

From: [Deeb Eid](#)
To: [Ditschman, Andria \(LARA\)](#)
Subject: Public Comments on MI Pharmacy Technician Rules 2020-29 LR
Date: Friday, January 15, 2021 6:13:28 PM
Attachments: [Michigan Board of Pharmacy Public Comment Submission 12-30-2020-Eid,D.pdf](#)
[MI PharmTech DraftRule \(RedLines-Eid\).doc](#)

**CAUTION: This is an External email. Please send suspicious emails to
abuse@michigan.gov**

Andria,

Hope you are doing well and off to a productive start to 2021. I am reaching out to submit public comments on behalf of Administrative Rules on Pharmacy Technicians 2020-29 LR. These comments are on behalf of myself as a member of the public and pharmacist within Michigan.

I prepared the comments a few weeks ago and completely forgot to send them to you, so I dated them for 12-30-2020 when they were prepared.

In addition to the comment document, I have attached a redline (tracked changes) Word version of the rules to supplement the suggested changes you'll note in the comment document for ease of reference.

If you have any questions, please let me know! Looking forward to the hearing on Tuesday. Have a great weekend.

--

Thanks very much,

Deeb D. Eid, Pharm.D.

From: Deeb D. Eid, PharmD, RPh

Purpose: Submitting comments on behalf of myself as a pharmacist and member of the public

Contact info: Deeb.eid@gmail.com

Date: 12-30-2020

Re: Public Comment on Administrative Rules for Pharmacy Technicians, Rule Set 2020-29 LR

Dear Michigan Board of Pharmacy,

I'd like to first commend you on the rule promulgation and changes proposed in Michigan. In my opinion, you are taking steps needed to increase patient safety and help to remove barriers to care with these proposed rules. As a public member, pharmacist in Michigan and policy researcher, I've been tracking topics associated with the rule rewrites taking place and wanted to provide comments, questions, and feedback for your consideration on Rule Set 2020-29 LR relating to Pharmacy Technicians.

I have also attached my suggested improvements to the direct language proposed with redlines (tracked changes) included. I have attempted to provide my rationale and other comments for consideration below.

Below are the thoughts and comments I'd like to share with the Board and State Agency (LARA) for consideration:

Section: Pg. 3, R338.3654 Examination requirements; board approval; approval process.

Comments, Rationale, or Questions:

- Number (2) in this section is confusing because if you reference MCL 333.17739a (1)(d)(iv) the language is specific to "employer-based training program examination" within statute, so it does not line up with a nationally recognized exam as currently mentioned.¹
- Number (4) is written in a way that seems like the employer-based training program exam must meet accreditation standards. Certification exams are usually only accredited if they are on the national level. Exams like PTCB and NHA go through their own set of accreditations for the exams themselves (ANSI and NCCA). Employer based training program exams would very unlikely reach this level of accreditation because they are not on the national level.^{2,3}
- Number (5) and (6) are non-feasible because a national certification exam program (such as PTCB or NHA) is not going to submit an application to the Board. In addition, providing a copy of the examination with correct answers for a national certification exam (such as PTCB or NHA) would compromise the exam. Each of these companies have question bank systems, etc. so they would never be able to provide this to the board without completely compromising their entire business model.^{2,3}

Recommendations:

- Delete current proposed language for (2).
- Removal of “accreditor’s accreditation” in (4).
- Removal of language relating to a nationally recognized certification exam in (5) and (6).

Language Changes:

~~(2) A nationally recognized pharmacy technician proficiency certification examination must cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.~~

(3) An employer-based training program proficiency examination must be offered in association with a specific employer-based training program and cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.

(4) Beginning July 1, 2022, an employer-based training program proficiency examination must meet the ~~accreditor’s accreditation~~ standards associated with the employer-based training program that is approved under R 338.3655.

(5) An entity that offers ~~a nationally recognized pharmacy technician proficiency certification examination or~~ an employer-based training program proficiency examination shall submit to the department a completed application on a form provided by the department and a copy of the examination with the correct answers clearly identified for each question.

(6) An entity that offers ~~a nationally recognized pharmacy technician proficiency certification examination or~~ an employer-based training program proficiency examination shall submit a modification to a proficiency examination during its approval term to the department on a form provided by the department pursuant to the requirements of this rule.

Citations or References:

1. MCL 333.17739a
2. <https://www.ptcb.org/about-ptcb>
3. <https://www.nhanow.com/accreditation>

Section: Pg. 3-5, R 338.3655 Approved pharmacy technician programs.

