

July 2022 PE 22-01-651

# REGULATORY BOARD REVIEW BOARD OF PHARMACY

# AUDIT OVERVIEW

Regulation of the Practice of Pharmacy Is Needed to Protect Public Health and Safety

The West Virginia Board of Pharmacy Complies with Most General Provisions of Chapter 30 of West Virginia Code

The Board Could Provide More Active Oversight of the Controlled Substance Monitoring Program's Contract Deliverables

Due to Inadequate Oversight of the Impaired Health Condition Treatment Program, the Board Does Not Have Reasonable Assurance that the Public Is Protected Against Improper Practice by Impaired Licenses

The West Virginia Board of Pharmacy's Website Needs Modest Improvements to Enhance User-Friendliness and Transparency

In Response to Concerns About Retention of CSMP Data, The Board Changed Requirements in the Contract with the Vendor to Reflect the Board's Practice



WEST VIRGINIA OFFICE OF THE LEGISLATIVE AUDITOR PERFORMANCE EVALUATION & RESEARCH DIVISION

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John Sylvia Director

June 13, 2022

The Honorable Mark Maynard West Virginia State Senate Building 1, Room 217-W 1900 Kanawha Boulevard, East Charleston, West Virginia 25305-0470

The Honorable Brandon Steele West Virginia House of Delegates Building 1, Room E-213 1900 Kanawha Boulevard, East Charleston, West Virginia 25305-0470

Dear Chairs;

Pursuant to the West Virginia Performance Review Act, we are transmitting a Regulatory Board Review of the Board of Pharmacy. The issues covered herein are "Regulation of the Practice of Pharmacy Is Needed to Protect Public Health and Safety," "The West Virginia Board of Pharmacy Complies with Most General Provisions of Chapter 30 of West Virginia Code," "The Board Does Not Exercise Adequate Oversight of the Controlled Substance Monitoring Program's Contract Deliverables," "Due to Inadequate Oversight of the Impaired Health Condition Treatment Program the Board Does Not Have Reasonable Assurance that the Public Is Protected Against Improper Practice by Impaired Licensees," "The West Virginia Board of Pharmacy's Website Needs Modest Improvements to Enhance User-Friendliness and Transparency," and "The Board Has Changed Requirements for CSMP Data Without Updating the Contract with the Vendor."

We transmitted a draft copy of the report to the Board of Pharmacy on May 23, 2022. We held an exit conference on June 1, 2022. We received the agency response on June 6, 2022.

Let me know if you have any questions.

John Sylvia

Joint Committee on Government and Finance

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# EXECUTIVE SUMMARY

The Performance Evaluation and Research Division (PERD) within the Office of the Legislative Auditor conducted a regulatory board review of the West Virginia Board of Pharmacy pursuant to West Virginia Code §4-10-10(b)(3). Objectives of this audit were to assess the continued need for the Board, its compliance with the general provisions of Chapter 30 and other applicable laws, assess its contract management and security governance practices for the Controlled Substance Monitoring Program, assess its contract management practices concerning the pharmacist recovery network, and evaluate the Board's website for user-friendliness and transparency. The issues of this report are highlighted below.

## **Frequently Used Acronyms**

PERD – Performance Evaluation and Research Division
W. Va. Code – West Virginia Code
OASIS – Our Advanced Solution with Integrated Systems
W. Va. CSR – West Virginia Code of State Rules
NABP – National Association of Boards of Pharmacy
CPE – Continuing Professional Education
CSMP – Controlled Substance Monitoring Program
HIPAA – Health Insurance Portability and Accountability Act
PRN – Pharmacist Recovery Network
RSS – Really Simple Syndication
FOIA – Freedom of Information Act

### **Report Highlights:**

# Issue 1: Regulation of the Practice of Pharmacy Is Needed to Protect the Public Health and Safety

- In 2002, the legislative auditor recommended continuation of the Board.
- The unregulated practice of pharmacy can result in death and substantial public harm.
- As of FY 2020, the Board has 16,759 licensees, registrants, and permittees.
- All 50 states regulate the practice of pharmacy.

# **Issue 2: The West Virginia Board of Pharmacy Complies with Most General Provisions of Chapter 30 of West Virginia Code**

- The Board is financially self-sufficient.
- The Board has established continuing education requirements.
- The Board has taken steps to reduce the risk of fraud.
- The Board is aware of handicap accessibility needs.
- The Board's rules generally protect the public.

## Issue 3: The Board Could Provide More Active Oversight of the Controlled Substance Monitoring Program's Contract Deliverables

- W. Va. Code §60A-9-3 requires the Board to maintain the Controlled Substance Monitoring Program, which tracks the prescribing and dispensing of controlled substances throughout the state.
- The Controlled Substance Monitoring Program is a public health tool.
- The Board has not attended to security provisions in its contract that would verify secure processes are in place and that the vendor would alert it to potential security breaches.
- Introducing a mechanism to monitor vendor compliance with contract provisions would introduce a critical layer of oversight to the administration of the Controlled Substance Monitoring Program

## Issue 4: Due to Inadequate Oversight of the Impaired Health Condition Treatment Program, the Board Does Not Have Reasonable Assurance that the Public Is Protected Against Improper Practice by Impaired Licensees

- The Pharmacist Recovery Network was established to encourage impaired pharmacy professionals to seek treatment for substance abuse and mental health issues.
- The Board has engaged a third-party vendor to administer the Pharmacist Recovery Network.
- The Board has limited knowledge of the Pharmacist Recovery Network's compliance with contract requirements.
- The Board should amend W. Va. CSR §15-10 et al. to allow for greater Board oversight of the program.
- The Board has accumulated an excess of funds related to the operation of the Pharmacist Recovery Network.

# **Issue 5: The West Virginia Board of Pharmacy's Website Needs Modest Improvements to Enhance User-Friendliness and Transparency**

- The Board's website needs additional features and content to enhance user-friendliness and transparency.
- There is a need for state government website standardization.

## Issue 6: In Response to Concerns About Retention of CSMP Data, The Board Changed Requirements in the Contract with the Vendor to Reflect the Board's Practice

• The Board changed the requirements for the management of the CSMP data within the contract to address PERD's concerns and to reflect the policy and practice of retaining data beyond the five-year window specified in the prior contract. Data older than five years are now retained in a separate and secure database.

# PERD's Response to the Agency's Written Response

On June 6, 2022, PERD received the Board of Pharmacy's written response, which is provided in Appendix D of this report. The Board indicates that it "is open to suggestions for how to better serve the public

and operate more efficiently and effectively" but takes issue with many of the findings and recommendations contained within this report. Below is PERD's response to some of the Board's comments on the report.

Agency Response: "Board Rule §15-9-2.5. states "[t]he board shall maintain a complaint log which records the receipt of each complaint, and the nature and the disposition of the complaint." In the State of West Virginia, administrative rules have the same force and effect as law. Therefore, the requirement that the Board maintain a Complaint Log is binding on the Board and the Complaint Log is an official state document required by law. PERD has determined that the Complaint Log is an insufficient record with respect to the dates recorded."

**PERD's Response:** This is incorrect. The rule the Board is referring to W. Va. CSR §15-9-2.5 is a procedural rule. Procedural rules are not approved by the Legislature and do not carry the full weight of law. Moreover, as further discussed below, PERD's issue is based upon the application of W. Va. Code §30-1-5, which mandates certain actions based upon the date *"of the complaint being filed"* rather than the issue of what is the correct ledger of record. The greater problem is that the Board is using the wrong date than required by statute. The correct date is the date that the compliant was actually received by the Board, not the date that the Board sent the compliant to be investigated.

PERD examined the complaint log provided by the Board and found inconsistencies between the information contained within the log and the documentation available in the complaint file. Furthermore, the dates contained in the log do not match the date the complaints were sent to investigators in each instance, despite the Board stating that it considers complaints filed when they are sent to investigators. Therefore, the dates in the complaint log do not follow the Board's stated procedure for filing complaints. PERD is not disputing that the complaint log should be maintained as required by W. Va. CSR §15-9-2.5, but documentation should nonetheless support the dates contained there. Rather, PERD is recommending the Board use the date a complaint is received, whether via online submission, United States Mail, or email as the date a complaint is filed. This is consistent with the requirements in W. Va. Code §30-5-1(c), which states that "Every board referred to in this chapter shall investigate and resolve complaints which it receives and shall, within six months of the complaint being filed, send a status report to the party filing the complaint and the respondent...' As W. Va. Code indicates, the status report is sent to the complainant within six months of being filed by the complainant. Thus, the date of receipt should be the date of record. Similarly, the Board itself, within W. Va. CSR §15-9-2.5 states that the complaint log is to record the receipt date by stating that the "Board shall maintain a complaint log which records the receipt of each complaint...". The rule does not contemplate using the wrong date. The Board should maintain complete complaint files and it is recommended that the information is kept in both the complaint log and the file itself. Moreover, the Board should confirm that the complaint log matches the files. As stated in the report, PERD recommends the Board adopt the practice of timestamping the receipt of complaints to avoid any discrepancies and comply with both W. Va. Code §30-5-1(c) and W. Va. CSR §15-9-2.5 by maintaining documentation of the date a complaint is received by the Board.

Agency Response: The Board indicated that PERD's analysis concerning the timeliness of the status reports was incorrect. The Board stated that all complaints PERD sampled had status reports sent as required.

**PERD's Response:** After review of the complaint files that we sampled, PERD acknowledges that the Board is correct and that all sampled complaints had the appropriate status reports, and they were timely. Therefore, PERD removed what was formerly recommendation 3 of the report which recommended the Board send status reports as required by law.

Agency Response: "Additionally, on Table 4 of PERD's report they state that one status letter did not comply with statutory timelines. PERD identified this as case number 2018-09-44."

**PERD's Response:** Upon review of its complaint analysis, PERD agrees that case number 2018-09-44 was included as not compliant with statutory timelines in error. PERD has amended the report to reflect this and thanks the Board for its attention to detail and timeliness in providing this correction.

Agency Response: "PERD conflates two very distinct types of cases: self-reported cases and Board referred cases. PERD states that the Board does not know if the PRN makes required contact. For self-reported cases, such contact does not make sense as by the very nature of the cases they are self-reporting and initial contact does not come into play. Therefore, no, the Board does not follow up on this as it does not occur. For Board referred cases, PERD's claim is entirely incorrect. The Board will work with the executive director on contacting the licensee and will be involved in every step of the process. The Board will know if the licensee is complying with the PRN or if they are refusing to do so."

**PERD's Response:** The problem with the Board's argument is that it is making a distinction between Boardreferred and self-reported licensees when the contract makes no such distinctions. Since there is no distinction in the contract between these two different referrals, the Board is providing a verbal interpretation of what the contract means. This is inappropriate because the contract should be very clear and explicit in what is required of the vendor. Moreover, this is required to avoid any possible liability that could occur from this ambiguous language. More importantly, the PRN is an arm of the Board towards protecting the public and therefore it should have the same amount of information for all participants in the program, not just a portion of them. Thus, the Board needs more effective oversight of all the cases in the PRN. The Board should not be in the dark concerning numerous cases.

# Agency Response: "Upon explanation by the Board of the volume of these reports, which are tens of millions of fields of data, PERD decided it no longer wished to receive this documentation."

**PERD's Response:** The database administrator explained that, due to the voluminous amount of data contained in the transaction and system access log, it was not feasible to provide PERD with this information. Due to the logistical issues related to securely transferring and storing this data, and the burdens this request could place on both PERD and the Board, PERD retracted its request for these items. As PERD did not receive these items, it did not assess their contents and compliance and therefore excluded them from the report. The report does not criticize the Board for not providing these items or otherwise indicate it does not manage these items as required by the contract. The decision to exclude these logs from PERD's assessment was based on a mutual understanding reached by the Board and PERD. Furthermore, as described above, PERD is not questioning the existence of these items, but rather the Board's engagement with them.

