Report To

The Mississippi Legislature

INVESTIGATIVE REVIEW OF THE STATE BOARD OF PHARMACY

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. The Pharmacy Board's practice of making its Executive Director totally responsible for the issuance of official board charges without written guidelines allows for inequitable enforcement of regulations. In addition, the board's discretionary authority and failure to review violation and fine patterns in determining penalties for noncomplying pharmacists can result in inequitable penalties.

The PEER Committee

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 standing joint committee, the PEER Committee is composed of five members of the House of Representatives appointed by the Speaker and five members of the Senate appointed by the Lieutenant Governor. Appointments are made for four-year terms with one Senator and one Representative appointed from each of the U. S. Congressional Districts. Committee officers are elected by the membership with officers alternating annually between the two houses. All Committee actions by statute require a majority vote of three Representatives and three Senators voting in the affirmative.

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

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INVESTIGATIVE REVIEW OF THE STATE BOARD OF PHARMACY

February 3, 1992

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Joint Committee on Performance Evaluation and Expenditure Review

PEER Committee

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February 3, 1992

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At its meeting of February 3, 1992, the PEER Committee authorized release of the report entitled **Investigative Review of the State Board of Pharmacy.**

Bill Canon

Senator Bill Canon, Chairman

This report does not recommend increased funding or additional staff.

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INVESTIGATIVE REVIEW OF THE STATE BOARD OF PHARMACY

February 3, 1992

EXECUTIVE SUMMARY

INTRODUCTION

PEER conducted this investigative review of the Board of Pharmacy in response to allegations of inequitable investigative procedures and selective enforcement of state laws and regulations by the board and its former Executive Director, H. W. Holleman. The review sought to determine whether the allegations were correct and whether violations of state laws had occurred.

Background

MISS. CODE ANN. Section 73-21-75 (1972) creates a seven-member state Board of Pharmacy whose primary duty is to enforce the provisions of the Mississippi Pharmacy Practice Act. To enforce these provisions, the board staff conducts investigations and adjudicative hearings.

Overview

PEER investigated allegations of inequitable investigative procedures and selective enforcement of state laws and regulations by the Pharmacy Board and its Executive Director. PEER found weaknesses in the board's enforcement of and compliance with state pharmacy laws and regulations.

The Pharmacy Board's current practice of making its Executive Director totally responsible for the issuance of official board charges without written guidelines allows for inequitable enforcement of regulations. PEER identified four cases of similar circumstances in which compliance agents documented instances of non-compliance with board regulations. In two of the cases, the Executive Director issued formal charges and the Pharmacy Board imposed penalties, while in the other two cases the Executive Director chose not to initiate formal board charges.

The Pharmacy Board's discretionary authority and failure to review violation and fine patterns in determining penalties for noncompliant pharmacists can result in inequitable penalties. PEER identified four cases of similar circumstances in which the board's actions appeared inequitable.

The Pharmacy Board does not adequately train its compliance agents to perform their assigned duties. The board's failure to train its agents in inspection and investigative techniques results in a lack of uniform treatment of pharmacists under review. In addition, the board does not provide its compliance agents with firearms training, although state law authorizes the agents to carry weapons.

The Pharmacy Board does not consistently adhere to its own regulations. For example, on at least four occasions the board approved continuing education programs after their presentation, even though board regulations prohibit such. In addition, the board does not require its central office staff to follow on-site narcotics destruction procedures which it requires of licensed pharmacists.

The board's former Executive Director, H. W. Holleman, violated MISS. CODE ANN. Section 73-21-79 (1972) by working as a consultant pharmacist in an institutional pharmacy regulated by the board. The board's appointment of its new Executive Director, Harold Stringer, also violates CODE Section 73-21-79 because Stringer has an indirect interest in a pharmacy regulated by the board.

FINDINGS

The Pharmacy Board's practice of making its Executive Director totally responsible for the issuance of official board charges without written guidelines allows for inequitable enforcement of regulations.

Through custom and practice, the Pharmacy Board makes its Executive Director totally responsible for the issuance of official board charges. Such decisions are made by the Executive Director with limited input from compliance agents and no input from board members. In addition, as a result of due process concerns, one of the board's former Attorney General representatives advised board members to ensure that they have no knowledge of a charge prior

to officially hearing the case. Therefore, the board has in practice made the Executive Director entirely responsible for determining which cases of noncompliance should result in board charges. In addition, because of due process concerns, the board has chosen to remain uninformed of ongoing inspections/investigations which may result in formal board charges.

The board has no oversight controls in place to ensure that the Executive Director bases his charge issuance decisions on objective and equitable criteria. Therefore, it is possible that the Executive Director could show favoritism toward selected registrants. PEER identified four cases of similar circumstances in which compliance agents documented instances of non-compliance with board regulations. In two of the cases, the Executive Director issued formal charges and the Pharmacy Board imposed penalties, while in the other two cases the Executive Director chose not to initiate formal board charges.

The Pharmacy Board's discretionary authority and failure to review violation and fine patterns in determining penalties for noncompliant pharmacists can result in inequitable penalties.

Subsequent to the Executive Director's issuance of a formal charge against a noncompliant pharmacist, the full board conducts a hearing to determine whether to sustain the charge and impose a penalty or reject the charge. According to state law, the Pharmacy Board has discretionary authority in determining penalties for noncompliant pharmacists. While MISS. CODE ANN. Section 73-21-103 establishes six types of penalties the board may impose against a pharmacist, the section lacks exactness in the imposition of such penalties. While PEER concedes that the Pharmacy Board should have a degree of flexibility in developing penalties, state law is silent as to the definition of "severity and grossness" [of violations], the penalty criteria currently utilized by the board.

The most important effect of the board's discretionary penalty authority is the possibility of preferential treatment among noncompliant pharmacists. According to two board members interviewed by PEER, the board uses its collective memory of prior cases to ensure that similar violations receive similar penalties. However, due to staggered terms served by board members, this informal method can result in inequitable penalties.

PEER reviewed ten cases, based on similarity of board charges and types of penalties imposed, in which the Pharmacy Board took official action. For six of the ten cases, the board appeared to impose a stronger penalty on pharmacists who had more instances of a particular violation. For four of the ten cases, the board's actions appeared inequitable, even though the charges and circumstances were similar.

The Pharmacy Board's failure to train compliance agents in inspection and investigative techniques results in a lack of uniform treatment of pharmacists under review.

The Pharmacy Board does not have a comprehensive compliance agent training program which ensures that agents are equally trained to criteria contained in state law and board regulations. In testimony before the PEER Committee, former and current compliance agents testified of the board's lack of training and the agents' use of judgment while performing their daily tasks.

The Pharmacy Board's compliance agent training efforts are inadequate for two primary reasons.

- The board's investigative unit manual contains few "how-to" steps for compliance agents to utilize when conducting inspections and investigations.
- None of the board's former executive directors had developed a comprehensive training program for compliance agents.

Due to the board's failure to train compliance agents formally and uniformly, pharmacists could be treated differently, depending upon the compliance agent assigned to their geographic area and their agent's level of training. The board's failure to provide its compliance agents with a "how-to" manual which clearly establishes evidence requirements also could jeopardize the board's ability to defend board decisions.

The Pharmacy Board has lax controls over and no written policies for the staff's destruction of excess or unwanted narcotics in the board's custody.

Current board regulations allow pharmacists to dispose of controlled substances by destroying them on site in the presence of witnesses or by mailing

them to the Pharmacy Board's office for destruction by board staff. As a matter of practice, all board employees receive excess or unwanted controlled substances sent to the board's office for disposal. However, the board staff's destruction practices vary from the board's regulations imposed on pharmacists.

Even though the board has acknowledged the necessity to develop on-premises disposal procedures for pharmacists, the board and its Executive Director have not developed internal procedures to govern the staff's destruction of excess or unwanted controlled substances. Neither the board or the Executive Director have assurances that all excess or unwanted controlled substances sent to the board for disposal are in fact destroyed.

From September 1990 to May 1991, the Pharmacy Board violated its regulations by approving at least four continuing education programs after their presentation, thereby compromising the consumer protection provided to the public.

Pharmacy Board regulations require pharmacists to renew their licenses biennially. As part of the renewal process a pharmacist must present evidence of continuing education credit. Board regulations stipulate the amount of continuing education credit a pharmacist must receive during a licensure period. Pharmacy Board regulations state that continuing education credit may be obtained by attending *"programs which have been approved by the Mississippi State Board of Pharmacy prior to presentation."* [emphasis added]. According to the board's Executive Director, the agency's regulations contain the prior approval requirement so that the board can determine a program's suitability for offering continuing education credit to participants. The director stated that the prior approval requirement was also a means by which the board controls the quality of programs offered for continuing education credit.

According to board minutes, at its meetings on September 13, 1990; October 4, 1990; and May 15, 1991, the Pharmacy Board violated its regulations by approving continuing education programs which had already been presented. By approving these continuing education programs after their presentation, the board clearly violated its own regulations. In effect, the board compromised the consumer protection value of continuing education courses by post-approving courses.

The board's former Executive Director, H. W. Holleman, violated MISS. CODE ANN. Section 73-21-79 (1972) by working as a consulting pharmacist in an institutional pharmacy regulated by the board.

H. W. Holleman, the Pharmacy Board's former Executive Director, was employed as a pharmacist by Simpson General Hospital during the period that he served as Executive Director. Like all pharmacies in Mississippi, Simpson General Hospital's pharmacy is licensed and regulated by the Pharmacy Board.

MISS. CODE ANN. Section 73-21-79 (1972) states that the board's Executive Director *"shall devote full time to the duties of his office and shall not be interested directly or indirectly in the operation of a pharmacy or engaged in any other business that will interfere with the duties of his office."* Although the Attorney General's office recently chose not to issue an official opinion relative to Section 73-21-79, PEER's position is that the section could be interpreted to preclude the board's Executive Director from owning any interest in a pharmacy or having an employment interest in a pharmacy.

