

Regulatory Board Evaluation

**West Virginia
Board of Pharmacy**

**The Board of Pharmacy Is Needed
to Protect Public Interest**

**The Board Complies with the General Provisions
of Chapter 30**



**September 2002
PE02-17-249**

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John Sylvia
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September 15, 2002

The Honorable Edwin J. Bowman
State Senate
129 West Circle Drive
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The Honorable Vicki V. Douglas
House of Delegates
Building 1, Room E-213
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0470


Dear Chairs:

Pursuant to the West Virginia Sunset Law, we are transmitting a *Full Performance Evaluation of the Division of Culture and History*, which will be presented to the Joint Committee on Government Operations on Sunday, September 15, 2002. The issue covered herein is "There is a Risk of Loss to the Archives and Museum Collections Due to Inadequate Storage and Insufficient Fire Protection."

We transmitted a draft copy of the report to the Division of Culture and History on August 28, 2002. We held an exit conference with the Division on September 3, 2002. We received the agency response on September 6, 2002.

Let me know if you have any questions.

Sincerely,


John Sylvia

JS/wsc

Joint Committee on Government and Finance

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Executive Summary

Issue 1: The Board of Pharmacy Is Needed to Protect Public Interest

Pharmacists are responsible for dispensing prescription medications, informing the consumer of possible side effects related to medications, ensuring that special directions and precautions for the medication are communicated to the patient, and providing techniques for self-monitoring drug therapy. These functions could be potentially harmful to the public if competency is not regulated. There is also a need for registration of pharmacy technicians. Pharmacy technicians are involved in preparing and dispensing medications. **There is a risk of physical harm, or even death, if the pharmacist and pharmacy technician professions were not regulated.** In addition to the licensing of pharmacists and pharmacy technicians, the Board of Pharmacy registers pharmacies, mail-order houses, wholesale distributors, and pharmacist consultants. The registration of these entities is also needed for public safety. **Therefore it is the opinion of the Legislative Auditor that it is necessary to continue licensing this profession to provide for protection of public health and safety.**

Issue 2: The Board Complies with the General Provisions of Chapter 30

The Legislative Auditor finds that the Board of Pharmacy has complied with applicable state laws and rules. These laws and rules, primarily found with the Board's own article of Code and in the general provisions of Chapter 30, are important in the effective operation of a licensing board.

The Board has developed an easy to use website with links to a wide range of information, such as general information on Board members, investigators, address, laws and some continuing education hours. In addition, the site displays licensees or registrants who currently have disciplinary action being taken against them. These are all very useful; however, the website could be revised to provide more in-depth information to the public.

Recommendations

1. *The Legislative Auditor recommends that the Legislature continue to require pharmacists, pharmacist interns, and pharmacy technicians be licensed by the State of West Virginia.*

2. *The Board should consider adding the following items to its website: a detail of Board-approved continuing education courses currently being offered, a listing of current licensed pharmacists, pharmacy technicians, terminal drug distributors, and wholesale drug distributors for verification, links to information necessary for obtaining various permits and registrations and details of pharmacists who have any illegal activity brought against them.*

Review Objective, Scope and Methodology

A Chapter 30 board review of the Board of Pharmacy is required and authorized by the West Virginia Sunset Law, Chapter 4, Article 10 of the West Virginia *Code*, as amended. As stated in the *Code*, a regulatory board evaluation is to determine whether a Board is 1) necessary for the protection of public health and safety, and 2) whether the Board is operating in compliance with applicable laws and rules.

This regulatory board evaluation covers the period from Calendar Year 1999 through June 2002.

Information for this report was compiled from annual reports, survey of complaint files, board minutes, expenditures, licensure qualifications, and continuing education information.

Issue 1

The Board of Pharmacy Is Needed to Protect Public Interest

This report is a *Regulatory Board Evaluation*, which requires by law a determination of whether or not the Board of Pharmacy is necessary for the protection of public health and safety. In determining if there is a need for the Board, a primary consideration is whether the unregulated practice of the profession would clearly endanger the public. **The finding of this issue is that licensing pharmacists is necessary for protecting the citizens of West Virginia.**

Licensure for Pharmacists

The Board of Pharmacy has 1,655 pharmacists. The primary responsibility of a pharmacist is to:

- i Dispense prescription medications;
- ii Inform the consumer of any possible side effects related to medications;
- iii Ensure that special directions and precautions for preparation, administration, storage, and use of the medication by the patient are communicated; and
- iv Provide techniques for self-monitoring drug therapy.

