

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

Report to
the Mississippi Legislature



A Review of the Board of Pharmacy

PEER determined that an essential need exists for regulation of the pharmacy profession in Mississippi. Although the Board of Pharmacy is responsible for fulfilling this need, some components of the board's licensure and registration and compliance operations may place the public at unnecessary risk:

- *Licensure and registration*--Although state law requires that applicants for pharmacist licensure and pharmacy technician registration "be of good moral character," state law and the board's rules and regulations do not contain formal, written criteria for this requirement. Also, because the board's jurisprudence examination is not properly developed or administered, the board cannot ensure that applicants have sufficient knowledge of state pharmacy laws and regulations to practice pharmacy.
- *Compliance*--State law confers the authority of sworn law enforcement officers on compliance agents even though their job description does not require this authority. State law does not require compliance agents to complete minimum standards training for firearms and the board is not in compliance with its own policies regarding firearms training. Thus compliance agents who carry firearms could potentially cause or incur injuries because they are not properly trained and could potentially place the state in a position of liability for their actions.

Regarding administrative issues, the board does not have formal, written policies for its administrative or licensing functions and has not established an agency-wide internal training program. Also, the board has paid per diem and expenses to a gubernatorial appointee to the board who was not confirmed by the Senate during the 2010 legislative session. Because that seat on the board is legally vacant, these expenditures would appear to have no basis in law.

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 and three at-large members appointed from each house. 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.

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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.

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Joint Committee on Performance Evaluation and Expenditure Review

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July 21, 2010

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

On July 21, 2010, the PEER Committee authorized release of the report entitled **A Review of the Board of Pharmacy.**


Senator Nolan Mettetal, Chair

This report does not recommend increased funding or additional staff.

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A Review of the Board of Pharmacy

Executive Summary

Introduction

In conducting this review, PEER first determined whether protecting the public's health, safety, and welfare through regulation of the pharmacy profession fulfills an essential social need.

After establishing the need for state regulation of the pharmacy profession, PEER evaluated the functions and operations of the board, including its licensure of pharmacists and registration of pharmacy technicians and activities to ensure compliance with state laws, rules, and regulations that govern the practice of pharmacy in Mississippi.

Additionally, PEER revisited conclusions of three previous PEER Committee reports on the Board of Pharmacy and assessed the board's progress regarding resolution of issues noted in these previous reports. PEER also addressed specific allegations from complainants regarding administrative issues.

Conclusions

Need for the Regulation of Pharmacy

Inadequate regulation of the pharmacy profession could expose the public to unnecessary risks and could contribute to improper, unethical, or criminal activity within the profession. Specific risks include:

- inadequate knowledge and skills associated with the study of pharmacy;
- illegal distribution of drugs;
- improper use of controlled substances;
- inadequate or unsanitary pharmaceutical facilities;
- mismanagement of drug inventories; or,
- inadequate clinical or technician supervision.

PEER concluded that Mississippi has an essential public need for regulation of the pharmacy profession.

Follow-Up Conclusions

Although the Board of Pharmacy is responsible for fulfilling the need for regulation of the pharmacy profession, some components of the board's licensure, registration, and compliance operations may place the public at unnecessary risk. In assessing the board's progress regarding resolution of issues noted in PEER's previous reports, PEER found the following.

Licensure and Registration

- Although state law requires that applicants for pharmacist licensure and pharmacy technician registration "[b]e of good moral character," state law and the board's rules and regulations still do not contain formal, written criteria for this requirement.
- In addition to the validated national pharmacy examination given by the National Association of Boards of Pharmacy, the board requires Mississippi's pharmacy applicants to pass an examination on state pharmacy laws (i. e., the board's own jurisprudence examination). Because the jurisprudence examination is not properly developed or administered, the board cannot ensure that applicants have sufficient knowledge of state pharmacy laws and regulations to practice pharmacy.

Compliance

- The board has taken steps toward improving efficiency and effectiveness in assigning compliance agents to inspection regions.

Statutory Authority for Compliance Agents to Serve as Sworn Law Enforcement Officers

- MISS. CODE ANN. Section 41-29-159 (1972) confers the authority of sworn law enforcement officers on compliance agents; however, compliance agents' job description does not require this authority. State law does not require compliance agents to complete minimum standards training for firearms and the board is not in compliance with its own policies regarding firearms training.

Administrative Issues

- Although the Compliance Division operates with formal, written policies and procedures, the board does not have formal, written policies for its administrative or licensing functions. Furthermore, the board has not established an agency-wide internal training program.

Board Membership

- A recent gubernatorial appointee to the Board of Pharmacy was not confirmed by the Senate during the 2010 legislative session prior to sine die adjournment. According to state law and opinions of the Attorney General, upon vacation of the Senate (i. e., sine die adjournment), that member's seat remains vacant. However, the board has paid \$390.60 in per diem and expenses to that member since the date on which the seat legally became vacant.

Status of Specific Concerns Regarding the Board's Administrative Functions

When conducting this review, PEER also addressed the following specific allegations by complainants:

- inappropriate business relationships between the board and the entities it regulates;
- whether duties performed by the Cornerstone Consulting Group, Inc., could be performed by board staff;
- mismanagement of federal grants;
- excessive or frivolous spending with regard to contracts, travel, training, and furnishings;
- whether the board is in compliance with State Personnel Board policies; and,
- whether there are adverse pending legal proceedings against the board.

Complaint 1: Business Relationships Between the Board and Entities It Regulates

Although an employee and board member formerly jointly owned a business regulated by the board, the company has been dissolved and the potential conflict of interest no longer exists.

Complaint 2: Contractual Expenditures

Based on PEER's analysis of available information, the MBP's decision to sacrifice a Bureau Director II position to fund a contract with Cornerstone Consulting to provide accounting and computer services was a cost-effective decision.

Complaint 3: Management of Federal Grants

Subsequent to an August 2006 audit of the Prescription Monitoring Program, federal auditors disallowed \$50,002 of the board's expenditures for that program. The board has since resolved these issues with the federal government and now operates the program with self-generated funds.

Complaint 4: Appropriateness of Expenditures

PEER reviewed the MBP's expenditures for FY 2005 through FY 2010 and did not detect expenditures that would not appear to be reasonable for a regulatory agency.

Complaint 5: Compliance with State Personnel Board Policies

In reviewing MBP operations, PEER found that the board has made improvements in its assignment of compliance agents and that it is operating within the bounds of its authority in the assignment of staff.

Complaint 6: Pending Legal Proceedings

The MBP has a federal court case pending against it that relates to a claim of employment discrimination and failure to promote.

Recommendations

1. In order to protect the public's health through licensure and registration, the board should:
 - adopt into its rules and regulations formal criteria to determine an applicant's moral character; and,
 - adopt the use of the Multistate Pharmacy Jurisprudence Examination (MPJE) administered by the NABP as the board's jurisprudence examination to test pharmacy applicants on their knowledge of

federal and state laws and regulations that govern the practice of pharmacy.

2. In order to protect the public's health through its compliance activities, the board should:
 - ensure that its new management system has the capability to conduct annual cost-benefit analysis to determine whether assigned inspection regions:
 - minimize state travel cost (gas, oil, and maintenance);
 - minimize travel distance for inspectors; and,
 - maximize available inspection time during each workday; and,
 - adopt a policy that prohibits compliance agents from performing any sworn law enforcement officer duties, including carrying firearms.
3. The Legislature should:
 - amend MISS. CODE ANN. Section 45-6-3 (1972) to remove authority for compliance agents to function as law enforcement officers; and,
 - amend MISS. CODE ANN. Section 41-29-159 (1972) to provide that 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).
4. In order to ensure the safety of the public through its administrative activities, the board should:
 - develop policy and procedures manuals for its administrative and licensing operations and ensure that its compliance manual is comprehensive and current; and,
 - establish an agency-wide internal training program to minimize the possibility of administrative, communications, and operational errors. The curriculum for this training program should cover, as a minimum, the information contained in the policy and procedure manuals.
5. The Executive Director of the Board of Pharmacy should consult with the Department of Audit regarding the proper procedure for reimbursing the board's fund

for the amounts paid to Mr. Leland McDivitt for the May 2010 board meeting. The board should also ensure that Mr. McDivitt is not paid or allowed to perform as a board member until such time as he may be reappointed and confirmed.

Implications for Change

Although improvements could be made to the state's existing regulatory structure for pharmacy regulation, implications for change also exist in approaching occupational regulatory efforts in a new way.

PEER notes that twenty-nine states have boards of pharmacy that operate within a shared services structure. In an enterprise model of regulation of professions, occupational regulation would be considered a single enterprise in which resources would be networked across occupational boards to achieve an optimal balance of central control and efficiency.

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A Review of the Board of Pharmacy

Introduction

Authority

The PEER Committee reviewed the functions and operations of the Mississippi Board of Pharmacy (MBP). PEER conducted the review pursuant to the authority granted by MISS. CODE ANN. Section 5-3-57 et seq. (1972).

Purpose and Scope

Need for Regulation of the Pharmacy Profession

In conducting this review, PEER first determined whether protecting the public's health, safety, and welfare through regulation of the pharmacy profession fulfills an essential social need.

Evaluation of the Board's Operations and Follow-Up on Previous PEER Reports

After establishing the need for state regulation of the pharmacy profession, PEER evaluated the functions and operations of the board, including its licensure of pharmacists and registration of pharmacy technicians and activities to ensure compliance with state laws, rules, and regulations that govern the practice of pharmacy in Mississippi.

Additionally, PEER revisited conclusions of the Committee's previous reports on the Board of Pharmacy:

- *Investigative Review of the State Board of Pharmacy* (Report #275; February 3, 1992)--PEER investigated allegations of inequitable investigative procedures and selective enforcement of state laws and regulations by the Pharmacy Board and its former Executive Director. PEER found weaknesses in the board's enforcement of and compliance with state pharmacy laws and regulations that included inequitable enforcement of regulations, failure to train compliance agents adequately, and failure to provide firearms training or require that compliance agents become firearms qualified.

- *Follow-Up Review of the 1992 Investigative Review of the State Board of Pharmacy* (Report #291; December 16, 1992)--PEER followed up on the February 3, 1992, report and concluded that the Board of Pharmacy had made significant progress in correcting deficiencies cited in the initial report. The corrections made included establishing a uniform penalty policy and a functioning Investigations Review Committee to hear reports on ongoing and potential investigations. The board also compiled a “how to” inspection/investigative manual and provided basic firearms training for compliance agents.
- *A Review of the Board of Pharmacy* (Report #470; September 14, 2004)--PEER conducted a “cycle review” (i. e., a review not driven by specific complaints or allegations of misconduct) of the board. The review was aimed at determining the public need for the regulation of pharmacy. Once PEER established the public need for the regulation of pharmacy, PEER then evaluated how well MBP carried out its regulatory functions. Although PEER found that MBP fulfills an essential public need, deficiencies were found in areas of licensure, enforcement, and administration. (See Appendix A, page 41, for conclusions and recommendations from the 2004 report.)

PEER assessed the board’s progress regarding resolution of issues noted in these previous reports.

