# The State Board of Pharmacy's Regulation of Prescription Controlled Substances

June 1999

Office of Performance Evaluations
Idaho State Legislature

Report 99-01

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Office of Performance Evaluations
700 W. State Street, Lower Level, Suite 10
P.O. Box 83720, Boise, Idaho 83720-0055

# Office of Performance Evaluations
# Idaho State Legislature

Joe R. Williams Building
Lower Level, Suite 10
P.O. Box 83720
Boise, Idaho 83720-0055
(208) 334-3880
FAX (208) 334-3871

**Nancy Van Maren**
Director

**Joint Legislative Oversight Committee**

**Senators**
Marguerite McLaughlin, Co-chair
Atwell J. Parry
Grant R. Ipsen
Lin Whitworth

**Representatives**
Debbie Field, Co-chair
Robert C. Geddes
June E. Judd
Larry C. Watson

June 9, 1999

Members
Joint Legislative Oversight Committee
Idaho State Legislature

At the direction of the Joint Legislative Oversight Committee, we have conducted an evaluation of the State Board of Pharmacy's regulation of prescription controlled substances. Interest in this evaluation resulted in part from a highly publicized case in which an overdose of prescription drugs led to the death of a Boise woman. Because concerns that this individual was illegally obtaining prescription controlled substances had been reported to the Board of Pharmacy prior to her death, her case raised questions about the board's effectiveness in handling controlled substance complaints.

I respectfully submit our completed evaluation for your review and consideration. We conclude that the Board of Pharmacy's controlled substance complaint handling procedures do not provide assurance that complaints have been addressed in an appropriate manner: investigative efforts were poorly documented, the timeliness of those efforts could not be determined, and there has been little to no oversight of the single investigator's work. In addition, we found the board has yet to fully implement and use the automated prescription tracking system funded by the Legislature in 1997, despite 19 months of effort and expenditures of nearly $100,000.

We conclude that, although responsibility for enforcement of the Uniform Controlled Substances Act is dispersed, the board has not fully exercised it authority to regulate non-pharmacist health professionals. Further, the statewide response to the diversion of prescription controlled substances by private citizens has been limited.

Overall, we recommend formalization of the investigative process, including improved documentation of investigative efforts and increased involvement by agency management and the board in reviewing investigative decisions and outcomes. In addition, to increase the state's effectiveness in responding to cases like the one that in part led to this evaluation, policymakers could consider establishing an interagency task force to coordinate all responsible parties. Additional recommendations are outlined in the full report.

Throughout this evaluation we received the full cooperation of the board's staff. This report was written and researched by Eric Milstead (co-lead), Ned Parrish (co-lead), Jim Henderson, and Bev Nicholson, with assistance from other Office of Performance Evaluations staff.

Respectfully submitted,

Nancy Van Maren

Nancy Van Maren

# Table of Contents


| | | Page |
|---|---|---|
| **Executive Summary** | **The State Board of Pharmacy's Regulation of Prescription Controlled Substances** | vii |
| | Summary of Report Recommendations | xv |
| **Chapter 1** | **Background and Introduction** | 1 |
| | Evaluation Methods and Summary of Conclusions | 2 |
| | Statutory Responsibilities of the Board of Pharmacy | 3 |
| | Board of Pharmacy Resources | 7 |
| **Chapter 2** | **Complaint Handling and Investigation Process** | 9 |
| | Investigation of Controlled Substance Complaints | 9 |
| | Documentation of Controlled Substance Complaint Investigations | 12 |
| | Oversight of Investigations by Agency Management and Board Members | 16 |
| **Chapter 3** | **Complaints About Non-Pharmacist Health Professionals and Private Citizens** | 25 |
| | Complaints About Non-Pharmacist Health Professionals | 25 |
| | Complaints About Private Citizens | 30 |
| **Chapter 4** | **The Board of Pharmacy's Electronic Prescription Tracking System** | 37 |
| | Prescription Tracking Systems | 37 |
| | Prescription Tracking in Idaho | 38 |
| **Response to the Evaluation** | Idaho State Board of Pharmacy (*Referenced exhibits available upon request*) | 47 |

# List of Figures and Tables


| | | Page |
|---|---|---|
| Figure 1.1 | Principal Statutory Responsibilities of the Board of Pharmacy | 4 |
| Figure 1.2 | Summary of Scheduled Drugs Under the Uniform Controlled Substances Act | 6 |
| Figure 3.1 | Board of Pharmacy Complaint Handling Process for Health Professionals, 1999 | 28 |
| Figure 3.2 | Board of Pharmacy Actions on Controlled Substance Registrations for Non-Pharmacist Health Professionals, 1995–1998 | 29 |
| Figure 3.3 | Board of Pharmacy Complaint Handling Process for Private Citizens, 1999 | 32 |
| Table 1.1 | Board of Pharmacy Licensees and Registrations, Fiscal Years 1994–1998 | 5 |
| Table 1.2 | Board of Pharmacy Revenues, Expenditures, and Fund Balances, Fiscal Years 1995–2000 | 8 |
| Table 2.1 | Controlled Substance Complaints and Related Inquiries Recorded by the Board of Pharmacy, 1995–1998 | 11 |
| Table 2.2 | Controlled Substance Complaints by Respondent Type, 1995–1998 | 11 |
| Table 3.1 | Complaints Involving Licensed Professionals by Type of Profession and Alleged Offense, 1995–1998 | 27 |
| Table 3.2 | Complaints Involving Private Citizens by Type of Offense Alleged, 1995–1998 | 33 |

# The State Board of Pharmacy's Regulation of Prescription Controlled Substances

## Executive Summary

In November 1998, we began a performance evaluation of the Idaho State Board of Pharmacy at the direction of the Joint Legislative Oversight Committee. The committee's directive followed a request by the Idaho House of Representatives Health and Welfare Committee seeking a review of the Board of Pharmacy's efforts to enforce current laws restricting access to and diversion of controlled substances.[1] This report examines how effectively the Board of Pharmacy investigates and researches complaints regarding the diversion or abuse of prescribed controlled substances; what standards exist for determining when and how a complaint will be investigated and how these standards have been applied in recent years; how effectively the board communicates with law enforcement agencies and with other health regulating boards regarding controlled substance cases; and, how well the board's new system for tracking controlled substance prescription activity has been implemented, and at what cost.

**Our review focused on the Board of Pharmacy's investigation of controlled substance complaints.**

### Methods

To conduct our review, we reviewed Idaho Code, administrative rules, and relevant Board of Pharmacy meeting minutes, developed a database of all controlled substance complaints and inquiries logged by the Board of Pharmacy from 1995 through 1998, and reviewed 509 available complaint files for 1997 and 1998. We also interviewed Board of Pharmacy members and staff, representatives of selected health regulatory boards and law enforcement agencies in Idaho, law enforcement and boards of

[1] Controlled substances include depressants, stimulants, hallucinogens, and other substances specifically designated as controlled substances by federal or state law or regulation.

pharmacy representatives in selected other states, as well as representatives of the U.S. Department of Justice's Drug Enforcement Administration, and representatives of two related professional organizations.

**The Board of Pharmacy is charged with administering the regulatory provisions of the Uniform Controlled Substances Act.**

## Background

In addition to its responsibilities for regulating the practice of pharmacy in Idaho, the Board of Pharmacy is charged with administering the regulatory provisions of the Uniform Controlled Substances Act. Under the act, the board's responsibilities and activities include:

- Scheduling controlled substances in statute based on categories denoting the substances' potential for abuse and current medical use.[2]
- Issuing controlled substance registrations to each person who manufactures, distributes, or dispenses controlled substances within the state.
- Investigating controlled substance complaints alleging violations of controlled substance laws, and, when necessary, taking disciplinary action such as revoking or suspending controlled substance registrations issued by the board.
- Tracking and recording Schedule II, III, and IV controlled substance prescriptions.

**Among its responsibilities, the board tracks controlled substance prescriptions and investigates complaints of violations.**

In fiscal year 1999, the board was appropriated $602,100 and allocated 8.75 full-time equivalent positions to carry out its responsibilities under the Idaho Pharmacy Act and the Uniform Controlled Substances Act. One of these positions plus some clerical support comprise the board's controlled substance investigative staff. The board's activities are funded by fees

[2] In the Uniform Controlled Substances Act, substances are listed under one of six different schedules. Substances are scheduled (categorized according to severity) based on their potential for abuse, the likelihood that abuse will lead to dependence, and their medical use. For example, Schedule I substances are those that the board has found to have a high potential for abuse and have no accepted medical use in the United States.

collected from pharmacists, pharmacies, and non-pharmacist health professionals who must be licensed or registered under the acts.

## Complaint Handling and Investigation Process

### *The Board of Pharmacy received a growing number of complaints between 1995 and 1998, with most involving citizens rather than pharmacists and non-pharmacist health professionals.*

In total, the board received 1,066 complaints alleging violations of controlled substance laws from 1995 through 1998. The number of complaints increased each year during this four-year period, with 49 percent more complaints received in 1998 than in 1995. Over the four years, most of the complaints received by the board (81 percent) involved citizens who were allegedly abusing or diverting prescription controlled substances. Only 13 percent of complaints involved health professionals, such as pharmacists and physicians. Another 4 percent involved facilities, such as pharmacies, hospitals, or nursing homes.

**Between 1995 and 1998, the board received 1,066 controlled substance complaints, 81% involving private citizens.**

### *Documentation of controlled substance complaint investigations was insufficient to demonstrate whether complaints were being appropriately and timely addressed.*

Controlled substance complaint files were often incomplete, showing little evidence of investigation work performed and key decisions made by the board's controlled substance investigator. We reviewed the case files for 509 complaints the board received in 1997 and 1998 and found 359 (71 percent) that contained no evidence of investigation by board staff.[3] Our review of complaints also showed that key decisions about whether to investigate complaints, what investigative work was needed to address complaints, how to prioritize among complaints, and whether to pursue disciplinary action were generally not documented.

**Of the 509 complaint files we reviewed from 1997 and 1998, 71 percent showed no evidence of investigation.**

[3] In our review, we included complaints about both registered health professionals and non-registrants (including citizens). We excluded requests for assistance and information updates received by the board from other agencies. Although these requests may require some action by the board's investigator, they are not investigated as complaints. Instead, in these cases, board staff support the efforts of other agencies.

**The timeliness of complaint handling efforts could not be determined, as even inactive files were kept open for three years and then destroyed.**

Lack of adequate documentation can impede efforts to take disciplinary action when appropriate, hamper management efforts to review investigative work performed by staff, and, over time, place the agency at risk of losing its base of information about complaints received and investigative work performed.

We also found that board staff did not officially close complaint cases or record a closure date when investigation efforts were no longer pursued. Instead, complaint cases typically remained open for three years, at which point the case files were destroyed. Without knowing the dates cases were closed, it is impossible to determine the timeliness with which complaints were addressed. In addition, it is difficult to determine how many complaints were being actively pursued at any given time.

To provide greater assurance that controlled substance complaints are being appropriately and timely addressed, we recommend that board staff fully document their complaint investigation work and key decisions, and close cases, noting the dates when complaints are no longer being actively pursued.

***Oversight of complaint investigations by board members and agency management was insufficient to assure that controlled substance complaints were handled properly.***

**The board's handling of complaints has relied heavily on the investigator's judgment, with little direction from the board or agency management.**

The Board of Pharmacy and the agency's management had not established a formalized process to monitor and oversee the controlled substance complaint handling function. Specifically, we found that investigative decisions relied heavily on the investigator's judgment as no written guidelines for investigation had been developed and cases were not reviewed. We also found that, until recently, the board had lacked an effective management information system for tracking complaints, hindering oversight efforts. Finally, we found that, aside from a small number of cases in which disciplinary action was being considered, the board had received little information from staff about controlled substance complaints or staff's efforts to investigate them. With little oversight, there is little assurance of proper case handling and the potential for inconsistency increases.

Experts recommend that boards establish uniform complaint handling processes to ensure that all investigations of complaints

are handled in an objective, prioritized, and timely manner.[4] Consequently, we recommend a variety of changes to strengthen oversight of the controlled substance investigation function, including the creation of a more formalized process.

## Non-Pharmacist Health Professional and Private Citizen Complaints

***The Board of Pharmacy has not fully exercised its authority to address alleged violations of controlled substance requirements by non-pharmacist health professionals.***

In fiscal year 1998, the board issued controlled substance registrations to 4,175 health professionals, over three-quarters of whom were non-pharmacists. From 1995 through 1998, non-pharmacist health professionals made up 12 percent of all controlled substance complaints received by the board. However, during this period, the board considered disciplinary actions for these professionals only three times.

