

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Do Not Mark In This Box

FILED

2011 AUG -1 P 3:51

Form #3

OFFICE WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: West Virginia Code Section 30-5-7

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: Series 12

TITLE OF RULE BEING AMENDED: Immunizations Administered By Pharmacists

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.



Authorized Signature

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 31, 2014

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: *(Agency Name, Address & Phone No.)* West Virginia Board of Pharmacy
2310 Kanawha Boulevard East
Charleston, WV 25311
304-558-0558

LEGISLATIVE RULE TITLE: Title 15, Series 12
Immunizations Administered By Pharmacists

1. Authorizing statute(s) citation WV Code Section 30-5-7

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
June 27, 2014

b. What other notice, including advertising, did you give of the hearing?
E-mailed copy to pharmacy stakeholders, including representatives of West Virginia Pharmacists Association, West Virginia Retailers Association, West Virginia Society of Health System Pharmacies, National Association of Chain Drug Stores, West Virginia University School of Pharmacy, Marshall University School of Pharmacy, and University of Charleston School of Pharmacy, as well as representatives of several chain pharmacies and others.

c. Date of Public Hearing(s) *or* Public Comment Period ended:
July 27, 2014

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

~~July 31, 2014~~ ^{DEP} August 1, 2014

f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule: (Please type)

David E. Potters
Executive Director & General Counsel
West Virginia Board of Pharmacy
2310 Kanawha Boulevard East
Charleston, WV 25311
304-558-0558
304-558-0572
david.e.potters@wv.gov

g. **IF DIFFERENT FROM ITEM 'F'**, please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

d. Attach findings and determinations and reasons:

Attached

**BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES
WHICH REQUIRE THE PROPOSED LEGISLATIVE RULE**

**Immunizations Administered By Pharmacists
Title 15, Series 12**

Summary and Statement of Circumstances: HB 3056, passed during the Regular Session, 2008, and duly enacted into law, permits pharmacists to administer immunizations to patients in this State. This provision was amended in 2013 to allow for pharmacist interns to administer immunizations under appropriate pharmacist supervision. West Virginia Code Section 30-5-7(d) and (e) requires rulemaking by the Board of Pharmacy with the advice and consent of the Board of Medicine and Board of Osteopathy for pharmacist administration of any immunizations beyond the influenza and pneumonia vaccines. The three boards have continued to work together over the past several years to amend the rules in Series 12 to provide for additional immunizations through joint rulemaking.

The modifications proposed here, if approved, would allow for pharmacist interns to administer immunizations under “personal” supervision of the immunizing pharmacist, and would add meningococcal vaccine to the list of approved immunizations which may be given by pharmacists or supervised pharmacy interns. Finally, in addition to requiring pharmacists to report any adverse events with administration to the CDC’s national Vaccine Adverse Events Reporting System (VAERS), with a copy the Board of Pharmacy, it would now also require a copy to the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services, and to the patient’s primary care physician or other licensed health care provider as identified by the person receiving the immunization.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, 2310 Kanawha Boulevard East, Charleston, West Virginia, 25311, telephone (304) 558-0558.

Note: This is a modification of the Series, such that changes are reflected by strike-throughs and underlining in the proposed rule.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Title 15 Series 12 "IMMUNIZATIONS ADMINISTERED BY PHARMACISTS"

Rule Title: _____
 Type of Rule: Legislative Interpretive Procedural
 Agency: WV Board of Pharmacy, jointly with Board of Medicine and Board of Osteopathy
 Address: 2310 Kanawha Boulevard East
Charleston, West Virginia 25311

 Phone Number: 304-558-0558 Email: david.e.potters@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This should have no fiscal impact on state government. It is revenue neutral.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Title 15, Series 12 "IMMUNIZATIONS ADMINISTERED BY PHARMACISTS"

Rule Title: _____

Rule Title: _____

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

There are no fee changes and no discernable impacts on board resources. The rules are simply changes in requirements to allow interns to immunize under the supervision of a training pharmacist, and to require some additional minimal reporting.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule would not have a fiscal impact, and/or any special issues not captured elsewhere on this form.

None. There are no fee changes and no discernable impacts on board resources. The rules are simply changes in requirements to allow interns to immunize under the supervision of a training pharmacist, and to require some additional minimal reporting.