Status of Specific Concerns Regarding the Board’s Administrative Functions

PEER also addressed specific allegations from complainants that included:

- inappropriate business relationships between the board and the entities it regulates;
- whether duties performed by Cornerstone Consulting Group, Inc., could be performed by board staff;
- mismanagement of federal grants;
- excessive or frivolous spending with regard to contracts, travel, training, and furnishings;
- whether the board is in compliance with State Personnel Board rules and regulations; and,
- whether there are adverse legal proceedings pending against the board.

Method

In conducting this review, PEER:

- reviewed state laws and regulations governing the practice of pharmacy in Mississippi;
- reviewed and analyzed records of the MBP;
- interviewed MBP staff and staff of the National Association of Pharmacy Boards; and,
- reviewed pharmacy and pharmacy practice literature.

Background

This chapter provides information on the scope of the pharmacy profession and how that profession is regulated in Mississippi.

Scope of the Pharmacy Profession

Pharmacy is the science dealing with collection, preparation, and standardization of drugs. Over the years, the pharmacy profession has expanded its role to include services such as:

- drug procurement and dispensation;
- storage and compounding of drugs;
- controlling access to controlled substances;
- providing appropriate information and advice to the patient; and,
- regular monitoring of both the prescribing and administration of medicines.

The Legislature created the Board of Pharmacy during the 1916 Regular Session to regulate the pharmacy profession, including the licensing of pharmacists, and to enforce the laws associated with the sale of certain drugs among practitioners. As of June 30, 2010, 3,723 pharmacists were licensed to practice pharmacy in Mississippi and 4,305 pharmacy technicians (i. e., pharmacy support staff who work under the supervision of licensed pharmacists) were registered in the state.

Regulation of the Pharmacy Profession in Mississippi

Role of the National Association of Boards of Pharmacy in Regulating the Pharmacy Profession

According to the mission statement of the National Association of Boards of Pharmacy (NABP), the association “assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.” Through its programs and services, the NABP helps state boards of pharmacy to promote the highest standards of

pharmacy practice and therefore plays a role in the regulation of the pharmacy profession.

According to NABP, it supports its member boards of pharmacy in the following ways:

- providing examinations to assess pharmacists' competency to practice pharmacy, including questions specific to certain states' pharmacy laws, thus giving boards a uniform, high-quality solution to test pharmacists' competency;
- administering a license transfer program that alleviates the administrative burden on boards by verifying applications for license transfer;
- administering accreditation programs that create uniform standards and perform inspections to supplement board staff and finances; and,
- providing other services to support the pharmacy boards by providing pertinent resources to assist them.

Statutory Authority and Requirements for Regulation of Pharmacy

The Mississippi Board of Pharmacy, which was created in MISS. CODE ANN. Section 73-21-75 (1972), operates as an independent board. It is a self-sustaining board charged with the responsibility of regulating the pharmacy profession, as well as administrative activities and the day-to-day operations associated with pharmacy regulation.

To accomplish these board roles, the MBP enforces the laws, rules, regulations, and policies that govern the pharmacy profession. In addition to regulatory activities, the board also controls and funds those administrative activities that are important in the day-to-day operations of the board.

Board Composition and Qualifications for Members

MISS. CODE ANN. Section 73-21-75 (1972) requires that the board be composed of seven members appointed by the Governor with the advice and consent of the Senate. Members are to be selected from a list provided by the Mississippi Pharmacists Association, with input from the Magnolia Pharmaceutical Society and other pharmacists associations or societies.

Also, CODE Section 73-21-75 requires that one member, at the time of appointment, shall have at least five years' experience as a pharmacist at a facility holding an institutional permit and that one member, at the time of

appointment, shall have five years' experience as a pharmacist at a facility holding a retail permit.

The Governor appoints one board member from each of the five congressional districts as they existed on July 1, 2001, and two from the state at large. Board members must meet the qualifications set by state law, which include:

- be an adult citizen of Mississippi for a period of five years preceding appointment;
- be a pharmacist licensed and in good standing to practice pharmacy in the State of Mississippi;
- have at least five years' experience as a pharmacist; and,
- be actively engaged full time in the practice of pharmacy in Mississippi.

No board member may serve more than two full terms of office during any fifteen-year period.

Regulation of Practitioners and Facilities

MISS. CODE ANN. Sections 73-21-81 and 73-21-83 (1972) authorize the Board of Pharmacy to act as the chief administrator for any decisions that must be made for the efficient and effective regulation of the practice of pharmacy. The board is primarily responsible for approving licenses to practice pharmacy in the state and for the regulation of those individuals who are associated with those practices—chiefly, pharmacy technicians, student interns, and externs. The board also issues permits to facilities that include community, institutional, and wholesale pharmacies. In addition, the board issues permits to medical gas wholesalers and durable medical equipment suppliers. MISS. CODE ANN. Section 73-21-107 (1972) states that the board may inspect any of those facilities within the state to which it has issued a permit to operate.

Regulation of Controlled Substances

MISS. CODE ANN. Section 41-29-159 (1972), part of the Uniform Controlled Substances Law, delegates to the Board of Pharmacy the responsibility of regulating and checking the legitimate drug traffic among pharmacists, pharmacies, hospitals, nursing homes, drug manufacturers, and any other related professions and facilities with the exception of the medical, dental, nursing, optometric, and veterinary professions.

MISS. CODE ANN. Section 73-21-127 (1972) gives the board the authority to develop and implement a computerized program to track prescriptions for controlled substances. From 2004 through April 30, 2010, Mississippi has received \$699,915 in federal funds to administer the Mississippi Prescription Monitoring Program (PMP) to monitor controlled substances dispensed in the state. The program has two key elements:

- *Data Submission:* Information about controlled substance dispensing activities is reported regularly to the state of Mississippi through the authorized data collection vendor. Any entity dispensing controlled substances, or specified non-controlled substances, in or into Mississippi is required by law to provide such information to the data collection vendor in approved formats and frequencies. This includes mail orders into the state.
- *Information Retrieval:* Mississippi's online reporting application allows authorized users to generate customized reports twenty-four hours a day, seven days a week. A report shows information for all the scheduled prescriptions a specified patient has had for a specified period. Individuals authorized to generate reports through this system are pharmacists, law enforcement officers involved in active investigations, Mississippi licensure boards, or any person that is responsible for prescribing medical treatment to an existing patient.

Controlled substances dispensers, both in-state and out-of-state, are required by law to report all dispensing activity to the state's authorized data collection vendor. The Pharmacy Board has contracted with RelayHealth, a network solutions company based in Atlanta, GA, to serve as Mississippi's authorized data collection vendor for the PMP.

Recent Pharmacy Law Changes

In the last six years, several statutory changes have occurred in the Mississippi Pharmacy Practice Act (MISS. CODE ANN. Sections 73-21-71 through 73-21-123) that impact MBP's regulation of pharmacy in Mississippi. These changes include:

- authority given to the board to conduct state and federal criminal history checks on applicants for pharmacy licensure and pharmacy technician registration;

- a change in required continuing education hours from twenty biennially to ten annually;
- a change in licensure renewal fees from \$200 biennially to \$100 annually; and,
- statutory language to develop and implement the computerized program to track certain prescriptions (Prescription Monitoring Program).

Staffing and Operations of the Board

Staffing and Core Functions of the Board of Pharmacy

MISS. CODE ANN. Section 73-21-79 (1972) states that the board shall employ an Executive Director who shall be a Mississippi resident, a licensed pharmacist in good standing to practice pharmacy in the state, and who has had five years' experience as a pharmacist.

In carrying out its responsibilities for the control and regulation of pharmacy, the Board of Pharmacy has three staff divisions that represent its core functions, as noted below.

- *Licensing Division*--is responsible for the licensure of pharmacists and the registration of pharmacy externs, interns, and technicians. Staffing for this division includes a division director, a special projects officer, and an enforcement agent.
- *Compliance Division*--is responsible for ensuring registrants' and licensees' compliance with pharmacy laws and regulations through education. Staffing for this division includes a division director, four compliance agents, and a special projects officer.
- *Prescription Monitoring Program (PMP)*--as noted on page 7, the PMP is responsible for monitoring controlled substances dispensed in the state. Staffing for this division consists of a division director.

The board also employs an administrative assistant, for a total of twelve staff members.

Management Information Systems

The Board of Pharmacy uses a management information system (MIS) to support its licensing and compliance activities. According to the board's staff, the current MIS is "fragile" and obsolete, growing more unreliable by the day, and has posed productivity limitations. For example, the board is limited in its ability to produce statistical reports that would aid MBP in making management and

operating decisions. As a result of the MBP's "fragile" management information system, MBP recently contracted with a vendor to develop a customized MIS for the board.

MBP, in conjunction with the Mississippi Department of Information Technology Services (ITS) released a request for proposals for the development of a new management information system for the board. On January 19, 2010, ACO Information Services, LLC, an Alabama-based technology company, was awarded a contract at a total not-to-exceed five-year lifecycle cost of \$284,213.90.

The MIS being developed by ACO Information Services, LLC, is expected to streamline the board's licensing and compliance functions. For example, the system will be able to record, issue, renew, and process permits for facilities, licenses for pharmacists, and registrations for technicians and students. Additionally, the system will be able to facilitate queries, statistics, reporting, correspondence, and official document production associated with the database of license holders and permitted facilities.

Revenues and Expenditures

The Board of Pharmacy is a special fund agency that supports its operations by collecting annual and biennial fees from those individuals, facilities, and other providers that it regulates. In addition, the board receives federal funding for the Prescription Monitoring Program. Because the number of renewals or new licenses and registrations fluctuates from year to year, the board's revenues also fluctuate.

According to reports obtained from the Department of Finance and Administration, the Board of Pharmacy's end-of-year cash was \$1,024,512 in Fiscal Year 2008 and \$769,298 in Fiscal Year 2009. Exhibit 1, page 10, shows revenues and expenditures for the last five years.

The board assesses the following fees:

- \$50 for student pharmacist interns during internships (one-time fee);
- \$50 annually for registered technicians, institutional emergency medical kits, medical gas wholesalers, and home health providers;
- \$50 annually for controlled substances permits;
- \$100 annually for durable medical equipment suppliers;
- \$105 annually for licensed pharmacists; and,

- \$300 biennially for the seven types of regulated pharmacy operations.

Exhibit 1: Board of Pharmacy's Revenues and Expenditures for Fiscal Years 2005 through 2009

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Revenues					
Beginning Cash	\$708,004	\$424,724	\$748,442	\$427,922	\$1,024,512
Special Funds ¹	719,430	2,091,273	770,454	1,779,433	1,475,433
Total Revenues	1,427,434	2,515,997	1,518,896	2,207,355	2,499,945
Expenditures³	\$1,002,710	\$1,077,514	\$1,090,974	\$1,182,843	\$1,730,647
Transfer to Contingency Fund²		\$690,041			
End of Year Cash	\$424,724	\$748,442	\$427,922	\$1,024,512	\$769,298

¹MBP received an allotment for a \$699,915 federal grant for the Prescription Monitoring Program for FY 2004 thru FY 2010. These funds were available for drawdown by MBP as needed and are included in special funds revenue for FY 2005 thru FY 2009.