Comments, Rationale, or Questions:

- First, it is essential for the board to consider evidence/research behind accredited education and/or training.
 - **Of note, there are no published studies/evidence to showcase that accreditation standards lead to increased patient safety or to show that accredited vs non-accredited education or training leads to less harm.**
 - **Patient safety is the key piece to consider as accreditation is a costly, time extensive, and challenging process to maintain.**
 - **Many assume that accreditation automatically means better outcomes, higher standards, and increased patient safety.**
 - **Less talked about is the actual outcomes or data to support these claims.**
 - **Does accreditation really mean increased patient safety?**

- The definition differences between pharmacy technician **certification, training, education, registration, and licensure** are commonly confusing and mixed up/interchanged incorrectly.
- To help clarify, comments have been provided below to ensure clarification and provide guidance/broaden the scope and ensure non-deterrence and non-favoritism of inclusion of various employers and organizations.
 - One major concern is anti-trust/anti-steering with inclusion of ASHP/ACPE as a mentioned entity for accreditation of **education programs**.
 - There are other accrediting bodies that accredit pharmacy technician education and training programs, which is why changing to a broadened language would be all inclusive.
- There also seems to be a non-recognition of differences between **training programs VS education programs**.^{1,2}
- **Training programs are often not the same as educational programs.**^{1,2}
 - Accreditation bodies such as ASHP/ACPE accredit educational programs and training programs. It is important to recognize the difference between these types of programs.
 - Educational programs often are conducted by schools, colleges, vocational programs, and/or specific entities.^{1,2}
 - Training programs are often conducted or held by employers, associations, and other entities.^{1,2}
 - Trainings can also be internal for employers and employers often do not have formal “education” programs.^{1,2}
- There needs to be clear distinction within the language to ensure there is not mix up of expectations for this section.

Recommendations:

- (1)(a) deletion of specification to ASHP/ACPE to ensure anti-trust or anti-steering does not exist.
 - Move towards unifying language with other parts (U.S. Dept of Education)
 - Specification of “education” programs to ensure accreditation is accurately depicted.
- (1)(b) specification of education, delete “pharmacist”
- (4), (8), and (9) specification of education and deletion of ASHP/ACPE to broaden and avoid anti-trust/anti-steering.

Language Changes:

(1) (a) A pharmacy technician **education** program that is accredited by **a body recognized by the United States (U.S.) Department of Education.** ~~the accreditation council American Society of Health-System Pharmacists/Accreditation Council for pharmacy education Pharmacy Education (acpe) Pharmacy Technician Accreditation Commission (ASHP/ACPE).~~

(b) A pharmacy technician program that is offered by ~~a pharmacist~~ an education program that is accredited by the ~~accreditation council for pharmacy education (acpe)~~ American Society of Health-System Pharmacists/Accreditation Council (ASHP/ACPE).

(4) A pharmacy technician education program that is accredited by a body recognized by the United States (U.S.) Department of Education ~~or ASHP/ACPE~~ will be approved by the board after submittal to the department of a completed application on a form provided by the department along with proof of accreditation.

(8) As of July 1, 2022, all board-approved pharmacy technician education programs must be accredited by an accrediting body recognized by the U.S. Department of Education ~~or ASHP/ACPE~~.

(9) Beginning July 1, 2022, a pharmacy technician education program that was board approved before July 1, 2022, must reapply and meet the requirements in subrules (4) to (8) of this rule. Beginning July 1, 2022, the board's approval of a program expires 5 years after the date of approval. After 5 years, upon review by the department, a pharmacy technician education program may be reapproved if it has maintained its accreditation.

Citations or References:

1. <https://collegeforamerica.org/difference-between-training-education/>
2. <https://becht.com/becht-blog/entry/what-is-the-difference-between-training-and-education/>

Section: Pg 14-15, R 338.3665 Performance of activities and functions; delegation.

