Joint Legislative Committee on Performance Evaluation and Expenditure Review (PEER)

Report to the Mississippi Legislature



A Review of the Board of Pharmacy

The Board of Pharmacy, created by the Legislature in 1916, licenses pharmacists and registers pharmacy technicians and pharmacy interns. The board issues permits to pharmaceutical wholesalers and other handlers of pharmaceuticals, regulates pharmacies and facilities that provide pharmaceutical products or services, and oversees administration of controlled substances. The board also cooperates with the Bureau of Narcotics, Drug Enforcement Administration, and state and local law enforcement agencies in investigating illegal use and distribution of pharmaceuticals. The board attempts to reduce risks to the public through licensure and enforcement.

The Board of Pharmacy's licensure process requires practitioners to meet specified minimum qualifications prior to licensure or registration. The board administers the application process and examines applicants for competency. However, the board's licensure process is compromised because the board has no formal, written criteria for screening applicants regarding their criminal histories. Also, although the board provides assurance to the public of applicants' competency to practice the profession of pharmacy by requiring passage of a validated national pharmacy examination, it cannot assure the public that its state examination sufficiently tests applicants' knowledge of state pharmacy laws and regulations.

The board's enforcement process includes inspecting pharmacies and related facilities to assure compliance with state pharmacy laws, rules, and regulations. The board also investigates complaints regarding practitioners' possible violations of state pharmacy laws, rules, and regulations and assesses penalties for violations. Due to problems with workload and staffing assignments, the Board of Pharmacy has only partially fulfilled its inspection responsibilities, an important component of its enforcement function. Also, the board's compliance agents, whose job description does not require them to perform law enforcement duties, carry firearms without a demonstrated need to do so.

PEER: The Mississippi Legislature's Oversight Agency

The Mississippi Legislature created the Joint Legislative Committee on Performance Evaluation and Expenditure Review (PEER Committee) by statute in 1973. A joint committee, the PEER Committee is composed of seven members of the House of Representatives appointed by the Speaker and seven members of the Senate appointed by the Lieutenant Governor. Appointments are made for four-year terms with one Senator and one Representative appointed from each of the U. S. Congressional Districts. Committee officers are elected by the membership with officers alternating annually between the two houses. All Committee actions by statute require a majority vote of four Representatives and four Senators voting in the affirmative.

Mississippi's constitution gives the Legislature broad power to conduct examinations and investigations. PEER is authorized by law to review any public entity, including contractors supported in whole or in part by public funds, and to address any issues that may require legislative action. PEER has statutory access to all state and local records and has subpoena power to compel testimony or the production of documents.

PEER provides a variety of services to the Legislature, including program evaluations, economy and efficiency reviews, financial audits, limited scope evaluations, fiscal notes, special investigations, briefings to individual legislators, testimony, and other governmental research and assistance. The Committee identifies inefficiency or ineffectiveness or a failure to accomplish legislative objectives, and makes recommendations for redefinition, redirection, redistribution and/or restructuring of Mississippi government. As directed by and subject to the prior approval of the PEER Committee, the Committee's professional staff executes audit and evaluation projects obtaining information and developing options for consideration by the Committee. The PEER Committee releases reports to the Legislature, Governor, Lieutenant Governor, and the agency examined.

The Committee assigns top priority to written requests from individual legislators and legislative committees. The Committee also considers PEER staff proposals and written requests from state officials and others.

PEER Committee Post Office Box 1204 Jackson, MS 39215-1204

(Tel.) 601-359-1226 (Fax) 601-359-1420 (Website) http://www.peer.state.ms.us

The Mississippi Legislature

Joint Committee on Performance Evaluation and Expenditure Review

PEER Committee

SENATORS LYNN POSEY Chair MERLE FLOWERS ROBERT (BUNKY) HUGGINS SAMPSON JACKSON DEAN KIRBY EZELL LEE RICHARD WHITE



Post Office Box 1204 Jackson, Mississippi 39215-1204

www.peer.state.ms.us

REPRESENTATIVES DIRK DEDEAUX Vice Chair ALYCE CLARKE Secretary WILLIE BAILEY JOEY HUDSON HARVEY MOSS WALTER ROBINSON RAY ROGERS

OFFICES: Woolfolk Building 501 North West Street, Suite 301-A Jackson, Mississippi 39201

TELEPHONE: (601) 359-1226

FAX: (601) 359-1457 Max K. Arinder, Ph.D. Executive Director

September 14, 2004

Honorable Haley Barbour, Governor Honorable Amy Tuck, Lieutenant Governor Honorable Billy McCoy, Speaker of the House Members of the Mississippi State Legislature

On September 14, 2004, the PEER Committee authorized release of the report entitled **A Review of the Board of Pharmacy.**

Senator Lynn Posey, Chair

This report does not recommend increased funding or additional staff.

Table of Contents

Letter of Transmittal		i
List of Exhibits		V
Executive Summary		vii
Introduction		1
Authority Scope and Purpo Method	se	1
Background		2
Authority and Re Organization and	rmacy Profession esponsibilities l Staffing penditures	2
Conclusions		8
Licensure Enforcement	rd of Pharmacy	
Recommendations		23
Appendix A:	Schedule of Narcotics and Controlled Substances in Mississippi	27
	Example of a Professional Code of Ethics from the Board of Registration for Professional Engineers and Land Surveyors	
Agency Response		

List of Exhibits

1.	Mississippi Pharmacy Inspection Regions with Workload, as of May 27, 20045
2.	FY 2004 Organization Chart for Board of Pharmacy
3.	Board of Pharmacy's Revenues and Expenditures for Fiscal Years 1999-2003
4.	PEER Analysis of the Board of Pharmacy's State Examination Procedures Compared to the Professional Testing Standards of the Council on Licensure, Enforcement and Regulation (CLEAR)14
5.	FY 1999-FY 2003 Growth in In-State Pharmacies, Other Providers, and Investigations with Corresponding Decrease in Number of Inspections

A Review of the Board of Pharmacy

Executive Summary

Introduction

The PEER Committee conducted a review of the Mississippi Board of Pharmacy. PEER conducted the review pursuant to the authority granted by MISS. CODE ANN. Section 5-3-57 et seq. (1972). This review is a "cycle review," which is not driven by specific complaints or allegations of misconduct.

In conducting this review, PEER first determined whether regulation of the pharmacy profession is necessary in order to reduce risks to the public. Once PEER established the public need for regulation of the pharmacy profession, PEER then evaluated how well the board carries out its two primary regulatory functions: (1) licensure of pharmacists and registration of pharmacy technicians, and (2) enforcement of state laws, rules and regulations governing the practice of pharmacy in Mississippi.

Background

The Legislature created the Board of Pharmacy in 1916 to license pharmacists, regulate the practice of pharmacy, and enforce laws regarding the sale of morphine among practitioners.

Currently, the Board of Pharmacy regulates 1,422 pharmacies doing business in the state of Mississippi; 3,331 licensed pharmacists; 3,415 registered technicians; and 1,485 other providers and facilities. From FY 1999 to FY 2003, the number of regulated pharmacies and other related facilities grew by 7% and the number of licensed pharmacists grew by 10%.

Need for the Board of Pharmacy

The Board of Pharmacy fulfills an essential public need through its licensing and enforcement activities for regulation of pharmacists, pharmacies, pharmaceutical services, and related private sector facilities. Unregulated practice would endanger public health and could contribute to existing illegal drug use and distribution.

> The nature of pharmaceutical services requires adherence to written orders of individuals authorized by law to prescribe drugs. Because the practice of pharmacy includes dispensing, compounding, and administering prescribed substances, incompetent practices would negatively impact healthcare. Due to

Licensure

The Board of Pharmacy's licensure process is compromised because the board has no formal, written criteria for screening applicants regarding their criminal histories. Also, although the board provides assurance to the public of applicants' competency to practice the profession of pharmacy by requiring passage of a validated national pharmacy examination, it cannot assure the public that its state examination sufficiently tests applicants' knowledge of state pharmacy laws and regulations.

> The Board of Pharmacy does not have formal, written criteria for accepting or rejecting applicants based on their criminal histories. State law requires pharmacists and pharmacy technicians to "be of good moral character," but the board has no definition or criteria related to "moral character" to serve as a basis for acceptance or rejection of a candidate. Also, the board accepts self-reporting of criminal history rather than initially utilizing background check resources of the Department of Public Safety or Federal Bureau of Investigation. As a result, the board may have compromised the security of controlled substances and increased risk to the public.

> The board provides assurance to the public of applicants' competency to practice the profession of pharmacy by requiring passage of a validated national pharmacy examination. However, because the board's examination of knowledge of state pharmacy laws and regulations has not been properly developed or administered, the board cannot assure the public that applicants have sufficient knowledge of state pharmacy laws and regulations, which constitute the environment in which they plan to practice. Since 1999, Mississippi has had a 5% failure rate on the first attempt of the state pharmacy exam; all candidates have passed upon re-examination. This relatively low failure rate illustrates that the examination may not have been properly developed and raises questions about the value that the state test provides.