The Pharmacy Board's appointment of its new Executive Director, Harold Stringer, violates MISS. CODE ANN. Section 73-21-79 (1972) because Stringer has an indirect interest in a pharmacy.

When H. W. Holleman retired effective December 31, 1991, the board selected Harold Stringer, a licensed pharmacist from Prentiss, Mississippi, as its new Executive Director. Stringer's wife, Ann Stringer, works for a retail pharmacy in Prentiss. As noted above, MISS. CODE ANN. Section 73-21-79 (1972) states that the board's Executive Director *"shall not be interested directly or indirectly in the operation of a pharmacy or engaged in any other business that will interfere with the duties of his office."*

Although neither the Ethics Commission nor the Attorney General's Office have issued an official opinion on this matter, the board's choice of hiring an Executive Director with potential conflicts could render the board subject to criticism for unequal treatment of regulated pharmacies, and could be viewed by the industry and public as a conflict of interest.

Pharmacy Board compliance agents carry firearms, for which they do not receive formal training.

Because compliance agents travel extensively throughout their assigned regions conducting inspections and investigations and have authority to take possession of controlled substances for adjudicative purposes or eventual destruction, the board allows them to carry firearms. Although the Pharmacy Board issues firearms to them, the board does not provide firearms training or require that they become firearms qualified. An untrained agent's use of a firearm in the line of duty could make board members personally liable for the agent's actions. Any person injured by a compliance agent's firearm could argue that the board was negligent in its duties by not providing firearms training to the armed agent.

RECOMMENDATIONS

1. The Legislature should amend MISS. CODE ANN. Section 73-21-99 (1972) to require the board's Executive Director and compliance agents to provide inspection/investigation status reports during the board's monthly meetings. Such reports to the board should limit the Executive Director's discretionary authority to decide which cases would result in formal charges and eventual presentation to the board. The board should base any adverse actions only upon competent evidence received during formal hearings.

2. The Legislature should amend MISS. CODE ANN. Section 73-21-103 (1972) to require the Pharmacy Board to develop a uniform penalty policy which can be applied to violations of state laws and regulations. For those unique violations which may not be subject to such a policy, state law should require the board to document specifically in its minutes rationale for the penalty imposed.

3. The Pharmacy Board should review its current policy position regarding inspections and investigations. Where possible, the board should officially adopt inspection/investigation standards to be utilized by its compliance agents. Once the board has adopted such standards, the board should instruct its Executive Director to revise the agency's investigative unit manual to include the board's inspection/investigation standards and any other necessary operational steps for major activities within the board's responsibilities.

4. The Pharmacy Board should instruct its Executive Director to develop and implement a formal training program for compliance agents.

5. The Pharmacy Board should direct its Executive Director to immediately develop internal custody, control, and reporting procedures for the staff's destruction of excess or unwanted controlled substances. Such procedures could be an expansion of the board's on-site disposal procedures for pharmacists.

6. To increase the accountability for items received by the Pharmacy Board staff for destruction, the staff should discontinue its practice of consolidating items received from various pharmacists into one box. After inventorying items to be destroyed from a pharmacist, board staff should seal the box in which the items were initially packed, assign a destruction identification code to the box, and store the box as a unique box until time for destruction. The board's Executive Director and legal counsel should vigorously investigate any spot-check inventory variances from initial inventories of such boxes.

7. The Pharmacy Board should require its Executive Director to include on each month's agenda a controlled substances destruction report, consisting of the name of the pharmacist/pharmacy for whom the board staff destroyed items, a listing of items destroyed, and their destruction date.

8. The Pharmacy Board's regulations should continue to require prior approval of continuing education programs and the board should strictly adhere to the requirement with no exceptions.

9. The Pharmacy Board should reconsider its hiring of Harold Stringer as Executive Director in light of MISS. CODE ANN. Section 73-21-79 (1972). The board should also ensure that its Executive Director has no financial, employment, or other interest in pharmacies for which the board has regulatory responsibilities.

10. Although state law authorizes compliance agents to carry weapons, the board should instruct its compliance agents to cease imme-

diately the practice of carrying weapons. If the board insists on its agents carrying weapons, the Legislature should amend MISS. CODE ANN. Section 45-6-3 (1972) to include Pharmacy Board compliance agents within the definition of a law enforcement officer. By doing so, the Legislature should require compliance agents to qualify with their weapons and be certified through the Law Enforcement Officer Standards and Training Board.

If the Legislature does not amend Section 45-6-3 and the board continues its practice of allowing compliance agents to carry weapons, the board should, at a minimum, make arrangements for its agents to receive applicable training from the Law Enforcement Officers' Training Academy.

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INVESTIGATIVE REVIEW OF THE STATE BOARD OF PHARMACY

INTRODUCTION

Authority

At its October 3, 1991, meeting, the PEER Committee began an investigative review of the state Board of Pharmacy (hereafter referred to as the Pharmacy Board or board). The Committee acted in accordance with MISS. CODE ANN. Section 5-3-57 (1972).

Scope and Purpose

PEER conducted this investigative review in response to allegations of inequitable investigative procedures and selective enforcement of state laws and regulations by the board and its former Executive Director, H. W. Holleman. The review sought to determine whether the allegations were correct and to determine whether violations of state laws had occurred.

Method

While conducting this review, PEER:

- conducted an investigative hearing on November 6, 1991, to receive sworn testimony from the board's three current compliance agents and two former compliance agents;
- interviewed three Pharmacy Board members and current and former Pharmacy Board employees and officials;
- interviewed the director of the Mississippi Pharmacists' Association and two pharmacists who had been subject to board action;
- interviewed representatives of the Attorney General's office and federal Drug Enforcement Administration; and,
- reviewed state and federal statutes and Pharmacy Board regulations and records.

Background

MISS. CODE ANN. Section 73-21-75 (1972) creates a seven-member state Board of Pharmacy whose primary duty is to enforce the provisions of the Mississippi Pharmacy Practice Act (MISS. CODE ANN. Section 73-21-71 et. seq.). State law empowers the board to employ an Executive Director and "*persons. . .in such other positions or capacities as it deems necessary to the proper conduct of board business.*" (See Exhibit 1, page 3, for the board's organization chart.) The board utilizes two methods to accomplish its enforcement duties:

-- routine inspections or special investigations by board compliance agents, and

-- board adjudicative hearings to determine non-compliance with regulations.

Overview

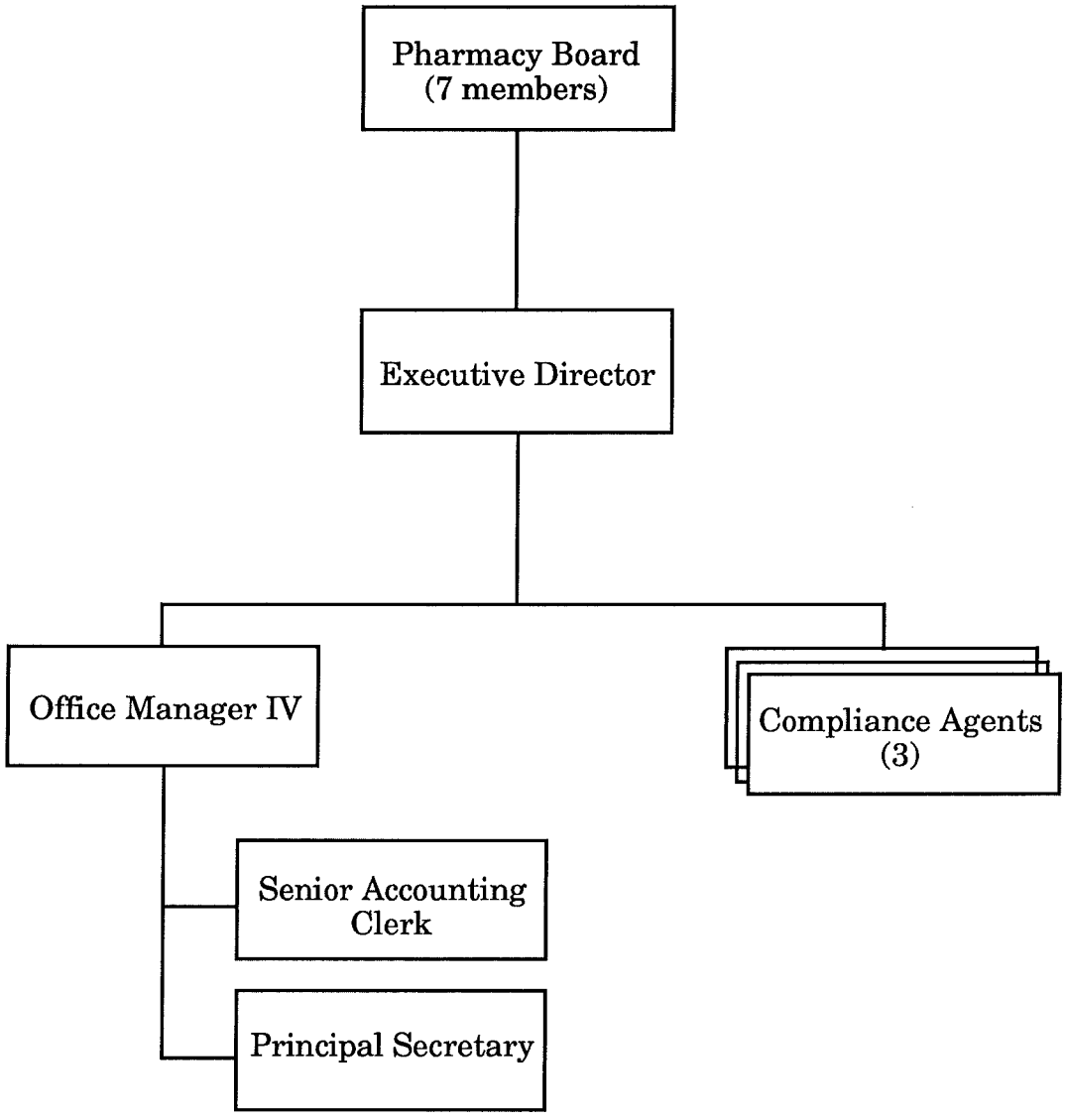
PEER investigated allegations of inequitable investigative procedures and selective enforcement of state laws and regulations by the Pharmacy Board and its Executive Director. PEER found weaknesses in the board's enforcement of and compliance with state pharmacy laws and regulations.

