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SUNRISE REPORT BOARD OF PHARMACY

AUDIT OVERVIEW

The Performance Evaluation and Research Division Recommends the Proposed Creation of Advanced Practice Pharmacy Technicians Be Tested, Approval for the Creation and Registration for Nuclear Pharmacy Technicians and Approval for Registration of Pharmacy Support Staff.



WEST VIRGINIA LEGISLATIVE AUDITOR

PERFORMANCE EVALUATION & RESEARCH DIVISION

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Note: On Monday, February 6, 2017, the Legislative Manager/Legislative Auditor's wife, Elizabeth Summit, began employment as the Governor's Deputy Chief Counsel. Most or all the actions discussed and work performed in this report occurred after this date. However, the Governor's Deputy Chief Counsel was not involved in the subject matter of this report, nor did the audit team have any communications with her regarding the report. As Deputy Chief Counsel, the Legislative Auditor's wife is not in a policy making position within the Executive Branch. Therefore, the Performance Evaluation and Research Division does not believe there are any threats to independence with regard to this report as defined in A3.06.a and A3. 06.b of the Generally Accepted Government Auditing Standards. Furthermore, the Legislative Auditor has instructed the Director of Performance Evaluation and Research Division to document and discuss any issues he believes are a threat to the division's independence with the President of the Senate and the Speaker of the House due to Ms. Summit's position.

CONTENTS

Executive Summary	7
Finding 1: The Performance Evaluation and Research Division Recommends the Proposed Creation of Advanced Practice Pharmacy Technicians Be Tested, Approval for the Creation and Registration for Nuclear Pharmacy Technicians and Approval for Registration of Pharmacy Support Staff	9

List of Tables

Table 1: Proposed Board Fees for Expanded Registrations	10
Table 2: Comparison of Pharmacy Technician and Proposed Advanced Practice Pharmacy Technician and Proposed Advanced Practice Pharmacy Technician Scope of Practice	12
Table 3: States with Core Elements of Tech-Check-Tech	13
Table 4: Proposed Scope of Practice for Nuclear Pharmacy Technicians	17
Table 5: Proposed Scope of Practice for Pharmacy Support Staff	20
Table 6: Drug Diversion Cases Investigated by WV Board of Pharmacy 2013 to Present.....	21

List of Appendices

Appendix A: Transmittal Letters.....	23
Appendix B: American Pharmacy Association Training Objectives for Nuclear Pharmacy Technician Program	25
Appendix C: Hospital Association Endorsement for Advanced Technicians	27
Appendix D: PharmaLogical Support Letter for Nuclear Pharmacy Technicians	29
Appendix E: Agency Responses.....	31

EXECUTIVE SUMMARY

The West Virginia Board of Pharmacy submitted a Sunrise application to the Joint Standing Committee on Government Organization. Pursuant to *West Virginia Code §30-1A-3*, the Performance Evaluation and Research Division (PERD) is required to analyze and evaluate the Sunrise application and provide recommendations regarding the Board's request to create and register Advanced Practice Pharmacy Technicians and Nuclear Pharmacy Technicians. Additionally, the Board requests to register pharmacy support staff.

The Legislative Auditor concludes that although some published research indicates a low risk of harm to the public in creating Advanced Practice Pharmacy Technicians, the Board should first request to test the proposal in hospitals and institutional pharmacy settings and report the findings back to Legislature. Additionally, the Legislative Auditor finds that the creation and registration of nuclear pharmacy technicians would reduce the risk of harm to the state and that the current requirements place an undue burden on pharmacy technicians working in nuclear pharmacies. Finally, the Legislative Auditor recommends approval of the Board's request to register all pharmacy support staff.

Frequently Used Acronyms in This Report:

PERD: Performance Evaluation and Research Division

TCT: Tech-Check-Tech

Report Highlights:

Finding: The Performance Evaluation and Research Division Recommends the Proposed Creation of Advanced Practice Pharmacy Technicians Be Tested, Approval for the Creation and Registration for Nuclear Pharmacy Technicians and Approval for Registration of Pharmacy Support Staff.

- PERD found no states that license or register advanced pharmacy technicians separately from pharmacy technicians. However, PERD found nine states, including Kentucky, currently allow for a similar type of expanded role for some pharmacy technicians. Moreover, some states plan to expand the role of pharmacy technicians with separate licensing or registration.
- The Board's current approved training programs for pharmacy technicians are not applicable to the skills, knowledge and abilities required for nuclear pharmacist technicians. However, individuals considered for employment as a pharmacy technician within a nuclear pharmacy in West Virginia must meet all training and continuing educations requirements for pharmacy technicians listed in W.Va. Code §30-5.
- The Board's primary reason for requesting the registration of pharmacy support staff is due to their access to pharmaceuticals and the diversion of drugs. The Board currently has no oversight over pharmacy support staff. Although the number of registered pharmacy

technicians disciplined each year for drug diversion is relatively low, there is no knowledge of drug diversion for pharmacy support staff. The Board indicates registration of support staff would provide additional controls to reduce the risk of overall drug diversion.

Recommendations

1. *The Legislative Auditor recommends disapproval of the request to allow the creation and registration of Advanced Practice Pharmacy Technicians.*
2. *The Legislative Auditor recommends the concept of utilizing Tech-Check-Tech and medication reconciliation be tested in hospitals and institutional settings, and the Board of Pharmacy report the findings to the Legislature within one year.*
3. *The Legislative Auditor recommends approval of the Board's request to allow the creation of Nuclear Pharmacy Technicians.*
4. *The Legislative Auditor recommends approval of the Board's request to allow for the registration of Pharmacy Support Staff.*

FINDING 1

The Performance Evaluation and Research Division Recommends the Proposed Creation of Advanced Practice Pharmacy Technicians Be Tested, Approval for the Creation and Registration for Nuclear Pharmacy Technicians and Approval for Registration of Pharmacy Support Staff.