**The board regulates non-pharmacist health professionals who are registered to prescribe or dispense controlled substances.**

The board's investigator told us the board had encouraged him to forward investigative reports documenting violations of controlled substance laws by non-pharmacist health professionals to the professional's own licensing board for action, rather than choosing to take disciplinary action itself. In fact, Idaho Code requires the board to obtain concurrence from the professional's licensing board prior to initiating procedures to revoke or suspend a controlled substance registration. This shared responsibility in statute appears to have resulted in confusion about enforcement responsibilities.

**Statutes require the board to obtain concurrence from a registrant's licensing board before initiating revocation or suspension of a controlled substance registration.**

To ensure the board's and other licensing boards' responsibilities are clearly defined, we recommend policymakers consider clarifying the various boards' roles in disciplining non-pharmacist health professionals who violate controlled substance laws.

However, even with the current limitations and ambiguities in the act, the Board of Pharmacy can do more to fulfill its statutory

[4] Pew Health Professions Commission, Taskforce on Health Care Workforce Regulation, *Reforming Health Care Workforce Regulation: Policy Considerations for the 21st Century* (1995), 29.

**Despite ambiguities about the limits of its role, the board could do more to meet its statutory responsibilities.**

responsibilities for disciplining non-pharmacist health professionals. Specifically, we recommend the board establish a mechanism whereby it routinely receives and reviews the disposition of cases referred to professional licensing boards to ensure that disciplinary actions are appropriate and consistent for all registrants. Further, to ensure boards concur on disciplinary action taken, we recommend the board work with other licensing boards to investigate the possibility of conducting joint disciplinary hearings.

***Idaho's statewide response to prescription controlled substance abuse and diversion by private citizens is limited.***

**Coordination among agencies sharing responsibility for enforcing the Uniform Controlled Substances Act could be improved.**

Under Idaho Code, responsibility for enforcement of the Uniform Controlled Substances Act is dispersed among the Board of Pharmacy, the Department of Law Enforcement, and local law enforcement agencies. Each of these entities is authorized to enforce some aspect of the provisions of the act. However, at the state level, efforts for handling complaints alleging abuse or diversion by private citizens is not clearly coordinated. While the act empowers the Board of Pharmacy to administer the regulatory provisions of the act, it does not expressly assign the board responsibility to handle complaints about private citizens. Further, board staff efforts sometimes result in the referral of cases to local law enforcement. On the other hand, the act charges the Department of Law Enforcement with administering "the state-level program of Idaho to suppress the unlawful traffic and abuse of controlled substances," but, according to a department official, the department focuses primarily on cases involving traffic in and abuse of Schedule I controlled substances and refers other cases to the Board of Pharmacy.[5]

Without a coordinated response to allegations of citizen diversion and abuse the effectiveness of enforcement may be limited. To strengthen the state's response:

- Policymakers could consider establishing an interagency task force comprised of representatives from relevant agencies to coordinate efforts and make recommendations about the

[5] IDAHO CODE § 37-2740(4)(b) (1994).

handling of controlled substance complaints involving citizens.[6]

**Establishing an interagency task force to respond to citizen complaints could increase effectiveness.**

Further:

- The Board of Pharmacy could investigate the possibility of working with the Drug Enforcement Administration to implement a PharmAlert program in Idaho, similar to that shown effective in two nearby states. PharmAlert Systems broadcast to pharmacists information about alleged abuse or diversion so that prescription information may be verified.

## Electronic Prescription Tracking System

### *Implementation of the automated tracking system took 19 months and over $80,000.*

In August 1997, after receiving legislative authorization and funding, the Board of Pharmacy entered into a contract with Atlantic Associates Inc. (AAI) to collect and audit prescription data from pharmacies. While these data were sent to the Board of Pharmacy each month beginning in November 1997, board staff did not review it and were unable to use it until April 1999. Payments to AAI during this period totaled approximately $83,000, although the data were not used.

**Use of automated controlled substance prescription data was delayed for about a year and a half.**

The board attributed delays in using the prescription data to the lack of a software application necessary for analysis. However, board staff had opted not to use software applications and other needed services that were made available to the board by another state and by AAI as early as November 1997.

### *The board may have accrued unnecessary costs by not using software resources made available to them.*

Instead of using available data analysis software or services, the board chose to have a software application developed by a local software development firm. The board received a supplemental

[6] In two states identified as having effective approaches to addressing citizen abuse and diversion of prescription controlled substances, interagency coordination and cooperation has been key to effectiveness in dealing with private citizen cases.

appropriation for this purpose during the 1999 legislative session, and, as of April 21, 1999, had received invoices from the vendor totaling $5,738. Although the developed application exceeds the capabilities of the software that had been available, some portion of these expenses may not have been necessary had the board used the software that had been made available earlier.

***The board may have exposed itself and the state to unnecessary legal and financial risks in its dealings with a software vendor.***

**The board allowed a software vendor to substantially complete its work without a signed contract, placing the state at risk.**

The Board of Pharmacy allowed the software vendor selected to begin and substantially complete its work without a signed contract, exposing itself and the state to contractual risks and liabilities that could have been avoided. We found additional problems with the contract terms which are detailed in Chapter 4.

To prevent future problems in contract arrangements, we recommend that the Board of Pharmacy management more carefully monitor contracts to ensure work is conducted pursuant to a signed agreement. In the absence of contractual expertise in board management, contracts should be reviewed by board counsel.

***The Board of Pharmacy has yet to develop a clear plan for using information generated by the automated prescription tracking system.***

**The board has yet to develop a plan for how it will use the prescription data it contracted for nearly two years ago.**

Although the board first entered into a contract to obtain controlled substance prescription data almost two years ago, it has yet to a develop a clear plan for how it will use the data it receives. At the time of our review, the board had not established set objectives for the prescription tracking system. In addition, staff had not developed a plan for regular and routine use of the prescription data and lacked a full working knowledge of the system's capabilities.

Because of multi-agency reliance of controlled substance data, we recommend that the Board of Pharmacy work with other agencies to develop a written plan for using the electronic prescription tracking system.[7]

[7] The U.S. Department of Justice's Drug Enforcement Administration notes that innovative uses of prescription monitoring program data can play a key role in assisting health regulatory agencies and state and federal law enforcement authorities with medical intervention/educational activities.

# Summary of Report Findings and Recommendations

1. The Board of Pharmacy received an increasing number of controlled substance complaints from 1995 through 1998, with most complaints about citizens rather than pharmacists and non-pharmacist health professionals. *Page 10.*

2. Controlled substance complaint files were often incomplete, containing insufficient evidence of investigative work and key decisions to determine whether complaints were properly addressed. *Page 12.*

3. Key decisions made by the board's investigative staff, either alone or in conjunction with the executive director, were generally not documented. *Page 13.*

4. Other health regulatory boards in Idaho and other states we contacted and law enforcement agencies generally require more complete documentation of investigative work done and decisions made. *Page 14.*

   - **We recommend Board of Pharmacy staff fully document all investigative work done on controlled substance complaints, as well as the rationale for key decisions made during the investigative process.** *Page 15.*

5. Complaint files were not officially closed or classified as inactive when investigation efforts were no longer pursued. As a result, the timeliness of complaint handling could not be determined. *Page 15.*

6. Most other health regulatory boards in Idaho and other states we contacted consistently record case closure dates and monitor the time taken to investigate and resolve complaints. *Page 15.*

   - **We recommend Board of Pharmacy staff officially close controlled substance complaint files when they**

**are no longer being actively pursued and record the dates the files are closed.** *Page 16.*

7. The Board of Pharmacy has not established written guidelines for the investigation of controlled substance complaints. As a result, the investigation process has been informal, offering the potential for inconsistency in complaint handling. *Page 17.*

8. Health regulatory boards in other states we contacted have either developed, or are in the process of developing, written guidelines for complaint handling. *Page 17.*

   - **We recommend the Board of Pharmacy develop written guidelines to govern the process for handling controlled substance complaints.** *Page 18.*

9. Until recently, the Board of Pharmacy has lacked an effective management information system for tracking complaints, hindering oversight efforts. *Page 19.*

   - **We recommend the Board of Pharmacy maximize the value of its new complaint database by taking steps to ensure that staff consistently enter complete information about controlled substance complaints in the system and regularly generate reports for management and board review.** *Page 20.*

10. Agency management did not formally review controlled substance investigative work or key decisions made. *Page 20.*

11. Management of other health regulatory boards and law enforcement agencies we contacted typically play a greater role in overseeing complaint investigations. *Page 20.*

    - **We recommend the Board of Pharmacy establish formal mechanisms for management oversight and review of complaint investigations.** *Page 21.*

12. Aside from cases brought to the board for disciplinary action, the Board of Pharmacy has received little information about controlled substance complaints and investigations. *Page 22.*

    - **We recommend the Board of Pharmacy require submission of quarterly reports on the status of all controlled substance complaints.** *Page 23.*

13. The Board of Pharmacy has not fully exercised its authority with respect to alleged violations of the Uniform Controlled Substance Act by non-pharmacist health professionals. *Page 26.*

    - **We recommend policymakers consider clarifying the roles of the Board of Pharmacy and other licensing boards with respect to disciplining non-pharmacist health professionals for violations of the Uniform Controlled Substances Act.** *Page 30.*

    - **We recommend the Board of Pharmacy establish a mechanism whereby it receives and reviews the disposition of cases referred to professional licensing boards.** *Page 30.*

    - **We recommend the Board of Pharmacy work with other licensing boards to investigate the possibility of conducting joint disciplinary hearings when appropriate.** *Page 30.*

14. Idaho has a limited statewide response to the diversion or abuse of prescription controlled substances by private citizens. *Page 31.*

    - **Policymakers could consider establishing an interagency task force comprised of representatives of involved agencies to coordinate efforts and make recommendations about the handling of controlled substance complaints about citizens.** *Page 34.*

    - **We recommend the Board of Pharmacy investigate the possibility of working with the federal Drug Enforcement Administration regional office in Seattle to implement a network similar to the Pharm Alert Network for Idaho.** *Page 35.*

15. The Board of Pharmacy spent more than $80,000 over 19 months for prescription tracking data it was unable to use until recently. *Page 39.*

16. Board staff elected not to use the software applications or other services available to them for use with AAI data, resulting in system implementation delays and increasing system costs. *Page 40.*

17. The Board of Pharmacy may have incurred unnecessary costs by not using software resources made available to them by another state. *Page 41.*

18. The Board of Pharmacy allowed its vendor to begin and complete work without a signed contract. *Page 41.*

    - **We recommend Board of Pharmacy management more carefully monitor contracts to ensure work is conducted pursuant to a signed agreement.** *Page 42.*

19. Despite the extended investment of time and money to develop the electronic prescription tracking system to date, the Board of Pharmacy has not developed a clear plan for using the information generated by the system. *Page 42.*

    - **We recommend the Board of Pharmacy develop a written plan for using the electronic prescription tracking system.** *Page 43.*

20. Implementation of the prescription tracking system has not eliminated a staff position as proposed in the request to get the system started, increasing the total cost of implementation. *Page 44.*

# Background and Introduction
## Chapter 1

In November 1998, we began a performance evaluation of the Idaho State Board of Pharmacy at the direction of the Joint Legislative Oversight Committee. The Idaho House of Representatives Health and Welfare Committee requested this evaluation due, in part, to a highly publicized case in which an overdose of prescription drugs led to the death of a Boise woman. Because concerns about her diversion of prescription controlled substances previously had been reported to the Board of Pharmacy, this case raised questions about the board's handling of complaints about persons who might be trying to obtain controlled substances illegally.[1] Three bills addressing the regulation of such substances were introduced during the 1997 legislative session; in lieu of acting upon any of the bills, the House Health and Welfare Committee made a request to the Joint Legislative Oversight Committee to review the Board of Pharmacy's efforts to enforce current laws restricting access to and diversion of controlled substances.[2] The committee responded in the affirmative, and the evaluation began when resources became available.

To conduct our evaluation, we asked:

- How effectively has the Board of Pharmacy investigated complaints regarding the diversion or abuse of prescription controlled substances in recent years?
- What standards exist for determining when and how a complaint will be investigated? Have these standards been consistently applied?

**Our review focused on the Board of Pharmacy's investigation of controlled substance complaints.**

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[1] Controlled substances include depressants, stimulants, hallucinogens, and other substances specifically designated as controlled substances by federal or state law or regulation.

[2] Diversion is obtaining otherwise legal and medically appropriate controlled substances through fraudulent means.

**We also examined the board's efforts to develop a new tracking system for controlled substance prescriptions.**

- How effectively has the Board of Pharmacy communicated with law enforcement agencies and with other health regulating boards regarding controlled substance cases?
- How well has the board's new system for tracking controlled substance prescription activity been implemented, and what has the system cost?

