stanton G. Ades
President; Long Term Care Representative

W. Irving Lottier
Secretary; At-Large Representative

Melvin Rubin
Treasurer; Chair, Unlicensed Personnel Task Force; Independent Representative

Wayne Dyke
Chair, Licensing Committee; Chain Drug Store Representative

Jeanne Gilligan Furman
Chair, Disciplinary Committee; Acute Care Hospital Representative

Barbara Faltz-Jackson
Chair, Public Relations Committee; Consumer Representative

Raymond Love
Chair, Practice Committee; Acute Care Representative

Donald Yee
Chair, Medication Errors Task Force; Home Infusion/Care Rep.

John Balch
Independent Pharmacy Representative

Ramona McCarthy Hawkins
At-Large Representative

Rev. William E. Johnson, Sr.
Consumer Representative

Laura Schneider
Chain Drug Store Representative

Staff

LaVerne G. Naesea
Executive Director

Michelle Andoll
Pharmacy Compliance Officer

Tamarra Banks
Network Specialist

Shirley A. Costley
Fiscal/Personnel Officer

Vladimir Konstantinov
Database Specialist

James Slade
Legislative Officer

Joan Lawrence
Public Education Officer (contractual)

Dietra M. Gale
Compliance Specialist

Doris D. Thomas
Licensing Supervisor

Angela Hamlin
Board/Executive Secretary (contractual)

Sandra Hines
Administrative Secretary

Vacant
Licensing Secretary (contractual)

LaKeya Davis
Licensing Renewal Clerk (contractual)

Brenda Seaman
Data Entry Clerk (temp)

Appendix 2. Draft Legislation

2lr0688

Bill No.: _____

Requested: _____

Committee: _____

Drafted by: Cohen
Typed by: marion
Stored – 10/31/01
Proofread by _____
Checked by _____

By:

A BILL ENTITLED

AN ACT concerning

Health Occupations – State Board of Pharmacy – Sunset Extension

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 a certain requirement for a certain manufacturing permit and related provisions of law; making certain technical changes; requiring an annual inspection of each pharmacy that holds a pharmacy permit issued by the Board; limiting discovery by establishing that a certain committee or individual be considered a medical review committee; requiring that an evaluation of the Board and the statutes and regulations that relate to the Board be performed on or before a certain date; requiring the Board to submit a certain report to certain committees on or before a certain date; and generally relating to the State Board of Pharmacy.

BY repealing

Article – Health Occupations

Section 12–601

Annotated Code of Maryland

(2000 Replacement Volume and 2001 Supplement)

BY repealing and reenacting, without amendments,

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

Article – Health Occupations

Section 12–201 and 14–501(c) through (g)

Annotated Code of Maryland

(2000 Replacement Volume and 2001 Supplement)

BY repealing and reenacting, with amendments,

Article – Health Occupations

Section 12–101(g)(2) and (p)(2), 12–601.1, 12–604, 12–707(b), 12–802, and 14–501(b)

Annotated Code of Maryland

(2000 Replacement Volume and 2001 Supplement)

BY repealing and reenacting, without amendments,

Article – State Government

Section 8–403(a)

Annotated Code of Maryland

(1999 Replacement Volume and 2001 Supplement)

BY repealing and reenacting, with amendments,

Article – State Government

Section 8–403(b)(47)

Annotated Code of Maryland

(1999 Replacement Volume and 2001 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That Section(s) 12–601 of Article – Health Occupations of the Annotated Code of Maryland be repealed.

SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

Article – Health Occupations

12–101.

(g) (2) "Distribute" does not include the operations of a person who holds a permit issued under **[**§§ 12–601 and**]** § 12–602 of this title.

(p) (2) "Practice pharmacy" does not include the operations of a person who holds a permit issued under **[**§§ 12–601 and**]** § 12–602 of this title.

12–201.

There is a State Board of Pharmacy in the Department.

[12–601.1.**]** 12–601.

(a) Subject to the hearing provisions of § 12–315 of this title, for a violation of this subtitle or any regulation adopted under **[**§ 12–601 or**]** § 12–602 of this subtitle, the Board may:

(1) Deny a permit to an applicant;

(2) Reprimand a permit holder;

(3) Place a permit holder on probation; or

(4) Suspend or revoke a permit.

(b) A person aggrieved by a final action of the Board under this subtitle may not appeal to the Secretary or the Board of Review but may appeal as provided under Title 10, Subtitle 2 of the State Government Article.