Finding Summary

In accordance with West Virginia Code §30-1A-1 et seq., the Board of Pharmacy submitted a Sunrise application to allow for the creation and registration of advanced practice pharmacy technicians. Additionally, the application requests to create and register nuclear pharmacy technicians and further to register pharmacy support staff. The Legislative Auditor finds that although published research indicates a low risk of harm to the public through the creation and registration of advanced practice pharmacy technicians, this proposal should be tested in hospitals and institutional pharmacy settings and report the findings back to the Legislature. However, the Legislative Auditor recommends approval by the Legislature to create a separate registration and certification for Nuclear Pharmacy Technicians, and approval of the Board's request to register all Pharmacy Support Staff.

The Legislative Auditor finds that although published research indicates a low risk of harm to the public through the creation and registration of advanced practice pharmacy technicians, this proposal should be tested in hospitals and institutional pharmacy settings and report the findings back to the Legislature.

Required Analysis

The Board of Pharmacy submitted a Sunrise application on May 25, 2018 in accordance with West Virginia Code §30-1A-1 et seq. seeking the creation and registration of Advanced Practice Pharmacy Technicians, and Nuclear Pharmacy Technicians. Additionally, the Board requests the registration of Pharmacy Support Staff. West Virginia Code §30-1A-3 requires the Performance Evaluation and Research Division (PERD) to evaluate Sunrise applications based on the following criteria:

- Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety or welfare of the public and whether the potential for harm is easily recognizable and not remote or dependent upon tenuous argument;
- Whether the practice of the profession or occupation requires specialized skill or training which is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational competence;

- Whether the public can be adequately protected by other means in a more cost-effective manner; and
- Whether the profession, occupational group or organization should be regulated as proposed in the application.

Background

The Sunrise application proposes the creation, registration and certification of advanced practice pharmacy technicians, Nuclear Pharmacy Technicians and the registration of non-licensed pharmacy support staff. The Board of Pharmacy (Board) currently registers and certifies pharmacy technicians throughout the state. The Board's three proposals request to allow for the expansion of pharmacy technician positions. The Boards' stated purpose for the request to register pharmacy support staff is to provide additional safeguards to protect the public from drug diversion. The Board indicates that there are 3,827 pharmacy technicians and 1,140 pharmacy technician trainees registered in West Virginia. Additionally, there are 556 residential licensed pharmacies, 73 hospital pharmacies, 6 nuclear pharmacies, 13 in-state mail order pharmacies and 640 out of state licensed pharmacies. All types of pharmacies employ support staff members that are not required by statute to register with the Board. The Board of Pharmacy estimates 1,100 new registrations if all three sunrise applications are approved under the proposed statute. Most of these are expected in the support staff category. Table 1 lists the Board's proposed fee schedule.

Table 1
Proposed Board Fees for
Expanded Registrations

Registration	Registration Fee	Annual Fees
Pharmacy Technicians	\$25	\$30
Advanced Practice Pharmacy Technician	\$35	\$40
Nuclear Pharmacy Technician	\$35	\$40
Support Staff	\$15	\$20

Source: Board of Pharmacy Sunrise Application.

The Board states that the request to create, register and certify Advanced Pharmacy Technicians is necessary to move the industry forward allowing pharmacists more time to devote to patient care. The Board further states that the request to register and certify Nuclear

Pharmacy Technicians is necessary to eliminate the requirement to complete Board approved pharmacy technician training which has “*no application in the world of nuclear pharmacy*”. Additionally, the proposed requirement to register pharmacy support staff is additional protection against drug diversion.

Proposed Creation of Advanced Practice Pharmacy Technicians

The Board’s application indicates that the use of advanced practice pharmacy technicians is an industry trend. The Board’s goal is to increase the role of pharmacy technicians and reduce the work load on pharmacists and some nurses to devote time to an expanded role for pharmacists in patient care. This proposed expanded role is a result of the increased complexity of patient needs and the pharmacists “*role as the medication expert*.” The Board’s application advocates:

...expanding the scope of practice (with proper training) for pharmacy technicians to include tech-check-tech (technician product verification) for processes like automated dispensing cabinet restock, crash cart trays, or cart fill, and medication reconciliation upon admission into an acute care setting....

Table 2 compares the scope of practice of pharmacy technicians and the Board’s proposed scope of practice for advanced practice pharmacy technicians.

Table 2
Comparison of Pharmacy Technician and Proposed
Advanced Practice Pharmacy Technician Scope of Practice

<u>Pharmacy Technician*</u>	<u>Advanced Practice Pharmacy Technician**</u>
1. Assist in the dispensing process.	1. Assist in the dispensing process.
2. Receive new written or electronic prescription drug orders.	2. Receive new written or electronic prescription drug orders.
3. Compound.	3. Compound.
4. Stock medications.	4. Stock medications.
5. Process medical coverage claims.	5. Process medical coverage claims.
6. Cashier.	6. Cashier.
	7. Perform pharmacy technician product verification also known as tech-check-tech.
	8. Complete a list of a patient's current prescription and non-prescription medications to provide for medical reconciliation.
	9. Supervise registered pharmacy technicians and pharmacy technician trainees.
	10. Medical records screening.
	11. Additional duties approved by the board.

* Current scope of practice for Registered Pharmacy Technicians as provided in W.VA. Code §30-5-12(a)(1) through (b)(2). Points 1 through 4 are under direct supervision of a Pharmacist and 5 through 6 are indirect supervision of a Pharmacist.

** Proposed scope of practice as provided in Board of Pharmacy proposed legislation included with Sunrise application.

PERD found no surrounding states that either license or register advanced pharmacy technicians separately from pharmacy technicians. However, PERD found nine states, including Kentucky, currently allow for a similar type of expanded role for some pharmacy technicians. Moreover, some states plan to expand the role of technicians in the future and that some states are planning for separate licensing or registration. One focus of this expansion is the use of the “tech-check-tech” practice model or TCT. This practice model utilizes pharmacy technicians to check the work of other technicians allowing pharmacists additional time to focus on patient care. Additionally, it includes medication reconciliation or the “process of comparing a patient’s medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions.”