Enforcement

Due to problems with workload and staffing assignments, the Board of Pharmacy has only partially fulfilled its inspection responsibilities, an important component of its enforcement function. Also, the board's compliance agents, whose job description does not require them to perform law enforcement duties, carry firearms without sufficient training and without the demonstrated need to do so.

As part of its enforcement responsibilities, the Board of Pharmacy conducts inspections of pharmacies and related facilities, conducts investigations of possible violations of pharmacy laws, and assesses penalties. PEER found problems with the number and frequency of the board's inspections, the assignment of compliance agents to inspection regions, and compliance agents' weapons certification. Concerning the number and frequency of inspections, due in part to increasing demands on the Board of Pharmacy's staff to conduct investigations, during the last five years the number of completed pharmacy and other provider inspections decreased by 24%, while the number of pharmacies and facilities subject to inspection grew by 7%. In FY 2003, the board's compliance agents inspected 794 of 1,849 eligible pharmacies and facilities.

Concerning the assignment of compliance agents to inspection regions, the Board of Pharmacy has not established logical, written criteria for assigning compliance agents to inspection regions in a manner that makes the best use of agency resources. The board's assignments do not minimize travel distance and resulting expenses to the state and do not take into account time management principles with which to maximize time available for conducting inspections.

Concerning compliance agents' weapons certification, although their job description does not require the Board of Pharmacy's compliance agents to perform law enforcement duties, state law confers upon these agents the authority of sworn law enforcement officers. The law allows these agents to carry a gun, but does not require them to complete minimum standards training for firearms. Thus the state has incurred the risk of agents with insufficient training carrying firearms without the demonstrated need to do so.

Administrative Issues

The Board of Pharmacy has not established policy and procedure manuals, other than for its Compliance Division. As a result, the board does not ensure that its staff has the proper information with which to fulfill its regulatory responsibilities.

> Without access to a source with current comprehensive policies and procedures, the staff must rely on other staff members, who may or may not provide correct information, thus risking errors in licensing, enforcement, and general administration.

Recommendations

1. The Board of Pharmacy should determine how it will enforce requirements of MISS. CODE ANN. Section 73-21-85 and 73-21-111 (1972) for pharmacists and pharmacy technicians to "[b]e of good moral character." One option would be to develop a Code of Professional Ethics, Character and Reputation such as is employed by the Board of Registration for Professional Engineers and Land Surveyors (see Appendix B, page 28), and require that pharmacists observe such a code or face penalties.

The Board of Pharmacy should then adopt formal, written criteria for accepting or rejecting pharmacist or pharmacy technician applicants on the basis of their criminal histories. In particular, these criteria should address applicants who have misdemeanor or felony convictions for violating federal or state laws governing alcohol, controlled substances, or theft.

- 2. The Legislature should amend MISS. CODE ANN. Section 73-21-85 and 73-21-111 (1972) to require the Board of Pharmacy to conduct background checks of applicants for a pharmacist's license and pharmacy technician's registration in order to ensure that they meet the statutory qualifications to "[b]e of good moral character" and further, to direct the Department of Public Safety to assist the board in conducting the background checks.
- 3. The Board of Pharmacy should ensure that its state pharmacy examination complies with professional testing standards, such as those promulgated by the Council on Licensure, Enforcement, and Regulation (CLEAR). The Board of Pharmacy should construct the examination so as to assure adequate coverage of the Pharmacy Practice Act, Uniform Controlled Substances Law, and most recent updates of pharmacy regulations.
- 4. The Board of Pharmacy should conduct a risk-based needs analysis to determine the best use of the two new positions authorized for FY 2005. The objective should be to use these positions in the most effective and efficient manner that will minimize risk to the public.
- 5. The Board of Pharmacy should conduct a risk-based needs analysis to determine the appropriate inspection cycle for pharmacies and regulated facilities. The board should adopt the results of the analysis into formal, written policy.
- 6. The Board of Pharmacy should adopt written criteria for making staff assignments to the pharmacy inspection regions. These criteria should seek to:
 - minimize state travel cost (gas, oil, and maintenance);
 - minimize travel distance for inspectors; and,
 - maximize available inspection time during each workday.
- 7. The Legislature should amend MISS. CODE ANN. Section 45-6-3 (1972) to remove any authority in law for compliance agents to function as law enforcement officers.

Further, the Legislature should amend MISS. CODE ANN. Section 41-29-159 (1972) to provide that the only personnel of the Board of Pharmacy authorized to carry out law enforcement functions shall be those law enforcement officers within the meaning of MISS. CODE ANN. Section 45-6-3 (1972) and who are trained in accordance with MISS. CODE ANN. Section 45-6-1 et seq. (1972).

8. The Board of Pharmacy should adopt a policy that prohibits compliance agents from performing any sworn law

enforcement officer duties, including carrying weapons, in conducting compliance inspections and assisting law enforcement officers in criminal investigations.

- 9. The Board of Pharmacy should develop policy and procedure manuals for its licensing and enforcement operations and ensure that its administrative and compliance manuals are comprehensive and current.
- 10. The Board of Pharmacy should establish a formal internal training program for its enforcement and licensing operations in order to minimize the possibility of administrative, communication, and operational errors.

For More Information or Clarification, Contact:

PEER Committee P.O. Box 1204 Jackson, MS 39215-1204 (601) 359-1226 http://www.peer.state.ms.us

Senator Lynn Posey, Chair Union Church, MS 601-786-6339

Representative Dirk Dedeaux, Vice Chair Gulfport, MS 228-255-6171

Representative Alyce Clarke, Secretary Jackson, MS 601-354-5453

A Review of the Board of Pharmacy

Introduction

Authority

The PEER Committee conducted a review of the Mississippi Board of Pharmacy. PEER conducted the review pursuant to the authority granted by MISS. CODE ANN. Section 5-3-57 et seq. (1972). This review is a "cycle review," which is not driven by specific complaints or allegations of misconduct.

Scope and Purpose

In conducting this review, PEER first determined whether regulation of the pharmacy profession is necessary in order to reduce risks to the public.

Once PEER established the public need for regulation of the pharmacy profession, PEER then evaluated how well the board carries out its two primary regulatory functions: (1) licensure of pharmacists and registration of pharmacy technicians; and, (2) enforcement of state laws, rules, and regulations governing the practice of pharmacy in Mississippi.

Method

In conducting this review, PEER:

- reviewed the Mississippi Uniform Controlled Substances Law, the Mississippi Pharmacy Practice Act, and other state laws, board rules, regulations, policies, and procedures;
- interviewed Board of Pharmacy and Law Enforcement Officer Training Academy personnel; and,
- analyzed the board's records and financial information.

Background

Scope of the Pharmacy Profession

The nature of pharmaceutical services requires precision as well as ethical behavior in controlling and dispensing drug products. Generally, pharmaceutical services include:

- maintaining an inventory of drugs;
- controlling access to controlled substances;
- accurately dispensing drugs in accordance with orders from individuals authorized by law to prescribe them;
- retaining records of prescriptions; and,
- advising patients on drug effects and interactions.

The Legislature created the Board of Pharmacy during the 1916 session to license pharmacists, regulate the practice of pharmacy, and enforce laws regarding the sale of morphine among practitioners.

The following sections discuss the board's statutory authority and responsibilities, organization and staffing, and revenues and expenditures.

Authority and Responsibilities

Regulation of Practitioners and Facilities

According to MISS. CODE ANN. Sections 73-21-75 and 73-21-81 (1972), the Board of Pharmacy functions as the executive policy and decisionmaking authority for regulation of the practice of pharmacy in Mississippi. This governing authority consists of seven practicing pharmacists who meet monthly to conduct business, primarily to approve new licenses and review disciplinary actions. Regulatory activities include licensing, inspecting, investigating, and determining disciplinary actions for pharmacists who do not comply with the Mississippi Pharmacy Practice Act. The board licenses pharmacists to practice in the state; registers student interns to permit them for issuing controlled substances during their internship; and registers pharmacy technicians to assist pharmacists. The board also issues permits for pharmaceutical wholesalers, institutional emergency medication kits, home health/hospice providers. durable medical equipment providers, and controlled substance research laboratories.

MISS. CODE ANN. Section 73-21-107 (1972) authorizes the board to inspect pharmacies and facilities that provide pharmaceutical products or services, such as drug wholesalers, medical gas wholesalers, durable medical equipment, and home health/hospice agencies. The board's investigative unit conducts inspections and investigations. The investigative function also includes the Investigations Review Committee, which recommends disciplinary actions to the full board as authorized in MISS. CODE ANN. Section 73-21-99 (1972). This committee consists of two board members who serve on a rotating basis, the Executive Director, and the board's legal counsel.

The Board of Pharmacy also receives advisory information from the Medical Equipment Advisory Committee, which advises the board on regulations that it makes regarding durable medical equipment, devices to administer prescription drugs, and medical gases (i.e., any gases or liquid oxygen intended for human consumption). The committee also reviews complaints concerning these areas in order to make recommendations to the Investigations Review Committee.

In FY 2004, the Board of Pharmacy regulated 1,422 pharmacies doing business in the state of Mississippi; 3,331 licensed pharmacists; 3,415 registered technicians; and 1,485 other providers and facilities. From FY 1999 to FY 2003, the profession experienced growth in Mississippi due to market demand for pharmaceutical services. For example, during that period, the number of regulated pharmacies and other related facilities grew by 7% and the number of licensed pharmacists grew by 10%.