The Pharmacy Board's major weaknesses involve the issuance of formal board charges and determination of penalties for non-compliant pharmacists. The Pharmacy Board's current practice of making its Executive Director totally responsible for the issuance of official board charges without written guidelines allows for inequitable enforcement of regulations. PEER identified four cases of similar circumstances in which compliance agents documented instances of non-compliance with board regulations. In two of the cases, the Executive Director issued formal charges and the Pharmacy Board imposed penalties, while in the other two cases the Executive Director chose not to initiate formal board charges. The Pharmacy Board's discretionary authority and failure to review violation and fine patterns in determining penalties for noncompliant pharmacists can result in inequitable penalties. The board reportedly bases penalties on the "severity and grossness" of the violation and the board's collective memory of prior penalties imposed in similar cases. PEER identified four cases of similar circumstances in which the board's actions appeared inequitable.

The Pharmacy Board does not adequately train its compliance agents to perform their assigned duties. In particular, the board's failure to train its agents in inspection and investigative techniques results in a lack of uniform treatment of pharmacists under review. In sworn testimony before the PEER Committee, the board's agents stated that their jobs involve a high degree of independent judgment with few written guidelines within

EXHIBIT 1

MISSISSIPPI STATE PHARMACY BOARD
ORGANIZATION CHART



SOURCE: Mississippi State Pharmacy Board.

which to operate. In addition, the board does not provide its compliance agents with firearms training, although state law authorizes the agents to carry weapons.

The Pharmacy Board does not consistently adhere to its own regulations. For example, on at least four occasions the board approved continuing education programs after their presentation, even though board regulations prohibit such. In addition, the board does not require its central office staff to follow on-site narcotics destruction procedures which it requires of licensed pharmacists.

The board's former Executive Director, H. W. Holleman, violated MISS. CODE ANN. Section 73-21-79 (1972) by working as a consultant pharmacist in an institutional pharmacy regulated by the board. The board's appointment of its new Executive Director, Harold Stringer, also violates CODE Section 73-21-79 because Stringer has an indirect interest in a pharmacy regulated by the board.

FINDINGS

PEER reviewed allegations of inequitable investigative procedures and selective enforcement of state laws and regulations by the board and its Executive Director, H. W. Holleman.

The Pharmacy Board's practice of making its Executive Director totally responsible for the issuance of official board charges without written guidelines allows for inequitable enforcement of regulations.

According to the Pharmacy Board's organization structure presented in Exhibit 1, page 3, the Executive Director supervises the board's compliance agents. Such supervision includes, but is not limited to, making assignments to agents and reviewing routine and investigative reports compiled by agents. The Executive Director conducts weekly meetings with the board's compliance agents, during which each agent discusses the results of the prior week's work and submits written reports. During these meetings, the agents also make recommendations to the Executive Director as to what type, if any, of disciplinary action should be taken against a noncompliant pharmacist. Exhibit 2, page 6, illustrates the board's investigative process.

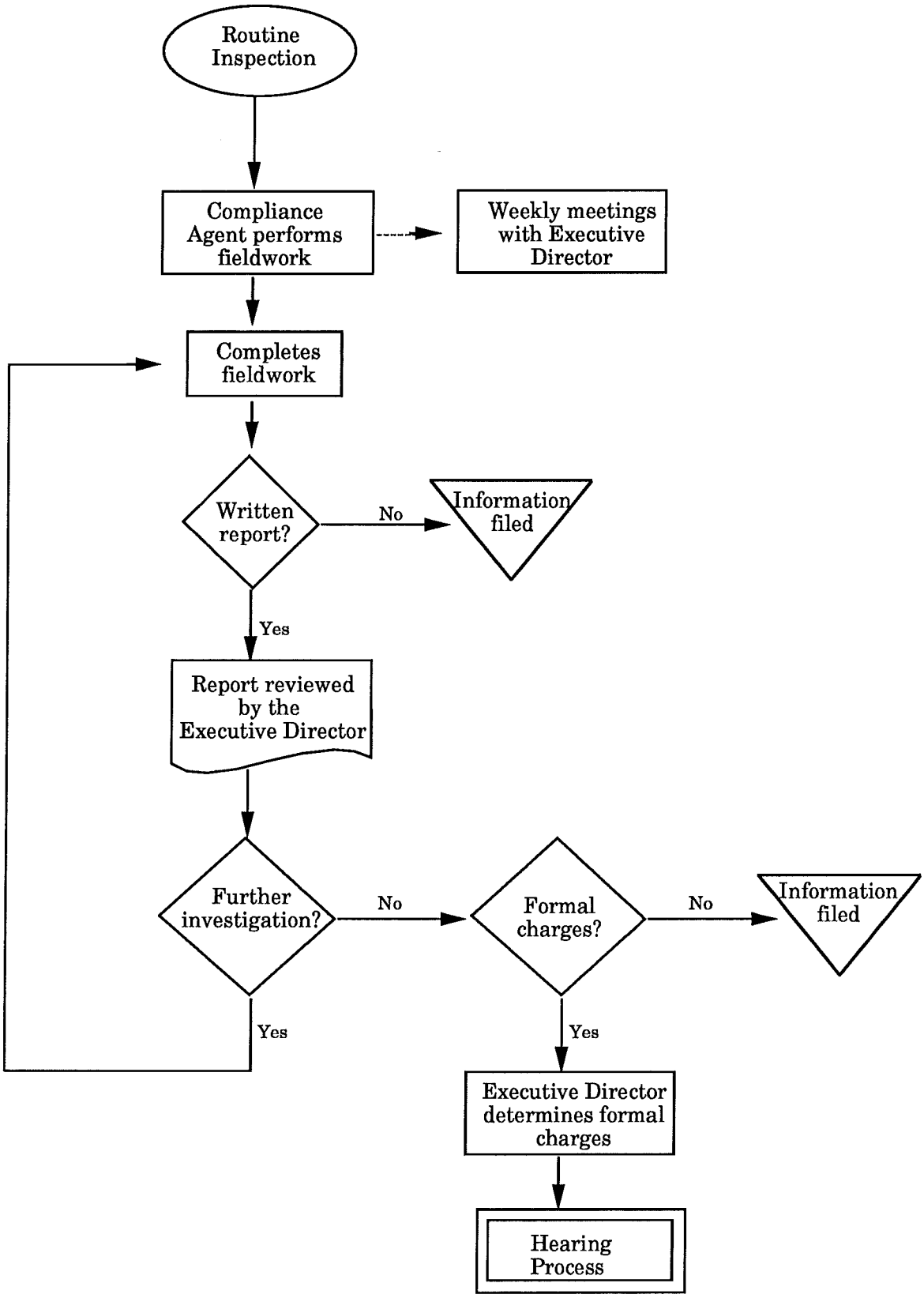
The board's Investigative Unit manual states that a compliance agent should complete either an inspection report form or narrative report following an inspection. The manual further states that following completion of a narrative report, "*the Agent shall discuss follow-up action with the Executive Director. Action may be the issuance of a warning notice or a notice of hearing and complaint.*" MISS. CODE ANN. Section 73-21-99 (1972) also states that hearings on violations may occur upon a "*finding by the Executive Director that reasonable cause exists to believe that a licensee or permit holder has committed an act which is grounds for disciplinary action as provided in section 73-21-97.*" The referenced section contains ten general categories for which pharmacists may be held in violation of board regulations. (See Appendix A, page 27.)

Through custom and practice, the Pharmacy Board makes its Executive Director totally responsible for the issuance of official board charges. Current and former board compliance agents, in sworn testimony before the PEER Committee, testified that the Executive Director has ultimate responsibility in determining whether official board charges will be initiated against a pharmacist. In practice, such decisions are made by the Executive Director with limited input from compliance agents and no input from board members.

In testimony before the PEER Committee, one current compliance agent, in responding to the question "Who has the ultimate authority to determine whether an investigative report will be utilized to initiate a formal board complaint?" stated: "*H. W. Holleman, the executive director*

EXHIBIT 2

STATE PHARMACY BOARD COMPLIANCE AGENTS' INVESTIGATIVE PROCESS



SOURCE: PEER interviews with State Pharmacy Board members and staff.

makes that decision." Another current agent, in responding to the same question, stated "*We* [compliance agents] *would prepare the investigative report; report would be discussed with my supervisor, Mr. Holleman; and usually on our recommendation, the Complaint would be issued by Mr. Holleman.*" The Committee posed the question "Who has the ultimate authority to determine whether a report of a violation of pharmacy regulations is pursued through the complaint stage to the board?" to another current compliance agent, who stated "*the Executive Director.*" A former compliance agent provided the following testimony regarding the Executive Director's control of the complaint process:

> . . . *when we completed investigations, you* [compliance agents] *went back to Mr. Holleman with the result of your investigation. Once that was done, it was totally out of your hands. He would either tend to it himself or either ask you to file a formal Complaint, and you would do that, sign an affidavit and then the Notice of Hearing and Complaint went out to the individual. But once you completed the investigation, then a determination of what happened after that was totally out of your hands. I don't disagree with that process, but I think that that process should not be in the hands of one individual.*

The Pharmacy Board also has a practice of remaining uninformed of the staff's investigative activities reportedly to prevent bias during the adjudication phase. For the last several years, the board has appointed one of its members to serve as a hearing officer to review all charges prior to hearings and develop a penalty recommendation. Because the hearing officer has prior knowledge of each case, the officer does not participate in the board's adjudication discussion. Even though the hearing officer has prior knowledge of official charges, the Pharmacy Board staff does not inform the hearing officer or board members of in-progress cases being worked by compliance agents which may eventually result in formal charges.