12–604.

(a) The Secretary, the Board, or the agents of either, during business hours, may:

(1) Enter any place where drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, or toilet articles are manufactured, packaged, stocked,

or offered for sale; and

(2) Inspect the drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, and toilet articles there.

(b) ANY PHARMACY ISSUED A PERMIT BY THE BOARD AND SUBJECT TO INSPECTION UNDER SUBSECTION (A) OF THIS SECTION SHALL BE INSPECTED ANNUALLY.

(C) A person may not hinder an inspection conducted under this section.

12–707.

(b) A person who violates any provision of the following sections of this title is guilty of a misdemeanor and on conviction is subject to a fine not exceeding $1,000 or imprisonment not exceeding 1 year or both:

(1) **[**§ 12–601 ("Manufacturing and packaging");

(2)**]** § 12–602 ("Distribution permits");

[(3)**]** (2) § 12–701 ("Practicing pharmacy without license");

[(4)**]** (3) § 12–702 ("License obtained by false representation");

[(5)**]** (4) § 12–703 ("Operating a pharmacy without permit"); and

[(6)**]** (5) § 12–704 ("Misrepresentations").

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, **[**2003**]** 2013.

14–501.

(b) For purposes of this section, a medical review committee is:

(1) A regulatory board or agency established by State or federal law to

license, certify, or discipline any provider of health care;

(2) A committee of the Faculty or any of its component societies or a committee of any other professional society or association composed of providers of health care;

(3) A committee appointed by or established in a local health department for review purposes;

(4) A committee appointed by or established in the Maryland Institute for Emergency Medical Services Systems;

(5) A committee of the medical staff or other committee, including any risk management, credentialing, or utilization review committee established in accordance with § 19–319 of the Health – General Article, of a hospital, related institution, or alternative health care system, if the governing board of the hospital, related institution, or alternative health care system forms and approves the committee or approves the written bylaws under which the committee operates;

(6) A COMMITTEE OR INDIVIDUAL DESIGNATED BY THE HOLDER OF A PHARMACY PERMIT, AS DEFINED IN § 12–101 OF THIS ARTICLE, THAT PERFORMS THE FUNCTIONS LISTED IN SUBSECTION (C) OF THIS SECTION, AS PART OF A PHARMACY'S ONGOING QUALITY ASSURANCE PROGRAM;

(7) Any person, including a professional standard review organization, who contracts with an agency of this State or of the federal government to perform any of the functions listed in subsection (c) of this section;

[(7)**]** (8) Any person who contracts with a provider of health care to perform any of those functions listed in subsection (c) of this section that are limited to the review of services provided by the provider of health care;

[(8)**]** (9) An organization, established by the Maryland Hospital Association, Inc. and the Faculty, that contracts with a hospital, related institution, or alternative delivery system to:

(i) Assist in performing the functions listed in subsection (c) of this section; or

(ii) Assist a hospital in meeting the requirements of § 19–319(e) of the Health – General Article;

[(9)] (10) A committee appointed by or established in an accredited health occupations school;

[(10)] (11) An organization described under § 14–501.1 of this subtitle that contracts with a hospital, related institution, or health maintenance organization to:

(i) Assist in performing the functions listed in subsection (c) of this section; or

(ii) Assist a health maintenance organization in meeting the requirements of Title 19, Subtitle 7 of the Health – General Article, the National Committee for Quality Assurance (NCQA), or any other applicable credentialing law or regulation;

[(11)] (12) An accrediting organization as defined in § 14–501.1 of this subtitle; or

[(12)] (13) A Mortality Review Committee established under § 5–801 of the Health – General Article.

(c) For purposes of this section, a medical review committee:

(1) Evaluates and seeks to improve the quality of health care provided by providers of health care;

(2) Evaluates the need for and the level of performance of health care provided by providers of health care;

(3) Evaluates the qualifications, competence, and performance of providers of health care; or

(4) Evaluates and acts on matters that relate to the discipline of any provider of health care.

(d) (1) Except as otherwise provided in this section, the proceedings, records, and files of a medical review committee are not discoverable and are not admissible in evidence in any civil action.