### Recommendations

- 1. The legislative auditor recommends the continuation of the Board of Pharmacy.
- 2. The Board should incorporate timestamps on its electronic complaint submission forms to track when complaints are received, rather than relying on the date a complaint is sent to an investigator.
- *3. The Board should comply with the requirements of W. Va. Code* §12-2-2(*a*) *and deposit revenue within* 24-hours.
- 4. The Board should consider using the State Treasurer's lockbox to further reduce risk of fraud.

- 5. The Board should take an active role in management of contract deliverables as it relates to the Controlled Substance Monitoring Program that includes receiving all required reports.
- 6. The Board should require a periodic independent review by a third party to evaluate the CSMP vendor's compliance with the contract.
- 7. The Board should exercise greater oversight over the Pharmacist Recovery Network program and receive all contract deliverables.
- 8. The Board should consider amending the contract for the Pharmacist Recovery Network to allow for periodical independent reviews of the program operations and contract compliance, either by the Board or by a third party.
- 9. The Board should consider whether the contract cost is appropriate.
- 10. The Board should consider providing additional elements on the website to improve the Board's transparency.

# **ISSUE 1**

## Regulation of the Practice of Pharmacy Is Needed to Protect Public Health and Safety

### **Issue Summary**

Per West Virginia Code (W. Va. Code) §4-10-9, the Performance Evaluation and Research Division, within the Office of the Legislative Auditor, is required to determine if there is a need for the continuation, consolidation, or termination of regulatory boards. In determining the need for a board, the primary consideration is whether the unregulated practice of the profession would endanger the public. In 2002, the Performance Evaluation and Research Division determined there is a continued need for the Board of Pharmacy because the unregulated practice of pharmacy would be harmful to the public. Since the previous audit, there have been no changes within the pharmacy profession that would warrant a change to the previous recommendation. **Therefore, the legislative auditor recommends the continuation of the Board of Pharmacy, as pharmacists and related professions and facilities continue to require regulation for public health and safety.** 

### The Board Licenses Over 15,000 Individuals and Facilities

The West Virginia Board of Pharmacy (Board) is established in W. Va. Code §30-5 et al. Its purpose is to regulate the profession of pharmacy and ensure its safe, lawful practice. The Board licenses pharmacists, technicians, trainees, and interns. In addition, it regulates pharmacy facilities, such as manufacturers, wholesalers/distributors, mail-order pharmacies, retail pharmacies, hospitals, and extended care facilities. Table 1 shows the number of licensees and registrants governed by the Board between FY 2018 and FY 2020. Although the total number of licensees regulated by the Board has declined since FY 2018, the Board continues to have a substantial licensee base. As of FY 2020, the Board has 16,759 licensees, registrants, and permittees.

In 2002, the Performance Evaluation and Research Division determined there is a continued need for the Board of Pharmacy because the unregulated practice of pharmacy would be harmful to the public.

The legislative auditor recommends the continuation of the Board of Pharmacy, as pharmacists and related professions and facilities continue to require regulation for public health and safety.

Table 1Pharmacy Licensees, Registrants, and PermitteesFY 2018 – 2020				
Туре	2018	2019	2020	
Manufacturer	537	637	708	
Wholesaler/Distributor	740	722	730	
Pharmacy	644	637	626	
Mail-Order Permit	640	643	698	
Controlled Substance permit only	1,592	600	648	
Limited Pseudoephedrine	14	10	12	
Pharmacist Total	5,165	5,309	5,649	
Pharmacy Technician	7,717	4,966	4,997	
Pharmacy Intern	790	855	847	
Consultant Pharmacist	150	110	99	
Immunizing Pharmacist	1,571	1,665	1,567	
Third-Party Logistics	159	157	178	
Totals	19,719	16,311	16,759	
Source: PERD calculations based on licensee data provided by the Board.				

There is a substantial risk of harm to individuals if the practice of pharmacy is not regulated. Drugs can be lethal if improperly dispensed.

In 2002, the legislative auditor found it was necessary to continue licensing pharmacists and pharmacy facilities to provide for the protection of public health and safety. There is a substantial risk of harm to individuals if the practice of pharmacy is not regulated. Drugs can be lethal if improperly dispensed. Medication errors that reach patients can involve incorrect drugs, dosage, quantity, and patient.

### All 50 States Regulate the Practice of Pharmacy

According to the National Association of Boards of Pharmacy, its membership consists of 50 state boards, as well as boards in the District of Columbia, Guam, Puerto Rico, the Virgin Islands, 10 Canadian provinces, and the Bahamas. While the structures and powers of boards vary, it is common to regulate the practice of pharmacy with a state board of pharmacy. **Given the current structure of occupational regulation in West Virginia, the legislative auditor sees no reason to recommend a change in regulatory placement for the practice of pharmacy.**  The legislative auditor sees no reason to recommend a change in regulatory placement for the practice of pharmacy.

### **The Board Inspects Pharmacies**

The Board employs inspectors to oversee the operation of pharmacies. Continued licensure for facilities manufacturing and distributing medications is necessary to ensure drugs are prepared and dispensed with competence in secure and sanitary conditions. Inspecting in-state pharmacies is one component of fulfilling the Board's mission of ensuring drugs are dispensed in a safe, clean environment by a licensed pharmacist or technician following applicable laws.

### Technology Has Not Changed Significantly to Warrant a Decrease in Regulation of the Practice of Pharmacy

While the profession has advanced since 2002, technology has not changed in such a way to warrant a decreased (or increased) degree of regulation. Specialized knowledge and training are still required to ensure public health and safety.

### Conclusion

Pharmacy professionals require specialized knowledge and training. Pharmacy professionals are responsible for preparing and dispensing medications, providing medication-related advice, and controlling addictive prescription drugs. Unregulated individuals practicing pharmacy pose a serious threat to public health and safety. Without regulation, there would be substantial risk to the public. Outcomes of irresponsible practice include physical harm and death. Therefore, it is the opinion of the legislative auditor that continued regulation of the profession is needed to protect public health and safety.

#### Recommendation

1. The legislative auditor recommends the continuation of the Board of Pharmacy.

While the profession has advanced since 2002 and faces increased time pressures and professional demands, technology has not changed in such a way to warrant a decreased (or increased) degree of regulation.

# **ISSUE 2**

## The West Virginia Board of Pharmacy Complies with Most General Provisions of Chapter 30 of West Virginia Code

### **Issue Summary**

The primary purpose of the Board of Pharmacy is to protect West Virginia citizens through the licensure and regulation of pharmacy professionals and facilities. The Board reviews applications made for licensure and licenses only individuals and entities qualified by West Virginia Code and rules to practice pharmacy. The Board meets the criteria for financial self-sufficiency, generally complies with complaint timelines, and its rules, as written, protect the public. The Board does not comply with all W. Va. Code requirements for its roster and register, and one board member has not attended an orientation session during his term of office.

### The Board Complies with Most General Provisions of Chapter 30 of West Virginia Code

The West Virginia Board of Pharmacy is compliant with most of the general provisions of Chapter 30 of the West Virginia Code. These provisions are important for the effective operation of regulatory boards. The Board is compliant with the following provisions:

- The chairperson, executive director, or the chief financial officer of the board must annually attend an orientation session conducted by the State Auditor.
- An official seal has been adopted.
- At least one board meeting a year has been held.
- Procedural rules have been promulgated specifying the investigation and resolution procedure of all complaints.
- The board is financially self-sufficient in carrying out its responsibilities.
- The board has established continuing education.
- An annual report has been submitted to the Governor and the Legislature describing transactions for the preceding two years.
- The board has complied with public access requirements as specified by §30-1-12c.
- The board's address and telephone number are in the state government listing of the Charleston area telephone directory.
- The Board maintains a roster with the information specified in code.

The Board meets the criteria for financial self-sufficiency, generally complies with complaint timelines, and its rules, as written, protect the public.

The West Virginia Board of Pharmacy is compliant with most of the general provisions of Chapter 30 of the West Virginia Code. These provisions are important for the effective operation of regulatory boards. The Board has not complied with the following Chapter 30 provisions:

- Each board member shall attend at least one orientation session during each term of office. One board member has not attended within his term.
- The Board does not have a register of all applicants with all information specified in code. The Board's register does not contain the date of application and examination required but otherwise complies with W. Va. Code.

### The Board Investigates Complaints Timely and Sends Status Reports as Required by Law

The audit team reviewed disciplinary data and complaints investigated by the Board for FY 2018 to FY 2020. Per *W. Va. Code of State Rules,* complaints against licensees can be filed with the Board by members of the public in any written form, although the Board provides a complaint form on its website. In the scope of this audit, the Board received 222 complaints. The audit team sampled 59 complaints to gain an overview of complaint population characteristics such as disciplinary action taken, the average time to resolve complaints, and to assess whether status reports were sent in compliance with W. Va. Code §30-1-5.

Table 2 shows the disposition of complaints and the frequency between FY 2018 and 2020. Within the sample, most complaints (78 percent) were dismissed. This may be due to the Board receiving several outside its jurisdiction, including customer service complaints and complaints otherwise not alleging improper practice or a violation of law or rule. The Board's in-house attorney works with the executive director and investigators to determine if there is an allegation that, on its face, involves a violation of law or rule over which the Board has jurisdiction. Public complaints are not considered filed until the Board completes this review. The Board does this to prevent resources from being consumed by frivolous or unactionable complaints, but according to the Board's attorney, the general approach is to "err on the side of caution" in accepting complaints. In other terms, the Board will file a complaint if the allegations, if true, represent a violation actionable under the Board's jurisdiction. The two complaint files under the category of "unknown" had incomplete or unclear documentation within the provided complaint files. In one case, the Board produced an investigation report but later determined it had no jurisdiction over the case, making its final disposition unclear. In the second case, the file only documented the finding of the investigation. Both incidents occurred in FY 2018, near the beginning of the scope of the audit.

Within the sample, most complaints (78 percent) were dismissed. This may be due to the Board receiving several outside its jurisdiction, including customer service complaints and complaints otherwise not alleging improper practice or a violation of law or rule.

The Board's in-house attorney works with the executive director and investigators to determine if there is an allegation that, on its face, involves a violation of law or rule over which the Board has jurisdiction. Public complaints are not considered filed until the Board completes this review.

Table 2Complaint DispositionFY 2018-2020			
Disposition	Number of Complaints	Percent of Total	
Unknown	2	3%	
Dismissed	46	78%	
Consent Agreement	8	13%	
Denied	1	2%	
Summary Suspension	1	2%	
Open 1 2%			
Source: PERD analysis of a sample of Board of Pharmacy complaint files.			

In general, compliance improved over time and the Board sends status updates most of the time they are required.

Table 3 shows the Board's compliance with the six-month status update requirement within the sampled complaints. The Board sends status updates when they are required. Most complaints were resolved within the statutory time frame. However, some dates used in these calculations represent approximations of when complaints were received, as the Board does not consistently track date of receipt, but rather when a complaint is sent to the investigator. **The Board should incorporate timestamps on its electronic complaint submission forms to track when complaints are received, rather than relying on the date a complaint is sent to an investigator.** 

Table 3Status Update Compliance of Sampled ComplaintsFY 2018 – 2020					
Fiscal YearAverage ResolutionStatus Updates RequiredTimes CompliedPercent Complied					
2018	66	0	0	N/A	
2019	119	4	4	100%	
2020	107	1	1	100%	
Total	97*	5	5	100%	
Source: PERD analysis of a sample of Board of Pharmacy complaint files *Average calculation based on the yearly averages					

The legislative auditor recommends the Board incorporate timestamps on its electronic complaint submission forms to track when complaints are received, rather than relying on the date a complaint is sent to an investigator.