PERD found no surrounding states that either license or register advanced pharmacy technicians separately from pharmacy technicians.

Nine States Currently Allow for the Use of Tech-Check-Tech

PERD found a total of nine states with language about TCT programs, and that use what is considered the core elements of TCT.¹ Each of these nine states defines the allowable practice setting, if specialized training is required for individual pharmacy technicians, if a method of quality assurance is in place and if TCT allows for the utilization of pharmacists in other clinical roles. Table 3 lists the nine states that utilize what is considered the core elements of TCT.

Table 3
States with Core Elements
of Tech-Check-Tech

State	Allowable Practice Settings		Technician Education or Training ^a	Quality Assurance ^b	Pharmacist Redeployment ^c
	Hospital or Institutional Pharmacy	Community Pharmacy ^e			
California	Y	N	Y	Y	Y
Idaho	Y	N	Y	Y	... ^d
Iowa	Y	N	Y	Y	...
Kansas	Y	N	Y
Kentucky	Y	N	Y
Minnesota	Y	N	Y	Y	Y
Montana	Y	N	Y	Y	Y
North Dakota	Y	Y	Y	Y	...
South Carolina	Y	N	Y

Source: American Journal of Health System Pharmacy, Tech-Check-Tech, A review of the Evidence on Its Safety and Benefits, Adams, Martin and Stolple,

^a State sets specific requirements for technician education or training as a prerequisite for TCT Participation.

^b State requires ongoing monitoring of safety and accuracy of TCT program.

^c State explicitly calls for use of pharmacist in more clinically oriented roles.

^d Not reported.

^e Community Retail Pharmacy.

Some studies indicate TCT is as effective as pharmacists in detecting errors in filling and checking medication orders. Additionally, 11 published studies indicate a similar accuracy rate for technicians and pharmacists of 99.6 and 99.3 percent respectively. According to Board, the total number of prescriptions filled in West Virginia during

¹ Some other states allow TCT through waivers or request of variance from board of pharmacy rules.

2017 is 35,909,450. Given this number of prescriptions, even slight variations in accuracy such as the 0.3 difference above can result in over 100,000 inaccurate prescriptions. Although mistakes may vary from minor mistakes to the wrong medication, such variations emphasize the importance of ensuring adequate training and focus for both pharmacists and pharmacy technicians.

However, there is some indication that not all studies were published. According to one paper:

Because many of the studies were conducted to convince the state board of pharmacy to permit the use of TCT, it is possible that studies showing that technicians were not as accurate as pharmacists might not have been submitted for publication.

Moreover, study limitations indicate a short testing period of seven days to six months indicating results could change. It is important to note that all but one of these nine states limit TCT to a hospital or institutional setting.

The Board's Application Does Not Limit Utilization to a Specific Setting

The Board's application is not specific in the intent for limiting the role of advanced practice pharmacy technicians to either a hospital and institutional setting, or community retail pharmacy settings. Follow up discussions with the Board indicate a desire to utilize advanced technicians and TCT in all settings, including community pharmacies. Although Chart 2 indicates only one state allows TCT in community retail pharmacies, research highlights a significant difference between the two. For example, “*institutional settings make frequent use of unit dose products whereas community pharmacies primarily fill from bulk containers.*” Additionally, “*institutional settings typically provide medications as a single dose or daily dose, whereas community pharmacies frequently dispense in 30- or 90-day supplies.*” Institutional pharmacies also have additional checks with other health professionals. However, another study in a community pharmacy setting in Iowa found “*no statistical difference in accuracy rates between pharmacists and technicians*” and that “*nearly all errors (88 percent) missed by technicians were administrative in nature, such as not including a safety cap when requested and unlikely to result in patient harm.*” All studies indicate time savings for pharmacists.

PERD received a letter of endorsement for the Sunrise proposal to allow advanced practice pharmacy technicians from the West Virginia Hospital Association, (see appendix C). The letter states in part:

Moreover, study limitations indicate a short testing period of seven days to six months indicating results could change. It is important to note that all but one of these nine states limit TCT to a hospital or institutional setting.

The proposed expansion of the scope of practice for pharmacy technicians to include functions such as medication reconciliation upon admission to an acute care facility would lead to increased efficiencies in the care delivery system by allowing pharmacists and nurses more time to focus on patient care. This expansion would also directly benefit patients by facilitating a more thorough and accurate medication record to be provided to physicians prior to treatment.

PERD received no such endorsement regarding community retail pharmacies.

As discussed previously, the Board's application for advance practice pharmacy technicians does not clearly state if the request is for all types of pharmacies, is limited to hospital and institutional settings, or includes community pharmacies.

The Board's Application Is Not Specific in Other Requirements

As discussed previously, the Board's application for advance practice pharmacy technicians does not clearly state if the request is for all types of pharmacies, is limited to hospital and institutional settings, or includes community pharmacies. However, much of the description of duties in section one of the applications appears to describe a hospital or institutional setting. In addition, the Board's application is not specific regarding additional requirements for advanced practice pharmacy technicians such as training requirements or quality assurance requirements to check the safety of TCT. It is clear from Table 2 that all the states with the core elements of TCT specify the training and education requirements for TCT and six of the nine utilize and require quality assurance programs. Although the application is not specific, it does offer suggestions such as:

With expansion of particular services, additional QA measures could be instituted in terms of proper training i.e. pharmacist must "check off" pharmacy technician for a specific number of tech check tech functions to validate accuracy prior to autonomy to perform said function. [sic]

There could be a set number of years of experience as a pharmacy technician to qualify to apply for an Advanced Practice Pharmacy Technician registration i.e. 2 years.