Regulation of Controlled Substances

The pharmacy environment often involves dispensing medications that contain narcotics. The issuance of narcotics must be carried out according to federal controlled substances laws, which Mississippi has adopted into state statutes. MISS. CODE ANN. Section 41-29-113 through 121 (1972) classifies narcotics into a schedule of drugs. One of the chief responsibilities of pharmacists is to administer narcotics according to schedule (see Appendix A, page 27, for the classification of controlled substances, their medicinal benefits, and examples of each). The Board of Pharmacy oversees the pharmacy profession's administering of these drugs and investigates any diversion of these substances for sale or improper use.

Because pharmacists administer controlled substances to the general public, the U. S. Drug Enforcement Administration requires pharmacists to make an annual inventory of these substances. The Board of Pharmacy does not require pharmacists to submit these annual inventories to the board, but expects pharmacists to be able to produce the updated inventories upon request.

Cooperation with Other Drug Enforcement Entities

When pharmacy personnel divert drugs for personal use, the Board of Pharmacy applies sanctions and penalties through regulations authorized by the Pharmacy Practice Act. However, the board's enforcement role also involves cooperating with the Bureau of Narcotics when pharmacy personnel participate in the trafficking of drugs as determined by volume of stolen drugs, lack of accountability in controlled substance records, and tracking to other parties. The Board of Pharmacy is required by law to cooperate with the Bureau of Narcotics and other law enforcement agencies for enforcement of the Uniform Controlled Substances Law with respect to illicit narcotic and drug traffic in the state.

The Board of Pharmacy also cooperates with the U. S. Drug Enforcement Administration and state and local law enforcement agencies in interstate and multiple jurisdiction cases (e.g., a robbery of a pharmacy's controlled substances). The board also notifies any other professional licensing board whose personnel may be involved in either personal diversion or criminal activity, such as the boards for nurses, medical licensure, or veterinarians.

Organization and Staffing

According to state law, the Board of Pharmacy accomplishes its responsibilities through an appointed Executive Director who is responsible for the board's personnel. This Executive Director must be a state-licensed, non-practicing pharmacist whom the board appoints. The Executive Director also has an administrative assistant who provides support to the staff and performs licensing functions.

The other personnel were divided into two divisions as of FY 2004:

- Compliance Division—This division has four licensed pharmacist compliance agents, one of whom serves as Compliance Director and chief investigator. The other three agents conduct inspections of pharmacies and related medical service and supply facilities in an assigned region of the state (Northern, Central, or Southern). The map at Exhibit 1, page 5, shows the pharmacy inspection regions, the counties included in each region, and the inspection workload information by pharmacies and facilities.
- Enforcement Division—This division has two technician compliance agents who are certified state law enforcement officers that conduct dangerous, high-risk investigations concerning pharmacists' practices or the dispensing of drugs.

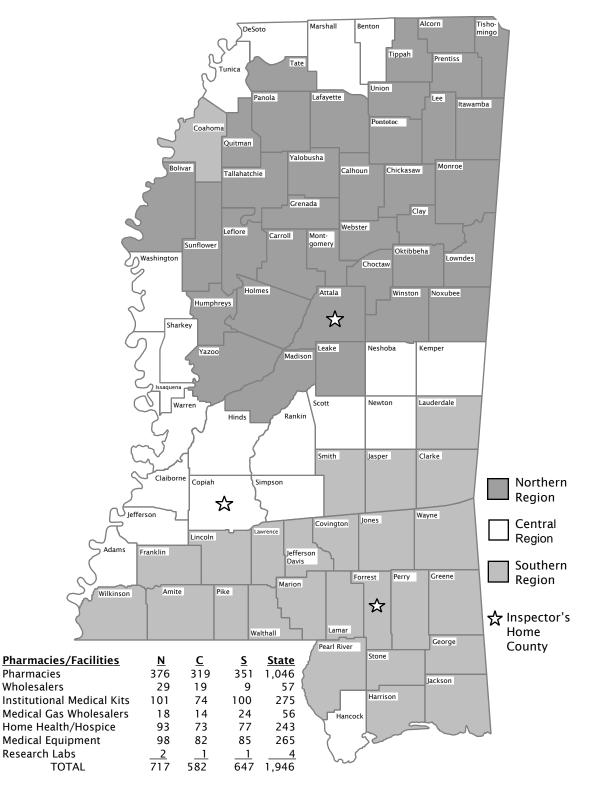


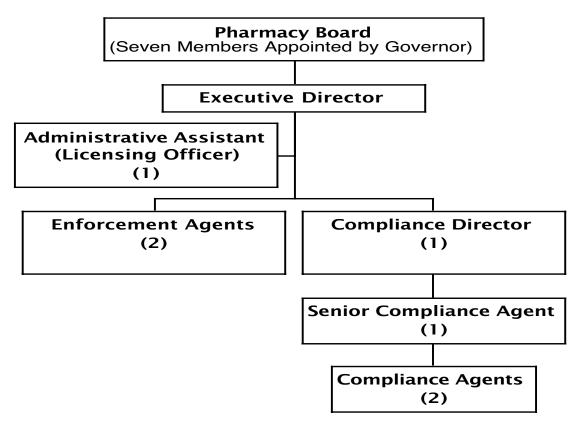
Exhibit 1: Mississippi Pharmacy Inspection Regions with Workload, as of May 27, 2004

SOURCE: Mississippi Board of Pharmacy (As of May 27, 2004)

Exhibit 2, below, shows the current organization of the Board of Pharmacy.

During the 2004 Regular Session, the Legislature passed Senate Bill 3153 that authorized two additional positions for FY 2005 and appropriated \$80,340 for compensating them. At this time, the Board of Pharmacy and its Executive Director have not made a final decision concerning the responsibilities and duties of these new positions.

Exhibit 2: FY 2004 Organization Chart for Board of Pharmacy



Note 1: Enforcement Division personnel perform the additional functions of office management, financial accounting, and information technology.

Note 2: Compliance Division personnel perform inspections and investigations only, except for the Compliance Director, who develops the state licensure test for pharmacists.

SOURCE: PEER analysis of State Personnel Board records (as of August 11, 2003).

Revenues and Expenditures

The Board of Pharmacy is a special fund agency that operates on annual and biennial fees generated from individuals and other providers and facilities that it regulates. Therefore, the revenues of the board fluctuate from one year to the next. For example, the board collected \$1,191,751 in Fiscal Year 2002 and \$562,227 in Fiscal Year 2003. Exhibit 3, below, shows the revenue and expenditure history for fiscal years 1999 through 2003.

MISS. CODE ANN. Sections 73-21-83, 73-21-91, 73-21-105, and 73-21-108 (1972) assess and establish the following fees for annual or biennial collection. These fees include:

- \$50 for student pharmacist interns during internships;
- \$50 annually for registered technicians, institutional emergency medical kits, medical gas wholesalers, and home health providers;
- \$100 annually for durable medical equipment providers;
- \$200 biennially for licensed pharmacists; and,
- \$300 biennially for the seven types of regulated pharmacy operations.

Exhibit 3: Board of Pharmacy's Revenues and Expenditures for Fiscal Years 1999-03*

	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003
Beginning Cash	\$1,217,427	\$1,025,963	\$1,495,374	\$1,289,775	\$1,348,851
Special Funds (Fees)**	402,667	1,088,710	459,003	1,191,751	562,227
Subtotal	1,620,094	2,114,673	1,954,377	2,481,526	1,911,078
Expenditures	(594,131)	(619,299)	(664,602)	(632,675)	(671,745)
Transfer to Contingency Fund				(500,000)	(700,000)
End of Year Cash	1,025,963	1,495,374	1,289,775	1,348,851	539,333
Full-time positions	7	8	8	8	8

* Numbers presented reflect actual amounts stated for the previously completed fiscal year.

** The source for these special funds is the annual and biennial licensing fees, as well as penalty fees for investigations.

SOURCE: FYs 2001-05 budget requests of the Mississippi Board of Pharmacy.

Conclusions

Need for the Board of Pharmacy

The Board of Pharmacy fulfills an essential public need through its licensing and enforcement activities for regulation of pharmacists, pharmacies, pharmaceutical services, and related private sector facilities. Unregulated practice would endanger public health and could contribute to existing illegal drug use and distribution.

> Because pharmacists perform essential roles such as supervision, consultation with patients, and serving as a contact point between doctor and patient, the board requires pharmacists to be licensed. The supervisory responsibility of the pharmacist includes overseeing medicine preparation and activities of pharmacy technicians and interns. The board also issues state registrations to pharmacists, pharmacy interns, and businesses that handle, dispense, or maintain controlled substances.

Risks to the Public

Because the practice of pharmacy includes dispensing, compounding, and administering prescribed substances, incompetent practices would negatively impact healthcare.