²Senate Bill 2066, Second Extraordinary Session of 2005, directed the transfer of \$690,041 in special funds from MBP to the Budget Contingency Fund.

³PEER notes that the \$547,804 increase in expenditures from FY 2008 to FY 2009 was largely due to an increase in contractual services for the administration of MBP's Prescription Monitoring Program.

SOURCE: PEER analysis of Department of Finance and Administration records.

Conclusions

An essential need exists for regulation of the pharmacy profession in Mississippi. Although the Board of Pharmacy is responsible for fulfilling this need, some components of the board's licensure and registration and compliance operations may place the public at unnecessary risk.

Need for the Regulation of Pharmacy

Mississippi has an essential public need for regulation of the pharmacy profession. Inadequate regulation of the profession could expose the public to unnecessary risks and could contribute to improper, unethical, or criminal activity within the profession.

The pharmacy profession is currently transforming itself from a primarily product-centered profession to a patient care-oriented profession. Pharmacists have generally been responsible for the dispensing, procurement, storage, and compounding of drugs, but the traditional role of the pharmacist is being expanded to include practice roles in community, ambulatory, long-term, and home-care health settings.

Adequate regulation becomes significantly more important as the profession moves away from mainly research and development, production, quality control, distribution, and clinical application toward an overall philosophy of pharmaceutical care in which the patient is the primary beneficiary. According to the National Association of Boards of Pharmacy:

. . .given that medications are an integral part of disease management, medication therapies and their delivery systems are becoming more complex, technological enhancements have improved the capabilities for patient monitoring, and entities motivated by economic gain are eroding standards of care, there is greater potential harm to the public and a greater need for patients' medication to be managed by a licensed pharmacist and State regulatory agencies to aggressively enforce standards of care.

It is essential that the public's health, safety, and welfare be protected and preserved through regulatory activities. Regulatory functions such as licensing, compliance, and prescription monitoring should seek to limit risks to the

public associated with the practice of pharmacy. Those risks include:

- inadequate knowledge and skills associated with the study of pharmacy;
- illegal distribution of drugs;
- improper use of controlled substances;
- inadequate or unsanitary pharmaceutical facilities; mismanagement of drug inventories; or,
- inadequate clinical or technician supervision.

Licensure and Registration

The Board of Pharmacy's licensure and registration process includes administrating the application process for pharmacists and pharmacy technicians and examining pharmacists for competency.

Components of Licensure and Registration

As noted on page 8, MBP's licensure of pharmacists and registration of pharmacy technicians is a core function of the board.

Pharmacist Licensure

MISS. CODE ANN. Sections 73-21-87 and 73-21-89 (1972) describe the requirements necessary for pharmacists to become licensed in Mississippi. Pharmacists may obtain a Mississippi license by one of two methods:

- licensure by examination; or,
- licensure by transfer.

Licensure by Examination

Applicants who receive licenses from the Board of Pharmacy through examination include pharmacy students who attended the University of Mississippi School of Pharmacy, students who attended an accredited pharmacy school out-of-state, and applicants who received their pharmacy education outside the United States (i. e., foreign graduates). Although students who attended pharmacy school both in-state and out-of-state undergo the same licensure process, MISS. CODE ANN. Section 73-21-85 (2) (1972) requires that foreign graduates take additional steps in the licensure process.

The board's regulations require that all applicants who receive their license by examination have 1600 pre-licensure (practical) hours and state law requires a certificate of graduation from an accredited pharmacy school. The board's regulations also require applicants to pass two examinations:

- *the North American Pharmacist Licensure Examination, or NAPLEX*—This exam was developed by the National Association of Boards of Pharmacy. The NAPLEX attempts to assess whether applicants:
 - can identify practice standards for safe and effective pharmacotherapy and optimize therapeutic outcomes in patients;
 - can identify and determine safe and accurate methods to prepare and dispense medications; and,
 - can provide and apply health care information to promote optimal health.

In order to ensure the NAPLEX's validity and reliability, NABP evaluated pharmacy practice outcomes and reviewed the knowledge and skills necessary to practice entry-level pharmacy safely and effectively. Also, through a survey of practicing pharmacists across the United States and Canada, NABP validated the NAPLEX blueprint content. The NAPLEX blueprint consists of NAPLEX Competency Statements of the topics covered on the examination, which include:

- assess pharmacotherapy to assure safe and effective therapeutic outcomes;
 - assess safe and accurate preparation and dispensing of medications; and,
 - assess, recommend, and provide health care information that promotes public health.
- *the state's jurisprudence exam*—This was developed by and is administered by the Mississippi Board of Pharmacy.

In addition to the examination requirements, since 2005, MISS. CODE ANN. Section 73-21-85 (4) (1972) has required that applicants submit fingerprints to MBP for a criminal history check. (See page 14.)

Applicants who are considered foreign graduates and receive licensure by examination must take additional steps for licensure. CODE Section 73-21-85 (2) (1972)

requires that foreign graduates complete the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from the NABP. The FPGEC Certification Program serves as a means of documenting the educational equivalency of an applicant's foreign pharmacy education. Foreign graduates are also required to pass the Test of English as a Foreign Language (TOEFL) as a prerequisite for licensure.

Licensure by Transfer

The board's regulations require that pharmacists who receive their licenses through transfer from another state complete several steps, which include:

- completion of an NABP Electronic Licensure Transfer Program application;
- completion of the MBP licensure application;
- passing MBP's jurisprudence exam; and,
- successful completion of a criminal history check (required since 2005).

Pharmacy Technician Registration

MISS. CODE ANN. Section 73-21-111 (1972) requires that every person who acts or serves as a pharmacy technician in a pharmacy that is located in the state be registered with the board and requires completion of a registration application. Since 2005, that CODE section has required that pharmacy technician applicants undergo a criminal history check.

PEER's Previous Conclusions and Recommendations: The Board's Licensure of Pharmacists and Registration of Pharmacy Technicians

In 2004, PEER determined that MBP did not have formal, written criteria for accepting or rejecting applicants based on their criminal histories. Also, the board relied on self-reporting of criminal history rather than utilizing the background check resources of the Department of Public Safety. The self-reporting of criminal history served as the board's check for "good moral character" as identified by MISS. CODE ANN. Section 73-21-85 and 73-21-111 (1972) as a requirement for pharmacists and pharmacy technicians.

PEER recommended that MBP adopt formal, written criteria for accepting or rejecting pharmacist and pharmacy technician applicants based on their criminal histories. Additionally, PEER recommended that the Legislature amend MISS. CODE ANN. Section 73-21-85 and 73-21-111

(1972) to require that the MBP conduct background checks of applicants for pharmacist's licenses and pharmacy technician's registrations in order to ensure that they meet the statutory qualifications to "[b]e of good moral character" and further, to direct Department of Public Safety to assist the board in conducting the background checks.

PEER also noted in 2004 that the board's examination of knowledge of state pharmacy laws and regulations (i. e., the jurisprudence exam) had not been properly developed or administered. The board could not ensure that its state pharmacy exam adequately tested professional knowledge relevant to pharmaceutical practice in the state of Mississippi. PEER recommended that MBP ensure that its state pharmacy examination complied with professional standards, such as those promulgated by the Council on Licensure, Enforcement, and Regulation (CLEAR).¹

Application Process

2010 Conclusion: Adequacy of the Board's Application Process
Although state law requires that applicants for pharmacist licensure and pharmacy technician registration "[b]e of good moral character," state law and the board's rules and regulations still do not contain formal, written criteria for this requirement.

MISS. CODE ANN. Section 73-21-85 and 73-21-111 (1972) require that applicants for pharmacy licensure and applicants for pharmacy technician registration "[b]e of good moral character."

As recommended by the PEER Committee's 2004 report and as noted on page 13, since 2005 the board has included criminal history checks as a requirement for pharmacy licensure and pharmacy technician registration.

In addition, as part of its check on "moral character," the board asks several questions on the pharmacy licensure and pharmacy technician registration application that include:

- Have you ever been arrested? What were the results of that arrest(s)?
- Do you have any felony or misdemeanor charges pending against you?

¹ CLEAR promotes regulatory excellence through conferences, educational programs, networking opportunities, publications, and research services for those involved with, or affected by, professional and occupational regulation.

- Have you ever been charged with and/or convicted of a felony or misdemeanor?
- Have you ever used controlled substances or prescription drugs recreationally or without a valid prescription?

Although the board asks applicants these questions about their criminal history and conducts electronic criminal history checks, the board still does not have formal, written criteria to use as a standard for making consistent decisions regarding the acceptance or rejection of individual applicants. Also, applicants' answers to the above questions are self-reported (thus with the potential for bias or inaccuracy) and are not documented. Furthermore, the board does not have formal, written criteria describing what professional or personal characteristics represent "good moral character."

In ensuring that professionals are of "good moral character," regulatory agencies that license professionals in other states have defined "good moral character" so that it is applicable to the licensure process. For example, Utah's Pharmacy Practice Act provides parameters for that state's Board of Pharmacy to determine an applicant's moral character. In addition to requiring "good moral character," Utah Code Section 58-17b-303 requires that evidence of good moral character be produced as it relates to the applicant's ability to practice pharmacy. Utah uses criminal history checks and a professional code of conduct as tools to determine applicant's moral character to practice pharmacy in Utah. According to Utah Code Section 58-17b-307, "If convicted of one or more felonies, an applicant must receive an absolute discharge from the sentences for all felony convictions five or more years prior to date of filing an application for licensure."

By not having formal, written criteria to determine whether an applicant is of "good moral character," the potential exists for unequal and unfair treatment of applicants. For example, the board may accept the existence of certain criminal charges for some individuals while not accepting them for others. Additionally, the potential also exists in the exposure of the public to unnecessary risk if applicants who are not of "good moral character" are awarded licensure or registration.

Examination Process

2010 Conclusion: Adequacy of the Board's Examination Process

In addition to the validated national pharmacy examination given by the National Association of Boards of Pharmacy, the board requires Mississippi's pharmacy applicants to pass an examination on state pharmacy laws (i. e., the board's own jurisprudence examination). Because the jurisprudence examination is not properly developed or administered, the board cannot ensure that applicants have sufficient knowledge of state pharmacy laws and regulations to practice pharmacy.

As noted on page 12, the licensure process for Mississippi pharmacists includes successfully passing an examination that measures an applicant's knowledge of pharmacy principles (i. e., the NAPLEX) and an examination that measures an applicant's knowledge of state laws and regulations that govern the practice of pharmacy in Mississippi (i. e., the state jurisprudence exam).

In addition to passing the NAPLEX, the Board of Pharmacy requires pharmacist candidates to score at least seventy-five (of a possible 100 points) on the test of Mississippi pharmacy law and Board of Pharmacy regulations, also known as the jurisprudence examination.

As noted on page 13, the Mississippi Board of Pharmacy has developed and administers its own jurisprudence examination. Because its purpose is to measure applicants' knowledge of the laws and regulations that govern the practice of pharmacy in the state, it should meet certain professional testing standards, such as those of the Council on Licensure, Enforcement and Regulation (CLEAR). These standards address:

- test development;
- test administration;
- statistical analysis and research;
- scoring and reporting; and,
- examination security.