Date: June 25, 2014

Signature of Agency Head or Authorized Representative

David E. Potters

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

FILED

2011 AUG -1 P 3: 51

SERIES 12
Board of Pharmacy Rules Regarding
Immunizations Administered By Pharmacists

OFFICE WEST VIRGINIA
SECRETARY OF STATE

§15-12-1. General.

1.1. Scope. -- To amend the rules for pharmacists and pharmacy interns licensed in West Virginia to administer immunizations to patients in this State, ~~providing for additional immunizations~~ through joint rulemaking by the West Virginia Board of Pharmacy, Board of Medicine, and Board of Osteopathy.

1.2. Authority. -- W. Va. Code §~~30-5-30~~ 30-5-7.

1.3. Filing Date. -- ~~April 4, 2012~~ _____.

1.4. Effective Date. -- ~~April 4, 2012~~ _____.

§15-12-2. Definitions.

2.1. "Board", unless otherwise specifically indicated, means the West Virginia Board of Pharmacy.

2.2. "Immunizations" means, for the purpose of this rule, the vaccines specifically listed in this subsection which a pharmacist or pharmacy intern may administer to any person eighteen years of age or older, including:

(a) Influenza;

(b) ~~Pneumonia~~ Pneumococcal;

(c) Hepatitis A;

(d) Hepatitis B;

(e) Herpes Zoster; ~~and~~

(f) Tetanus, tetanus-diphtheria (commonly referred to as "Td"), or tetanus-diphtheria-and-pertussis (commonly referred to as "Tdap"); and

(g) Meningococcal.

2.3. "Personal supervision" means the supervising immunizing pharmacist is physically present in the room during the administration of a vaccine.

§15-12-3. Qualifications.

3.1. A pharmacist licensed by the Board may administer immunizations to any person eighteen years of age or older provided the pharmacist has met all of the following requirements:

(a) -registered with the board to administer immunizations;

(b) successfully completed the American Pharmacists Association's (APhA) immunization training program, or such other immunization training course as may be approved by the Board, which courses must be based on the standards established for immunization training by the Centers for Disease Control and Prevention in the public health service of the United States Department of Health and Human Services;

(c) maintains current certification in basic life-support training, including basic cardiopulmonary resuscitation (CPR), offered by the American Heart Association or the American Red Cross; and

(d) completed a minimum of ~~two (2)~~ 2 hours ~~annually~~ of continuing pharmacy education related to immunizations each licensing year for a total of 4 hours each renewal period. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (A.C.P.E.).

3.2. A pharmacy intern registered by the Board may administer immunizations as permitted by this rule provided that:

(a) the pharmacy intern is under the personal supervision by a pharmacist who is registered with the board to administer immunizations as required by this rule; and

(b) has completed all of the training and current certification required by subsections 3.1 (b) and (c) of this section.

3.23.3. It is unprofessional conduct for a ~~pharmacist~~ pharmacist or pharmacy intern to administer an immunization, who is not in compliance with this rule.

§15-12-4. Registration.

4.1. Prior to administering immunizations, a pharmacist shall submit an application supplied by the Board for review and approval of the Board, providing that all of the requirements of Section 3(a) have been met. The application must be submitted along with a required fee of \$10.00. Provided all requirements of Section 3(a) have been

met and the required fee is received, the Board shall issue a registration to administer immunizations. Registrations shall expire bi-annually on June 30 of year in which the pharmacist's license to practice pharmacy expires.

4.2. A pharmacist may not administer an immunization unless currently registered with the Board to do so under this rule. Further, such registration must be posted conspicuously at any location at which the registered pharmacist is doing any administration.

4.3 Prior to administering immunizations, a pharmacy intern shall provide to his or her supervising pharmacist documentation that the pharmacy intern has completed all of the training and current certification required by subsections 3.1 (b) and (c) of this rule. The supervising pharmacist shall maintain this documentation in the pharmacy where the pharmacist and pharmacy intern who administers an immunization is employed or otherwise practicing at the time any immunization is given by the pharmacy intern.

§15-12-5. Immunizations.

5.1. Immunizations authorized by this rule shall be administered:

(a) in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), including, but not limited to, CDC's "Recommended Adult Immunization Schedule, by Vaccine and Age Group" and "Recommended Adult Immunization Schedule, by Vaccine and Medical and Other Indications", including the footnotes provided for each schedule (available at www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm); or

(b) in accordance with a proper order from a properly authorized practitioner.