The nature of pharmaceutical services requires adherence to written orders of individuals authorized by law to prescribe drugs. According to MISS. CODE ANN. Section 73-21-105 (1972), essential service providers and their services for prescription drugs shall include every facility or business that engages in:

- wholesale distribution (includes drug manufacturing in this state; distribution into, from, or within this state; or selling/offering to sell in this state); or,
- dispensing and delivery of prescription drugs to consumers.

Because prescribed substances may contain narcotic agents, regulation of this profession becomes even more essential. Lack of regulation of pharmacy could produce the following risks to the public:

- a lack of practitioners' knowledge, skills, and abilities that would increase the potential for:
 - -- medication preparation or dispensing errors;
 - negative drug-to-drug interactions or improper prescription intake; or,
 - -- mismanagement of controlled substance inventories, office records, or staff supervision.
- the wholesale distribution of controlled substances without accountability to the public for documenting and inspecting the manufacture (including in-store preparation) of controlled

substances, inventory, distribution, and sale for retail purposes;¹

- the theft of controlled substances through counterfeit prescriptions or diversion by pharmacy personnel;
- the sale of counterfeit drugs--i.e., a substance without the ingredients and potency to alleviate suffering or prevent death;² or,
- retail pharmacies that do not observe cleanliness and recordkeeping standards or meet structural requirements for controlled substances (e.g., safe storage to protect shelf life of medications and guard against theft).

Thus state government and citizens incur certain risks from the practice of pharmacy, requiring enforcement of laws and regulations to ensure that pharmaceutical services are provided in a precise and ethical manner.

Framework for Regulation: Licensure and Enforcement

The Board of Pharmacy attempts to reduce risks to the public through licensure and enforcement.

The primary purpose of regulation is to protect the public from risks of the pharmacy profession. The Board of Pharmacy accomplishes this through licensure and enforcement.

The board's licensure process includes requiring practitioners to meet specified minimum qualifications prior to licensure (for pharmacists) or registration (for pharmacy technicians). The board does this through administering the application process for these individuals and examining them for competency.

The board's enforcement process includes inspecting pharmacies and related facilities to assure compliance with state pharmacy laws, rules, and regulations. The board also investigates complaints regarding practitioners' possible violations of state pharmacy laws, rules, and regulations. The board assesses penalties for violations.

¹ The Board of Pharmacy works with the U. S. Food and Drug Administration on complaints concerning instore preparation of drug compounds, since that federal agency has approval authority for manufactured drugs for wholesale or resale in the United States.

²The U. S. Food and Drug Administration and the U. S. Department of Health and Human Services are particularly concerned with preventing the manufacture and sale of counterfeit drugs from other countries.

Licensure

The Board of Pharmacy's licensure process is compromised because the board has no formal, written criteria for screening applicants regarding their criminal histories. Also, although the board provides assurance to the public of applicants' competency to practice the profession of pharmacy by requiring passage of a validated national pharmacy examination, it cannot assure the public that its state examination sufficiently tests applicants' knowledge of state pharmacy laws and regulations.

> As noted on page 9, the board's licensure process includes administering the application process for pharmacists and pharmacy technicians and examining pharmacists for competency.

Components of Licensure/Registration

The board allows licensed pharmacists to transfer out-of-state licenses to Mississippi by reciprocity. Mississippi requires all practicing pharmacists to meet established minimum qualifications for licensing through the Board of Pharmacy prior to working in a state wholesale, retail, or institutional pharmacy. The Board of Pharmacy licenses pharmacists based on completing a pharmacy school program, passing a national pharmacy test, completing a 1,600-hour internship, and passing the state pharmacy law test. The board assesses an application fee and a biennial licensing fee and pharmacists must complete twenty hours of continuing education annually. The board also allows licensed pharmacists to transfer out-of-state licenses by reciprocity. Reciprocity allows pharmacists who were licensed in another state to practice in Mississippi without re-examination on the national test if the applicant is in good standing with the licensing board in the state in which he/she formerly resided.

The state also requires all pharmacy technicians who work in licensed retail or institutional pharmacies to register annually so that the board can monitor and investigate pharmacy technicians practicing in Mississippi.

All candidates for pharmacist licensure or pharmacy technician registration must complete an application form and be screened by the board.

Adequacy of the Application Process

The Board of Pharmacy does not have formal, written criteria for accepting or rejecting applicants based on their criminal histories. Also, the board accepts self-reporting of criminal history rather than initially utilizing background check resources of the Department of Public Safety or Federal Bureau of Investigation. As a result, the board may have compromised the security of controlled substances and increased risk to the public.

If an applicant indicates criminal history, the board may subsequently conduct a background check on that individual.

Although state law requires pharmacists to be "of good moral character," the board has no formal, written criteria related to "moral character" to serve as a basis for acceptance or rejection of a candidate. During the application process, the Board of Pharmacy requires pharmacist and pharmacy technician candidates to complete an application form that requests information on the applicants' criminal histories. The board accepts self-reporting of criminal history during the application process to screen the background of pharmacist and pharmacy technician applicants for felony or misdemeanor convictions. If an applicant indicates criminal history, the board may subsequently conduct a background check on the individual. In the occasional instances in which the staff conducts a background check, the staff uses resources such as those of the Bureau of Narcotics.

MISS. CODE ANN. Section 73-21-85 and 73-21-111 (1972) do not require background checks of applicants, but do require the pharmacists and pharmacy technicians to "[b]e of good moral character." According to the Board of Pharmacy, self-reports of criminal history serve as the board's check for "good moral character." However, the board has no formal, written criteria related to "moral character" to serve as a basis for acceptance or rejection of a candidate. When the Legislature created the board, it stated the following regarding "good moral character" in Section 21 of House Bill 91, 1916 Session:

> Any pharmacist convicted before any court of competent jurisdiction for unlawfully selling morphine, cocaine or habit-forming drug or intoxicating liquors, shall be deemed of not good moral character...

However, the law no longer contains this language and the Board of Pharmacy has no formal, written criteria on how to make this judgment.

As of April 16, 2004, of the five most recent pharmacist applications, none reported a conviction and the board did not request further criminal background checks from the Mississippi Crime Information Center (MCIC) or fingerprint checks from the Federal Bureau of Investigation. However, of the five most recent pharmacy technician applications, four reported past convictions that included public drunkenness, driving under the influence of alcohol, marijuana possession, and shoplifting. The board had the Bureau of Narcotics run further background checks on one of these applicants through the MCIC but found only traffic violations. The board approved registering all five pharmacy technician applicants. According to the board's Executive Director, the board considers the four offenses listed above to be misdemeanors and believes that if it excluded pharmacy technician applicants with misdemeanors from registration, that the potential pool of employees from this occupational class would be insufficient, since this is a relatively low-paying occupation in relatively high demand. However, PEER contends that some of these offenses could be felonies, depending upon the situation (e.g., a third DUI charge is a felony), and that part of the board's responsibility is to screen out such applicants.

Because the board has no written criteria regarding criminal history, the potential exists that the board could treat some applicants unfairly. Because the Board of Pharmacy has no formal, written criteria for accepting or rejecting applicants on the basis of criminal history, the board has not taken a formal stand on how it will interpret "good moral character." Also, by not having written criteria, the potential exists that the board could treat applicants unfairly, accepting existence of certain criminal charges for some individuals and not accepting them for others.

Also, reliance on applicants' self-reporting of criminal history increases the chances that an applicant or applicants with serious criminal history might slip through the application process, become licensed, and expose the public to increased risk. In an environment with opportunity for theft and substance abuse, the lack of criminal background checks in the screening process could be especially serious.

Adequacy of the Examination Process

The Board of Pharmacy provides assurance to the public of applicants' competency to practice the profession of pharmacy by requiring passage of a validated national pharmacy examination. However, because the board's examination of knowledge of state pharmacy laws and regulations has not been properly developed or administered, the board cannot assure the public that applicants have sufficient knowledge of state pharmacy laws and regulations, which constitute the environment in which they plan to practice.

> After candidates for pharmacist licensure in Mississippi meet the minimum qualifications noted on page 10, licensure examination in Mississippi has two phases: assurance of knowledge of and competency in practicing the pharmacy profession and assurance of knowledge of how Mississippi law regulates the practice of pharmacy.

National Pharmacy Examination

Prior to their advancing in the state licensure process, the Board of Pharmacy requires applicants to pass the North American Pharmacist Licensure Examination (NAPLEX). This is a national examination validated by the National Association of Boards of Pharmacy. The NAPLEX is administered daily at one of Mississippi's four Prometric Testing Center sites (Hattiesburg, Jackson, Mississippi State, or Tupelo). The state board accepts an applicant's passage of this exam as assurance of knowledge of and competency in practicing the pharmacy profession. Once an applicant has passed the national pharmacy test, completed an internship, and been cleared of any criminal convictions or board disciplinary actions in other states, the applicant is eligible to take the state pharmacy examination, which pertains to laws regulating the practice of pharmacy in Mississippi. The Board of Pharmacy's Compliance Director developed the state pharmacy examination and the staff administers the test.

In order to ensure the public that licensees are fully knowledgeable of Mississippi's Pharmacy Practice Act and pharmacy regulations, the board's development of an examination to test this knowledge should follow guidelines such as those of the Council on Licensure, Enforcement, and Regulation (CLEAR). CLEAR provides standard professional testing guidelines for state regulatory boards. These guidelines cover the actions associated with the elements of test development, administration, statistical analysis and research, scoring and reporting, and examination security.