In its 2004 PEER report, PEER used the Council on Licensure, Enforcement, and Regulation (CLEAR) standards as guidelines to determine whether MBP's jurisprudence examination contained the major elements to meet professional testing standards. As noted in Appendix A, page 41, the board's jurisprudence exam did not fully meet professional testing standards.

For this 2010 report, PEER analyzed MBP's current jurisprudence exam, using CLEAR standards, to determine whether the Board of Pharmacy has taken the necessary steps to develop and administer its state test for licensing pharmacy applications. Exhibit 2, page 19, contains the results of this analysis.

This analysis found that the Board of Pharmacy's jurisprudence exam:

- *fully met the scoring and reporting standard and examination security standard.* The board ensures that applicants are notified of their examination scores immediately after they are graded in a fair and uniform manner. The board also provides adequate security for the exam.
- *partially met the test development standard and test administration.*
 - The board has not conducted an analysis of the skills and knowledge necessary to practice pharmacy in Mississippi as a blueprint for test development.
 - PEER found occurrences of inconsistencies in grading outcomes in answer selections. For example, if an exam question required the answer choice "Mississippi of Bureau of Narcotics," test takers might have responded with answer choices such as "law enforcement," "police," or "local law enforcement." The answer choices "law enforcement" and "police" were graded as correct answers, while "local law enforcement" was graded as incorrect. Although the correct answer choice was "Mississippi Bureau of Narcotics," all possible answers refer to sworn law enforcement officers and no explanation was provided as to why the closely related answers were incorrect.
 - The board does not readily supply licensure applicants with up-to-date content on which they will be tested. Applicants are directed by the board to access electronically from MBP's website the content information they will be tested on, but the information posted has not been updated since January 1999. (As noted on page 7, state pharmacy

Exhibit 2: PEER Analysis of the Mississippi State Board of Pharmacy's Jurisprudence 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?
<p>Test Development</p>	<ol style="list-style-type: none"> Analyze skills and knowledge required for pharmacy competency. Ensure test includes questions on each necessary skill. Set a valid passing score based on entry-level knowledge and skills. Develop oral, practical, and essay exams with standard answers that can be consistently graded. 	<p><i>Partially.</i></p> <p>Actions Taken: The Mississippi Board of Pharmacy has reviewed state laws pertaining to the practice of pharmacy in Mississippi. Examination content is based on pharmacy law. Board employees review the test for face validity.</p> <p>The State Board has three versions of the pharmacy jurisprudence examination. The exams consist of multiple choice questions, true/false and fill-in-the-blank. One version has 60 questions, one has 66 questions, and one has 63 questions.</p> <p>Standards Not Addressed: PEER found no documentation showing an analysis of the skills and knowledge necessary to practice pharmacy in Mississippi. Inconsistencies were found in the grading of the jurisprudence exam. Occurrences were found where specific questions were graded differently based on answer selection. For example, when a question require the answer choice "Mississippi of Bureau of Narcotics," the test takers responded with answer choices such as "law enforcement," "police," or "local law enforcement." In this example, the answer choices "law enforcement" and "police" were graded as correct answers, while "local law enforcement" was graded as incorrect.</p> <p><i>Partially.</i></p> <p>Actions Taken: Applicants for licensure are directed by the board to access electronically from MBP's website the content information they will be tested on. The application packet that the board sends to applicants includes information about the test date, location, time of test, and exam fees.</p> <p>The board has an annual exam administration date in May at the University of Mississippi School of Pharmacy. The board also offers individual exam administration on Mondays in the board's office.</p> <p>Standards Not Addressed: Although the board directs applicants to access laws and regulations from its website, the regulations posted are as of January 1999. As noted in this report, since that time, state laws and regulations have been amended that impact the practice of pharmacy in Mississippi. As a result, these outcomes and/or options exist: (1) the board is testing applicants based on outdated rules and regulations and/or (2) the board is testing applicants without their having access to the necessary content information for the exam. Although the same exam is given to applicants tested at both the University of Mississippi School of Pharmacy and the board's office, applicants who take the exam at the board's office pay a \$50 examination fee, while applicants who take the exam at the University of Mississippi School of Pharmacy pay a \$25 examination fee.</p> <p><i>No.</i></p> <p>Standards Not Addressed: The board has not conducted formal research analysis on test items or the test as a whole. The board cannot provide formal assurance of the test's sufficiency through item analysis or a complete test analysis.</p>
<p>Test Administration</p>	<ol style="list-style-type: none"> Provide applicants with detailed information on testing times and dates, test content, test site conditions, grading procedures, and disclosure of test scores to applicants. Develop a written plan for accommodating candidates with disabilities that complies with the Americans with Disabilities Act. 	<p><i>Yes.</i></p> <p>Action Taken: The board's staff notify the applicants of their score immediately after exams are graded.</p>
<p>Statistical Analysis and Research</p>	<ol style="list-style-type: none"> Analyze test items to determine how effectively each test question functions. Analyze test to determine how effectively the test as a whole functions 	<p><i>Yes.</i></p> <p>Actions Taken: The exams are developed and printed in the board's office. The compliance director provides security for the exams. The exams are stored in the board's business office, to which only the compliance staff has access.</p>
<p>Scoring and Reporting</p>	<ol style="list-style-type: none"> Ensure that tests are graded and test results are reported to students in a fair and uniform manner 	<p><i>Yes.</i></p>
<p>Examination Security</p>	<ol style="list-style-type: none"> Ensure secrecy of test questions in advance Maintain test materials in secure locations Ensure students have no access to tests during printing, storage, transportation, and distribution 	<p><i>Yes.</i></p>

SOURCE: Adapted from the Council on Licensure, Enforcement, and Regulation Standards for Regulatory Boards (CLEAR), *Development, Administration, Scoring and Reporting of Credentialing Examinations: Recommendations for Board Members*, 2004, Lexington, KY.

laws and regulations have undergone numerous changes since 1999.)

- The board's examination fees are different based on test site without logical documentation for a tiered examination fee schedule. Applicants who take the exam at the board's office pay a \$50 examination fee, while applicants who take the exam at the University of Mississippi School Pharmacy pay a \$25 examination fee.
- *did not meet the statistical and analysis and research standard.* The board has not conducted formal analysis on test results to assure the test's sufficiency.

Based on this analysis, PEER concludes that the board cannot ensure that its state jurisprudence exam adequately tests professional knowledge relevant to the practice of pharmacy in Mississippi.

PEER notes that the Multistate Pharmacy Jurisprudence Examination (MPJE) administered by the NABP is an example of a jurisprudence exam that meets professional testing standards. The MPJE combines federal- and state-specific questions to test applicants' jurisprudence knowledge by testing candidates on:

- legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and care of patients;
- licensure, registration, certification, and operational requirements; and,
- regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors.

Currently, forty-six jurisdictions utilize the MPJE as part of their licensure requirements, with Arkansas, California, Guam, Mississippi, Oklahoma, Puerto Rico, Virginia and the Virgin Islands not participating.

Compliance

Components of Compliance

As noted on page 8, ensuring the compliance of pharmacy professionals with the state's pharmacy laws and

regulations is a core function of the board. The role of the board's compliance agents is to obtain the compliance of pharmacy practitioners through education about the laws and regulations affecting the practice of pharmacy. The two major activities of compliance agents are conducting inspections and investigations. The board experienced a 29% increase in the number of inspections conducted in FY 2010 over FY 2009. The board also experienced a 25% increase in investigations for FY 2010 over FY 2009.

Inspections

MISS. CODE ANN. Section 73-21-107 (1972) gives the board the authority to inspect facilities/businesses that engage in the wholesale distribution of prescription drugs and facilities/businesses/pharmacies that engage in or propose to engage in the dispensing and delivery of drugs to consumers. By conducting inspections, the board has an opportunity to identify procedural violations so that they may be corrected. Some of the activities performed by compliance agents in an inspection include:

- examining purchase records to determine what medications are being purchased and the quantity and frequency of the purchase of controlled substances and prescription drugs;
- examining dispensing records;
- inspecting dispensing areas for cleanliness and clutter;
- examining areas where prescription drugs are stored, and;
- verifying that employees in dispensing areas and those employees that are involved in the prescription dispensing process are properly registered with the board as pharmacy technicians.

Investigations

The Board of Pharmacy initiates investigations as a result of information, complaints, or intelligence received from other regulatory agencies, state or federal law enforcement agencies, consumers, pharmacists, pharmacy technicians, or pharmacy employees or as a result of a routine inspection conducted by a compliance agent. Investigations are conducted by one or more members of the Compliance Division's staff, sometimes in conjunction with other regulatory or law enforcement agencies.

PEER's Previous Conclusions and Recommendations: The Board's Assignment of Compliance Agents and Their Performance of Law Enforcement Functions

In 2004, PEER noted that the board's assignment of counties to inspection regions did not meet reasonable criteria for efficiency and effectiveness and staff assignments did not minimize travel distance and costs to the state. Although the division of counties into three regions balanced the compliance agents' workload, the assignment of counties within the regions was not logical. (See Exhibit 3, page 24.) For example, counties that would have been expected to lie within the Northern inspection region (i. e., Tunica, DeSoto, Marshall, and Benton) were assigned to the compliance agent designated as the Central region inspector. As a result, the board's compliance agents could literally pass each other on the highway going to their respective assignments, traveling unnecessary mileage at state expense.

PEER recommended that the board adopt written criteria for making staff assignments to pharmacy inspection regions that would seek to:

- minimize state travel cost (gas, oil, and maintenance);
- minimize travel distance for inspectors; and,
- maximize available inspection time during each workday.

PEER also recommended that the board conduct a risk-based needs analysis to determine the best use of two new authorized positions and determine the appropriate inspection cycle for pharmacies and regulated facilities.

PEER also concluded in 2004 that the board's compliance agents, whose job description did not require them to perform law enforcement duties, carried firearms without sufficient training and without a demonstrated need to do so. (Although state law allows compliance agents to carry a gun, they are not required to complete minimum standards training for firearms.) PEER recommended that the Legislature amend state law to remove authority for compliance agents to function as law enforcement officers. Further, PEER recommended that the Legislature amend state law to provide that the only MBP personnel authorized to carry out law enforcement functions should 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). In addition to legislative recommendations, PEER also recommended that board

adopt a policy that prohibits compliance agents from performing any sworn law enforcement duties.

Assignment of Compliance Agents

2010 Conclusion: Assignments of Compliance Agents to Inspection Regions

The board has taken steps toward improving efficiency and effectiveness in assigning compliance agents to inspection regions.

MISS. CODE ANN. Section 73-21-107 (1972) authorizes the board to inspect every facility/business that engages in the wholesale distribution of prescription drugs and every business/facility/pharmacy located in Mississippi that engages in or proposes to engage in the dispensing and delivery of prescription drugs to consumers.

The board made changes to its inspection regions in October 2009, changing the number of regions from three to four (see Exhibit 4, page 25). The new inspection regions are divided so that compliance agents live close to their inspection region and each agent has a comparable number of facilities to inspect (see Exhibit 5, page 26).