The Pharmacy Board has afforded its Executive Director total control over the charge issuance process primarily because state law allows the Executive Director to initiate board charges based on "*reasonable cause.*" In addition, as a result of due process concerns, one of the board's former Attorney General representatives advised board members to ensure that they have no knowledge of a charge prior to officially hearing the case. Therefore, the board has in practice made the Executive Director entirely responsible for determining which cases of non-compliance should result in board charges. In addition, because of due process concerns, the board has chosen to remain uninformed of ongoing inspections/investigations which may result in formal board charges.

The primary effect of the board having a "hands off" policy regarding issuance of charges is that the Executive Director has unfettered authority

to issue formal charges on behalf of the board. Because of the due process concerns, the board has no oversight controls in place to ensure that the Executive Director bases his charge issuance decisions on objective and equitable criteria. Therefore, it is possible that the Executive Director could show favoritism toward selected registrants. PEER identified four cases of similar circumstances in which compliance agents documented instances of non-compliance with board regulations. In two of the cases, the Executive Director issued formal charges and the Pharmacy Board imposed penalties, while in the other two cases the Executive Director chose not to initiate formal board charges. (See Exhibit 3, page 9.) With regard to the southwest Mississippi pharmacist cited in Exhibit 3, a current compliance agent told the PEER Committee that *"there's no question that that* [cocaine shortage] *might have been followed up more vigorously at some other location."*

A current compliance agent testified before the PEER Committee that he had knowledge of another compliance agent who "*found shortages of controlled substances there* [a north Mississippi pharmacy], *and returned to inform Mr. Holleman about that particular one, and it never resulted in a Notice of hearing and Complaint.*" The same agent told the Committee about a Jackson pharmacist who maintained and dispensed physician samples in violation of the board's regulations. The agent stated: "*I had him caught, and nothing was ever done in that particular case.*" A former compliance agent told the Committee of investigating and documenting a south Mississippi pharmacist dispensing drugs without a legitimate prescription. The former agent stated that "*He* [Holleman] *declined to do anything with that case. . .Nothing was ever prosecuted or done with that particular case. . .*" With regard to the Executive Director's control of board charges, another former compliance agent told the Committee "*there's glaring inequality there. You know, some cases are brought before* [the Pharmacy Board], *some are not.*"

The Pharmacy Board's discretionary authority and failure to review violation and fine patterns in determining penalties for noncompliant pharmacists can result in inequitable penalties.

Subsequent to the Executive Director's issuance of a formal charge against a noncompliant pharmacist, the full board conducts a hearing in compliance with MISS. CODE ANN. Section 73-21-99 (1972) to determine whether to sustain the charge and impose a penalty or reject the charge. Subsection 5 of the section states that "*all hearings shall be conducted by the board, which shall not be bound by strict rules of procedure or by the laws of evidence in the conduct of its proceedings, but the determination shall be based upon sufficient evidence to sustain it.*" CODE Section 73-21-103 provides the Pharmacy Board authority to impose penalties against non-compliant pharmacists for violations. CODE Section 73-21-101 establishes the route of appeal a pharmacist may take to seek relief from adverse board

EXHIBIT 3

EXECUTIVE DIRECTOR'S HANDLING OF CASES OF NONCOMPLIANCE

UNPROFESSIONAL CONDUCT

Pharmacist	Board Charges	Background of Charges	Board Penalties
Sammy Chow	Unprofessional Conduct (Two counts)	On May 3, 1991, a board compliance agent conducted a routine inspection of Chow's Westgate Drugs in Clarksdale, Mississippi. While conducting the inspection, the agent noted four empty "sample" drug packages in the pharmacy's trash container, which formerly contained eighty Premarin tablets. The pharmacist on duty stated that a local health care professional had traded the drug samples for other prescription medications. The pharmacist told the compliance agent that she had accepted the sample drugs and placed them in the pharmacy's regular stock. Chow stated that he was unaware of the incident and believed the transaction was an isolated incident which had not occurred in the past. ARTICLE V of the Pharmacy Board's regulations prevents the selling or bartering of prescription drug samples.	• Suspension of Chow's pharmacist license for three months (with last two months held in abeyance) • Payment of $1,000 fine within thirty days of board action • Achievement of passing score on a state pharmacy law test taken within thirty days of board action
East Central Mississippi Pharmacist	No formal charges against this pharmacist	On February 18, 1987, a compliance agent conducted a routine inspection of a pharmacy located in east central Mississippi. While conducting the inspection, the agent noted that the pharmacy had sample drugs received from local physicians included in its drug inventory. The compliance agent seized and removed from the pharmacy 203 sample tablets and sixty cubic centimeters of a sample liquid. On April 28, 1987, the compliance agent made a follow-up inspection of the pharmacy and again located at least nine different physician samples in the pharmacy, some of which had been placed in the pharmacy's drug inventory. The agent also found evidence of "shucking" (removing sample drugs from their original packaging) in the pharmacy's trash containers. The agent packaged and sealed the contraband	Because the Executive Director did not pursue formal charges, the board was never officially made aware of the pharmacist's noncompliance with state regulations. Therefore, the board did not have an opportunity to determine the pharmacist's guilt or innocence and impose an appropriate penalty.

SOURCE: Pharmacy Board files.

drugs and left them at the pharmacy for eventual destruction by Pharmacy Board staff.

Subsequent to each inspection of the pharmacy, the compliance agent discussed with the board's Executive Director the presence of samples in the pharmacy. The Executive Director reportedly told the agent that he would "handle" the situation. However, the Executive Director never issued formal charges against the pharmacist.

ARTICLE V of the Pharmacy Board's regulations prevents the *"dispensing, selling, bartering, receiving or maintaining drugs which the pharmacist knows, or should know, have been stolen or diverted from a legitimate source."*

INADEQUATE RECORDKEEPING

Pharmacist	Board Charges
Fred Cruse	Inadequate recordkeeping of controlled substances (two counts)

Background of Charges

On November 16, 1990, compliance agents conducted an inspection of Medical Arts Pharmacy in Picayune, Mississippi. (Fred Cruse is co-owner and permit holder for the pharmacy.) As part of the inspection, the agents conducted an accountability audit of selected controlled substance drugs located at the pharmacy. The audit determined that the pharmacy had shortages in five Schedule II controlled substances and two Schedule III and IV controlled substances, representing 3,944 tablets or dosage units. Cruse told the agents that he was unaware of the shortages and speculated that a part-time employee of his pharmacy, who was known by the Pharmacy Board to be a substance abuser, may have diverted the missing controlled substances. The compliance agents did not aggressively pursue Cruse's explanation.

After concluding the accountability audit, the compliance agents discussed their findings with the Executive Director, who decided to issue formal board charges against Cruse.

ARTICLES XXI AND XXII of the board's regulations require pharmacists to maintain complete and accurate records of controlled substances.

Board Penalties

- Suspension of Cruse's pharmacist license for ninety days (with the last sixty days held in abeyance)
- Suspension of the pharmacy's controlled substance registration for ninety days (with the entire period held in abeyance)
- Payment of $1,000 fine paid within thirty days of board action
- Probation for three years
- Submission to urine screenings upon request of Pharmacy Board agents
- Requirement to maintain perpetual inventory on Schedule II drugs
- Achievement of passing score on a state pharmacy law test taken within thirty days of board action

Pharmacist	Board Charges	Background of Charges	Board Penalties
Southwest Mississippi Pharmacist	The board's Executive Director did not pursue formal charges against this pharmacist	On September 17, 1986, a compliance agent conducted an inspection of a southwest Mississippi pharmacy. While conducting the inspection, the agent noted that he could not account for a five-gram bottle of cocaine powder. Without performing additional investigative steps, the compliance agent departed the pharmacy and advised the owner/permit holder to treat the missing cocaine as a "mysterious disappearance" and conduct a complete controlled substance inventory. On October 15, 1986, approximately one month later, the permit holder reported to the Pharmacy Board that he conducted such an inventory and documented, in addition to the missing cocaine, shortages of eleven different Schedule II controlled substances, representing 3,064 tablets or dosage units. The permit holder speculated that the missing controlled substances were diverted by a substance abuser friend of one of his relatives who worked at the pharmacy. At the time the compliance agent detected the missing cocaine, the permit holder was serving as a Pharmacy Board member. The board's Executive Director never issued formal charges against the pharmacist. ARTICLES XXI AND XXII of the board's regulations require pharmacists to maintain complete and accurate records of controlled substances.	Because the Executive Director did not pursue formal charges, the board was never officially made aware of the pharmacist's noncompliance with state regulations. Therefore, the board did not have an opportunity to determine the pharmacist's guilt or innocence and impose an appropriate penalty.

action. See Exhibit 4, page 13, for a description of the board's hearing process.

According to state law, the Pharmacy Board has discretionary authority in determining penalties for non-compliant pharmacists. While Section 73-21-103 establishes six types of penalties the board may impose against a pharmacist, the section lacks exactness in the imposition of such penalties. State law allows the board to utilize its subjective professional judgement to determine the magnitude of a violation and the severity of penalty imposed to ensure future compliance with state laws and regulations. According to the board's former Executive Director, the board bases its penalty decisions on the "severity and grossness" of each violation. While PEER concedes that the Pharmacy Board should have a degree of flexibility in developing penalties, state law is silent as to the definition of "severity and grossness," the penalty criteria currently utilized by the board. (It should be noted that most other Mississippi regulatory boards' enabling legislation is also inexact with regard to imposition of penalties.)

The most important effect of the board's discretionary penalty authority is the possibility of preferential treatment among noncompliant pharmacists. According to two board members interviewed by PEER, the board uses its collective memory of prior cases to ensure that similar violations receive similar penalties. However, due to staggered terms served by board members, this informal method could fail result in inequitable penalties.