PEER compared the above-noted elements of the state test to CLEAR's testing standards to determine whether the Board of Pharmacy has properly developed and administered its state test for licensing pharmacy applicants. Exhibit 4, page 14, contains the results of this comparison.

This analysis found that the Board of Pharmacy's state test:

- *fully met the scoring and reporting standard.* The board ensures that tests are graded and test results are reported to students in a fair and uniform manner.
- *partially met the test administration and the examination security standards.* The board has not specifically addressed test administration with a written plan in its policy statement acknowledging compliance with the Americans with Disabilities Act. Further, the board has developed only one version of the test each year instead of multiple equivalent versions of the exam for security purposes.
- *did not meet the test development and statistical analysis and research standards.* The board has not:
 - analyzed skills and knowledge required for pharmacy competency through a job or practice analysis of the work.
 - included knowledge questions on all state-regulated areas. The Compliance Director should have selected the test items from a comprehensive dictionary of testing items, which shows all source areas in the law. However, he randomly selected the test questions and did not cover all source areas in the law. For example, the test contained only one item regarding discipline for violating the Pharmacy Practice Act and had no questions specifically regarding violations and penalties of the Uniform Controlled Substances Law.

The board has not analyzed test results to determine whether any test questions need revision to ensure that the test is measuring appropriate knowledge and skills.

Exhibit 4: PEER Analysis of the Board of Pharmacy's State Examination Procedures Compared to the Professional Testing Standards of the Council on Licensure, Enforcement and Regulation (CLEAR)

CLEAR Test Standards	Actions Needed to Meet Testing Standard	Did the Board Follow Professional Testing Standards of the Council on Licensure, Enforcement and Regulation?				
Test Development	1. Analyze skills and knowledge required for pharmacy competency.	 No. The State Pharmacy Licensure Exam is used to assure the board that practitioners have been tested in all areas necessary for a comprehensive understanding of the state's pharmacy regulations. This is typically done through a job or practice analysis of the work process. The test developer did not conduct a formal practice analysis. 				
(Not Met)	2. Ensure test includes questions on each necessary skill.	 No. Test development lacks a dictionary of constructs to define areas tested, including multiple related items scattered throughout the test for reliability of practitioner knowledge regarding particular regulations. 				
	 Set a valid passing score based on entry-level knowledge and skills. Develop oral, practical, and essay exams with standard answers that can 	3. No. The board has established a cutoff score of 75. However, test developers did not conduct formal analysis such as studying the distribution of scores to determine whether test scores correlate with a measure such as compliance history. Such an analysis should be used to determine whether a valid passing score has been set for the exam.				
	be consistently graded.	4. Partially . The pharmacy licensure exam is not an open-ended assessment such as an oral, practical, and essay exam, which typically results in subjectivity if raters do not use standard guidelines for grading to ensure fair evaluation. All test items on the pharmacy licensure exam have objective closed-ended responses that would require a single response. However, it is not clear whether the true-false and fill-in-the-blank formats are testing guessing skills and rote memorization or knowledge of pharmacy regulations. The board's exam uses six objective response questions to test knowledge of pharmaceutical practice, but the board has not determined whether this section is a reliable indication of practice knowledge.				
Test Administration (Partially Met)	1. Provide applicants with detailed information on testing times and dates, test content, test site conditions, grading procedures, and disclosure of test scores to applicants	1. Yes. The board sends each applicant a copy of the actual laws and regulations on which he or she is tested. The packet that the board sends applicants also includes information about the test date, location and map, time of test, and scoring information. The board administers the exam annually in May at the University of Mississippi School of Pharmacy. The board holds individual exam administrations in the board's office following application and appointment.				
	2. Develop a written plan for accommodating candidates with disabilities which complies with the Americans with Disabilities Act	2. <i>Partially</i> . The board's test developer, the compliance director, stated that the board has not encountered special needs to accommodate. The board's policy statement acknowledging compliance with the Americans with Disabilities Act does not specifically reflect test administration, and the board has not developed a written plan.				
Statistical Analysis and Research (Not Met)	1. Analyze test results to determine which test questions need revision to ensure the test is measuring appropriate knowledge and skills	 No. The board has not conducted formal research analysis on test results. Although the board periodically updates the exam to reflect disciplinary actions and item content, the board cannot provide formal assurance of the test's sufficiency. The board also cannot assure that six practical exam questions at the beginning of the exam are fairly constructed or are a reasonable sample of practical knowledge, skills, and abilities. 				
Scoring and Reporting1. Ensure that tests are graded and test results are reported to students in a fair and uniform manner(Met)Image: Constraint of the student of the		1. Yes. Compliance agents grade the exams after they administer the test. The compliance agents notify the candidates of their score immediately. After the compliance staff notifies the candidates of their test results, the staff gives a report to the board.				
Examination Security	1. Ensure secrecy of test questions in advance	1. Partially. The compliance director develops test items with input from the executive director and other compliance staff. The board develops only one version of the test each year. The board should have multiple equivalent versions of the exam for security purposes. For example, theft of the test or sharing test questions would allow future test takers in the same year to pass the test.				
(Partially Met)	2. Maintain test materials in secure locations	2. Yes. The exams are developed and printed in the board's office.				
	3. Ensure students have no access to tests during printing, storage, transportation, and distribution	3. Yes. The compliance director provides security for the exams. The exams are stored in the board's business office, where only the compliance staff has access.				

SOURCE: PEER analysis of Board of Pharmacy records and Council on Licensure, Enforcement, and Regulation testing standards for regulatory boards.

established a valid passing score based on entry-level knowledge and skills. The board arbitrarily established a cutoff score of 75. However, the test developer has not conducted formal analysis of test content to determine whether the test confirms mastery of the body of knowledge. analyzed test results to determine which test questions 0 need revision to ensure the test is measuring appropriate knowledge and skills. As a result, the board cannot provide formal assurance of the test's sufficiency and cannot assure that the practical exam questions at the beginning of the exam are fairly constructed or are a reasonable sample of practical knowledge, skills, and abilities. Thus the board cannot ensure that its state pharmacy exam adequately tests professional knowledge relevant to pharmaceutical practice in the state of Mississippi. The relatively low Since 1999, 27 of 525 candidates have failed to pass Mississippi's failure rate on the pharmacy test on the first attempt; they all passed upon restate exam raises examination. This relatively low failure rate of 5% may also questions about the illustrate that the examination may not have been properly value that it provides. developed and raises questions about the value that the state test provides to the public for assessing candidates' knowledge of

Enforcement

Due to problems with workload and staffing assignments, the Board of Pharmacy has only partially fulfilled its inspection responsibilities, an important component of its enforcement function. Also, the board's compliance agents, whose job description does not require them to perform law enforcement duties, carry firearms without sufficient training and without demonstrated need to do so.

state pharmacy laws.

Components of Enforcement

As part of its enforcement responsibilities, the Board of Pharmacy inspects of pharmacies and related facilities, investigates possible violations of pharmacy laws, and assesses penalties.

PEER found problems with the number and frequency of the board's inspections, the assignment of compliance agents to inspection regions, and compliance agents' weapons certification.

Inspections

MISS. CODE ANN. Section 73-21-107 (1972) authorizes the Board of Pharmacy to inspect pharmacies and related facilities. The board's compliance agents may inspect drug storage and security, equipment, sanitary conditions, and check for records, reports, or other documents required in state laws, rules, and regulations.

The agents may also take an inventory of the stock of prescription drugs or devices in the facilities. The board requires compliance agents to follow an inspection checklist with established standards. These inspections are designed to help protect the public from the risks described on page 8 of this report. As previously noted, Exhibit 1, page 5, shows the pharmacy inspection regions, the counties included in each region, and the inspection workload of pharmacies and facilities as of May 27, 2004.

Investigations

The board's staff members receive information from various sources regarding possible violations of pharmacy laws. Once a formal complaint is documented and all the necessary elements are ascertained for investigation, the staff either handles the case administratively or makes a formal presentation to the board's Investigations Review Committee. The purpose of this presentation is to obtain authority for a full investigation of the violation.

Most pharmacy law violations pertain to diversion of controlled substances, typically for personal use. Formal investigations often ensue from problems discovered during compliance agents' inspections. For example, although only about 3% of regulated parties (practitioners, pharmacies, or facilities) were formally investigated for state law violations, the majority of cases involved pharmacists and technicians violating controlled substances laws from FY 2000 through FY 2004. Most pharmacy law violations (78% of all formal board investigations) pertain to diversion of controlled substances, typically for personal use.

Assessment of Penalties

The board enforces its regulation of pharmacy laws and regulations through penalties outlined in MISS. CODE ANN. Section 73-21-103 (1972). Disciplinary actions range from public or private reprimands to revoking a pharmacist's license. If an incident requires investigation, the investigative unit of the Board of Pharmacy works with the board's Investigations Review Committee to determine evidence that is used in board deliberations.