In adopting the new inspection regions, the board has sought to meet the criteria for the assignment of compliance agents recommended in the 2004 PEER report.² Based on face value, the board's implementation of the new inspection regions appears to be moving toward making the better use of agency resources. Additionally, as noted on page 21, the number of inspections conducted by compliance agents has increased, although this increase could be a result of increased staff, new inspection regions, or a combination of both.

In order to ensure that the new inspection regions seek to minimize state travel cost and travel distance for inspectors and maximize available inspection time during each work day, the board should rely on data derived from implementation of a new management information system, described on page 8, which should provide the information needed to determine the efficiency and effectiveness of daily operations.

² PEER notes that the board made changes to its inspection regions subsequent to PEER's 2004 report *A Review of the Board of Pharmacy*, which recommended that the Board of Pharmacy adopt written criteria for making staff assignments to pharmacy inspection regions.

Exhibit 3: Mississippi Pharmacy Inspection Regions with workload as of May 2004

Northern Region

717

Number of
Facilities

South Central Region

582

Number of
Facilities

Southern Region

647

Number of
Facilities

Total Number
of Facilities: 1,946

Source: MS Board of Pharmacy, May 2004

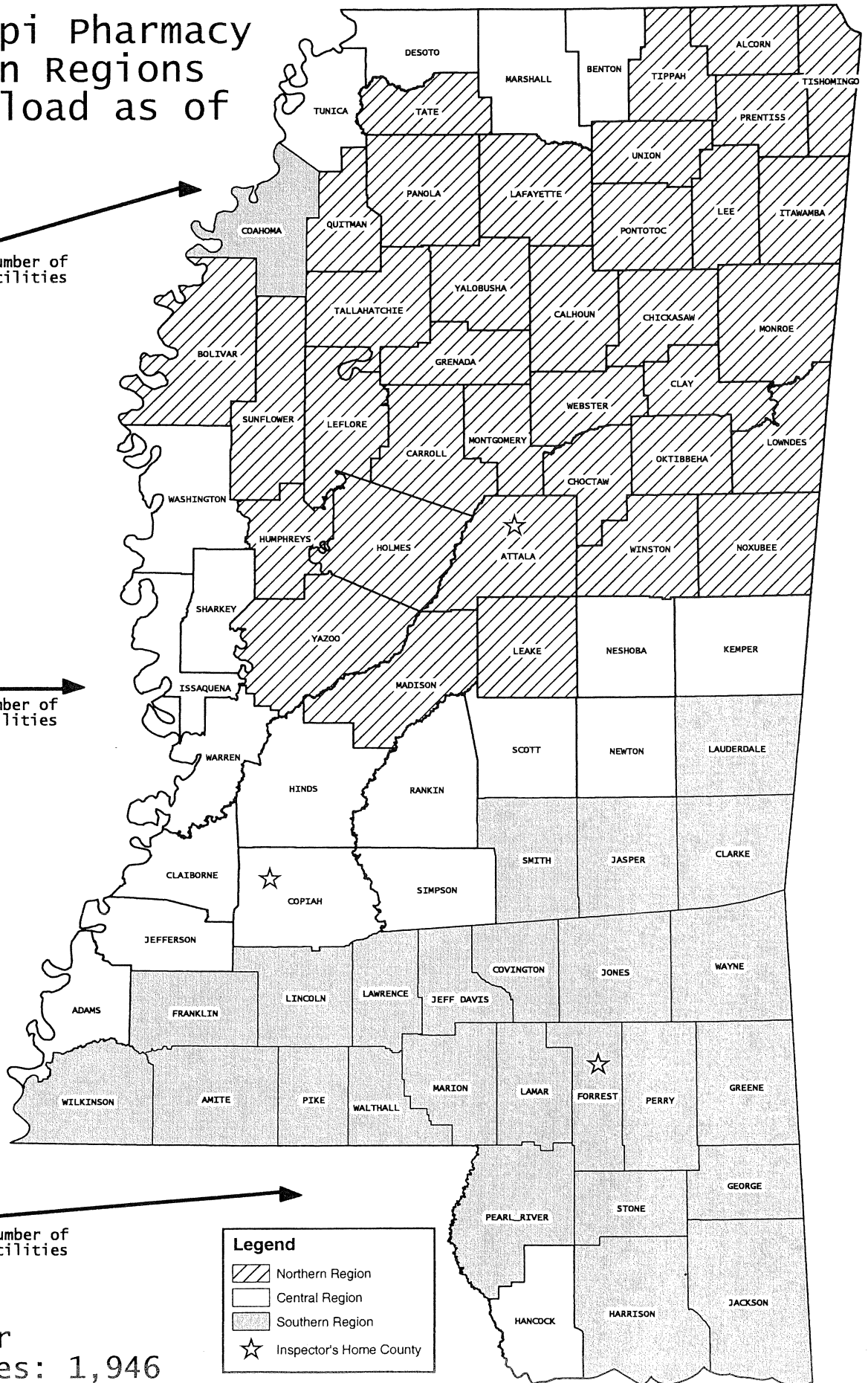


Exhibit 4: Mississippi Pharmacy Inspection Regions with workload as of May 2010

Northern Region
509 Number of Facilities

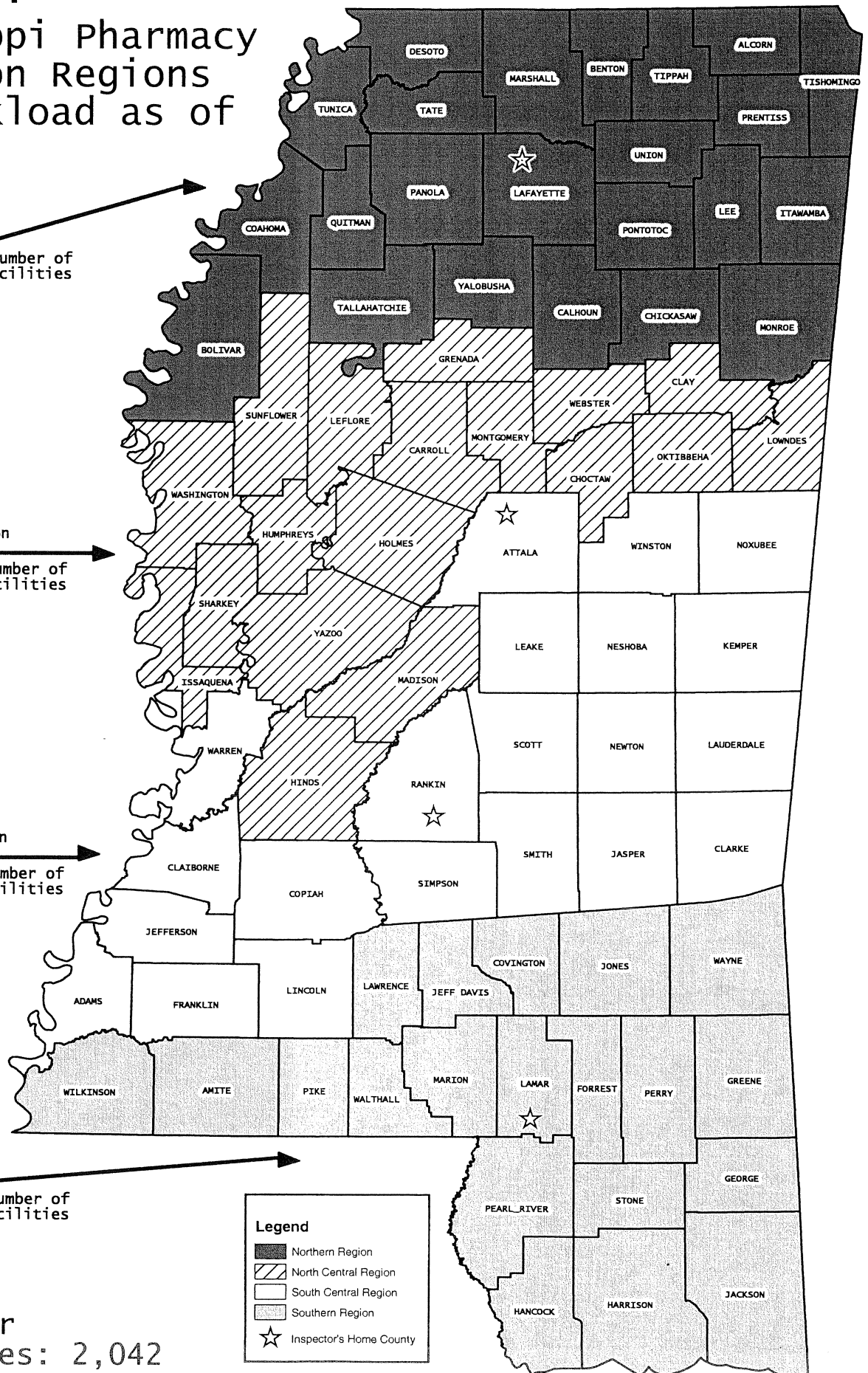
North-Central Region
505 Number of Facilities

South Central Region
503 Number of Facilities

Southern Region
525 Number of Facilities

Total Number
of Facilities: 2,042

Source: MS Board of Pharmacy, May 2010



Legend

- Northern Region
- North Central Region
- South Central Region
- Southern Region
- Inspector's Home County

Exhibit 5: Location of Compliance Agents in Respect to Assigned Inspection Region and Number of Facilities to be Inspected Within that Region, as of October 2009

Inspection Region	Location of Agent	Number of Facilities to be Inspected
Northern Region	Oxford, MS	509
North Central Region	Kosciusko, MS	505
South Central Region	Brandon, MS	503
Southern Region	Purvis, MS	525

SOURCE: Mississippi Board of Pharmacy.

Compliance Agents' Performance of Law Enforcement Functions

2010 Conclusion: Statutory Authority for Compliance Agents to Serve as Sworn Law Enforcement Officers

MISS. CODE ANN. Section 41-29-159 (1972) confers the authority of sworn law enforcement officers on compliance agents; however, the compliance agents' job description does not require this authority. State law does not require compliance agents to complete minimum standards training for firearms and the board is not in compliance with its own policies regarding firearms training.

According to the MBP's policy and procedures manual for the Compliance Division, the role of a compliance agent is to educate, inform, and assist pharmacists and registrants in complying with state and federal laws and regulations that pertain to the practice of pharmacy. Compliance agents' routine duties also include:

- conducting routine inspections of pharmacies and facilities permitted by and under the jurisdiction of the MBP;
- conducting investigations of permitted facilities when necessary;
- maintaining a thorough knowledge of laws and regulations, both state and federal, that pertain to the practice of pharmacy, and;
- making a responsible effort to educate pharmacists on all law and regulation changes.

MISS. CODE ANN. Section 41-29-159 (1972) also gives compliance agents the authority 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 the Uniformed Controlled Substances Law committed in their presence, or if they have probable cause to believe that the person to be arrested has committed or is committing a crime; and,
- make seizures of property pursuant to the Uniformed Controlled Substances Law.

While compliance agents have law enforcement authority, the professional duties of compliance agents are not directly related to law enforcement. Specifically, according to the policy and procedures manual for MBP's Compliance Division:

The primary objectives of the Compliance Agent are to (1) obtain voluntary compliance of all registrants through education and assistance with pertinent State and Federal Laws and Regulations; (2) inspect pharmacies and provide for the correction of procedural violations of the law that may be found.