Although the Board offers suggestions, PERD is concerned that the application is not specific and sufficiently complete to provide an accurate picture of the final requirements for advanced practice pharmacy technicians. Two states, Minnesota and Montana, both with core TCT requirements require individuals to complete "a self-study" training along with "practical training" with "direct observation of pharmacists

Two states, Minnesota and Montana, both with core TCT requirements require individuals to complete "a self-study" training along with "practical training" with "direct observation of pharmacists performing final verification in a unit dose distribution system."

performing final verification in a unit dose distribution system.” These same states also require “*technicians to be audited and achieve a minimum accuracy rate before they are permitted to independently perform final verification.*” **The Legislative Auditor is concerned with the lack of details provided in the Board’s Sunrise application.** Therefore, the Board must specify key details if its intent is to allow some pharmacy technicians to assume some duties normally provided by the pharmacist. **This proposed expansion of registrations requires measurable specialized skills, training, and continuing education to ensure the safety of the public.** It is the Legislative Auditor’s opinion that there is potential risk to the public without clear guidance and understanding from testing and research. **Given the minimum number of states that currently allow advanced functions for pharmacy technicians and none with registration for advanced practice pharmacy technicians, the Legislative Auditor recommends the proposal be tested in hospital and institutional settings only and within one year report the findings to the Legislature.**

Chapter §30 of the West Virginia Code contains no licensing or registration requirements for either nuclear pharmacists or nuclear pharmacy technicians.

Proposed Creation of Nuclear Pharmacy Technicians

The Board’s proposal to create a separate registration and certification for Nuclear Pharmacy Technicians is an acknowledgment of the education, training and experience of the 34 Nuclear Pharmacist Technicians already practicing in the six Nuclear Pharmacies within West Virginia. Chapter §30 of the West Virginia Code contains no licensing or registration requirements for either nuclear pharmacists or nuclear pharmacy technicians. Moreover, the Board approved training programs are not applicable to the skills, knowledge and abilities required for pharmacy technicians working in nuclear pharmacies. The Board licenses pharmacists or registers pharmacy technicians that work only in nuclear pharmacies despite significant differences in the management and requirements required for the storage, sale, and handing of nuclear pharmaceuticals. In addition, all nuclear pharmacies and pharmacists must also meet certain federal requirements through the Federal Drug Administration and the Nuclear Regulatory Commission. Table 4 lists the Board’s proposed scope of practice for nuclear pharmacy technicians.

Table 4
Proposed Scope of Practice for
Nuclear Pharmacy Technicians

1. Assist in the dispensing process.
2. receive new written or electronic prescription drug orders.
3. Mix compound ingredient for liquid products, suspensions, ointments, mixes or blends for tablet granulations and capsule powders.
4. Prepare radiopharmaceuticals.
5. Record keeping.
6. File and organize prescriptions.
7. Create reports.
8. Inventory tasks.
9. Handle raw materials and intermediate or finished products.
10. Perform general maintenance as required on pumps, homogenizers, filter presses, tablet compression machines, and other like machines.
11. Perform standard operating procedures to meet current good manufacturing practices (GMP)
12. Maintain records.
13. Monitor and verify quality in accordance with statistical process or other control procedures.
14. Stock medications.

** Proposed scope of practice as provided in Board of Pharmacy proposed legislation included with Sunrise application.*

West Virginia Code Requires Completion of a Non-Nuclear Focused Training Program

West Virginia Code §30-5-11 through 11a requires individuals employed by either pharmacies or nuclear pharmacies as either pharmacy technician trainees or pharmacy technicians to apply and register with the Board. Additionally, trainees must, according to W.Va. Code §30-5-1 enroll in and complete:

... a competency-based pharmacy technician education and training program as approved by legislative rule of the board; or complete a pharmacy provided, competency-based education and training program approved by the board and (Effective July 1, 2014), successfully pass an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the board....

According to a Nuclear Pharmacist writing in support of the Boards

sunrise application, “*the profession of a nuclear pharmacist technician is distinct and separate from traditional pharmacy technicians* (see Appendix D).” He further states:

When presented with this obstacle, many chose not to pursue the profession of a nuclear pharmacy technician, because the coursework involved in pursuing a standard pharmacy technician license bares no relevance to the profession they are interested in. The knowledge obtained in the traditional course work, while valuable, in no way prepares the individual to work in a nuclear pharmacy. This is significant time wasted for anyone interested in the field, because the training they need has been postponed while they overcome this obstacle. [sic]

Completion of the approved pharmacist technician training required by code does however, allow the individual to easily move to other pharmacy technician positions outside of nuclear pharmacies without being required to retake the approved training programs.

Requirements of Nuclear Pharmacy Technician Training Programs

Individuals considered for employment as a pharmacy technician within a nuclear pharmacy in West Virginia must meet standards over and above the basic requirements for Pharmacy Technicians listed in W.Va. Code §30-5. PERD reviewed the statutes of neighboring states and found Kentucky’s statute contains many requirements regarding nuclear pharmacies. Although there is no separate title for pharmacist technicians who work in nuclear pharmacies, the Kentucky statute allows for the completion of training focused on nuclear pharmacies and not training focused on non-nuclear pharmacies. To work in a nuclear pharmacy, the Kentucky code, specifically 201 KAR 2:045, requires individuals to complete “*the Nuclear Pharmacy Training program at the University of Tennessee.*”

PERD reviewed the statutes of neighboring states and found Kentucky’s statute contains many requirements regarding nuclear pharmacies. Although there is no separate title for pharmacist technicians who work in nuclear pharmacies, the Kentucky statute allows for the completion of training focused on nuclear pharmacies and not training focused on non-nuclear pharmacies.