## Evaluation Methods and Summary of Conclusions

To answer these questions, we:

- Reviewed Idaho Code, administrative rules, and the minutes of Board of Pharmacy meetings between January 1995 and October 1998;
- Developed a database of all logged complaints and inquiries for 1995 through 1998, and reviewed those complaints;
- Reviewed all available Board of Pharmacy controlled substance investigation case files for 1997 and 1998, and reviewed recordkeeping systems related to those cases;
- Interviewed two Board of Pharmacy members and pertinent board staff; representatives of other Idaho health regulatory boards, and federal, state, and local law enforcement personnel;
- Surveyed representatives from pharmacy boards or similar entities in five other states;
- Spoke with the National Association of Boards of Pharmacy and the National Association of State Controlled Substance Authorities to identify states with effective controlled substance tracking systems; and
- Interviewed staff from two states about their efforts to develop a controlled substance prescription tracking system.

**Insufficient board and management oversight contributed to many of the problems we identified.**

In summary, we found problems in several key areas related to enforcement efforts. The board's complaint handling procedures do not provide assurance that complaints have been addressed in an appropriate and timely manner. Cases were poorly documented to the extent that key information and the rationale for decisions were unclear or missing altogether, and board

members and agency management have not been significantly involved in overseeing the process for investigating most complaints. The board also has not fully exercised its authority to regulate non-pharmacist health rofessionals. In addition, the state's limited response to diversion and abuse of prescription controlled substances by private citizens has been uncoordinated. The system for tracking controlled substance prescriptions is still not being used effectively and fully, despite 19 months of effort and expenditures approaching $100,000.

**The automated prescription tracking system was unreasonably delayed.**

## Statutory Responsibilities of the Board of Pharmacy

Until 1939, the Board of Pharmacy was part of the Department of Law Enforcement. The board became an independent agency in July 1939, and in July 1974, it became a part of the Department of Self-Governing Agencies. Under Idaho Code, the board is composed of five members (four licensed pharmacists and one public member) who are appointed by the Governor for a five-year term (members may be re-appointed for a second term). The board employs a licensed pharmacist as an executive director and has authority to hire other employees it deems necessary to fulfill its responsibilities.

**The Board of Pharmacy is overseen by a five-member board.**

The Board of Pharmacy is charged with responsibilities primarily under two acts: the Idaho Pharmacy Act and the Uniform Controlled Substances Act.[3] Figure 1.1 summarizes the primary statutory responsibilities of the Board of Pharmacy.

### *The Idaho Pharmacy Act*

Under the Idaho Pharmacy Act, the board is principally charged with regulating the practice of pharmacy and registering drug outlets.[4] In carrying out these responsibilities, the board performs a number of functions, including the examination and licensing of pharmacists, inspection of pharmacies and drug outlets to ensure compliance with board rules, establishment and monitoring of continuing education requirements, and investigation of alleged

[3] IDAHO CODE § 54-1701–1750 (1998), and § 37-2701–2751 (1998).

[4] IDAHO CODE § 54-1729 (1994), and IDAHO ADMIN. CODE, July 1, 1993, Vol. 7, IDAPA 27.01.01.292.

**Figure 1.1: Principal Statutory Responsibilities of the Board of Pharmacy**

The purpose of the Board of Pharmacy as stated in Idaho Code is to:

"...promote, preserve and protect the health, safety and welfare of the public by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease." (Idaho Code § 54-1703).

To carry out this purpose, the board:

- Investigates the diversion or abuse of all scheduled drugs under the Controlled Substances Act.
- Licenses and regulates all pharmacists and pharmacies within the state and all out-of-state mail service pharmacies that provide services to Idaho residents.
- Registers every person who manufactures, distributes, or dispenses any controlled substance within the state.
- Regulates and controls the sale and distribution of drugs and medical supplies and ensures those individuals engaged in these practices have received the proper education and training.
- Registers and inspects all wholesaler and retail drug outlets.

Source: IDAHO CODE § 54-1701–1750 and § 37-2701–2751 (1994).

violations of the Pharmacy Act and subsequent imposition of disciplinary sanctions.

**In addition to regulating the practice of pharmacy, the board regulates the manufacture, distribution, and dispensing of controlled substances.**

Table 1.1 reflects the number of licensed pharmacists and registered facilities (pharmacies and drug outlets) in Idaho from 1994 through 1998. As shown, the number of total licenses, individual registrations, and facility registrations has grown gradually over the last five years.

*Uniform Controlled Substances Act*

Under the Uniform Controlled Substances Act, the board is directed to regulate the manufacture, distribution, and dispensing of controlled substances. The board is also authorized to add to, delete from, or re-schedule controlled substances that are listed in the act.[5] Substances are scheduled (categorized according to

[5] IDAHO CODE § 37-2702 (1994).

## Table 1.1: Board of Pharmacy Licensees and Registrations, Fiscal Years 1994–1998

**Individual Licensees and Registrations[a]**

| | 1994 | 1995 | 1996 | 1997 | 1998 |
|---|---|---|---|---|---|
| Pharmacists | | | | | |
| In state[b] | 752 | 772 | 801 | 816 | 866 |
| Out of state[c] | 555 | 560 | 565 | 568 | 500 |
| **Total** | **1,307** | **1,332** | **1,366** | **1,384** | **1,366** |
| Controlled substance registrations | **3,400** | **3,685** | **3,922** | **3,922** | **4,175** |

**Facility Registrations[d]**

| | 1994 | 1995 | 1996 | 1997 | 1998 |
|---|---|---|---|---|---|
| Pharmacies | 418 | 442 | 451 | 504 | 532 |
| Institutional drug outlets | 81 | 78 | 75 | 103 | 79 |
| Wholesalers | 382 | 418 | 410 | 417 | 457 |
| Controlled substance wholesalers[e] | 133 | 189 | 198 | 198 | 213 |
| Non-pharmacy drug outlets | 1,417 | 1,380 | 1,348 | 1,363 | 1,280 |
| **Total** | **2,431** | **2,507** | **2,482** | **2,585** | **2,561** |

[a] Does not include approximately 170 licenses/registrations for pharmacy interns and veterinary drug technicians.
[b] In-state pharmacists are those licensed to practice within the state and who do so.
[c] Out-of-state pharmacists are those who are licensed to practice within the state but who reside and work out-of-state.
[d] Does not include approximately 130 registrations for preceptor or training sites.
[e] Includes wholesalers, manufacturers, and re-packagers.

Source: Board of Pharmacy annual reports, fiscal years 1994–1998.

severity) based on their potential for abuse, the likelihood that abuse will lead to dependence, and their medical use. For example, Schedule I substances are those the board has found to have a high potential for abuse and have no accepted medical use in the United States. Substances listed in Schedule III have less potential for abuse than the substances found in Schedules I and II and have currently accepted medical use in treatment in the United States.

**The board investigates complaints alleging violations of controlled substance laws by health professionals and private citizens.**

Figure 1.2 summarizes the six schedules of controlled substances found in the act.

The board also receives and investigates allegations of controlled substance violations. These allegations, or complaints, generally concern three categories of individuals.

- **Pharmacists**: Complaints most often allege that licensed pharmacists are diverting or abusing controlled substances;
- **Non-pharmacist health professionals**: Complaints generally allege that other registered health professionals, such as physicians, nurses, dentists, or veterinarians, are diverting or abusing controlled substances; and

**Figure 1.2: Summary of Scheduled Drugs Under the Uniform Controlled Substances Act**

| | |
|---|---|
| Schedule I: | Substances that have a high potential for abuse and have no accepted medical use in the United States. Includes certain opiates, opium derivatives, hallucinogenic substances, depressants, and stimulants. |
| Schedule II: | Substances that have a high potential for abuse and have accepted medical uses with severe restrictions. Abuse may lead to severe psychological or physical dependence. Includes certain opiates, stimulants, and depressants. |
| Schedule III: | Substances that have a potential for abuse and have accepted medical use. Abuse may lead to moderate or low physical dependence or high psychological dependence. Includes certain stimulants, depressants, narcotics, and anabolic steroids. |
| Schedule IV: | Substances that have a low potential for abuse relative to Schedule III substances and have accepted medical use. Abuse may lead to limited physical or psychological dependence relative to Schedule III substances. Includes narcotics in limited quantities found in certain compounds and brand name drugs, depressants, fenfluramine, stimulants, and other substances. |
| Schedule V: | Substances that have a low potential for abuse relative to Schedule IV substances and have accepted medical use. Abuse may lead to limited physical or psychological dependence. Includes narcotics (except those listed in other schedules), narcotic drugs containing non-narcotic active medicinal ingredients, and other substances. |
| Schedule VI: | Substances that have volatile nitrates not found in Schedules I–V. |

Source: *Uniform Controlled Substances Act*, Idaho Code § 37-2702–2713(a) (1994).

- **Private citizens**: Complaints typically allege that individuals are diverting prescribed controlled substances or "doctor shopping."[6]

## Board of Pharmacy Resources

### *Budget*

The Board of Pharmacy's activities are funded by fees collected from pharmacists, pharmacies, and non-pharmacist health professionals required to be licensed or registered under the Idaho Pharmacy Act or the Uniform Controlled Substances Act.[7] For fiscal years 1995 and 1996, the board also received a General Fund appropriation, equal to $43,900 in fiscal year 1996. However, in fiscal year 1997, General Fund appropriations were removed from all regulatory boards statewide. Table 1.2 reflects the annual receipts and expenditures for fiscal years 1995 through 1998, and projected information for fiscal years 1999 and 2000.

**The board's activities are funded by fees collected from pharmacists and other registered health professionals.**

### *Staffing*

The board's staff consists of 8.75 full-time equivalent positions: an executive director, a fiscal officer, two full-time and one part-time compliance officers (inspectors), a licensing officer, and clerical staff. Board staff also includes a controlled substance investigator and other clerical staff supporting the controlled substance function. Although the board's budget and licensing activities have increased in the past six years, there has been little change in the board's staffing levels from fiscal year 1995 through fiscal year 2000. In fiscal year 1996, the board received an increase of one full-time position replacing part-time contract staff, and has neither requested nor had approved any increase in staffing since then. The allocation of staff to various board activities also has not changed since that time.

**Board staff includes an investigator and clerical support to carry out its responsibilities under the Controlled Substances Act.**

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[6] Doctor shopping is the act of a patient seeing a number of different physicians to illegitimately obtain controlled substances through prescriptions.

[7] IDAHO ADMIN. CODE, December 7, 1994, Vol. 7, IDAPA 27.01.01.403.01 establishes a $50 annual registration fee for all individuals with a controlled substance registration.

**Table 1.2: Board of Pharmacy Revenues, Expenditures, and Fund Balances, Fiscal Years 1995–2000**

| | Revenues From All Sources | Expenditures | New Fund Balance |
|---|---|---|---|
| 1995 | $573,300 | $399,700 | $540,000 |
| 1996 | 568,200 | 410,200 | 698,000 |
| 1997 | 577,800 | 489,700 | 786,100 |
| 1998 | 576,500 | 528,900 | 833,700 |
| 1999[a] | 612,500 | 602,100 | 844,100 |
| 2000[a] | 626,800 | 696,200 | 774,700 |

[a] Figures are estimates.

Source: Office of Performance Evaluations analysis of Board of Pharmacy budgets.

# Complaint Handling and Investigation Process
## Chapter 2

We reviewed the Board of Pharmacy's process for investigating controlled substance complaints involving pharmacists, non-pharmacist health professionals, and private citizens. In general, we found the board's complaint handling procedures have not provided assurance that complaints are addressed in an appropriate and timely manner. The board's complaint files were often incomplete and did not contain necessary documentation to demonstrate whether complaints were properly addressed. In addition, we found the agency's executive director and board have provided insufficient oversight of the investigation of controlled substance complaints. Review of other health regulatory agencies with similar complaint handling responsibilities showed they often had in place more structured procedures than the Board of Pharmacy. We recommend establishing a more uniform investigation process to better assure that future complaints are consistently and timely addressed.

**The board investigates complaints alleging violations of controlled substance laws by registrants, including pharmacists and other health professionals.**

### Investigation of Controlled Substance Complaints

Under Idaho's Uniform Controlled Substances Act, the board is authorized to suspend or revoke board-issued controlled substance registrations.[1] As part of this role, board staff investigate complaints involving alleged violations of the act by registrants, including pharmacists and non-pharmacist health professionals.

Board staff also receive complaints concerning non-registrants, such as private citizens and certain categories of nurses, alleging violations of the act. While, as discussed in Chapter 3, the board's jurisdiction in these cases is limited, the board's

[1] IDAHO CODE § 37-2718 (1994).

**The board also receives and investigates complaints alleging controlled substance violations by private citizens.**

investigator often performs some investigative work on these cases and may attempt to resolve the complaint informally or refer the case to local law enforcement for follow-up.