Complicating this situation is the fact that although MISS. CODE ANN. Section 41-29-159 (1972) confers law enforcement authority upon the board's compliance agents, another state law excludes compliance agents from minimum standards training for firearms. MISS. CODE ANN. Section 45-6-3 (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. The term "law enforcement officer" also includes employees of the Department of Corrections who are designated as law enforcement officers by the Commissioner of Corrections pursuant to Section 47-5-54, and includes

*those district attorney criminal investigators who are designated as law enforcement officers. However, **the term “law enforcement officer” shall not mean or include** any elected official or any person employed as a legal assistant to 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 MBP'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.

Furthermore, the board is not in compliance with its own policies regarding firearm training. According to MBP's policy and procedures manual for the Compliance Division:

Every employee of the Board who is authorized to carry a firearm shall at least on an annual basis complete a periodic course of qualification or evaluation training in the proper handling effective use of firearms conducted by a Training Officer of the Mississippi Bureau of Narcotics or NRA Certified instructor.

No weapon shall be issued to or carried by any employee prior to satisfactory completion of an extensive training course in the safe handling and effective use of firearms.

From a review of MBP's firearm training records, PEER determined that MBP's compliance agents have not undergone training from a training officer of the Mississippi Bureau of Narcotics or National Rifle Association certified instructor since August 20, 2007.

Although MBP has taken initiative in developing policies to ensure that compliance agents receive firearm training, MBP is not in compliance with its own policies. Compliance agents continue to place the state in a position of potential liability for their actions. Additionally, compliance agents could potentially cause or incur injuries though the misuse of firearms because they are not properly trained.

Administrative Issues

Operational policies are important in systematically formulating and standardizing policy and procedural matters within an organization. Additionally, policies and procedures serve as guides and aids to more efficient operation of an organization's employee efforts.

PEER's Previous Conclusions and Recommendations: The Board's Administrative Functions

In 2004, PEER noted that the board did not have a comprehensive policies and procedures manual or set of manuals with which to govern its total operations. The board had not published any formal, written policies or procedures for its administrative, licensure, or enforcement operations. PEER recommended that the board develop a policy and procedures manual and establish a formal internal training program.

2010 Conclusion: Lack of Written Policies for Administrative and Licensing Functions and No Agency-Wide Internal Training Program

Although the Compliance Division operates with formal, written policies and procedures, the board does not have formal, written policies for its administrative or licensing functions. Furthermore, the board has not established an agency-wide internal training program.

Currently, MBP's Compliance Division is the only component of the board's staff that operates with formal, written policies and procedures. While general state policies exist for state agencies (e. g., *Mississippi Agency Accounting Policies and Procedures*, Mississippi Department of Finance and Administration administrative rules, and *Mississippi State Personnel Board Policies and Procedures*), the board has failed to develop formal, written policies specific to its administrative and licensing functions.

Without formal, written policies, the board cannot assure that its staff has the knowledge of administrative or operating policies and procedures or other information necessary to fulfill duties and responsibilities.

2010 Conclusion: Board Membership

A recent gubernatorial appointee to the Board of Pharmacy was not confirmed by the Senate during the 2010 legislative session prior to sine die adjournment. According to state law and opinions of the Attorney General, upon vacation of the Senate (i. e., sine die adjournment), that member's seat remains vacant. However, the board has paid \$390.60 in per diem and expenses to that member since the date on which the seat legally became vacant.

On July 14, 2009, the Governor appointed Mr. Leland McDivitt to serve on the Board of Pharmacy. PEER notes that the Senate Public Health and Welfare Committee did not act on Mr. McDivitt's appointment prior to the Senate's adjournment sine die on April 23, 2010, and thus Mr. McDivitt has not been confirmed by the Senate.

The legal effect of a failure to confirm is the subject of statute law and several opinions of the Attorney General. MISS. CODE ANN. Section 7-1-35 (1972) addresses the effects of a failure to confirm. This section provides:

The governor shall fill by appointment, with the advice and consent of the senate, all offices subject to such appointment when the term of the incumbent will expire within nine months after the meeting of the legislature, and also vacancies in such offices occurring from any cause during the session of the senate or during the vacation of that body. All such appointments to offices made in vacation shall be reported to the senate within ten days after the commencement of the session of that body for its advice and consent to the appointment, and the vacancy shall not be filled if caused by the senate's refusal to confirm any appointment or nomination, or if it do not occur during the last five days of the session, by the appointment of the governor in the vacation of the senate, without its concurrence. Any appointment in vacation to which the senate shall refuse to consent shall be thereby annulled from that date, but the acts of the appointee prior thereto shall not be affected thereby. [Emphasis added]

The Attorney General has consistently opined that when the Senate fails to act affirmatively on an appointment, the appointee is rejected, and the seat remains vacant in the vacation of the Senate. (See *Attorney General's Opinion to*

Smith, March 21, 1977; see also *Attorney General's Opinion to Bennett*, January 18, 2000.)

On May 12, 2010, Mr. McDivitt attended a Board of Pharmacy meeting for which he was paid a total of \$390.60 in per diem and expenses (\$40.00 per diem, \$62.00 for meals, \$75.60 for lodging, and \$213.00 for travel). According to the aforementioned CODE section and Attorney General opinions, Mr. McDivitt's position became vacant and his appointment annulled from and after April 23, 2010. Following annulment, he cannot legally perform services for the Board of Pharmacy as a board member and any per diem or travel expenses paid to him would appear to have no basis in law.

As noted on page 2 of this report, PEER received specific complaints regarding administrative issues of the board. These will be addressed in the following chapter.

Status of Specific Concerns Regarding the Board's Administrative Functions

As noted on page 2, when conducting this review, PEER also addressed the following specific allegations by complainants that include:

- inappropriate business relationships between the board and the entities it regulates;
- whether duties performed by the Cornerstone Consulting Group, Inc., could be performed by board staff;
- mismanagement of federal grants;
- excessive or frivolous spending with regard to contracts, travel, training, and furnishings;
- whether the board is in compliance with State Personnel Board policies; and,
- whether there are adverse pending legal proceedings against the board.

The following sections address these allegations.

Complaint 1: Business Relationships Between the Board and Entities It Regulates

Although an employee and board member formerly jointly owned a business regulated by the board, the company has been dissolved and the potential conflict of interest no longer exists.

As noted on page 4, the Board of Pharmacy is responsible for regulation of the pharmacy profession, including practitioners, facilities, and controlled substances. The complainant alleged that an inappropriate business relationship existed between the board and an entity it regulated--specifically, F & J Pharmaceuticals, Inc.

This company was jointly owned by a member of the Board of Pharmacy and an employee of the board (i. e., a compliance agent). The complainant questioned whether it was proper for these individuals to participate in regulation of that company (for example, the compliance agent inspecting the company's facilities).

The compliance agent eventually accepted the position of Executive Director of the Board of Pharmacy and the MBP

subsequently sought guidance from the Mississippi Ethics Commission regarding this business relationship. It was the opinion of the Ethics Commission that the board could be faced with a conflict of interest under MISS. CODE ANN. Section 25-4-105 (1972). Subsequently, the individuals dissolved the business on August 14, 2009, and the potential conflict of interest no longer exists.

Complaint 2: Contractual Expenditures

Based on PEER's analysis of available information, the MBP's decision to sacrifice a Bureau Director II position to fund a contract with Cornerstone Consulting Group, Inc., to provide accounting and computer services was a cost-effective decision.

The board currently contracts with the Cornerstone Consulting Group, Inc., for accounting and other services. Complainants are concerned that Cornerstone is performing tasks and operations that would be more cost effective if performed by MBP staff.

Prior to FY 2007, a member of the board's staff performed accounting and computer support tasks for MBP. After that employee left the agency, the board did not fill the position and entered into a contract with Cornerstone and has contracted with that company to provide accounting services since July 1, 2006. Since that time, MBP has expanded the contract to cover computer support services.

The former employee who performed accounting and computer support tasks for MBP was classified as a Bureau Director II. According to the State Personnel Board, the current annual salary range for that position is \$53,600.93-\$93,801.63. Since July 1, 2006, the board has paid Cornerstone a total of \$79,444.50 for accounting and computer services (\$21,925 for FY 2007, \$23,832.50 for FY 2008, and \$33,687 for FY 2009).

MBP has not paid the salary and benefits of the Bureau Director II position since FY 2006 and has paid a considerably smaller amount for the provision of accounting and computer support services by a contractor. Under the assumption that the Bureau Director II classification was originally justified, MBP has had to either forego the services and tasks normally assigned to a Bureau Director II or has had to reallocate those services and tasks to other staff. Based on the information provided, it appears that the MBP has made the needed accommodations and the sacrifice of a Bureau Director II to fund a contract for accounting and computer services has been a cost-effective decision.

Complaint 3: Management of Federal Grants

Subsequent to an August 2006 audit of the Prescription Monitoring Program, federal auditors disallowed \$50,002 of the board's expenditures for that program. The board has since resolved these issues with the federal government and now operates the program with self-generated funds.

In 2004, the U. S. Department of Justice's Bureau of Justice Assistance awarded the Board of Pharmacy federal funding to administer the Prescription Monitoring Program (see page 7). In August 2006, federal auditors took issue with some of the board's program expenditures; as a result, the auditors disallowed \$50,002 of MBP's expenditures for the program and the board covered this amount through use of its own special fund revenues.

In addition, the board's previous Executive Director executed a contract with his son that was paid for by PMP grant funds. The Mississippi Ethics Commission found this to be a violation of Mississippi's ethics laws and the previous Executive Director subsequently paid a fine of \$5,000.

The federal grant for this program ended April 30, 2010. The board continues to operate the PMP, but does so with its own self-generated funds.

Complaint 4: Appropriateness of Expenditures

PEER reviewed the MBP's expenditures for FY 2005 through FY 2010 and did not detect expenditures that would not appear to be reasonable for a regulatory agency.

The MBP is special fund agency that generates the revenue to support its regulatory operations. However, complainants have alleged that MBP is engaged in "frivolous and excessive spending" on travel, training, contractual services, and furnishings.

PEER reviewed the MBP's expenditures for FY 2005 through FY 2010 and did not detect expenditures that would not appear to be reasonable for a regulatory agency.

- *Travel and training*--At the highest level of travel expenditures during this period (\$56,404 in FY 2008), the board's travel expenditures included \$21,724 for in-state travel expenditures (e. g., travel for the Compliance Division, regular board meetings, and in-state conference travel). The board's out-of-state travel expenditures for FY 2008 were \$34,680, which included conference/training expenditures for both board members and staff.

PEER would note that the Compliance Division has statewide jurisdiction for inspection of pharmacy facilities and that this, in conjunction with higher fuel costs, could have accounted for that fiscal year's increase in travel expenditures. Regarding conference/training-related travel expenditures, PEER found no expenditures during the 2008 or 2009 fiscal years that were not related to the board's regulatory operations.