Several online programs exist for Nuclear Pharmacy Technician Training throughout the country. However, the American Pharmacy Association offers guidelines with 10 training objectives for nuclear pharmacy technician programs, (see Appendix B of this report). These requirements demonstrate a focus on the use of mathematics, compounding and safety in working with radiopharmaceuticals, which are advanced compared to traditional pharmacies. Moreover, it demonstrates the need for either a distinct registration from regular pharmacy technicians or the Board allowing individuals to qualify as a pharmacy technician through

completion of nuclear pharmacy technician training. The current requirements place a burden on individuals to complete training that is irrelevant to the requirements of a technician working in a nuclear pharmacy. **Therefore, the Legislative Auditor recommends approval of the Board's sunrise request to create a separate registration and certification for nuclear pharmacist technicians.** This would lower the risk to the public from unregistered individuals working in the industry given the current requirements. Moreover, allowing a separate registration from the traditional pharmacy technician classification will have minimal impact on the Board and public given the small number of nuclear pharmacies in the state. It also allows individuals that complete nuclear pharmacy training in other states to take positions in West Virginia without being required to then complete the current requirement of traditional pharmacy training benefiting the individual and nuclear pharmacies. The Board anticipates no net gain of registrants since the Board estimates only 34 individuals currently work as nuclear pharmacy technicians.

The current requirements place a burden on individuals to complete training that is irrelevant to the requirements of a technician working in a nuclear pharmacy.

Registration of Pharmacy Support Staff

The Board also requests to register all pharmacy support staff. All pharmacies employ staff other than pharmacists and technicians to support daily operations. The Legislature exempted cashiers from Board oversight during the 2018 legislative session through House Bill 4332 in W.Va. Code §30-5-29(d)5(f). Previously, “*any individual working in a pharmacy had to either be registered as a pharmacist, a pharmacy technician trainee, or a pharmacy technician.*” This proposed registration does not subject support staff to the training or continuing education requirements of pharmacy technicians or trainees.

The Board also requests to register all pharmacy support staff. All pharmacies employ staff other than pharmacists and technicians to support daily operations.

Table 5 lists the Board's proposed scope of practice for support staff.

Table 5
Proposed Scope of Practice for
Pharmacy Support Staff
1. Patient Scheduling
2. General customer service
3. Contact patient when prescription is not picked up
4. Placing drug orders
5. Provide final drug product to patient.
6. Prescription deliver, both internal and external.
7. Sell pseudoephedrine products
8. General recordkeeping
9. Prepare pharmacy reports for pharmacy review.
10. Manage technology systems, including programming, routine database management, and billing systems.
11. General insurance billing/auditing.
12. Act as cashier.
13. Add and update third party insurance information.
14. Additional duties assigned by the pharmacist on duty that do not require clinical or professional judgement nor fall under the scope of practice of technicians or advanced practice technicians.
<i>* Proposed scope of practice as provided in Board of Pharmacy proposed legislation included with Sunrise application.</i>

PERD requested legal research to determine the number of legal cases involving pharmacists, pharmacy technicians and pharmacy staff in West Virginia and surrounding states. However, due to the way prosecutors' file cases, legislative legal staff found nothing connected to pharmacists, technicians, or support staff.

The Board's primary reason for requesting the registration of support staff is due to the concern for the diversion of drugs. The reasoning is that if a pharmacy discovers drug diversion and dismisses an individual working as support staff, nothing prevents the individual from obtaining employment at another pharmacy. Registration provides the Board oversight of all individuals with access to the pharmacy area. Statistics provided by the Board do indicate such diversion exists among licensed and registered pharmacy staff. Table 6 indicates that since 2013 the Board received 98 complaints regarding drug diversion.

Table 6
Drug Diversion Cases Investigated by
WV Board of Pharmacy 2013 to Present

Registrants	2013	2014	2015	2016	2017	2018
Pharmacy Technicians	7	5	7	12	3	3
Pharmacy Technician Trainees	5	1	9	6	4	2
Registered Pharmacists	3	9	0	13	6	3
Total	15	15	16	31	13	8*

*Source: Board of Pharmacy complaint log (Current as of October 2018)

However, the Board's complaint logs list only those positions currently licensed, registered and certified by the Board. Since support staff are not required to register with the Board, it cannot receive and investigate complaints against pharmacy support staff.

The Board Plays a Key Role in the Prevention of Drug Diversion

One important function of the Board involves the operation of the Controlled Substances Monitoring Program. Through this program mandated in W. Va. Code §60A-9, the Board operates a database of all prescriptions “written for schedule II, III, and IV controlled substances written or filled in this state.” Additionally, the Board works with the State Police and other licensing boards to identify drug diversion within the state. According to the State’s opioid response plan, “West Virginia leads the nation in drug overdose deaths per capita.”

PERD requested information from the West Virginia Health Statistics Center regarding deaths from prescription drugs. However, the Director responded, the Center “does not have an analysis that indicates how many deaths are due solely to prescription pharmaceuticals.” The Director did indicate that overdose deaths, occurring in the state, as a result of prescription pharmaceuticals peaking around 2011.² However,

Since support staff are not required to register with the Board, it cannot receive and investigate complaints against pharmacy support staff.

² Source: WV Health Statistics; The majority of deaths at this time were as a result prescription pharmaceutical - primarily oxycodone and hydrocodone are often co-used with benzodiazepines.

he also emphasized deaths resulting from pharmaceuticals are still an issue.

Although the number of registered individuals disciplined each year for drug diversion by the Board is low, it still poses a risk that the Board intends to reduce. Even one person involved in diverting drugs can impact several individuals within a community and families. **The Legislative Auditor supports the Board's desire to register pharmacy support staff who have access to pharmaceuticals.** This registration is a minimal cost to either the individual or company and is in keeping with the Board's mission to fight drug diversion.

Conclusion

Pharmacy technicians require specialized knowledge and proficiency to protect the public. PERDs review of the Board's Sunrise request to create advance practice pharmacy technicians indicates that there are still questions regarding the safety of advancing the role of pharmacy technicians. Additionally, PERD supports the Board's request to allow the creation of nuclear pharmacy technicians and to register pharmacy support staff. The Legislative Auditor makes the following recommendations.