### The Board Is Financially Self-Sufficient

The Board maintains an end-of-year cash balance that is more than one year of expenditures (see Table 4). *W. Va. Code* §30-1-6(c) requires boards to be financially self-sufficient. It is the legislative

auditor's opinion that cash reserves in the amount of one to two times a board's annual expenditures is an acceptable level. Table 4 represents the Board's beginning and ending cash balances, revenue, and disbursements. As indicated, except for FY 2020, the Board maintained its end-of-year cash balance at between 100 and 200 percent of its annual expenditures.

	Table 4Board of Pharmacy Budget InformationFY 2018-2020						
Fiscal Year	Beginning Cash Balance	Revenue	Disbursements	Ending Cash Balance	End-of-Year Cash as a Percent of Annual Expenditures		
2018	\$3,777,007	\$2,841,099	\$2,419,984	\$4,201,232	174%		
2019	\$4,201,059	\$3,442,851	\$2,990,980	\$4,657,151	156%		
2020	\$4,657,151	\$2,741,473	\$2,363,699	\$5,035,755	213%		
Average	\$4,211,739	\$3,009,835	\$2,591,554	\$4,631,379	181%		
Source: WV (	Source: WV OASIS reports (WV-FIN-GL-151) and PERD calculations.						

The Board's annual revenues come from fees for applications, licensure, and renewals. Annual disbursements include payroll, utilities, operational costs, travel, office supplies, and maintenance. The largest category, excluding payroll costs, is external computer services, comprising, on average, 29 percent of the Board's expenditures; this largely represents the cost of administration for the Controlled Substance Monitoring Program. However, the Board receives grant funds to offset the cost of the CSMP and the administration of other overdose-related programs.

To assess the risk of fraud and gain a reasonable assurance fraud has not occurred, the audit team examined the Board's revenue and expenditures. For revenue, the audit team calculated the minimum expected revenue for the Board by multiplying annual fees by the number of licensees for each category of licensee and found that actual revenue exceeded expected revenue in FY 2018 and 2020. Table 5 shows the Board's expected and actual revenues for each fiscal year. It should be noted that actual revenue exceeds expected revenue in part because the Board receives grants from the Centers for Disease Control and Prevention for the administration of the Controlled Substance Monitoring Program. For fiscal years 2018 through 2020, grant revenue averaged \$653,000. However, as actual revenue exceeds expected revenue, the risk of fraud on the revenue side is low. Except for FY 2020, the Board maintained its end-of-year cash balance at between 100 and 200 percent of its annual expenditures.

Table 5Board of Pharmacy Expected and Actual RevenuesFY 2018-2020					
Fiscal Year	Number of Active Licensees	Annual Renewal Fee	Expected Revenue	Actual Revenue	
2018	19,719	Varies	\$1,828,455	\$2,842,654	
2019	16,311	Varies	\$1,806,750	\$3,444,961	
2020	16,759	Varies	\$1,911,475	\$2,741,888	
Source: WV OASIS reports (WV-FIN-GL-151) and PERD calculations.					

The audit team also calculated the percentage of total expenses that are expected or required expenditures. PERD determined that on average 95% of the Board's expenditures are expected or required for FY 2018 - 2020. Table 6 below shows expected expenditures as a percent of all expenditures. The legislative auditor's opinion is that when the Board's required and expected expenditures are 90 percent or more of the Board's total annual expenditures, the likelihood of fraud having occurred on the expenditure side is relatively low. However, if expected and required expenditures are significantly below 90 percent, then the likelihood of fraud and abuse occurring is greater and PERD would conduct a more detailed examination of expenditures. For the three fiscal years examined, the Board surpassed the threshold where there is a low likelihood of fraud.

PERD determined that on average 95%	%
of the Board's expenditures are expect	t-
ed or required for FY 2018 – 2020.	

Table 6Expected and Required ExpendituresFY 2018-2020			
Fiscal Year	Percent of Expected & Required Expenditures		
2018	94%		
2019	96%		
2020	96%		
Average 95%			
Source: PERD calculations based on OASIS (WV- FIN-GL-151) data for fiscal years 2018 through			

FIN-GL-151) data for fiscal years 2018 through 2020.

For the three fiscal years examined, the Board surpassed the threshold where there is a low likelihood of fraud.

### The Board Has Established Continuing Education Requirements and Uses the National Association to Verify Compliance

The Board has established continuing education requirements for pharmacists by rule in West Virginia Code of State Rules (W. Va. CSR) §15-3 et al. The audit team requested the Board describe its procedure for verification of continuing professional education units. The Board stated that the National Association of Boards of Pharmacy (NABP) maintains various databases that function for all 50 states. The Board referred specifically to CPE Monitor as the system it relies on to verify continuing education. It stated that "Each pharmacist has an e-profile with NABP, and the CPE Monitor allows pharmacists to utilize a list of available CEs and keep track of their state required CEs through this profile. When the pharmacist applies for licensure/renewal with us [the Board], they upload a copy of their CPE monitor [information] from NABP to show proof of hours." The online application will not proceed if this requirement is not filled. As such, the Board does not have denials for lack of compliance with continuing education requirements. However, this system is not infallible. In a 2018 complaint, a licensee used continuing education hours that were not eligible in the current period. This issue, however, was identified as part of an inspection and was not caught during the renewal process.

For other categories of licensees, the Board does not formally require individuals to submit separate documentation of continuing education. Most pharmacy technicians must maintain a national certification as a requirement for licensure renewal and the Board believes maintaining the continuing education necessary for the national certification is sufficient. Pharmacy interns must be enrolled in an accredited pharmacy degree program, which the Board views as sufficient continuing education.

# The Board Has Taken Steps to Reduce the Risk of Inappropriate Use of Resources

As of April 2022, the Board has 15 staff members (9 board administration staff, 5 CSMP staff, and 1 employee of both programs). The Board has sufficient employees to segregate duties for proper internal control. Segregation of duties is important because it safeguards against improper use or loss of the Board's resources. To have adequate segregation of duties, there should be controls in place that prevent one person from performing two or more control activities associated with purchasing and receiving revenue, such as authorizing transactions, receiving merchandise, recording transactions, and maintaining custody of assets.

The Board has established continuing education requirements for pharmacists by rule in West Virginia Code of State Rules (W. Va. CSR) §15-3 et al.

The Board has sufficient employees to segregate duties for proper internal control. The process for receiving revenue is as follows: office staff opens the mail and removes the paperwork and checks, office staff records the check number and amount on the paperwork, and office staff inserts checks into a slot on the safe, which only the program coordinator and chief financial officer have access to. The program coordinator removes the checks from the safe weekly to deposit them (this was previously done daily). However, W. Va. Code §12-2-2(a) requires all officials and employees of the State to keep a daily itemized record of moneys received and to deposit them within one business day with the State Treasurer. **The Board should comply with the requirements of W. Va. Code §12-2-2(a) and deposit revenue within one business day.** 

While the Board does not accept cash payments, and most payments are submitted online using credit cards, the Board was unable to determine what percentage of payments are made online. The Board does not utilize the State Treasurer's Lock-Box system, which can minimize the handling of revenue. The State Treasurer's Office provides a lockbox operation whereby remittances can be picked up from a post office box, opened and sorted, imaged, deposited, and the information forwarded to the Board by the Treasurer's Office for a fee. Use of the lockbox operation helps to mitigate the risk of fraud. **The Board should consider using the State Treasurer's lockbox to further reduce risk of fraud.** 

# The Board's Office Is Generally Accessible to the Public, with Some Exceptions

The audit team conducted a site visit to the Board's office located at 2310 Kanawha Blvd. in Charleston. This visit was to determine if the office and building meet select guidelines established by the Americans with Disabilities Act.

The audit team found no designated handicap parking, and the entrance to the building used by the audit team was not handicap accessible. However, the building has a large, flat driveway that adjoins a path to the handicap-accessible entrance. The restroom on the first floor met basic guidelines for wheelchair accessibility and its fixtures do not require tight grasping, pinching, or twisting of the wrist.

The audit team's review did not assess the entire building, nor is the review intended to certify the building as compliant with the Americans with Disabilities Act. The audit team used professional judgment and a checklist provided by the Institute for Human Centered Design as a guide to determine if the building appears to provide reasonable access for disabled individuals. Figure 1 below is an exterior photograph of the Board's building, including the driveway and wheelchair-accessible ramp.

The Board should comply with the requirements of W. Va. Code §12-2-2(a) and deposit revenue within 24-hours.

The legislative auditor recommends the Board consider using the State Treasurer's lockbox to further reduce risk of fraud.

# Figure 1: Exterior Image of the Board of Pharmacy



## The Board's Rules Generally Protect the Public

The audit team reviewed the rules promulgated by the Board and found that, as written, they are generally intended to protect the public and do not unduly favor the profession. The audit team noted five rules of concern, as follows:

> 1. W. Va. CSR §15-1-3.7, which gives an agent of the Board the power to temporarily close pharmacies because an "authorization holder's cognitive, interpersonal, or psychomotor skills are affected by psychiatric, psychological, or emotional problems, or excessive alcohol or drug use or addiction." The audit team is concerned by the lack of criteria for making this judgment and the unilateral power this gives to agents of the Board. Moreover, a legal opinion by the Legislative Services Division of the Office of the Legislative Auditor found that the Board does not have the authority to delegate this responsibility to an agent of the Board. Specifically, the "closure or suspension of a pharmacy is a function that may only be exercised by the Board or a court....There is no statutory or constitutional authority for an "agent of the board" to take such unilateral action."

The audit team reviewed the rules promulgated by the Board and found that, as written, they are generally intended to protect the public and do not unduly favor the profession.

- 2. W. Va. CSR §15-1-3.9, which makes agents of the Board immune from civil liability "when acting in good faith and without malice... within the scope of their duties as such agents of the Board." The legislative auditor is concerned this provision could be interpreted more broadly than intended, as each agent's scope of duties is not specifically defined in rule or code. In addition, a legal opinion by the Legislative Services Division of the Office of the Legislative Auditor found that the Board does not have the authority to delegate immunity to agents of the Board. Specifically, "the rule exceeds the scope of the board's statute. In addition, the Legislature, rather than an administrative body, must wield the power to define liabilities of state officials and employees."
- 3. W. Va. CSR §15-2-8.19, which is missing a word (not), making its written meaning opposite of its presumed intent. As written, it says, "A pharmacist may dispense a controlled substance...which is not a prescription drug... without a prescription to a purchaser at retail, unless..."
- 4. W. Va. CSR §15-5-6 requires wholesale drug distributors and third-party logistics providers to require "each person employed in any prescription drug wholesale distribution activity" to be qualified "to perform the assigned functions in such manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law." The open-endedness of this requirement and its lack of defined scope makes this rule difficult to enforce.
- 5. W. Va. CSR 15-9, when considered with the complaint process as reviewed by the audit team, raises concerns about due process provided to licensees. Six-month status updates serve as notification letters to respondents and say, "Due to the confidentiality of the investigative process, no further information is being provided at this time." Some licensees may not know they are under investigation until they receive this six-month status update, which only informs them they are being investigated for an unspecified offense against an unnamed individual. The legislative auditor understands the need for confidentiality in cases where evidence could be compromised by licensee notification, but recommends the Board provide for exceptions to licensee notification in such instances rather than investigating licensees for a non-specified offense and only notifying them after six months have passed.

Other requirements within the rules are standard for regulatory boards, required by code, technical provisions outside the audit team's ability to evaluate, or procedural in nature (relating to the requirements and processes of licensure). Notably, rules pertaining to the Controlled Substance Monitoring Program are oriented towards protecting the public. While some of these provisions may benefit pharmacists and the industry, they also protect the public.