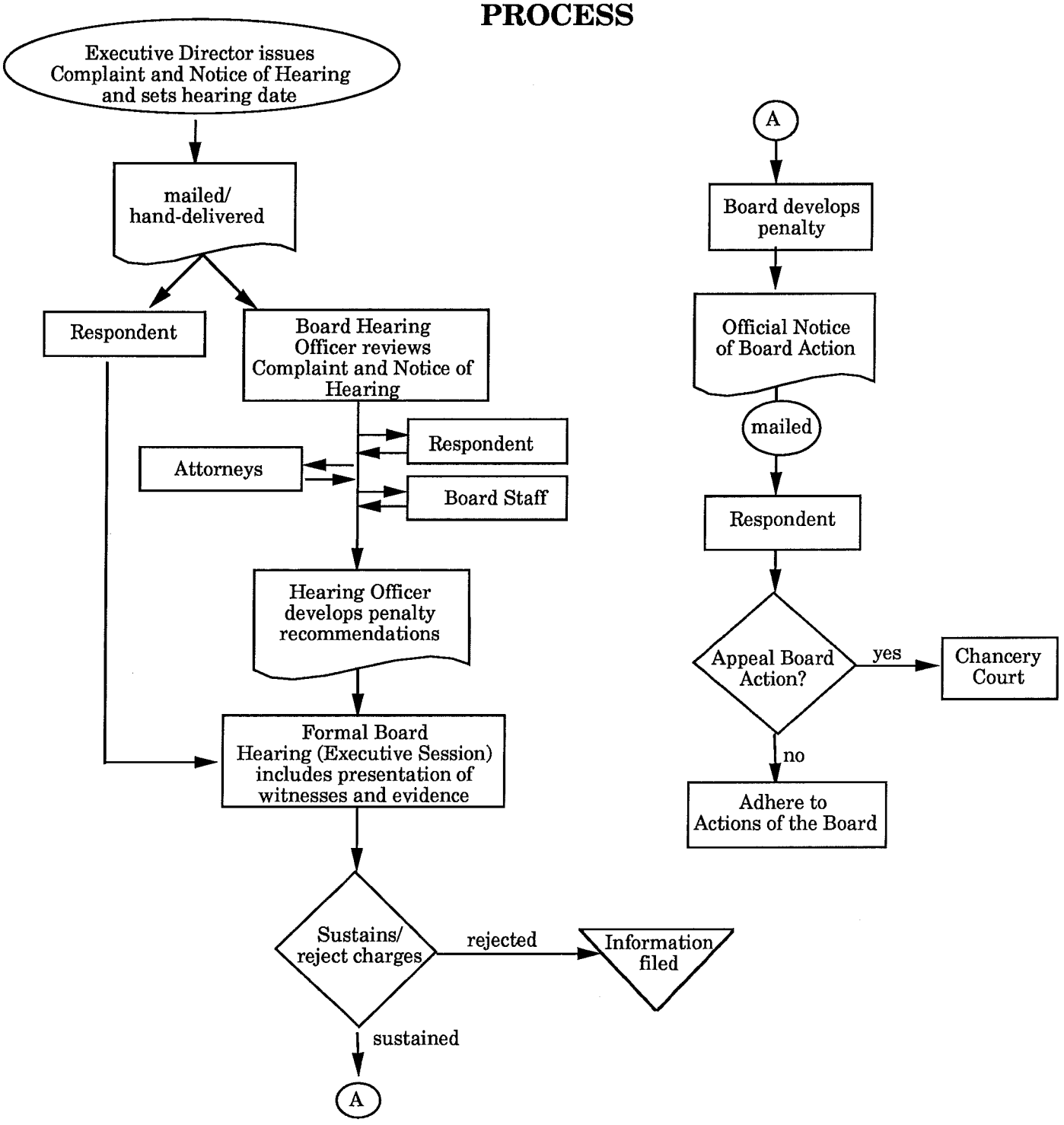
From the period August 1986 to August 1991, PEER reviewed ten cases, based on similarity of board charges and types of penalties imposed, in which the Pharmacy Board took official action. PEER's purpose in reviewing the cases was to determine whether the board imposed equitable penalties for similar charges. For six of the ten cases, the board appeared to impose a stronger penalty on pharmacists who had more instances of a particular violation. For four of the ten cases, the board's actions appeared inequitable, even though the charges and circumstances were similar. See Exhibit 5, page 14, for details of these four cases. The board's actions in all ten cases were consistent with state law because there are no comprehensive statutory requirements with regard to board penalties.

The Pharmacy Board's failure to train compliance agents in inspection and investigative techniques results in a lack of uniform treatment of pharmacists under review.

The board's Executive Director assigns compliance agents to specific geographic regions of the state to perform routine inspections and special investigations. Within their assigned regions, compliance agents independently perform their duties with limited supervision from the Executive Director. Compliance agents meet weekly with the Executive Director to discuss the status of inspections and investigations. On October

EXHIBIT 4

STATE PHARMACY BOARD HEARING PROCESS



SOURCE: PEER interviews with State Pharmacy Board members and staff.

EXHIBIT 5

EXAMPLES OF INCONSISTENT PENALTIES IMPOSED BY THE PHARMACY BOARD

Board Charges	*Board Penalties*
Michael Joe Houston	
Prescriptions being refilled with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber (Thirty-five instances)	• Suspension of Houston's license for six months (with the entire period held in abeyance) • Payment of $3,000 fine within thirty days of board action • Probation for ten years • Achievement of passing score on a state pharmacy law test taken within thirty days of board action
James Cooley	
Prescriptions being refilled with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber (Thirty-one instances)	• Payment of $1,500 fine within thirty days of board action • Probation for three years • Achievement of passing score on a state pharmacy law test taken within thirty days of board action
Robert Snyder	
Failure to maintain hard copies of original prescriptions filed in numerical order	• Payment of $500 fine within thirty days of board action • Probation for two years
Dwight McGraw	
Failure to maintain complete and accurate records of disposal of all controlled substances	• Payment of $300 fine within thirty days of board action

SOURCE: Pharmacy Board files.

4, 1990, the Pharmacy Board discussed and approved an amended version of the *Mississippi State Board of Pharmacy Policy and Procedures Manual-Investigative Unit.* According to the board's minutes, the manual had been used by the agency for approximately ten years and the recent amendments were "housekeeping" in nature. The board's investigative manual serves as a training tool and contains a compliance agent position description and general explanations of the agency's process, personnel and administrative procedures. In addition to the investigative unit manual, the board's training process involves assigning new compliance agents to two or three weeks of on-the-job training with a senior compliance agent. The board's investigative unit manual states that "*the scheduling of training for Compliance Agents will be the responsibility of the Executive Director. All training will be based on the individual needs of the Agent.*"

The Pharmacy Board does not have a comprehensive compliance agent training program which ensures that agents are equally trained to criteria contained in state law and board regulations. The board's failure to train compliance agents in inspection and investigative techniques results in a lack of uniform treatment of pharmacists under review. In testimony before the PEER Committee, former and current compliance agents testified of the board's lack of training and the agents' use of judgment while performing their daily tasks.

The Pharmacy Board's compliance agent training efforts are inadequate for two primary reasons.

- *The board's investigative unit manual contains few "how to" steps for compliance agents to utilize when conducting inspections and investigations.* Even though the board has adopted an investigative unit manual, the board has not developed specific "how-to steps" for routine inspections and special investigations. Therefore, the board allows individual compliance agents to determine methods to be utilized in conducting inspections and investigations. In sworn testimony before the PEER Committee, a current compliance agent stated that "*We* [compliance agents] *have a policy and procedures manual, but it doesn't get into the steps to take to do an investigation...it doesn't--as far as a detailed outline for the agent to go by, there's not anything that I'm aware of that's written on that.*" The board's compliance agents agreed that a "how-to" manual would be beneficial in conducting their fieldwork. However, these agents stated that such a manual could be difficult to develop because, as one agent told the Committee, "*each case is separate. . . each case is different.*"

- *None of the board's former executive directors had developed a comprehensive training program for compliance agents.* As previously stated, newly employed compliance agents are assigned to work with senior employees. Therefore, a new compliance

agent's knowledge and understanding of assigned tasks is dependent on that of the trainer to whom the new agent is assigned. The former Executive Director had no comprehensive training program in place to ensure that all compliance agents were trained to statutory and regulatory criteria and utilized uniform field techniques.

Due to the board's failure to train compliance agents formally and uniformly, pharmacists could be treated differently, depending upon the compliance agent assigned to their geographic area and their agent's level of training. The board's failure to provide its compliance agents with a "how-to" manual which clearly establishes evidence requirements also could jeopardize the board's ability to defend board decisions appealed to chancery court. MISS. CODE ANN. Section 73-21-101 (1972) may declare a decision of the board unlawful for the reason that it was ". . . *not supported by substantial evidence.*" Because compliance agents are allowed to function independently without adequate written directives, the board has no assurance that evidence gathered to support each case can withstand chancery court scrutiny.

An illustration of the board's inadequate compliance agent training was presented in sworn testimony before the PEER Committee. Compliance agents related to the Committee that neither the board nor the former Executive Director developed tolerance levels or thresholds for them to utilize to determine acceptable non-compliance with board regulations. The agents testified that the primary goal for their routine inspections was to ensure compliance through education of state regulations and laws, rather than developing disciplinary cases for presentation to the board. However, because the board has not developed tolerance levels, compliance agents testified that they utilize personal judgment to determine if formal board action is needed.

In testimony before the PEER Committee, one compliance agent stated that he uses a personal "rule of three"--i.e., if the agent cites a pharmacist three times for the same violation, the agent recommends to the Executive Director that the board take formal action against the pharmacist. Because the board has not established formal investigative procedures, it is possible that another compliance agent, who did not utilize the "rule of three'" could recommend formal action against a registrant after only a single violation. A formal training program and inspection standards would limit personal judgment and ensure a higher degree of uniformity.

The Pharmacy Board has lax controls over and no written policies for the staff's destruction of excess or unwanted narcotics in the board's custody.

Approximately ten years ago, the Pharmacy Board began providing assistance to pharmacists who needed help disposing of excess or

unwanted controlled substances. Current board regulations allow pharmacists to dispose of such controlled substances by destroying them on site in the presence of witnesses or by mailing them to the Pharmacy Board's office for destruction by board staff.