Recommendations:

1. *The Legislative Auditor recommends disapproval of the request to allow the creation and registration of Advanced Practice Pharmacy Technicians.*
2. *The Legislative Auditor recommends the concept of utilizing Tech-Check-Tech and medication reconciliation be tested in hospitals and institutional settings, and the Board of Pharmacy report the findings to the Legislature within one year.*
3. *The Legislative Auditor recommends approval of the Board's request to allow the creation of Nuclear Pharmacy Technicians.*
4. *The Legislative Auditor recommends approval of the Board's request to allow for the registration of Pharmacy Support Staff.*

Appendix A Transmittal Letter

WEST VIRGINIA LEGISLATURE *Performance Evaluation and Research Division*

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John Sylvia
Director

December 28, 2018

Mr. Dennis Lewis, President
West Virginia Board of Pharmacy
2310 Kanawha Blvd E.
Charleston, WV 25311

Dear President Lewis:

This is to transmit a draft copy of the Sunrise report on the Board of Pharmacy. This report is tentatively scheduled to be presented during the January 6-8, 2019 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.

If you would like to have a written response to the report distributed to the committee and any other material, please provide them to us by Thursday, January 3, 2019.

We request that your personnel not disclose the report to anyone not affiliated with your agency. If you have questions please contact Michael Midkiff at 304-347-4890. Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink that reads "John Sylvia".

John Sylvia

Enclosure

Joint Committee on Government and Finance

Appendix B

American Pharmacy Association Training Objectives for Nuclear Pharmacy Technician Programs

- The nuclear pharmacy technician should demonstrate appropriate knowledge and understanding of the nuclear pharmacy practice site with emphasis on the technician duties and responsibilities, including standards of ethics governing pharmacy practice.
- The nuclear pharmacy technician should have a working knowledge of the radiopharmaceutical terms, abbreviations, and symbols commonly used in prescribing, compounding and dispensing radiopharmaceuticals.
- The nuclear pharmacy technician should demonstrate an ability to perform the mathematical calculations required for the usual dosage determinations and solution preparations in the preparation and dispensing of radiopharmaceuticals.
- The nuclear pharmacy technician should demonstrate the ability to perform the essential functions relating to drug purchasing and inventory control.
- The nuclear pharmacy technician should demonstrate a working knowledge of drug dosages by imaging procedure, routes of administration, dosage forms, and be able to distinguish therapeutic from diagnostic radiopharmaceutical utilization.
- The nuclear pharmacy technician should have working knowledge of the procedures and operations relating to the reconstitution, packaging and labeling of radiopharmaceuticals.
- The nuclear pharmacy technician should have a working knowledge of the procedures and techniques relating to aseptic compounding of radiopharmaceuticals and drug products and the associated parenteral admixture operations.
- The nuclear pharmacy technician should demonstrate the ability to perform the usual technician functions associated with a specific nuclear pharmacy.
- The nuclear pharmacy technician should demonstrate the ability to perform the appropriate handling techniques and record keeping functions associated with the reconstitution and dispensing of radiopharmaceuticals.
- The nuclear pharmacy technician should demonstrate the appropriate handling techniques and record keeping functions associated with quality control testing of radiopharmaceuticals.

Appendix C

WV Hospital Association Endorsement for Advanced Technicians



100 Association Drive
Charleston, WV 25311-1571
Phone (304)344-9744
www.wvha.org

October 16, 2018

Performance Evaluation & Research Division
State Capitol Complex
Building 1, Room 314W
Charleston, WV 25305

Dear Mr. Sylvia:

Re: West Virginia Board of Pharmacy's Sunrise Application for Advanced Practice Pharmacy Technicians

On behalf of the West Virginia Hospital Association and its 63 member hospitals and health systems, we respectfully submit this letter in support of the West Virginia Board of Pharmacy's Sunrise Application for Advanced Practice Pharmacy Technicians.

The proposed expansion of the scope of practice for pharmacy technicians to include functions such as medication reconciliation upon admission to an acute care facility would lead to increased efficiencies in the care delivery system by allowing pharmacists and nurses more time to focus on patient care. This expansion would also directly benefit patients by facilitating a more thorough and accurate medication record to be provided to physicians prior to treatment.

It is important that this expansion be governed by a new advanced license as these new functions are beyond the traditional scope of a pharmacy technician. By allowing for this advanced license, hospitals will be able to better identify qualified applicants for pharmacy technician positions in an inpatient setting.

If you have any questions or concerns, please contact me at (304) 353-9720.

Sincerely,


Brandon Hatfield
General Counsel

Appendix D

PharmaLogic Support Letter for Nuclear Pharmacy Technicians



Performance Evaluation & Research Division

State Capitol Complex
Building 1, Room 314W
Charleston, West Virginia 25305

To Whom it may concern,

I am writing this letter in support of the proposed legislation to recognize nuclear pharmacy technicians as a distinct and separate profession from traditional pharmacy technicians. As a nuclear pharmacist of over 25 years, I have worked with many individuals who have mastered the skill set required to safely and effectively operate within the confines of the proposed legislation, but who have been unable to due to the strict requirement of obtaining one's traditional pharmacy technician license. When presented with this obstacle, many chose not to pursue the profession of a nuclear pharmacy technician, because the coursework involved in pursuing a standard pharmacy technician license bares no relevance to the profession they are interested in. The knowledge obtained in the traditional coursework, while valuable, in no way prepares the individual to work in a nuclear pharmacy. This is significant time wasted for anyone interested in the field, because the training they need has been postponed while they overcome this obstacle.