The board assesses the cost of investigations and imposes a fee on those pharmacists who violate the Pharmacy Practice Act to recover associated expenses. The board has authority to assess two types of monetary penalties. One is a standard penalty that is deposited into the general fund of the State Treasury. The other is a cost of investigation monetary penalty that goes to the agency's special funds. The board assesses the cost of investigations and imposes a fee on those pharmacists who violate the Pharmacy Practice Act to recover expenses associated with licensure revocations, suspensions, or restrictions. These expenses include the costs of drug sale audits, court reporters, process service, expert witnesses, and board investigators. From FY 1999 to February 19, 2004, the board collected \$68,801 that had been assessed to cover the cost of investigations and collected \$7,954 in fines and delinquent fees.

Number and Frequency of Inspections

Due in part to increasing demands on the Board of Pharmacy's staff to conduct investigations, during the last five years the number of completed pharmacy and other provider inspections decreased by 24%, while the number of pharmacies and facilities subject to inspection grew by 7%. In FY 2003, the board's compliance agents inspected 794 of 1,849 eligible pharmacies and facilities.

As noted on page 3, although MISS. CODE ANN. Section 73-21-107 (1972) authorizes the board to inspect pharmacies and related facilities of in-state regulated pharmacies and other pharmaceutical service and supply providers, it does not specify the number of inspections that the board must conduct or the frequency with which they should be conducted. The Executive Director of the board has stated that his goal is to inspect all pharmacies and facilities by the end of each biennial (two-year) licensing renewal period, although the board has never formally adopted this goal.

As shown in Exhibit 5 on page 18, the number of pharmacies, facilities, and other providers subject to the Board of Pharmacy's inspection grew 7% from FY 1999 to FY 2003. However, the number of inspections that the board conducted decreased by 24% during that same period. In FY 2003, the board's compliance agents inspected 794 of 1,849 facilities eligible for inspection. This decline in the number of completed inspections could place the public at increased risk.

According to the Board of Pharmacy's staff, one cause for the decrease in the number of inspections the board has conducted in the past five fiscal years is the increase in the number of investigations conducted over the same period. While the number of annual inspections conducted decreased 24% from FY 1999 to FY 2003, the number of investigations that the Board of Pharmacy conducted or assisted in during that period increased from 60 to 123 (105%). Most of these investigations dealt with alleged diversion of controlled substances (78% of all formal board investigations from FY 1999 through FY 2003), typically for personal use.

The board's staff also states that the board has registered a large number of pharmacy technicians, a growing occupational class, in recent years and that a large number of investigations (which adds to workload) has been tied to this trend. The number of pharmacy technician investigations increased from 13 to 24 from FY 2000 to FY 2004. A majority of these investigations involved controlled substances violations.

The board's formal investigations are usually multiple-day cases that include covert operations to collect evidence. They require the use of licensed pharmacists who can conduct in-depth accountability audits of controlled substances. The board's

The decline in the number of completed inspections could place the public at increased risk.

From FY 1999 to FY 2003, the number of investigations that the Board of Pharmacy conducted or assisted in increased by 105%. The board's existing staff resources are not sufficient to handle increasing workload requirements for inspections and investigations. compliance agents, who are licensed pharmacists, must conduct the investigations or must accompany another employee conducting the investigation. Thus the board has had to cover a large increase in the number of investigations, in addition to the inspection workload, with three compliance agents.

Although the board reclassified two staff members as certified law enforcement officers in FY 2004 and these officers can perform law enforcement investigative duties, they are not licensed pharmacists and therefore cannot be used to conduct an investigation without an accompanying compliance agent. Therefore, the board's existing staff resources are still not sufficient to handle the increasing workload requirements for inspections and investigations.

The board's investigations of alleged violations of pharmacy laws and regulations should certainly be a high priority, particularly those dealing with alleged diversion of controlled substances. However, when pharmacies and related facilities are not inspected, risks to the public could be increased.

Exhibit 5: FY 1999-FY 2003 Growth in In-State Pharmacies, Other Providers, and Investigations with Corresponding Decrease in Number of Inspections

	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	Five-Year Growth Rates
Pharmacies	959	905	917	955	912	(5%)
Other Providers	775	666	731	656	937	21%
TOTAL	1,734	1,571	1,648	1,611	1,849	7%
Investigations	60	73	80	114	123	105%
Inspections	1,045	817	786	899	794	(24%)
Inspection Percentage of Total Pharmacies and Other Providers	60%	52%	48%	56%	43%	(17%)

Note 1: The number of pharmacies and other providers includes only in-state licensees and permittees, since the Board of Pharmacy does not inspect out-of-state ones.

Note 2: Other providers include drug wholesalers, medical gas wholesalers, durable medical equipment suppliers, and controlled substance research laboratories.

Note 3: Institutional emergency medication kits contain drugs that may be required to meet the immediate therapeutic needs of patients and that are not available from any other authorized source in sufficient time to prevent risk of harm to patients. They can be maintained at facilities, except hospitals, under the jurisdiction of the Board of Pharmacy.

SOURCE: PEER analysis of FYs 1999-03 records of the Board of Pharmacy.

Assignment of Compliance Agents

The Board of Pharmacy has not established logical, written criteria for assigning compliance agents to inspection regions in a manner that makes the best use of agency resources.

As shown in Exhibit 5 on page 18, from FY 1999 to FY 2003, the Board of Pharmacy's workload of inspections and investigations grew 10%, from 1,794 to 1,972. Because the board has only four compliance agents on staff (with the possible addition of up to two agents from positions added by the Legislature for FY 2005), it is imperative that the board uses its staff resources wisely to fulfill its enforcement responsibilities.

Exhibit 1, page 5, shows the assignment of counties to inspectors in the three regions. As the map shows, counties that might be expected to lie within the Northern inspection region (i.e., Tunica, DeSoto, Marshall, and Benton) have been assigned to the compliance agent designated as the Central region inspector. Coahoma County, which would also logically fall within the Northern inspection region, was assigned to the compliance agent designated as the Southern region inspector. Hancock County, the southernmost county of the state, was assigned to the Central regional inspector. As a result, the board's agents could literally pass one another on the highway going to their respective assignments, traveling unnecessary mileage at state expense. This additional, unnecessary travel time reduces the amount of time that compliance agents have in which to conduct inspections.

While the assignment of these counties to inspection regions may balance the compliance agents' workload on a relative basis, the method of assignment does not meet reasonable criteria for efficiency and effectiveness. These assignments do not minimize travel distance and resulting expense to the state (i.e., gasoline, oil, and automobile maintenance). They also do not take into account time management principles with which to maximize the time available for conducting inspections during each workday. The Compliance Director made these assignments without any formal, written criteria.

Because the Board of Pharmacy has not developed formal, written criteria that address efficiency and cost-effectiveness issues upon which to base assignments to inspection regions, the board has not used its resources prudently in operating its inspection system. As a result, some licensed pharmacies, industry facilities, or their staffs that may go uninspected due to wasted staff resources may be violating state pharmacy laws, rules, or regulations and could harm the public.

Due to some of the assignments of counties to inspection regions, the board's agents could literally pass one another on the highway going to their respective assignments, traveling unnecessary mileage at state expense.

The board has not used its resources prudently in operating its inspection system.

Compliance Agents' Performance of Law Enforcement Officers' Functions

Although their job description does not require the Board of Pharmacy's compliance agents to perform law enforcement duties, state law confers upon these agents the authority of sworn law enforcement officers. The law allows these agents to carry a gun, but does not require them to complete minimum standards training for firearms. Thus the state has incurred the risk of agents with insufficient training carrying firearms without the demonstrated need to do so.

The Board of Pharmacy's job description for its compliance agents requires them to perform regulatory functions for the practice of pharmacy and dispensing of drugs for the protection of the public. The board's law enforcement officers are involved in the prevention and detection of crime in the practice of pharmacy.

> According to MISS. CODE ANN. Section 41-29-159 (1972), the Board of Pharmacy is responsible for regulating the legitimate drug traffic among pharmacists, pharmacies, hospitals, nursing homes, drug manufacturers, and other related professions and facilities with the exception of the medical, dental, nursing, and veterinary professions.

> To carry out these responsibilities, the Board of Pharmacy has a Compliance Division composed of four compliance agents with the following job duties:

- conducting routine compliance inspections;
- conducting education programs for pharmacists;
- conducting complaint investigations and accountability audits of controlled substances, if necessary; and,
- securing evidence of violations of state or federal laws or regulations.

To accomplish these functions, compliance agents must have knowledge of related federal and state laws and regulations and technical knowledge of the practice of pharmacy. They also must have knowledge of computers and their use in the storage and retrieval of information relevant to drugs and prescription orders. The job description does not require that these compliance agents perform any law enforcement officer functions or complete any law enforcement officer training requirements. In practice, the Board of Pharmacy's compliance agents do not make arrests in criminal investigations, but depend on the Bureau of Narcotics or the appropriate local law enforcement agency to do so.