Board of Pharmacy staff have used a logbook to record basic information about controlled substance complaints received. We reviewed logbook entries to determine how many complaints board staff recorded receiving from 1995 through 1998. We included complaints about registrants and non-registrants (including citizens) in our review. We excluded requests for information or assistance and updates on information received by the board from other agencies.[2] Although these requests and updates may require some action by the board's investigator, they are not investigated as complaints. Instead, in these cases, board staff support the efforts of other agencies. We found:

- **The Board of Pharmacy received an increasing number of controlled substance complaints from 1995 to 1998, with most complaints about citizens rather than pharmacists and non-pharmacist health professionals.**

**Between 1995 and 1998, 81 percent of all controlled substance complaints the board received involved private citizens.**

Table 2.1 shows that from 1995 through 1998 the board received 1,066 complaints alleging violations of the Uniform Controlled Substances Act. The board received 49 percent more complaints in 1998 than in 1995. In addition to these complaints, during the four-year period, the board's staff received a total of 198 requests for assistance and 148 information updates.

Table 2.2 shows that over the four-year period, 81 percent of the complaints involved citizens that allegedly abused or diverted prescription controlled substances. Only 14 percent of all controlled substance complaints involved health professionals and another 3 percent involved facilities, such as hospitals or pharmacies.[3]

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[2] Requests for assistance include requests from other health regulatory boards and local law enforcement agencies to gather prescription history information or review controlled substance prescription records. Information updates include notifications of disciplinary actions taken and reports of missing or stolen controlled substances received from pharmacies.

[3] In addition to complaints about registered health professionals (e.g. pharmacists, physicians, dentists, veterinarians, and certain types of nurses), the board has received complaints about health professionals without controlled substance registrations, such as registered nurses.

**Table 2.1: Controlled Substance Complaints and Related Inquiries Recorded by the Board of Pharmacy, 1995–1998**

| Category | 1995 | 1996 | 1997 | 1998 | Total |
|---|---|---|---|---|---|
| Controlled substance complaints[a] | 209 | 265 | 281 | 311 | 1,066 |
| Requests for assistance | 51 | 54 | 46 | 47 | 198 |
| Information updates | 43 | 31 | 43 | 31 | 148 |

[a] Does not include entries categorized as pharmacy practice issues.

Source: Office of Performance Evaluations review of Board of Pharmacy logbook entries.

**Table 2.2: Controlled Substance Complaints by Respondent Type, 1995–1998**

| Respondent | 1995 | 1996 | 1997 | 1998 | Total Complaints | Percent of Total |
|---|---|---|---|---|---|---|
| Private citizens | 174 | 215 | 223 | 256 | 868 | 81% |
| Non-pharmacist health professionals | 15 | 35 | 43 | 39 | 132 | 12 |
| Hospitals and nursing homes | 7 | 6 | 9 | 4 | 26 | 2 |
| Pharmacists | 6 | 3 | 4 | 4 | 17 | 2 |
| Pharmacies | 3 | 5 | 1 | 1 | 10 | 1 |
| Other | 4 | 1 | 1 | 7 | 13 | 1 |
| **Total** | **209** | **265** | **281** | **311** | **1,066** | **100%[a]** |

[a] Percents do not sum due to rounding.

Source: Office of Performance Evaluations review of Board of Pharmacy logbook entries.

## Documentation of Controlled Substance Complaint Investigations

Investigating complaints is a key part of the Board of Pharmacy's efforts under the Uniform Controlled Substances Act. Determining whether a registrant has violated the terms of his or her controlled substance registration involves investigative work which may also serve as the basis for disciplinary action. The board's investigative efforts may also help determine whether non-registrants are abusing and/or diverting prescription controlled substances. Although the extent of investigative efforts undertaken by board staff may be less for non-registrant complaints than for complaints about registrants, documenting the work performed and evidence gathered is necessary in both instances to provide assurance that all complaints are being handled in a consistent and timely manner.

### *Documenting That Complaints Have Been Investigated*

To assess the Board of Pharmacy's performance in investigating controlled substance complaints, we reviewed all available (509) case files for complaints the board received in 1997 and 1998. We found:

- **Controlled substance complaint files were often incomplete, containing insufficient evidence of investigative work and key decisions to determine whether complaints were properly addressed.**

**Seventy-one percent of the board's 1997 and 1998 complaint files we reviewed showed no evidence of investigation.**

Of the 509 complaint files reviewed, 359 (71 percent) contained *no* evidence of investigative work by board staff.[4] The remaining files (29 percent) showed varying degrees of investigation, such as requests for patient prescription profiles and notes of phone conversations.

Seventy-three of the 509 files (14 percent) we reviewed were complaints about pharmacists and non-pharmacist health professionals. In seven of these cases, the board's investigator prepared a formal investigation report documenting violations of

[4] Like the general population of complaints, many (84 percent) of the complaint files with no evidence of investigation involved complaints about private citizens.

controlled substance laws and supporting evidence.[5] About half of these (38 of 73), or a lower percentage than overall, contained no evidence of investigation. However, half of these (19 of 38) involved nurses who may not have been required to obtain a controlled substance registration, and another 4 involved allegations of overprescribing by physicians, which may be more accurately considered a medical practice issue. As a result, the total number of complaints involving health professionals with controlled substance registrations may be even lower.

**Complaint files for pharmacists and other health professionals were more likely to have some evidence of investigation than were complaints about private citizens.**

We also reviewed the 1997 and 1998 case files for information about key decisions made about complaints received. We found:

- **Key decisions made by the board's investigative staff, either alone or in conjunction with the executive director, were generally not documented.**

These decisions included:

- Determining whether to open a complaint investigation;
- Establishing investigation priorities among complaints;
- Deciding what investigation work needed to be performed; and
- Determining whether to pursue disciplinary action once investigation efforts were complete.

**The rationale for key decisions, such as what investigation work was needed and whether to seek disciplinary action, was typically not documented.**

The controlled substance investigator acknowledged he had not consistently documented the investigative work he performed or the decisions he made. He acknowledged the importance of documenting investigative efforts, but told us that spending time documenting investigative efforts would reduce the time available to investigate complaints and provide assistance to other health regulatory and law enforcement agencies. In addition, the investigator pointed out that because no one in agency management reviewed his case files, he tended to use a shorthand approach to documentation and had not felt it necessary to document all of the investigative work performed.

[5] During the course of our work we identified six other cases from 1997 and 1998 in which an investigation report was developed. The case files for these complaints were not available at the time of our review and, as a result, were not included in the analysis.

**Other health regulatory boards and law enforcement agencies in Idaho that rely on information the board provides were generally satisfied with the assistance received.**

Consequently, the absence of documentation does not necessarily indicate that investigative work was not performed. Furthermore, our interviews with representatives of other health regulatory boards in Idaho and law enforcement agencies, including the U.S. Drug Enforcement Administration and the Idaho Department of Law Enforcement, suggested they were generally satisfied with the assistance provided by the board's investigator.

However, we found:

- **Other health regulatory boards in Idaho and other states we contacted and law enforcement agencies generally require more complete documentation of investigative work done and decisions made.**

For example:

- In Texas, statutes require the state's Board of Pharmacy to keep an information file on all complaints filed with the board. Statutes require these files be kept current and contain a record of all persons contacted in relation to the complaint, a summary of the results of the investigation of the complaint, and, for complaints in which the board took no action, an explanation of the reason the complaint was closed with no action.

- The Idaho State Board of Nursing rules require a written record of all investigations. Complaints are logged and entered into an automated system, and a complaint file is created. Each file includes a checklist for the key steps in the process. In addition, board staff maintain on computer a running record of investigative work done in response to complaints, with a printed copy included in the case file.

- Within the Prosecutorial Assistance Unit of the Idaho Office of the Attorney General, all information gathered as part of an investigation is documented and placed in the case file. This includes all research, interviews, communications/ correspondence, police reports, court filings, and other materials.

**However, the lack of adequate documentation impedes effectiveness.**

Lack of adequate documentation can impede efforts to take disciplinary action when appropriate, limit the ability of agency management and outside evaluators to determine whether

complaints are appropriately investigated, and, as time passes, place the agency at risk of losing historical knowledge of the complaints received and the work performed. Therefore:

***We recommend Board of Pharmacy staff fully document all investigative work done on controlled substance complaints, as well as the rationale for key decisions made during the investigative process.***

### *Documenting the Timeliness of Complaint Handling*

We attempted to assess the timeliness of controlled substance complaint investigations by measuring the time that elapsed between complaint receipt and resolution. However, we found:

- **Complaint files were not officially closed or classified as inactive when investigation efforts were no longer pursued. As a result, the timeliness of complaint handling could not be determined.**

**The timeliness of complaint handling efforts could not be determined, as even inactive files were kept open for three years and then destroyed.**

During 1997 and 1998, the board's investigator produced 13 formal investigative reports regarding health professionals. In these instances, the report was sent to the related health regulatory board (e.g., Board of Pharmacy, Medicine, Nursing, etc.) for resolution. In most other cases, the investigator kept the complaint open for three years, even if it was no longer being actively pursued. As a matter of routine, at the end of the three years, the case file was destroyed.[6] Further, our review of the complaint files confirmed that the investigator generally did not record the date on which active investigation ceased.

In contrast, we found:

- **Most other health regulatory boards in Idaho and other states we contacted consistently record case closure dates and monitor the time taken to investigate and resolve complaints.**

[6] The board's investigator reported that complaint files regarding health professionals were retained for more than three years if there was some merit to the complaint, regardless of whether formal disciplinary action had been taken. Files for health professionals have been retained dating back to 1983.

For example:

- The Idaho Board of Medicine records a case closure date for all complaints received. All complaints are reviewed by the Board of Professional Discipline after investigation work is complete. If the Board of Professional Discipline determines there is insufficient evidence to warrant disciplinary action, the case is closed with no action and the date is recorded. For those cases that continue on for disciplinary action, the date of final board action is recorded.

- The Texas Board of Pharmacy records the dates on which complaints are received and closed. This information is used to determine how long it took to investigate and resolve complaints, the number of complaint cases closed during a designated time period, and the number of active or pending complaints that remain. The agency generates quarterly reports with this type of information.

**Timeliness is a measure of effectiveness and should be tracked.**

Without formally closing complaint investigations or moving complaint cases to inactive status and documenting the date on which action was taken, it cannot be determined whether controlled substance complaints were handled in a timely manner or how many cases were active at a given time. In addition, recent literature has identified the timeliness of complaint investigation and adjudication as an important measure to examine in evaluating health regulatory boards.[7] Therefore:

***We recommend Board of Pharmacy staff officially close controlled substance complaint files when they are no longer being actively pursued and record the dates the files are closed.***

## Oversight of Investigations by Agency Management and Board Members

We examined the agency's oversight of complaint handling by looking at the extent to which agency management and the board had established guidelines to govern the process, received

[7] Pew Health Professions Commission, Taskforce on Health Care Workforce Regulation, *Reforming Health Care Workforce Regulation: Policy Considerations for the 21st Century* (1995), 29, 35.

information about the administration of complaints, and made efforts to review investigative work.

### *Development of Investigation Guidelines*

We interviewed board members and staff to determine if there were written guidelines governing the investigative process for controlled substance complaints. We found:

- **The Board of Pharmacy has not established written guidelines for the investigation of controlled substance complaints. As a result, the investigation process has been informal, offering the potential for inconsistency in complaint handling.**

**The board's complaint handling process has been informal, relying on the investigator to decide when and how to proceed.**

The board's investigator told us he generally determined what investigation work was needed, when complaints would no longer be investigated, and when complaint cases were to be forwarded for possible disciplinary action. In the process he relied on his experience and judgment, rather than established guidelines for making investigation decisions.

However, we found:

- **Health regulatory boards in other states we contacted have either developed, or are in the process of developing, written guidelines for complaint handling.**

For instance:

- Statutes require the Texas Board of Pharmacy to adopt policies and procedures for complaint investigations. Among other things, these policies must specify how the board will determine the seriousness of the complaint, ensure the person who filed the complaint had an opportunity to explain the allegations made in the complaint, and ensure complaints are not closed without appropriate consideration.

- The Massachusetts Division of Registration, an umbrella agency for 33 boards of registration including the Board of Pharmacy, has established written guidelines for investigations.

- The Washington Board of Pharmacy is in the process of developing investigation guidelines.