### Conclusion

The legislative auditor finds the Board of Pharmacy complies with most of the general provisions of Chapter 30 of the West Virginia Code, including provisions for financial self-sufficiency. Additionally, the Board has adequate staff to segregate duties, although responsibilities could be more clearly delineated, and risk of fraud further reduced by use of the State Treasurer's Lockbox system. The Board and its rules generally protect the public. However, the Board can improve compliance with the general provisions of Chapter 30 of W. Va. Code and should work to correct the issues noted in this report.

### Recommendations

- 2. The Board should incorporate timestamps on its electronic complaint submission forms to track when complaints are received, rather than relying on the date a complaint is sent to an investigator.
- *3. The Board should comply with the requirements of W. Va. Code* §12-2-2(*a*) *and deposit revenue within one business day.*
- 4. The Board should consider using the State Treasurer's lockbox to further reduce risk of fraud.

While some of these provisions may benefit pharmacists and the industry, they also protect the public.

# **ISSUE 3**

## The Board Could Provide More Active Oversight of the Controlled Substance Monitoring Program's Contract Deliverables

### **Issue Summary**

As required by W. Va. Code §60A-9-3, the Board is required to maintain the Controlled Substance Monitoring Program (CSMP), which tracks the prescribing and dispensing of controlled substances throughout the state. The CSMP is an important public health database that contains sensitive medical information accessible by thousands of users. The Board has contracted with a third party to conduct various procedures to manage and secure the CSMP. PERD finds that although the Board is responsible for the CSMP and has contracted with a third party to secure the database, there is no evidence that the Board knows if the contractor has complied with vital aspects of the contract. The Board does not receive or maintain periodic reports on attempted illegal access to the database or the findings of an independent review of the contractor's system controls. The Board also does not have knowledge of whether the contractor has developed a system disaster recovery plan or if the contractor has complied with other security and management provisions. Although PERD's review of the documents found no evidence CSMP security has been breached the Board has not attended to security provisions in its contract that would verify secure processes are in place and that the vendor would alert it to potential security breaches. The Board should take an active role in management of contract deliverables as it relates to the database.

# The Board Is Responsible for the Operation of the Controlled Substance Monitoring Program

W. Va. Code §60A-9-2 requires the Board to implement a program establishing a central repository containing information regarding controlled substance prescriptions written or filled in West Virginia. W. Va. Code §60A-9 et al. further details operational requirements and what information is to be collected. Pursuant to this statutory requirement, the Board maintains a statewide electronic database recording legally dispensed controlled substances and other information as part of the CSMP-- West Virginia's prescription drug monitoring program. The Legislature established the program in 1995 with the passage of HB 2492. The purpose of the program "is to require the recordation and retention in a single repository of information regarding the prescribing, dispensing and consumption of certain controlled substances." It is "a web-based system that optimizes the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled substances and Drugs of Interest." The system is designed to assist regulators, prescribers, and dispensers with monitoring certain controlled PERD finds that although the Board is responsible for the CSMP and has contracted with a third party to secure the database, there is no evidence that the Board knows if the contractor has complied with aspects of the contract.

W. Va. Code §60A-9-2 requires the Board to implement a program establishing a central repository containing information regarding controlled substance prescriptions written or filled in West Virginia. substances to prevent diversion, abuse, and misuse. Data collected can be used for education and information, early intervention, prevention of diversion, investigation, and enforcement of controlled substance laws. The administrative guide states the monitoring program is "a valuable tool in the effort to protect the health and welfare of the citizens of West Virginia by reducing the abuse of prescription drugs."

The Board considers the CSMP a tool to improve patient care. Many of its functions reflect this philosophy. For example, as part of operating the database, the Board receives and maintains suspected overdose reports (although these can be inaccurate) and statistical information on naloxone (linking dispensed naloxone to a name can create complications for individuals who obtain it for someone else). Additionally, the CSMP incorporates an algorithm that "scores" patients; for example, a patient with overlapping prescriptions for opioids and benzodiazepines from multiple doctors would have a "high" score, indicating an increased risk of overdose. These functions are used to improve the care provided by professionals utilizing the system. However, the CSMP can be used for other purposes, including active investigations. Specifically, authorized law enforcement officials, agents of licensing boards, agents of the Office of the Chief Medical Examiner, agents of the Bureau for Medical Services, agents of the Office of Health Facility Licensure and Certification, medical school dean, facility chief medical officers, and persons with an enforceable court order may also obtain specific data under certain circumstances (the executive director noted it is a misdemeanor to run a report without a proper reason and a felony to disclose the results of such a report).

Additionally, the Board makes use of the CSMP in its own operations. One notable function performed by the Board is identifying "abnormal prescribing" and providing this information to the practitioner's licensing board. This is required under W. Va. Code §60A-9-5(a)(2), which requires the Board of Pharmacy review the CSMP data and "issue reports that identify abnormal or unusual practices of patients and practitioners with prescriptive authority." Additionally, the Board uses de-identified data to identify areas that may need further education, permitted under W.Va. Code §60A-9-5(2). The Board also employs two epidemiologists and two data analysts to analyze trends which may be apparent in the data. For example, the data in the CSMP allowed the Board to identify a decline in the dispensation of hydrocodone and oxycodone (from 2011 to 2018, there was a decrease of 61 million doses). and identify that only buprenorphine (used to treat opioid addiction) and codeine products are trending upwards. Furthermore, as part of an annual report, the Board provides a list of drug categories compared to numbers of doses dispensed. Information in the database can be combined with geographic data for further insights. The executive director provides updates, information about the statistics compiled from the database, and reports on the functionality of the CSMP. As required under W. Va. Code The Board considers the CSMP a tool to improve patient care. Many of its functions reflect this philosophy.

The CSMP can be used for other purposes, including active investigations.

§60A-9-5(i), the Board submits annual CSMP reports to the Legislative Oversight Commission on Health and Human Resources Accountability to enable legislative oversight of program operations.

# The Board Does Not Know If the CSMP Vendor Complies with Important Requirements of the Contract

Since the Board lacks the information technology expertise to implement a large-scale prescription drug monitoring program such as the CSMP, it contracted with a third-party vendor to fulfill its mandate. Nevertheless, as specified by the contract, the Board maintains ownership of and responsibility for the database. Moreover, the CSMP is an integral component of the Board's statutory mandate to protect the public. Therefore, the Board cannot be in the dark concerning the third-party administrator's compliance with the contract. The Board must have sufficient knowledge that the third-party administrator complies with the contract to have reasonable assurance the public is protected. PERD finds that the Board does not provide adequate management of contract deliverables, and therefore, the Board does not know if the third-party administrator complies with stated requirements of the contract.

According to the Certified Information Systems Auditor manual, produced by the Information Systems Audit and Control Association, client organizations are ultimately accountable for the system. Specifically, the manual states:

> "...while service delivery is transferred, accountability remains firmly with the management of the client organization, which must ensure that the risk is properly managed..."

In other terms, while the vendor operates and maintains the database, the Board retains responsibility and accountability for its security. There must be a mechanism in place to ensure the third-party vendor is held accountable for its performance. The manual further states:

"Every organization using the services of third parties should have a service delivery management system in place to implement and maintain the appropriate level of information security and service delivery in line with third-party service delivery agreements.

The organization should check the implementation of agreements, monitor compliance with the agreements, and manage changes to ensure that the services delivered meet all requirements agreed to with the third party. "(emphasis added) Since the Board lacks the information technology expertise to implement a large-scale prescription drug monitoring program such as the CSMP, it contracted with a third-party vendor to fulfill its mandate. Nevertheless, as specified by the contract, the Board maintains ownership of and responsibility for the database.

PERD finds that the Board does not provide adequate contract management, and therefore, the Board does not know if the third-party administrator complies with stated requirements of the contract. Consequently, the audit team requested select items required by the contract to verify if the vendor complied with the provisions and if the Board was aware of these provisions. These include:

- the comprehensive user's manual,
- a log identifying illegal access attempts,
- a third-party privacy and security assessment,
- a risk analysis in compliance with the HIPAA security rule,
- written reports of any breaches, and
- a system disaster recovery plan.

When the audit team inquired about these items, the Board did not have them on file. The Board needed to request them from the vendor. As a result, the audit team concluded the Board does not request or receive copies of these documents, which are required by the contract, from the vendor at regular intervals, nor does the vendor provide them unprompted. If the Board does not receive and review these documents, then the Board cannot request the vendor address any deficiencies identified in these items unless the vendor proactively communicates results or anomalies to the Board.

Additionally, there is nothing in the contract that requires these documents and other items be provided to the Board periodically, nor that the results be discussed with the Board. For instance, the Board demonstrated that it could view an online log of illegal access attempts, but even though the vendor is to provide a daily log of such activity, this online file was not updated in the seven months since PERD initially requested it. To ensure the Board can adequately monitor the vendor's compliance, the contract should specify that certain items essential to the contract's effective implementation should be provided to the Board, and the frequency at which this should occur.

While the security assessment is important, it is not an audit of management of contract deliverables. The audit team found some provisions are being fulfilled. The vendor does have a security assessment performed by an independent third party. The most recent assessment indicates that the vendor maintains a secure database. However, there are significant provisions not covered by the security assessments, such as:

- whether the vendor performs data checks to ensure the data submitted is accurate and complete,
- whether data is deleted from the system after five years, and
- whether the vendor updates the system following changes in security standards or changes in State information technology requirements.

The Board cannot request the vendor address any deficiencies identified in these items unless the vendor proactively communicates results or anomalies to the Board. Additionally, although the Board's contract with its vendor requires that CSMP data be deleted from the system after five years, PERD has learned that the Board's practice is to archive all the data instead. Though there may be compelling reasons for this decision, the Board has not modified its contract with the vendor to reflect this (see Issue 6).

While the Board may lack expertise in information security, it can contract with an independent third party to ensure the provisions of the contract are fully, properly, and appropriately implemented by the vendor. Unless the Board introduces a mechanism to review vendor performance and compliance, the Board cannot know the provisions of the contract are being carried out. Therefore, the Board should exercise diligent management of contract deliverables and consider contracting with a third party to evaluate vendor compliance.

### Conclusion

The Board uses the CSMP as a public health tool, tracking prescribing and dispensing practices for controlled substances throughout the state. Given that the Board is responsible for the CSMP, and it is integral to the Board's function in protecting the public, the Board must have sufficient knowledge that the third-party administrator of the CSMP complies with the contract procedures. However, the Board does not provide adequate management of contract deliverables or seek to determine the third-party's compliance with the contract. As such, the Board does not have reasonable assurance that the CSMP is adequately protected against breaches and illegal use, or if the contract requirements are being fulfilled. The Board should exercise greater management of contract deliverables and require an independent compliance review of the third-party administrator.

### Recommendations

- 5. The Board should take an active role in management of contract deliverables as it relates to the Controlled Substance Monitoring Program that includes receiving all required reports.
- 6. The Board should require a periodic independent review by a third party to evaluate the CSMP vendor's compliance with the contract.

The Board should exercise adequate contract management and consider contracting with a third party to evaluate vendor compliance.

The Board does not provide adequate contract management or seek to determine the third-party's compliance with the contract. As such, the Board does not have reasonable assurance that the CSMP is adequately protected against breaches and illegal use.

# **ISSUE 4**

### Due to Inadequate Oversight of the Impaired Health Condition Treatment Program, the Board Does Not Have Reasonable Assurance that the Public Is Protected Against Improper Practice by Impaired Licensees

### **Issue Summary**

West Virginia Code §30-5-7(a)(14) requires that the Board promulgate legislative rules to establish an alcohol and chemical dependency treatment program for impaired licensees. The Board has contracted with a third party to administer the Pharmacist Recovery Network (PRN) for impaired licensees. The PRN is meant to support intake, referrals, treatment, rehabilitation, monitoring, and post-treatment support for pharmacy professionals who are struggling with alcohol and chemical dependency or other impairing health conditions that may compromise their ability to practice pharmacy. The Board has stated it does not have a mechanism for assessing vendor compliance with the contract. However, the PRN is an important component of the Board's responsibility to protect the public. PERD finds that the Board does not know if the PRN has implemented and consistently carries out the required procedures for effective operations. Given the importance of the PRN program in protecting the public, the Board should not be in the dark concerning the vendor's compliance with essential procedures of the contract. Therefore, the legislative auditor recommends that the PRN contract should require an independent review of the vendor's implementation of and compliance with the procedures required in the contract.