According to their job description, the Board of Pharmacy's law enforcement officers are involved in the prevention and detection of crime within the practice of pharmacy. The job description requires them to apprehend criminals and enforce criminal laws of the Uniform Controlled Substances Law as well as federal drug laws and regulations. To accomplish these responsibilities, these law enforcement officers accompany compliance agents when

The board's compliance agents do not make arrests in criminal investigations, but depend on the Bureau of Narcotics or the appropriate local law enforcement agency to do so. arrests or other law enforcement procedures are required during investigations to enforce the provisions of the Pharmacy Practice Act. These officers also directly monitor pharmacy technicians statewide to enforce compliance.

State law, in effect, confers upon the board's compliance agents the authority to make arrests and carry firearms but does not require them to be trained as law enforcement officers.

Since 1972, MISS. CODE ANN. Section 41-29-159 (1972) has allowed the Board of Pharmacy's compliance agents to:

...carry firearms; execute and serve search warrants, arrest warrants, subpoenas, and summonses issued under the authority of this state; make arrests without warrant for any offense under this article committed in his presence, or if he has probable cause to believe that the person to be arrested has committed or is committing a crime; and make seizures of property pursuant to this article.

This language confers upon compliance agents the authority to carry out the duties of sworn law enforcement officers (e.g., make arrests, carry firearms).

However, another section of state law excludes compliance agents from the definition of "law enforcement officer" for purposes of minimum standards training for firearms. MISS. CODE ANN. Section 45-6-3 (c) (1972) states:

> (c) "Law enforcement officer" means any person *appointed or employed full time by the state or any political subdivision thereof, or by the state military* department as provided in Section 33-1-33, who is duly sworn and vested with authority to bear arms and make arrests, and whose primary responsibility is the prevention and detection of crime, the apprehension of criminals and the enforcement of the criminal and traffic laws of this state and/or the ordinances of any political subdivision thereof... However, the term "law enforcement officer" *shall not mean or include any elected official or* any person employed as an assistant to or investigator for a district attorney in this state, compliance agents of the State Board of **Pharmacy**, or any person or elected official who, subject to approval by the board, provides some criminal justice related services for a law *enforcement agency.* [Emphasis added]

This exclusion means that the Board of Pharmacy's compliance agents are not required to qualify annually with their weapons or to attend state-certified law enforcement training, as other law enforcement officers are required to do. The risk presented by compliance agents carrying firearms when they are not properly trained to do so outweighs any benefit that the board might gain. The risk presented by compliance agents carrying firearms when they are not properly trained to do so outweighs any benefit that the Board of Pharmacy might gain from the practice. These agents could cause or incur injuries through misuse of firearms because they are not properly trained.

State law should mandate that any employee of the Board of Pharmacy who performs law enforcement officer duties meet the same minimum standards requirements for firearms as do other full-time law enforcement officers.

The assignment of law enforcement officer duties, including the issuance of firearms to employees, signals an intention to give recipients the responsibility of making life and death decisions. The public is entitled to assurance that all law enforcement officers have knowledge, understanding, and judgment about weapons and their use in dangerous situations. State law should require that employees who perform law enforcement functions meet the same minimum standards requirements for firearms set for other full-time law enforcement officers.

Requiring that employees who perform law enforcement functions meet statewide minimum standards for firearms training would limit implementation of the Board of Pharmacy's law enforcement authority to the board's sworn law enforcement officers. Thus compliance agents could continue to perform their job duties as listed on page 20, but would not perform any duties of sworn officers.

Administrative Issues

The Board of Pharmacy has not established policy and procedure manuals, other than for its Compliance Division. As a result, the board does not ensure that its staff has the proper information with which to fulfill its regulatory responsibilities.

Without a current policy and procedure manual, the staff must rely on other staff members who may or may not provide correct information, thus risking errors. The Board of Pharmacy has not established a comprehensive policies and procedures manual or set of manuals with which to govern its total operation. The board has not published any formal, written policies or procedures for its administrative, licensure, or enforcement operations. As a result, the board cannot assure that its staff has the knowledge of the administrative or operating policies and procedures or other information necessary to fulfill the duties and responsibilities of their positions.

The Board of Pharmacy should ensure that its staff members have access at all times to a source with current comprehensive policies and procedures. Without this information, the staff must rely on other staff members, who may or may not provide correct information, thus risking errors in licensing, enforcement, and general administration.

Recommendations

Licensure

Adequacy of the Application Process

1. The Board of Pharmacy should determine how it will enforce requirements of MISS. CODE ANN. Section 73-21-85 and 73-21-111 (1972) for pharmacists and pharmacy technicians to "[b]e of good moral character." One option would be to develop a Code of Professional Ethics, Character and Reputation such as is employed by the Board of Registration for Professional Engineers and Land Surveyors (see Appendix B, page 28), and require that pharmacists observe such a code or face penalties.

The Board of Pharmacy should then adopt formal, written criteria for accepting or rejecting pharmacist or pharmacy technician applicants on the basis of their criminal histories. In particular, these criteria should address applicants who have misdemeanor or felony convictions for violating federal or state laws governing alcohol, controlled substances, or theft.

2. The Legislature should amend MISS. CODE ANN. Section 73-21-85 and 73-21-111 (1972) to require the Board of Pharmacy to conduct background checks of applicants for a pharmacist's license and pharmacy technician's registration in order to ensure that they meet the statutory qualifications to "[b]e of good moral character" and further, to direct the Department of Public Safety to assist the board in conducting the background checks.

Adequacy of the Examination Process

3. The Board of Pharmacy should ensure that its state pharmacy examination complies with professional testing standards, such as those promulgated by the Council on Licensure, Enforcement, and Regulation (CLEAR). The board should construct the examination so as to assure adequate coverage of the Pharmacy Practice Act, Uniform Controlled Substances Law, and most recent updates of pharmacy regulations.

Number and Frequency of Inspections

- 4. The Board of Pharmacy should conduct a risk-based needs analysis to determine the best use of the two new positions authorized for FY 2005. The objective should be to use these positions in the most effective and efficient manner that will minimize risk to the public.
- 5. The Board of Pharmacy should conduct a risk-based needs analysis to determine the appropriate inspection cycle for pharmacies and regulated facilities. The board should adopt the results of the analysis into formal, written policy.

Assignment of Compliance Agents

- 6. The Board of Pharmacy should adopt written criteria for making staff assignments to the pharmacy inspection regions. These criteria should seek to:
 - minimize state travel cost (gas, oil, and maintenance);
 - minimize travel distance for inspectors; and,
 - maximize available inspection time during each workday.

Compliance Agents' Performance of Law Enforcement Officers' Functions

7. The Legislature should amend MISS. CODE ANN. Section 45-6-3 (1972) to remove any authority in law for compliance agents to function as law enforcement officers.

Further, the Legislature should amend MISS. CODE ANN. Section 41-29-159 (1972) to provide that the only personnel of the Board of Pharmacy authorized to carry out law enforcement functions shall be those law enforcement officers within the meaning of MISS. CODE ANN. Section 45-6-3 (1972) and who are trained in accordance with MISS. CODE ANN. Section 45-6-1 et seq. (1972).

8. The Board of Pharmacy should adopt a policy that prohibits compliance agents from performing any sworn law enforcement officer duties, including carrying weapons, in conducting compliance inspections and assisting law enforcement officers in criminal investigations.

- 9. The Board of Pharmacy should develop policy and procedure manuals for its licensing and enforcement operations and ensure that its administrative and compliance manuals are comprehensive and current.
- 10. The Board of Pharmacy should establish a formal internal training program for its enforcement and licensing operations in order to minimize the possibility of administrative, communication, and operational errors. The curriculum for this training program should cover, as a minimum, the information in the policy and procedure manuals.

Appendix A: Schedule of Narcotics and Controlled Substances in Mississippi

Risk to the Public	Narcotic Effect vs. Medicinal Benefit	Examples
Schedule I	Narcotic concentration is pure. They have no established medicinal benefits.	heroin, marijuana
Schedule II	The narcotic is a high active ingredient, but mixture with other substances has established medicinal benefits such as a codeine-Tylenol mixture.	cocaine, morphine, opium, Oxycodone, codeine
Schedule III	The narcotic concentration is moderate compared to medicinal ingredients	barbiturate derivatives, Hydrocodone
Schedule IV	The narcotic concentration is low compared to medicinal ingredients.	Darvocet-N
Schedule V	The narcotic concentration is very low compared to medicinal qualities.	Robitussin AC with Codeine

SOURCE: Mississippi Uniform Controlled Substances Law (MISS. CODE ANN. Section 41-29-113 through 121[1972]).