With the implementation of the proposed legislation, the state of West Virginia will be highly progressive in its recognition of nuclear pharmacy technicians as being qualified for a specialized field that will promote the expansion of nuclear medicine, and in turn improve patient care for West Virginia. These individuals are invaluable to the services we provide as nuclear pharmacists, and the proposed legislation will allow for a more structured platform of training, and subsequently, recognition for these individuals who pursue mastery of this particular specialty of medicine.

Thank you for your consideration in the matter,

A handwritten signature in black ink, appearing to read 'Glen Palmer'.

Glen Palmer RPh
Pharmalogic COO

Appendix E

Agency Responses

BOARD MEMBERS

*Dennis Lewis, President
John J. Bernabei, Vice President
Vicky Skaff, Secretary
Everett Frazier *
Chuck Jones*
Sam Kapourales
David Bowyer
(*Public Member)*

Office

*2310 Kanawha Blvd. East
Charleston, WV 25311*

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STAFF

*Michael L. Goff,
Executive Director &
CSMP Administrator*

*John P. Smolder,
CFO/COO*

*Ryan L. Hatfield
General Counsel*

Phone

*(304) 558-0558
(304) 558-0572 (fax)*

January 3, 2019

Joint Committee on Government Operations
Joint Standing Committee on Government Organization
West Virginia Legislature
1900 Kanawha Blvd E,
Charleston, WV 25305

Re: West Virginia Board of Pharmacy Sunrise Application

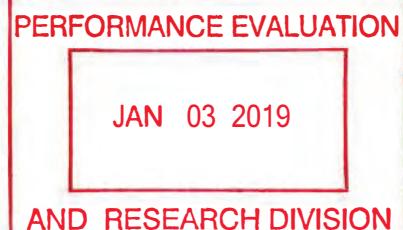
Dear Committee Members,

The West Virginia Board of Pharmacy (“Board”) has received the Sunrise Report from the Performance Evaluation and Research Division (“PERD”). This letter serves as the Board’s official response to PERD’s report.

While the Board is pleased with PERD’s approval of nuclear technicians and support staff, the Board respectfully disagrees with PERD’s decision to disapprove the creation of advanced practice pharmacy technicians. It is our hope that this letter will serve to address the concerns outlined by PERD in its Sunrise Report and persuade the Joint Committee on Government Operations and Joint Standing Committee on Government Organization that the creation of advanced practice technicians is a proven model supported by industry leaders that will promote patient care and safety in the State of West Virginia.

I. Advanced Practice Technicians are a proven model.

Advanced Practice Technicians (“APT”) are a proven model implemented in many states across the nation. In multiple states that do not currently have APTs, there has been legislation proposed to create APTs. The creation of APTs in West Virginia would certainly be following the national trend.



The statistics presented by PERD in Table 3 of its Sunrise Report do illustrate several states utilizing Tech-Check-Tech ("TCT"), a major component of APT's scope of practice. However, the statistics provided by PERD appear to be from 2011. The 2018 statistics are below in Table 1.

TABLE 1
States with Core Elements of Tech-Check-Tech

State	Hospital/Institutional Pharmacy	Community Pharmacy
Arizona	Y	Y
California	Y	
Colorado	Y	Y
Idaho	Y	Y
Iowa	Y	Y
Kansas	Y	
Michigan	Y	Y
North Dakota	Y	Y
Oregon	Y	
South Carolina	Y	Y
Texas	Y	
Utah	Y	
Washington	Y	Y

Source: National Association of Board of Pharmacy (2018). *Survey of Pharmacy Law*. Mount Prospect, IL: National Association of Boards of Pharmacy, pp.47, 48, 51, 52.

As illustrated above, in the years between the 2011 data and the 2018 data, the number of states allowing TCT in the hospital/institutional pharmacy setting went from nine to thirteen and the number of states allowing TCT in the community pharmacy setting went from one to eight. Thus, it is evident that the national trend is moving toward the creation of APTs allowing for TCT.

The PERD Sunrise Report also points out that eleven published studies indicate a similar accuracy rate for technicians and pharmacists of 99.6% and 99.3%, respectively. However, PERD's use of this statistic is a bit misleading. PERD's report states the following:

According to the Board, the total number of prescriptions filled in West Virginia during 2017 was 35,909,450. Given this number of prescriptions, even slight variations in accuracy such as the 0.3% difference above can result in over 100,000 inaccurate prescriptions.

For this to be the case, pharmacy technicians would have to fill all 35,909,450 prescriptions to result in 100,000 inaccurate prescriptions. This is not the case. Additionally, and perhaps most

importantly, pharmacy technicians in the State of West Virginia are already allowed to assist in the dispensing process. See *West Virginia Code § 30-5-12(a)(1)*.

II. Final Requirements for Advanced Practice Technicians will be set forth in Board rules.

In its Sunrise Report, PERD states its concern that the Board's application was not specific enough as it relates to training requirements and quality assurance requirements. This was not an oversight on the part of the Board. Rather, the Board intends to spend the next several months utilizing a working group to establish such requirements. These requirements will be laid out in Board rule and Board policy. This timeline should not be viewed as problematic because the earliest APTs will be able to practice in West Virginia would be June or July, assuming the Board's legislation is approved.

The Board has begun the process of eliminating unnecessary and burdensome regulations on the practice of pharmacy. It was the Board's belief that including such requirements in code would be improper due to the inflexible nature of codified language. Rather, the Board would prefer to set such requirements in Board policy which would allow the Board the ability to modify such requirements should such action be necessary without having to pass additional bills through the lengthy legislative process.

It should be noted that this approach is in line with how pharmacy technician training programs are currently regulated by the Board. West Virginia Code § 30-5-11(a) states as follows:

To be eligible for registration as a pharmacy technician to assist in the practice of pharmacist care, the applicant shall:

(4) Have

(A) Graduated from a competency-based pharmacy technician education and training program as approved by legislative rule of the board; or

(B) Completed a pharmacy provided, competency-based education and training program approved by the board;

Training programs for pharmacy technicians are currently approved by the Board on a case-by-case basis. It is the Board's intent to approve training programs for APTs in the same manner.

