

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS DIRECTOR

MICHIGAN BOARD OF PHARMACY APRIL 7, 2021 MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on April 7, 2021. The meeting was held via Zoom, pursuant to MCL 15.263, MCL 15.263a., and Ingham County Resolution #21-138.

CALL TO ORDER

Charles Mollien, PharmD, JD, Chairperson, called the meeting to order at 10:00 a.m.

ROLL CALL

Members Present: Charles Mollien, PharmD, JD, Chairperson

Attended remotely from the city of Hudsonville, Ottawa County, Michigan.

Kathleen Pawlicki, MS, FASHP, Vice Chairperson

Attended remotely from the city of Novi, Oakland County, Michigan.

Cynthia Boston, BHS, R.Ph.T.

Attended remotely from the city of Utica, Macomb County, Michigan.

Kathleen Burgess, Public Member

Attended remotely from the city of Farmington Hills, Oakland County, Michigan.

David Hills, Public Member (left at 11:30 a.m.)

Attended remotely from the city of St. Joseph, Berrien County, Michigan.

Kyle McCree, Public Member

Attended remotely from the city of Grand Blanc, Genesee County, Michigan.

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Kelli Oldham, Public Member

Attended remotely from the city of East Lansing, Ingham County, Michigan.

Michael Sleiman, PharmD

Attended remotely from the city of Dearborn, Wayne County, Michigan.

Sandra Taylor, R.Ph.

Attended remotely from the city of Royal Oak, Oakland County, Michigan.

Maria Young, R.Ph. (left at 12:11 a.m., returned at 12:16 a.m.) Attended remotely from the city of Detroit, Wayne County, Michigan.

Members Absent: Grace Sesi, PharmD

Staff Present: Weston MacIntosh, Senior Policy Analyst, Boards and Committees Section

Kerry Przybylo, Manager, Boards and Committees Section Jennifer Shaltry, Senior Analyst, Compliance Section Michele Wagner-Gutkowski, Assistant Attorney General

Stephanie Wysack, Board Support, Boards and Committees Section

APPROVAL OF AGENDA

MOTION by Pawlicki, seconded by Hills, to approve the amended agenda as presented.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Navs: None

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Burgess, seconded by Taylor, to approve the February 10, 2021 meeting minutes as written.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Navs: None

MOTION PREVAILED

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REGULATORY CONSIDERATIONS

Proposal for Decision

Kimberly Ann Ringer

MOTION by Boston, seconded by Pawlicki, to accept the Proposal for Decision and deny licensure.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None

MOTION PREVAILED

OLD BUSINESS

None.

NEW BUSINESS

Continuing Education

Mollien directed the Board to the list of continuing education programs for consideration (Attachment #1).

MOTION by Pawlicki, seconded by Hills, to discuss.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None

MOTION PREVAILED

Discussion was held.

MOTION by Pawlicki, seconded by Sleiman, to approve the continuing education

programs.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None

MOTION PREVAILED

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Master Resolution Discussion

MacIntosh provided an overview of the Board of Pharmacy Master Resolution, approved October 11, 2017. The Board had no recommended changes.

Employer-Based Pharmacy Technician Training Program

Countryside Drug Company I, II, and III

MOTION by Pawlicki, seconded by Taylor, to discuss.

A roll call vote was taken: Yeas: Burgess, Hills, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None Recuse: Boston

MOTION PREVAILED

MOTION by Pawlicki, seconded by Taylor, to table the matter requesting additional information on what online tools are used for training, the evaluation process for trainees, on-the-job training, and if there are any sanctions on either the facility or pharmacists involved in training.

A roll call vote was taken: Yeas: Burgess, Hills, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None Recuse: Boston

MOTION PREVAILED

SpotRx/Oak Street Health Pilot Project Progress Report

Seema Siddiqui provided a short slideshow titled 1st Quarter Progress Report.

Sinclair v Board of Pharmacy Update

Wagner-Gutkowski proved an overview of the case history and stated that on March 30, 2021, the Michigan Supreme Court denied the application for leave to appeal.

Rules Discussion

Mollien stated that a public hearing for the Pharmacy – Pharmacy Technician Rules was held on January 19, 2021. The Rules Committee Work Group met twice to go over the Public Comment Summary (Attachment #2) and make recommendations to the Board.

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MOTION by Burgess, seconded by Taylor, to approve the Rules Committee Work Group suggested changes as presented for R 338.3654 Examination requirements; board approval; approval process.

Discussion was held.