Appendix B: Example of a Professional Code of Ethics from the Board of Registration for Professional Engineers and Land Surveyors

The Board of Registration for Professional Engineers and Land Surveyors' *Rules and Regulations* promulgates a code of ethics by Rule 17.06:

The registrant shall contribute to the maintenance, integrity, independence and competency of the engineering and/or land surveying profession as follows:

- 1. The registrant shall not violate any provision of Mississippi Law regulating the practice of engineering and land surveying;
- 2. The registrant shall not participate, directly or indirectly, in any plan, scheme or arrangement attempting or having as its purpose the violation of any provision of the Law regulating the practice of engineering and land surveying;
- 3. The registrant shall exercise reasonable care to assure that his partners, associates, and employees do not engage in conduct which, if done by him, would violate any provision of Law regulating the practice of engineering and land surveying;
- 4. The registrant shall not engage in any illegal conduct involving moral turpitude;
- 5. The registrant shall not engage in any conduct that discredits or tends to discredit the profession of engineering and/or land surveying;
- 6. The registrant shall not permit or allow himself, his professional identification, seal, firm, or business name, or his services to be used or made use of, directly or indirectly, or in any manner whatsoever, so as to make possible or create an opportunity for the unauthorized practice of engineering and/or land surveying by any person, firm or corporation in this state;
- 7. The registrant shall not perform any acts, allow omissions or make any assertions or representations which are fraudulent, deceitful, or misleading, or which in any manner whatsoever tend to create a misleading impression;
- 8. The registrant shall not knowingly associate with or permit or allow the use of his name, firm name or professional identification or seal in any business venture, project or enterprise which he knows or has reason to believe is involved in professional practices which violate any provision of the Law regulating the practice of engineering and/or land surveying;
- 9. The registrant shall not knowingly associate with or permit the use of his name, professional identification, seal, firm or business name in connection with any venture or enterprise which he knows, or has reason to believe, involves trade, business or professional practice of a fraudulent, deceitful or dishonest nature;

- 10. The registrant shall not injure or attempt to injure the professional reputation of another registrant. This shall not relieve a registrant of the obligation to expose unethical or illegal conduct to the proper authorities or preclude an honest appraisal of registrants considered for employment;
- 11. The registrant shall not aid or abet, directly or indirectly, any nonregistrant in the practice of engineering and/or land surveying.
- 12. The registrant shall be personally and professionally responsible and accountable for the care, custody, control and use of his engineer's and/or land surveyor's seal, his professional signature and identification. A seal which has been lost, misplaced or stolen shall, upon discovery of its loss, be reported immediately to the Board, which may invalidate the registration number of said seal, if it deems this necessary, and issue another registration number to said registrant.
- 13. The registration shall not, directly or indirectly, use or make use of any property, facility or service of any governmental body, agency or department for the benefit of any private business or activity in which the registrant also may be engaged.
- 14. The registrant shall not, directly or indirectly, use or make use of any property, facility or service of his client or employer for his own benefit.
- 15. The registrant shall not practice or offer to practice engineering and/or land surveying in any governmental jurisdiction in which to do so would be in violation of the Laws regulating the practice of professional engineering and/or professional land surveying in that jurisdiction.

Rules and Regulations promulgates standards of character and reputation by Rule 17.07:

The registrant shall be responsible for maintaining good character and reputation. Suspension of a certificate of registration by another jurisdiction, becoming a habitual drunkard, being grossly immoral, or addicted in the use of narcotics, being finally adjudged insane, or incompetent by a court of competent jurisdiction or being convicted of a felony or misdemeanor involving moral turpitude shall be grounds for a disciplinary hearing which may result in revocation of his certificate of registration.

MISSISSIPPI BOARD OF PHARMACY

204 KEY DRIVE, SUITE C : MADISON, MS 39110 601-605-5388 : Fax 601-605-9546

June 16, 2004



Dr. Max K. Arinder, Ph.D.
Director
Joint Committee on Performance Evaluation and Expenditure Review
P. O. Box 1204
Jackson, MS 39215

Dear Dr. Arinder,

This letter is in response to the recent review of the Mississippi Board of Pharmacy by PEER. I would like to address each of your recommendations as listed in your Executive Summary by number:

- 1. The Board on July 8, 2004, will consider adoption of criteria for the acceptance or rejection of applicants for Pharmacy Technician Registration or Pharmacist Licensure which have a prior history of felony or misdemeanor convictions.
- 2. The office staff is now seeking information regarding implementation of a system of conducting background checks of all applicants for Pharmacist Licensure and Pharmacy Technician Registration and a method of determination of the cost of implementing and operating such a system including the charge to be made to the applicant for the check.
- 3. The Board on July 8, 2004, will consider adoption of the MPJE (Multistate Pharmacy Jurisprudence Examination) as the Pharmacy Law exam for the state. We have found that the cost to each licensure applicant for this exam at the present time would be \$170.00.
- 4. The Board on July 8, 2004, will make a decision on the most efficient means to utilize the two new positions authorized for FY 2005
- 5. The Board on July 8, 2003, will consider adoption of a formal written policy regarding intervals at which pharmacies and other registrants under the jurisdiction of the Board should be inspected. It is the intent of the compliance staff that each facility be inspected at least every year and a half. A minimum of two compliance agents will be assigned to inspection only duty beginning July 1, 2004, to allow us to bring our inspection numbers to an acceptable level.

Emphasis will be placed on those facilities that have never been inspected or a significant period of time has lapsed since the last inspection.

- 6. The inspection territories have been divided relatively equally between three compliance agents to increase efficiency and minimize cost and travel distance. I have enclosed a copy of the new state division and the breakdown of the number of facilities by agent.
- 7. It continues to be the policy of the Board that Compliance Agents do not make arrests. For the present time, each compliance agent will qualify bi-annually with a handgun. Results of each qualification and training exercise will be documented in detail. Training and qualification exercises will be conducted by NRA Certified Enforcement Agent Steve Stovall. Additional training in defensive shooting skills will be provided by Major Tim Rutledge of the Mississippi Bureau of Narcotics on an annual basis.
- 8. Policy and procedure manuals are in the process of being developed for Enforcement Agents and manuals addressing Licensing and agency operations will begin to be developed as soon as possible.
- 9. A formal internal training program for enforcement and licensing operations will be developed with appropriate policy and procedures for agency operations.

The recommendations and comments made by the PEER staff are well taken and each recommendation will be addressed as quickly as possible. During the course of the review of our agency, your staff has conducted themselves in a courteous and highly professional manner.

Sincerely,

heland MCT with

Leland "Mac" McDivitt Executive Director Mississippi Board of Pharmacy

Agent Atwood

Desoto	53
Tate	15
Tunica	4
Marshall	15
Benton	7
Tippah	8
Alcorn	34
Tishomingo	11
Prentiss	15
Itawamba	9
Lee	53
Union	17
Lafayette	34
Panola	24
Quitman	9
Coahoma	25
Bolivar	34
Sunflower	20
Leflore	23
Tallahatchie	12
Yalobusha	11
Calhoun	16
Pontotoc	18
Chickasaw	15
Monroe	24
Clay	11
Lowndes	49
Oktibbeha	22
Choctaw	6
Webster	8
Montgomery	13
Grenada	21
Carroll	2
Holmes	17

655

Agent Gammill

Copiah	36
Hinds	146
Warren	42
Rankin	77
Scott	27
Newton	15
Lauderdale	68
Kemper	4
Neshoba	21
Leake	18
Madison	65
Yazoo	17

Washington Humphreys Attala Winston Noxubee	39 13 18 16 9
	637
Agent Keith	
Hancock Harrison Jackson George Stone Pearl River Greene Perry Forrest Lamar Marion Walthall Pike Amite Wilkinson Adams Franklin Lincoln Lawrence Jeff Davis Covington Jones Wayne Clarke Jasper Smith Simpson Jefferson Claiborne	$ \begin{array}{c} 21\\ 122\\ 64\\ 15\\ 14\\ 26\\ 7\\ 9\\ 56\\ 24\\ 20\\ 10\\ 32\\ 3\\ 15\\ 27\\ 10\\ 25\\ 8\\ 9\\ 13\\ 34\\ 13\\ 10\\ 8\\ 7\\ 27\\ 6\\ 9\\ \end{array} $
Claiborne	9 644





OFFICE OF THE DIRECTOR

204 KEY DRIVE, SUITE C • MADISON, MS 39110 Telephone 601-605-5388 • Fax 601-605-9546

July 1, 2004

To: Peer Committee

From: Mac McDivitt - Pharmacy Board

Re: Firearms

In reference to the use of fire arms by our staff without meeting minimum standard, I offer the following:

* Our purpose for the use of firearms is defensive not offensive. We are routinely involved with situations that destroy people's lives and livelihood.

* A firearm is a deterrent as well as protection if needed.

A situation does not exist that provides minimum standard training with a firearm that does not involve intense physical training. You do not need physical training to use a firearm properly with good judgment.

Pharmacies and Pharmacist are armed. There have been multiple shootings in pharmacies over the past years.

Sincerely,

he and

Leland "Mac" McDivitt Executive Director

PEER Committee Staff

Max Arinder, Executive Director James Barber, Deputy Director Ted Booth, General Counsel

Evaluation

David Pray, Division Manager Linda Triplett, Division Manager Larry Whiting, Division Manager Antwyn Brown Pamela O. Carter **Kim Cummins** Barbara Hamilton Kelly Kuyrkendall Karen Land Sara Miller Joyce McCants Charles H. Moore John Pearce Brad Rowland Sara Watson **Candice Whitfield**

Editing and Records Ava Welborn, Editor and Records Coordinator Tracy Bobo Sandra Haller

<u>Administration</u> Mary McNeill, Accounting and Office Manager Terry Littlefield Gale Taylor

<u>Data Processing</u> Larry Landrum, Systems Analyst

<u>Corrections Audit</u> Louwill Davis, Corrections Auditor