III. The West Virginia Board of Pharmacy does not prefer to conduct a pilot program.

The recommendation of PERD is that the Sunrise Application for APTs be disapproved. Instead, PERD recommends a sort of pilot program. The Board strongly disagrees with this suggestion.

The lack of specification in PERD's recommendation is concerning to the Board. First, the Board is unclear as to how to go about selecting which institutions would be able to host TCT. Second, aside from usual inspections, the Board does not have the staff to oversee a pilot program such as this. In conclusion, the Board feels that the creation of a pilot program would create an unnecessary level of bureaucracy that would be difficult to implement.

IV. The creation of Advanced Practice Technicians is supported by both hospitals and community pharmacies.

The Sunrise Report states that the Board was unclear as to what settings APTs would be allowed to work. The Board's intent is to allow for APTs in both the hospital/institutional setting as well as community pharmacies. In the Board's Sunrise Application, a letter in support of APTs from the West Virginia Hospital Association was attached. Thus, the support of West Virginia hospitals was clear to PERD. However, it was an oversight on the part of the Board not to include letters of support from community pharmacies.

Once the Board received the Sunrise Report from PERD and noted this shortcoming in our application, we immediately reached out to representatives of community pharmacies. As such, please see attached letters in support of the creation of APTs from both the West Virginia Independent Pharmacy Association and the West Virginia Retailers Association. When viewed in conjunction with the letter from the West Virginia Hospital Association, it is clear that the creation of APTs has broad support across all pharmacy settings.

V. Conclusion.

The Board's idea for APTs was presented to the Board from industry leaders. The Board feels as though the creation of APTs would deregulate the practice of pharmacy in the sense that APTs would be able to function to their full potential according to their training. By allowing APTs to function at a higher level, pharmacists will have more time to devote to higher level tasks thus promoting public health and safety. It should again be emphasized the broad support the creation of APTs has amongst industry leaders.

The APT model has been proven across the country and is the current trend in the practice of pharmacy. APTs are a recurring and leading topic at nearly every national conference. The Board believes the creation of APTs in the State of West Virginia is necessary to ensure that the state does not fall behind national trends and stays at the forefront of the practice of pharmacy. Any specific details not included in the Board's Sunrise Application or proposed bill will be addressed by a working group over the next several months to ensure APTs receive the appropriate training and have proper oversight.

The Board would like to thank PERD for their hard work throughout this process. While we do not agree with PERD's final recommendation as it relates to APTs, we have appreciated their diligence and communication during these last several months.

In conclusion, the Board strongly urges members of the Joint Committee on Government Operations and Joint Standing Committee on Government Organization to approve the creation of APTs in the State of West Virginia.

Sincerely,



Ryan L. Hatfield
General Counsel

Enclosures (2)



West Virginia Retailers Association

January 2, 2019

Ryan Hatfield, General Counsel
West Virginia Board of Pharmacy
2310 Kanawha Blvd., East
Charleston, WV 25311

Dear Mr. Hatfield:

West Virginia Retailers Association and the community pharmacies we represent have participated in the process to develop legislation defining the registration process for advanced practice pharmacy technicians and the registration for pharmacy support staff. Retail pharmacies across the state recognize the need to modernize pharmacy practices where both pharmacists and technicians are able to utilize their full skill set. Our industry embraces the technological advances that have been made and believes that patient access to care is a number one priority.

WVRA looks forward to participating with the WV Board of Pharmacy in pursuing new and innovative pharmacy standards in our state.

Best regards,

Bridget Lambert, President
WV Retailers Association

2110 Kanawha Blvd., East, Suite 220
Charleston, WV 25311
(304) 342-1183
Fax (304) 342 1471
wvra@teays.net



West Virginia Independent Pharmacy Association

Charleston Office: 2017 Quarrier Street, Charleston, WV 25311

Barboursville Office: 650 Main Street, Barboursville, WV 25504

Phone: (304) 654 - 4214

Fax: (681) 265 - 9024 or (304) 733 - 6486

Web: www.WVIPA.com

Email: matt@walkerandstevens.com

To: West Virginia Board of Pharmacy; Performance Evaluation & Research Division
From: West Virginia Independent Pharmacy Association
Date: January 2, 2019
Re: Letter of Support

My name is Matt Walker. I am the Executive Director of the West Virginia Independent Pharmacy Association ("WVIPA"), a non-profit organization representing independent pharmacies in the Mountain State. I am writing on behalf of the 45 WVIPA members operating 60 pharmacy sites in West Virginia.

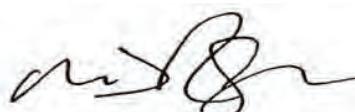
We appreciate the opportunity to write in support of the West Virginia Board of Pharmacy's sunrise application for Advanced Practice Pharmacy Technicians. It is our belief that passage of the proposed bill would greatly enhance patient care and safety in West Virginia.

Thank you for your careful consideration of the matter. The WVIPA and pharmacies across West Virginia appreciate the time and effort spent on this issue. Please do not hesitate to contact us for further clarification if needed.

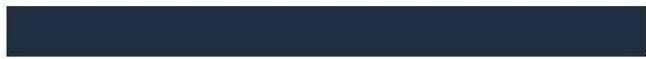
Respectfully Submitted,



Matthew Walker, Executive Director
West Virginia Independent Pharmacy Association



Michael Rudge, Board President
West Virginia Independent Pharmacy Association



WEST VIRGINIA LEGISLATIVE AUDITOR

PERFORMANCE EVALUATION & RESEARCH DIVISION

Building 1, Room W-314, State Capitol Complex, Charleston, West Virginia 25305

telephone: 1-304-347-4890 | www.legis.state.wv.us/Joint/PERD/perd.cfm | fax: 1-304-347-4939