- A 1998 report by the Arizona Office of the Auditor General recommended that the Board of Medical Examiners "develop and implement written policies and procedures that describe the investigation process, including information that should be obtained and interviews that should be conducted."[8]

**Heavy reliance on the investigator's judgment can result in inconsistent complaint handling.**

Without written guidelines for complaint investigations, the investigation process relies primarily on the board's investigator. While we saw no evidence of abuse reflecting arbitrary or capricious investigation practices, heavy reliance on the investigator's judgment, with little direction from management or the board, offers the potential for inconsistent handling of controlled substance complaints. Further, recent literature recommended that boards establish uniform complaint handling processes to ensure that all investigations of complaints are handled in an objective, prioritized, and timely manner.[9] Therefore:

***We recommend the Board of Pharmacy develop written guidelines to govern the process for handling controlled substance complaints.***

The guidelines should:

- Define the process for complaint intake and initial review;
- Identify any required investigation steps or tasks;
- Specify documentation standards for complaint investigations; and
- Establish a process for determining when complaint cases may be closed without disciplinary action.

### *Development of Management Information*

To determine what types of information have been routinely and regularly available to the Board of Pharmacy's executive director and board members, we requested available management information about complaints from the board's investigator.

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[8] Arizona Office of the Auditor General, *Board of Medical Examiners*, Report 98-16 (September 1998), 10.

[9] Pew Health Professions Commission, Taskforce on Health Care Workforce Regulation, *Reforming Health Care Workforce Regulation: Policy Considerations for the 21st Century* (1995), 29.

We found:

- **Until recently, the Board of Pharmacy has lacked an effective management information system for tracking complaints, hindering oversight efforts.**

**The board has used an antiquated system to record information about complaints, making use of this information difficult.**

Prior to March 1999, board staff used a manual system for logging complaints and recording information about complaint investigation efforts. When a complaint was received, the board's investigator, or other board staff, recorded the complaint in a logbook and assigned a case number. Since complaints were entered into the logbook chronologically, the investigator also used a card file system, arranged alphabetically by the suspect's name, to help identify when there were previous complaints about an individual. No information concerning complaints was kept in an automated management information system.

**Monitoring of investigative efforts also was complicated by the lack of readily available information.**

Without an automated management information system for controlled substance complaints, the board's and agency management's ability to monitor investigation efforts and identify patterns in complaints reported was limited. For instance, while board staff could provide the total number of complaints received each year, they could not readily provide a breakdown of complaints by suspect or respondent type, complainant type, or by the types of offenses alleged. In addition, even if information about complaint investigation efforts and case closure had been consistently recorded in the case files, without an automated information system the board and agency had limited ability to assess the adequacy and timeliness of complaint investigation.

However, in early 1999, as part of its efforts to develop an automated system for controlled substance data (see Chapter 4), the Board of Pharmacy obtained programming services to develop a database to use in logging controlled substance complaints and recording detailed information about the complaint and investigative work performed by board staff. The board's investigator told us that all complaints received since 1996 have been entered in this database.

The value of this new database will depend on the quality and completeness of the information entered into the system, and the use of this system as an investigation and oversight tool.

**A recently developed computerized system shows promise.**

Therefore:

***We recommend the Board of Pharmacy maximize the value of its new complaint database by taking steps to ensure that staff consistently enter complete information about controlled substance complaints in the system and regularly generate reports for management and board review.***

*Management Review of the Investigator's Work*

As part of our review of the Board of Pharmacy's oversight of the complaint handling function, we gathered information about management's review of the investigation process. We found:

- **Agency management did not formally review controlled substance investigative work or key decisions made.**

The board's executive director and investigator told us they met periodically to discuss complaint cases. However, according to the investigator, discussions focused primarily on those cases deemed likely to be forwarded to the board or another health regulatory board for action, a small percentage of all complaints. Furthermore, these discussions were not documented in the files.

**There has been little to no review of the adequacy of complaint investigations and key decisions made.**

Except for these limited discussions, there appeared to be little oversight of the investigator's work. Complaint case files were not reviewed to assess the adequacy of investigative efforts and case documentation. The investigator made key decisions about complaints (for example, setting investigation priorities, determining what investigative work would be done, and determining when complaints would be addressed informally or no longer investigated) without management involvement and review. The executive director did not receive, nor review, periodic reports on the status of all active complaint cases.

In contrast, we found:

- **Management of other health regulatory boards and law enforcement agencies we contacted typically play a greater role in overseeing complaint investigations.**

For example:

- At the Nevada Board of Pharmacy, the executive director, investigator, and assigned legal counsel meet weekly to

review complaints received and investigated. This "investigative committee" makes the initial determination as to whether a complaint will be investigated, reviews investigated cases to decide if further investigation is needed, and decides if the case will be closed with no action or forwarded to the board for consideration of disciplinary action.

**Other states we contacted had more formalized processes to oversee complaint investigations.**

- In Washington, the Board of Pharmacy has a "case management team" comprised of the executive director, chief investigator, staff attorney, and program manager. This team decides whether a complaint is within the board's jurisdiction, whether it is serious enough to warrant investigation, and how to proceed when an investigation is complete. The decisions made by the committee, and the rationale for these decisions, are then documented in the case files.

- In the Idaho State Board of Nursing, the associate executive director, administrative assistant, and the agency's representative from the Office of the Attorney General meet biweekly to discuss active complaint cases. The executive director is updated monthly about this information, and according to the associate executive director, is typically involved in determining whether complaint cases will be closed without pursuing disciplinary action.

Regular review of complaint investigations by management and management involvement in key decisions in the investigative process can help ensure that established guidelines are followed and complaints are appropriately and timely addressed. Therefore:

***We recommend the Board of Pharmacy establish formal mechanisms for management oversight and review of complaint investigations.***

**Establishing a formal review process could provide greater assurance that complaints are handled appropriately.**

These mechanisms could include:

- Ongoing review of controlled substance complaint case files by management;
- Submission of monthly status reports for all active complaints; and
- Regularly scheduled case management meetings to review investigations and make key decisions.

*Board Review of the Investigator's Work*

To determine the board's role in the investigation of controlled substance complaints, we reviewed board meeting minutes from the past four years and interviewed two of the five current board members. We found:

- **Aside from cases brought to the board for disciplinary action, the Board of Pharmacy has received little information about controlled substance complaints and investigations.**

**Information board members received about investigations was limited primarily to those few complaints brought to them for disciplinary action.**

According to Board of Pharmacy meeting minutes from 1995 through 1998, the board seldom received information about complaints unless the complaints were specifically brought before the board for disciplinary action. During this period, 13 cases were brought before the board for disciplinary action related to controlled substance violations.[10] On only one occasion during the four-year period the board received an update about the larger body of controlled substance complaints the board staff had received. Further, we could find no indication in the minutes that the board received updates on the number and type of controlled substance complaints received, the status of complaint investigations, or the outcome of complaint investigations.

**We identified only one instance from 1995 through 1998 when the board received information concerning the larger body of complaints.**

Interviews with two long-standing board members confirmed that the board had received little information about investigation of controlled substance complaints generally. The two members indicated they primarily received information about those complaints that were brought before them for disciplinary action against registrants. As noted previously, such complaints made up a small percentage of all controlled substance complaints received.

To provide overall direction and oversight to agency staff in the administration of the Uniform Controlled Substances Act, the board should be generally knowledgeable about the complaints received, the investigative efforts of staff, and the outcome of

[10] In six other instances in which the board considered taking disciplinary action, the nature of the violation was not specified in the board's meeting minutes. These cases may have involved controlled substance violations as well. From 1995 through 1998 the board received 149 complaints involving health professionals.

controlled substance complaints cases referred to other health regulatory boards for action. Therefore:

**Staff communication with the board should be increased.**

***We recommend the Board of Pharmacy require submission of quarterly reports on the status of all controlled substance complaints.***

These reports should include:

- The number of new complaints received;
- The number of complaint cases closed with no action;
- The number of complaint cases forwarded to other health regulatory boards for possible disciplinary action;
- The average length of time complaints currently being investigated have been open; and
- The outcome of complaint cases involving individuals with controlled substance registrations that were referred to other health regulatory boards.

# Complaints About Non-Pharmacist Health Professionals and Private Citizens

## Chapter 3

To carry out the provisions of the Uniform Controlled Substances Act, the board regulates health professionals that manufacture, distribute, prescribe, or dispense controlled substances, including pharmacists, physicians, dentists, certain categories of nurses, veterinarians, and others. In addition, the board receives complaints alleging diversion or abuse of controlled substances by citizens. Overall, we conclude that under the Uniform Controlled Substances Act, the board has not fully exercised its authority with respect to alleged violations of the act by non-pharmacist health professionals, which may have led to inconsistent enforcement. In addition, Idaho's statewide response to prescription controlled substance abuse by its citizens has been limited. We recommend the Board of Pharmacy play a stronger role in dealing with diversion or abuse of controlled substances by non-pharmacist health professionals. Additionally, we suggest ways the board could improve its response to complaints involving private citizens.

**In 1998, the Board of Pharmacy issued 4,175 controlled substance registrations, 3/4 of which were to non-pharmacist health professionals.**

### Complaints About Non-Pharmacist Health Professionals

According to its 1998 annual report, the Board of Pharmacy provided controlled substance registrations to 4,175 health professionals during fiscal year 1998, 77 percent of whom were non-pharmacists.[1] Under the Uniform Controlled Substances Act,

[1] Some licensed health professionals do not hold controlled substance registrations either because they choose to limit their scope of practice to exclude controlled substances or because their professional licensure does not permit them to prescribe or dispense controlled substances.

the board is empowered to revoke or suspend a controlled substance registration upon a finding that the health professional:

- Furnished false or fraudulent material information in any application filed under the act;
- Has been found guilty of any state or federal law relating to any controlled substance;
- Has had his or her federal controlled substance registration suspended or revoked;[2] or
- Has violated any rule of the board adopted under the act or any federal regulation relating to controlled substances.[3]

**From 1995 through 1998, 12 percent of all controlled substance complaints involved non-pharmacist health professionals.**

Of the complaints received by the board from 1995 through 1998, 12 percent involved non-pharmacist health professionals. As shown in Table 3.1, complaints alleged diversion, questionable prescribing, fraud, questionable distributing or dispensing, drug abuse, and prescription forgery. The board also responded to requests for assistance regarding health professionals from other licensing boards and law enforcement agencies. As shown, complaints about pharmacists accounted for 17 of 149 (11 percent) of all complaints against health professionals during this period.

**For these professionals, the board's investigator generally forwarded investigative reports to the professional's licensing board.**

To determine how the board has handled controlled substance complaints involving non-pharmacist health professionals, we reviewed the minutes of board meetings and complaint records for 1995 through 1998. We found:

- **The Board of Pharmacy has not fully exercised its authority with respect to alleged violations of the Uniform Controlled Substances Act by non-pharmacist health professionals.**

The board's investigator told us that when he investigated allegations of violations of the act by non-pharmacist health professionals, he generally provided investigative reports to the

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[2] A state controlled substance registration is not valid without a Drug Enforcement Administration registration. The board's investigator told us that when a Drug Enforcement Administration registration is suspended or revoked, board staff notes that fact in the licensing database. These actions are not brought to the board.

[3] IDAHO CODE § 37-2718 (1994).

**Table 3.1: Complaints Involving Licensed Professionals by Type of Profession and Alleged Offense, 1995–1998**

| | Nurses[a] | Doctors | Veterin-arians | Dentists | Pharm-acists | Total |
|---|---|---|---|---|---|---|
| Diversion/fraud | 53 | 10 | 0 | 0 | 10 | 73 |
| Questionable prescribing/dispensing | 5 | 30 | 0 | 3 | 5 | 43 |
| Drug abuse | 4 | 4 | 0 | 2 | 1 | 11 |
| Forgery | 3 | 1 | 0 | 0 | 0 | 4 |
| All others | 12 | 5 | 0 | 0 | 1 | 18 |
| **Subtotal** | **77** | **50** | **0** | **5** | **17** | **149** |
| Requests for assistance | 11 | 46 | 2 | 8 | 5 | 72 |
| **Total** | **88** | **96** | **2** | **13** | **22** | **221** |

[a] Controlled substance registrants and non-registrants.