### The Board Contracted a Vendor to Run the Day-to-Day Operations of Its Impaired Health Condition Treatment Program

The Board's enabling statute requires that it issue rules for an alcohol and chemical dependency program and set up standards and requirements for agreements with organizations to form professional recovery networks. In 2003 the Board set up its PRN to support the intervention, referrals, monitoring, treatment, rehabilitation, and post-treatment support of licensed pharmacy professionals who have potentially impaired health conditions (e.g., mental illness, chemical dependency, physical illness) that may compromise their ability to practice pharmacy.

The Board provides the PRN through a contracted vendor for the day-to-day operations of doing intakes for licensees referred to the PRN and for the monitoring of licensee recovery and treatment. The Board pays the vendor from a PRN-specific assessment added to each pharmacist (\$20), pharmacy intern (\$5), and pharmacy technician's (\$10) annual renewal fee. Pursuant to W. Va. CSR §15-10-15, any revenue The Board has stated it does not have a mechanism for assessing vendor compliance with the contract.

In 2003 the Board set up its PRN to support the intervention, referrals, monitoring, treatment, rehabilitation, and post-treatment support of licensed pharmacy professionals who have potentially impaired health conditions (e.g., mental illness, chemical dependency, physical illness) that may compromise their ability to practice pharmacy. generated by the assessment is to be dedicated to the operation of the PRN. Since at least fiscal year 2018, the Board has annually engaged the same vendor to administer the PRN at an annual cost of \$58,500 in FY 2020. Between FY 2017 and FY 2020, the PRN had between 21 and 29 participants at any given time. Table 7 shows the revenues the Board collects from its licensees and its expenditures to its PRN vendor.

Table 7 Impaired Health Condition Treatment Program Revenue and Expenditures FY 2018 through FY 2020				
FY	Revenues	Expenditures	Difference	
2018	\$94,185	\$58,000	\$36,185	
2019	\$82,195	\$58,000	\$24,195	
2020	\$85,710	\$58,500	\$27,210	
Total	\$262,090	\$174,500	\$87,590	
Source: PERD calculations based on licensee data and contract costs				

Table 7 shows the revenues the Boardcollects from its licensees and its expenditures to its PRN vendor.

On average there are 26 participants each year, which calculates to about \$2,266 per participant annually. However, the Board does not know what the PRN's actual costs are to administer this program for its participants. This is compounded by the vendor serving other professionals besides pharmacy professionals, and the vendor assessing each participant additional fees. Additionally, the vendor assesses each working participating pharmacist a one-time administrative fee of \$100 and \$50 for pharmacy technicians, interns, and non-working pharmacists. However, the PRN contract says, "[The] Vendor is not permitted to charge additional fees or assess additional charges that were not...expressly provided for in the solicitation...." Appropriate contract management requires that the Board know whether the PRN vendor is assessing added fees to program participants, and what the vendor's actual costs are to administer the program.

# The Board Does Not Provide Adequate Contract Oversight of the PRN

The Board's contract with the PRN mirrors extensively the Board's rules established by CSR §15-10 et al. The PRN is an important component to the Board's mandate of protecting the public against harm from the pharmacy profession. If the PRN vendor does not adequately perform the contract requirements, impaired licensees may be allowed to continue practicing or impaired licensees may not receive adequate services to become rehabilitated.

If the PRN vendor does not adequately perform the contract requirements, impaired licensees may be allowed to continue practicing or impaired licensees may not receive adequate services to become rehabilitated. The rule that governs the PRN program contained significant provisions for confidentiality:

"All information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the program, all communications to or from the program, and all proceedings, findings, and conclusions of the program, including those relating to intervention, treatment, or rehabilitation, that in any way pertain to or refer to a person participating in a pharmacist recovery network shall be privileged and confidential."

#### and:

"All records and proceedings of the program that pertain or refer to a person participating in a pharmacist recovery network shall be privileged and confidential, used by the program and its members only in the exercise of the proper function of the program, not be considered public records, and not be subject to court subpoena, discovery, or introduction as evidence in any civil, criminal, or administrative proceedings."

PERD finds that the Board does not adequately oversee the PRN contract or the vendor's compliance with required procedures. The contract imposes important requirements and deliverables on the vendor that either the Board does not receive or know if the vendor is performing them. In addition, the Board has not inquired as to why certain deliverables were not provided or insist that the deliverables be provided by the vendor. Below is a list of the various requirements of the PRN contract along with the status of if the vendor has responded or if the Board knows the vendor's compliance.

#### 1. **PRN Contract Reporting Requirements:**

- a. Quarterly Status Report -- The contract requires a quarterly report be provided to the Board on the status of all licensees involved in the program who were previously reported to the Board. These are licensees who may not be in active treatment but are required to be monitored. These licensees may be back in the workplace. <u>The Board receives this report</u>.
- **b.** Annual Comprehensive Statistical Report -- The contract requires an annual report be provided to the Board that compiles comprehensive statistics on suspected impairments, impairments, self-referrals, post-treatment support, and other significant demographic and

PERD finds that the Board does not adequately oversee the PRN contract or the vendor's compliance with required procedures. substantive information collected through the program. The executive director stated that the Board receives these reports verbally.

#### 2. Contract Performance Requirements:

- a. When a pharmacy professional is reported as possibly impaired or self-reports being impaired, the executive director of the PRN shall make contact with the licensee to confirm the information. If it is determined there is sufficient reason for action, the executive director of the PRN shall encourage the licensee to present himself or herself to the PRN within seven days. If the licensee resists going to the PRN, the executive director will make another attempt. If after two unsuccessful attempts within a period not to exceed 14 days, the executive director shall inform the licensee that the case will be disclosed to the Board. **The Board does not know if the PRN is in compliance with these timeframes.**
- b. Once a licensee has entered into the program and intervention is to begin, the executive director of the PRN shall draw up a final agreement between the licensee and the PRN to enter into a treatment program. The executive director shall also collect and maintain appropriate paperwork as specified in the contract concerning treatment progress, group therapy participation, and urine and blood analysis. The Board does not know if the vendor develops and maintains appropriate case information.
- c. The executive director shall work with treatment providers to determine treatment guidelines and consult with the primary care giver on a regular basis. The Board does not know if the vendor adequately works with treatment providers or consults with primary care givers as required by the contract.
- d. The PRN must designate monitoring requirements for each licensee in the program. The Board does not know if monitoring requirements have been developed for each licensee in the program.

### Conclusion

The function of the Pharmacist Recovery Network is an important component of the Board's statutory mandate to protect the public from harm due to the pharmacy profession. Given the importance of the PRN program to the Board's responsibilities, the Board cannot be in the dark Given the importance of the PRN program to the Board's responsibilities, the Board cannot be in the dark concerning the vendor's compliance with critical procedures that are necessary for effective operation and public safety. concerning the vendor's compliance with critical procedures that are necessary for effective operation and public safety. Consequently, the Board does not have reasonable assurance that it is protecting the public's health and safety from impaired pharmacy professionals, or that the PRN is operating as required and that licensees returning to the workplace after treatment can practice safely. PERD received no evidence that the vendor has complied with some of the reporting requirements. This indicates that the Board has not exercised adequate oversight of the PRN contract. To reduce the risk of harm to the public, the Board should insist on receiving all deliverables of the contract and have a contract provision requiring an independent evaluation be performed concerning the vendor's compliance with implementing and conducting contract procedures.

#### **Recommendations**

- 7. The Board should exercise greater oversight over the Pharmacist Recovery Network program and receive all contract deliverables.
- 8. The Board should consider amending the contract for the Pharmacist Recovery Network to allow for periodical independent reviews of the program operations and contract compliance, either by the Board or by a third party.
- 9. The Board should consider whether the contract cost is appropriate.

To reduce the risk of harm to the public, the Board should insist on receiving all deliverables of the contract and have a contract provision requiring an independent evaluation be performed concerning the vendor's compliance with implementing and conducting contract procedures.

# **ISSUE 5**

# The West Virginia Board of Pharmacy's Website Needs Modest Improvements to Enhance User-Friendliness and Transparency

### **Issue Summary**

The Office of the Legislative Auditor conducted a literature review on assessments of governmental websites and developed an assessment tool to evaluate West Virginia's state agency websites (see Appendix C). The assessment tool lists several website elements. Some elements should be included in every website, while other elements such as social media links, graphics and audio/video features may not be necessary or practical for state agencies. This has been a standard part of PERD's review of Chapter 30 boards since 2012. Table 8 indicates that the Board integrates 60 percent of the checklist items in its website. This measure shows that the Board website needs modest improvement in both userfriendliness and transparency.

Table 8West Virginia Board of PharmacyWebsite Evaluation Score			
Substantial Improvement Needed	More Improvement Needed	Modest Improvement Needed	Little or No Improvement Needed
0-25%	26-50%	51-75%	76-100%
		Board 60%	
Source: The Legislative Auditor's review of the West Virginia Board of Pharmacy's website.			

### The Board's Website Scores Moderately High in User-Friendliness and Transparency

To actively engage with the agency online, citizens must first be able to access and comprehend the information on government websites. Therefore, government websites should be designed to be user-friendly. A user-friendly website is understandable and easy to navigate from page to page. Government websites should also provide transparency of an agency's operation to promote accountability and trust.

The legislative auditor reviewed the Board's website for both user-friendliness and transparency and found that the website needs modest enhancements in these areas (see Table 9). The Board may want to consider adding some elements that could be beneficial to the public.

Table 9Board Website Evaluation Score				
Category	Possible Points	Agency Points	Percentage	
User-Friendly	18	13	72%	
Transparent	32	17	53%	
Total	50	30	60%	
Source: Legislative Auditor's review of the Board's website as of September 16, 2021.				

Additionally, the Board uses a ".com" domain rather than a ".gov" domain. While there is no requirement for state and local governments to use the .gov domain, it is generally considered an accurate indicator of a government website, which in turn signifies legitimacy and authority. The ability to identify a site as legitimate is an important part of usability.

### The Board's Website Is Navigable, But Additional User-Friendly Features Should Be Considered

The Board's website is easy to navigate as there is a link to every page on the top of the website and a site map; however, the website lacks foreign language accessibility, an online survey of website quality, social media links, and RSS feeds. According to the Flesch-Kincaid Reading Test, the average readability of the text is at a 9<sup>th</sup>-grade level, which is slightly higher than the recommended 7<sup>th</sup>-grade level for readability.

#### **User-Friendly Considerations**

Although some items may not be practical for this board, the following are some attributes that could improve user-friendliness:

- **Foreign Language Accessibility-** A link to translate all web pages into languages other than English.
- <u>Online Survey/Poll-</u> A short survey that pops up and requests users to evaluate the website.
- <u>Social Media Links-</u>Links that allow users to post an agency's content to social media pages such as Facebook and Twitter.
- **<u>RSS Feeds-</u>** This allows subscribers to receive regularly updated work (i.e., blog posts, news stories, audio/video, etc.) in a standardized format.

### The Website Has Several Transparency Features but Some Improvements Can Be Made

A transparent website should promote accountability and provide information for citizens about how well the Board is performing, as well

The Board uses a ".com" domain rather than a ".gov" domain. While there is no requirement for state and local governments to use the .gov domain, it is generally considered an accurate indicator of a government website, which in turn signifies legitimacy and authority. as encourage public participation. The Board's website has 53 percent of the core elements that are necessary for a general understanding of the Board's mission and performance. The Board's website contains important transparency features such as email contact information, its telephone number, and public records such as meeting minutes and annual reports.