Comments, Rationale, or Questions:

- Tech-check-tech, or as some states are now terming it "accuracy checking" or "technician product verification" has been successfully and safely practiced in states for decades.
- There are now over 20 studies to date on the topic ranging back 40 years in various settings including community based and health systems.⁵
- [Adams et al](#) reviewed and demonstrated safety data, including that results of 11 studies published since 1978 indicate that technicians' accuracy in performing final dispensing checks is very comparable to pharmacists' accuracy (mean \pm S.D., **99.6%** \pm 0.55% versus **99.3%** \pm 0.68%, respectively).¹
- [Frost et al](#) also reviews data in the community setting and showed that in 2 studies that reported accuracy rates, pharmacy technicians performed at least as accurately as pharmacists (**99.445** vs **99.73%**, P = .484; **99.95** vs **99.74**, P < .05).²
- There have been multiple pilot and research programs in states such as Wisconsin, Tennessee, Iowa, South Dakota, and more which have been studying the workflow and outcomes of implementing these models.

- I encourage the board and other stakeholders to move forward on this as it will only help to improve patient care initiatives and allow for pharmacists to spend more time with patients as demonstrated by [Andreski et al.](#)³
- I'd also encourage the board to refer to [Adams](#) for deliberations of the Idaho regulatory board on advancing technician practice, which an example from.⁴

Recommendations:

- (b)(i) remove the language of “another pharmacy technician”.
 - This language is outdated to actual pharmacy practice and operations.
 - The major goal is to enable pharmacy technicians who can be trained to conduct product verification utilizing the safety of bar code technology.
 - Technicians may not be checking the work of other technicians, it may be of a pharmacist, intern, technician, robot...etc.
 - In terms of patient safety, the important part is to include the requirement of technology.
- (b)(ii)-(iv) removal of highlighted language below.
 - This language as is clouds and confuses.
 - Including a pharmacist verifying the processing depleted the entire process...it deems this as non-functionable language. The point is to allow technicians to conduct product verification safely with the assistance of technology for patient safety.
 - Multiple studies have showcased the ability of technicians to conduct product verification safely, accurately, and with technology to improve patient safety.
- (C) removal of 1,000 hours.
 - This number is arbitrary, and evidence/studies prove this.
 - In various studies ranging from minimal work experience, to 2,000 hours, the results are still the same repeatedly (20+ studies over 40 years).⁵
 - The important piece to consider is the training program and ensuring the technicians and pharmacy team are properly trained with a program focused on this function.
 - Evidence and research do not support that a certain quantity of hours is what makes this task safe, rather the training programs.
- (I) deletion of this language
 - This is especially relevant with the COVID-19 pandemic to showcase that remote work with pharmacy technicians can be an essential task to move forward with.
 - Many other states have adopted rules and/or emergency orders to allow for remote work from technicians.
 - There are no published data/evidence to support that remote work by pharmacy technicians is unsafe to the public.

Language Changes:

(a) Reconstituting non-sterile dosage forms consistent with approved labeling provided by the manufacturer of a commercially available product.

(b) Technology-assisted final product verification, which includes all the following:

(i) A licensed pharmacy technician uses a technology-enabled verification system to perform final product verification. ~~verifies the work of another licensed pharmacy technician.~~

~~—(ii) The first licensed pharmacy technician processes a medication order or prescription.~~

(iii) ~~The first licensed~~ pharmacy technician processes the medication order or prescription using bar coding or another board-approved error prevention technology.

~~(iv) A pharmacist verifies the first licensed pharmacy technician's processing of the medication order or prescription.~~

(v) The technology-assisted final product verification is subject to all of the following requirements:

(A) The licensed pharmacy technician holds a current full pharmacy technician license in this state, not a temporary or limited license.

(B) The licensed pharmacy technician performing technology-assisted final product verification has completed a board approved pharmacy technician program under R 338.3655.

(C) The licensed pharmacy technician performing technology-assisted final product verification has professionally appropriate ~~not less than 1,000 hours of pharmacy technician~~ work experience in the same kind of pharmacy practice site in which the technology-assisted final product verification is performed while he or she holds a current full pharmacy technician license in this state, not a temporary or limited license.

(D) The practice setting where a licensed pharmacy technician performs technology-assisted final product verification has in place policies and procedures including a quality assurance plan governing pharmacy technician technology-assisted final product verification.

(E) The licensed pharmacy technician uses a technology-enabled verification system to perform final product verification.

(F) The technology enabled verification system must document and electronically record each step of the prescription process including which individuals complete each step.

(G) A licensed pharmacy technician shall not perform technology-assisted final product verification for sterile or nonsterile compounding.

(H) Technology-assisted final product verification by a licensed pharmacy technician is not limited to a practice setting.