Currently, all states have a licensing board to regulate the practice of pharmacy.

Currently, all states have a licensing board to regulate the practice of pharmacy. Without proof of a pharmacist's competence via the examination and licensure process, uneducated and incompetent individuals could be preparing potentially lethal drugs for dispensing to patients. The possible consequences of an unregulated pharmacist could result in death.

In addition to licensing pharmacists, the Board oversees the licensure of pharmacist interns. As of July 2002, the Board licensed 346 interns. All interns must work 1500 hours under the direct supervision of a licensed pharmacist before the intern can become a fully licensed pharmacist. Licensed interns may compound, assist in preparing, and dispense prescriptions and prescription refills.

Registration of Pharmacy Technicians

West Virginia was one of the first ten states to register pharmacy technicians...

Pharmacy Technician is defined in the WV Code (30-5-1b(w)) as *registered supportive personnel who work under the direct supervision of a pharmacist who have passed an approved training program.* There are a total of 1,931 pharmacy technicians currently registered in the State. West Virginia was one of the first ten states to register pharmacy technicians; there are now 25 states that register pharmacy technicians.

Work tasks of pharmacy technicians may include the following: receipt of prescription requests, retrieval and measurement of medication, preparation of labels and prescription containers, stocking and taking of inventory, and maintenance of patient profiles. Given the level of involvement pharmacy technicians have in preparing and dispensing medications, there is a risk of physical harm, or even death, if the profession were not regulated. As a result, the Legislative Auditor feels that the registration of pharmacy technicians is necessary for the protection of the public.

Pharmacists	1,655
Pharmacy Technicians	1,931
Interns	346

Registration of Mail-Order Houses, Wholesale Distributors, Pharmacies, and Pharmacist Consultants; Permits Issued for Manufacture and Packaging of Drugs or Medicines

In addition to the licensure and registration of pharmacists, interns, and pharmacy technicians, the Board is required to register mail-order houses, wholesale distributors, pharmacies, and pharmacist consultants, and to issue permits for the manufacture and packaging of drugs or medicines. Table 2 illustrates the total number of registrations and permits issued as of February 2002:

Table 2
Registrations and Permits Issued for Mail-Order Houses, Pharmacies,
and for the Manufacture and Packaging of Drugs or Medicines

Type of Registration/Permit	Number Issued
Mail-Order Houses	239
Wholesale Distributors	417
Pharmacies	563
Pharmacist Consultants	268
Manufacture and Packaging of Drugs or Medicines	10

Source: Rosters provided by the Board of Pharmacy

West Virginia relies upon other state boards of pharmacy to conduct a thorough inspection of the pharmacies in their respective states that hold a mail-order pharmacy permit from our state, and they rely upon West Virginia to do the same for mail-order pharmacies in West Virginia. Also, there are pharmacies in West Virginia that obtain a mail-order pharmacy permit from the state because more than 10% of their annual prescription volume is delivered by US mail or otherwise. Once the mail-order pharmacies are approved, they must renew their permit annually and send annual inspection results. Given the role the above entities play in the distribution of drugs to the public, it is the opinion of the Legislative Auditor that the registrations and permits issued are an important function of the Board of Pharmacy in the protection of the public.

Inspections of Pharmacies

To oversee the inspection of pharmacies, the Board of Pharmacy employs four part-time inspectors. These inspectors are retired pharmacists who work out of their homes. There are 563 pharmacies divided between the inspectors. Specific duties of the inspectors include the following:

- i Inspection of pharmacies applying for an initial registration;
- ii Biennial inspection of existing pharmacies (note that in the year that a pharmacy is not up for a review, a self inspection must be completed by the pharmacy and returned to the inspector);

-
- ï Advise on consumer complaints; and
 - ï Assistance in the administration of exams, reciprocity agreements, and technician exams.

Each inspector covers a specific region of the State. Some of the requirements an inspector looks for when evaluating a pharmacy are:

- ï Security of the pharmacy;
- ï Professional work environment;
- ï Drug reliability (i.e. outdated drugs);
- ï Controlled substance records;
- ï Adequate completion of responsibilities by the pharmacy technicians and the pharmacist-in-charge; and
- ï Accurate and up-to-date continuing education certificates.