5.2 Administration must be done in accordance with the training required by Section 3.1(b) of this Series, including, but not limited to indications, contraindications, route of administration, sanitary environment for administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this rule;

5.3. Administration must include implementation of the CDC's recommended appropriate observation for an adverse reaction of an individual following an immunization.

5.4. Under no circumstances may a pharmacist delegate his or her authority to administer immunizations to any other person, including but not limited to, any pharmacy technician, except as otherwise provided herein for a properly trained pharmacy intern who is administering under the direct supervision of the pharmacist.

5.5. A current Vaccine Information Statement, as provided by CDC, shall be provided to each person receiving an immunization for each immunization administered.

§15-12-6. Record-keeping and reporting.

6.1. An immunization questionnaire and consent form shall be completed for each person receiving an immunization. A record of the immunization administration shall be forwarded to the primary care physician or other licensed health care provider as identified by the person receiving the immunization, within not more than 30 days of the date of the administration. In the event that the patient affirmatively indicates in writing that he or she does not have a primary care physician or other health care provider to whom to forward the report, the ~~pharmacist~~pharmacist or pharmacy intern must document such in the immunization record, and provide a record of the immunization administration to the patient. Such record shall also contain the name of the pharmacist, and, where applicable, the name of the pharmacy intern, administering the immunization.

6.2. In addition, the pharmacist must report the administration of the patient immunization to the West Virginia Statewide Immunization Information (WVSII) database in the format and containing such information as may be required by the WVSII within not more than 30 days of the date of the administration.

6.3. The immunization questionnaire and consent form and record of the immunization administration shall be filed in the pharmacy in a manner that will allow timely retrieval, and shall be kept on file for a time period not less than five (5) years from the date of the immunization. All such records shall be maintained in the pharmacy where the immunization is administered. In the event it is administered off-site, then the records shall be maintained in the pharmacy where the ~~pharmacist~~pharmacist or pharmacy intern who administered the immunization is employed or otherwise practicing at the time the immunization is given.

6.4 Pharmacists shall report all adverse events to the Vaccine Adverse Events Reporting System (VAERS), and promptly provide a copy of all reports to the Board; the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services; and the patient's primary care physician or other licensed health care provider as identified by the person receiving the immunization per subsection 6.1. VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), and is available at <http://vaers.hhs.gov/index>.

§15-12-7. Emergencies.

7.1. A ~~pharmacist~~pharmacist or pharmacy intern authorized to administer immunizations under this rule may administer epinephrine and diphenhydramine in the

management of an acute allergic reaction to an immunization following guidelines issued by CDC for such situations.

7.2. A ~~pharmacist~~ pharmacist or pharmacy intern shall have a readily retrievable emergency response plan as outlined ~~in~~ by the CDC, and maintain a readily retrievable emergency kit to manage an acute allergic reaction to an immunization administered.

§15-12-8. Immunization Training Programs.

8.1. The Board must approve a course or program in immunization administration for that course to be used to meet the qualification requirement of section 3.1(b). In order to be approved by the Board, the course or program, at a minimum, must include practical training and instruction on the following:

- (a) basic immunology, including the human immune response;
- (b) adverse reactions, contraindications, warnings and precautions;
- (c) response to emergency situations, including administration of epinephrine and diphenhydramine;
- (d) storage and handling requirements;
- (e) recordkeeping and reporting requirements, including screening and informed consent documentation;
- (f) proper environment for administration and observation;
- (g) legal and regulatory issues, including, but not limited to, state law and regulations, OSHA compliance, biohazard control, and such other relevant and applicable standards; and
- (h) policies and procedures for establishing and implementing appropriate immunization treatment guidelines.

8.2. Any course approved by the Board must include a minimum of 15 hours of didactic and practical based components of instruction and training, including self study and live instruction. The live instruction must be a minimum of six (6) hours, and shall include documented and supervised instruction on physical administration of vaccinations.