~~—(I) Except for a remote pharmacy that is regulated under sections 17742a and 17742b of the code, MCL 333.17742a and MCL 333.17742b, a pharmacy technician shall not participate in technology-assisted final product verification remotely. Technology-assisted product verification must be done on site.~~

(J) A pharmacist using his or her professional judgment may choose to delegate technology-assisted final product verification after ensuring licensed pharmacy technicians have completed and documented relevant training and education.

Citations or References:

1. Adams, Alex J., et al. "Tech-Check-Tech': A Review of the Evidence on Its Safety and Benefits." American Journal of Health-System Pharmacy: AJHP: Official Journal of the

- American Society of Health-System Pharmacists, vol. 68, no. 19, Oct. 2011, pp. 1824–33. PubMed, doi:10.2146/ajhp110022.
2. Frost, Timothy P., and Alex J. Adams. “Tech-Check-Tech in Community Pharmacy Practice Settings.” *The Journal of Pharmacy Technology : JPT : Official Publication of the Association of Pharmacy Technicians*, vol. 33, no. 2, Apr. 2017, pp. 47–52. PubMed Central, doi:10.1177/8755122516683519.
 3. Andreski, Michael, et al. “The Iowa New Practice Model: Advancing Technician Roles to Increase Pharmacists’ Time to Provide Patient Care Services.” *Journal of the American Pharmacists Association*, vol. 58, no. 3, May 2018, pp. 268-274.e1. www.japha.org, doi:10.1016/j.japh.2018.02.005.
 4. Adams AJ. Advancing technician practice: Deliberations of a regulatory board. *Res Social Adm Pharm*. 2018;14(1):1-5. doi:10.1016/j.sapharm.2017.02.008
 5. Eid, D.; A Summary For Anyone Still Doubting Technician Product Verification (also known as Tech-Check-Tech). LinkedIn. March 6, 2020. <https://www.linkedin.com/pulse/summary-anyone-still-doubting-technician-product-verification-eid/>

Thanks for your consideration and time!



Deeb D. Eid, PharmD, RPh
deeb.eid@gmail.com

From: [Brian Sapita](#)
To: [BPL-Board](#)
Cc: [Ditschman, Andria \(LARA\)](#)
Subject: Pharmacy Technician Administrative Rules
Date: Tuesday, January 19, 2021 1:28:23 PM
Attachments: [Pharmacy Technician Comments.pdf](#)

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Please see the attached comments from the Michigan Pharmacists Association on the administrative rules governing pharmacy technicians.

Thanks,
Brian

Brian Sapita
Government Affairs Manager
Michigan Pharmacists Association

408 Kalamazoo Plaza, Lansing, MI 48933
ph (517) 377-0254
fx (517) 484-4893
Brian@MichiganPharmacists.org

Michigan Pharmacists Association: Working together to strengthen the profession and advance pharmacy practice

This email is not providing legal advice, but rather our interpretation of the Public Health Code and our understanding on how the Board of Pharmacy is currently enforcing the statute and other provisions. For legal advice, contact an attorney.



January 19, 2021

Andria M. Ditschman, JD
611 W. Ottawa Street
P.O. Box 30670
Lansing, Michigan 48909

Dear Ms. Ditschman,

The Michigan Pharmacists Association (MPA) would like to thank the Michigan Department of Licensing and Regulatory Affairs for allowing us to submit our comments on the administrative rules governing the practice of Pharmacy Technicians. MPA represents pharmacy technicians, along with pharmacists and student pharmacists across the state. We are strong proponents of offering increased access to care to all Michiganders in a safe and effective way. Our suggested changes are below in **bold**.

R. 338.3665 – MPA would suggest that the rules are more precise on the use of a second licensed pharmacy technician during the technology-assisted final product verification process. Currently as written we believe the rules could be misconstrued that a single pharmacy technician would be allowed to process an entire medication order from start to finish without any checks or balances. Our suggested wording changes are below:

- (i) A licensed pharmacy technician verifies the work of **a second** licensed pharmacy technician.
- (v) The technology-assisted final product verification **after being verified by a second licensed pharmacy technician** is subject to all of the following requirements:

Again, the Michigan Pharmacists Association would like to thank you for taking the time to review our comments and suggested plan of action. If you have any additional questions, I can be reached at the information below.

Thank you,

Brian Sapita
Manager of Government Affairs
Michigan Pharmacists Association
Brian@MichiganPharmacists.org
O: 517.377.0254
C: 616.745.5824