Conclusion

It is the opinion of the Legislative Auditor that it is necessary to continue licensing this profession to provide for the protection of public health and safety.

Pharmacists, pharmacist interns, and pharmacy technicians are responsible for dispensing drugs to the consumer. These drugs, if dispensed improperly by pharmacists, could be lethal. As a result, there is a risk to the public if competency is not regulated. It is the opinion of the Legislative Auditor that it is necessary to continue licensing this profession to provide for the protection of public health and safety. In addition to licensing pharmacists, pharmacist interns, and pharmacy technicians, the Board of Pharmacy oversees the registration of mail-order houses, wholesale distributors, pharmacies, and pharmacist consultants, and the issuance of permits for the manufacture and packaging of drugs or medicines. Given the level of involvement all of these entities have in the distribution of drugs to the public, the Legislative Auditor sees the issuance of these registrations and permits by the Board of Pharmacy to also be necessary in the protection of the public. Finally, the Board of Pharmacy employs four part-time inspectors to visit pharmacies. These inspections help ensure the security of the drugs maintained within a pharmacy and assist the Board of Pharmacy in monitoring drug reliability and controlled substance records.

Recommendation 1

The Legislative Auditor recommends that the Legislature continue to require pharmacists, pharmacist interns, and pharmacy technicians be licensed by the State of West Virginia.

The Board Complies with the General Provisions of Chapter 30

The Board of Pharmacy has complied with applicable state laws and rules. These laws and rules, primarily found within the Board's own article of Code, and in the general provisions of Chapter 30, are important in the effective operation of a licensing board. The Board has complied with the following:

- i The Board is listed in the state government section of the Charleston area telephone book and it has enhanced its accessibility through the development of a useful internet site (β30-1-12(c));
- i A Board representative attended the orientation session provided by the State Auditor's Office in the required two year time frame (β30-1-2a(e));
- i The Board meets at least once annually (β30-1-5(a));
- i The Board maintains a record of its proceedings (β30-1-12(a));
- i The Board submits annual reports to the Governor and the Legislature (β30-1-12(b));
- i The Board conducts open meetings and gives timely public notice (β30-1-5(a));
- i The Board maintains a roster of licensees and a register (β30-1-12);
- i The Board maintains a permanent and historical record of the names of all pharmacists, interns, and pharmacy technicians (β30-5-2(a));
- i The Board reports to the Secretary of State a list of all pharmacists (β30-5-8);
- i The Board utilizes increased fees for the employment of an investigator, including the reimbursement of expenses and salary of the investigator; any remaining funds are allocated to the Board to be used for operating purposes (β30-5-14b).

Continuing Education Requirements

Continuing education hours are verified upon yearly inspection of the pharmacy by presenting a certificate of hours completed for the previous year.

The Board of Pharmacy requires pharmacist licensees to complete 30 hours of continuing education biennially, of which at least two hours of continuing education course work shall be in the subject of end-of-life care, including pain management, during each continuing education reporting period. Continuing education hours are verified upon yearly inspection of the pharmacy by presenting a certificate of hours completed for the previous year. Pharmacists must keep copies of their continuing education certificates at the pharmacy and must present these during routine inspections of the pharmacy. A self-inspection report also emphasizes the requirement to keep records of continuing education credits at the pharmacy for further verification.

During a pharmacist's period of internship, the intern must submit an internship affidavit that lists the hours obtained and is verified by their pharmacist preceptor. If the hours were obtained through a school curriculum, a letter from the institution's school of pharmacy is required to verify the hours. If the hours were obtained in another state, a letter of verification from that state's Board is required. A total of 1500 hours of internship is required before the intern can become a licensed pharmacist.

Complaint Process

The Board logs all complaints. Table 3 shows the total number of complaints for the past five years and the actions taken.