BOARD MEMBERS

Carl K. Hedrick, Jr., President
Charles Woolcock, Vice President
Rebekah E. Heavener, Secretary
Martin Castleberry
*Lydia Main**
*Sam Kapourales**
*George Karos**
*(*Past President)*

Office Address
2310 Kanawha Blvd, East
Charleston, WV 25311



www.wvbop.com

STAFF

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Executive Director &
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Betty Jo Payne,
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Michael L. Goff
CSMP Administrator

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

**RESPONSE TO PUBLIC COMMENTS RECEIVED
TO PROPOSED RULES**

(Including explanation of any amendments made to the proposed rule as a result of comments)

**TITLE 15, SERIES 12 (WV CSR 15-12-1, et seq.)
IMMUNIZATIONS ADMINISTERED BY PHARMACISTS**

The Board of Pharmacy received written public comments to the proposed joint rules filed with the Secretary of State on June 27, 2014, making amendments to Title 15, Series 12. The Board reviewed those comments at a public meeting on July 29, 2014. Following are the Board's responses to those comments.


The Board received two very similar comments from EPIC pharmacies through its counsel, and from the National Association of Chain Drug Stores ("NACDS") concerning reporting of any adverse reactions as required by Rule Section 15-12-6.4. As currently enacted, any adverse reaction must be reported to the Vaccine Adverse Events Reporting System (VAERS) operated by the United States Center for Disease Control and Prevention and the Food and Drug Administration, and send a copy of it to the Board of Pharmacy. In working on the current proposed rules, the Boards of Medicine and Osteopathy requested that pharmacists who realizes a patient with an adverse reaction to an immunization administered by the pharmacist to also be required to send a copy of the VAERS report to the West Virginia Department of Health and Hyman Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services (DHHR/DIS). Epic pharmacies indicates that this adds further administrative burden to pharmacists which they feel would be more efficient for the Board of Pharmacy to forward the information to DHHR/DIS, or to otherwise accomplish this notice through the West Virginia Statewide Immunization Information System (WVSIIS) web application to which all pharmacist-administered vaccines must be reported. Slightly differently, NACDS points out that this third reporting to DHHR/DIS "is redundant" given the reporting to the CDC's VAERS system and a copy to the Board. NACDS asserts that the agencies already have access to this information online.

The Board President, Jody Hedrick, and the undersigned, Mr. Potters, contacted DHHR/DIS and learned that they do not get the VEARS adverse events data from the CDC until a year and sometimes up to two years after the fact. Likewise, WVSIIS is not set up for adverse events reporting, but for reporting of administration of vaccines. However, DHHR/DIS indicated that they accept the VAERS reporting form by simply having it faxed to them at 1-888-558-1941. The DHHR/DIS staff member also indicated that they take the VAERS reports and

themselves report them to the CDC's VEARS system so that they act as a single-site reporting on behalf of those who report adverse incidents to them, and those practitioners do not have to send it to both them and VAERS. As such, the Board discussed modifying the rules language to require reporting to DHHR/DIS with a copy to the Board, and that DHHR/DIS would then report to VAERS. In speaking with counsel for EPICS pharmacies prior to the meeting, he indicated that this would be an acceptable solution so far as he knew at the time. Unfortunately, the representatives of the pharmacy community present at the meeting, including the West Virginia Retailers Association and Walgreens, indicated that they were not sure at that time if it would fulfill their obligations under their required training and CDC protocols to allow DHHR/DIS to report to VAERS for them, as they are responsible to report to VAERS themselves. They indicated they would need to research this option further. The Board determined that, since this is a joint rule and this issue must also go before the Boards of Medicine and Osteopathy, it would not make any changes to the proposed rule based upon these comments at this time, and will proceed forward with this rule provision as proposed.

The Board at its public meeting on July 29, 2014, authorized this response and the proposed rules to be filed with the Secretary of State and the Legislative Rule-Making and Review Committee. Because this is a joint rule, the comments also have to be reviewed by the Board of Medicine and Board of Osteopathy, so that we will need to file a supplemented response after they have taken up the comments in their respective board meetings.

Prepared by:


David E. Potters
Executive Director & General Counsel

600 Quarrier Street
Charleston, West Virginia 25301

101 South Queen Street
Martinsburg, West Virginia 25401

511 7th Street
Moundsville, West Virginia 26041

501 Avery Street
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July 25, 2014

J. Robert Alsop
Telephone — (304) 285-2564
Facsimile — (304) 285-2575

E-Mail Address:
ralsop@bowlesrice.com

David E. Potters
Executive Director and General Counsel
West Virginia Board of Pharmacy
2310 Kanawha Boulevard East
Charleston, West Virginia 25311

VIA HAND DELIVERY

RECEIVED ON

JUL 25 2014

WV BOARD OF PHARMACY

Dear Mr. Potters:

On behalf of EPIC pharmacies, this letter concerns a proposed amendment to Section 6.4 of the proposed amendments to Series 12 of Title 15 of the Board of Pharmacy's Rules relating to Immunizations Administered by Pharmacists. Under current law, Section 6.4 requires that pharmacists are required to report all adverse events not only to the Board, but also to the Vaccine Adverse Events Reporting System ("VAERS"). The proposed rule would also require pharmacists to notify the patient's primary care physician or other licensed healthcare provider and the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services ("WVDHHR Division of Immunization Services").