A roll call vote was taken: Yeas: Boston, Burgess, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None

MOTION PREVAILED

MOTION by Pawlicki, seconded by Taylor, to reject in part and approve in part, the Rules Committee Work Group suggested changes to R 338.3655 Approved pharmacy technician programs as follows:

Subdivision (1)(a): Reject the strike through and addition of the word "training" but leave the addition of "including an employer-based training program." The subdivision to read "A pharmacy technician program including an employer-based training program that is accredited by the American Society of Health System Pharmacists/Accreditation Council for Pharmacy Education Pharmacy Technician Accreditation Commission (ASHP/ACPE)."

Subdivision (1)(b): Reject the removal of ASHP and the addition of the word "educational" but leave the addition of "or by an agency accredited by the United States Department of Education." The subdivision to read "A pharmacy technician program that is offered by an education program that is accredited by the ASHP/ACPE or by an agency accredited by the United States Department of Education.

A roll call vote was taken: Yeas: Boston, Burgess, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None

MOTION PREVAILED

MOTION by Pawlicki, seconded by Boston, to reject the Rules Committee Work Group recommendation to remove subrules (4) and (8) in R 338.3655 Approved pharmacy technician programs.

A roll call vote was taken: Yeas: Boston, Burgess, Pawlicki

Nays: McCree, Oldham, Sleiman, Taylor, Mollien

Abstain: Young

MOTION FAILED

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MOTION by Burgess, seconded by Oldham, to approve the Rules Committee Work Group suggested changes as presented for R 338.3665 Performance of activities and functions; delegation.

A roll call vote was taken: Yeas: Boston, Burgess, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None

MOTION PREVAILED

Chair Report

None.

Department Update

MacIntosh stated that the Bureau will hold the next Board Member Training on July 13, 2021, via Zoom. All board members are welcome to attend.

Wysack reminded McCree and Pawlicki that they should apply for reappointment now as their terms expired on June 30, 2021.

Wysack reminded the Board Members to check their state email address regularly as it is the source of communication with the Department. She stated that the state email address is used as the User ID for Egress, so it is important to get in the habit of checking the email on a regular basis.

PUBLIC COMMENT

None.

ANNOUNCEMENTS

The next regularly scheduled meeting will be held June 9, 2021 at 10:00 a.m. at the Ottawa Building, 611 West Ottawa Street, Upper-Level Conference Center Room 3, Lansing, Michigan 48933.

ADJOURNMENT

MOTION by McCree, seconded by Boston, to adjourn the meeting at 12:25 p.m.

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A roll call vote was taken: Yeas: Boston, Burgess, McCree, Oldham, Sleiman,

Taylor, Young, Pawlicki, Mollien

Nays: None

MOTION PREVAILED

Minutes approved by the Board on June 9, 2021.

Prepared by:

Stephanie Wysack, Board Support Bureau of Professional Licensing

April 7, 2021

PHARMACY CONTINUING EDUCATION REVIEW April 7, 2021

RECOMMENDED APPROVAL(S) for PHARMACISTS:

Approval from April 7, 2021 to April 30, 2024.

Spectrum Health Hospitals, Department of Pharmacy Services

• Pharmacy Grand Rounds – New Drug Updates at Spectrum Health

Ascension St. John Hospital, Department of Inpatient Services

Antidotes in the Setting of Toxicology

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – Diagnosis and Treatment of Skin and Soft Tissue Infections (SSTI) in Adult Hospitalized Patients

Ascension St. John Hospital, Department of Inpatient Services

• Opportunistic Infections in Kidney Transplant Recipients

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – The Effects of FEIBA* and Andexanet Alfa for the Reversal of Apixaban and Rivaroxaban in Uncontrolled Hemorrhage AND Clinical pharmacy specialists' impact in reducing A1C levels when embedded in a primary care practice

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – Impact of a pharmacy-led post-discharge phone call on 30-day readmission rates and economic outcomes AND Ouch, Part II! Comparison of liposomal bupivacaine versus continuous ropivacaine in plane blocks for rib fracture pain management

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – Evaluation of Pediatric Critical Care Sedation Taper Protocol AND Evaluation of sirolimus for graft-versus-host disease prevention in patients intolerant of calcineurin inhibitors following allogeneic stem cell transplantation: a pilot study

Covenant HealthCare

 Approaching Chemo Dispensing, Compounding, and Therapies: A Guide for the Everyday Pharmacist/Pharmacy Technician

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – Association of Rapid Pattern Pathogen Identification and Antimicrobial Susceptibility Platform for Gram-negative Bacteremia on Time to Optimize Antibiotic Therapy AND Evaluation of vitamin K and tiered 4F-PCC protocol for rapid reversal of INR in patients receiving heart transplantation

Covenant HealthCare

Beating Burnout (April 16, 2021)

RECOMMENDED APPROVAL(S) for PHARMACY TECHNICIANS:

Approval for date of event only.