As a matter of practice, all board employees receive excess or unwanted controlled substances sent to the board's office for disposal. After reviewing the inventory reporting forms submitted by a pharmacist, a board employee (usually the Executive Director or a compliance agent) "spot-checks" some of the items to compare the quantity received to the quantity contained on the reporting form. The person conducting the spot-check initials the reporting form and returns a copy to the pharmacist.

As the board staff receives excess or unwanted controlled substances, the Executive Director or a compliance agent empties (or consolidates) the items into a cardboard box, which is kept in a combination lock supply cabinet located in an interior storage room. According to the board's former Executive Director, this mixture of drugs with a higher street value (Schedule 2 controlled substances) with those having less appeal to thieves is a deterrent to theft. Although only three board employees have knowledge of the lock's combination, the supply cabinet remains unlocked and accessible to all board employees during office hours. When the cardboard box reaches its capacity, the Executive Director or a compliance agent seals the box and obtains another cardboard box in which to empty other controlled substances received by the board. Once each week, usually on Fridays, the Executive Director or a compliance agent takes the cardboard box(es) to the Board of Animal Health's offices to be incinerated.

The Pharmacy Board staff does not adhere to the board's regulations for the recording and disposal of excess or unwanted controlled substances. As illustrated in Exhibit 6, page 18, Pharmacy Board regulations allow pharmacists to dispose of liquid controlled substances on-site by following certain requirements. For example, the pharmacist must inventory and record the items to be destroyed. The on-site destruction must be witnessed by the pharmacist and two witnesses. All three witnesses to the destruction must sign the inventory of controlled substances destroyed. The pharmacist must retain a copy of the items destroyed.

The board staff's destruction practices vary from the board's regulations imposed on pharmacists. For example, the board staff does not maintain a comprehensive inventory of items kept in the box to be destroyed. Even though a board employee conducts a spot-check of selected items upon receipt of items to be destroyed, no one reconciles the total number of items to be destroyed to the reporting form. In addition, the board staff loses virtually all accountability of the items to be destroyed by consolidating all items to be destroyed into one box. According to the Executive Director, the consolidation process is usually performed by a single employee without a witness. The board staff also does not maintain records as to which employees consolidated which pharmacist's items into

EXHIBIT 6

EXCERPT FROM BOARD OF PHARMACY REGULATIONS, ARTICLE XXVI

1. A registrant who wishes to dispose of any excess or unwanted controlled substances may contact the Mississippi State Board of Pharmacy for assistance in disposal of these substances. The disposal of these controlled substances shall be as follows:

A. All controlled substances to be disposed of shall be inventoried by the pharmacist, or a person designated by the pharmacist.

(1) This inventory shall be sent to the State Board of Pharmacy along with a request for the disposal of these controlled substances.

(2) Upon receipt of the inventory and the request, the Board of Pharmacy shall furnish the registrant the necessary forms and instructions for disposal of the controlled substances.

B. Tablets, capsules and injectable dosage forms in Schedules II, III, IV and V, plus liquids in Schedule II, shall be listed on an inventory form supplied to the registrant by the Board of Pharmacy.

(1) All controlled substances thus inventoried shall be sent prepaid to the State Board of Pharmacy by U.S. REGISTERED MAIL.

(2) The original copy of the inventory shall be sent to the Board of Pharmacy under separate cover.

(3) The duplicate copy of the inventory shall be sent to the Board of Pharmacy along with the controlled substances.

(4) The triplicate copy of the inventory shall be retained by the registrant.

(5) Upon receipt of the controlled substances, the duplicate copy of the inventory shall be returned to the registrant by the Board.

B. Liquids in Schedules III, IV and V may be listed on an inventory form supplied to the registrant by the Board of Pharmacy.

(1) All controlled substances thus inventoried, shall be destroyed on premises by flushing.

(2) The destruction must be witnessed by the pharmacist and two other witnesses.

(3) All three witnesses to the destruction shall sign the inventory of controlled substances destroyed.

(4) The registrant shall send to the Board of Pharmacy the original copy of the inventory of drugs destroyed.

(5) The registrant shall retain the duplicate copy of this inventory.

SOURCE: Pharmacy Board regulations (1991 edition)

the box. The board staff does not require a Board of Animal Health employee to attest that the staff actually incinerated controlled substances in that person's possession. The board staff also does not maintain records which show the items destroyed, their destruction date, and the employee responsible for their destruction.

At PEER's request, representatives of the federal Drug Enforcement Administration (DEA) reviewed the Pharmacy Board's policies for destruction of controlled substances. DEA officials told PEER that they were not aware that the Pharmacy Board had a controlled substances destruction service and warehoused such items prior to their destruction. After reviewing the board's state office destruction policies, DEA officials concluded that "*there appears to be no procedural policy concerning the witnessing of any destruction at the board office.*" The existing regulations apply to recordkeeping, but include no process for actual destruction.

Even though the board has acknowledged the necessity to develop on-premises disposal procedures for pharmacists, the board and its Executive Director have not developed internal procedures to govern the staff's destruction of excess or unwanted controlled substances. Neither the board or the Executive Director have assurances that all excess or unwanted controlled substances sent to the board for disposal are in fact destroyed. Therefore, it is possible that a board employee could divert some of the items to be destroyed for personal use or gain. While PEER has no evidence that board employees have diverted warehoused controlled substances prior to their destruction, potential certainly exists for a major diversion to occur.

From September 1990 to May 1991, the Pharmacy Board violated its regulations by approving at least four continuing education programs after their presentation, thereby compromising the consumer protection provided to the public.

Pharmacy Board regulations require pharmacists to renew their licenses biennially. As part of the renewal process a pharmacist must submit a renewal application form, present evidence of continuing education credit, and pay a renewal fee. Board regulations stipulate the amount of continuing education credit a pharmacist must receive during a licensure period. Continuing education programs are offered by either the American Council on Pharmaceutical Education (ACPE) or local sponsoring organizations. Pharmacy Board regulations state that continuing education credit may be obtained by attending "*programs which have been approved by the Mississippi State Board of Pharmacy prior to presentation.*" [emphasis added]. According to the board's Executive Director, the agency's regulations contain the prior approval requirement so that the board can determine a program's suitability for offering continuing education credit to participants. The director stated that the prior approval requirement was also a means by which the board controls the quality of programs offered for continuing education credit. At its April

12, 1990, meeting, the Pharmacy Board considered its guidelines for approving programs for continuing education and agreed to maintain its policy of not approving programs after their presentation.

At its meetings on September 13, 1990; October 4, 1990; and May 15, 1991, the Pharmacy Board violated its regulations by approving continuing education programs which had already been presented. At its September 13, 1990, meeting, the board gave post-approval to two continuing education programs, one presented on August 14, 1990, and the other presented on September 10, 1990. At its October 4, 1990 meeting, the board gave post-approval to a continuing education program on "Topical Steroids in Rhinitis" presented by Schering Laboratories at Pass Christian, Mississippi, on August 29, 1990. At its May 15, 1991, meeting, the board gave post-approval to a continuing education program on "Sinusitis" presented by Schering Laboratories at the Laurel Country Club on May 7, 1991.

By approving these continuing education programs after their presentation, the board clearly violated its own regulations, which had been reaffirmed by the board on April 12, 1990. In effect, the board compromised the consumer protection value of continuing education courses by post-approving courses. In addition, the board established precedents which will make it difficult to deny future post-approval requests.

The board's former Executive Director, H. W. Holleman, violated MISS. CODE ANN. Section 73-21-79 (1972) by working as a consulting pharmacist in an institutional pharmacy regulated by the board.

According to the administrator of Simpson General Hospital (Mendenhall, Mississippi), that hospital employed H. W. Holleman as a consulting pharmacist from January 2, 1984, through February 15, 1985. Holleman worked three days per week, usually between the hours of 5:00 p.m. to 10:00 p.m., and received $200 per week for his services. Holleman resigned his part-time position when the hospital employed a full-time pharmacist. Like all pharmacies in Mississippi, Simpson General Hospital's pharmacy is licensed and regulated by the Pharmacy Board.

Holleman violated state law by working as a consulting pharmacist and having an indirect interest in an institutional pharmacy regulated by the Pharmacy Board. MISS. CODE ANN. Section 73-21-79 (1972) states that the board's Executive Director "*shall devote full time to the duties of his office and shall not be interested directly or indirectly in the operation of a pharmacy or engaged in any other business that will interfere with the duties of his office.*" The Attorney General's office recently chose not to issue an official opinion relative to Section 73-21-79. (See page 22.) However, PEER's position is that the section could be interpreted to preclude the board's Executive Director from owning any interest in a pharmacy or having an employment interest in a pharmacy.

The former Executive Director told PEER that he engaged in his part-time employment with the full knowledge of the Pharmacy Board. However, the pharmacist who served as the board's chairman at the time of Holleman's part-time employment told PEER that he was not aware of the employment arrangement. Review of the board's FY 1984 minutes also did not contain the board's official approval of Holleman's part-time employment. The former Executive Director failed to inform the board of his activities which could result in a potential conflict with state law. Therefore, the board did not enforce Section 73-21-79 which would have prevented Holleman's part-time employment at the hospital pharmacy.

Holleman's part-time employment violated CODE Section 73-21-79 and compromised the position of Executive Director because he had an indirect interest in an institutional pharmacy for which his agency had regulatory responsibilities. Holleman's part-time employment also placed the agency's compliance agents in the awkward position of inspecting an institutional pharmacy for which their immediate supervisor, Holleman, was responsible. Holleman and the compliance agents could not perform their regulatory responsibilities due to the lack of independence caused by Holleman's part-time employment status with the hospital.

The Pharmacy Board's appointment of its new Executive Director, Harold Stringer, violates MISS. CODE ANN. Section 73-21-79 (1972) because Stringer has an indirect interest in a pharmacy.