#### **Transparency Considerations**

The Board should consider providing additional elements on the website to improve the Board's transparency. The following are some attributes that could be beneficial:

- <u>Location of Agency Headquarters-</u> The agency's contact page could include an embedded map that shows the agency's location.
- <u>Administrator(s) Biography</u> A biography explaining the administrator(s) professional qualifications and experience.
- **<u>Budget-</u>** Budget data are available at the checkbook-level, ideally in a searchable database.
- **FOIA Information-** Information on how to submit a FOIA request, ideally with an online submission form.
- <u>Mission statement</u>. The agency's mission statement located on the homepage.
- <u>Agency history</u>. The agency's website could include a page explaining how the agency was created, what it has done, and how, if applicable, has its mission changed over time.
- **<u>Graphic capabilities-</u>** Allows users to access relevant graphics such as maps, diagrams, etc.
- <u>Audio/video features-</u> Allows users to access and download relevant audio and video content.
- <u>Performance measures/outcomes-</u> A page linked to the homepage explaining the agency's performance measures and outcomes.
- Job Postings/Links to Personnel Division Website- A section on the homepage for open job postings and a link to the application page with the Personnel Division.

# The Legislature Has Previously Addressed the Need for Government Website Standardization

In 2019, the Legislature passed HB 2992, which included the requirement that state executive agencies include certain contact information for their offices and employees. This included office contact information, staff member contact information, an organizational chart, administrative officials, governing statutes and legislative and procedural rules, meeting minutes, and annual reports, when applicable. This bill In 2019, the Legislature passed HB 2992, which included the requirement that state executive agencies include certain contact information for their offices and employees. resembled HB 2446, which passed in 2017. However, both bills were vetoed. The veto messages cited overly broad application, noting the lack of exemptions for employees who work from their personal residence, or would be placed at risk should their information be published online (e.g., undercover law enforcement officers). Both veto messages affirmed the importance of providing the public with readily accessible information about state and local government.

While these bills would address content standardization, the legislative auditor further recommends the creation of a central design standard for state websites, including the use of the .gov domain. Consistency in website design would promote board accessibility and recognition, as well as address other concerns more completely (such as usability for the vision impaired). Boards could continue to be responsible for specific content and submissions but use a standardized web format or have dedicated sections within a single domain. Sharing and standardizing technology resources would not only promote consistency but address accessibility issues that may be beyond the ability of small boards to correct given limited resources. While web accessibility may be an issue for all government agencies, the specific state and needs of regulatory boards should be considered in addition to general government accessibility and transparency needs.

#### Conclusion

The legislative auditor finds that only modest improvements are needed to the Board's website in the areas of user-friendliness and transparency. The website can benefit from incorporating several common features. The Board has pertinent public information on its website. The Board's contact information is also provided. However, providing website users with additional elements and capabilities, as suggested in the report, would improve user-friendliness and transparency.

Recommendation

10. The Board should consider providing additional elements on the website to improve the Board's transparency.

The legislative auditor further recommends the creation of a central design standard for state websites, including the use of the .gov domain.

The legislative auditor finds that only modest improvements are needed to the Board's website in the areas of user-friendliness and transparency.

# ISSUE 6

# In Response to Concerns About Retention of CSMP Data, The Board Changed Requirements in the Contract with the Vendor to Reflect the Board's Policy and Practice

In Issue 3 of this report, PERD noted that the security assessment required by the contract between the Board and the CSMP vendor does not cover all security related issues within the contract. One item PERD noted not covered by the security assessment is Mandatory Requirement 5.1.2.32 in the contract, which states "*The Vendor shall maintain the information in the database for five (5) years, rolling monthly, and be made available to all system users. All information more than five (5) years old shall be deleted from the database by the vendor.*"

However, the Board took exception to PERD's statement that the security assessment does not verify that this requirement is being followed. In the Board's response to PERD's audit, provided after the conclusion of the audit and the exit conference, it noted:

"Whether data a [sic] is deleted from the system after five years" is not a requirement. W. Va. Code §60A-9-5(a) (2) states that "the Board of Pharmacy shall maintain the information required by this article for a period of not less than five years." We remove data older than five years from production but keep that data archived. We have considered purging the data after five years, but it is not required, and its involvement with numerous opioid litigations made that notion potentially problematic."

Prior to its response to the draft PERD report, the Board did not disclose that the data were retained beyond the five-year window period specified in the previous contract. Thus, the Board's response presented significant issues. The first issue was that the Board's response was not clear on who was removing the data or archiving the data. Moreover, the Board does not disclose - if it is the entity archiving the data - what protocols the Board has in place to safeguard the archived information.

After the completion of PERD's report, on August 18, 2022, the Board changed the requirement for the management of the CSMP data within the contract with the vendor. Beginning September 1, 2022, the contract now states the vendor "maintains the most recent five (5) years of data within the production of the PDMP system. Data in excess of five years old is removed from the data that is called upon to create patient reports and other day-to-day information requestions (i.e the production dataset) and then is stored offline in a separate and secure research database only accessible by the West Virginia Board of Pharmacy." The revision of the contract to reflect the Board's practice, as well as delineate the role of the vendor in the process, addresses PERD's concern regarding Prior to its response to the draft PERD report, the Board did not disclose that the data were retained beyond the fiveyear window period specified in the previous contract.

After the completion of PERD's report, on August 18, 2022, the Board changed the requirement for the management of the CSMP data within the contract with the vendor.

The revision addresses PERD's concern regarding the potential liability brought about by the decision to retain data outside the terms of the contract. the potential liability brought about by the decision to retain data outside the terms of the contract.

#### Conclusion

In prior iterations, the vendor had a contractual requirement to delete CSMP data after five years. Nonetheless, in practice the Board did not enforce this provision, and, instead, retained the data in an archive. However, in response to PERD's concern, the Board altered the contract provision to reflect the reality of its practice. This addresses PERD's concerns about the potential liability of the retention of data outside of the prior five-year window.

# Appendix A Transmittal Letter

#### WEST VIRGINIA LEGISLATIVE

Performance Evaluation and Research Division

1900 Kanawha Blvd. East Building 1, Room W-314 Charleston, WV 25305-0610 (304) 347-4890



John Sylvia Director

May 23, 2022

Michael Goff, Executive Director West Virginia Board of Pharmacy 2310 Kanawha Blvd. E. Charleston, WV 25311

Dear Mr. Goff:

This is to transmit a draft copy of the regulatory board review of the Board of Pharmacy. This report is tentatively scheduled to be presented during the June 12 through 14 interim meetings of the Joint Committee on Government Operations, and the Joint Committee on Government Organization. We will inform you of the exact time and location once the information becomes available. It is expected that a representative from your agency be present at the meeting to orally respond to the report and answer any questions committee members may have during or after the meeting.

We need to schedule an exit conference to discuss any concerns you may have with the report. We would like to have the meeting on Friday, May 27, 2022. Please notify us to schedule an exact time. In addition, we need your written response by noon on Friday, June 3, 2022 in order for it to be included in the final report. If your agency intends to distribute additional material to committee members at the meeting, please contact the House Government Organization staff at 304-340-3192 by Thursday, June 9, 2022 to make arrangements.

We request that your personnel not disclose the report to anyone unaffiliated with your agency. However, the Legislative Auditor advises that you inform any non-state government entity of the content of this report if that entity is unfavorably described, and request that it not disclose the content of the report to anyone unaffiliated with its organization. Thank you for your cooperation.

ohn Sylvia

Enclosure

# Appendix B Objectives, Scope and Methodology

The Performance Evaluation and Research Division (PERD) within the Office of the Legislative Auditor conducted this Regulatory Board Review of the Board of Pharmacy (Board) as required and authorized by the West Virginia Performance Review Act, Chapter 4, Article 10, of the West Virginia Code, as amended. The purpose of the Board as established in West Virginia Code §30-4-et. al., is to protect the public through its license process, and to be the regulatory and disciplinary body for pharmacy professionals and facilities throughout the state.

# **Objectives**

The objectives of this review are to determine if the Board should be continued, consolidated, or terminated, and if conditions warrant a change in the degree of regulations. In addition, this review is intended to assess the Board's compliance with the general provisions of Chapter 30, Article 1 of the West Virginia Code, the Board's enabling statute §30-5-et al., and other applicable rules and laws. Another objective is to determine whether the Board exercises adequate contract management over the Controlled Substance Monitoring Program to ensure vendor compliance with its provisions. A further objective is to determine if the Board's substance abuse diversion program provides adequate protection to the public against improper practice by impaired providers. Finally, it is the objective of the legislative auditor to assess the Board's website for user-friendliness and transparency.

### Scope

The scope of this performance audit consists of the Board's internal controls, policy and procedures, meeting minutes, complaint files from fiscal years 2018 through 2020, the complaint-resolution process, disciplinary procedures and actions, revenues and expenditures for the period of fiscal years 2018 through 2020, continuing education requirements and verification, the Board's compliance with the general statutory provisions found in W. Va. §30-1 for regulatory boards and other applicable laws, and key features of the Board's website. Furthermore, the evaluation included a review of open meeting notices for fiscal years 2019 through 2020. This audit also included an evaluation of the Board's contract oversight of the Controlled Substance Monitoring Program, and the Pharmacist Recovery Network.

### Methodology

PERD gathered and analyzed several sources of information and conducted audit procedures to assess the sufficiency and appropriateness of the information used as audit evidence. The information gathered and audit procedures are described below.

PERD staff visited the Board's Charleston Office in Kanawha County and met with its staff. Testimonial evidence was gathered through interviews with the Board's staff to gain a better understanding of the Board's internal control, and policy and procedures. Other agencies were also interviewed to understand their processes and requirements as they relate to the Board. All interviews were confirmed by written statements and in some cases by corroborating evidence.

In order to determine if the Board complies with the general provision of W. Va. Code §30-1, its enabling statute and rules, and other applicable laws, PERD collected and analyzed a sample of the Board's complaint files, meeting minutes, annual reports, budget information, procedures for investigating and resolving complaints, and continuing education verification procedures. PERD also obtained information from the State Auditor's Office, Secretary of State's Office, the State Treasurer's Office, and the Department

of Administration's Purchasing Division. This information was assessed against statutory requirements in §30-1 and §6-9A of the West Virginia Code as well as the Board's enabling statute §30-5-et al. to determine the Board's compliance with such laws. Some information was also used as supporting evidence to determine the sufficiency and appropriateness of the overall evidence.

The legislative auditor compared the Board's actual revenues to expected revenues to assess the risk of fraud, and to obtain reasonable assurance that revenue figures were sufficient and appropriate. Expected revenues were approximated by applying license fees to the number of licensees for the period of fiscal years 2018 to 2020. Expected revenues were higher than actual revenues. Therefore, our evaluation of expected and actual revenues allowed us to conclude that the risk of fraud on the revenue side was reasonably low, would not affect the audit objectives, and actual revenues were sufficient and appropriate.

The legislative auditor also tested the Board's expenditures for fiscal years 2018 through 2020 to assess the risk of fraud on the expenditure side. The test involved determining if required and expected expenditures were at least 90 percent of total expenditures. Required and expected expenditures include salaries and benefits, travel reimbursement, board-member compensation, insurance, office rent, payments to other agencies, and utilities. The legislative auditor determined that during the scope of the review, required and expected expenses were between 94 and 96 percent of total expenditures. These percentages gave reasonable assurance that the risk of fraud on the expenditure side was not significant enough to affect the audit objectives.

To evaluate the Board's oversight of the contracts related the Controlled Substance Monitoring Program (CSMP) and Pharmacist Recovery Network (PRN), the legislative auditor reviewed the contracts and the deliverables required by the contracts. The audit team interviewed the Board to determine what documentation the Board maintained regarding the contract deliverables and what process staff use to verify vendor compliance with the deliverables. The audit team requested supporting documentation for statements made by the Board regarding oversight of the contract and the Board's monitoring of vendor compliance. PERD used the statements and documentation to determine if the Board exercised adequate oversight of the contract.