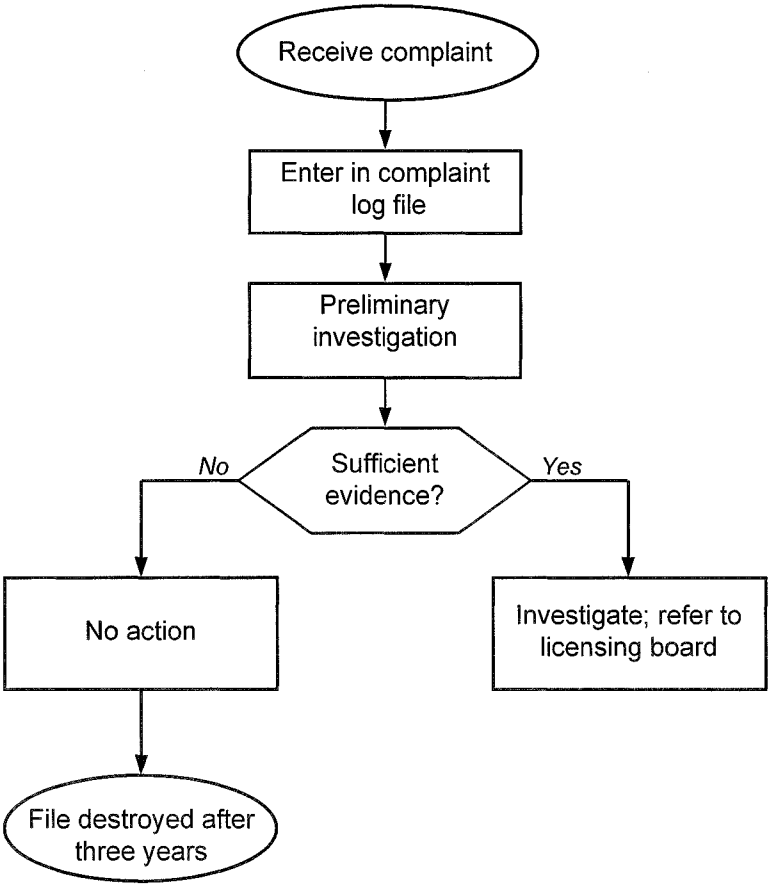
Source: Office of Performance Evaluations analysis of Board of Pharmacy logbook.

appropriate licensing boards, rather than forwarding them to the Board of Pharmacy for disciplinary action. The key steps in the investigation of these cases are shown in Figure 3.1. According to the investigator, the board had encouraged him to forward investigative reports about non-pharmacist health professionals to their own licensing boards without first taking action. Furthermore, two long-standing board members with whom we spoke told us that, in their view, disciplinary measures by other licensing boards take precedence over controlled substance registration actions.

**From 1995 through 1998, the Board of Pharmacy considered disciplinary action against non-pharmacists three times.**

A review of board meeting minutes confirmed that the Board of Pharmacy seldom considered disciplinary action against non-pharmacist health professionals. From 1995 through 1998, the board received 132 complaints about non-pharmacist health professionals (including registrants and non-registrants). During this time period, the board considered disciplinary action against non-pharmacist health professionals for violating controlled

**Figure 3.1: Board of Pharmacy Complaint Handling Process for Health Professionals, 1999**




Source: Office of Performance Evaluations rendering of Board of Pharmacy process description.

substance laws three times.[4] Figure 3.2 summarizes the offenses and the board's actions on these cases.

[4] We identified two other instances from 1995 through 1998 in which the board discussed non-pharmacist health professionals. The first involved the revocation and subsequent reinstatement of a physician's controlled substance registration for failure to pay child support. The second involved a request for assistance from the Board of Veterinary Medicine requesting that the investigator assess whether restrictions should be placed on a veterinarian's controlled substance registration.

**Figure 3.2: Board of Pharmacy Actions on Controlled Substance Registrations for Non-Pharmacist Health Professionals, 1995–1998**

| Board Meeting Date | Type of Non-Pharmacist Health Professional | Board of Pharmacy Action | Reason Cited |
|---|---|---|---|
| January 1996 | Physician | Restricted controlled substance prescribing authority | Addiction to Codeine |
| June 1997 | Physician | Accepted voluntary surrender of controlled substance registration | Revocation of medical license |
| June 1997 | Physician | Approved consent order on physician's controlled substance registration | Illegally prescribing Methadone |

Note: According to the board's investigator, other licensing boards such as the Board of Medicine sometimes revoke, suspend, or restrict controlled substance registrations when taking action on professional practice licenses. These actions are not routinely brought to the board.

Source: Office of Performance Evaluations review of Board of Pharmacy meeting minutes.

**Statutes assigning the board responsibility for revocation or suspension of controlled substance registrations are unclear.**

Although the Board of Pharmacy is assigned responsibility for taking appropriate disciplinary action against health professionals' controlled substance registrations under the act, what that entails is not clear. While the board may revoke or suspend the controlled substance registration of a non-pharmacist health professional for violating its rules or federal regulations relating to controlled substances, the act requires the concurrence of the professional's own licensing board before the Board of Pharmacy can initiate revocation or suspension procedures.[5] However, the act does not more specifically define at what point the Board of Pharmacy must obtain the professional licensing board's concurrence—before initiating an investigation, before conducting a hearing, or before issuing a suspension or revocation order.

To ensure agency responsibilities are clearly defined for disciplining non-pharmacist health professionals who violate controlled substance laws:

[5] IDAHO CODE § 37-2718(a)(4) (1994).

**Despite ambiguities in law, the board could do more to meet statutory obligations.**

***We recommend policymakers consider clarifying the roles of the Board of Pharmacy and other licensing boards with respect to disciplining non-pharmacist health professionals for violations of the Uniform Controlled Substances Act.***

Even with the act's current limitations and ambiguities, the Board of Pharmacy can do more to fulfill its statutory responsibilities for disciplining non-pharmacist health professionals with controlled substance registrations.

**The board has not established a mechanism to receive and review disciplinary actions taken by other licensing boards so that it may then take appropriate action.**

As noted above, the Board of Pharmacy generally refers violations of controlled substance laws by non-pharmacist health professionals to the registrant's licensing board for disciplinary action. However, the board has not established a formal mechanism to ensure that it receives notification of the disciplinary action taken. As a result, once a case is referred to another board, the Board of Pharmacy may not hear what disciplinary action was taken. Furthermore, through our examination of Board of Pharmacy meeting minutes we learned that the board did not review the disciplinary actions taken by other licensing boards against registrants that violated controlled substance laws.

Therefore, to ensure that appropriate and consistent disciplinary action is taken when registrants violate controlled substance laws:

***We recommend the Board of Pharmacy establish a mechanism whereby it receives and reviews the disposition of cases referred to professional licensing boards.***

In addition, to better ensure the Board of Pharmacy and other licensing boards are in concurrence regarding the disciplinary action to be taken:

***We recommend the Board of Pharmacy work with other licensing boards to investigate the possibility of conducting joint disciplinary hearings when appropriate.***

## Complaints About Private Citizens

To understand the prevalence of, and the investigative procedures for, handling controlled substance complaints regarding private citizens, we spoke with law enforcement officials, interviewed

officials with responsibility for enforcing controlled substances laws in other states, and reviewed related documents and legislative history.

We found:

- **Idaho has a limited statewide response to the diversion or abuse of prescription controlled substances by private citizens.**

**Responsibility for enforcement of the Uniform Controlled Substances Act is dispersed.**

Under Idaho Code, responsibility for enforcement of the Uniform Controlled Substances Act is dispersed among the Board of Pharmacy, the Department of Law Enforcement, and local law enforcement agencies.[6] The act empowers the Board of Pharmacy to administer the regulatory provisions of the act. However, it does not expressly assign the board responsibility for handling complaints alleging abuse of controlled substances by private citizens, nor does it provide direction to the board about handling these cases. Instead, the act gives the Department of Law Enforcement responsibility to "administer the state-level program of Idaho to suppress the unlawful traffic and abuse of controlled substances" and the authority to appoint and commission agents to enforce the provisions of this act.[7]

**Board staff investigates complaints about citizens and either handles these cases informally or refers them to law enforcement.**

According to the Board of Pharmacy's investigator, in citizen cases, he may gather prescription history information and, at times, informally counsel the citizen involved about the danger of his or her actions. He may also alert pharmacists and doctors of the activities, and, in some cases, contact appropriate local law enforcement agencies.[8] Figure 3.3 illustrates this process. The investigator also provides prescription history information obtained from pharmacies and from the board's prescription tracking system to local law enforcement agencies in response to requests for assistance.

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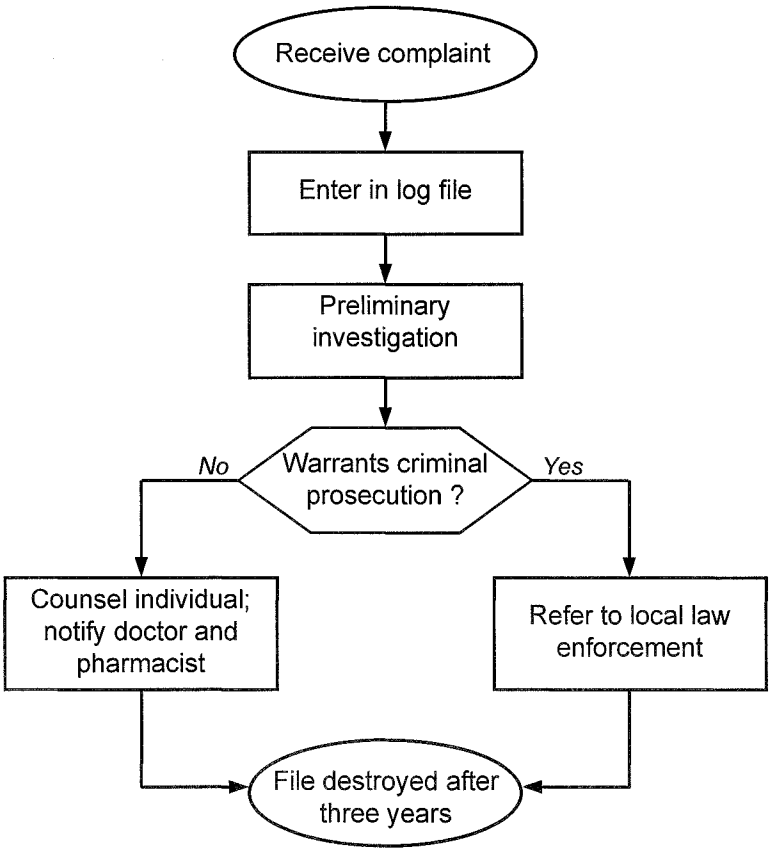
[6] As initially enacted in 1971, the act assigned full responsibility for enforcement and administration to the Board of Pharmacy. However, a 1972 amendment inserted the words "the regulatory provisions" in its description of the Board of Pharmacy's authority. The same amendment designated the Attorney General as responsible for administering the statewide program to suppress the abuse of controlled substances. A 1974 amendment shifted statewide program responsibility to the Department of Law Enforcement.

[7] IDAHO CODE § 37-2740(4)(b) (1994).

[8] As discussed in Chapter 2, we were unable to verify that the investigator consistently followed these steps because the files often lacked documentation of actions taken.

**Figure 3.3: Board of Pharmacy Complaint Handling Process for Private Citizens, 1999**




Source: Office of Performance Evaluations rendering of Board of Pharmacy process description.

As noted previously, from 1995 through 1998, complaints involving private citizens comprised 81 percent of all controlled substance complaints the board received. As Table 3.2 illustrates, complaints often alleged "doctor shopping," prescription forgery, fraud, and "phony call-ins."[9] During this period, the board's investigator also responded to 60 citizen-related requests for assistance from state and local law enforcement agencies. Although charged with administering the state-level program to

[9] A "phony call-in" is the practice of calling a pharmacy, pretending to be a doctor, and ordering a controlled substance prescription.

**Table 3.2: Complaints Involving Private Citizens by Type of Offense Alleged, 1995–1998**

| Offense Type | 1995 | 1996 | 1997 | 1998 | Total Number of Offenders |
|---|---|---|---|---|---|
| Doctor shopping | 83 | 102 | 107 | 145 | 437 |
| Forgery/fraud | 51 | 54 | 56 | 58 | 219 |
| Drug abuse/possession | 26 | 31 | 23 | 30 | 110 |
| Phony call-ins | 9 | 19 | 36 | 21 | 85 |
| Others | 5 | 9 | 1 | 2 | 17 |
| **Subtotal** | **174** | **215** | **223** | **256** | **868** |
| Requests for assistance | 29 | 29 | 17 | 28 | 103 |
| **Total** | **203** | **244** | **240** | **284** | **971** |

Source: Office of Performance Evaluations analysis of Board of Pharmacy logbook.

suppress the unlawful traffic and abuse of controlled substances, the Department of Law Enforcement plays a limited role in enforcing laws concerning prescription controlled substances. According to an official in the Department of Law Enforcement, the department focuses, instead, on cases involving traffic in and abuse of Schedule I (non-medical) controlled substances. In other cases about diversion the department refers the information to the Board of Pharmacy.

**The Department of Law Enforcement limits its role in enforcing prescription controlled substance laws.**

Without a coordinated response to allegations of citizen diversion and abuse, the effectiveness of enforcement may be limited. Elsewhere, a statewide response has been shown to be effective in reducing incidents of controlled substance abuse by private citizens. Experts we consulted identified two states with particularly effective approaches to addressing citizens' diversion and abuse of prescription controlled substances.[10]

[10] A federal Drug Enforcement Administration official and the executive directors of two national associations involved with suppressing the abuse of prescription controlled substances each identified these states as exemplary.