- *Contractual services*--MBP has two major areas of contractual services expenditures. These are accounting services (see page 33 for a discussion of the contract with Cornerstone Consulting Group) and the contract with RelayHealth for the Prescription Monitoring Program (see page 7). PEER notes that because the MBP has a relatively small staff, it may have a justifiable need to contract for some services.
- *Furnishings*--During site visits to the board's office, PEER did not note any evidence of excessive spending on the board's furnishings.

Complaint 5: Compliance with State Personnel Board Policies

In reviewing MBP operations, PEER found that the board has made improvements in its assignment of compliance agents and that it is operating within the bounds of its authority in the assignment of staff.

In requesting this review, complainants alleged that the MBP might not be complying with State Personnel Board policies regarding the assignment of permanent and temporary staff. In reviewing this complaint, PEER determined that, while the MBP is subject to the rules and regulations of the State Personnel Board, there was no evidence of personnel actions involving staff assignment that appeared to place the MBP outside its management authority or in conflict with State Personnel Board policy.

Currently MBP operates with a staff of twelve employees, including eleven full-time positions and one contract employee. (See page 8 for a description of the agency's staffing.) All positions were properly defined and the assignment of duties and work locations was in keeping with general management principles. PEER found no basis for concluding that the MBP was in conflict with State Personnel Board policies and procedures as they pertain to assignment of staff.

Complaint 6: Pending Legal Proceedings

The MBP has a federal court case pending against it that relates to a claim of employment discrimination and failure to promote.

Although PEER found no evidence of personnel actions involving staff assignment that appeared to place the MBP outside its management authority or in conflict with State Personnel Board policy, according to the Attorney General's office, the MBP has a federal court case pending against it that relates to a claim of employment discrimination and failure to promote. PEER was informed that this case was expected to be resolved in the near future.

Recommendations

Licensure and Registration

1. In order to protect the public's health through licensure and registration, the board should:
 - adopt into its rules and regulations formal criteria to determine an applicant's moral character; and,
 - adopt the use of the Multistate Pharmacy Jurisprudence Examination (MPJE) administered by the NABP as the board's jurisprudence examination to test pharmacy applicants on their knowledge of federal and state laws and regulations that govern the practice of pharmacy.

Compliance

2. In order to protect the public's health through its compliance activities, the board should:
 - ensure that its new management system has the capability to conduct annual cost-benefit analysis to determine whether assigned inspection regions:
 - minimize state travel cost (gas, oil, and maintenance);
 - minimize travel distance for inspectors; and,
 - maximize available inspection time during each workday; and,
 - adopt a policy that prohibits compliance agents from performing any sworn law enforcement officer duties, including carrying firearms.
3. The Legislature should:
 - amend MISS. CODE ANN. Section 45-6-3 (1972) to remove authority for compliance agents to function as law enforcement officers; and,

- amend MISS. CODE ANN. Section 41-29-159 (1972) to provide that 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).

Administrative Issues/Concerns

4. In order to ensure the safety of the public through its administrative activities, the board should:
 - develop policy and procedures manuals for its administrative and licensing operations and ensure that its compliance manual is comprehensive and current; and,
 - establish an agency-wide internal training program to minimize the possibility of administrative, communications, and operational errors. The curriculum for this training program should cover, as a minimum, the information contained in the policy and procedure manuals.
5. The Executive Director of the Board of Pharmacy should consult with the Department of Audit regarding the proper procedure for reimbursing the board's fund for the amounts paid to Mr. Leland McDivitt for the May 2010 board meeting. The board should also ensure that Mr. McDivitt is not paid or allowed to perform as a board member until such time as he may be reappointed and confirmed.

Implications for Change

Although improvements could be made to the state’s existing regulatory structure for pharmacy regulation, implications for change also exist in approaching occupational regulatory efforts in a new way.

This review examining the regulation of pharmacy in Mississippi offers the opportunity to examine the way in which the regulatory efforts of the Board of Pharmacy, as well as other occupational boards, are performed in Mississippi.

While the recommendations in this report (pages 37 through 38) are aimed toward improving an existing system and regulatory structure, PEER believes that real progress in improving the regulatory efforts of the Board of Pharmacy and other occupational boards is contingent on the concept of shared services and considering their functions as being part of a single enterprise rather than a confederation of boards.

A Shared Services Approach to Pharmacy Regulation

Twenty-nine states have boards of pharmacy that operate within a shared services structure.

Pharmaceutical care demands that consideration be given to the risks associated with improper, unprofessional, or illegal conduct in the supply and distribution of medicines or other health care products. As a result of these risks, another organizational approach to protect the public’s health and regulate the pharmacy profession exists according to the National Association of Boards of Pharmacy (NABP)—i. e., the *shared services* model.

The shared services approach is an organizational concept that provides for “the consolidation of administrative or support functions (such as human resources, finance, information technology and procurement) from several departments or agencies into a single, stand-alone organizational entity whose only mission is to provide services as efficiently and effectively as possible.”³ Under this model, boards of pharmacy are only responsible for regulatory activities, while their administrative activities (i.e., human resources, finance, information technology, procurement) are shared with other entities that have

³ Accenture, *Driving High Performance in Government: Maximizing the Value of Public-Sector Shared Services* (January 2005), 3.

different functions. A shared services model for occupational regulation in Mississippi would provide an opportunity for improved accountability in protecting the health, welfare, and safety of Mississippians.

Twenty-nine states have boards of pharmacy that operate within a shared services structure (see Appendix B, page 46). For example, Georgia has the Professional Licensing Boards Division within the Secretary of State's office. This division provides administrative and support services to thirty-six professional licensing boards, including the Georgia Board of Pharmacy.

The Enterprise Model of Professional Regulation

In an enterprise model of regulation of professions, occupational regulation would be considered a single enterprise in which resources would be networked across occupational boards to achieve an optimal balance of central control and efficiency.

The above-described approach to the regulatory efforts of occupational boards would be a change from the current "silo" approach to regulation (i. e., keeping units separate with their own budgets and hierarchies and focusing on their service or delivery specialty) and a move toward an enterprise model as described in PEER Report #518, *Enterprise Mississippi: A Vision for State Government* (December 9, 2008).

An enterprise model would direct decisionmakers to look differently at how occupational boards regulate their respective professions in Mississippi. An enterprise model would guide us to revise our thinking about the regulation of professions as a collection of boards in favor of thinking about occupational regulation as a single enterprise in which resources would be networked across occupational boards to achieve an optimal balance of central control and efficiency.

By using an enterprise model to regulate professions in Mississippi, the potential exists for combining occupational boards into a newly created entity, the Division of Professional Occupational Boards. If a shared services approach was adopted for occupational regulation, the state could benefit from reduced costs, "increased transparency of services and results, and improved accountability in serving citizens."⁴ More importantly, occupational regulation could achieve an optimal balance of control, efficiency, and improved accountability in protecting the health, welfare, and safety of Mississippians.

⁴ Deloitte Consulting, LLC, *State of Illinois Savings Validation Results*, 2005, 1.

Appendix A: Conclusions and Recommendations from *A Review of the Board of Pharmacy* (PEER Report #470, September 14, 2004)

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.

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 the fact that prescribed substances may contain narcotic agents, regulation of this profession becomes even more essential.

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 better 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 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.

Appendix B: States that Regulate Pharmacy through a Shared Services Model

State	Agency
Alaska	Division of Corporations, Business, and Licensing
California	Department of Consumer Affairs
Colorado	Department of Regulatory Agencies
Connecticut	Department of Consumer Protection
Delaware	Division of Professional Regulation
Florida	Department of Health
Georgia	Professional Licensing Boards Division
Hawaii	Department of Commerce and Consumer Affairs (Professional and Vocational Licensing)
Illinois	Department of Financial and Professional Regulation
Indiana	Professional Licensing Agency
Maine	Office of Licensing and Registration
Maryland	Department of Health and Mental Hygiene
Massachusetts	Department of Health and Human Services
Michigan	Department of Community Health
Missouri	Division of Professional Registration
Montana	Department of Labor and Industry
Nebraska	Department of Health and Human Services
New Jersey	Department of Consumer Affairs
New Mexico	Regulation and Licensing Department
New York	Office of Professions
Pennsylvania	Department of State
Rhode Island	Office of Health Professionals Regulations (Department of Health)
South Carolina	Department of Labor, Licensing, and Regulations
Tennessee	Department of Health
Utah	Division of Occupational and Professional Licensing
Vermont	Office of Professional Regulation
Virginia	Department of Health Professions
Washington	Department of Health
Wisconsin	Department of Regulation and Licensing

SOURCE: PEER analysis of websites of the NABP and state pharmacy regulatory boards.

Agency Response



STATE OF MISSISSIPPI MISSISSIPPI BOARD OF PHARMACY

July 12, 2010



Mr. Max Arinder
Joint Committee on Performance Evaluation and Expenditure Review
PEER Committee
P. O. Box 1204
Jackson, MS 39215

Dear Mr. Arinder,

The Mississippi Board of Pharmacy is responsible for the Regulation of the Practice of Pharmacy within the State. The Board is responsible for the permitting, inspection and investigation, when necessary, of in excess of 2,040 facilities located within the state. Further, the Board is responsible for the licensing and/or registration and investigation, when necessary, of in excess of 3,600 pharmacists, 4,500 pharmacy technicians as well as Student Extern/Interns.

The Joint Committee on Performance Evaluation and Expenditure Review (PEER Committee) began an extensive review of the Mississippi Board of Pharmacy in February of this year allegedly prompted by receipt of complaints and/or allegations received by the Committee regarding various operations of the Board. At the end of June, the Committee completed its review and issued a draft report of its findings which include a number of recommendations to address Board procedures. The Board has reviewed the report in its entirety and has the following responses to each of the recommendations.

1. In Order to protect the public's health through licensure and registration, the Board should:

Adopt formal criteria to determine an applicant's moral character.

The Board is in the process of revision of Regulations at this time and will incorporate a suitable definition of "Good Moral Character".

Section 73-21-85, (4) of the Mississippi Code specifically states that "To insure that all applicants are of good moral character, the board shall conduct a criminal history records check on all applicants for a license." Implicit in this mandate, is that a criminal history records check that reveals a criminal history creates a rebuttable presumption that the applicant does not have the requisite "good moral character" for licensure or registration. Conversely, in the absence of

any criminal conviction an applicant is presumed to have met the character standard. This practice is consistent with case law as well as the practice of most regulatory agencies.

In its 2004 report, the PEER Committee recommended that the board include criminal history checks as a requirement for pharmacy licensure and pharmacy technician registration. The Board has used, since 2005, criminal history records checks conducted by the Mississippi Department of Public Safety and the Federal Bureau of Investigation to **determine** an applicant's "Moral Character" and suitability for licensing or registration. The system compares an applicant's responses to various questions on an affidavit questionnaire to the results of the criminal history. Evidence of omissions, deception or falsification constitutes grounds for denial of the issuance of the license or registration.

It should also be noted that, historically, the Board does not license applicants under the jurisdiction of a criminal court at the time of application. While the board will endeavor to create a catalog of various types of offenses revealed by previous criminal history records checks to establish guidelines for issuance or exclusion from licensure and registration based on the type of offense to ensure equal and fair treatment of all applicants it firmly believes that its current procedure for determining good moral character provides public protection, complies with constitutional due process and encourages rehabilitation.