Year	# of Complaints	Dismissed	Pending	Letter of Caution	Probations	Suspensions/Revocations	Consent
1997*	10	5	0	2	2	1	2
1998*	24	8	1	5	2	1	9
1999	21^	8	0	3	0	0	9
2000	19	10	0	4	0	0	6
2001	46	12	7	13	0	0	13

**In the years 1997 and 1998 four of the complaints had more than one action taken.
^One of the complaints from 1999 was turned over to the Drug Enforcement Agency.*

Due process is provided by the Board as required in §30-1-5(b) for licensees against whom a complaint has been filed. The Board's rules outline the procedures for investigation and resolution of complaints, denied licensees and hearing procedures. The Board acknowledges complaints. A brochure is mailed to the licensee with a notice of complaint outlining the Board's disciplinary procedures. The licensee is informed of his/her rights for responding to the complaint, a description of the process, and the possible timeliness of the final order. Allegations can be denied by the licensee and a hearing can be brought before members of the Board and/or a hearings officer.

A full review of the complaint files found that in 2000 and 2001, 90% of the complaints were resolved in six to nine months.

The Board conducts investigations upon receiving consumer complaints or any indication of drug diversion activity and takes appropriate disciplinary action against the licensee or permit holder or seeks criminal prosecution, if necessary. The total time concerning the resolution of a complaint will vary depending upon the complexity of the investigation. A full review of the complaint files found that in 2000 and 2001, 90% of the complaints were resolved in six to nine months. If the complaint filed indicates that there is an immediate threat to the public harm, it will be dealt with immediately, so that a dangerous licensee would be removed from practice. Otherwise, once the investigation is complete, it is presented to the complaint committee, which makes a recommendation on the action to be taken. Periodically, a Disciplinary Actions Report is sent to the National Association of Board of Pharmacy (NAPB). The NAPB is the authorized reporting body for the West Virginia Board of Pharmacy to enter this information into the National Practitioner Data Bank and the Healthcare Integrity & Protection Data Bank (NPDB-HIPDB).

Regarding criminal proceedings of pharmacists involving drugs, the Board assists the Drug Enforcement Agency (DEA) and the United States Attorney's Office by providing investigative support, collection of evidence, and testimony from its investigator. This involvement allows the Board to identify and investigate possible convictions of pharmacists. Upon acceptance of that recommendation, the letter of dismissal, letter of caution, or proposed consent agreement is sent to the licensee. The amount of time until final action then could also depend upon whether the consent is immediately accepted or negotiations regarding a counterproposal are necessary. The amount of time is never dependent upon the type of sanction that is being sought, only upon the amount of time needed to come to a final resolution of the matter.

Voluntary Agreements

As stated in the West Virginia Code §30-5-7b:

In order to encourage voluntary reporting of alcohol or other chemical dependency impairment and in recognition of the fact that alcoholism and chemical dependency are illnesses, a pharmacist or pharmacy technician or other licensee or registrant or the board may enter into a voluntary agreement with the board reporting his or her participation in an alcohol or chemical dependency treatment program or reporting an alcohol or chemical dependency impairment to the board and seek treatment for his or her dependency.

The Board of Pharmacy is allowing pharmacists to enter into voluntary agreements in accordance with the Code. As of July 2002, 9 pharmacists entered into such agreements. During the 2002 legislative session, House Bill 4277 was passed, which expanded legislation on voluntary agreements. Specifically, House Bill 4277 provides authorization for the Board of Pharmacy to enter into agreements with organizations to form pharmacist recovery networks (PRNs). The PRNs are in place to assist in the identification and treatment of pharmacists suffering from alcohol or drug abuse or a physical or mental condition. According to the Board, it is awaiting review by the Legislative Rule-Making Review Committee and will begin operation of the PRN upon approval of the legislative rules. Until the PRNs are in use by the Board, any reports of impairment continue to be handled through the Board office and the voluntary agreement process.

Public Accessibility

The Board has developed an easy to use website with links to a wide range of information, such as general information on Board members, investigators, address, laws, and some continuing education hours. In addition, the site displays licensees or registrants who currently have disciplinary action being taken against them. These are all very useful; however, the website could be revised to provide more in-depth information, such as:

- i Detail of Board approved continuing education courses currently being offered;
- ii A listing of current licensed pharmacists, pharmacy technicians, terminal drug distributors, and wholesale drug distributors for verification;
- iii Links to information necessary for obtaining permits for West Virginia pharmacies, out-of-state pharmacies, wholesale/manufacture, etc.; and

- i A list of pharmacists who have had any illegal activity brought against them.