(2) The proceedings, records, and files of a medical review committee are confidential and are not discoverable and are not admissible in evidence in any civil action arising out of matters that are being reviewed and evaluated by the medical review committee if requested by the following:

(i) The Department of Health and Mental Hygiene to ensure compliance with the provisions of § 19–319 of the Health – General Article;

(ii) A health maintenance organization to ensure compliance with the provisions of Title 19, Subtitle 7 of the Health – General Article and applicable regulations;

(iii) A health maintenance organization to ensure compliance with the National Committee for Quality Assurance (NCQA) credentialing requirements; or

(iv) An accrediting organization to ensure compliance with accreditation requirements or the procedures and policies of the accrediting organization.

(3) If the proceedings, records, and files of a medical review committee are requested by any person from any of the entities in paragraph (2) of this subsection:

(i) The person shall give the medical review committee notice by certified mail of the nature of the request and the medical review committee shall be granted a protective order preventing the release of its proceedings, records, and files; and

(ii) The entities listed in paragraph (2) of this subsection may not release any of the proceedings, records, and files of the medical review committee.

(e) Subsection (d)(1) of this section does not apply to:

(1) A civil action brought by a party to the proceedings of the medical review committee who claims to be aggrieved by the decision of the medical review committee; or

(2) Any record or document that is considered by the medical review committee and that otherwise would be subject to discovery and introduction into evidence in a civil trial.

(f) A person shall have the immunity from liability described under § 5–637 of the Courts and Judicial Proceedings Article for any action as a member of the medical review committee or for giving information to, participating in, or contributing to the function of the medical review committee.

(g) Notwithstanding this section, §§ 14–410 and 14–412 of this title apply to:

(1) The Board; and

(2) Any other entity, to the extent that it is acting in an investigatory capacity for the Board.

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:

(47) Pharmacy, State Board of (§ 12–201 of the Health Occupations Article: July 1, **[**2002**]** 2012);

SECTION 3. AND BE IT FURTHER ENACTED, That the State Board of Pharmacy shall report to the Senate Education, Health, and Environmental Affairs Committee and the House Environmental Matters Committee on or before October 1, 2002, in accordance with § 2–1246 of the State Government Article, on the implementation of the recommendations of the Department of Legislative Services contained in the sunset evaluation report dated October 2001.

SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2002.

Appendix 3. Pharmacy Inspection Form

STATE OF MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Division of Drug Control
Pharmacy Inspection Report

NOTICE: Failure to comply with any of the applicable provisions set forth in Article 27, Section 276-302, Annotated Code of Maryland; and/or Health General Title 21, Food, Drug, and Cosmetics, Subtitle 1, 2, 11, and 12, Annotated Code of Maryland; and/or Health Occupations Title 12, Pharmacists and Pharmacies, Subtitles 1, 2, 3, 4, 5, 6, 7, and 8, Annotated Code of Maryland; and/or Health General Title 22, Poisons and Child Resistant Packaging, Subtitles 2 and 3, Annotated Code of Maryland and/or Regulations thereof-- may subject you to civil proceedings by the Department of Health and Mental Hygiene and/or possible prosecution by the State's Attorney's Office; may lead to suspension or revocation of your Controlled Dangerous Substances Registration and/or appropriate action by the Maryland Board of Pharmacy. Consent of the owner, operator, or agent in charge to inspect the premises is granted to the drug inspector unless stated to the contrary.

Pharmacy Name:_____ Address:_____

City:_____ ZIP :_____ County:_____

Shopping Ctr.:_____ Fax No.:_____ Phone No:_____

Pharmacy Hours: Mon.-Fri.:_____ Sat.:_____ Sun.:_____ Hol.:_____

Inspection Date:_____ Arrival Time:_____ Departure Time: _____

DIVISION OF DRUG CONTROL

1. MD CDS Registration expires:_____
2. Fed. DEA Registration No.: _____ Exp.:_____
3. CDS Rx filing as req.: _____ File system _____
4. Red "C" used properly on Rx when req.
5. Federal "No Transfer" label for CDS Rxs with no less than 6-point type
6. CDS biennial inventory properly completed
7. Sch. III-V invoices dated & initialed when received
8. Who is authorized to sign Form 222
9. 3rd copy Form 222 properly completed and filled
10. Patient's address on CDS Rxs
11. Practitioner's address on CDS Rxs
12. Practitioner's DEA No. on CDS Rxs
13. Sch. II drugs disperse/lock & key
14. CDS orders for office use (Form 222)
15. Sch. II emergency procedure
16. Outdated products (holding, possession)
17. Misbranded products (holding, possession)
18. Pertinent label data not obstructed
19. Amphet/Methamphet dispensing procedure
20. Nitroglycerin dispensing
21. Refrig./protection of drugs from light, exposure, etc.
22. Safety closure utilized Yes _____ No _____
    a. Documentation if not desired by patient
23. Computer utilized Yes _____ No _____
    If yes, does system provide:
    a. Immed. retrieval of orig. Rx info.
    b. Documentation of pharmacist's verification that refill info is correct
    c. Printout of info. necessary for audit
    d. "Down-time" procedure for proper documentation of refills properly handled