It makes sense to provide the information to the patient's primary care physician or other licensed healthcare provider and we support that addition. However, instead of adding an additional administrative burden to require pharmacists to provide such information to the WVDHHR Division of Immunization Services, a better, more efficient solution would be to simply provide that the Board is to forward such information to the WVDHHR Division of Immunization Services or to otherwise accomplish this notice process through the use of the West Virginia Statewide Immunization Information System (WVSIS) Web Application.

We appreciate the opportunity to comment.

Very truly yours,

J. Robert Alsop
Special Counsel

July 24, 2014

David Potters, Esq.
Executive Director & General Counsel
and Members of the Board of Pharmacy
West Virginia Board of Pharmacy
2310 Kanawha Blvd East
Charleston, WV 25311

RECEIVED ON
JUL 25 2014
WV BOARD OF PHARMACY

RE: Series 7 and 12 Comments - Proposed Rules for Registration of Pharmacy Technicians and Proposed Rules for Immunizations Administered by Pharmacists

Dear Mr. Potters and Members of the Board of Pharmacy:

On behalf of our members operating pharmacies in the state of West Virginia, the National Association of Chain Drug Stores is writing to provide our comments on the above-mentioned proposed rules for registration of pharmacy technicians and for immunizations. We thank you for consideration of our comments.

We appreciate the work of the Board of Pharmacy in drafting the proposed rules recognizing the efforts required by the board of pharmacy. We offer the comments in the spirit of achieving optimal rules that allow pharmacy technicians to provide valuable assistance to pharmacists in order to allow pharmacists to engage in valuable pharmacist services such as medication therapy management, disease management and other pharmacist patient care services, and for promoting efficiencies in the reporting of immunization adverse events. Chain pharmacies truly, appreciate the value that pharmacy technicians provide to pharmacists.

Proposed Rule for Registration of Pharmacy Technicians

Our comments on the proposed rule for registration of pharmacy technicians are directed at the following provisions:

- Section 3.1(b) on board approval of training programs
- Section 4.2 on pharmacy technician training
- Section 4.3 on the pharmacist in charge notifying the board of pharmacy
- Section 5.3 on the pharmacy technician ratio

1. **Section 15-7-3.1(b) - approval of pharmacy technician education and training programs**

The proposed rule provides that an option for pharmacy technicians seeking registration is the pharmacy-provided, on the job, competency-based education and training program approved by the board. Currently, a number of pharmacies have such programs that are already approved by the board. As these programs are approved, and in the interest of continuing pharmacy technician education and

training without interruption of the training, we understand that the programs would continue to be approved and not require re-approval.

REQUEST: We ask that the board affirm that the pharmacy technician training programs that are currently approved by the board of pharmacy do not need to be re-approved.

2. Section 15-7-4.2 – pharmacy technician education and training programs

The proposed rule provides that beginning July 1, 2014, on-the-job, competency-based pharmacy technician training program shall consist of a minimum of 960 hours of employment within a 9 month period.

The 9 month limit to complete the 960 hours of employment for the technician training will present an unworkable situation for many pharmacy technician trainees. This equates roughly to 107 hours per month. A considerable number of pharmacy technicians would be unable to work this number of hours in a month. It is quite common for pharmacy technicians to be part time and work much fewer hours. For example, some pharmacy technicians may work weekends, some only part of the day for several days a week. Often these schedules accommodate their school or other schedules. In short, if this requirement is not changed, these pharmacy technicians would not be able to meet the 960 hours of employment in 9 months. As a result, a number of pharmacy technician employees would be effectively shut out of their desire to become pharmacy technicians. We doubt that the board intended to present these hurdles for pharmacy technician employees but nonetheless, the proposed rule to require training in a 9 month period would lead to such an arbitrary effect.