Adopt the use of the Multistate Pharmacy Jurisprudence Examination (MPJE).

While the Board disagrees with the PEER Committee's assessment of the various law exams administered by the Board and the alleged inability of Board staff to develop and properly administer such a test, the Board voted on July 8, 2010, to adopt the use of the MPJE at the earliest possible date. The National Association of Boards of Pharmacy (NABP) has been contacted regarding procedures for implementation of the Examination.

2. In Order to protect the public's health through its compliance activities the Board should:

Ensure that its new management system has the capability to conduct annual cost benefit analysis to determine whether assigned inspection regions minimize travel cost, minimize travel distance and maximize available inspection time.

The Board, as acknowledged in the report, has made adjustments in the assignment of compliance areas to maximize efficiency and to conserve state resources. Inspection areas have been equally divided between four compliance agents and each compliance agent is strategically located in or adjacent to his/her respective inspection territory to minimize travel cost distance and maximize inspection time. The new licensing/case tracking/compliance system currently being implemented by the Board will assure that inspections of facilities permitted by the Board are conducted in a timely manner. The system will assist in organization of work flow and will allow offsite communication and access to data stored in the office system by laptop computer to enhance productivity. Once the system is operational, inspections will be completed on a

notepad, a copy of the inspection report form printed and left with the registrant/licensee and an electronic copy of the form will be transmitted to the Board office.

Adopt a policy that prohibits compliance agents from performing any sworn law enforcement officer duties, including carrying firearms.

The authority of Compliance Agents to Function as Law Enforcement Officers is strictly within the purview of the Mississippi Legislature. The issue of the “carrying” of weapons by Compliance Agents has previously been visited by the Legislature in 1992 and 2004 and the Legislature chose to take no action regarding the matter on either occasion. The report raises concerns about the authority of the compliance agents to function as law enforcement officers. Regulating and checking the legitimate drug traffic among pharmacists, pharmacies, hospitals, nursing homes and drug manufacturers is a responsibility delegated to the Board by MISS CODE ANN, Section 41-29-159, Mississippi Code of 1972. By Board policy, for more than twenty-eight years, Compliance Agents have not been authorized to make arrests, under any circumstances, and have no need to make seizures of property. However, Compliance Agents have a demonstrated need, at times, to carry weapons for defensive purposes only as is approved by Board policy. Past evidence of such need has been clearly provided to your evaluators. During the course of conducting investigations of permitted facilities, primarily involving thefts of controlled substances by pharmacy personnel, Compliance Agents are required to work in areas of the state that are unsafe late into the evening or early morning hours. These investigations can only be conducted by a Compliance Agent with pharmaceutical knowledge. Further, Compliance Agents have been confronted by pharmacists and pharmacy employees carrying weapons and others have been found to have multiple felony arrests. Compliance Agents that are currently issued weapons have demonstrated proficiency with firearms time and time again. With the loss of two training officers in a two-year period and two failed attempts to reschedule training since 2007, they have fallen behind on their training but to say they are not trained in the use of firearms is not true. At the time of the beginning of the PEER review, arrangements had already been made with a training officer of the Ridgeland Police Department to provide updated State approved training in the use of firearms to come into compliance with their training policy.

3. The Legislature should:

Amend MISS. CODE ANN. Section 45-6-3 (1972) to remove authority for compliance agents to function as law enforcement officers; and

Compliance Agents of the Board are not included in the definition of “Law enforcement officer” under 45-6-3.

Amend MISS CODE ANN. Section 41-29-159 (1972) to provide that 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).

Compliance Agents of the Board do not “carry” weapons on a daily basis and do not execute and serve search warrants, make arrests with or without warrant or seize property. The Board's investigative relationship with the Mississippi Bureau of Narcotics, the U. S. Drug Enforcement Administration and other State and Local law enforcement agencies is a key function of the Compliance Division of the Board resulting in arrest and conviction of numerous individuals responsible for the theft and diversion of controlled substances over the last twenty years. To remove authority of Compliance Agents to conduct investigations in conjunction with these law enforcement agencies will severely hamper investigative activity concerning the theft and diversion of controlled substances from permitted facilities.

4. In order to ensure the safety of the public through its administrative activities, the Board should:

Develop policy and procedure manuals for its administrative and licensing operations and ensure that its compliance manual is comprehensive and current.

Establish a formal internal training program for its compliance and licensing operations in order to minimize the possibility of administrative, communications, and operational errors.

The MBP staff consists of twelve (12) employees, five of whom are Compliance Officers. PEER suggests that without a formal internal training program the Board cannot assure that the staff members are familiar with their job duties and responsibilities. The Board rejects this assertion. Due to the small size of the staff, individual orientations are adequate and appropriate to orient a new member to his job duties and responsibilities relative to specific pharmacy board tasks. The report acknowledges that the compliance division has formal written policies and procedures. Other rights and responsibilities pertaining to Board staff, as well as state employees from accounting to personnel management, are adequately covered by State Personnel Board and other statewide policies and procedures. PEER recommends that the Board develop policy and procedure manuals for its administrative and licensing operations and ensure that its compliance manual is comprehensive and current. The Compliance Division of the Board utilizes and operates with a comprehensive, current and frequently updated Policy and Procedure Manual. Compliance Agents are knowledgeable of State and Federal laws as they apply to the practice of Pharmacy and are aware of their respective duties and responsibilities of their positions. No further internal training programs are necessary.

**IMPLICATIONS FOR CHANGE
A SHARED SERVICES APPROACH TO PHARMACY REGULATION**

The National Association of Boards of Pharmacy (NABP) does not support a shared services approach to pharmacy regulation as implied in the report. It is NABP’s position that “autonomous boards operate more effectively and efficiently than consolidated agencies.” The Board concurs with the position of the NABP as set forth in NABP’s letter to the Board dated July 9, 2010 which is attached hereto and incorporated herein by reference.

**STATUS OF SPECIFIC CONCERNS REGARDING THE BOARD’S
ADMINISTRATIVE FUNCTIONS**

COMPLAINT 1: Business Relationships Between the Board and Entities it Regulates:

The Board appreciates PEER’s acknowledgment that the potential conflict of interest no longer exists. Because this allegation has caused injury to the personal and professional reputations of individuals associated with the Board, even though “officially” unnamed, the Board is compelled to state the following for the record. The Board undertook appropriate steps to ascertain whether or not an impermissible conflict of interest existed by requesting an Official Advisory Opinion from the Mississippi Ethics Commission on this matter.

The advice of the Ethics Commission was accepted, and as noted in the report, all potential for conflict was eliminated. The Board, states affirmatively that no actual conflict existed. The Board further states that at no time did an employee or member of the board ever inspect any entity in which they may have had a financial interest.

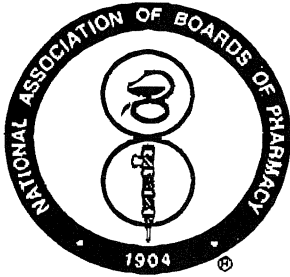
COMPLAINTS 2-5:

The PEER Review Report addressed specific allegations from complainants that included accusations of whether duties performed by a consulting agency could be performed by Board staff, mismanagement of federal grants, excessive or frivolous spending, and an absence of compliance with State Personnel Board policies and procedures. Without reiterating the entirety of the complaints, the Board concurs with the findings of PEER that these allegations are unsubstantiated. The Board further appreciates the affirmative acknowledgment by PEER that some of the decisions made by the Board upon which some of the allegations were based have been objectively demonstrated to have been cost-effective and appropriate.

FOR THE MISSISSIPPI BOARD OF PHARMACY



FRANK E. GAMMILL, JR.
EXECUTIVE DIRECTOR



nabp

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July 9, 2010

Frank E. Gammill, R.Ph.
Executive Director
Mississippi Board of Pharmacy
204 Key Drive Suite C
Madison, MS 39110

Dear Frank:

NABP is knowledgeable about the differences and distinctions between boards of pharmacy which are autonomous and those that are consolidated (shared services). It is our experience that, in general, autonomous boards operate more effectively and efficiently than consolidated agencies. Our assertion is based upon a number of critical factors:

1. Responsiveness of the Board of Pharmacy to patient/citizen inquiries and complaints.

NABP receives complaints through email and regular mail from patients who are unable to contact or resolve with their respective board of pharmacy complaints and threats to the public health. The number of complaints which we receive involving consolidated boards of pharmacy is higher than for autonomous boards. The nature of those complaints center around the inability of the patient to contact board staff because of a complex labyrinth of agencies and personnel. The second most frequent complaint is the consolidated board of pharmacy failed to respond.

2. Responsiveness of the Board of Pharmacy to NABP Licensure Verifications and Validations

NABP interacts with every board of pharmacy on an almost daily basis. It is our experience, again in general, that requests for information and licensure verifications are received and processed by autonomous boards in a more efficient and effective manner than consolidated boards of pharmacy. The processing time for applications for initial licensure and the transfer of licensure is significantly less for autonomous boards than consolidated boards and with some consolidated boards of pharmacy result in delays to the pharmacist of weeks. Such delays have a significant impact on the access to care (situations where the licensure of the pharmacist is critical to provide or continue pharmacy services) and the economic loss to the pharmacist.

3. Involvement in Standard Setting and Practice Determinant Committees and Task Forces

Autonomous boards of pharmacy are able to participate and be a part of the decision making process for national committees and task forces exploring various critical public health issues challenging the boards of pharmacy. Consolidated boards of pharmacy often will not be able to or are prohibited from participating in such activities, which has both short and long term detrimental effects on the states and their citizens.

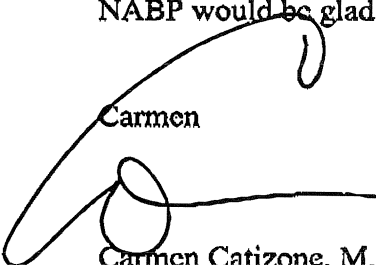
4. Overall Cost and Economies of Scale

Although advocates of consolidation indicate that such a system will allow for the economies of scale and reduced costs, boards of pharmacy report to us that the opposite result often occurs and the operating expense of a consolidated board of pharmacy is greater than for an autonomous board of pharmacy. This result has been explained to NABP in that the sharing of services through a consolidated format for activities such as IT, licensure processing and renewal, continuing education monitoring, investigations, and legal matters often results in higher costs than when the board was autonomous and services that try to equate all of the professions and occupations to the same process and standards. The application of all professions and occupations to the same processes and standards has resulted in less efficiency, increased patient complaints, and decisions that may be effective for customers of cosmeticians but extremely detrimental to patients of surgeons or pharmacists because the across the board approach that one size fits all is simply not viable.

I summarized some of the findings and information that has been reported to NABP over the years as states struggle to decide which structure will work best for them and the citizens they are charged to protect. Again, based upon NABP's over 100 years of experience in working with the state boards of pharmacy, in general, an autonomous board of pharmacy is more cost effective, responsive, fiscally prudent and responsible, and efficient than a consolidated board of pharmacy.

NABP would be glad to provide additional information if you so request.

Carmen



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