The Board has sought to make a large amount of information available; however, it is the opinion of the Legislative Auditor that the Board could make further improvements to provide information to its licensees and to the public.

Financial Self-Sufficiency

Financial self-sufficiency of regulatory boards is required by West Virginia Code §30-1-6(c). The Board had a starting cash balance for FY 2001 of \$367,011. The Board's licensing fees and administrative fees imposed against its licensees are remitted to the Board's special revenue fund, and the fines imposed are remitted to the State's general fund in accordance with the Code §30-1-8. As shown in Table 4, the Board is self-sufficient.

	FY 1999	FY 2000	FY 2001
Revenues	\$244,138	\$805,298	\$422,077
Expenditures	\$395,787	\$492,026	\$469,935
EOY Cash Balance	\$53,740	\$367,012	\$319,153
<i>Source: FIMS Reports</i>			

According to the Board of Pharmacy, the fluctuation found in the revenues within FIMS are due to the timing of the Board's license renewal period, which overlaps the end of the fiscal year. Most fees are received by the Board during May, June, July, and August. Depending on the *timing of deposit*, 2001 fees can be deposited during fiscal year 2000, if those fees were received in May or June 2000. The Board does maintain a separate record of the appropriate year fees received relate to, which shows that the Board has averaged approximately \$650,000 in revenue over the past two fiscal years.

Conclusion

The Board of Pharmacy has complied with the general provisions of Chapter 30 of the West Virginia Code. The Board is accessible to the public through its telephone listing and its website. The Board meets regularly and maintains adequate records of its meetings. Also, the Board requires and verifies continuing education of its licensees, responds to complaints, provides due process to licensees against whom a complaint has been filed and maintains financial independence. The Board fully complies with the Open Meetings Law and maintains a register as required by §30-1-12.

Recommendation 2

The Board should consider adding the following items to its website: a detail of Board approved continuing education courses currently being offered, a listing of current licensed pharmacists, pharmacy technicians, terminal drug distributors, and wholesale drug distributors for verification, links to information necessary for obtaining various permits and registrations, and details of pharmacists who have any illegal activity brought against them.



Appendix A: Transmittal Letter to Agency

WEST VIRGINIA LEGISLATURE *Performance Evaluation and Research Division*

Building: L, Room W-314
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0610
(304) 347-4890
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John Sylvia
Director

August 27, 2002

William T. Douglass, Jr.
Board of Pharmacy
232 Capitol Street
Charleston, WV 25301-2206

Dear Mr. Douglass:

This is to transmit a draft copy of the Regulatory Board Evaluation of the Board of Pharmacy. This report is scheduled to be presented at the Sunday, September 15, 2002 interim meeting of the Joint Committee on Government Operations. It is expected that a representative from your agency be present at the meeting to orally respond to the report and answer any questions the committee may have. If you would like to schedule an exit conference to discuss any concerns you may have with the report between August 28, 2002 and September 4, 2002, please notify us. We need your written response by noon on September 5, 2002 in order for it to be included in the final report.

We request that your personnel treat the draft report as confidential and request that it not be disclosed to anyone except those agency employees who will prepare the response to the report or who will participate in the exit conference. Thank you for your cooperation.

Sincerely,

Handwritten signature of John Sylvia in cursive script.
John Sylvia

Joint Committee on Government and Finance

Appendix B: Agency Response



Board of Pharmacy

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September 5, 2002

John Sylvia, Director
West Virginia Legislature, Performance Evaluation and Research Division
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Dear Mr. Sylvia:

I am writing to respond to the Regulatory Board Evaluation of the Board of Pharmacy. The Board agrees with the content of the report and accepts the recommendations provided therein. The Board was already in the process of gaining the capability to upload information about continuing education courses to the website. A listing of current licensees for verification will be possible in the near future through a program that the National Association of Boards of Pharmacy (NABP) is starting called Renewal Application Processing System (RAPS) which will allow the public to verify licensure status online and allow licensees to renew online. The other suggestions for improvement to the website would be beneficial and will be pursued by the Board. I thank you for the opportunity to respond to the report and would like to thank your staff for their professionalism and courtesy throughout this process.

Sincerely,

A handwritten signature in black ink, appearing to read "William T. Douglass, Jr.".

William T. Douglass, Jr.
Executive Director and
General Counsel