MARYLAND BOARD OF PHARMACY

24. Current pharmacy permit posted conspicuously _____ Permit No. _____
25. Pharmacist's certificate of renewal available. List other pharms.
    Name: _____
    No.: _____ Exp.: _____
26. Required pharmacy equip. on hand
27. Running water available (hot & cold)
28. Pharmacy area clean, neat, well organized
29. Rx files maintained for 5 years
30. Required data on patient label
31. Service nursing homes, other facilities
32. Paraphernalia register correctly maintained
33. Rx presented more than 120 days after issue
34. Adequate Rx Dept. security
35. Rx pick-up after hours _____ Hours posted _____
    (Pharmacies inside other businesses)
36. Name of mfg. of generic substitute recorded on Rx
37. Name of mfg./distributor of generic substitute on label
38. Refrigerator/drugs only
39. Refrigerator temperature (36F-46F) _____
40. Current generic substitution info. available.
41. Rx Dept. enclosed & locked if pharmacist absent
42. Number of pharmacist on duty _____
    Number of support personnel on duty_____
43. Reference library _____
44. Owner: Pharmacist _____
    Non-pharmacist _____
45. Rx storage areas locked
46. Rx shelf items properly stored (59F-86F)
47. Dispensing date & pharmacist's initials on Rxs.
48. OBRA compliance: (a) screening, (b) counseling, (c) documentation
49. Prescriber's name printed, stamped or typed
50. Facsimile transmission
51. Pharmacist only receive telephone order for new Rx or refill authorization

Received by:_____ Inspected by:_____

Appendix 4. Written Comments of the State Board of Pharmacy

STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
4201 Patterson Avenue • Baltimore, Maryland 21215-2299
Parris N. Glendening, Governor - Georges C. Benjamin, M.D., Secretary

State Board of Pharmacy

October 29,2001

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 Draft Sunset Review Evaluation

Dear Mr. Deschenaux:

Thank you for the opportunity to comment on the draft Sunset Review. The board has read the review and attaches comments herewith. Comments are offered to ensure that the board operations and responsibilities are factually correct.

The board will continue to meet its commitments using the recommendations contained in the Sunset Review report as a guide. The board and staff want to thank Ms. Robyn Elliott and Susan Johns for their thorough review of its programs and activities. At all times they exhibited professionalism and expertise in analyzing some very complicated issues. Overall, the report is clearly written and accurately reflects the operations of the board.

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: Dr. Georges C. Benjamin
President Stanton Ades

410-764-4794 • Fax 410-358-9512 • TDD 800-542-4964
Toll Free 1-877-4MD-DHMH • TTY for Disabled - Maryland Relay Service 1-800-735-2258
Web Site: www.mdbop.com

Appendix 1. Written Comments of the **Maryland Board of Pharmacy**

Italicized language represents quotes from the report.

Page 3, 3rd paragraph under recommendation 1 – *Staff consist of a total of nine permanent positions and one or two contractual positions.*

Board staff currently consist of nine permanent positions, three contractual positions, and one temporary position. At the time of the legislative analysts' initial visit, Board staff consisted of nine permanent staff and four contractual positions, of which two were vacant. They were the Board Executive Secretary, and Licensing Secretary positions. The former position was filled in June 2001 and the latter position remains vacant, despite several trials to fill it. Also, since the analysts' initial visit, the Board identified a need for a data entry person that was filled by a temporary agency in June 2001.

Page 7, 2nd paragraph – *There has not been a demand for this type of [home hemodialysis distribution] permit because distributors of home hemodialysis products want to be licensed under the general distributor category.*

The home hemodialysis distribution permit and distributor permit are not interchangeable. The hemodialysis distribution permit would allow the holder to distribute directly to patients, while a general distributor permit limits distribution to authorized prescribers, establishments and facilities.