Spectrum Health Hospitals, Department of Pharmacy Services

• Pharmacy Grand Rounds – New Drug Updates at Spectrum Health (April 27, 2021)

Spectrum Health Hospitals, Department of Pharmacy Services

• Pharmacy Grand Rounds – Overview of Antifungal and Antiviral Agents (April 27, 2021)

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – The Effects of FEIBA* and Andexanet Alfa for the Reversal of Apixaban and Rivaroxaban in Uncontrolled Hemorrhage AND Clinical pharmacy specialists' impact in reducing A1C levels when embedded in a primary care practice (June 1, 2021)

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – Impact of a pharmacy-led post-discharge phone call on 30-day readmission rates and economic outcomes AND Ouch, Part II! Comparison of liposomal bupivacaine versus continuous ropivacaine in plane blocks for rib fracture pain management (May 18, 2021)

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – Evaluation of Pediatric Critical Care Sedation Taper Protocol AND Evaluation of sirolimus for graft-versus-host disease prevention in patients intolerant of calcineurin inhibitors following allogeneic stem cell transplantation: a pilot study (June 8, 2021)

Covenant HealthCare

 Approaching Chemo Dispensing, Compounding, and Therapies: A Guide for the Everyday Pharmacist/Pharmacy Technician (April 16, 2021)

Spectrum Health Hospitals, Department of Pharmacy Services

 Pharmacy Grand Rounds – Association of Rapid Pattern Pathogen Identification and Antimicrobial Susceptibility Platform for Gram-negative Bacteremia on Time to Optimize Antibiotic Therapy AND Evaluation of vitamin K and tiered 4F-PCC protocol for rapid reversal of INR in patients receiving heart transplantation (May 25, 2021)

Covenant HealthCare

• Beating Burnout (April 16, 2021)

Pharmacy -Pharmacy Technician Rules - ORR 2020-029 LR Public Comment Summary Rules Committee's Recommendations to January 19, 2021 Public Comments

Testimony/Comments Received:

Rose M. Baran, PharmD, MA, Assistant Professor, College of Pharmacy, Ferris State University

Deeb D. Eid, PharmD, RPh

Brian Sapita, Government Affairs Manager, Michigan Pharmacists Association (MPA)

Rule 338.3654 Examination requirements; board approval; approval process.

Rule Numbers	Commenter	Comment
Section (2)	Deeb Eid	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. Delete current proposed language for (2).
Section (4)		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 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. Removal of "accreditor's accreditation" in (4).
Section (5) and (6)		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.

Removal of language relating to a nationally recognized certification exam in (5) and (6).

- (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.

Rules Committee Response

Section (2): The Rules Committee agrees with the comment to delete (2) as the Code requires an employer-based proficiency examination to cover the topics listed in the Code, it does not require a national recognized pharmacy technician examination to cover the topics in the Code.

Section (4): The Rules Committee agrees with the comment that a proficiency examination should not be required to meet program accreditation standards and, therefore, the provision should be deleted.

Section (5) and (6): The Rules Committee agrees that the questions on an accredited nationally recognized pharmacy technician proficiency examination do not need to be reviewed by the Board. The Board can rely on the accreditation process. Therefore, the Rules Committee recommends that a nationally recognized pharmacy technician proficiency examination should be submitted by an application to the Department with proof of accreditation in order to be considered Board approved, and further that modifications to the examination do not need review by the Board. However, if the accreditation is lost, the examination will no longer be considered Board approved.

R 338.3654 Examination requirements; board approval; approval process.

Rule 4. (1) Except for the PTCB and NHA examinations, a nationally recognized pharmacy technician proficiency certification examination and an employer-based training program proficiency examination must be approved by the board.

(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)(2) 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)(3) An entity that offers a nationally recognized pharmacy technician proficiency certification examination shall submit to the department a completed application on a form provided by the department with proof of current national accreditation in order to be approved by the board. If the examination is nationally accredited, after the department processes the application, it shall be considered approved by the board. If national accreditation is lost, the examination will no longer be approved by the board.

(4) An entity that offers 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) (5) 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.

(7) (6) Beginning July 1, 2022, a nationally recognized certification proficiency examination or employer-based training program proficiency examination approved by the board before July 1, 2022, shall submit an application consistent with this rule for approval.