After twenty-two years of service with the Pharmacy Board, H. W. Holleman, the board's former Executive Director, retired effective December 31, 1991. The board selected Harold Stringer, a licensed pharmacist from Prentiss, Mississippi, as its new Executive Director effective January 1, 1992.

While serving as the Pharmacy Board's new Executive Director, Harold Stringer will have day-to-day regulatory responsibilities over his wife, who is a licensed pharmacist. (Stringer's wife, Ann Stringer, works for a retail pharmacy in Prentiss.) As noted above, MISS. CODE ANN. Section 73-21-79 (1972) states that the board's Executive Director "*shall devote full time to the duties of his office and shall not be interested directly or indirectly in the operation of a pharmacy or engaged in any other business that will interfere with the duties of his office.*"

In an October 4, 1991, advisory opinion, the Mississippi Ethics Commission stated that a Pharmacy Board Executive Director whose wife was a licensed pharmacist may have the appearance of being in conflict with Section 73-21-79. (The Ethics Commission acknowledged that the applicable CODE section was not under the commission's purview and referred the requestor to the Attorney General's office for an official opinion.) In November 1991, a Pharmacy Board member asked the

Attorney General to issue an opinion interpreting Section 73-21-79 and the compliance of Harold Stringer's employment as Executive Director. During the latter part of December 1991, the Attorney General's office decided not to issue an opinion on the section because the Pharmacy Board had already officially employed Stringer as its new Executive Director. The Attorney General's office reasoned that its authority to issue opinions, found in MISS. CODE ANN. Section 7-5-25 (1972), allows for the issuance of opinions to public officers *prior to* their acting on the matter for which they are seeking advice and guidance of the Attorney General, but does not allow for the issuance of opinions which would be used to either validate or invalidate past actions of public officers. Therefore, the Pharmacy Board has no official Attorney General's opinion on which to assess its employment of Harold Stringer and potential conflict of interest concerns associated with his employment.

The Pharmacy Board employed Harold Stringer as its Executive Director even though his wife is a licensed pharmacist and is employed at a retail pharmacy regulated by the board, in violation of CODE Section 73-21-79. It can be argued that the conflict of interest provision of CODE Section 73-21-79 was intended to insure that an Executive Director who has no biases favoring a particular pharmacy serves as the chief executive officer of the board. In light of the considerable powers conferred upon the Executive Director by statute and by custom, the board's choice of hiring an Executive Director with potential conflicts could render the board subject to criticism for unequal treatment of regulated pharmacies, and could be viewed by the industry and public as a conflict of interest.

Pharmacy Board compliance agents carry firearms, for which they do not receive formal training.

Because compliance agents travel extensively throughout their assigned regions of the state conducting inspections and investigations and have authority to take possession of controlled substances for adjudicative purposes or eventual destruction, the board allows them to carry firearms. (MISS. CODE ANN. Section 41-29-159 (1972) empowers the board's compliance agents with much the same authority as other law enforcement agents, such as carrying firearms, executing and serving search warrants, and making arrests.) In lieu of board-issued Smith and Wesson .38 calibre weapons, the board allows compliance agents to carry their personal weapons. Pharmacy Board procedures state that "*firearms may be carried in a Compliance Agent's automobile. Under no circumstances, shall the Compliance Agent carry firearms on his/her person on the premises of a pharmacy, hospital or nursing home during the course of an inspection.*"

Compliance agents told PEER that although the Pharmacy Board issues firearms to them, the board does not provide firearms training or require that they become firearms qualified. The board and Executive

Director have recognized the necessity of compliance agents having a degree of personal protection while performing their duties. However, they have not acknowledged the negative repercussions of allowing compliance agents to bear firearms without being properly trained.

By issuing firearms to compliance agents, the board's inferred policy is that an agent may make use of the firearm while acting within the scope of his employment. Because the agency does not provide compliance agents with firearms training, an untrained agent's use of a firearm in the line of duty could make board members personally liable for the agent's actions. Any person injured by a compliance agent's firearm could argue that the board was negligent in its duties by not providing firearms training to the armed agent.

RECOMMENDATIONS

(Appendix B, page 29, contains proposed legislation concerning the Pharmacy Board.)

1. The Legislature should amend MISS. CODE ANN. Section 73-21-99 (1972) to require the board's Executive Director and compliance agents to provide inspection/investigation status reports during the board's monthly meetings. The reports should include information on all documented cases for each month of noncompliance with state pharmacy laws or regulations. Such reports to the board should limit the Executive Director's discretionary authority to decide which cases would result in formal charges and eventual presentation to the board. In receiving and considering the monthly inspection/investigative reports, board members should be careful to avoid pre-judging the cases and violating each pharmacist's due process rights to an unbiased adjudicatory hearing. The board should base any adverse actions only upon competent evidence received during formal hearings.

2. The Legislature should amend MISS. CODE ANN. Section 73-21-103 (1972) to require the Pharmacy Board to develop a uniform penalty policy which can be applied to violations of state laws and regulations. For those unique violations which may not be subject to such a policy, state law should require the board to document specifically in its minutes the rationale for the penalty imposed. Beginning immediately, the board should require its Executive Director to maintain a comprehensive record of cases according to violation categories and types of penalties imposed by the board for each category.

3. The Pharmacy Board should review its current policy position regarding inspections and investigations. Where possible, the board should officially adopt inspection/investigation standards to be utilized by its compliance agents. Once the board has adopted such standards, the board should instruct its Executive Director to revise the agency's investigative unit manual to include the board's inspection/investigation standards and any other necessary operational steps for major activities within the board's responsibilities.

4. The Pharmacy Board should instruct its Executive Director to develop and implement a formal training program for compliance agents. All existing agents should immediately undergo training to ensure uniform exposure to board-approved enforcement standards. Future compliance agents employed by the board should also undergo formal training. All compliance agents should be required to undergo in-service training at least once each year. The Executive Director

should place certification of all training in each agent's personnel file.

5. The Pharmacy Board should direct its Executive Director to immediately develop internal custody, control, and reporting procedures for the staff's destruction of excess or unwanted controlled substances. Such procedures could be an expansion of the board's on-site disposal procedures for pharmacists. DEA officials recommend that "*controlled substances awaiting destruction at the Mississippi State Board of Pharmacy office be kept to a minimum for safeguarding purposes and that each destruction be witnessed by at least one additional Board Investigator.*"

6. To increase the accountability for items received by the Pharmacy Board staff for destruction, the staff should discontinue its practice of consolidating items received from various pharmacists into one box. After inventorying items to be destroyed from a pharmacist, board staff should seal the box in which the items were initially packed, assign a destruction identification code to the box, and store the box as a unique box until time for destruction. Periodically, a board employee independent of the consolidation process should perform and document a spot-check inventory of some of the boxes prior to their destruction. The board's Executive Director and legal counsel should vigorously investigate any spot-check inventory variances from initial inventories.

7. The Pharmacy Board should require its Executive Director to include on each month's agenda a controlled substances destruction report, consisting of the name of the pharmacist/pharmacy for whom the board staff destroyed items, a listing of items destroyed, and their destruction date.

8. The Pharmacy Board's regulations should continue to require prior approval of continuing education programs and the board should strictly adhere to the requirement with no exceptions. The board should also reconsider its September 13, 1990; October 4, 1990; and May 15, 1991, actions.

9. The Pharmacy Board should reconsider its hiring of Harold Stringer as Executive Director in light of MISS. CODE ANN. Section 73-21-79 (1972). The board should also ensure that its Executive Director has no financial, employment, or other interest in pharmacies for which the board has regulatory responsibilities.

10. Although state law authorizes compliance agents to carry weapons, the board should instruct its compliance agents to cease immediately the practice of carrying weapons. If the board insists on its agents carrying weapons, the Legislature should amend MISS. CODE ANN. Section 45-6-3 (1972) to include Pharmacy Board compliance agents

within the definition of a law enforcement officer. By doing so, the Legislature should require compliance agents to qualify with their weapons and be certified through the Law Enforcement Officer Standards and Training Board. If the Legislature does not amend Section 45-6-3 and the board continues its practice of allowing compliance agents to carry weapons, the board should, at a minimum, make arrangements for its agents to receive applicable training from the Law Enforcement Officers' Training Academy.

APPENDIX A

SECTIONS OF MISSISSIPPI CODE CONTAINING CATEGORIES FOR WHICH PHARMACISTS MAY BE HELD IN VIOLATION OF PHARMACY BOARD REGULATIONS

73-21-97. Denial of renewal; suspension, revocation or restrictions on licenses or permits; grounds.

The board may refuse to issue or renew, or may suspend, revoke or restrict the license or permit of any person upon one or more of the following grounds:

(a) Unprofessional conduct as defined by the rules and regulations of the board;

(b) Incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, confidence and safety to the public;

(c) Being found guilty by a court of competent jurisdiction of one or more of the following:

(i) A felony;

(ii) Any act involving moral turpitude or gross immorality; or

(iii) Violation of pharmacy or drug laws of this state or rules or regulations pertaining thereto, or of statutes, rules or regulations of any other state or the federal government;

(d) Fraud or intentional misrepresentation by a licensee or permit holder in securing the issuance or renewal of a license or permit;

(e) Engaging or aiding and abetting an individual to engage in the practice of pharmacy without a license;

(f) Violation of any of the provisions of this chapter or rules or regulations adopted pursuant to this chapter;

(g) Failure to comply with lawful orders of the board;

(h) Negligently or wilfully acting in a manner inconsistent with the health or safety of the public;

(i) Addiction or dependence on alcohol or other habit-forming drugs or the habitual use of narcotics, barbiturates, amphetamines, hallucinogens or other drugs having similar effects; or

(j) Misappropriation of any prescription drug.

73-21-99. Hearings on violations; notice; procedure.