In order to evaluate state agency websites, the legislative auditor conducted a literature review of government website studies, reviewed top-ranked government websites, and reviewed the work of groups that rate government websites in order to establish a master list of essential website elements. The Brookings Institute's "2008 State and Federal E-Government in the United States" and the Rutgers University's 2008 "U.S. States E-Governance Survey (2008): An Assessment of State Websites" helped identify the top ranked states in regards to e-government. The Legislative Auditor identified three states (Indiana, Maine and Massachusetts) that were ranked in the top 10 in both studies and reviewed all 3 states' main portals for trends and common elements in transparency and open government. The legislative auditor also reviewed a 2010 report from the West Virginia Center on Budget and Policy that was useful in identifying a group of core elements from the master list that should be considered for state websites to increase their transparency and e-governance. It is understood that not every item listed in the master list is to be found in a department or agency website because some of the technology may not be practical or useful for some state agencies. Therefore, the legislative auditor compared the Board's website to the established criteria for user-friendliness and transparency so that the Board of Pharmacy can determine if it is progressing in step with the e-government movement and if improvements to its website should be made.

As a means to test data from the State's Our Advanced Solution with Integrated Systems (OASIS), from which various financial and human resource data are used in this audit, the Office of the Legislative Auditor reviews the statewide single audit and the Division of Highways financial audit annually with regards

to any issues related to OASIS data. The legislative auditor's staff on a quarterly basis request and reviews any external or internal audit of OASIS. In addition, through its numerous audits, the Office of the Legislative Auditor continuously tests the financial information contained in OASIS. Also, at the start of each audit, PERD asks audited agencies if they have encountered any issues of accuracy with OASIS data. Based on these actions, along with the audit tests conducted on the audited agency, it is our professional judgement that the information in OASIS is reasonably accurate for auditing purposes under the 2018 Government Auditing Standards (Yellowbook). However, in no manner should this statement be construed as a statement that 100 percent of the information in OASIS is accurate.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

# Appendix C Website Criteria Checklist and Points

Board of Pharmacy Website Criteria Checklist and Points System			
User-Friendly	Description	Total Points Possible	Total Agency Points
Criteria	The ease of navigation from page to page along with the usefulness of the website.	18	13
		Individual Points Possible	Individual Agency Points
Search Tool	The website should contain a search box (1), preferablyon every page (1).	2 points	2 points
Help Link	There should be a link that allows users to access a FAQsection (1) and agency contact information (1) on a single page. The link's text does not have to contain the word help, but it should contain language that clearly indicates that the user can find assistance by clicking the link (i.e. "How do I", "Questions?" or "Need assistance?")	2 points	2 points
Foreign language accessibility	A link to translate all webpages into languages otherthan English.	1 point	0 points
Content Readability	The website should be written on a 6 <sup>th</sup> -7 <sup>th</sup> grade readinglevel. The Flesch-Kincaid Test is widely used by Federal and State agencies to measure readability.	No points, see narrative	
Site Functionality	The website should use sans serif fonts (1), the websiteshould include buttons to adjust the font size (1), and resizing of text should not distort site graphics or text (1).	3 points	3 points
Site Map	A list of pages contained in a website that can be accessed by web crawlers and users. The Site Map actsas an index of the entire website and a link to the department's entire site should be located on the bottomof every page.	1 point	1 point
Mobile Functionality	The agency's website is available in a mobile version (1) and/or the agency has created mobile applications(apps) (1).	2 points	1 point
Navigation	Every page should be linked to the agency's homepage (1) and should have a navigation bar at the top of everypage (1).	2 points	2 points
FAQ Section	A page that lists the agency's most frequent askedquestions and responses.	1 point	1 point
Feedback Options	A page where users can voluntarily submit feedbackabout the website or particular section of the website.	1 point	1 point
Online survey/poll	A short survey that pops up and requests users to evaluate the website.	1 point	0 points

Board of Pharmacy Website Criteria Checklist and Points System			
Social Media Links	The website should contain buttons that allow users to post an agency's content to social media pages such asFacebook and Twitter.	1 point	0 points
RSS Feeds	RSS stands for "Really Simple Syndication" and allowssubscribers to receive regularly updated work (i.e. blogposts, news stories, audio/video, etc.) in a standardizedformat.	1 point	0 points
Transparency	Description	Total Points Possible	Total Agency Points
Criteria	A website which promotes accountability and provides information for citizens about what the agency is doing. It encourages public participation while also utilizing tools and methods to collaborate across all levels of government.	32	17
		Individual	Individual
P	Consultantiality control	Points Possible	Agency Points
Email Physical Address	General website contact.	1 point	1 point
Telephone Number	General address of stage agency. Correct telephone number of state agency.	1 point 1 point	1 point 1 point
Location of Agency	The agency's contact page should include an	1 point	1 point
Headquarters	embeddedmap that shows the agency's location.	1 point	0 points
Administrative	Names (1) and contact information (1) of administrative officials.	2 points	2 points
Administrator(s) biography	A biography explaining the administrator(s) professional qualifications and experience.	1 point	0 points
Privacy policy	A clear explanation of the agency/state's online privacypolicy.	1 point	1 point
Complaint form	A specific page that contains a form to file a complaint(1), preferably an online form (1).	2 points	2 points
Budget	Budget data is available (1) at the checkbook level (1), ideally in a searchable database (1).	3 points	0 points
FOIA information	Information on how to submit a FOIA request (1), ideally with an online submission form (1).	2 points	0 points
Calendar of events	Information on events, meetings, etc. (1) ideally imbedded using a calendar program (1).	2 points	2 points
Mission statement	The agency's mission statement should be located on the homepage.	1 point	0 points

Board of Pharmacy Website Criteria Checklist and Points System			
Agency history	The agency's website should include a page explaining how the agency was created, what it has done, and how, if applicable, has its mission changed over time.	1 point	0 points
Public Records	The website should contain all applicable public records relating to the agency's function. If the website contains more than one of the following criteria the agency will receive two points: • Statutes • Rules and/or regulations • Contracts • Permits/licensees • Audits • Violations/disciplinary actions • Meeting Minutes • Grants	2 points	2 points
e-Publications	Agency publications should be online (1) and downloadable (1).	2 points	2 points
Agency Organizational Chart	A narrative describing the agency organization (1), preferably in a pictorial representation such as a hierarchy/organizational chart (1).	2 points	1 point
Graphic capabilities	Allows users to access relevant graphics such as maps, diagrams, etc.	1 point	0 points
Audio/video features	Allows users to access and download relevant audioand video content.	1 point	0 points
Performance measures/outcomes	A page linked to the homepage explaining the agenciesperformance measures and outcomes.	1 point	0 points
Website updates	The website should have a website update status onscreen (1) and ideally for every page (1).	2 points	2 points
Job Postings/links to Personnel Division website	The agency should have a section on homepage for open job postings (1) and a link to the application pagePersonnel Division (1).	2 points	0 points

# Appendix D Agency Response

BOARD MEMBERS Dennis Lewis, President John J. Bernabei, Vice President Dave Bowyer, Secretary Jenna Misiti\* James Rucker\* Sam Kapourales Vicky Skaff (\*Public Member)



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June 6, 2022

Performance Evaluation & Research Division State Capitol Complex Building 1, Room 314W Charleston, WV 25305 VIA EMAIL: <u>Noah.Browning@wvlegislature.gov</u> Brooke.Hypes@wvlegislature.gov

Re: PERD Audit of WVBOP

#### I. <u>Introduction.</u>

The Board appreciates PERD's hard work in compiling this audit report. The Board agrees with PERD's overarching mission to help state agencies run more efficiently and effectively. However, regarding this audit specifically, the Board takes issue with many of the findings. First, the Board believes that the Complaint Log is an official state document that should be properly relied upon. Second, contract management requirements were not provided to the Board upon entering its contracts and therefore, the Board takes issue with being held to a heightened standard than found is state law, rule, and the contracts themselves. The Board believes it has adequate oversight over both the West Virginia Pharmacist Recovery Program contract and the Controlled Substance Monitoring Program contract. The Board respectfully requests PERD to consider the points raised below and revise its final report.

#### II. <u>All complaint resolution timelines for complaints have been met by the Board.</u>

The PERD audit states that eight complaints did not have a start date supported by documentation. Upon inquiring as to the case numbers, these cases were researched. The dates were readily retrievable on the Board's Complaint Log.

Board Rule §15-9-2.5. states "[t]he board shall maintain a complaint log which records the receipt of each complaint, and the nature and the disposition of the complaint." In the State of West Virginia, administrative rules have the same force and effect as law. Therefore, the requirement that the Board maintain a Complaint Log is binding on the Board and the Complaint Log is an official state document required by law.

PERD has determined that the Complaint Log is an insufficient record with respect to the dates recorded. The Board disagrees and believes that the Complaint Log should be used as evidence that statutory deadlines were met. As the custodian of the Complaint Log, I am more than happy to provide a certificate verifying the authenticity of the Complaint Log.

It was stated by the PERD auditor team that anyone could simply fabricate the dates included in the Complaint Log. If we are operating from a position of bad faith actors, I believe that anyone willing to falsify the Complaint Log would also be willing to falsify supporting documents to satisfy PERD.

I offer the following information from the Complaint Log regarding the eight cases noted by PERD:

2017-10-41
 Complaint filed: 10/2/2017
 Date Complaint Dismissed: 12/10/2017
 Status Letter: Not required as the case was resolved prior to the six-month mark.

2. 2018-03-13
Complaint filed: 3/28/2018
Date Complaint Dismissed: 6/25/2018
Status Letter: Not required as the case was resolved prior to the six-month mark.

2018-04-15
 Complaint filed: 4/6/2018
 Date Complaint Dismissed: 6/25/2018
 Status Letter: Not required as the case was resolved prior to the six-month mark.

4. 2018-06-26
Complaint filed: 6/18/2018
Date Complaint Dismissed: 9/10/2018
Status Letter: Not required as the case was resolved prior to the six-month mark.

5. 2018-07-31 Complaint filed: 7/19/2018

2

Date Complaint Dismissed: 9/10/2018 Status Letter: Not required as the case was resolved prior to the six-month mark.

6. 2019-02-11 Complaint filed: 02/12/2019 Date Complaint Dismissed: 9/30/2019 Status Letter: 08/6/2019, in compliance.

7. 2020-04-31
Complaint filed: 04/20/2020
Date Complaint Dismissed: 9/14/2020
Status Letter: Not required as the case was resolved prior to the six-month mark.

8. 2020-06-39
Complaint filed: 06/22/2020
Date Complaint Dismissed: 9/14/2020
Status Letter: Not required as the case was resolved prior to the six-month mark.

Additionally, on Table 4 of PERD's report they state that one status letter did not comply with statutory timelines. PERD identified this as case number 2018-09-44. Below is the information for this case from the Complaint Log.

2018-09-44
 Complaint Filed: 09/28/2018
 Date Complaint Dismissed: 12/10/2018
 Status Letter: Not required as the case was resolved prior to the six-month mark.

As you will see, the Board fully complied with all timelines for all cases noted by PERD.

#### III. <u>The Board is in full compliance with its contract with the West Virginia</u> <u>Pharmacist Recovery Network and exercises adequate oversight.</u>

The headline of Issue 4 as stated by PERD is very misleading. First, the Board does not have inadequate oversight on the West Virginia Pharmacist Recovery Network ("PRN") as will be clarified below. Second, the Board has a robust complaint process for addressing allegations of impairment.

PERD states "[t]he Board has stated it does not have a mechanism for assessing vendor compliance with the contract." This is entirely misleading. What the Board conveyed to PERD was that, aside from the current practices of contract management by the Board, additional audits are expressly prohibited by Board Rule.