(8) (7) Beginning July 1, 2022, the board's approval of an examination expires 5 years after the date of approval.

Rule 338.3655 Approved pharmacy technician programs.

Rule Numbers	Commenter	Comment
Section (1)(a),	Deeb Eid	First, it is essential for the board to consider evidence/research behind accredited education and/or
(1)(b), (4), (8), and		training.
(9)		o 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.

- o Patient safety is the key piece to consider as accreditation is a costly, time extensive, and challenging process to maintain.
- o Many assume that accreditation automatically means better outcomes, higher standards, and increased patient safety.
- o Less talked about is the actual outcomes or data to support these claims.
- o 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.
- o One major concern is anti-trust/anti-steering with inclusion of ASHP/ACPE as a mentioned entity for accreditation of education programs.
- o 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.
- Training programs are often not the same as educational programs.
- o Accreditation bodies such as ASHP/ACPE accredit educational programs and training programs. It is important to recognize the difference between these types of programs.
- o Educational programs often are conducted by schools, colleges, vocational programs, and/or specific entities.
- o Training programs are often conducted or held by employers, associations, and other entities.
- o Trainings can also be internal for employers and employers often do not have formal "education" programs.
- 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.

	o Move towards unifying language with other parts (U.S. Dept of Education) o 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.
	(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 pharmcist 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.
Rules Committee Response	Section 1: The Rules Committee agrees with the comment that the rule should be modified to clarify the approval regulations that pertain to employer-based training programs versus pharmacy technician educational programs. Further, the Rules Committee agrees with the comment that requiring pharmacy technician employer-based training programs to

be accredited does not by itself protect the public as there are non-accredited training programs that should continue to train pharmacy technicians. Therefore, the Rules Committee recommends the following:

- Accredited pharmacy technician training programs, and pharmacy technician educational programs that are accredited by ACPE or the U.S. Department of Education are considered approved by the Board and will be approved by the Department after submittal of an application and proof of accreditation.
- Delete the reference to "pharmacist" educational programs.
- Accreditation for training programs will not be required in 2022.
- Delete the reference to ASHP in the rules.

R 338.3655 Approved pharmacy technician programs.

- Rule 5. (1) Pursuant to sections 16171(a), 17739(2), and 17739a(1) of the code, MCL 333.16171(a), MCL 333.17739(2), and MCL 333.17739a(1), a student in an approved pharmacy technician program is exempt from, and not eligible for, licensure while in the program. Any of the The following pharmacy technician programs are considered board-approved after a completed application on a form provided by the department along with proof of accreditation is submitted to and reviewed by the department for this purpose:
- (a) A pharmacy technician training program including an employer-based training program that is accredited by the accreditation council American Society of Health-System Pharmacists/Accreditation Council for pharmacy education Pharmacy Education (acpe) Pharmacy Technician Accreditation Commission (ACPE).
- (b) A pharmacy technician educational program that is offered by a pharmacist an education program that is accredited by the accreditation council for pharmacy education (acpe) ASHP/ACPE or by an agency accredited by the United States Department of Education.
- (2) If either of the following pharmacy technician programs do not meet the requirements in subrule (1) of this rule, the program may apply for board approval by submitting an application to the department on a form provided by the department, along with an attestation form that verifies compliance with the information required in subrule (3) of this rule.
- (e) (a) A comprehensive curriculum-based pharmacy technician education and training program conducted by a school that is licensed pursuant to the Proprietary Schools Act proprietary schools act, 1943 PA 148, MCL 395.101 to 395.103.
- (d) (b) A pharmacy technician training program utilized by a pharmacy or employer that includes training in the functions, specified in section 17739(1) of the code, MCL 333.17739(1), and R 338.3665, required to assist the pharmacist in the technical functions associated with the practice of pharmacy.