(1) Upon one or more of the following:

(a) A sworn affidavit filed with the board charging a licensee or permit holder with an act which is grounds for disciplinary action as provided in section 73-21-97, or

(b) The finding by the executive director that reasonable cause exists to believe that a licensee or permit holder has committed an act which is grounds for disciplinary action as provided in section 73-21-97

(c) Order of the board, the executive director or designee of the board shall fix a time and place for a hearing and shall cause a written notice specifying the offense or offenses for which the licensee or permit holder is charged and notice of the time and place of the hearing to be served upon the licensee or permit holder at least twenty (20) days prior to the hearing date. Such notice may be served by mailing a copy thereof by certified mail, postage prepaid, to the last-known residence or business address of the licensee or permit holder.

(2) The board, acting by and through its executive director, is hereby authorized and empowered to issue subpoenas for the attendance of witnesses and the production of books and papers at such hearing. Process issued by the board shall extend to all parts of the state and shall be served by any person designated by the board for such service.

(3) The accused shall have the right to appear either personally or by counsel or both to produce witnesses or evidence in his behalf, to cross-examine witnesses and to have subpoenas issued by the board.

(4) At the hearing, the board shall administer oaths as may be necessary for the proper conduct of the hearing. All hearings shall be conducted by the board, which shall not be bound by strict rules of procedure or by the laws of evidence in the conduct of its proceedings, but the determination shall be based upon sufficient evidence to sustain it.

(5) Where, in any proceeding before the board, any witness fails or refuses to attend upon a subpoena issued by the board, refuses to testify, or refuses to produce any books and papers the production of which is called for by a subpoena, the attendance of such witness, the giving of his testimony or the production of the books and papers shall be enforced by any court of competent jurisdiction of this state in the manner provided for the enforcement of attendance and testimony of witnesses in civil cases in the courts of this state.

(6) The board shall, within sixty (60) days after conclusion of the hearing, reduce its decision to writing and forward an attested true copy thereof to the last-known residence or business address of such licensee or permit holder by way of United States first-class, certified mail, postage prepaid.

SOURCE: Mississippi Code Annotated, 1972

APPENDIX B

PROPOSED LEGISLATION CONCERNING THE PHARMACY BOARD

MISSISSIPPI LEGISLATURE REGULAR SESSION, 1992

BY:

BILL

AN ACT TO AMEND SECTION 73-21-99, MISSISSIPPI CODE OF 1972, TO REQUIRE THAT THE INVESTIGATORS OF THE PHARMACY BOARD PROVIDE STATUS REPORTS TO MEMBERS OF THE BOARD AT EACH MONTHLY MEETING; TO AMEND SECTION 73-21-103, MISSISSIPPI CODE OF 1972, TO REQUIRE THAT THE PHARMACY BOARD DEVISE A UNIFORM PENALTY SCHEDULE FOR VIOLATIONS OF BOARD REGULATIONS AND LAWS; TO AMEND SECTION 45-6-3, MISSISSIPPI CODE OF 1972, TO INCLUDE PHARMACY BOARD INVESTIGATORS AND COMPLIANCE AGENTS WITHIN THE SCOPE OF THE DEFINITION OF "LAW ENFORCEMENT OFFICER"; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

Section 1. Section 73-21-99, Mississippi Code of 1972, is amended as follows;

§ 73–21–99. Hearings on violations; notice; procedure.

(1) Upon one or more of the following:

(a) A sworn affidavit filed with the board charging a licensee or permit holder with an act which is grounds for disciplinary action as provided in section 73–21–97, or

(b) The finding by the executive director that reasonable cause exists to believe that a licensee or permit holder has committed an act which is grounds for disciplinary action as provided in section 73–21–97, or

(c) Order of the board, the executive director or designee of the board shall fix a time and place for a hearing and shall cause a written notice specifying the offense or offenses for which the licensee or permit holder is charged and notice of the time and place of the hearing to be served upon the licensee or permit holder at least twenty (20) days prior to the hearing date. Such notice may be served by mailing a copy thereof by certified mail, postage prepaid,

to the last-known residence or business address of the licensee or permit holder.

(2) The Board shall require its investigators to provide status reports to its entire membership during monthly meetings. Such reports shall be made on all on-going investigations, and shall apply to any routine inspections which may give rise to the filing of a complaint.

(2) ~~(2)~~ The board, acting by and through its executive director, is hereby authorized and empowered to issue subpoenas for the attendance of witnesses and the production of books and papers at such hearing. Process issued by the board shall extend to all parts of the state and shall be served by any person designated by the board for such service.

(3) ~~(3)~~ The accused shall have the right to appear either personally or by counsel or both to produce witnesses or evidence in his behalf, to cross-examine witnesses and to have subpoenas issued by the board.

(4) ~~(4)~~ At the hearing, the board shall administer oaths as may be necessary for the proper conduct of the hearing. All hearings shall be conducted by the board, which shall not be bound by strict rules of procedure or by the laws of evidence in the conduct of its proceedings, but the determination shall be based upon sufficient evidence to sustain it.

(5) ~~(5)~~ Where, in any proceeding before the board, any witness fails or refuses to attend upon a subpoena issued by the board, refuses to testify, or refuses to produce any books and papers the production of which is called for by a subpoena, the attendance of such witness, the giving of his testimony or the production of the books and papers shall be enforced by any court of competent jurisdiction of this state in the manner provided for the enforcement of attendance and testimony of witnesses in civil cases in the courts of this state.

(6) ~~(6)~~ The board shall, within sixty (60) days after conclusion of the hearing, reduce its decision to writing and forward an attested true copy thereof to the last-known residence or business address of such licensee or permit holder by way of United States first-class, certified mail, postage prepaid.

SOURCES: Laws, 1983, ch. 414, § 15, eff from and after July 1, 1983.

Section 2. Section 73-21-103, Mississippi Code of 1972, is amended as follows;

§ 73–21–103. Penalties for violations; requirement of rehabilitation or additional education; reinstatement of licenses or permits; enforcement proceedings.

(1) Upon the finding of the existence of grounds for discipline of any person holding a license or permit, seeking a license or permit, or seeking to renew a license or permit under the provisions of this chapter, the board may impose one or more of the following penalties:

(a) Suspension of the offender's license and/or permit for a term to be determined by the board;

(b) Revocation of the offender's license and/or permit;

(c) Restriction of the offender's license and/or permit to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a particular manner for a term to be determined by the board;

(d) Imposition of a monetary penalty as follows:

(i) For the first violation, a monetary penalty of not less than Fifty Dollars ($50.00) nor more than Five Hundred Dollars ($500.00) for each violation;

(ii) For the second violation and subsequent violations, a monetary penalty of not less than One Hundred Dollars ($100.00) nor more than One Thousand Dollars ($1,000.00) for each violation;

(e) Refusal to renew offender's license and/or permit;

(f) Placement of the offender on probation and supervision by the board for a period to be determined by the board.

Whenever the board imposes any penalty under this subsection, the board may require rehabilitation and/or additional education as the board may deem proper under the circumstances, in addition to the penalty imposed.

(2) Any person whose license and/or permit has been suspended, revoked or restricted pursuant to this chapter, whether voluntarily or by action of the board, shall have the right to petition the board at reasonable intervals for reinstatement of such license and/or permit. Such petition shall be made in writing and in the form prescribed by the board. Upon investigation and hearing, the board may, in its discretion, grant or deny such petition, or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant such modifications.

(3) Nothing herein shall be construed as barring criminal prosecutions for violation of this chapter where such violations are deemed as criminal offenses in other statutes of this state or of the United States.

(4) A monetary penalty assessed and levied under this section shall be paid to the board by the licensee or permit holder upon the expiration of the period allowed for appeal of such penalties under Section 73-21-101, or may be paid sooner if the licensee or permit holder elects.

(5) When payment of a monetary penalty assessed and levied by the board against a licensee or permit holder in accordance with this section is not paid by the licensee or permit holder when due under this section, the board shall have the power to institute and maintain proceedings in its name for enforcement of payment in the chancery court of the county and judicial district of residence of the licensee or permit holder, or if the licensee or permit holder is a nonresident of the State of Mississippi, in the Chancery Court of the First Judicial District of Hinds County, Mississippi. When such proceedings are instituted, the board shall certify the record of its proceedings, together with all documents and evidence, to the chancery court and the matter shall thereupon be heard in due course by the court, which shall review the record and make its determination thereon. The hearing on the matter may, in the discretion of the chancellor, be tried in vacation.

SOURCES: Laws, 1991, ch. 527, § 17, eff from and after July 1, 1991.

(6) The board shall develop and implement a uniform penalty policy which shall set the minimum and maximum penalty for any given violation of board regulations and laws governing the practice of pharmacy. The board shall adhere to its uniform penalty policy except in such cases where the board specifically finds by majority vote that a penalty in excess of, or less than, the uniform penalty is appropriate. Such a vote shall be reflected in the minutes of the board, and shall not be imposed unless such appears as having been adopted by the board.

Section 3. Section 45-6-3, Mississippi Code of 1972, is amended as follows;

§ 45-6-3. Definitions.

For the purposes of this chapter, the following words shall have the meanings ascribed herein, unless the context shall otherwise require:

(a) "Commission" shall mean the Criminal Justice Planning Commission.

(b) "Board" shall mean the Board on Law Enforcement Officer Standards and Training.

(c) "Law enforcement officer" shall mean any person appointed or employed full time by the state or any political subdivision thereof, who is duly sworn and vested with authority to bear arms and make arrests, and whose primary responsibility is the prevention and detection of crime, the apprehension of criminals and the enforcement of the criminal and traffic laws of this state and/or the ordinances of any political subdivision thereof. However, the term "law enforcement officer" shall not mean or include any elected official or any person employed as an assistant to or investigator for a district attorney in this state. As used in this paragraph "appointed or employed full time" means any person who is receiving gross compensation for his duties as a law enforcement officer of One Hundred Twenty-five Dollars ($125.00) or more per week Five Hundred Dollars ($500.00) or more per month. This definition shall include the compliance agents of the State Board of Pharmacy.

SOURCES: Laws, 1990, ch. 434, § 1, eff from and after passage (approved March 15, 1990).

Section 4. This act shall take effect and be in force from and after July 1, 1992.

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