Page 10, 2nd full paragraph – *It is unlikely that the board could contribute anything that is not already provided by the federal government [in regulating manufacturers].*

Though the board's regulatory oversight of manufacturers is limited and much is conducted by the FDA, monitoring through the issuance of permits allows the Board to regulate activities related to repackaging, central fill and manufactures that do not need to have FDA registration.

Page 11, 3rd paragraph – *The renewal process may soon be improved by the use of electronic applications. The board plans to accept renewal applications over the Internet sometime in fiscal 2002.*

This information is correct, however the improvements (i.e., decreased staff requirements) will not be realized until after the Board has successfully promoted the idea of pharmacists renewing on-line. The Board anticipates that it will take at least two year s after the on-line system is in place before an impact on current staff resources is realized

Page 12, last paragraph – *To examine the possibility of a shortage in Maryland, the board is establishing an internal task force.*

At the time that the analysts interviewed the board, it was thought that an internal task force would be convened. Since that time, the board has met with the Department Secretary and determined that a task force, consisting of state appointed members will be convened. Therefore the task force, which will hold its first meeting in December 2001, will not be an 'internal' task force.

Page 14, Recommendation 6 – *The Board and DDC should revise the inspection form and process so that inspectors assess: (1) the adequacy or quality assurance systems to ensure that all prescriptions are correct; and (2) the adequacy of training and supervision of unlicensed personnel working in pharmacies.*

The board does not feel that it or DDC should prescribe and assess the adequacy of the content of quality assurance programs, since the programs may vary greatly based on the operational needs and systems in place at individual pharmacies. Rather, the board is interested in performance outcomes based on the facts that the quality assurance programs have been developed and are in continuous use. The board agrees that the inspection forms should be revised, but feel that they should query (1) whether a quality system has been implemented (2) whether it is regularly updated and (3) whether regular staff training is documented.

Page 15, Recommendation 7 – *DHMH should commit to the development of a pharmacy inspection database to be used jointly by DDC and the board.*

That board has been contacted by the Division of Drug Control to provide assistance in developing the database fields that will be placed in their new database system.

Page 18, Recommendation 8 – *If full board disciplinary hearings become more frequent, the board should consider using the services of the Office of Administrative Hearings. Because OAH charges could be considerable, the board should also consider seeking statutory changes needed to conduct disciplinary hearings with a subset of board members.*

At its September 12, 2001 meeting, the board considered similar recommendations presented by its Assistant Attorney General. The board decided to evaluate the costs associated with referring cases that are anticipated to proceed beyond one day to the OAH. Additionally, it is exploring the feasibility of conducting disciplinary hearings with a subset of board member.

Page 19, Recommendation 9 – *The board should assert its contractual authority with PEAC to ensure that it receives adequate information to monitor pharmacists referred to PEAC.*

The board agrees with this recommendation and has initiated steps to insure adequate monitoring by PEAC.

Page 20, Second paragraph – *The board may be able to curb growth in expenditures with an increasing level of automation the board may have less of a need for clerical support.*

The Board anticipates that it will take at least two year s after the on-line system is in place before an impact on current staff resources is realized. Also, if the board begins to register technicians as a result of addressing the shortage and unlicensed personnel issues, the workload may only be balanced out only by increased automation. Data entry requirements would increase since technicians are more transient and their status' are like to change often.

Page 21, Exhibit 2.4 *Balance carried Forward from Fiscal 1999...Fund Balance at End of Fiscal 2000.*

These balances should reflect those carried forward from 2001 and at the end of 2002, respectively.

Page 22, first full paragraph – *...the board is planning to raise the pharmacist renewal fee...from its current level of $95 to $200...*

The board reversed its decision at its October 15, 2001 board meeting and will only propose raising fees to $150 for pharmacists renewals.

Page 29, Recommendation 12 – *...The board should proceed with its plan to introduce legislation seeking limited discovery in order to facilitate pharmacists voluntarily reporting medication errors to the board.*

The board's plan is to introduce legislation that seeks protection of information collected from discovery. Also, the board will not have sufficient staff resources to receive and evaluate voluntary reports. It wants legislation in place that requires establishments to collect error related information as a part of their quality assurance programs. The board and DDC should have access to the data for review in relation to quality improvements only.

Last paragraph – *...the Environmental Matters Committee formed a Work Group on Drug Therapy Management and Cooperative Procedures...*

The Env. Matters Committee directed that the issue of drug therapy management be referred to the board for summer study. The board of pharmacy actually convened the work group and hosted the meetings.

Page 34, Appendix 1– *Board Staff list*

An updated list is attached.