- (2) (3) The contents of the training programs offered under subdivisions (c) and (d) of subrule (1) (2) of this rule must include, at a minimum, all of the following:
- (a) The duties and responsibilities of the pharmacy technician and a pharmacist, including the standards of patient confidentiality, and ethics governing pharmacy practice.
- (b) The tasks and technical skills, policies, and procedures related to the pharmacy technician's position pursuant to the duties specified in section 17739(1) of the code, MCL 333.17739(1), and R 338.3665.
 - (c) The pharmaceutical-medical terminology, abbreviations, and symbols commonly used in prescriptions and drug orders.
 - (d) The general storage, packaging, and labeling requirements of drugs, prescriptions, or drug orders.
 - (e) The arithmetic calculations required for the usual dosage determinations.
 - (f) The essential functions related to drug, purchasing, and inventory control.
 - (g) The recordkeeping functions associated with prescriptions or drug orders.
- (3) To gain approval under subdivisions (c) and (d) of subrule (1) of this rule, an application shall be submitted to the department on a form provided by the department, along with an attestation form that verifies compliance with the information required by subrule (2) of this rule.
- (4) A pharmacy technician 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.
- (4) The pharmacy technician program shall maintain A a record of a student's pharmacy technician training and education, shall be maintained by the pharmacy technician training program, employer, or pharmacy specified in subrule (1) of this rule, for a period of 2 years and shall include both of the following for 3 years after a student completes or leaves the program, whichever is earlier, that must include all of the following:
 - (a) The full name and date of birth of the pharmacy technician student.
 - (b) The starting date of the pharmacy technician education program and date the student successfully completed the program.
 - (c) The program syllabus and activities performed in the program.
- (6) (5) A student shall complete a board-approved pharmacy technician program within 2 years of beginning the program in order to maintain his or her exemption from licensure in subrule (7) of this rule, and R 338.3651.
- -(7) (6) A student in a board-approved pharmacy technician program is exempt from, and not eligible for, licensure while in the program.
- (8) As of July 1, 2022, all board-approved pharmacy technician educational programs must be accredited by an accrediting body recognized by the U.S. Department of Education or ASHP/ACPE.

(9) (7) Beginning July 1, 2022, a pharmacy technician 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 program may be reapproved if it has maintained its accreditation.

Rule 338.3665 Performance of activities and functions; delegation.

Rule Numbers	Commenter	Comment
Section (b)(i)	Sapita/MPA	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.
Section (b)(i) – (iv)	Rose Baran	Draft rule 338.3665(b)(i to iv) states: (b) Technology-assisted final product verification, which includes all the following: (i) A licensed pharmacy technician 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. The rule only mentions a "first-licensed technician" implying there should be a second-licensed technician involved in this process but there is no further mention of another licensed pharmacy technician after (b)(i) "A licensed pharmacy technician verifies the work of another licensed pharmacy technician." As the rule is currently drafted the first-licensed pharmacy technician processes the order and the pharmacist checks it. Nothing in the rule discusses what the other licensed technician (second-licensed pharmacy technician or checking technician) tasks or functions are. As currently drafted,

		there is no need for (b) in this rule as current pharmacy practice allows the licensed technician to process the medication order or prescription and the pharmacist verifying the medication order or prescription the technician has processed.
Section (b)(iii)	Rose Baran	Draft rule 338.3665 in 338.3665(b)(iii) uses the term "board-approved error prevention technology". This term is used a number of times in other rules 338.486(4)(d), 338.588(4)(a) and (5), and 338.354(6)(b)(vii). It is not defined in the rules. A definition is needed, and a process is needed on how to obtain Board approval for "board-approved error prevention technology".
Section (b)(v)	Brian Sapita	Modify to: (v) The technology-assisted final product verification after being verified by a second licensed pharmacy technician is subject to all of the following requirements:
Section (b)(i)-(iv)	Deeb Eid	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.
(v)(C) and (L)		 There are now over 20 studies to date on the topic ranging back 40 years in various settings including community based and health systems. 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 ± S.D., 99.6% ± 0.55% versus 99.3% ± 0.68%, respectively. 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). There have been multiple pilot and research programs in states such as Wisconsin, Tennessee, lowa, 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. 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.
		Recommendations:

- (b)(i) remove the language of "another pharmacy technician".
- o This language is outdated to actual pharmacy practice and operations.
- o The major goal is to enable pharmacy technicians who can be trained to conduct product verification utilizing the safety of bar code technology.
- o Technicians may not be checking the work of other technicians, it may be of a pharmacist, intern, technician, robot...etc.
 - o In terms of patient safety, the important part is to include the requirement of technology.
- (b)(ii)-(iv) removal of highlighted language below.
- o This language as is clouds and confuses.
- o 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.
- o This number is arbitrary, and evidence/studies prove this.
- o 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. 	
Rules Committee Response		

R 338.3665 Performance of activities and functions; delegation.

Rule 15. In addition to performing the functions described in section 17739(1) of the code, MCL 333.17739(1), a licensed pharmacy technician may also engage in reconstituting dosage forms as defined in 17702(4) of the code, MCL 333.17702(4) the following tasks, under the delegation and supervision of a licensed pharmacist.:

(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 second licensed pharmacy technician verifies the work of the first another licensed pharmacy technician to perform final product verification.
 - (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 second licensed pharmacy technician 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 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.