**Without coordination among responsible bodies, the effectiveness of enforcement may be limited.**

- In Nevada, a task force oversees the state's response to controlled substance complaints about private citizens. The task force, which is comprised of representatives of the Board of Pharmacy and the Nevada Division of Investigation, implemented a prescription tracking system in 1997 to identify possible instances of abuse or diversion of prescription controlled substances. The number of controlled substances prescribed to identified individuals declined significantly. Specifically, after about seven months of operation: (1) for 89 percent of the profiled individuals, there were significant reductions in the number of controlled substance prescriptions received; and (2) the average rate of reduction in controlled substance prescriptions received was 64 percent.[11]

**Other states say coordination and cooperation are key to effectively dealing with complaints about citizens.**

- In Oklahoma, responsibility for regulatory and criminal aspects of its controlled substance laws is assigned to the Bureau of Narcotics and Dangerous Drugs, a state law enforcement agency. According to the bureau's Chief Agent, the bureau suspends or revokes controlled substance registrations and otherwise disciplines registrants independent of any disciplinary action by professional licensing boards. In some instances, the bureau also criminally prosecutes both health professionals and private citizens for violating controlled substance laws.

In both states, coordination and cooperation, either within or between agencies, have been key to effectiveness in dealing with citizen cases. Therefore, should policymakers wish to increase the effectiveness of controlled substance enforcement:

***Policymakers could consider establishing an interagency task force comprised of representatives of involved agencies to coordinate efforts and make recommendations about the handling of controlled substance complaints about citizens.***

The benefits of providing such an interagency response include:

- Enhanced communication and coordination among agencies;

[11] According to the executive director of Nevada Board of Pharmacy, Nevada's board has enforcement limitations, such as on its authority to investigate and prosecute citizens and on its ability to discipline health care professionals, that are similar to those in Idaho.

- Availability of a variety of expertise already present in the member agencies;
- Encouraged sharing of information among relevant agencies; and
- Cooperation between the rehabilitative and criminal options for citizens abusing prescription controlled substances.

**Establishing an interagency task force to respond to citizen complaints could increase effectiveness.**

We also learned of another program two states use that appears to have helped reduce diversion and abuse of controlled substances. The PharmAlert Network, operating in Colorado and Wyoming since 1996, provides a FAX network between local pharmacists and the federal Drug Enforcement Administration's (DEA) Rocky Mountain Division in Denver. When a pharmacist is presented with what appears to be a fraudulent prescription he or she verifies the prescription with the physician and, if indeed fraudulent, the pharmacist faxes the individual's name and physical description to the DEA's regional office. The DEA, using the broadcast fax service of a commercial telephone company, provides this information to all pharmacies in the region. The information alerts pharmacists to contact the physician to verify prescription information from anyone matching the description of the individual. Because the DEA's office funds the network and maintains the registry of pharmacy fax numbers, Wyoming and Colorado participate without cost. Therefore:

**Other steps may be possible to reduce diversion and abuse of controlled substances.**

***We recommend the Board of Pharmacy investigate the possibility of working with the federal Drug Enforcement Administration regional office in Seattle to implement a network similar to the PharmAlert Network for Idaho.***

Such a network would provide a low-cost way to share information about alleged controlled substance abuse and diversion.

# The Board of Pharmacy's Electronic Prescription Tracking System

## Chapter 4

As noted in Chapter 1, in 1997, the Board of Pharmacy received legislative authorization to establish an automated system to collect information about prescription controlled substances. We reviewed the Board of Pharmacy's efforts to implement the new system and learned the board has been slow to develop a program to use the automated prescription information: over 19 months the board spent more than $80,000 for automated data that, until recently, it did not have the capacity to use effectively. The board rejected two programming options that could have been used to make use of this data, deciding instead to hire a vendor to develop a program deemed more appropriate for Idaho's needs. This program was in place in April 1999, although a contract had not been signed. In addition, despite these expenses over an extended period, the board has yet to develop a plan for using the information the software is to make available.

### Prescription Tracking Systems

Systems for tracking controlled substance prescriptions can be powerful tools in reducing controlled substance prescription diversion and abuse. These systems centrally collect controlled substance prescription information so that prescription activities of health professionals and private citizens may be monitored. Information is collected about which drugs are being prescribed, in what quantities, by whom, and to whom. Through central collection, the data can be used to determine, for example, when controlled substances are prescribed by several professionals for a single individual, even if prescriptions are filled at more than one pharmacy.

**Prescription tracking systems can be powerful tools in combating diversion and abuse of controlled substances.**

A number of states have begun establishing automated systems. According to an official with the U.S. Department of Justice Drug Enforcement Administration's Office of Diversion Control, 18

states have established or are currently in the process of establishing prescription tracking systems. Recently, the National Association of State Controlled Substance Authorities passed a resolution to encourage and support states in developing electronic prescription controlled substance tracking systems.

## Prescription Tracking in Idaho

**The Board of Pharmacy has used paper forms to collect information about some controlled substances since 1971.**

Since 1971, the Board of Pharmacy has collected information on controlled substance prescriptions filled by Idaho pharmacies. Statutes have required prescribers to use a special state-issued, serial numbered prescription form when writing prescriptions for Schedule II controlled substances.[1] Until 1997, a triplicate form was used. When writing a prescription for a Schedule II drug, the prescriber kept a copy of the form and gave the two remaining copies to the patient. Then, when the prescription was filled, the pharmacist retained a copy and forwarded the third copy to the Board of Pharmacy. In 1997, an automated collection system was approved, allowing the elimination of one copy. Duplicates are now used. Board staff reported that the use of these special prescription forms has virtually eliminated diversion of Schedule II controlled substance.

**By 1997, a significant backlog of forms had developed, rendering the system unuseful.**

For many years the board used a manual entry system to collect and record the data from these forms. Board staff entered information from the prescription forms into a database for tracking purposes. By 1997, a six- to ten-month backlog of prescription information had not been entered into the board's database. According to the board's investigator, current data are essential in identifying individuals that are beginning to abuse prescription controlled substances before their problems escalate. He reported that these individuals often stop at an early stage of abuse when informed that their use has been noticed and that diversion of prescription controlled substances is illegal.

In 1997, the Board of Pharmacy successfully proposed legislation to expand coverage of the tracking system to Schedule III and IV controlled substances and automate the collection of prescription

[1] Schedule II controlled substances have a high potential for abuse because their use can lead to severe psychological or physical dependence. No special form is required for Schedule III and IV substances.

data from pharmacies.[2] Under this new automated collection system, pharmacists send electronic prescription information for Schedule II, III, and IV controlled substance data to an independent data collection firm, which then audits the data and transmits it to the Board of Pharmacy in electronic format. In the statement of purpose for the legislation that authorized this system, the Board of Pharmacy stated that the automated system would provide a more efficient and effective method of tracking prescribed controlled substances.[3] The board also indicated that automation would result in the reduction of one full-time equivalent position, whose time had been spent manually entering the data received on triplicates into a computer database.

**In 1997, the board was authorized to expand the prescriptions tracked and automate the collection of this data from pharmacies.**

In our review of the Board of Pharmacy's efforts to develop an automated collection system, we found:

- **The Board of Pharmacy spent more than $80,000 over 19 months for prescription tracking data it was unable to use until recently.**

In August 1997, the board contracted with an out-of-state firm, Atlantic Associates, Inc. (AAI), to develop software for data collection, begin coordinating data collection from pharmacies, and begin collecting and auditing data. Start-up costs totaled $36,200. In addition, since November 1997, the board has purchased audited data from AAI at a cost of $2,900 per month. As of April 1999, the board had made payments to AAI totaling $82,600. However, until April 1999, board staff had not reviewed the monthly data received. Further, they were unable to use the data because they lacked the software application necessary for analysis.[4]

**Although the board began receiving automated prescription data in November 1997, it was unable to use the information until April 1999.**

[2] U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Prescription Accountability Resource Guide* (September 1998) Message from the Administrator. "The Drug Enforcement Administration (DEA) considers the state-administered multiple copy/ electronic data transmission prescription monitoring program one of the most important methods in combating the diversion and abuse of controlled substances." With the implementation of the automated collection system, the Board of Pharmacy will have just such a multiple copy/electronic data transmission program.

[3] HB 69, 54th Leg., 1st Sess. (Idaho 1997).

[4] In a few instances, the board made special requests for and received prescription data from AAI regarding specific individuals.

We examined the board's efforts to make use of the data AAI provided. According to AAI and board staff, AAI has provided data in an agreed upon standard electronic format. A software application, such as Access or Excel, is needed to access and use the data. However, we found that:

- **Board staff elected not to use the software applications or other services available to them for use with AAI data, resulting in system implementation delays and increasing system costs.**

**Needed resources were made available to the board early on.**

Needed software applications were made available to the board on two occasions, but the investigator opted not to use it.

- In late 1997, during a visit to the Nevada Board of Pharmacy—the agency responsible for maintaining Nevada's prescription tracking system—board staff were given a copy of the software application Nevada had developed to access and analyze similar AAI data. Despite Nevada receiving data from AAI in a form identical to that of Idaho, board staff told us they considered Nevada's software application inappropriate for Idaho's system, and did not attempt to use it. Board staff characterized Nevada's software application as a "skeleton" that would be unusable. Officials with the Nevada office, however, told us the application was fully usable.

- In November 1997, according to officials with Atlantic Associates, they offered the Board of Pharmacy a software application package, used by at least one other state, at a cost of $1,500 per month. However, board staff declined to use this software. Staff stated that AAI's proposal was only for report generation services instead of software that would allow the board to thoroughly use and review the prescription data. In contrast, AAI told us that in November 1997 they informed the Board of Pharmacy that the board could have full and complete access to Idaho data through a system provided by AAI. AAI also told us that in February 1998, the board and AAI specifically discussed the costs of such access.

**The board's failure to use available software or services led to an unnecessary 17 month delay in using prescription data.**

The delays were unnecessary. Two other states we contacted began using prescription data provided by AAI in a much shorter period of time. Nevada's Board of Pharmacy and the Oklahoma Bureau of Narcotics and Dangerous Drugs each had a system in place to analyze data from AAI at the time they began receiving

it. Nevada used the data from AAI immediately, and Oklahoma's system was operational within three months. Had the board used either option made available to them, the prescription tracking system could have been operational as early as November 1997.[5]

**In contrast, two other states began using prescription data within three months of contracting for the collection of this information.**

We calculated the cost of staff's decision to not use the software program offered to the board at no charge by the Nevada Board of Pharmacy. We found:

- **The Board of Pharmacy may have incurred unnecessary costs by not using software resources made available to them by another state.**

In January 1999, the Board of Pharmacy accepted a proposal from a software development firm to develop an application to import and access data from AAI. The agreement called for the firm, CRI/The Resource Group, Inc. (CRI), to provide technical assistance in two phases to construct a software program to be used as a reporting and querying tool for existing databases. As of April 21, 1999, CRI had submitted to the board invoices totaling $5,738.

**As of April 1999 a vendor had billed the board nearly $6,000 to develop a software application to use the prescription data.**

As noted, much of what CRI provided was made available to the board through other avenues in late 1997. Board staff told us, however, that CRI provided additional programming to automate information about complaints received and controlled substance registrations.

In further review, we found:

- **The Board of Pharmacy allowed its vendor to begin and complete work without a signed contract.**

CRI conducted work between January 25 and March 6, 1999, at which point work was essentially complete. However, as of June

[5] We also learned that the board may have further delayed and compromised useful analysis by failing to exercise two contractual rights: (1) The board failed to run an acceptance test on the initial data submitted by AAI. Consequently, this check was not performed to ensure the data were reliable and useful for the board; and, (2) The board failed to provide AAI officials with lists of current registered pharmacies. Because of that failure, AAI was unable to contact all non-reporting pharmacies, as required by contract. Consequently, AAI may not be receiving prescription information from all pharmacies in the state.

2, 1999, no contract has been signed. According to the board's executive director, he reached an oral agreement with CRI to develop a software application to use AAI data and drafted an agreement. The agreement also stated that "each phase [of the project] will begin upon Client's [the board's] execution of a Notice to Proceed." However, despite the work having been essentially completed, the board has not issued a notice to proceed.

**The board's failure to sign a contract with its vendor prior to the initiation of work exposed the state to unnecessary risks.**

It is impossible to determine, absent a signed agreement, whether invoices are consistent with contractual terms. Furthermore, the board's use of a contractor without having a signed contract exposed the board and the state to contractual risks and liabilities that could otherwise be avoided through a written agreement. In addition, without a signed agreement, the board faces a more difficult task in remedying problems with the software in the event problems arise.

In light of the board's handling of the CRI contract:

***We recommend Board of Pharmacy management more carefully monitor contracts to ensure work is conducted pursuant to a signed agreement.***

Furthermore, in the absence of contractual expertise in board management, contracts should be reviewed by board counsel.