REQUEST: We ask that the proposed rule be changed to allow the pharmacy technician trainee to complete the minimum of 960 hours in an 18 month period. This would equate roughly to about 53 hours per month which provides a reasonable and sufficient number of work hours per month for a pharmacy technician trainee.

3. Section 15-7-4.3 – pharmacist-in-charge notification within 7 days of a pharmacy technician trainee starting work in the pharmacy

The proposed rule amends the existing rule to require that the pharmacist-in-charge (PIC) notify the board of pharmacy in writing within 7 days of a pharmacy technician trainee starting work in the pharmacy. The current rule provides the pharmacist 30 days to provide such notice.

We ask that the rule not be changed to 7 days for the PIC to notify the board of pharmacy of the technician trainee starting work, and remain at 30 days. The 7 day time period places an unnecessarily short deadline on the PIC. When a pharmacy

technician starts to work in a pharmacy, there are a number of activities that the PIC would be focused on, such as introducing the technician to the pharmacy, beginning training, and other support for the new employee. We do not agree with pulling the PIC away to provide notification so quickly when his or her time is better spent with orienting the new pharmacy technician.

REQUEST: We ask that the 7 day time period be removed and that the proposed rule revert to the 30 day time period.

4. Section 15-7-5.3 -pharmacy technician ratio

The proposed rule provides for a ratio of no more than four pharmacy technicians and/or pharmacy technician trainees per on duty pharmacist. Rather than setting a ratio, the board of pharmacy should eliminate the pharmacy technician ratio for the reasons we discuss below.

Not having a pharmacy technician ratio allows the pharmacy to determine the optimal number of pharmacy technicians for the particular pharmacy. This achieves numerous benefits. Patients benefit because it optimizes the pharmacy patient care services they receive. The healthcare system benefits as this promotes effective timely delivery of pharmacy patient services. It allows the pharmacy to operate efficiently and safely. For instance, some community pharmacies have technology and a number of customer areas where a sufficient number of pharmacy technicians are critical to good customer service along with benefitting the pharmacist by having a smoothly run pharmacy. Conversely, another pharmacy may operate differently. The point is that each pharmacy should be allowed to determine what ratio is workable and optimal for that pharmacy. A pharmacy would not have more pharmacy technicians than are needed and optimal for that particular pharmacy practice setting. In short, setting an arbitrary ratio of pharmacy technicians per pharmacist creates an unnecessary impediment to pharmacies operating efficiently and in the best interests of patients. By way of example, it would not make sense to limit the number of nurses that a physician determines is needed for his or her office practice.

Many valid reasons exist for eliminating pharmacy technician ratios:

- Pharmacists would have sufficient support staff to allow them to engage in patient care activities, allowing pharmacists to delegate non-judgmental tasks to technicians.
- The pharmacist to technician ratio is not necessary as pharmacy technicians are well trained and integral to assisting pharmacists with non-discretionary, non-judgmental tasks.

David Potters, Esq.
Executive Director & General Counsel and Members of the Board of Pharmacy
July 24, 2014
Page 4 of 4

- Many state boards of pharmacy in recognition of the important role of pharmacy technicians performing non-discretionary, non-judgmental tasks have over the years increased or eliminated restrictive ratios to allow for optimal use of pharmacy technicians.
- With the increasing number of patients in the healthcare system, pharmacists along with other health care providers are of increasing importance to provide health care services to patients.
- Pharmacy technicians are an integral part of pharmacy practice by performing administrative and non-discretionary tasks that enable the time that pharmacists have to spend with patients.
- Elimination of pharmacist to technician ratios will enable pharmacists to focus on patients, and provide enhanced services such as medication therapy management, disease management, and other important pharmaceutical patient care services.

Proposed Rule for Immunizations

We also have one concern with the proposed immunization rule. We routinely report to the VAERS and agree that it is an important system to track patient care. However, we question whether it is truly necessary to send additional reports when agencies have access to this information online. We believe the point of making this system web-based was to provide for the interactive, open sharing of this information, as opposed to sending reports on paper that are not likely to be easy to track. As we see it, providing additional reports is redundant.

We thank you for consideration of our comments on the proposed rules for registration of pharmacy technicians. Please don't hesitate to contact me if you require further information.

Sincerely,



Jill McCormack, Director
State Government Affairs
National Association of Drug Stores
jmccormack@nacds.org
(717) 525-8962