PERD states that the Board does not know what the PRN's actual costs are. This is correct because such costs are moot. The contract for the PRN is bid out and the lowest bidder meeting the requirements of the contract is selected. This contract went through the Purchasing Division. To my knowledge, no state agency audits vendors to see whether they are making a profit or to determine what their actual costs are. Therefore, PERD's point that the Board is unaware of the

actual costs of operating the PRN are entirely inappropriate and misleading as they infer that the Board ought to know this information.

PERD outlines the confidentiality of the PRN, but then goes on to make statements which seem to completely disregard the provisions just quoted. Specifically, PERD quotes the following from Board Rule § 15-10-13:

All information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the program, all communications to or from the program, and all proceedings, findings, and conclusions of the program, including those relating to intervention, treatment, or rehabilitation, that in any way pertain to or refer to a person participating in a pharmacist recovery network shall be privileged and confidential.

And

All records and proceedings of the program that pertain or refer to a person participating in a pharmacist recovery network shall be privileged and confidential, used by the program and its members only in the exercise of the proper function of the program, not be considered public records, and not be subject to court subpoena, discovery, or introduction as evidence in any civil, criminal, or administrative proceedings.

After this section is cited, PERD goes on to state that the Board does not adequately oversee th PRN contract or the vendor's compliance with required procedures. The Board is to be embargoe from information related to self-reported impaired licensees. Therefore, the Board cannot audit th PRN's compliance any more than it already does. As for impaired licensees referred to the PR by the Board, the Board receives numerous updates on the status of those licensees including th results of urine tests, the evaluations of healthcare providers, and other relevant updates.

PERD states that the Board does not ensure PRN compliance with contract reporting requirement However, on page 19, PERD goes on to state that the Board receives both required reports from the PRN including quarterly status reports and annual comprehensive statistical reports.

On page 19 of its report, PERD conflates two very distinct types of cases: self-reported cases ar Board referred cases. PERD states that the Board does not know if the PRN makes required contact. For self-reported cases, such contact does not make sense as by the very nature of th cases they are self-reporting and initial contact does not come into play. Therefore, no, the Board does not follow up on this as it does not occur. For Board referred cases, PERD's claim is entire incorrect. The Board will work with the executive director on contacting the licensee and will t involved in every step of the process. The Board will know if the licensee is complying with the FRN or if they are refissing to do so. If they are refissing to comply with Board ordered PRN requirements, the Board may take disciplinary action. For licensees that do comply with the PRN, the Board is updated regularly as to their status.

PERD goes on to state that the Board does not know if the vendor develops and maintains appropriate case information. Again, PERD is conflating two very distinct cases: self-reports and Board referrals. For self-reports, the Board is not to receive this information as it is clearly meant to be kept confidential by the PRN. For Board referred cases, this statement is incorrect as the Board receives a litany of documents pertaining to each referred licensee.

Next, PERD states that the Board does not know if the vendor adequately works with treatment providers or consults with primary care givers as required by the contract. Again, PERD is conflating two very distinct types of cases: self-reports and Board referrals. For self-reports, the Board would have no way of obtaining confirmation as to obtain such information would be a clear violation of the governing rule. For licensees referred to the PRN by the Board, this statement is incorrect. The Board receives documentation including the opinions of bealthcare providers for referred cases. Further, the rule and contract both make clear that bealthcare decisions are to be made by the PRN based on their expertise as they see fit.

Finally, FERD states that the Board does not know if monitoring requirements have been developed for each licensee in the program. Again, PERD is conflating two distinct type of cases: self-reports and Board referrals. For self-reports, as stated above, the Board is prohibited from receiving such information. For Board reported cases, the Board receives a great deal of such information.

In conclusion, PERD's report has not cited any law, rule, or contract clause that the Board or the PRN have not complied with. If PERD believes that additional andits should be conducted, then PERD should recommend that the Board rule be revised to allow for such additional monitoring and the contract with the PRN be revised. The Board has adequately overseen the PRN contract as it is written.

#### IV. <u>The Board is in full compliance with its Controlled Substance Monitoring</u> <u>Program contract and exercises adequate oversight.</u>

FERD states "[t]he Board does not exercise adequate oversight of the Controlled Substance Monitoring Program's contract." This statement is incurrect. There are approximately seventyseven enumerated items in the contract that was in effect during the audit period. PERD has only cited a couple as deficient in their opinion. While the Board does not believe any deficiencies are present as discussed below, if we were to concede to PERD's point that a couple of the seventyseven items in the contract had deficient documentation, this certainly does not support PERD's statement that the Board has inadequate oversight of the CSMP contract.

PERD states "the Board does not receive or maintain reports on attempted illegal access to the database or the findings of an independent review of the contractor's systems controls." This is inaccurate. These items were produced to PERD during the course of the andit. Additionally, these items are readily accessible by the CSMP Administrator from his online dashboard. A screenshot of the CSMP Administrator's dashboard was also produced to PERD.

At one point, PERD requested both the transaction log and the system access log for the CSMP for the period being examined. Upon explanation by the Board of the volume of these reports, which are tens of millions of fields of data, PERD decided it no longer wished to receive this documentation.

The report goes on to state, "the Board also does not have knowledge of whether the contractor has developed a system disaster recovery plan or if the contractor has complied with other security and management provisions." This is also inaccurate. These items were produced as requested.

PERD makes the broad statement that "the Board does not provide adequate contract management, and therefore, the Board does not know if the third-party administrator complies with stated requirements of the contract." This broad statement is entirely inaccurate. The Board has produced all documentation requested. All aspects of the CSMP contract were verified at the time it was initiated and are continually monitored on a daily basis. The Board is in constant contact with the vendor and through this contact the Board frequently verifies compliance with various aspects of the contract. The Board has also verified the existence of all required components of the contract, which were signed off on by the Board and the State Purchasing Division, prior to initiating the contract. The Board has five dedicated staff, including the CSMP Administrator, who are tasked daily with running the CSMP and ensuring the vendor is in compliance with the contract.

Most of the issues PERD had during its audit of the CSMP contract revolved around the Board not having hard-copy documentation readily available. However, having hard-copy documentation readily available was never something the Board was told was a requirement of its management of the CSMP contract. All documents requested, as well as documentation for the entire seventy-seven enumerated items, are readily available to the CSMP Administrator electronically. If PERD seeks to place additional contract management requirements on the Board beyond those found in state law, rule, and the contract itself, then such requirements ought to be formally adopted so state agencies are on notice as discussed above.

Again, statements by PERD such as "[e]ssentially, the Board is not overseeing the compliance of the third-party administrator that is managing an important database for which the Board is responsible to maintain" is grossly inaccurate and unduly damaging to the Board. Such a statement seems to be simply based on an audit of a couple of items out of seventy-seven items, and findings that sufficient documentation was not readily available. As stated above, such documentation was available and produced. However, even if the Board were to concede that proper documentation was not available, which the Board does not, that still would not support the broad sweeping statements by PERD regarding the Board's management of the CSMP contract.

#### V. <u>The Board does know that the Controlled Substances Monitoring Program</u> vendor is in compliance with all requirements of the contract.

The statement "PERD finds that the Board does not provide adequate contract management, and therefore, the Board does not know if the third-party administrator complies with stated

requirements of the contract" is also inaccurate since all documents and reports asked for were produced. All aspects of the current contract were verified at the time it was initiated and are continually monitored by Board staff. The report also states "consequently, the audit team requested select items required by the contract to verify if the vendor complied with the provisions and if the Board was aware of these provisions. These include:

- the comprehensive user's manual,
- a log identifying illegal access attempts,
- a third-party privacy and security assessment,
- a risk analysis in compliance with the HIPAA security rule,
- written reports of any breaches, and
- a system disaster recovery plan.

We have provided copies of all listed items and have since also produced numerous screenshots and other data reflecting various specific items required by the contract, and where these documents are available. We are well aware of the provisions of our contract, and we are in constant contact with the vendor. Through this daily contact we constantly verify compliance with numerous aspects of the contract. We have also verified the existence of all required components of the contract. Some of the documents listed are not on file, but they are available through our various accessible online accounts. Like not retaining copies of bank statements or credit card statements, we have access to all documentation through these accounts, and they can be produced at any time. The vendor was asked to provide us copies of some requested documents on a thumb drive, rather than rely on Board staff, since they have far more expertise in this area.

At one point, the report states "the audit team concluded the Board does not request or receive copies of these documents, which are required by the contract, from the vendor at regular intervals, nor does the vendor provide them unprompted. This isn't accurate because the reports are always available. The report goes on to state "in fact, the contract does not have any provisions mandating the vendor provide these documents, nor does it specify the frequency at which they should be performed, updated, or provided", which is contrary to the statement before. Auditors go on to state "there is nothing in the contract that requires these documents and other items be provided to the Board periodically, nor that the results be discussed with the Board". The contract requires these documents to exist, and current versions are always available to the Board for inspection and review, so we believe compliance is monitored sufficiently.

There is also mention of the insufficiency of the vendor's security audit. Auditors state that "the vendor maintains a secure database", then finds that there are "significant provisions" not covered in the assessment that have nothing to do with that security. "Whether the vendor performs data checks to ensure the data submitted is accurate and complete" is one of the provisions not covered under the security audit. The vendor receives data from pharmacies and other entities from across the country. They verify that data is complete and complies with national standards for controlled substance dispensation reporting. If required standards are not met, the data submitted is rejected

and the party submitting that data is notified so that they may make corrections and resubmit. With regard to data accuracy, Board staff is contacted about an error and our staff works with those same parties to get the data corrected using functions that our vendor created (as part of the contract). Additionally, staff epidemiologists are provided access to vendor production data, which they can query to find a multitude of potential data issues. "Whether data a is deleted from the system after five years" is not a requirement. W. Va. Code §60A-9-5(a)(2) states that "the Board of Pharmacy shall maintain the information required by this article for a period of not less than five years." We remove data older than five years from production but keep that data archived. We have considered purging the data after five years, but it is not required, and its involvement with numerous opioid litigations made that notion potentially problematic. "Whether the vendor updates the system following changes in security standards or changes in State information technology requirements" is a matter also verified on a regular basis. Their system updates are required not only as part of the national standards mentioned earlier, but also federal standards (more stringent than State information technology requirements) that must be met in order for them to remain at the data center that they operate from.

#### VI. <u>Conclusion.</u>

Whether it is the date a complaint was initiated or a provision of a Board contract, most all PERD's issues seem to stem from lack of documentation on the Board's part. PERD's report includes a lot of broad statements and conclusions based on things like best practices or private sector manuals, but the report is short on state law, rule, and contract violations. Essentially, while PERD believes the Board should have more supporting documentation in various instances, PERD has been unable to cite any law or rule or contract clause that such lack of documentation violates.

The Board and Board staff take a great deal of pride in their work serving the Citizens of West Virginia. The Board is open to suggestions for how to better serve the public and operate more efficiently and effectively. However, the Board takes issue with claims that it has inadequate oversight of important state contracts, particularly with the CSMP, and suggestions that statutory requirements were not met. The West Virginia CSMP receives millions of prescriptions a year from all over the country. The system is interacted with over ten million times a month by thousands of practitioners. Perhaps more robust explanations or a detailed tour of the operations and functionality of the vast CSMP program would help PERD better understand the topic and how the numerous complexities of the contract work.

PERD should rewrite its report in a tone that suggests the Board should adopt certain best practices and other opinions of PERD. However, to say that because the Board does not do things as PERD would do them and is therefore operating in violation of statute or inadequately managing contracts is inappropriate. Overall, PERD's report is very negative. The Board believes many conclusions reached within the report are unsupported and inaccurate. The Board requests the report be revised in a manner to distinguish best practices more clearly from inadequate oversight or lack of meeting statutory requirements.



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