It should be noted that, beginning in April 1999, the board's legal counsel reviewed the draft agreement between the board and CRI and was negotiating final terms for a written contract. Many of the changes recommended by counsel dealt with legal language required in state contracts, although others dealt with payment and notice to proceed with contract work.

We also asked board members and staff about the board's plans for using the prescription tracking system when it becomes operational. We found:

- **Despite the extended investment of time and money to develop the electronic prescription tracking system to date, the Board of Pharmacy has not developed a clear plan for using the information generated by the system.**

In our discussions, board members appeared to lack a clear understanding of the system and had not set objectives for

prescription tracking, although much of the work to develop a system for using the prescription data had already been completed. Staff had not developed a plan for regular or routine data querying of the controlled substance prescription data, and, until recently, had not received training in the software application that will be used to analyze the AAI data. Staff still lack a full working knowledge of the capabilities of the system; our discussions revealed, for example, they were unsure whether the data being queried were for the current month or the entire database, and were unable to limit data searches to a specific time period.

**The board has yet to develop a plan for how it will use the prescription data it contracted for nearly two years ago.**

According to experts, during the planning stages, an agency implementing a prescription tracking system should carefully consider ways to maximize benefit of the system, to describe its expected effects, and to prepare and distribute educational information about the system. To be fully effective, the plan should account for the needs of other health regulatory boards and law enforcement entities involved in investigating complaints of controlled substance diversion and abuse. In short, the agency should have a clear idea of how it will use the system and how information will be disseminated.[6] Consequently, the board could incur additional costs to modify the system to accomplish currently unstated objectives.

**The board could incur additional costs to modify the system if other program objectives are identified.**

Although late in the stages of development:

***We recommend the Board of Pharmacy develop a written plan for using the electronic prescription tracking system.***

This plan should be developed, in part, with other Idaho health regulatory boards and law enforcement entities to ensure that the full potential of the tracking system is being met for all agencies that deal with controlled substance diversion and abuse.

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[6] U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Establishing a State Prescription Monitoring Program* (Charleston, 1995), 3, 8–9. For example, many states with systems make the full data available to the state licensing and regulatory agencies for the health care professions and to the federal, state, and local investigative agencies that have jurisdiction over controlled substances. In addition, it is incumbent upon state agencies implementing a system to develop educational materials and make information available regarding the system because the public, many health professionals, Legislators, and other officials may not be knowledgeable about prescription accountability systems or prescription drug abuse.

**Despite indications to the Legislature when requesting funding, the new system has not eliminated a position at the board.**

Finally, we found:

- **Implementation of the prescription tracking system has not eliminated a staff position as proposed in the request to get the system started, increasing the total cost of implementation.**

In 1997, the board was six- to ten-months behind in data entry of Schedule II prescription information. According to our review of committee meeting minutes, the board explained that the tracking system could eliminate the need for a full-time position devoted to the manual entry of prescription data. The board indicated to the Legislature that it planned to finance part of the costs of the new tracking system through expected salary savings from an unnecessary data entry position that would be eliminated as a result of the new system. Although there have been staff changes, this position is still filled by a full-time employee who is partially responsible for the prescription tracking system.

# Response to the Evaluation

# Idaho State Board of Pharmacy

280 N. 8th, Suite 204 P.O. Box 83720 Boise, Idaho 83720-0067
Telephone (208) 334-2356 FAX (208) 334-3536

June 8, 1999

Nancy Van Maren
Office of Performance Evaluations
Idaho State Legislature
STATEHOUSE MAIL

Re: Response to Audit Report

Dear Ms. Van Maren:

**Introduction.**

At your request, the Board is addressing this response to you. The Board understands that this response will be attached to your Report and will be presented to the Joint Legislative Oversight Committee (Committee). With that in mind, the response has been drafted essentially for the Committee.

The Board welcomes and appreciates the input and analysis offered by the Committee's Audit Staff. The Board and its staff commend the Audit Team on their courtesy and professionalism in conducting their review.

It should be noted that the Board's Executive Director encouraged the Oversight Committee's decision to review the State's response to controlled substance diversions by private citizens.

**Time-frame for Response.**

The Board notes that the time frame for this written response encompassed only nine working days after release of the final draft. The Board is responding to a forty-three page draft report that was prepared by the Committee's staff over a period of eight months (from November 1998 to June 4, 1999). The five members of the Board are spread out in all corners of the State. Communication is made even more difficult because the Board must comply with the formalities of the open meeting laws to gather and discuss any matter, including this report. As a result, this response is necessarily general in nature. The Board's intends to more fully examine the Audit Team's findings and recommendations and to utilize them in conjunction with the Boards ongoing program to develop an improved statewide response to controlled substance diversions.

**New Board of Pharmacy Controlled Substance Program.**

a. Program Development - Database and Reporting System.

While the time frame for response has been short, the Board has been aided by the fact that it currently sits on a significant threshold with respect to the issues of citizen abuse and diversion of prescription drugs in Idaho. The Board is nearing completion of the development of its Abuse Prevention and Diversion Investigation Program which will significantly enhance the State's ability to evaluate and identify instances of abuse and diversion in Idaho.

For the past three years the Board's controlled substances investigator has been developing the Abuse Prevention and Diversion Investigation Program. This program incorporates enhanced computer technology to create a database compiled from all prescriptions for controlled substances (Schedules II through IV) filled by pharmacies in the state. This database will allow tracking and reporting of these prescriptions by patient, the prescribing practitioner, the prescribed substance, and the time and place the prescription was filled. The data can be organized and reported along any of these criteria. To illustrate these capabilities, Exhibit A to this response is a draft of the Functional Requirements Document prepared by CRI, The Resource Group, the firm retained by the Board to create the software for accessing and reporting this data.

With this information, the Board's Controlled Substances staff will be better able to aid pharmacists, practitioners, licensing boards and law enforcement in identifying instances of citizen abuse and diversion. This information will also improve the Board's own investigative abilities with respect to actions against its licensees or in aid of actions by other boards against their licensees. With this information the Board can give local law enforcement a quicker start identifying and acting against citizen diverters.

This information gathering and disbursing function has been perceived by the Board as one of its primary duties under Idaho's Controlled Substances Act.

b. Integration with Existing Diversion Prevention Programs.

The Board's new program is intended to work in conjunction with the Board's existing program of duplicate prescriptions of controlled substances. The duplicate prescription program mandates that all prescriptions for Schedule II drugs (the prescription drugs deemed by the Board to be the most dangerous and addictive) be written on serially numbered documents which are specific to the prescribing practitioner. A duplicate copy of each prescription is retained by the practitioner. These documents are highly controlled, and, as a result, diversion of Schedule II drugs through forgery or alteration of prescriptions (two common methods of citizen diversion) is virtually non-existent in Idaho.

The Federal Government has recognized that the combination of a duplicate prescription program and prescription tracking as the most efficient method for controlling diversion of prescription drugs. Idaho may well be the first state to implement both.

c. Remaining Steps to be Completed

Two additional steps must be completed before the program can reach its full potential. First, in order for the State of Idaho to get the most "bang for the buck" from this program, there must be cooperation and participation among all medical licensing boards and law enforcement.

The gathering of information without corresponding action serves no purpose. The Board of Pharmacy has little power, questionable jurisdiction, and few resources to act upon the information it gathers about citizen prescription drug abuse. The Board of Pharmacy's expertise lies in the identification of those substances susceptible to abuse, and the identification of instances where the prescription information available to the Board indicates the probability that abuse exists.

The two groups with the expertise, the jurisdictional power and the ability to act against specific instances of abuse are 1) the prescribing medical community, and 2) law enforcement. The Board agrees wholeheartedly with the Audit Team that now is the time for an interagency task force to examine the means to address prescription drug abuse in Idaho.

In addition to interagency cooperation and participation, the second step is to establish a clear legal framework governing the gathering and use of this highly sensitive and personal medical information. Given the legal environment in which we all live and operate (sue first and ask questions later), the State can ill afford the legal risks inherent in moving ahead without a solid legal basis. The power and the right to gather information, and the power and right to act on that information must be clearly established. The mechanisms necessary to protect the honest and proper use of medications must also be established.

Once again, there will be a need for interagency cooperation and participation in this area. The expertise of the pharmacists, the prescribing medical community and law enforcement must all be called upon to see that all aspects of the program are properly and adequately addressed in statute and rule.

**Specifics of the Audit Report.**

a. Chapter 2 - Investigative file documentation and formalized investigation procedures.

The findings and recommendations of the Audit Team set out in Chapter Two of its Report can be encapsulated into 1) investigative file documentation and 2) formalizing investigation procedures. The Audit Team finds room for improvement in both documentation of investigations and in formalizing the investigation procedures.

The Audit Team reviewed 509 Board case files which the Audit Team deemed to be "complaint" files. Eighty-six percent of these files involved information received by the Board's investigator regarding non-licensed individuals.

The Board has traditionally defined a "complaint" as a matter where the Board has both jurisdiction over the individual and actual power to act against the individual. This definition encompasses Licensed Pharmacists and registered or licensed pharmacies where the Board has direct disciplinary jurisdiction and regulatory power. This definition also encompasses, to a lesser degree, other licensed practitioners with controlled substance licenses. The Board has traditionally viewed its jurisdiction and power over these non-pharmacist licensees as secondary to the jurisdiction and power of the individual's professional licensing board.

It is only arguable at best, that this definition would include matters dealing with unlicensed individual citizens. The Board has traditionally viewed its responsibility in this area as one of information gathering and aid to law enforcement.

The differences in what the Audit Team determined to be a "complaint" and what the Board viewed as a complaint, highlight the need for a more defined interagency response to citizen abuse of prescription drugs.

Irrespective of these differences, the Board recognizes the Audit Teams point that there is a need for improvement with respect to investigative file documentation and the development of more formal investigative procedures and guidelines. The Board intends to use this Audit Report as a basis for developing file documentation requirements and more formal investigative procedures, including increased oversight.

At the same time, the Board notes that while it may have relied on the unwritten judgment of its Controlled Substance investigator more than it should, there has not been any indication that this reliance was misplaced in any significant fashion. The Board's investigator has a fine reputation in the medical and law enforcement community. Our investigator has earned the respect of the Board, other licensing Boards and law enforcement over his 16 years of service to the Board and the State. Attached to this response are letters from other licensing boards and law enforcement officials indicating this respect and support.

b. Chapter 3 – Action against Citizen Diverters.

As discussed above, the Board agrees with the Audit Teams recommendations in Chapter 3 regarding an interagency task force. The Board welcomes the creation of such a force and looks forward to many benefits from active participation in the task force.

c. Chapter 4 – Prescription Tracking System.

The Board has been laboring for the last three years on the prescription tracking system, as a major part of its Abuse Prevention and Diversion Investigation Program. The idea of such a system as an enhancement to the State's ability to prevent prescription drug abuse, goes back even further. The program being developed is specifically tailored to Idaho's needs, while still drawing on the expertise and experience of other jurisdictions. While there is always room to improve operations, the Board feels that its staff developed this program in good fashion within the budgetary and staffing parameters available.

The Board appreciates the analysis and recommendations of the Audit Team with respect to the implementation of this program. The Board also recognizes that this program deals with medical information about Idaho citizens that is highly sensitive and personal. The Board agrees that a clear plan and procedure for the use of this information is critical. The Board continues to work in this area. The procedural and legal requirements of the Board's Abuse Prevention and Diversion Investigation program, encompass both the medical community and law enforcement as a whole. The Board urges policymakers to assist by establishing an inter-agency task force to ensure a fully integrated program that will give the State of Idaho the best program for its investment.

**Closing.**

This Audit Report focussed solely on the Board of Pharmacy's role with respect to controlled substances. Let us not lose sight of the fact that the major impetus for this Committee's attention was the unfortunate experience of Renee Wilson, a private citizen. **The Policymakers want to know what the system can do about citizen diversion of prescription drugs.** How can the State (not only the Board of Pharmacy, but the remainder of the medical community and law enforcement community) prevent such a tragic abuse by its citizens? The Board's Prevention Program may go a long ways towards more quickly identifying these people. However, the issue remains, how can these people, once identified, get the help, treatment and counseling that they so desperately need to escape the cycle of abuse and diversion?

It is clear that answers to these questions are difficult. It is equally clear that for any program to have a practical impact, there must be a statewide organized and uniform response. The Board looks forward to working with the Legislature and other state agencies as a part of that statewide, organized and uniform response.

Very truly yours,

Frank Casabonne

FRANK CASABONNE
Vice Chairman
Idaho Board of Pharmacy

/pm

Note: Exhibits referenced in this response are available upon request through the Office of Performance Evaluations.

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